PUBLIC COMMENTS FOR: ARC 1769C – Amend IAC 653 – Chapter 13, Telemedicine

Hamed Tewfik, MD, Pres.
IA Board of Medicine
400 SW 8th St., Ste C
Des Moines, IA, 50309

Re: Proposed Telemedicine Standards

Dear Dr. Tewfik:

Please accept the following comments and suggestions for modifications of your board's proposed telemedicine standards.

My name is Rebecca Hafner-Fogarty. I am a primary care physician, the CMO of Zipnosis a telemedicine company headquartered in MN, and a member of the MN BMP where I chair the licensure committee. I do want to carefully and clearly state that I do not represent the MN BMP in this testimony.

However, because of my role as an experienced medical regulator, I believe that I have a unique understanding of the tension between our mission as medical regulators to protect the public, and the need for innovation in health care to improve access and decrease costs. As a clinician, I work hard to practice evidence based medicine. As a regulator, I strongly believe that our policy making decisions should be informed by the most current medical evidence. It is my personal belief that on-line care/telemedicine is the practice of medicine. Furthermore, I believe that a single standard of care should apply. With that in mind, I'd now like to make a couple of specific comments on your proposed standards.

First, congratulations on your thoughtful and thorough attempts to articulate a standard for reputable telemedicine clinicians.

I would strongly encourage you to substitute another term for telemedicine. I believe that the term telemedicine too narrowly defines the current and evolving practices of mHealth/ virtual medicine. By using the term telemedicine, you may find yourself having to re-visit your standards in the very near future when patient administered technologies are combined with internet messaging between doctors and patients to provide medical care that does not involve real time video imaging.

I would suggest using the term virtual medicine. So on page 2 section653.11(1) Definitions, line 5; I would substitute virtual medicine for the word telemedicine and remove the word audio-visual. I would also recommend removing lines 8-10 at the bottom of the page.

In light of its wide acceptance, you may also wish to keep the term telemedicine, but define it more broadly to explicitly include current and emerging technologies that do not rely on real time video conferencing.

Medical history and physical examination (653—13.11(8)). Having served on the MN BMP during the "bad old days" of rogue internet pharmacies, I understand the inclusion of the final sentence of this section on lines 9-11. I would suggest adding an additional sentence for clarity: Adaptive interviews which may include the capture of relevant patient supplied photos or other data do not constitute questionnaires.

Unlike most conventional telemedicine companies, Zipnosis provides asynchronous (store and forward) internet triage and care for mild acute primary care conditions. Since 2011 we have safely provided triage or treatment for over 70,00 patients (over 10,00 in 2014). The vast majority of these patients are patients of our partner health systems. These innovative organizations use our sophisticated adaptive interview (NOT a "simple" on-line questionnaire) to efficiently and effectively collect a structured chief complaint and patient history (sometimes including patient supplied vital signs or photos where appropriate). This information is then reviewed by a physician (NP or PA) who makes an assessment, and if appropriate a treatment plan. Patients with conditions not appropriate for virtual care are triaged to the next best point at care—either by the expert logic built into the interview, or by the clinician at the end of the interview. Where there is evidence to support the safety and effectiveness of treatment based on history alone, clinicians are given the option to prescribe. The medical record of the virtual visit is transmitted and stored as part of the patient's EHR within the health system.
In this capacity Zipnosis provides both another way for clinicians to effectively and efficiently connect with existing patients, and equally important an entry point into the medical system for patients without a medical home.

To equate this highly sophisticated virtual care encounter (and others still in development) with a simple internet questionnaire is grossly inaccurate. Yet, without the addition of the clarifying statement, future boards may be tempted to do just that.

Thank you for the opportunity to comment on the proposed standards and congratulations on your fine work. I would be happy to answer any questions or supply additional information that you might find helpful

Sincerely,

Rebecca J. Hafner-Fogarty, MD, MBA, FAAFP
CMO Zipnosis

Hello Mr. Bowden:

Mr. Eastman reminded me of upcoming review of telemedicine in Iowa. I have contacted the AAD to hopefully give you information on the Store and Forward Telemedicine protocol that the AAD started called ACCESSDERM. The University of Iowa (Department of Dermatology) has been one of the participants in this process using accessderm.

Mr. Eastman has helped me evaluate in-patients via direct telemedicine at Mercy but this is plagued by timing issues of the videography along with the physician and the patient being present at the same time. Typically, it is impossible to schedule the consulting physician, consultant physician, the videographer, and the patients at the same time. Store and Forward (such as accessderm) would allow the CONSULTING PHYSICIAN to take photos and details at the TIME OF THE EVENT/CONSULT and send the consultant for review. The consultant physician can ask for more information or photos if needed but the time of consultation and photos are immediate and speed the consultant reviews the information avoids logistics that slow care or make specialty care difficult if not impossible. The consulting physician using ACCESSDERM also knows if the photos are good images prior to sending the photos. This is not as predictable using video. More physician and nurses are familiar with taking photos vs running a video camera with less predictable lighting issues.

I ask that the new rules allow for STORE and FORWARD TELEDERMATOLOGY using ACCESSDERM as a model. For Teledermatology to work effectively, STORE AND FORWARD is essential!

The AAD (American Academy of Dermatology) is currently using ACCESSDERM at select sites including the University of Iowa:
https://www.aad.org/members/publications/member-to-member/2013-archive/october-11-2013/enhance-patient-care-with-teledermatology-

https://www.aad.org/members/volunteer-and-mentor-opportunities/accessderm-teledermatology-program

AAD testing with store and forward started in 2009:
https://www.aad.org/members/publications/member-to-member/2014-archive/april-25-2014/with-accessderm-as-a-bridge-no-patient-is-an-island

General info on store and forward teledermatology:
https://www.aad.org/members/practice-and-advocacy-resource-center/practice-arrangements-and-operations/teledermatology

I have included the AAD current position statement:
https://www.aad.org/forms/policies/uploads/ps/ps-teledermatology.pdf

Position Statement on Teledermatology

(Approved by the Board of Directors February 22, 2002
Amended by the Board of Directors May 22, 2004
Amended by the Board of Directors November 9, 2013
Amended by the Board of Directors August 9, 2014)

Telemedicine is an innovative, rapidly evolving method of care delivery. The Academy supports the appropriate use of telemedicine as a means of improving access to the expertise of Board certified dermatologists to provide high-

quality, high-value care. Telemedicine can also serve to improve patient care coordination and communication between other specialties and dermatology.
The Academy strongly supports coverage and payment for telemedicine services provided by Board certified dermatologists when several important criteria are met (see details below in section III). These criteria are essential to ensure that dermatologic care provided by telemedicine is of high quality, contributes to care coordination (rather than fragmentation), meets state licensure and other legal requirements, maintains patient choice and transparency, and protects patient privacy.
While teledermatology is a viable option to deliver high-quality care to patients in some circumstances, the Academy supports the preservation of a patient's choice to have access to in-person dermatology services.
Teledermatology is the practice of medicine. Board certified dermatologists have extensive knowledge and expertise in cutaneous medicine, surgery, and pathology. Whether in-person or via teledermatology, the optimal delivery of dermatologic care involves board certified dermatologists.
Teledermatology providers choose between or combine two fundamentally different care delivery platforms (Store-and-Forward vs. Live Interactive), each of which has strengths and weaknesses.

I. LIVE INTERACTIVE TELEDERMATOLOGY

a. Definition

Live interactive teledermatology takes advantage of videoconferencing as its core technology. Participants are separated by distance, but interact in real time. By convention, the site where the patient is located is referred to as the originating site and the site where the consultant is located is referred to as the distant site.

b. Technology

A high resolution video camera is required at the originating site, and a monitor with resolution matched to the camera resolution is required at the distant site. Videoconferencing systems work optimally when a connection speed of >384 kbps is used. Slower connection speeds may necessitate that the individual presenting the patient perform either still image capture or freeze frame to render a quality image. For most diagnostic images, a minimum resolution of 800 x 600 pixels (480,000) is required, but higher resolution may increase diagnostic fidelity.

c. Credentialing and Privileging

The Joint Commission (TJC) has implemented standards for telemedicine. Under the TJC telemedicine standards, practitioners who render care using live interactive systems are subject to credentialing and privileging at the distant site when they are providing direct care to the patient. The originating site may use the credentialing and privileging information from the distant site if all the following requirements are met: (i) the distant site is TJC-accredited; (ii) the practitioner is privileged at the distant site for those services that are provided at the originating site; and (iii) the originating site has evidence of an internal review of the practitioner's performance of these privileges and sends to the distant site information that is useful to assess the practitioner's quality of care, treatment, and services for use in privileging and performance management.

d. Privacy and Confidentiality

Practitioners who practice telemedicine should ensure compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended, and it's implementing regulations. While video or store-and-forward transmissions over ISDN infrastructure are thought to be secure, IP transmissions should be encrypted when transmitted over the public internet to ensure security. IP encryption in other settings such as private or semi-private networks is also highly recommended. The handling of records, faxes,

and communications is subject to the same HIPAA standards as apply in a standard office environment.

e. Licensing

Interactive telemedicine requires the equivalent of direct patient contact. In the U.S., teledermatology using interactive technologies is restricted to jurisdictions where the provider is permitted, by law, to practice. In other words, the provider using interactive technologies usually must be licensed to practice medicine in the jurisdiction where the patient is located.

f. Current Reimbursement

Medicare reimburses for live-interactive consultations, office visits, individual psychotherapy, and pharmacologic management delivered via a telecommunications system for patients located in non-metropolitan statistical areas (non-MSAs). This includes nearly all rural counties. A definition and listing of qualified areas is available via U.S. Census data at http://www.census.gov/population/metro. However, there is no limitation on the location of the health professional delivering the medical service. In some states, Medicaid reimburses for telemedicine services as well, but many have restrictions. Private insurers vary in their policies, but most will reimburse services provided to patients in rural areas. It is recommended that the provider write a letter of intent to the insurer informing them that the provider will be billing for telemedicine services. For the latest reimbursement information, see the American Telemedicine Association or CMS websites.

g. Responsibility / Liability

If a direct-patient-care-model (provider to patient) is used (no provider at the referring site), the consulting dermatologist bears full responsibility (and potential liability) for the patient's care. The diagnostic and therapeutic recommendations rendered are based solely on information provided by the patient. Therefore, any liability should be based on the information available at the time the consult was answered. In a consultative model (provide to provider), liability may be shared; however, the allocation of responsibilities will vary on a case-by case and state-by state basis. In either case, dermatologists should verify that their medical liability insurance policy covers telemedicine services, including telemedicine services provided across state lines if applicable, prior to the delivery of any telemedicine service.

II. STORE-AND-FORWARD TELEDERMATOLOGY

a. Definitions

Store-and-forward teledermatology refers to a method of providing asynchronous consultations to referring providers or patients. A dermatologic history and a set of images are collected at the point of care and transmitted for review by the dermatologist. In turn, the dermatologist provides a consultative report back to the referring provider or patient at the point of care. **Position**

Store-and-forward teledermatology is used in several settings:

1. Teletriage involves the review of patient cases transmitted by a referring provider to determine which patients need to be seen in-person by a dermatologist, which patients can be cared for by teleconsultation, and which patients may not need dermatologic referral.
2. Teleconsultation involves the review of patient cases transmitted by a referring provider and the provision of a consultative report back to the referring provider. Unless the patient's care is then transferred to the consulting dermatologist, the referring provider typically maintains responsibility for carrying out treatment recommendations.
3. Direct-to-patient telemedicine involves a patient originating his/her own consultation by transmitting a medical history and images to a dermatologist, who then receives some form of care from the dermatologist

b. Technology
A digital camera, whether integrated in a mobile handheld device or comprehensive telecommunications system or a stand-alone product, with a minimum of 800 x 600 pixel (480,000) resolution is required; however, higher resolutions may increase diagnostic fidelity. For systems that transmit over the Internet, a minimum 128-bit encryption and password-level authentication are recommended.
c. Credentialing and Privileging
Practitioners who render care using store-and-forward systems are viewed by TJC as "consultants" and may not be required to be credentialed at the originating site. However, standards can vary by state and organization.
d. Privacy and Confidentiality
In this case, HIPAA compliance is largely a matter of the originating site letting patients know that their information will be traveling by electronic means to another site for consultation. This should be noted in the consent form at the point of care, and the HIPAA notice of privacy practices. In addition, all electronic transmissions should be encrypted and reasonable care should be taken to authenticate those providers who have electronic access to the records.
e. Licensing
Most states require the physician to be licensed in the same state as where the patient resides, even when he or she acts only as a consultant. Providers who wish to provide store-and-forward consultations across state lines should limit such consultations to originating states in which they are permitted, by law, to provide care.
f. Current Reimbursement
As of 2014, CMS reimburses store-and-forward teledermatology only as a demonstration project in Hawaii and Alaska. However, several states are currently reimbursing store- and-forward teledermatology for Medicaid patients. There are also private insurers that are paying for store and forward modalities, including those that are part of a Medicare Advantage plan. Providers who wish to provide store-and-forward services should inquire with their payers regarding reimbursement.
g. Responsibility / Liability
In the teletriage and teleconsultation models (provider to provider), the referring provider ultimately manages the patient with the aid of the consultant’s recommendations. The referring provider may accept the recommendations in part or whole or none at all, and the responsibility and potential liability in this scenario may be shared (between the referring provider and the consultant) based on the extent to which the recommendations were followed by the referring provider. If a direct-to-patient model (provider to patient) is used (no provider at the referring site), the responsibility and potential liability rests entirely on the teledermatologist. In this case, the teledermatologist would also be responsible to ensure proper follow up and to address any medication complications. Dermatologists should verify that their medical liability insurance policy covers telemedicine services, including telemedicine services provided across state lines if applicable, prior to the delivery of any telemedicine service.
III. CRITERIA for HIGH QUALITY TELEDERMATOLOGY
The Academy supports the use of telemedicine services provided by Board certified dermatologists, as well as coverage and payment for those services, when several important criteria are met:
a. Physicians delivering teledermatology services must be licensed in the state in which the patient receives services, and must abide by that state’s licensure laws and medical practice laws and regulations. Emergency treatment and situations that arise when a dermatologist’s existing patient is

traveling to another state should be exceptions to this requirement, though existing laws and regulations may still apply. The Academy supports efforts by State Medical Boards to facilitate and lower burdens for physicians to obtain licenses in multiple states.

b. Patients or referring physicians seeking teledermatology services must have a choice of dermatologist, and must have access in advance to the licensure and board certification qualifications of the clinician providing care. The delivery of teledermatology services must be consistent with state scope of practice laws. The Academy strongly believes that any use of non-physician clinicians in the delivery of teledermatology should abide by the supervision requirements in the Academy's Position Statement on the Practice of Dermatology.

c. The patient's relevant medical history must be collected as part of the provision of teledermatology services. For teletriage and teleconsultation, appropriate medical records should be available to the consulting dermatologist prior to or at the time of the telemedicine encounter. Consulting dermatologists should have a good understanding of the culture, health care infrastructure, and patient resources available at the site from which consults are originating.

d. The provision of teledermatology services must be properly documented. These medical records should be available at the consultant site, and for teletriage and teleconsultation services, should also be available at the referral site.

e. The provision of teledermatology services should include care coordination with the patient's existing primary care physician or medical home, and existing dermatologist if one exists. This should include, at a minimum, identifying the patient's existing primary care physician and dermatologist in the teledermatology record, and providing a copy of the medical record to those existing members of the treatment team who do not have electronic access to it. This is especially important so that information about diagnoses, test results, and medication changes are available to the existing care team.

f. Organizations and clinicians participating in teledermatology should have an active training and quality assurance program for both the distant and receiving sites. In addition, those programs that are using teledermatology should have documentation of their training programs for any technician who is capturing clinical images and for any manager who is handling consults. Each organization should also maintain documentation on how the program protects patient privacy, promotes high quality clinical and image data, continuity of care, and care coordination for patients who may require subsequent in-person evaluations or procedures.

g. Organizations and clinicians participating in teledermatology must have protocols for local referrals (in the patient's geographic area) for urgent and emergency services.

h. The physician-patient relationship:

a. For teletriage and teleconsultation services where a referring provider ultimately manages the patient (including the prescription of medications), the consulting dermatologist is **not** required to have a pre-existing, valid patient-physician relationship. It is optimal, however, if the patient has available access to in-person follow-up with a local, board-certified dermatologist if needed.

b. For direct-to-patient teledermatology, the Academy believes that the consulting dermatologist must either:

i. Have an existing physician-patient relationship (having previously seen the patient in-person), or
ii. Create a physician-patient relationship through the use of a live-interactive face-to-face consultation before the use of store-and-forward technology, or
iii. Be a part of an integrated health delivery system where the patient already receives care, in which the consulting dermatologist has access to the patient's existing medical record and can coordinate follow-up care.

i. The use of ***direct-to-patient teledermatology*** raises several additional issues (and all of the above criteria still apply):

a. Providers must exercise caution regarding direct prescribing for patients via electronic communications. Most states have regulations that discourage or prohibit practitioners from prescribing for patients that they have not seen face to face. In many cases, the wording of these regulations is such that a live interactive teleconsultation would meet the requirements for a "face to face exam." The Federation of State Medical Boards established a National Clearinghouse on Internet Prescribing located at http://www.fsmb.org/ncip_overview.html. The Clearinghouse includes a state-by-state breakdown of jurisdiction, regulations, and actions related to the regulation of Internet prescribing.
b. Dermatologists providing direct-to-patient teledermatology must make every effort to collect accurate, complete, and quality clinical information. When appropriate, the dermatologist may wish to contact the primary care providers or other specialists to obtain additional corroborating information.
c. Photographs obtained by patients, their family members, or their friends outside of a clinical setting may not be of adequate quality, or may not include the appropriate lesions or areas, to make an accurate diagnosis.
d. Mechanisms to facilitate continuity of care, follow-up care, and referrals for urgent and emergency services in the patient's geographic area must be in place. Any new medications prescribed or changes in existing medications must be communicated directly to the patient's existing care team (unless they have easy electronic access to the teledermatology record).

e. The Academy does not support direct-to-patient teledermatology services designed ***primarily*** for profit, or direct-to-patient teldermatology services designed ***primarily*** to provide prescriptions to patients via electronic means.
Disclaimer This Position Statement is intended to be for informational and educational purposes only. It is not intended to establish a legal, medical, or other standard of care. Individual physicians should make independent treatment decisions based on the facts and circumstances presented by each patient. The information presented herein is provided "as is" and without any warranty or guarantee as to accuracy, timeliness, or completeness. AAD disclaims any liability arising out of reliance on this Position Statement for any adverse outcomes from the application of this information for any reason, including but not limited to the reader's misunderstanding or misinterpretations of the information contained herein. Users are advised that this Position Statement does not replace or supersede local, state, or federal laws. As telemedicine laws vary by State, this Position Statement is not a substitute for an attorney or other expert advice regarding your State law, policies and legal compliance with applicable statutes. The material in this Position Statement is based on information

available at the time of publication. As laws and regulations continually change, practitioners must keep themselves informed of changes on an

Please ensure that STORE AND FORWARD TELEDERMATOLOGY is included as an option.

Please discuss with the Univeristy of Iowa Dermatology Department and AAD respresentatives before finalizing the new rules.

Another resource to consider is Alaska and Hawaii. They have been LEGALLY BILLING MEDICARE for STORE AND FORWARD TELEDERMATOLOGY FOR the last DECADE....Their respective Boards of Medicine have 10 (ten) years of experience with this process.

Timothy G. Abrahamson MD
Greater Des Moines Dermatology PC
2424 NW 128th Street
Urbandale, Iowa 50323
515-243-8676 phone
515-243-0487 fax
lbrtga@yahoo.com

From: Susan Koehler

Here is the text of the proposed rule, with concerning verbage in CAPS

653—13.11(9)

*Non-physician health care providers. If a licensee who uses telemedicine relies upon or delegates medical services to a **non-physician health care provider who requires physician supervision, the licensee shall:*

a. Ensure that each non-physician health care provider is qualified and competent to safely perform each medical service being provided by PERSONALLY ASSESSING the non-physician health care provider's EDUCATION, TRAINING, experience and ability;

b. Ensure that each medical service provided is within the scope of practice of the licensee, and the non-physician health care provider, including their EDUCATION, TRAINING, experience, ability, LICENSURE OR CERTIFICATION;

c. Ensure that the licensee is available electronically to consult with non-physician health care providers, particularly in case of injury or an emergency;

The goal of these proposed rules is to ensure that individuals who provide telemedicine services are appropriately qualified and supervised.

However, the broad reference to **NON-PHYSICIAN HEALTH CARE PROVIDERS fails to recognize that PAs are already appropriately supervised, educated, trained, credentialed and qualified through laws and rules of both the Iowa Board of Medicine and Iowa Board of Physician Assistants. Thus there become potentially confusing and conflicting rules.

Therefore a simple solution with precedent already set would be to add:

Physician assistants. Nothing in these rules shall be interpreted to contradict or supersede the rules established in IAC 645—Chapters 326 and 327.

This is language that has previously been used in rules governing the regulation of medical spas, and would avoid conflicting or confusing rules.

("IAC 653-13.8(7) *Physician assistants.* Nothing in these rules shall be interpreted to contradict or supersede the rules established in 645—Chapters 326 and 327.")

IOWA HOSPITAL ASSOCIATION

January 12, 2015

Mark Bowden
Board of Medicine
400 SW Eighth Street, Suite C
Des Moines, IA 50309

Dear Mr. Bowden,

On behalf of the 118 hospitals providing medical care in Iowa, the Iowa Hospital Association ("IHA") writes to provide the following comments regarding the Board of Medicine's proposed telemedicine rule (ARC 1769C).

IHA is pleased to see the changes made to section 13.11(16), which allows for all three categories of telemedicine technologies: store and forward, remote monitoring and real-time. IHA believes the language contained in this section to be beneficial not only for providers, but for patients. IHA believes a broad definition of telemedicine allows for increased access and reduced costs to the health care system. Restricting the technologies allowed for by this proposed rule would have a significant negative impact on the ability of providers to use telemedicine technology to serve patients. It is important that providers and hospitals understand the scope of this somewhat uncharted territory.

IHA supports and advocates for telemedicine policy that provides for reimbursement parity from all payers operating in the state, as well as policy that creates an environment where physicians and health care providers are able to provide care within their scopes of practice and make care decisions based on their own professional judgment. Telemedicine policy, whether in law or rule, that is inclusive of these considerations would help to promote consistent telemedicine adoption across the state, which would increase access for patients, cushion the current shortage of providers in areas like behavioral health, and decrease health care costs through achieved efficiency.

Thank you for allowing IHA to provide comment on this noticed rule.

Sincerely,

Sara Allen
Director of Government Relations/Staff Attorney
(515)288-1955

4500 N. Lewis Ave
Sioux Falls, SD 57104

November 11, 2014

Mark Bowden
Iowa Board of Medicine
400 SW 8th Street, Suite C
Des Moines, IA 50309-4686

Mr. Bowden,

Avera eCARE supports the Iowa Board of Medicine in establishing standards of practice for physicians who use telemedicine in their medical practices and we agree with your proposed amendment for 653 Iowa Administrative Code Chapter 13, "Standards of Practice and Principles of Medical Ethics". Avera eCARE currently supports several hospitals, clinics and long term care centers in northwest Iowa with our eEmergency, eICU, ePharmacy, eConsult, and eLTC services. These telemedicine services are making a positive impact on each community by keeping patients local, reducing the burden and expense of traveling to a larger city for specialty care, lowering total cost of care and improving patient quality which leads to better outcomes. Each service operates in a unique fashion, keeping the needs of the patient and practice of quality medicine as the foremost priorities.

We have carefully read your proposed amendments and have several points of concern we would like to draw your attention to.

1) **653—13.11(10) Informed consent.**

"A licensee who uses telemedicine shall ensure that the patient provides appropriate informed consent for the medical services provided, including consent for the use of telemedicine to diagnose and treat the patient, and that such informed consent is timely documented in the patient's medical record."

Currently, informed consent occurs at the originating site where the patient is located. We feel that separate informed consent for the telemedicine services is redundant, confusing and burdensome for the patient especially in cases of emergency medicine and intensive care. Consent for the use of telemedicine to diagnose and treat the patient is directed by the local provider, therefore, one consent-to-treat form should cover all services needed to diagnose and treat the patient.

2) **653—13.11(13) Emergency services.**

"A licensee who uses telemedicine shall establish written protocols for referral of the patient to an acute care facility or an emergency department when it is necessary for the safety of the patient in case of emergency."

We feel that written protocols for referral of the patient to an acute care facility or an emergency department are the responsibility of the originating site where the patient is located. In the event of an emergency, the local facility would ensure the safety of the patient and understand best what local resources are available. Avera eCARE partners effectively with eight Iowa facilities and while we strive to understand the dynamics and resources of each facility, ultimately we rely on local staff for these protocols. The telemedicine provider will follow the protocols established by the originating site when referring the patient to a higher level of care.

3) 653—13.11(14) Medical records.

"The licensee shall note in the patient's record when telemedicine is used to provide diagnosis and treatment."

When we work in ICUs (eICU) and emergency rooms (eEmergency) the local provider retains the patient and the role of primary caregiver; therefore, the local provider retains the medical record and we may or may not have rights or access to the EMR. In these cases, a licensee who uses telemedicine may not have the ability to note in the patient's record in situations where they do not have access to the EMR. The originating site, where the medical record resides, is the primary owner and source for maintenance of the patient's medical record. As an alternative, we suggest that a licensee who uses telemedicine shall ensure that each encounter is documented in a log or separate record for timely access to all information obtained during the telemedicine encounter. The licensee will also ensure that any electronic communications, records physician-patient communications, laboratory and test results, evaluations and consultations, prescriptions, and instructions obtained or produced in connection with the use of telemedicine technologies are provided in writing to the originating site to include in the patient's medical record.

4) 653—13.11(17) Disclosures and functionality of telemedicine services.

"A licensee who uses telemedicine shall clearly disclose the following information to the patient:

a. Types of services provided;
b. Contact information for the licensee;
c. Identity, licensure, board-certification, credentials, and qualifications of all health care providers who are providing the telemedicine services;
d. Limitations in the drugs and services that can be provided via telemedicine:
e. Fees for services, cost-sharing responsibilities, and how payment is to be made;
f. Financial interests, other than fees charged, in any information, products, or services provided by the licensee(s);
g. Appropriate uses and limitations of the technologies, including emergency situations;
h. Uses and response times for e-mails, electronic messages and other communications transmitted via telemedicine technologies;

i. To whom patient health information may be disclosed and for what purpose;
j. Rights of patients with respect to patient health information; and
k. Information collected and passive tracking mechanisms utilized."

Avera eCARE supports the CTeL telemedicine guideline where "the telemedicine encounter must be equal or superior to the same encounter done in-person." Each originating site is responsible for ensuring the credentials and privileges for the providers offering services to patients in their facility. We feel that a separate disclosure for the licensee who uses telemedicine is unnecessary, burdensome and excessive since the in-person provider is not required to provide this information. This has the potential to unnecessarily restrict access to telemedicine. As an alternative, we recommend stating that this information be made available to patients upon request.

Thank you for your consideration of our comments. We look forward to the continued expansion of telemedicine services in the state of Iowa and are happy to answer any questions or provide more clarification and examples to support your proposed standards.

Sincerely,

David Erickson, MD
Executive Vice President / Chief Medical Officer, Avera Health

TELADOC.

January 14, 2015

VIA EMAIL AND FEDEX

Mark Bowden
Executive Director
Iowa Board of Medicine
400 SW 8th Street
Suite C
Des Moines, Iowa 50309-4686

Re: Comments to Notice of Intent to Publish Rule on Standards for Physicians Who Use Telemedicine

Dear Mr. Bowden:

Teladoc, Inc. ("Teladoc") appreciates the opportunity to submit the following comments in response to the notice of intended action to establish a rule regarding standards for telemedicine. While Teladoc commends the effort of the Iowa Board of Medicine ("Board") to establish standards for telemedicine, there are a number of provisions in the proposed rule that we believe will adversely impact the availability and quality of health care in the state of Iowa. As such, and for reasons discussed below, we urge the Board to carefully consider our comments as we believe they better comport with current telemedicine practice, including the Federation of State Medical Boards Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine and the American Telemedicine Association Practice Guidelines for Real-time, Direct-to-Patient Primary Urgent Care.

Background

By way of background, Teladoc is the first and largest provider of telemedicine consultations in the United States. Teladoc has the industry's deepest experience in telemedicine and partners with various stakeholders in the health care space, including employers, insurers/payors, hospital systems, clinicians, and regulatory professionals. Teladoc has the industry's only dedicated in-house clinical quality capability, which includes provider credentialing, evidenced based clinical protocols, and proprietary guidelines specific to telemedicine. Teladoc has a rigorous quality assurance program in which the company reviews 15 percent of all its consultations monthly to ensure quality and compliance with Teladoc telemedicine protocols. The company also has a quality improvement program in place to assess physician satisfaction on a quarterly basis. Teladoc has 95 percent member satisfaction and is the only telemedicine company to be certified by the National Committee for Quality Assurance ("NCQA"). We performed approximately 300,000 telemedicine consults in 2014. Teladoc was able to provide this number of consultations while maintaining an exceptional safety record.

All Teladoc physicians are board certified and have an average of 15 years of experience when they start working with the company. Teladoc has also worked to develop the only evidence-based clinical guidelines for asynchronous store and forward telephonic and audio-visual treatment of common, uncomplicated medical conditions. Today, the company has over a hundred evidenced-

based proprietary guidelines that assist the practice of its physicians. Consequently, after more than a decade of service and approaching 1 million telemedicine consultations, Teladoc has yet to be subject to a single malpractice claim.

Teladoc Delivery Model

Teladoc provides cross coverage telemedicine services via asynchronous store and forward telephonic consultations or web-based video consultations, as selected by the patient. Teladoc physicians only treat minor, non-emergent, non-recurring medical issues (*e.g.*, cold and flu symptoms, bronchitis, allergies, conjunctivitis, respiratory infection, sinus problems)—with short-term prescriptions of common medications. Teladoc physicians, where appropriate, will advise the patient regarding whether that patient should seek an in-person consultation with a specialist or go to an emergency room. The Teladoc physician may also refer the patient back to his or her primary care physician when appropriate. Teladoc physicians do not act as primary care physicians for Teladoc patients, and users are required to acknowledge that fact before requesting a telemedicine consultation. Teladoc's telemedicine services are only provided to patients through their employer, health-insurance company or hospital system and are not open to the direct-to-consumer market. Only patients who have been appropriately validated through the Teladoc system may make appointments with Teladoc physicians.

Teladoc physicians do not prescribe DEA controlled substances, non-therapeutic drugs, and certain other drugs which may be harmful because of their potential for abuse. For emergencies, patients are told to immediately visit their local emergency room or call 911. To the extent a patient presents with a condition not appropriately treatable via telemedicine, Teladoc will refer them to their primary care physician or another physician for an in-person evaluation.

Given Teladoc's position as the nation's largest and fastest growing providing of telemedicine, we work very closely with Medical Boards from across the country as they develop rules and regulations regarding telemedicine. We have paid close attention to Iowa's proposed rule. In reviewing the proposed rule, we believe the Iowa Medical Board has done a very good job of drafting a comprehensive, well-thought out rule. That being said, we have a few comments and suggestions regarding that rule, which follow below.

Definition of Telemedicine (§ 653—13.11(1))

We recommend that the Board change its proposed definition of telemedicine to better reflect current telemedicine practice which includes the ability of providers to use store-and-forward telephonic consultations. Accordingly, the definition of "telemedicine" should be changed to read:

> [T]he practice of medicine using electronic audio-visual communications and information technologies or other means, ***including interactive audio with asynchronous store and forward transmission,*** between a licensee in one location and a patient in another location with or without an intervening health care provider. ***Telemedicine includes store-and-forward technologies, remote monitoring, and real-time interactive services.*** Telemedicine shall not include the provision of medical services only through an audio-only telephone, email

> messages, facsimile transmissions, U.S. mail or other parcel service, or any combination thereof.

We further recommend that "asynchronous store and forward transmission" be defined as "the transmission of a patient's health information from an originating site to a health care provider at a distant site without the presence of the patient." We believe these changes reflect current telemedicine practice. For example, the Federation of State Medical Boards ("FSMB"), an organization representing the 70 medical and osteopathic boards of the United States and its territories, supports Teladoc's approach in defining telemedicine to include interactive audio asynchronous store and forward consultations. Earlier this year, the FSMB adopted the Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine ("Model Policy"), in which it set forth standards for the practice of telemedicine.[1] Among other things, the Model Policy provides that telemedicine:

> [T]ypically involves the application of secure videoconferencing or store and forward technology to provide or support healthcare delivery . . . .

The leading association in the telemedicine sector, the American Telemedicine Association, has also affirmed the viability of the use of asynchronous store and forward telephonic consultations between providers and patients (i.e., direct-to-patient) in the delivery of primary and urgent care services.[2] This only confirms our extensive experience that when given the choice, consumers of telemedicine prefer interactive audio asynchronous store and forward consultations over video consultations the vast majority of the time. More than 4,000 U.S. employers, many of which are Fortune 1000 companies, offer coverage for telemedicine services to their employees. In most instances, this coverage allows the consumer to choose between video consultations or interactive audio asynchronous store and forward consultations. In states where Teladoc offers both video and asynchronous store and forward telephonic consultations (at the same cost), the vast majority of users elect to have the asynchronous store and forward telephonic consultation. We strongly believe that there is an appropriate time and place for the use of such store and forward telephonic consultations, namely, for the evaluation and treatment of conditions for which diagnoses can be made based on history and conditions reported by patients (e.g., cold and flu symptoms, bronchitis, allergies, conjunctivitis, respiratory infection, sinus problems) with short-term prescriptions of common medications and physician advice regarding whether in-person consultation with a specialist may be most appropriate.

Nationally Recognized Telemedicine Guidelines (§§ 653—13.11(2) & 653—13.11(7)(3))

The draft proposed rule requires physicians practicing telemedicine to be aware "that nationally recognized medical specialty organizations have established comprehensive telemedicine practice guidelines which address the clinical and technological aspects of telemedicine for many medical

---

[1] FSMB Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine: Report of the State Medical Boards' Appropriate Regulation of Telemedicine (SMART) Workgroup (April 2014).

[2] American Telemedicine Association, Practice Guidelines For Real-time, Direct-to-Patient Primary Urgent Care Telemedicine (May 2014).

specialties." The provision goes on to require that physicians use evidence-based telemedicine practice guidelines to ensure patient safety and quality of care. While Teladoc agrees with the approach in concept, we believe that the provision does not reflect the reality of current telemedicine practice. Very few specialty organizations or societies have developed what could be considered "comprehensive telemedicine practice guidelines." Many organizations have instead developed short position or policy statements broadly outlining concepts and approaches to telemedicine practice—far short of what any reasonable observer would consider comprehensive practice guidelines. For example, the American Academy of Dermatology has developed a six-page "Position Statement on Teledermatology" which briefly touches on issues such as licensure, credentialing, privacy, and technology.[3] As it does not include any practice details, the Statement is more accurately described as a policy document rather than a comprehensive practice guideline as likely envisioned in the draft proposed rule. Many other organizations such as the American Academy of Family Physicians and the American Academy of Neurology and have similar broad policy statements, an illustration that nationally recognized medical organizations have yet to develop a body of comprehensive telemedicine practice guidelines.[4] Interestingly, however, many providers have developed their own telemedicine practice guidelines. Teladoc, for example, has developed over a hundred of its own comprehensive practice guidelines its physicians follow. We consistently reexamine various aspects of the guidelines as developments warrant. Moreover, as specialty organizations begin to develop comprehensive practice guidelines, we will analyze incorporating aspects of those guidelines into our existing framework, if appropriate. Given the relative lack of practice guidelines developed by specialty organizations, we recommend that the provision be changed as follows:

> ~~A licensee who uses telemedicine should be aware that nationally recognized medical specialty organizations have established comprehensive telemedicine practice guidelines which address the clinical and technological aspects of telemedicine for many medical specialties.~~ A licensee who uses telemedicine shall utilize evidence-based telemedicine practice guidelines, to the degree they are available, to ensure patient safety, quality of care, and positive outcomes.

We note that the draft proposed rule also includes a provision (section 653—13.11(7)(3)(b)(3)) that permits a physician-patient relationship to be established "in accordance with evidence-based telemedicine practice guidelines established by nationally recognized medical specialty organizations . . . ." As discussed above, there is little in the way of telemedicine practice guidelines from these organizations. Thus, we recommend that this section be changed as follows:

> (3) In accordance with evidence-based telemedicine practice guidelines ~~that are established by nationally recognized medical specialty organizations and address the clinical and technological aspects of telemedicine~~.

<u>Identification of Patient and Physician (§ 653—13.11(6))</u>

---

[3] American Academy of Dermatology, Position Statement on Teledermatology (Amended by the Board of Directors August 9, 2014).

[4] The American Telemedicine Association has developed guidelines especially in the areas of telemental health and telepathology, and along with others is currently developing more comprehensive practice guidelines.

The draft proposed rule notes that the patient must have "the ability to verify the identity, licensure status, board-certification, credentials, and qualifications of all health care providers who provide telemedicine services prior to the provision of care."

Teladoc believes that the provision of telemedicine should be available when a patient cannot get to his/her own existing primary care physician in a timely manner. In cross-coverage situations, similar to those in the urgent care or retail clinic settings, patients do not select the treating physician. Rather, patients receive care form a pool of physicians who have been assigned to work during a particular shift. We have no objection to disclosing a provider's identity and credentials so long as patients are not encouraged to pre-select a physician through pictures, bios, and other means. In our view, such pre-selection causes an emotional attachment to form between a patient and the physician providing services to that patient—thereby encouraging a more permanent rather than episodic relationship. By allowing pre-selection of physicians, a telemedicine-based solution takes the place of an existing patient-physician relationship—and automated assignment as employed by Teladoc reduces this possibility. As such, we recommend that the Board make it clear that while the patient can verify information about the physician, the patient not be allowed to pre-select physicians. As such, we recommend that proposed regulation's provision be changed as follows:

> A licensee who uses telemedicine shall verify the identity of the patient and ensure that the patient has the ability to verify the identity, licensure status, certification, credentials, and qualifications of all health care providers who provide telemedicine services ~~prior to the provision of care~~.

Medical History and Physical Examination (§ 653—13.11(8))

We appreciate the inclusion in the draft proposed rule of language that provides that the physical examination may not be in-person "if the technology utilized in a telemedicine encounter is sufficient to establish an informed diagnosis as if the medical interview and physical examination had been performed in-person." Teladoc believes such language accurately reflects recent national trends easing restrictions on the practice of telemedicine.

The FSMB Policy, designed to "provide guidance to state medical boards . . . and educate licensees" regarding the appropriate use of telemedicine, provides that the physician-patient relationship can be validly established "whether or not there has been an encounter in person between the physician and patient," and that "prescribing medications, in-person or via telemedicine, is at the professional discretion of the physician." In addition, the American Telemedicine Association in its Practice Guidelines for Real-time, Direct-to-Patient Primary Urgent Care Telemedicine, allows providers to "perform a virtual physical exam (for video or telephone-based visits) as indicated by the patient complaint . . . ." Finally, the American Medical Association released a report in June 2014 advocating for the reasonable expansion of telemedicine. The report notes that a valid physician-patient relationship "must be established, through at minimum a face-to-face examination . . . [which] could occur in person or virtually . . . ."

States have also adopted specific rules to improve access, ensure quality and patient safety for telemedicine delivery. Nevada, for example, amended its statute to eliminate the requirement for a physician to physically examine a patient, and now allows a patient to be "examined in person,

electronically, telephonically, or by fiber optics within or outside this State or the United States."[5] In Maryland, a physician, in lieu of a prior in-person face-to-face interaction, must "incorporate real-time auditory communications or real-time visual and auditory communications to allow a free exchange of information between the patient and the physician performing the patient evaluation."[6] North Carolina just last month released its revised telemedicine policy in which it deleted its requirement (in the draft policy) for the use of peripherals and diagnostics to one emphasizing the use of appropriate technology to satisfy the standard of care. Other states (*e.g.*, Alaska, New Mexico, Hawaii, Maine, Vermont) have followed suit.

Follow Up Care (§653—13.11(12)

While Teladoc commends the inclusion of follow up care regarding telemedicine, we believe that the provision needs to be slightly modified to reflect the fact that physicians and other healthcare professionals may not always have ready knowledge regarding the nature and availability of local medical resources, but can access such information quickly. We recommend that the provision be modified as follows:

> A licensee who uses telemedicine shall ensure that the patient has access to appropriate follow-up care following a telemedicine encounter. The physician shall have ***access to,*** or adequate knowledge of, the nature and availability of local medical resources to provide appropriate follow-up care to the patient following a telemedicine encounter.

Circumstances When a Physician May Not Personally Examine a Patient (§§ 653—13.11(20)(c) & (d))

We appreciate the history and background that the Board has provided to us regarding this section. While we understand that this section is designed to apply to those situations in which a physical exam is not required as opposed to those situations in which telemedicine is used, we would ask that the Board add some clarifying language for on call and cross coverage situations.

The draft proposed rule allows a physician to treat a patient the physician has not personally interviewed, examined, and diagnosed under certain circumstances, including in on call and cross coverage situations. The provisions, however, only give the power to the physician to designate the on call or cross coverage physician. Teladoc believes that in addition to such physician designation, the patient should also have the power to make such a designation. We believe in patient-directed care, and that patients should be empowered to designate their own on call or cross coverage physician just as they select their primary care physician and any specialist physicians. Such an approach is in keeping with modern medical practice in which patients play a much larger role in their care than in the past.

---

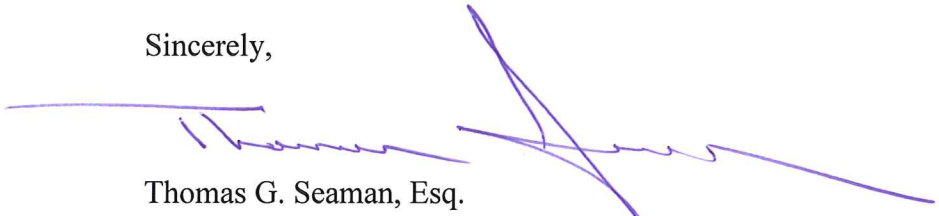
[5] Nev. Rev. Stat. § 633.165.
[6] Md. Code Regs. 10.32.05.05.

Given our practice experience with on call and cross coverage service, and our commitment to patient-directed care, we recommend the following changes:

> c. Call situations in which a licensee, ***designated by the patient or other licensee, is taking call for such other licensee,*** who has an established physician-patient relationship with the patient;
>
> d. Cross coverage situations where a licensee, ***designated by the patient or other licensee is providing cross coverage for such other licensee,*** is providing coverage for another licensee who has an established physician-patient relationship with the patient;

Teladoc appreciates the opportunity to comment on the draft proposed rule. If you need more information or have any additional questions please do not hesitate to contact me.

Sincerely,



Thomas G. Seaman, Esq.
General Counsel & Chief Compliance Officer
Teladoc, Inc.

cc: Henry DePhillips, M.D.
Chief Medical Officer (Teladoc)
Claudia Tucker
Vice-President Government Affairs (Teladoc)

Mr. Bowden,

I am writing to you regarding the noticed rules to establish telemedicine standards for Iowa licensed physicians in 653-13.11.

As we discussed on Friday, January 19th, The Iowa Clinic physicians have concerns regarding the ability to prescribe through telemedicine/telehealth interactions. Of particular concern are narcotics or other prescription drugs that could have life threatening consequences without a full and complete physical performed by the physician. We fully understand that the need for standards to be set by the Board of Medicine but the rules as currently written do not go far enough to patients and consumers.

As you know, this is of particular concern for The Iowa Clinic and the Iowa Independent Physician Group in conjunction with the Iowa Board of Medicine's legislative proposal for an Interstate Medical Licensure Compact. The clinics do not believe the potential unintended consequences have been fully vetted or studied regarding the use of telemedicine and adequate regulation by all state licensure boards who are potential compact members.

Please do not hesitate to contact me if you have questions. Thank you for the opportunity to continue to work with you on issues coming before the IBM.

Karla Fultz McHenry
Fultz McHenry Consulting LLC

515 E. Locust Street, Suite 400
Des Moines, IA 50309
515 223-1401 • 800 747-3070
Fax 515 223-0590
www.iowamedical.org

IMS Board of Directors

President
Jeff Maire, DO
Des Moines

President-elect
K. John Hartman, MD
Davenport

Chair
Paul Mulhausen, MD
West Des Moines

Secretary/Treasurer
Joyce Vista-Wayne, MD
Des Moines

Past President
Victoria Sharp, MD
Iowa City

Directors
Marygrace Elson, MD
Iowa City

Janice Kirsch, MD
Mason City

Michael McCoy, MD
West Burlington

Harold Miller, MD
Davenport

Curtis Page, MD
Dubuque

Brian Privett, MD
Cedar Rapids

Michael Romano, MD
Council Bluffs

Douglas Steenblock, MD
Marshalltown

Mark Tannenbaum, MD
West Des Moines

Scott Truhlar, MD
Coralville

William John Yost, MD
Des Moines

John Heineman, MD, R2
Iowa City
(Resident Director)

Helen Myers, M4
Iowa City
(Medical Student Director)

Executive Vice President
Clare M. Kelly
Des Moines

IMS
IOWA MEDICAL SOCIETY

January 15, 2015

Mark E. Bowden
Executive Director
Iowa Board of Medicine
400 SW 8th Street, Suite C
Des Moines, IA 50309-4686

RE: ARC 1769C Standards of Practice – Telemedicine

Dear Mr. Bowden:

On behalf of the 6,400 physician and medical student members of the Iowa Medical Society (IMS), thank you for this opportunity to comment on the Board of Medicine's proposed rule ARC 1769C—Standards of Practice—Telemedicine. IMS supports the effort to increase access to health care for Iowans in rural and underserved areas. Appropriate telehealth practice holds the potential to help in these efforts. To this end, IMS recommends the following amendments to **ARC 1769C**:

653 – 13.11(7)(b) A valid physician-patient relationship may be established:

1. Through an in-person medical interview and a physical examination (when medically necessary) <u>conducted prior to the use of telemedicine</u>, where an in-person encounter would otherwise be required in the provision of the same service not delivered via telemedicine;

2. Through consultation with another licensee (or other healthcare provider) who has an established relationship with the patient and who agrees to participate in, or supervise, the patient's care; or,

3<u>(a).</u> In accordance with evidence-based telemedicine practice guidelines that are established by nationally recognized medical specialty organizations and address the clinical and technological aspects of telemedicine

<u>(b). Where such nationally recognized medical specialty organization telehealth guidelines have not yet been established, by establishing via telemedicine a patient diagnosis through the use of acceptable medical practices, including patient history, mental status examination, physical examination (when medically necessary), and appropriate diagnostic and</u>

laboratory testing to establish diagnoses, as well as to identify underlying conditions or contraindications, or both, to treatment recommended or provided.

This proposed language clarifies that there are multiple ways to establish a valid physician-patient relationship other than in person and is consistent with AMA Policy H-480.946. The AMA guidelines, as well as the proposed language, outline that a valid patient-physician examination may be established in person, in consultation with a physician who has an ongoing relationship with the patient, or by meeting the standards established by national medical specialty organizations. The proposed language goes beyond the AMA guidelines to offer a method of establishing that relationship when no applicable national medical specialty organizations have established standards. This allows a physician to establish a valid relationship without an in-person encounter while still ensuring a baseline of appropriate care.

653—13.11(9) Non-physician health care providers. Except in emergent care situations or consultations provided pursuant to 13.11(7)(d)(2), ~~I~~ if a licensee who uses telemedicine ~~relies upon or~~ delegates the provision of the medical services to be provided by telemedicine to a non-physician health care provider who requires physician supervision, the licensee shall~~:~~

~~a. Personally assess each non-physician health care provider's education, training, experience, and ability to ensure that each provider is qualified and competent to safely perform each medical service being provided;~~

~~b. Ensure that each medical service provided is within the scope of practice of the licensee, and that of the non-physician health care provider, as evidenced by the education, training, experience, ability, licensure or certification of the licensee and the non-physician healthcare provider;~~

a. Ensure that the non-physician health care provider is qualified and trained to provide that service within the scope of the non-physician health care provider's practice;

~~c.~~ b. Ensure that the licensee is available electronically to consult with non-physician health care providers, particularly in case of injury or an emergency;

The proposed rule imposes a degree of responsibility upon physicians that does not currently exits when a medical service is provided in-person. IMS believes it is unreasonable to require physicians to "personally" assess the qualifications of nonphysician providers to whom patient care when responsibilities are delegated. IMS believes that physicians should, generally speaking, be able to rely upon the credentialing and employment processes of the facilities in which they practice.

The IBM's proposed language is more specific than AMA Policy H-480.946, which states that practitioners delivering telemedicine services must be licensed in the state or otherwise authorized by that state's board, and that the physician is responsible for the safety and quality of services provided to patients by nonphysician providers through telemedicine. Additionally, the Federation of State Medical Boards, in its model policy for telemedicine, does not require personal assessment of credentials.

> **653 – 13.11(18)(e)** Fees for services, cost-sharing responsibilities, and how payment is to be made, <u>if these differ from an in-person encounter.</u>

This is not current practice for in-person visits given the administrative complexities of differing fee schedules for each payer and contracting arrangement. IMS believes this language is more in line with the Board's intention of ensuring that patients are informed if there is an additional financial responsibility for receiving care via telemedicine, but that providers are not faced with an additional administrative burden if there are no additional fees for receiving care via telemedicine.

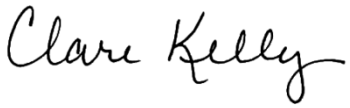
> **653 – 13.11(21) Prescribing ~~controlled substances~~ <u>based solely on an internet request, internet questionnaire or a telephonic evaluation</u> – prohibited.** Prescribing ~~controlled substances~~ to a patient based solely on an internet request <u>or</u> internet questionnaire <u>is prohibited.</u> <u>Absent a valid patient-physician relationship, prescribing to a patient based solely on</u> ~~or~~ a telephonic evaluation is prohibited.

IMS recognizes the need to ensure appropriate virtual and telephonic practice, and concurs with the IBM that prescribing based solely on internet requests or internet questionnaires is inappropriate and a patient safety concern. Iowa should prohibit

all prescribing on this basis to put in place even stronger public protections. It is common practice for physicians with an established patient relationship to evaluate patients telephonically from time to time. This language change would ensure that practice may continue, however, it would clarify that prescribing to a patient absent a valid existing relationship is inappropriate.

Thank you again for the opportunity to provide comment.

Sincerely,



Clare M. Kelly
Executive Vice President

American Telemedicine Association
1100 Connecticut Avenue, NW, Suite 540, Washington, DC 20036-4146
202.223.3333 • Fax: 202.223.2787 • www.americantelemed.org

January 15, 2015

Mark Bowden
Executive Director
Iowa Board of Medicine
400 SW 8th Street
Suite C
Des Moines, Iowa 50309-4686

RE: Telemedicine Draft Rulemaking and Notice of Intended Action

Dear Mr. Bowden:

The American Telemedicine Association (ATA) appreciates the opportunity to comment on the Iowa Board of Medicine ("the Board") Telemedicine Draft Rulemaking and Notice of Intended Action. However, we find that parts of the proposed rule are overly prescriptive, duplicative and conflicting and believe it will interfere with the intent of the Board to ensure safe and effective medical practice via telemedicine.

ATA strongly supports mechanisms that assure patient safety and promote that all health services delivered either in-person or via telemedicine are of the highest quality. Specifically with regard to medical practice rules, we believe that, as much as possible, the practice of telemedicine should not be regulated differently than in-person care. While there are important clinical differences that should be recognized, allowed, and appropriately regulated, the provision of telemedicine should not be held to a different standard than in-person care.

Your existing medical practice rules provide that consistency. In fact, Iowa was graded an "A" by ATA for having a supportive policy landscape that accommodates telemedicine adoption and usage in our *50 State Telemedicine Gaps Analysis: Physician Practice Standards & Licensure*.[1] We do not see a need for the Board to change existing policies.

We highlight important areas where the draft guidance would impose different and higher standards – and thus objectionable standards – for telemedicine. To facilitate your understanding and consideration of our comments we are including some specific comments in this letter.

13.11(1) Definitions

While we commend the Board for streamlining definitions pertaining to telemedicine, it is important to underscore that telemedicine is a delivery method and not a separate service such as surgery or anesthesia. Therefore it is not necessary to arbitrarily redefine the practice of medicine or patient encounters as it applies to those using telemedicine tools.

ATA recommends that the Board consolidate the definitions for "telemedicine" and "telemedicine technologies" and allow licensed physicians to rely on their own medical judgment in the delivery of critical care services just as they would if the patient were present in the physician's office.

> *"Telemedicine" means the provision of services to a patient by a physician from a distance by electronic communication in order to improve patient care, treatment or services.*

The Board should maintain a consistent position and uphold your opinion that the "licensees using telemedicine will be held to the same standards of care and professional ethics as licensees using traditional in-person medical care".

13.11(3) Licensure

We recommend that the Board observe its current policy on professional licensure and not create a separate and disruptive licensure standard for telemedicine providers. Currently a physician must obtain a full and unrestricted license in order to practice medicine in the state of Iowa. Moreover, the Board currently grants licensure exemptions to out-of-state physicians who meet the following criteria:

- Physicians and surgeons or osteopathic physicians and surgeons of the United States army, navy, air force, marines, public health service, or other uniformed service when acting in the line of duty in this state, and holding a current, active permanent license in good standing in another state, district, or territory of the United States; and

- Physicians and surgeons or osteopathic physicians and surgeons licensed in another state, when incidentally called into this state in consultation with a physician and surgeon or osteopathic physician and surgeon licensed in this state.

There are several reasons for these exemptions. The current rules are consistent with laws and policies of federal agencies, such as those affecting the health care for hundreds of thousands of military and veteran Iowa residents. The proposed changes create a conflict with such a federal law. Additionally, the licensure exemption for out-of-state physician-to-physician consultations is an adequate policy and should apply to consultations provided via telemedicine. Forty-five states allow similar exemptions for out-of-state consultations via telemedicine.

One of the important uses of telemedicine is in emergencies, including both a patient's medical emergency and other types of emergencies affecting a locality. Sometimes telemedicine is the only alternative when no care is available. It is important that regulations not hinder patients from getting the best care that can be done under extenuating circumstances. The Board should extend licensure exemptions to out-of-state providers that meet the conditions outlined in section 13.11(20).

13.11(7) Physician-Patient Relationship

The proposed rule outlines a unique set of standards for the physician-patient relationship when telemedicine is employed. However, like with in-person care, the range of service needs and care circumstances for telemedicine varies too widely for a "one size fits all" relationship requirement. In particular, the nature of a required relationship is usually very different between on-going primary care and medical emergencies requiring a specialist. We believe the most critical factor is whether the physician has sufficient, appropriate clinical and other information to provide a specific medical service.

We are concerned that the Board would be taking an unprecedented step to propose higher standards for telemedicine-provided services than services provided in-person regarding relationship with a patient. Accordingly, we recommend that the Board delete this section and maintain a consistent position and uphold your opinion that the "a licensee who uses telemedicine shall be held to the same standards of care and professional ethics as a licensee using traditional in-person encounters with patients". Therefore, any such a requirement should apply to all licensees regardless of their method of providing care.

13.11(10) Informed Consent

It is important to underscore that telemedicine is a delivery method and not a separate service, such as surgery or anesthesia care. Additionally, there are no national trends for requiring patient informed consent as a medical practice standard for telemedicine. In fact, only 12 state medical boards have any patient informed consent requirements for telemedicine – and none have the draft's set of specifics.

We agree that it is important that the patient must be appropriately informed and limitations disclosed about their medical care. However, we recommend this section be re-titled as Informing the Patient and moderating the specifications to be more guidance than rigid regulations.

Sections 13.11(11-19)

We believe these sections are overly prescriptive and recommend that the Board remove provisions 13.11(11-19). Generally, the outlined proposed rules overlook existing regulations and interfere with the original intent of the rulemaking which is to increase access to health care, expand utilization of specialty expertise, and achieve potential cost savings. Telemedicine collaborations must be facilitated by streamlined processes that encourage physician participation if the transformative value of telemedicine is to be fully achieved. Yet these proposed rules will reduce physician engagement and participation in any telemedicine program implemented in Iowa. The net effect of these provisions would be to choke patient access to care that would become available through the use of telemedicine.

Further ATA believes that the prescriptive nature of the language disregards a physician's training, experience, and medical judgment in the provision of acceptable medical care, and dismisses evidence-based medical practice guidelines established by nationally recognized groups. Therefore, we recommend that the Board maintain a consistent position and uphold your opinion that the "a licensee who uses telemedicine shall be held to the same standards of care and professional ethics as a licensee using traditional in-person encounters with patients."

13.11(22) Internet Prescribing

ATA strongly recommends that the Board delete this section and reevaluate its position on prescribing. Section 13.11(22) requires a physician to be "physically present in the same location as the patient when prescribing, administering, or dispensing medication or providing treatment regimens that can be administered only by a physician". Although it may not be intended, the language may even prohibit a

patient from receiving follow-up care for normal interactions such accessing a different anti-biotic on the basis of a follow-up phone call. The fact is many physicians already issue non-controlled prescriptions based on either a phone or video visit. For mental health services such practice has commonly been in place for years and such a prohibition could seriously jeopardize existing mental health programs. This section starkly contrasts section 13.11(20), which outline circumstances when a physician may treat a patient without being physically present.

In conclusion, we urge the Board to propose consistent application among medical practices. To help understand how difficult different and higher standards would be, we suggest the Board consistently measure the impact and use of the proposed standards as if they were applied to all medical care.

Sincerely,

Jonathan D. Linkous
Chief Executive Officer

[1] American Telemedicine Association, 50 State Telemedicine Gaps Analysis: Physician Practice Standards & Licensure. September 2014; http://www.americantelemed.org/docs/default-source/policy/50-state-telemedicine-gaps-analysis--physician-practice-standards-licensure.pdf?sfvrsn=6

Iowa Physician Assistant Society
6919 Vista Drive
West Des Moines, IA 50266
ph: (515) 282-8192 fax: (515) 282-9117

January 14, 2015
Re: ARC 1769C, Medical Board's proposed telemedicine rules

Dear Mr. Bowden,

I am writing today on behalf of the Iowa Physician Assistant Society (IPAS), the only state organization representing the 1,100 PAs licensed to practice in the state. IPAS would like to comment on the Iowa Board of Medicine's proposed plan to promulgate rules to regulate telemedicine in the state (ARC 1769C).

As we face unprecedented provider shortages coupled with the strain of covering millions of uninsured patients in a reformed health care system, barriers must be removed to allow providers to extend the reach of medicine to underserved communities and at-risk populations. Regulations providing clarity to those who practice telemedicine will allow health professionals to consult with physicians, PAs, and other health professionals by way of telehealth technology.

The proposed regulations will benefit rural hospitals, rural communities, on-call physicians, PAs staffing the rural hospitals – and, most importantly, the patients who reside in rural communities and who rely on rural hospitals to provide excellent medical care.

IPAS is concerned with the following section of proposed rule:
653—13.11(9)
Non-physician health care providers. If a licensee who uses telemedicine relies upon or delegates medical services to a non-physician health care provider who requires physician supervision, the licensee shall:
a. Ensure that each non-physician health care provider is qualified and competent to safely perform each medical service being provided by personally assessing the non-physician health care provider's education, training, experience and ability;
b. Ensure that each medical service provided is within the scope of practice of the licensee, and the non-physician health care provider, including their education, training, experience, ability, licensure or certification;
c. Ensure that the licensee is available electronically to consult with non-physician health care providers, particularly in case of injury or an emergency;

Our concern is that PAs are not exempted from the definition of "licensed or unlicensed non-physician person" in section 653-13.11(9) of the draft rules. The goal of these proposed rules is to ensure that individuals who provide telemedicine services are appropriately supervised. PAs are already appropriately supervised, through laws and rules promulgated by both the Iowa Board of Medicine and Iowa Board of Physician Assistants.
As you know, the laws and regulations governing PA practice already require physician supervision of PAs in every clinical setting. PAs work as members of physician-directed teams, and must comply with the supervision requirements expressed in §645-326.8 of the Iowa Administrative Code.

Under those regulations, PAs cannot practice unless they are supervised by a licensed physician. Supervising physicians are required to accept responsibility for care provided by PAs. The physical presence of the supervising physician is not necessarily required so long as the physician is readily available via telecommunication.

The existing regulations governing PA practice also authorize supervising physicians to determine the scope of practice of PAs, as long as services provided by the PA are within the scope of practice of the supervising physician and the supervising physician has determined that the PA has sufficient training and experience to perform them: *"Diagnostic and therapeutic medical tasks for which the supervising physician has sufficient training or experience may be delegated to the physician assistant after a supervising physician determines the physician assistant's proficiency and competence."* - §645-327.1(1)
IPAS would respectfully request that language be added to this telemedicine regulation to avoid conflicting rules that may confuse practitioners. Such language may read as follows:

Physician assistants. Nothing in these rules shall be interpreted to contradict or supersede the rules established in IAC 645—Chapters 326 and 327.

This is language that has previously been used in rules governing the regulation of medical spas, and would avoid conflicting or confusing rules.

Thank you for your consideration of this request.

Sincerely,

Laurie Clair, PA
President Elect, Iowa PA Society

Mercy
HEALTH NETWORK

Sponsored by Catholic Health Initiatives–Englewood, CO and Trinity Health–Livonia, MI

1755 59th Place
West Des Moines, IA 50266

January 15, 2015

Mark Bowden
Board of Medicine
400 SW Eighth Street, Suite C
Des Moines, IA 50309
Via E-mail: Mark.Bowden@iowa.gov

Re: Comments on Proposed Telemedicine Rule – ARC 1769C

Dear Mr. Bowden:

Mercy Health Network and the Midwest Rural Telemedicine Consortium appreciate the opportunity to comment on the Board of Medicine's proposed rules on the practice of telemedicine in the Iowa. MHN applauds the Board's interest in advancing telemedicine. MHN has been an early adopter of telemedicine and has developed innovative uses for telemedicine across the state which is providing more access to health care service for Iowa and delivering high quality care in an efficient way.

Mercy Health Network (MHN) is a statewide system comprised of 11 owned and 27 contract-affiliated hospitals, and 142 physician clinics with 625 physicians. MHN is based in West Des Moines and includes the Mercy Medical Centers in Des Moines, Sioux City, Mason City, Dubuque and Clinton. It also includes owned community hospitals in Centerville, Dyersville, New Hampton, Primghar, West Des Moines and Oakland, Nebraska. MHN also has numerous long-term care, assisted living, and senior living facilities as well as many home health and hospice programs in Iowa. MHN has long worked to bring high-quality patient care to Iowa communities across the state.

The Midwest Rural Telemedicine Consortium, or MRTC, a service of Mercy Health Network, is a membership organization including 30 hospitals in Iowa and 2 hospitals in Nebraska. The Consortium was formed in 1994 and began providing telemedicine services using two-way interactive video and audio in 1995. MRTC has taken a broad view in defining telemedicine and includes clinical, educational and administrative services. Among the Consortium's first goals was to support Medicare's efforts to research and recommend payment models for telemedicine. Following those early efforts Medicare has recognized and expanded reimbursement for telemedicine, now frequently referred to as telehealth. Many states have legislated coverage for telehealth services. In Iowa, although coverage is not mandated through legislation, Medicare, Wellmark, Medicaid and some other third party payers cover some telemedicine services. On the national front, Medicare has recognized the benefits of telehealth to the point that it covers telehealth services provided in the hospital, emergency room and skilled nursing facilities and has recently added remote patient monitoring reimbursement.

While supportive of several aspects of the proposed rules, MHN has concerns about a few provisions in the rules. Our concerns are in six areas: definition of telemedicine, physician-patient relationship, informed consent, technology requirements, medications or treatment regimens and barriers to care and reimbursement.

Definition of Telemedicine
We applaud the Board for defining the clinical practice of telemedicine. We also request clarification that in defining telemedicine as between a licensee in one location and a patient in another location that common practices, such as tele-pathology or tele-radiology are not excluded from reimbursement in the state. These practices do not require patient participation. Also, the definition as written (a licensee in one location and a patient in another location) would appear to exclude Medicare approved group activities (HCPCS codes G0420 and G0421, kidney disease education; G0108 and G0109, diabetes self-management training services, CPT codes 96150 – 96154, health assessment and intervention; HCPCS G0270 and CPT 97802 – 97804, medical nutrition therapy). It would also exclude family engagement for services approved by Medicare for telehealth reimbursement (CPT code 90846, family psychotherapy (without the patient present); 90847, family psychotherapy (conjoint psychotherapy) (with patient present). Overall, the proposed rules, as they relate to defining telemedicine, impose a higher standard on a licensee providing care via telemedicine.

Physician-Patient Relationship
We are pleased to see clarification that interactive video and audio (face-to-face) encounter is an approved way to establish a physician-patient relationship. Additionally, we support the rule confirming interactive video and audio is allowed to perform a history and physical exam. These will allow for more patient access and patient choice in providers. We also support giving the provider the ability to decide whether or not telemedicine is appropriate to determine a diagnosis and provide treatment. It is important to allow providers to use professional judgment in this area.

Informed Consent/Privacy and Security
We appreciate and share the concerns the Board of Medicine has related to privacy and the security of patient information. However, we do not agree that telemedicine needs to be held to a higher standard. Given the extensive protections currently in place under HIPAA and current requirements regarding informed consent, these additional requirements are not necessary. Adding further requirements will only create an obstacle for expansion of telemedicine.

Technology Requirements
We appreciate that the Board of Medicine did not attempt to dictate technology and equipment technical specifications. Equipment capabilities change rapidly and any guidelines will quickly be outdated. The Board lists concerns related to safety laws for technology and devices. However, placing all of that responsibility on the provider is not reasonable – and is a more onerous burden than the physicians have in an in-person patient visit. It should also be noted that the use of the word "all" in these requirements could be misinterpreted. For example: all technology and equipment used in a telemedicine encounter may not interact with patients or be integral to patient care, but any equipment would be required to meet those high standards as the rule is written. Some technology aspects of electronic medical records seem to have been combined with the provision of telemedicine services (i.e., rapid availability of patient records, HIPAA compliant). The expectation that an individual physician, physician practice or medical facility would be able to provide electronic access to patient medical records is a higher standard than currently available or a realistic standard to impose at this time. And, whereas the EMR shares stored electronic patient information and is addressed under HIPAA transmission media guidelines, not all telemedicine services include or exchange previously electronically stored information, so the transmission may meet the same conditions as the phone or a fax and not be considered transmission via electronic media.

Medications or Treatment Regimens
In the proposed rules, section 13.11(21) creates restrictions for "Medications or treatment regimens that can be administered only by a physician." However, there is no definition of "treatment regimen". A further clarification is important as not to overly restrict what treatments can be provided via telemedicine.

Barriers to Care and Reimbursement
Although not addressed in these rules, there are artificial barriers to providing telemedicine care and receiving reimbursement for that care. These barriers have to do with artificially imposed definitions of where medical care via telemedicine can be provided, as in the case of CMS identifying MSAs and non-MSAs for telehealth originating sites. Under these rules, rural critical access hospitals may not qualify to offer reimbursable telemedicine services. These rules also reduce non-rural patient access to specialty care. By not reimbursing a specialist to remotely see a patient in an urban hospital the efficiency telemedicine provides is limited. Another barrier is third party insurers' restrictions on telehealth payment. These barriers add to the confusion surrounding telemedicine approved services and payment policies.

In closing, MHN advocates for telemedicine policy that provides for reimbursement from all payers for telemedicine, as well as allows physicians to use their professional judgment to determine the best course of treatment for his/her patients.

Thank you for the opportunity to comment on this proposed rule.

Sincerely,

Dale F. Andres, DO
Medical Director
Midwest Rural Telemedicine Consortium

Fred Eastman
Program Coordinator
Midwest Rural Telemedicine Consortium

HealthPartners
8170 33rd Avenue South
Bloomington, MN 55425

healthpartners.com

Mailing Address:
PO Box 1309
Minneapolis, MN 55440-1309

Mark Bowden, MD, Executive Director
Iowa Board of Medicine
400 SW Eighth Street, Suite C
Des Moines, Iowa 50309-4686

Submitted electronically to mark.bowden@iowa.gov

Date: January 15, 2015

Re: ARC 1769C – Amend IAC 653 – Chapter 13.11 to establish the standards of practice for physicians who use telemedicine.

Dear Dr. Bowden:

Thank you for the opportunity to comment on the proposed standards of practice for physicians who use telemedicine. We are excited by the important role of telemedicine in today's health care landscape and are grateful for the opportunity to provide input on related rules. We hope that our ideas and recommendations are useful to you.

HealthPartners is a Minnesota-based, non-profit healthcare organization, which offers health plan products and provides health care services through a large integrated health system that includes six hospitals and more than 100 medical and dental clinics. In 2010, HealthPartners launched *virtuwell*, a 24/7 telemedicine medical clinic for common conditions like bladder infection, sinus infection or pink eye. *virtuwell's* online diagnosis and treatment services are currently available to residents in Minnesota, Wisconsin, North Dakota, Michigan, Arizona, and Virginia and we are pleased to have offered these services to Iowa residents since July 2014.

I. Background on *virtuwell*

Designed by physicians, *virtuwell* reinvents the diagnosis and treatment process while taking a thoughtful and rigorous approach to ensuring quality and safety. *virtuwell* offers a limited range of healthcare services (for about 50 simple conditions), and has engineered hundreds of safety protocols based on rigorous clinical best practices to ensure safe and effective care. We are particularly proud of our 3rd quarter 2014 quality data that we recently had a chance to share with you via email.

At *virtuwell*, we ask patients the same questions you'd expect from a doctor's office visit, except we do it through an online adaptive interview process. As patients pace themselves through relevant presenting symptoms and medical history questions, *virtuwell* leverages sophisticated evidenced-based clinical algorithms to make sure all the right questions are asked. Then the interview is reviewed by a board-certified nurse practitioner, who double checks allergies and medications, initiates a phone call as appropriate, writes a diagnosis and treatment plan and sends

electronic prescriptions, if indicated, to the patient's pharmacy of choice. If a patient's answers show that she needs to be seen in person, we tell her to see her primary doctor and do not charge for the advice. We also follow up with every patient to make sure they're getting better. And, patients may contact *virtuwell* with any follow up questions for which there is never an additional charge.

virtuwell is an example of how unique and innovative approaches to telemedicine can improve patient access to care and provide high quality services all while reducing overall healthcare costs. As published in the February 2013 edition of peer reviewed *Health Affairs*, after tens of thousands of cases of patients using *virtuwell*.com, detailed analysis of cases treated show strong indicators of clinical effectiveness.

While telemedicine holds much promise for improving access to high quality health care services, we know that *virtuwell* and other types of telemedicine are not right for every condition or every person. In fact, about 20% of the people who begin the interview process through *virtuwell* will be referred to a doctor's office because the standard of care suggests an in-person physical exam or lab test is appropriate. These people will receive recommendations that they see their primary care physician, go to urgent care, etc., as appropriate, based on the information the patient has provided.

Our *virtuwell* team of certified nurse practitioners has provided about 125,000 treatment plans for patients and 98 percent of our customers say that they would recommend us to a family member or friend. The success HealthPartners has experienced with *virtuwell* in increasing access to convenient, high-quality, and more affordable care informs our comments on the proposed rule.

II. Proposed rule

We first would like to thank you for your work on the proposed rule and to highlight the areas of the rule of which we are particularly supportive. These include the following sections:

- 653–13.11(147, 148, 272C) Standards of practice–telemedicine
- 13.11(3) *Iowa medical license required.*
- 13.11(4) *Standards of care and professional ethics.*
- 13.11(5) *Scope of practice.*
- 13.11(6) *Identification of patient and physician.*
- 13.11(9) *Nonphysician health care providers.*
- 13.11(13) *Emergency services.*
- 13.11(14) *Medical records.*
- 13.11(15) *Privacy and security.*
- 13.11(16) *Technology and equipment.*
- 13.11(21) *Prescribing controlled substances–prohibited.*

HealthPartners is committed to providing its patients with high quality health care and supports the concept that licensees using telemedicine should be held to the same standards of care and professional ethics as licensees using traditional in-person medical care.

Additionally, we are dedicated to providing telemedicine services that comply with privacy and security laws and to ensuring that our technology is in compliance with relevant safety laws, rules, and regulations. We appreciate and support the manner that you have addressed these items in the proposed rule.

We would also like to share comments and recommendations on other parts of the proposed rule with which we have some concerns.

Establishing a practitioner-patient relationship through a telemedicine encounter

The practitioner-patient relationship has been and continues to be a keystone of medical care whether that relationship is with a physician, certified nurse practitioner, physician assistant, or other practitioner. At *virtuwell*, our certified nurse practitioners provide care to our patients by using physician developed algorithms and protocols and are supported through ongoing oversight by our medical directors. We have thus framed our recommendations for section 13.11(7) *Physician-patient relationship* as the "practitioner-patient relationship."

We believe that a practitioner-patient relationship can be established through a telemedicine encounter where the standard of care does not require an in-person encounter. By illustration, *virtuwell* offers treatment for approximately 50 simple conditions that are generally associated with high diagnostic accuracy and treatment efficacy in both traditional and online care venues. Patients who use *virtuwell* choose to use an online convenience care service where the practitioner-patient relationship is established with a board-certified nurse practitioner at the time of the consultation. The nurse practitioner reviews each patient's interview, initiates a phone call if appropriate, writes a diagnosis and treatment plan and can send electronic prescriptions. Patients can call the nurse practitioner with questions and also request a follow-up call after their session has ended. We thus recommend the following changes to the proposed rule to address the formation of a practitioner-patient relationship through a telemedicine encounter.

Recommendation: We recommend including language to explicitly address the establishment of a practitioner-patient relationship through a telemedicine encounter where the standard of care does not require an in person encounter. We also ask that the phrase *"are established by nationally recognized medical specialty organizations"* be removed. We believe in the importance of evidence–based telemedicine practice guidelines, but these are not limited to those developed by medical specialty organizations.

13.11(7) *Physician-patient relationship.*

a. A licensee who uses telemedicine shall establish a valid physician-patient relationship with the person who receives telemedicine services. The physician-patient relationship begins when:

(1) The person with a health-related matter seeks assistance from a licensee;

(2) The licensee agrees to undertake diagnosis and treatment of the person; and

(3) The person agrees to be treated by the licensee whether or not there has been an in person encounter between the physician and the person.

b. A valid physician-patient relationship may be established:

(1) Through an in person medical interview and a physical examination (when medically necessary) where the standard of care would require an in person encounter ~~would otherwise be required in the provision of the same service not delivered via telemedicine~~;

(2) Through telemedicine, where the standard of care does not require an in person encounter;

~~(2)~~(3) Through consultation with another licensee (or other health care provider) who has an established relationship with the patient and who agrees to participate in, or supervise, the patient's care; or

~~(3)~~(4) In accordance with evidence-based telemedicine practice guidelines that ~~are established by nationally recognized medical specialty organizations~~ and address the clinical and technological aspects of telemedicine.

Narrowly defining "Internet questionnaire"

We are attuned to the fact that a static Internet questionnaire is insufficient to achieve an acceptable standard of care, however we recommend adding further explanation to this section to differentiate between static questionnaires and adaptive, interactive and responsive online interviews that are used in coordination with relevant evidenced-based clinical protocols.

The adaptive, interactive and responsive question and answer format *virtuwell* uses is based on sophisticated physician developed interview algorithms that gather a patient's medical history, on-set of symptoms, digital pictures (e.g. rashes), medications, allergies and the like, allowing nurse practitioners to accurately diagnose common medical conditions while identifying situations where an in-person visit is needed. The service does not offer treatment for conditions in which the standard of care requires a lab test, imaging study, or in-person physical exam. In addition to the use of an interactive interview, a certified nurse practitioner examines each patient's information and provides a diagnosis and treatment plan. Both patient- and clinician-initiated telephonic interactions are available around the clock. And nurse practitioners benefit from additional decision-support tools which alert them to initiate outbound calls to customers in about half of the cases. While we recognize the concerns of relying solely on a basic questionnaire that may fail to provide adequate information, we want to emphasize the usefulness of a sophisticated adaptive, interactive, and responsive online interview when used in coordination with widely accepted clinical protocols and telephonic interactions.

Recommendation: We recommend narrowly defining "Internet questionnaire" to differentiate between a static questionnaire and an adaptive, interactive, and responsive online interview to guide a provider who maintains the ultimate responsibility for making a diagnosis and treatment plan. This would prevent unintentionally limiting the potential positive impact technology could have on patient care.

13.11(8) *Medical history and physical examination.* Prior to providing treatment, including issuing prescriptions, electronically or otherwise, a licensee who uses telemedicine shall ensure that the patient is interviewed to collect the patient's relevant medical history and that the patient receives a physical examination, when medically necessary, sufficient for the diagnosis and treatment of the patient. Generally, the licensee shall perform an in-person medical interview and a physical examination of the patient. However, the medical interview and physical examination may not be in person if the technology utilized in a telemedicine encounter is sufficient to establish an informed diagnosis as though the medical interview and physical examination had been performed in person. An Internet questionnaire (i.e., a static questionnaire provided to a patient, to which the patient responds with a static set of answers, in contrast to an adaptive, interactive and responsive online interview) alone does not constitute an acceptable medical interview and physical examination for the provision of treatment, including issuance of prescriptions, electronically or otherwise, by a licensee.

Coordination of Care and Follow-up Care

HealthPartners appreciates the importance of coordination of care when medically necessary as well as creating patient experiences that are more empowering regardless if the care was delivered in a clinic, an urgent care center or a telemedicine clinic. A provider delivering care through telemedicine should be expected to help coordinate care when in-person follow up is needed. By illustration, at *virtuwell*, if the standard of care suggests a patient needs to be seen in person we recommend she see her primary care provider, and there is no charge for the service.

HealthPartners also believes that when a provider establishes a relationship with a patient, she should be responsible for medically appropriate follow up care, even if that care originated in a telemedicine visit. Care delivered through telemedicine should include medically appropriate follow up. And if that includes an in-person visit, that telemedicine provider should be knowledgeable about options for that patient.

Recommendation: We recommend clarifying that coordination of care and follow-up care shall be provided based on what is medically appropriate to the particular circumstances and services.

> **13.11(11)** *Coordination of care.* A licensee who uses telemedicine shall, when medically appropriate, identify the medical home or treating physician(s) for the patient, when available, where in-person services can be delivered in coordination with the telemedicine services. Upon request of the patient, ~~The~~ the licensee shall provide a copy of the medical record to the patient's medical home or treating physician(s).
>
> **13.11(12)** *Follow-up care.* When medically appropriate, a licensee who uses telemedicine shall ensure that the patient has access to appropriate follow-up care following a telemedicine encounter. In such cases, ~~The~~ the physician shall have adequate knowledge of the nature and availability of local medical resources to provide appropriate follow-up care to the patient following a telemedicine encounter.

Financial Interests

We agree that physician decision-making should be based on the standard of care rather than the personal financial interests of the physician. However, we believe that current federal anti-kickback, self-referral and civil monetary penalty laws are well-developed and provide strong enforcement in this area. Adding this rule specific to telemedicine makes the regulation of telemedicine unnecessarily more complex and prescriptive than regulation of the same issues in other clinical settings.

We also understand the concern about internet prescribing being tied to a specific pharmacy, where the prescribing and dispensing are inextricably linked. However, a "preferred" pharmacy relationship could occur in any clinical setting, and should not be automatically prohibited. The important thing is that the patient retains the freedom of choice in her ultimate selection of a pharmacy.

Recommendation: **For the reasons cited above, we recommend striking this section. As an alternative to striking this section, we would recommend narrowing it, as follows:**

> **13.11(19)** *Financial interests.* Advertising or promotion of goods or products from which the licensee(s) receives direct remuneration, benefit or incentives (other than the fees for the medical services) is

prohibited to the same extent as those activities are prohibited by federal law. ~~Notwithstanding such prohibition, Internet services may provide links to general health information sites to enhance education; however, the licensee(s) should not benefit financially from providing such links or from the services or products marketed by such links.~~ When providing links to other sites, physicians should be aware of the implied endorsement of the information, services or products offered from such sites. The maintenance of a preferred relationship with any pharmacy is prohibited, to the extent such relationship limits the patient's freedom of choice in selecting a pharmacy. ~~Licensees shall not transmit prescriptions to a specific pharmacy, or recommend a pharmacy, in exchange for any type of consideration or benefit from the pharmacy~~.

On behalf of HealthPartners and our *virtuwell* program would like to thank you again for the opportunity to provide input to the Iowa Board of Medicine on this proposed rule and we welcome any chance to discuss this with you further either in person or via phone. If you have any additional questions or if we can be of assistance in any other way, please contact Kevin Palattao, Vice President of Clinic Patient Care Systems at Kevin.J.Palattao@HealthPartners.com, 952-883-5348.

Sincerely,

Andrew Zinkel, MD
Associate Medical Director

Brian Rank, MD
Executive Medical Director

Mr. Mark Bowden
Executive Director
Iowa Board of Medicine
Mark.bowden@iowa.gov

RE: ARC 1769C establishing standards of practice for telemedicine
VIA EMAIL

January 15, 2014

Dear Mr. Bowden,

Thank you for the opportunity to comment on the Board of Medicine's (Board) proposed rules published at ARC 1769C. UnityPoint Health operates in the states of Iowa, Illinois and Wisconsin, with over 30,000 employees including more than 900 doctors and specialists. Our team of professionals communicate with our patients to clearly and effectively address the patient's healthcare in the most appropriate setting, including through use of telemedicine which aids in the delivery of high quality, efficient and value-based health care. UnityPoint Health thanks the Board of Medicine for taking a leadership role to standardize the use of telemedicine in the practice of medicine.

The proposed rules appear to be designed to address the possibility that telemedicine-enabled outpatient clinic visits between providers and patients may result in compromised, inadequate, inappropriate, or substandard care for patients in Iowa. We agree with the intent to preclude such a possibility through the implementation of a standard of practice for telemedicine.

In order to ensure proper patient care, these proposed standards have the stated intent of ensuring that care provided through telemedicine technologies must be equivalent to care provided in-person. Again UnityPoint Health agrees with this position in concept. However, there are several areas addressed in these proposed standards that overreach the intention of equivalent care and place undue burden on visits conducted through telemedicine that do not exist for in-person visits.

Telemedicine is a capability that should enhance access to care and care coordination by removing geographic barriers between patients and providers within the state of Iowa. By creating incremental burdens on providers using telemedicine in the provision of care, telemedicine use can be discouraged and the benefits of its use lost to Iowa patients.

Specific comments regarding the proposed standards include the following:

- Amend proposed rule 13.11(6) to hold telemedicine providers to the standards that all Board licensees must comply with. The clinical setting should not impact the standard. It is unclear why and how the licensee can "ensure" that the patient has the ability to verify the list of items. At a minimum, we suggest the following changes to keep the standards for all Board licensees consistent.

13.11(6) Identification of patient and physician. A licensee who uses telemedicine shall verify the identity of the patient and ensure that the patient has the ability to verify the identity, ~~licensure status, certification~~, credentials, and ~~qualifications~~ of all health care providers who provide telemedicine services prior to the provision of care.

- Clarify when an in-person physical examination is "medically necessary." It is unclear in proposed rules 13.11(8) and 13.11(20) when a medical interview and physical exam may not be in-person. Although the proposed rule is consistent with AMA policy regarding the collection of the patient's medical history the requirement for a physical exam is not considered in AMA guidance. The rule appears to require the telemedicine physician to perform a medical interview and physical examination of the patient in-person. This assumption is further supported by the Board listing several limited instances in which an in-person exam of a patient may not be required, none of which fit UnityPoint Health's current MDLive process. The rules states that a physical exam may not be in person if the technology utilized in a telemedicine encounter is sufficient to establish an informed diagnosis. We suggest striking the sentence as indicated below.

  13.11(8) Medical history and physical examination. Prior to providing treatment, including issuing prescriptions, electronically or otherwise, a licensee who uses telemedicine shall ensure that the patient is interviewed to collect the patient's relevant medical history and that the patient receives a physical examination~~, when medically necessary,~~ sufficient for the diagnosis and treatment of the patient. ~~Generally, the licensee shall perform an in-person medical interview and a physical examination of the patient. However,~~ The medical interview and physical examination may not be in person if the technology utilized in a telemedicine encounter is sufficient to establish an informed diagnosis as though the medical interview and physical examination had been performed in person. An Internet questionnaire alone does not constitute an acceptable medical interview and physical examination for the provision of treatment, including issuance of prescriptions, electronically or otherwise, by a licensee.

- Clarify the consent required by 13.11(10). This seems clear for outpatient clinic visits, but it is unclear for other telemedicine environments. UnityPoint Health and its rural affiliate hospitals currently use telehealth technologies for inpatient consultations and emergency department consultations. In these situations, consent to care is already required from the patient. Would 13.11(10) require additional consent for telemedicine consultations, or can this be included within general consent to care?

- Amend to require that medical records be transferred to the patient's medical home or treating physician upon the request of the patient. We propose the following amendment to 13.11(11):

  13.11(11) *Coordination of care.* A licensee who uses telemedicine shall identify the medical home or treating physicians(s) for the patient, when available, where in-person services can be delivered in coordination with telemedicine services. Upon the patients request, the ~~The~~ licensee shall provide a copy of the medical record to the patient's medical home or treating physician(s).

- Language as proposed in 13.11(12) in particular use of the term "ensure" indicates that the telemedicine provider will guarantee that the patient has access to appropriate follow-up care. This is different than providing the information and it would appear that deleting the first sentence and leaving the second would appropriately address this issue.

  13.11(12) *Follow-up care.* ~~A licensee who uses telemedicine shall ensure that the patient has access to appropriate follow-up care following a telemedicine encounter.~~ The physician shall have adequate knowledge of the nature and availability of local medical resources to ~~provide~~ offer appropriate follow-up care to the patient following a telemedicine encounter.

- Clarify the Board's intent in 13.11(13). Specifically, if a patient is referred to call 911 for emergency services, does this satisfy the requirement that a patient be referred to an acute care facility or an emergency department.

- Clarify the requirements in 13.11 (16) (b). The requirements for sufficient quality, size, resolution and clarity for safe and efficient provision of telemedicine services appear to be highly subjective. Would sufficiency be determined by the physician, or by another entity or agency?

UnityPoint Health would welcome the opportunity to discuss our comments and concerns further with you and would be happy to meet at your convenience.

Respectfully Submitted,

Kate Walton

NATIONAL WOMEN'S LAW CENTER
EXPANDING THE POSSIBILITIES

January 15, 2015
Mark Bowden, Executive Director
Board of Medicine
400 S.W. Eighth Street
Suite C
Des Moines, IA 50309-4686

Submitted Electronically

Attention: ARC 1769C

RE: Notice of Intended Action

Dear Director Bowden:

The National Women's Law Center (NWLC) submits these comments in response to ARC 1769C ("the Rule") which would amend Iowa Administrative Code 653 Chapter 13 and establish standards of practice for physicians using telemedicine. NWLC is a non-profit legal advocacy organization that has been working since 1972 to protect and advance the progress of women and their families in core aspects of their lives, with an emphasis on the needs of low-income women. The National Women's Law Center has long advocated for women's health care and reproductive rights. The Center's efforts reflect extensive research and expertise regarding women's specific health needs.

The Rule promotes telemedicine as a "useful tool" for improving health care in the state; however, r. 653.13.11(22) keeps in place the Board's attempt to ban telemedicine for the administration of medication abortion. Specifically, r. 653.13.11(22) singles out the use of telemedicine for medication abortion by stating that the Rule does not "contradict or supersede" Iowa Administrative Code 653.B.10 (147,148,272C), a provision promulgated by the Board in 2013.[1] The 2013 Rule requires a physician to be physically present when a woman is provided with the drugs necessary for a medication abortion. This prohibition has been challenged and is currently under consideration by the Iowa Supreme Court, yet the Board has reinforced the 2013 Rule prohibiting the use of telemedicine for medication abortion.[2] NWLC respectfully urges the Iowa Board of Medicine (Board) to delete entirely r. 653.13.11(22).

As ARC 1769C states, telemedicine "can provide important benefits to patients, including increased access to health care, expanded utilization of specialty expertise, rapid availability of patient records, and potential cost savings."[3] The Iowa Department of Public Health has also acknowledged telemedicine as a necessary tool for improving the health care of rural residents.

---

[1] ARC 1769C Notice of Intended Action, r. 653.13.11(22).
[2] Prior to publication of the current Rule, the Iowa Supreme Court temporarily stayed implementation of Iowa Administrative Code r. 653.B.10 (147,148,272C). *See Planned Parenthood of the Heartland, Inc. v. Iowa Board of Medicine*, No. 14-1415 (Iowa Sep. 16, 2014). The Court has not yet made a final decision in PPH's challenge to that rule, so it would be improper for the Board to continue with these efforts to ban the use of telemedicine in abortion care.
[3] ARC 1769C, r. 653.13.11(147,148,272C).

In fact, the Department of Public Health Director Dr. Marinette Miller-Meeks stated, "Telemedicine will be very important in a state like [Iowa] because we are rural. With telemedicine, we will be able to do more."[4] The Rule establishes standards that generally promote and will improve access to health care; however, r. 653.13.11(22) undermines these efforts by excluding the use of telemedicine for medication abortion.

Like other forms of telemedicine, telemedicine for medication abortion will improve the health and well-being of Iowa women. Telemedicine is safe, increases access to medication abortion, and makes it possible for many women to obtain earlier abortions. This is particularly important for women who already have significant barriers to care, such as rural women, women living in poverty, and women facing intimate partner violence. Without telemedicine many of these women would be forced to obtain an abortion later in pregnancy or might not be able to obtain an abortion at all. Singling out medication abortion and prohibiting telemedicine serves only to limit access to needed care which is directly contrary to the purpose of the Rule. In order to promote the health of Iowa women, NWLC urges the deletion of r. 653.13.11(22) and recommends that the Board recognize the importance of telemedicine for Iowa women by treating medication abortion the same as other types of health care in Iowa's telemedicine policies.

I. Using telemedicine to administer medication abortion is a safe method of increasing access to care.

Medication abortions provided using telemedicine have been found to be just as safe and effective as those in which the prescribing physician and patient are in the same room. Medical groups, including the American College of Obstetrics and Gynecology, strongly support the use of telemedicine for medication abortion.[5]

Telemedicine has already been safely used in Iowa for over six years. In 2008, Planned Parenthood of the Heartland (PPH) implemented a telemedicine program that connects patients and staff at outlying clinics to a physician in Des Moines or Iowa City using a live, two-way video conferencing system. Since its inception, PPH's telemedicine program has significantly improved access to abortion without compromising patient safety or satisfaction.[6] Under PPH's telemedicine program, women receiving a medication abortion through telemedicine have significant in-person contact with providers at the clinic and complete an ultrasound and an education counseling session with clinic staff before the doctor's visit.[7] The only difference between a telemedicine visit and an in-person visit with the physician is that the conversation

---

[4] Iowa Dep't. of Pub. Health, *Iowa Rural and Agricultural Health and Safety Resource Plan* 97, 101 (2011) *available at* http://www.idph.state.ia.us/IDPHChannelsService/file.ashx?file=B1C024BE-5252-4075-BE16-E57A2E914D4B.

[5] Am. College of Obstetrics & Gynecology, *Medical Management of First Trimester Abortion*, 143 Practice Bulletin 1, 4 (2014).

[6] Daniel Grossman et al., *Effectiveness and Acceptability of Medical Abortion Provided Through Telemedicine*, 118 Obstetrics & Gynecology 296, 300 (2011).

[7] Kate Grindlay et al., *Women's and Providers' Experiences with Medical Abortion Provided Through Telemedicine: A Qualitative Study*, 23 Women's Health Issues e117, e119 (2012).

between the patient and the doctor takes place using a two-way camera rather than sitting in the same room.

The procedures used by PPH are typical for the administration of medication abortions through telemedicine and illustrate the safety and value of allowing medication abortion through telemedicine. A study of PPH's program found *no difference* in the complication rate between women receiving a medication abortion through telemedicine and those who had in-person visits with the physician.[8] In fact, research found women who used the telemedicine program were more likely to return for a follow-up visit than women who did not use the telemedicine program.[9]

II. Many women prefer telemedicine for abortion because it increases access to medication abortion.

Telemedicine improves women's health by increasing the use of medication abortion. Through telemedicine, clinics are able to see patients earlier in pregnancy before the window of eligibility for medication abortion ends.[10] In Iowa the use of medication abortion, particularly among women living more than 50 miles from a clinic offering surgical abortion, has increased since the inception of PPH's telemedicine program.[11] Women who have used telemedicine often report choosing it because it enabled them to undergo the procedure sooner, guaranteeing them the ability to use medication abortion, rather than undergoing a surgical abortion. Seventy-one percent of women in a study of PPH's telemedicine program reported that they strongly wanted a medication abortion and 94% said that having the abortion as early as possible was very important to them.[12] Indeed, the percentage of second trimester abortions has decreased since the program's inception.[13] Although second trimester abortion is very safe, it is invasive and the risk of complications increases with each week of pregnancy.[14] It is also more expensive.[15]

---

[8] Daniel Grossman et al., *Effectiveness and Acceptability of Medical Abortion Provided Through Telemedicine* at 299-300.

[9] *Id.* at 298.

[10] Before the telemedicine program was implemented, patients could be forced to wait up to 2 weeks for an appointment. Because medication abortion can only be used up to a certain point in pregnancy, some women were unable to have a medication abortion. Kate Grindlay et al., *Women's and Providers' Experiences with Medical Abortion Provided Through Telemedicine: A Qualitative Study* at e121.

[11] Daniel Grossman et al., *Changes in Service Delivery Patterns After Introduction of Telemedicine Provision of Medical Abortion in Iowa*, 103 Am. J. Pub. Health 73, 76 (2012).

[12] Daniel Grossman et al., *Effectiveness and Acceptability of Medical Abortion Provided Through Telemedicine* at 300.

[13] Daniel Grossman et al., *Changes in Service Delivery Patterns After Introduction of Telemedicine Provision of Medical Abortion in Iowa* at 76.

[14] Bonnie Scott Jones & Tracy A. Weitz, *Legal Barriers to Second-Trimester Abortion Provision and Public Health Consequences*, 99 Am. J. Pub. Health 623, 623 (2009).

[15] The median cost of a first-trimester abortion in the United States is $490, with a range between $225 and $750. The median cost for an abortion between 14 and less than 20 weeks is $750, with a range of $490 to $1,500. Sarah C.M. Roberts et al., *Out-of-Pocket Costs and Insurance Coverage for Abortion in the United States*, 24 Women's Health Issues e211, e214 (2014).

In general, women often have a strong preference for medication abortion[16] because it offers greater privacy and autonomy, is less invasive, and seems more "natural" than surgery.[17] For example, one woman describing her experience with medication abortion stated, "I was so thankful that there was an alternative to having a surgical abortion. And that was… my biggest concern."[18] Another woman stated, "I was in my own home. I wasn't in a hospital bed or anything. . . . I was with my family. . . . My ex was there with me. My mom was there."[19] Women also report choosing medication abortion over surgical abortion because medication abortion allowed them to maintain control[20] and because it was easier for them to talk to a doctor in a more removed manner.[21]

Sexual assault survivors in particular may prefer medication abortion. Intimate exams and childbirth can trigger post-traumatic stress in sexual assault survivors.[22] Medication abortion is less invasive, allows women to have the abortion at home with the support of their families, and gives them more control. Telemedicine for medication abortion provides sexual assault survivors with a vital alternative to an invasive procedure at a time when they most need to assert control over their lives.[23]

III. Telemedicine is necessary for many women for health reasons.

Telemedicine improves access to medication abortion which is particularly important for women with pre-existing medical conditions for whom first-trimester surgical abortion is contraindicated. Medication abortion is preferred over surgical abortion for patients at risk of surgical and anesthetic complications.[24] Medication abortion may also be safer for extremely obese women and women with pelvic tumors that interfere with access to the cervix. It is also safer for women with orthopedic conditions, such as hip disease, because medication abortion does not require lithotomy positioning.[25]

Telemedicine allows more women to access medication abortion when they are already facing what can be an extremely difficult decision. Denying access to a medical procedure that is best able to preserve a woman's health jeopardizes women's health and wellbeing.

---

[16] Beverly Winikoff, *Acceptability of Medical Abortion in Early Pregnancy*, 27 Family Planning Perspectives 142, 148 (1995).
[17] Mitchell Creinin & Maureen Park, *Acceptability of Medical Abortion with Methotrexate and Misoprostol*, 52 Contraception 41, 42 (1995).
[18] Stephen Fielding, *Having an Abortion Using Mifepristone and Home Misoprostol: A Qualitative Analysis of Women's Experiences*, 34 Persp. Sexual & Reprod. Health 34, 38 (2002).
[19] *Id.*
[20] M. Antonia Biggs et al., *Understanding Why Women Seek Abortions in the U.S.*, 13 BMC Women's Health 1–13, 7 (2013).
[21] Kate Grindlay et al., *Women's and Providers' Experiences with Medical Abortion Provided Through Telemedicine: A Qualitative Study* at e120.
[22] Erica Sharkansky, *Sexual Trauma: Information for Women's Medical Providers*, National Center for PTSD (last updated Jan. 3, 2014), www.ptsd.va.gov/professional/treatment/women/ptsd-womens-providers.asp.
[23] *See, e.g. Id.* (for discussion of the importance of control to sexual assault survivors).
[24] Maryam Guiahi & Anne Davis, *First-Trimester Abortion in Women with Medical Conditions*, 86 Contraception 622, 625 (2012).
[25] *Id.*

IV. Telemedicine for medication abortion is particularly valuable for many Iowa women who already face barriers to accessing an abortion.

A. Telemedicine increases access to necessary health care for women living in a rural area.

Telemedicine improves access to abortion for rural residents by ensuring that more women are able to obtain abortion services closer to home and in a timely manner. Thirty-five percent of Iowa's population lives in a rural area,[26] and a majority of Iowa women live in a county without an abortion provider.[27] As a result, telemedicine is particularly important for Iowa women.

Because telemedicine allowed PPH to offer abortions near where more of their patients lived,[28] the use of telemedicine for medication abortion decreased the average distance that women traveled from their home to the clinic. [29] Without telemedicine, patients are forced to travel long distances in order to access an abortion. For example, a woman living in Les Mars could have to travel up to 450 miles round trip to a clinic in Des Moines rather than accessing a medication abortion via telemedicine at a much closer clinic in Sioux City. Travel can be a significant barrier for many women. Up to 10% of women who obtained a later abortion reported that difficulties in travel contributed to the delay.[30] In addition, the percentage of women able to obtain an abortion decreases the farther they have to travel to reach an abortion provider.[31] Telemedicine can help to overcome these barriers by allowing rural women to obtain a medication abortion closer to home.

B. Telemedicine helps to remove barriers to obtaining an abortion for women living in poverty or who face other obstacles in obtaining health care.

Telemedicine not only reduces travel time but also eases burdens faced by other vulnerable communities because it reduces the indirect costs of obtaining an abortion. Although the direct cost of a medication abortion is the same whether a woman uses the telemedicine program or has an in-person visit, the overall cost—including factors such as transportation, child-care, and lost wages—is lower for women using telemedicine because they do not have to travel as far.

Reducing the indirect costs of an abortion is particularly important for the thirteen percent of women in Iowa living in poverty.[32] The rates of poverty are even higher for minority women—36% of African American women, 23% of Latinas, 18% of Asian women, and 34% of Native

---

[26] *Iowa Quick Facts*, State Data Center of Iowa (last updated Apr. 7, 2014 9:20 AM), http://www.iowadatacenter.org/quickfacts.
[27] App. to Pet'r's Br. 18, Jan. 21, 2014.
[28] Daniel Grossman et al., *Effectiveness and Acceptability of Medical Abortion Provided Through Telemedicine* at 300.
[29] Daniel Grossman et al., *Changes in Service Delivery Patterns After Introduction of Telemedicine Provision of Medical Abortion in Iowa* at 75.
[30] Diana G. Foster et al., *Predictors of Delay in Each Step Leading to an Abortion*, 77 Contraception 289, 292 (2007).
[31] *See, e.g.* Daniel Grossman et al., *Change in Abortion Services After Implementation of a Restrictive Law in Texas*, 90 Contraception 496 (2014) (discussing the effect of clinic closures in Texas on women's access to abortion).
[32] National Women's Law Center, *Poverty Rates by State, 2013* (September 2014) http://www.nwlc.org/sites/default/files/pdfs/compiled_state_poverty_table_2013_final_v2.pdf.

American women in Iowa live in poverty.[33] Telemedicine reduces the additional burdens and expenses of obtaining an abortion that may otherwise be insurmountable for some women, forcing them to forgo having an abortion.

These costs also take their toll on the twenty percent of Iowa women who work in low-wage jobs,[34] which do not typically offer any benefits, such as paid time off, and often do not have fixed schedules.[35] Women in low-wage jobs may be given their schedule only a few days in advance and may not be allowed to request particular days off or ask for changes.[36] This can make it extremely hard or even impossible to schedule an appointment weeks in advance, arrange for travel and child care, find someone to go with them to the appointment, get time off from work, miss a day's or more pay, and explain why they need to travel or miss work in order to get an abortion.

Over a quarter of women obtaining later abortions report that the need to save money for the procedure contributed to the delay.[37] Telemedicine helps alleviate some of these burdens by making it easier to make and schedule an appointment and reducing travel times. Because women are able to visit a clinic closer to their homes, they are able to get appointments sooner. According to clinic staff, telemedicine allows them to offer services more frequently with a wider range of times.[38] Staff found that greater flexibility was particularly beneficial for women who could only take a specific day off from work or school.[39]

As the staff at one of PPH's telemedicine clinics reported, telemedicine allows clinics to use their resources more efficiently because there are fewer cancellations and delays related to travel in inclement weather.[40] One 36-year-old telemedicine patient explained, "I did not want to drive to Iowa City and have it done and then have to drive back… I didn't want an hour and a half ride home in bad weather."[41]

An individual woman might have multiple barriers that make accessing abortion services challenging. As a 19-year-old telemedicine patient explained:

> Traveling, that'd be a full tank of gas for me there and back and I don't have money like that to blow around, [I'm] trying to get

---

[33] *Id.*
[34] National Women's Law Center, *Underpaid and Overloaded: Women in Low-Wage Jobs* 25 (2014) *available at* http://www.nwlc.org/sites/default/files/pdfs/final_nwlc_lowwagereport2014.pdf.
[35] *Id.* at 3 (citing Claudia Williams et al., *44 Million U.S. Workers Lacked Paid Sick Days in 2010: 77 Percent of Food Service Workers Lacked Access*, Institute for Women's Policy Research, (Jan. 2011), http://www.iwpr.org/publications/pubs/44-million-u.s.-workers-lacked-paid-sick-days-in-2010-77-percent-of-food-service-workers-lacked-access).
[36] *Id.*
[37] Lawrence B. Finer et al., *Timing of Steps and Reasons for Delays in Obtaining Abortions in the United States*, 74 Contraception 334, 341–42 (2006).
[38] Kate Grindlay et al., *Women's and Providers' Experiences with Medical Abortion Provided Through Telemedicine: A Qualitative Study* at e121.
[39] *Id.*
[40] *Id.* at e120.
[41] *Id.* at e119.

> everything started and get a house and everything. So money's kind of tight . . . and then being able to get my mom to have work off so she could go with me 'cause I wanted her to be there with me, and just making sure that I wouldn't have to tell other people, "Well why are you going to Des Moines?" or something. I wouldn't have had to tell them why I was going there all day.[42]

Similarly, a member of PPH's clinic staff participating in the telemedicine program described how telemedicine relieves many of the burdens facing vulnerable women seeking an abortion and improves access to care:

> The helplessness you feel about not being able to help people because they can't get here—they don't have a ride, they don't have the money, they don't have whatever, you know—a lot of those problems have gone away.[43]

C. Telemedicine increases access for women who face particular difficulties obtaining an abortion because of intimate partner violence.

Telemedicine has similar benefits for Iowa women experiencing intimate partner violence. There were 5,625 reported instances of intimate partner violence against women in Iowa in 2009, the most recent year for which data are available.[44] Women in small, rural towns in Iowa are more likely than other women to experience intimate partner violence and the violence becomes more severe the more geographically isolated a woman is.[45] Among Iowa women who reported intimate partner violence, 61.5% of isolated rural women reported four or more events of physical violence in the past year compared with 39.3% of urban women.[46] Iowa women living in rural areas also have fewer domestic violence intervention programs available to them and have to travel farther to obtain help.[47]

The use of telemedicine for medication abortion is a critical health care service for these women because of the unique need for and barriers they face in accessing abortion. Women in abusive relationships are more likely to experience an unintended pregnancy than other women.[48] Abusive partners may engage in "reproductive coercion"—behaviors, such as interfering with contraception, intended to promote pregnancy.[49] In one study, eight percent of women seeking

---

[42] *Id.*
[43] *Id.* at e121.
[44] Iowa Dep't of Pub. Safety, *2009 Iowa Uniform Crime Report* 125 (2009) *available at* http://www.dps.state.ia.us/commis/ucr/2009/2009_UCR_Table_16_DMVChar.pdf.
[45] Corinne Peek-Asa et al., *Rural Disparity in Domestic Violence Prevalence and Access to Resources*, 20 J. Women's Health 1743, 1745 (2011).
[46] *Id.*
[47] *Id.* at 1746.
[48] Elizabeth Miller et al., *Reproductive Coercion: Connecting the Dots Between Partner Violence and Unintended Pregnancy*, 81 Contraception 457, 457–58 (2010).
[49] *Id.*

an abortion reported they did so because of an abusive partner.[50] A 40-year-old woman in that study stated, "Our relationship became violent and I couldn't see bringing another kid into a life that was going to be surrounded by violence."[51] Another woman echoed this sentiment. "I didn't want to[raise a child] by myself. I couldn't and the man was abusive and horrible."[52]

Not surprisingly, women reported that having a child with an abusive partner would make it harder for them to leave the abusive relationship.[53] According to one woman, "I was trying to leave an abusive relationship and I didn't want to have any ties."[54] This woman's concerns were well-founded. Among women seeking an abortion, the chance of experiencing violence decreases if they have an abortion but remains the same if they do not.[55] Women denied an abortion remain tethered to the abusive man and at risk for continued violence, even if they are able to end the romantic relationship.[56]

Yet, obtaining an abortion can be especially difficult for women in abusive relationships. Abusive partners often engage in controlling behaviors such as isolating women from family and friends, keeping track of a woman's whereabouts and phone calls, and controlling access to money or otherwise limiting her movements.[57] Because telemedicine makes it possible for women to access medication abortion close to home, it might be the only way for a woman in an abusive relationship to obtain an abortion, enabling her to escape a violent relationship.

Conclusion

The use of telemedicine to provide medication abortions is a safe way to increase access to health care for all Iowa women. It has made it possible for many women to obtain medication abortions earlier in pregnancy, which some women prefer and others need for health reasons. Given that telemedicine for medication abortion is safe and is an effective means of achieving the Board's stated goal of using telemedicine to increase access to necessary health care, NLWC urges the Board to delete 653.13.11(22) from the proposed Rule. Governing the use of telemedicine for medication abortion no differently than other forms of telemedicine will further the Rule's stated goal of "provid[ing] important benefits to patients" and improve the health and well-being of Iowa women.[58]

---

[50] Karuna S Chibber et al., *The Role of Intimate Partners in Women's Reasons for Seeking Abortion*, 24 Women's Health Issues e131, e134 (2014).
[51] *Id.*
[52] M. Antonia Biggs et al., *Understanding Why Women Seek Abortions in the U.S.* at 7.
[53] *Id.*
[54] *Id.*
[55] Sarah C.M. Roberts et al., *Risk of Violence From the Man Involved in the Pregnancy After Receiving or Being Denied an Abortion*, 12 BMC Medicine 1, 5-6 (2014).
[56] *Id.* at 5.
[57] Joan B. Kelly & Michael P. Johnson, *Differentiation Among Types of Intimate Partner Violence: Research Update And Implications for Interventions*, 46 Family Court Review 477, 481 (2008) (describing "coercive controlling violence" as including "intimidation; emotional abuse; isolation; minimizing, denying and blaming; use of children; asserting male privilege; economic abuse; and coercion and threats") (internal citations omitted).
[58] ARC 1769C, r. 653.13.11(147,148,272C).

For more information, please contact Kelli Garcia, Senior Counsel, National Women's Law Center at 202-588-5180 or kgarcia@nwlc.org.

Respectfully Submitted,

Gretchen Borchelt
Acting Vice President, Health and Reproductive Rights

Executive Director Bowden,

Thank you for offering stakeholders the opportunity to submit comments on ARC 1769C. The Iowa Health Care Association and Iowa Center for Assisted Living represents long-term and post-acute care providers in the state of Iowa. With Iowans needing long-term and post-acute services projected to grow in the future, we want to ensure our providers, particularly rural providers, have access to innovative health technology to continue their tradition of delivering quality care. With that said, we have some concern over proposed rule 13.20(i).

The rule as drafted states: "certain nursing home and hospice settings". The inclusion of the word certain implies various nursing homes would not be covered by the exceptions as provided in 13.11.20. We would recommend 13.20(i) be struck and replaced with "entities licensed under Iowa Code 135C and certified under Iowa Code 231C".

Thank you for your time and consideration.

Ted Stopulos
Director of Governmental and Regulatory Affairs
IHCA ICAL

DAVISBROWN
LAW FIRM

REPLY TO DES MOINES OFFICE

January 15, 2015

Mr. Mark Bowden
Executive Director
Iowa Board of Medicine
400 SW Eighth Street, Suite C
Des Moines, Iowa 50309-4686

Dear Mr. Bowden:

This firm represents several Iowa hospitals that are designated as Critical Access Hospitals under the Medicare Program, in part because the hospitals provide necessary health care services to persons living in the rural communities of this state. These entities provide general and specialty health care services and, due to the financial and logistical challenges of operating in a rural area, the hospitals have greatly expanded the use of telemedicine as a means of providing physician services to patients in their communities. On behalf of these clients, we would like to comment on the Iowa Board of Medicine's ("Board") proposed regulations ("Proposed Rule") regarding standards of practice for physicians who use telemedicine.

We first commend the careful effort to create meaningful guidelines for the practice of telemedicine. We believe that it is important to have such guidelines to ensure the availability and quality of healthcare in Iowa and also to help expand reimbursement for telemedicine on the state and federal level. Our purpose here is to comment on several areas of the Proposed Rule, which in our view could serve to limit or dissuade physicians in engaging in telemedicine and thereby to hold back its continued expansion. An unnecessary restriction of telemedicine in Iowa would not best serve the state's provider or patient community.

The Proposed Rule seems to define telemedicine itself and a pre-requisite to the practice narrowly vis-à-vis how hospitals and other providers are currently using telemedicine to care for their patients. Under § 653—13.11(1), the definition of "telemedicine" includes the use of "electronic audio-visual communications and information technologies or other means." As other commentators have suggested, the qualifying "audio-visual" language – which is absent from the model rule of the Federation of State Medical Boards ("FSMB") – seems to leave out purely audio communications, such as certain asynchronous store-and-forward consultations which have gained considerable acceptance. In similar fashion, the Proposed Rule adopts but

#2552528

PHONE 515.288.2500
FIRM FAX 515.243.0654
WWW.DAVISBROWNLAW.COM

THE DAVIS BROWN TOWER, 215 10TH ST., STE. 1300, DES MOINES, IA 50309
THE HIGHLAND BUILDING, 4201 WESTOWN PKWY., STE. 300, WEST DES MOINES, IA 50266
THE AMES OFFICE, 2605 NORTHRIDGE PKWY., STE. 101, AMES, IA 50010
THE EMMETSBURG OFFICE, 2214 MAIN ST., P.O. BOX 314, EMMETSBURG, IA 50536

revises what the American Medical Association ("AMA") says may be one way for a physician to establish a patient-physician relationship in a telemedicine encounter. While the AMA permits a telemedicine provider to establish a patient-physician relationship by having a "face-to-face" encounter with the patient, whether in person or via telemedicine technology, § 653—13.11(7) of the Proposed Rule would require a telemedicine provider to have an "in-person encounter." Such a situation is relatively rare in telemedicine.

The Proposed Rule also imposes several requirements on physicians who practice telemedicine that are above and beyond what the physician would face in other practice settings. Notably, the Proposed Rule places sole responsibility for meeting these many standards on the individual physician, even though the practice of telemedicine has generally been embraced by health systems and group practices that have the resources to ensure that the many intricacies of telemedicine practice are appropriately handled. Because the standards set forth in the Proposed Rule may give rise to Board discipline against the physician (see § 653—13.11 "Standards of practice—telemedicine"), we believe they are more appropriate in an updated Board policy statement on telemedicine.

We are concerned the following standards could deter physicians from providing telemedicine services and unnecessarily limit rural patients' access to health care services.

- Non-physician health care providers (§ 653—13.11(9)). The Proposed Rule would have physicians ensure that non-physician providers whom they supervise in a telemedicine encounter are "competent to safely perform each medical service." This imposes a higher duty on the physician than the physician would have with in-person patient encounters. It is more in line with current standards to say that the physician ensures that any care the physician delegates to a non-physician provider is within the provider's scope of practice.
- Follow-up care (§ 653—13.11(12)). The Proposed Rule also would have physicians "ensure that patients has access to appropriate follow-up care" or have "adequate knowledge" of the nature and availability of local medical resources. Having access to such information or ensuring such information is available, and making referrals where appropriate, would appear sufficient.
- Medical Record (§ 653—13.11(14)). Reference to a physician noting in the "patient's record" should be "a medical record of the patient," so as not to imply that a physician using telemedicine has access to the patient's electronic health record. A similar reference is in § 653-13.11(10).
- Disclosures (§ 653—13.11(17)) and Informed Consent (§ 653—13.11(10)). The Proposed Rule would have physicians make numerous disclosures. In practice, however, the disclosure and consent process is often handled by the originating site, and thus it could be fairly said that a physician can ensure that the patient "has been provided" such consent. Moreover, consistent with § 653-13.11(6), it would appear

sufficient to have physicians ensure that certain information such as information on a physician's credentials would simply be available to the patient.

- Controlled Substances (§ 653—13.11(17)). While well intended to combat diversion of controlled substances, the prohibition against prescribing such medications based solely on internet request, internet questionnaires, or a telephonic evaluation may infringe upon the developing telemedicine practice. Ultimately, if prescribing controlled substances in this fashion is within appropriate standards of care and/or professional ethics, it would seem permissible with telemedicine, provided that other standards of practice with telemedicine are met.

Finally, we note that the Proposed Rule would appear to apply to longstanding telemedicine practices in certain specialties, including radiology and pathology. While the rule accommodates those particular specialties in some fashion, e.g. by allowing the establishment of a patient-physician relationship based on the patient's relationship with the referring provider, the Proposed Rule imposes many additional standards of practice, some noted above, that are above and beyond what these specialists have operated under for the past decade or so. Notably, the Proposed Rule also provides that physicians should be cognizant of and use guidelines from nationally recognized medical specialty organizations, and we do not expect that such guidelines would impose these same standards of practice on these specialists. The Proposed Rule may need to clarify these points.

Thank you for the opportunity to comment on this important issue.

Very truly yours,

DAVIS, BROWN, KOEHN, SHORS & ROBERTS, P.C.

Craig Sieverding

Iowa Osteopathic Medical Association

950 - 12th Street • Des Moines, Iowa 50309
(515) 283-0002 • Fax (515) 283-0355
leah@ioma.org • www.ioma.org

January 13, 2015

Mark Bowden
Executive Director
Iowa Board of Medicine
400 SW Eighth St. SW, Suite C
Des Moines, IA 50319

RE: ARC 1769C Notice of Intended Action regarding Iowa Administrative Code 653 - Chapter 13 entitled "Standards of Practice and Principles of Medical Ethics"

Dear Mark,

On behalf of the members of the Iowa Osteopathic Medical Association (IOMA), thank you for this opportunity to comment on the Iowa Board of Medicine's (Board or IBM) proposed rule notifying physicians and others of the IBM's intent to adopt disciplinary standards of practice for telemedicine. IOMA offers the following comments for Board consideration.

653-13.11(2) Nationally recognized telemedicine guidelines

IOMA and American Osteopathic Association (AOA) policy supports holding telemedicine services to the same standard of care as services provided in-person, and it seems like it would be easier/cleaner to state:

SERVICES PROVIDED THROUGH TELEMEDICINE WILL BE HELD TO THE SAME STANDARD OF CARE AS THOSE PROVIDED IN-PERSON, AS ESTABLISHED BY NATIONALLY RECOGNIZED CLINICAL GUIDELINES DEVELOPED FOR THE PRACTICE OF EACH SPECIALTY.

IOMA would recommend deletion of the current language and insertion of the above paragraph.

653-13.11(9) Non-physician health care providers

If a licensee who uses telemedicine ~~relies upon or~~ delegates ~~medical service~~ to a non-physician health care provider who requires physician supervision, A MEDICAL SERVICE PROVIDED BY TELEMEDICINE, the licensee shall:

~~a. Personally assess each nonphysician health care provider's education, training, experience and ability to~~ Ensure that ~~each~~ THE NON-PHYSICIAN HEALTH CARE provider is qualified and competent to safely perform WITHIN THE SCOPE OF THEIR TRAINING AND LICENSURE each medical service being provided;

~~b. Ensure that each medical service provided is within the scope of practice of the licensee and that of the nonphysician health care provider, as evidenced by the education, training, experience, ability, licensure or certification of the licensee and the nonphysician health care provider.~~

~~c.~~ b. Ensure that the licensee is available electronically OR TELEPHONICALLY to consult with non-physician health care providers, particularly in the case of injury or an emergency.

653—13.11(11) Coordination of care.

A licensee who uses telemedicine shall identify the medical home or USUAL treating physician(s) for the patient, when available, where in-person services can be delivered in coordination with the telemedicine services. The licensee shall provide a copy of the medical record to the patient's medical home and/or treating physician(s).

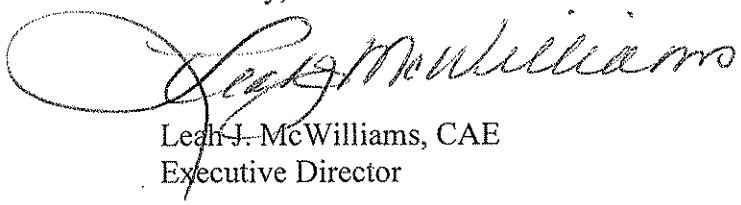
13.11(18) Disclosures and functionality of telemedicine services

e. Fees for services, cost-sharing responsibilities, and how payment is to be made, IF THESE DIFFER FROM AN IN-PERSON ENCOUNTER.

Certainly a patient has the right to know if there is an additional financial obligation for a telemedicine encounter. However, this requirement is not the current practice for an in-person visit due to differing fee schedules of the many insurance plans available.

Thank you for allowing us the opportunity to provide these comments and suggestions for language changes.

Sincerely,



Leah J. McWilliams, CAE
Executive Director

Iowa Osteopathic Medical Association

950 - 12th Street • Des Moines, Iowa 50309
(515) 283-0002 • Fax (515) 283-0355
leah@ioma.org • www.ioma.org

January 13, 2015

Mark Bowden
Executive Director
Iowa Board of Medicine
400 SW Eighth St. SW, Suite C
Des Moines, IA 50319

RE: ARC 1769C Notice of Intended Action regarding Iowa Administrative Code 653 - Chapter 13 entitled "Standards of Practice and Principles of Medical Ethics"

Dear Mark,

On behalf of the members of the Iowa Osteopathic Medical Association (IOMA), thank you for this opportunity to comment on the Iowa Board of Medicine's (Board or IBM) proposed rule notifying physicians and others of the IBM's intent to adopt disciplinary standards of practice for telemedicine. IOMA offers the following comments for Board consideration.

653-13.11(2) Nationally recognized telemedicine guidelines

IOMA and American Osteopathic Association (AOA) policy supports holding telemedicine services to the same standard of care as services provided in-person, and it seems like it would be easier/cleaner to state:

SERVICES PROVIDED THROUGH TELEMEDICINE WILL BE HELD TO THE SAME STANDARD OF CARE AS THOSE PROVIDED IN-PERSON, AS ESTABLISHED BY NATIONALLY RECOGNIZED CLINICAL GUIDELINES DEVELOPED FOR THE PRACTICE OF EACH SPECIALTY.

IOMA would recommend deletion of the current language and insertion of the above paragraph.

653-13.11(9) Non-physician health care providers

If a licensee who uses telemedicine ~~relies upon or~~ delegates ~~medical service~~ to a non-physician health care provider who requires physician supervision, A MEDICAL SERVICE PROVIDED BY TELEMEDICINE, the licensee shall:

~~a. Personally assess each nonphysician health care provider's education, training, experience and ability to~~ Ensure that ~~each~~ THE NON-PHYSICIAN HEALTH CARE provider is qualified and competent to safely perform WITHIN THE SCOPE OF THEIR TRAINING AND LICENSURE each medical service being provided;

~~b. Ensure that each medical service provided is within the scope of practice of the licensee and that of the nonphysician health care provider, as evidenced by the education, training, experience, ability, licensure or certification of the licensee and the nonphysician health care provider.~~

~~c.~~ b. Ensure that the licensee is available electronically OR TELEPHONICALLY to consult with non-physician health care providers, particularly in the case of injury or an emergency.

653—13.11(11) Coordination of care.

A licensee who uses telemedicine shall identify the medical home or USUAL treating physician(s) for the patient, when available, where in-person services can be delivered in coordination with the telemedicine services. The licensee shall provide a copy of the medical record to the patient's medical home and/or treating physician(s).

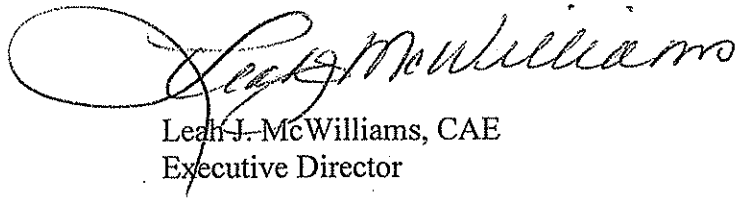
13.11(18) Disclosures and functionality of telemedicine services

e. Fees for services, cost-sharing responsibilities, and how payment is to be made, IF THESE DIFFER FROM AN IN-PERSON ENCOUNTER.

Certainly a patient has the right to know if there is an additional financial obligation for a telemedicine encounter. However, this requirement is not the current practice for an in-person visit due to differing fee schedules of the many insurance plans available.

Thank you for allowing us the opportunity to provide these comments and suggestions for language changes.

Sincerely,



Leah J. McWilliams, CAE
Executive Director

Mercy
HEALTH NETWORK

Sponsored by Catholic Health Initiatives–Englewood, CO and Trinity Health–Livonia, MI

1755 59th Place
West Des Moines, IA 50266

January 15, 2015

Mark Bowden
Board of Medicine
400 SW Eighth Street, Suite C
Des Moines, IA 50309
Via E-mail: Mark.Bowden@iowa.gov

Re: Comments on Proposed Telemedicine Rule – ARC 1769C

Dear Mr. Bowden:

Mercy Health Network and the Midwest Rural Telemedicine Consortium appreciate the opportunity to comment on the Board of Medicine's proposed rules on the practice of telemedicine in the Iowa. MHN applauds the Board's interest in advancing telemedicine. MHN has been an early adopter of telemedicine and has developed innovative uses for telemedicine across the state which is providing more access to health care service for Iowa and delivering high quality care in an efficient way.

Mercy Health Network (MHN) is a statewide system comprised of 11 owned and 27 contract-affiliated hospitals, and 142 physician clinics with 625 physicians. MHN is based in West Des Moines and includes the Mercy Medical Centers in Des Moines, Sioux City, Mason City, Dubuque and Clinton. It also includes owned community hospitals in Centerville, Dyersville, New Hampton, Primghar, West Des Moines and Oakland, Nebraska. MHN also has numerous long-term care, assisted living, and senior living facilities as well as many home health and hospice programs in Iowa. MHN has long worked to bring high-quality patient care to Iowa communities across the state.

The Midwest Rural Telemedicine Consortium, or MRTC, a service of Mercy Health Network, is a membership organization including 30 hospitals in Iowa and 2 hospitals in Nebraska. The Consortium was formed in 1994 and began providing telemedicine services using two-way interactive video and audio in 1995. MRTC has taken a broad view in defining telemedicine and includes clinical, educational and administrative services. Among the Consortium's first goals was to support Medicare's efforts to research and recommend payment models for telemedicine. Following those early efforts Medicare has recognized and expanded reimbursement for telemedicine, now frequently referred to as telehealth. Many states have legislated coverage for telehealth services. In Iowa, although coverage is not mandated through legislation, Medicare, Wellmark, Medicaid and some other third party payers cover some telemedicine services. On the national front, Medicare has recognized the benefits of telehealth to the point that it covers telehealth services provided in the hospital, emergency room and skilled nursing facilities and has recently added remote patient monitoring reimbursement.

While supportive of several aspects of the proposed rules, MHN has concerns about a few provisions in the rules. Our concerns are in six areas: definition of telemedicine, physician-patient relationship, informed consent, technology requirements, medications or treatment regimens and barriers to care and reimbursement.

Definition of Telemedicine
We applaud the Board for defining the clinical practice of telemedicine. We also request clarification that in defining telemedicine as between a licensee in one location and a patient in another location that common practices, such as tele-pathology or tele-radiology are not excluded from reimbursement in the state. These practices do not require patient participation. Also, the definition as written (a licensee in one location and a patient in another location) would appear to exclude Medicare approved group activities (HCPCS codes G0420 and G0421, kidney disease education; G0108 and G0109, diabetes self-management training services, CPT codes 96150 – 96154, health assessment and intervention; HCPCS G0270 and CPT 97802 – 97804, medical nutrition therapy). It would also exclude family engagement for services approved by Medicare for telehealth reimbursement (CPT code 90846, family psychotherapy (without the patient present); 90847, family psychotherapy (conjoint psychotherapy) (with patient present). Overall, the proposed rules, as they relate to defining telemedicine, impose a higher standard on a licensee providing care via telemedicine.

Physician-Patient Relationship
We are pleased to see clarification that interactive video and audio (face-to-face) encounter is an approved way to establish a physician-patient relationship. Additionally, we support the rule confirming interactive video and audio is allowed to perform a history and physical exam. These will allow for more patient access and patient choice in providers. We also support giving the provider the ability to decide whether or not telemedicine is appropriate to determine a diagnosis and provide treatment. It is important to allow providers to use professional judgment in this area.

Informed Consent/Privacy and Security
We appreciate and share the concerns the Board of Medicine has related to privacy and the security of patient information. However, we do not agree that telemedicine needs to be held to a higher standard. Given the extensive protections currently in place under HIPAA and current requirements regarding informed consent, these additional requirements are not necessary. Adding further requirements will only create an obstacle for expansion of telemedicine.

Technology Requirements
We appreciate that the Board of Medicine did not attempt to dictate technology and equipment technical specifications. Equipment capabilities change rapidly and any guidelines will quickly be outdated. The Board lists concerns related to safety laws for technology and devices. However, placing all of that responsibility on the provider is not reasonable – and is a more onerous burden than the physicians have in an in-person patient visit. It should also be noted that the use of the word "all" in these requirements could be misinterpreted. For example: all technology and equipment used in a telemedicine encounter may not interact with patients or be integral to patient care, but any equipment would be required to meet those high standards as the rule is written. Some technology aspects of electronic medical records seem to have been combined with the provision of telemedicine services (i.e., rapid availability of patient records, HIPAA compliant). The expectation that an individual physician, physician practice or medical facility would be able to provide electronic access to patient medical records is a higher standard than currently available or a realistic standard to impose at this time. And, whereas the EMR shares stored electronic patient information and is addressed under HIPAA transmission media guidelines, not all telemedicine services include or exchange previously electronically stored information, so the transmission may meet the same conditions as the phone or a fax and not be considered transmission via electronic media.

Medications or Treatment Regimens
In the proposed rules, section 13.11(21) creates restrictions for "Medications or treatment regimens that can be administered only by a physician." However, there is no definition of "treatment regimen". A further clarification is important as not to overly restrict what treatments can be provided via telemedicine.

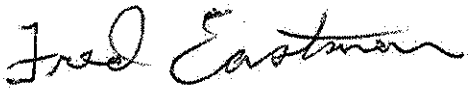
Barriers to Care and Reimbursement
Although not addressed in these rules, there are artificial barriers to providing telemedicine care and receiving reimbursement for that care. These barriers have to do with artificially imposed definitions of where medical care via telemedicine can be provided, as in the case of CMS identifying MSAs and non-MSAs for telehealth originating sites. Under these rules, rural critical access hospitals may not qualify to offer reimbursable telemedicine services. These rules also reduce non-rural patient access to specialty care. By not reimbursing a specialist to remotely see a patient in an urban hospital the efficiency telemedicine provides is limited. Another barrier is third party insurers' restrictions on telehealth payment. These barriers add to the confusion surrounding telemedicine approved services and payment policies.

In closing, MHN advocates for telemedicine policy that provides for reimbursement from all payers for telemedicine, as well as allows physicians to use their professional judgment to determine the best course of treatment for his/her patients.

Thank you for the opportunity to comment on this proposed rule.

Sincerely,

Dale F. Andres, DO
Medical Director
Midwest Rural Telemedicine Consortium



Fred Eastman
Program Coordinator
Midwest Rural Telemedicine Consortium

Planned Parenthood of the Heartland (PPH), submits these comments to the proposed amendment for 653 Iowa Administrative Code Chapter 13 ("the Rule").

At the outset, the Iowa Supreme Court has stayed the Board's attempt to ban PPH's telemedicine abortion protocols, while the Court considers PPH's challenge to that ban. *Planned Parenthood of the Heartland, Inc. v. Iowa Board of Medicine*, No. 14-1415 (Iowa Sep. 16, 2014). Thus it would be improper to adopt r. 653-13.11(22) until the Iowa Supreme Court has ruled.

Regardless of ongoing litigation, and out of a shared interest in furthering the health and safety of Iowans, PPH respectfully urges the Board to cease its efforts to ban PPH's telemedicine protocols. These carefully-designed protocols have been safely used for over six years, have extended access to early abortion for over 6000 women living in rural and outlying areas, and have proved highly acceptable to patients. By extending access, PPH's protocols have improved women's health in a number of ways: 1) increasing access to early screening for pregnancy-related complications such as ectopic pregnancy; 2) enabling women to obtain an abortion earlier in their pregnancy, thereby reducing rates of later abortion and ensuring that women who need a medication abortion for health or other reasons are afforded this option; 3) increasing access to important post-abortion follow-up; and 4) ensuring that women are not forced to carry an unwanted pregnancy to term.

As set forth below, PPH urges the Board to delete entirely r. 653.13.11(22) because it effectively bans telemedicine for medication abortion, will do nothing to enhance patient safety, and in fact will increase risks for patients as well as violating their constitutional rights. Additionally, PPH urges the Board to clarify certain other aspects of the proposed rule, specifically with respect to how physicians can establish a physician-patient relationship under 13.11(7)(b)(2)&(3) and what it means to "personally" examine patients under 13.11(20). Finally, if the Board does adopt practice standards for telemedicine, then PPH urges the Board to apply these standards across the board, including to telemedicine abortion, by rescinding Rule 653-13.10(147,148,272C).

I. R. 653-13.11(22) effectively bans the telemedicine delivery of medication abortion.

By requiring a physician's physical presence "when prescribing, administering, or dispensing medications . . . that [by law] can be administered only by a physician," r. 653-13.11(22) effectively bans the telemedicine delivery of medication abortion. This provision serves no medical purpose, and will in fact harm women's health by restricting access to care. It should be removed from the proposed amendment.

II. Telemedicine is critical to women's access to abortion.

PPH has only three physicians providing abortion in the entire state, and they are concentrated in Iowa City and Des Moines (and, once a week, Ames). These physicians cannot travel throughout the state to provide in-person services while still meeting the needs of their local patients. PPH is aware of only one other Iowa abortion provider, in

Iowa City (the Emma Goldman Clinic). The scarcity of abortion providers in outlying communities is a national problem. Even when physicians living in these communities want to provide abortion services, it is often impossible for them to do so either because the practice they join prohibits it or because they would be stigmatized within the community and unable to maintain an overall practice. Lori Freedman, *Willing and Unable: Doctors' Constraints in Abortion Care* 92-97 (2010) (Attachment A); *Planned Parenthood Se., Inc. v. Strange*, ___ F. Supp. 2d ___, 2014 WL 3809403, at *16-19 (M.D. Ala. Aug. 4, 2014).

Through telemedicine, PPH's three physician providers are able to provide services to patients in six additional clinics spread throughout Iowa—in Burlington, Cedar Falls, Council Bluffs, Dubuque, Quad Cities and Sioux City—as well as more consistent services in a seventh clinic in Ames. Without this program, some women would have to travel hundreds of miles, multiple times, in order to receive a safe and legal abortion.

III. Restricted access to abortion services delays or prevents women from obtaining care.

It is well established that restricting access to abortion delays or prevents women from receiving this care.

Most women who seek abortion are struggling financially, which makes it particularly hard for them to arrange transportation, child-care, and time off work. Rachel K. Jones et al., *Characteristics of U.S. Abortion Patients, 2008* 8 (May 2010) (Attachment B). Most are caring for children, and over a third have multiple children. *Id.* And many face additional logistical obstacles. Kate Grindlay et al., *Women's and Providers' Experiences with Medical Abortion Provided Through Telemedicine*, 23(2) WOMEN'S HEALTH ISSUES e117, e118-19 (2013) (Attachment C). Women employed in Iowa are more than twice as likely as men to work low-wage jobs, National Women's Law Center, *Underpaid and Overloaded: Women in Low-Wage Jobs* 25 (2014) (Attachment D), and consequently lack paid sick time and face unpredictable and inflexible work schedules that make it difficult or impossible to schedule out-of-town appointments without risking their jobs, *id* at 3; *id.* at 29-31; Liz Watson et al., *Collateral Damage: Scheduling Challenges for Workers in Low-Wage Jobs and Their Consequences* (Apr. 2014) (Attachment E).

Some women, moreover, face abusive or coercive family members who may use violence, threats, or other measures to prevent them from obtaining abortions, and these women could resort to unsafe, self-induced abortion if they fear they might otherwise be forced to disclose their pregnancies to abusive family members. ACOG, *Committee Opinion 554: Reproductive and Sexual Coercion* 1 (Feb. 2013) (Attachment F); Ann M. Moore et al., *Male Reproductive Control of Women Who Have Experienced Intimate Partner Violence in the United States*, 70 SOC. SCI. & MED. 1737, 1741 (2010) (Attachment G). American Medical Association Council on Ethical and Judicial Affairs, *Mandatory Parental Consent to Abortion*, 269(1) J. AM. MED. ASS'N 82, 83 (1993) (Attachment H). (Of course, these are reasons why so many women, when counseled about their various options, have chosen a telemedicine abortion.)

During the August 28, 2013 hearing before the Board on this same subject, for example, a certified sexual assault advocate testified about a nineteen-year-old woman who came into a rural outreach center after being raped and impregnated by her father. The woman wanted to terminate the pregnancy, but a significant obstacle for her was getting to a clinic, "as she had very little income, no transportation, and no support system." The advocate testified that "[i]t was only through telemedicine that this woman was able to access her legal right to termination at her local clinic." Natalie Scarpino Comments, Audio Recording of Public Hearing: Iowa Board of Medicine Administrative Record, Law No. CVCV046429 (Iowa Board of Medicine 11/01/2013) at 2:44:30.

Researchers have studied the factors that influence the timing of abortions, and have found that the farther a woman has to travel to reach a provider, the more likely she is to have the abortion later in pregnancy. For example, a study of abortion in Washington State found that women who had to travel more than 75 miles to obtain an abortion were two to three times more likely than other women to terminate their pregnancy after 12 weeks. Sharon A. Dobie et al., *Abortion Services in Rural Washington State, 1983-1984 to 1993-1994: Availability and Outcomes*, 31 FAM. PLAN. PERSP. 241, 244 (1999) (Attachment I). Indeed, PPH's program significantly reduced the incidence of second-trimester abortions by making first trimester abortions far more accessible. Daniel Grossman et al., *Changes in Service Delivery Patterns After Introduction of Telemedicine Provision of Medical Abortion in Iowa*, 103(1) AM. J. PUB. HEALTH 73, 76 (Nov. 2012) (Attachment J) ("*Changes in Service Delivery Patterns*"). It follows that banning the program will push a significant number of women past the nine-week window when medication abortion is available and into their second trimester before they can obtain an abortion.

For some women, this reduction in access will not only delay them but prevent them altogether from reaching a legal abortion provider. ACOG, *Practice Bulletin Number 143: Medical Management of First-Trimester Abortion* 123 OBSTETRICS & GYNECOLOGY 11 (Mar. 2014) (Attachment K) ("ACOG Bulletin 143") (noting that, after PPH implemented its program, "women in remote parts of the state were more likely to obtain an abortion than before"); Theodore Joyce, *The Supply Side Economics of Abortion*, 365 NEW ENG. J. MED. 1466 (Oct. 20, 2011) (Attachment L); *Planned Parenthood Ariz., Inc. v. Humble*, 753 F.3d 905, 916 (9th Cir. 2014) (noting evidence that distances similar to the ones at issue here prevent women from obtaining an abortion).

IV. Restricted access to abortion services jeopardizes women's health.

By delaying women in their efforts to obtain an abortion, the Rule exposes them to medical or safety risks in a number of ways. Some women have medical conditions that make medication abortion significantly safer than surgical abortion. If delayed past nine weeks, they will be deprived of their safest option and left only with higher-risk options. *See* Affidavit of Daniel Grossman ¶ 37 (Attachment M) ("Grossman Aff.") (explaining conditions for which medication abortion is safer than surgical abortion); *see also Planned Parenthood Cincinnati Region v. Taft*, 444 F.3d 502, 511-12 (6th Cir. 2006). Other women are at risk unless they can conceal their abortion from abusive family members, *see* Exhibits F-H, *supra*, (harder to do the farther they must travel) or disguise

it as a miscarriage (as medication abortion, but not surgical abortion, allows them to do), Grossman Aff. ¶ 11.

By depriving many women of their only non-surgical abortion option, the Rule also imposes psychological harms on them. Many women have deeply personal reasons for preferring a medication abortion, including that it "is less invasive than surgical abortion, which is a particularly important consideration for survivors of rape or sexual abuse." *Humble*, 753 F.3d at 908. Seventy-one percent of women who choose medication abortion express a strong preference for this form over surgical abortion. Daniel Grossman et al., *Effectiveness and Acceptability of Medical Abortion Provided Through Telemedicine* 118(2) OBSTETRICS & GYNECOLOGY 296, 300 (Aug. 2011) (Attachment N) ("*Effectiveness and Acceptability*").

By causing delay, the Rule also imposes risk on patients in general. It increases the risk that ectopic pregnancies will go undiagnosed because it makes it harder for women to receive the necessary ultrasound screening for this condition. *Compare* Kelly Cleland et al., *Significant Adverse Events and Outcomes After Medical Abortion*, 121 OBSTETRICS & GYNECOLOGY 166, 168 (2013) (Attachment O), *with* Andreea Creanga et al., *Trends in Ectopic Mortality in the United States 1985-2007*, 117(4) OBSTETRICS & GYNECOLOGY 837, 837 (2011) (Attachment P) (mortality rate for ectopic pregnancy among medication abortion patients is lower than national maternal mortality rate from ectopic pregnancy).

Delay also increases risk because abortion, while a safe procedure generally, is safest when performed early in pregnancy. Linda Bartlett, et al., *Risk Factors for Legal Induced Abortion-Related Mortality in the United States*, 103 OBSTETRICS & GYNECOLOGY 729, 735 (2004) (Attachment Q); ACOG, *Guidelines for Women's Health Care* 719 (4th ed. 2014) (Attachment R). Moreover, women who must travel farther for follow-up care are at a greater risk of not receiving that important care. *Effectiveness and Acceptability* at 298.

Women who are forced to carry their unwanted pregnancy to term face the risks of pregnancy and childbirth, which are far higher than those associated with early medication abortion and higher still for rural women. Elizabeth Raymond & David Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 OBSTETRICS & GYNECOLOGY 215, 216 (Feb. 2012) (Attachment S); Thomas S. Nesbitt et al., *Access to Obstetric Care in Rural Areas: Effect on Birth Outcomes*, 80(7) AM. J. PUB. HEALTH 814, 814 (1990) (Attachment T) (rural women with less access to prenatal and other obstetric care have significantly higher rates of birth-associated complications and premature delivery); Jonathan M. Snowden et al., *The Impact of Hospital Obstetric Volume on Maternal Outcomes in Term, Non-Low-Birthweight Pregnancies*, AM. J. OBSTETRICS & GYNECOLOGY (Sep. 28, 2014) (Attachment U) (women delivering in low-volume rural hospitals experience higher rates of postpartum hemorrhage). Some of these women will also be exposed to increased risk of domestic violence. Sarah CM Roberts, *Risk of Violence from the Man Involved in the Pregnancy after Receiving or Being Denied an Abortion* 12 BMC MEDICINE 144 (2014) (Attachment V).

Some of these women, moreover, will attempt to self-induce an abortion out of desperation, a result that carries its own medical risks. *See, e.g.*, Emily Bazelon, *A Mother In Jail for Helping Her Daughter Have an Abortion*, N.Y. TIMES MAGAZINE, Sept. 22, 2014, (Attachment W) (Pennsylvania woman jailed for ordering abortion medication over the internet for her daughter; family had limited transportation and lived 75 miles from the nearest abortion provider); Erica Hellerstein, *The Rise of DIY Abortions in Texas*, THE ATLANTIC, June 27, 2014 (Attachment X).

V. There is no medical reason to restrict the telemedicine provision of medication abortion.

A. Medication abortion is extremely safe.

Medication abortion is an extremely safe and effective non-surgical method of terminating an early pregnancy (in the first nine weeks) that has been available to women in the United States since 2000. It is a two-drug regimen: First, at the clinic, the patient takes mifepristone, which blocks the hormones necessary for a pregnancy to continue; then, at home two days later, she takes misoprostol, which induces contractions that empty the uterus. ACOG Bulletin 143 at 2-3. To date, over two million women in the United States have accessed this treatment.

Screening out the small number of women who have contraindications to medication abortion is a straightforward process, involving blood tests, a vital signs check, an ultrasound, and a medical history. *Id.* at 6; Grossman Aff. ¶ 10. Complications would occur only after the patient has left the clinic, and these are extremely rare; the rate of clinically significant adverse events is 0.16-.31 percent, comparable to those of commonly prescribed antibiotics. Cleland, *supra*, at 169; Ushma Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 OBSTETRICS & GYNECOLOGY 175, 178 (2015) (Attachment Y); Grossman Aff. ¶¶ 13, 18; *see also* Nadine Shehab et al., *Emergency Department Visits for Antibiotic-Associated Adverse Events*, 47 CLINICAL INFECTIOUS DISEASES 735, 738 (2008) (Attachment Z). Importantly, these rates are far lower than those associated with pregnancy and childbirth. Raymond & Grimes, *supra*.

B. PPH's program is safe and appropriate.

PPH's telemedicine program is carefully set up so that patients are professionally cared for in person at the telemedicine site, under physician supervision. After trained PPH staff have provided counseling and taken blood tests, an ultrasound image, and a medical history to screen for contraindications, the physician reviews these results and reads the ultrasound to confirm an intrauterine pregnancy within the appropriate gestational age range. Notably, as with any pregnancy-related ultrasound, the machine itself estimates the gestational age.

The physician then meets with the patient via videoconference (with a PPH staff member in the room with the patient the entire time), answers her questions, and confirms that she

is an appropriate candidate for the treatment and is giving informed consent. If so, the physician presses a button that triggers the release of a drawer where the patient is sitting, thereby providing her with the first medication she needs to take. The physician and the other staff member observe her ingesting that medication, and the physician makes sure she understands the instructions for the rest of the regimen.

Not surprisingly, given the lack of any clinical need for the physician to be physically present for routine screening tests or for the oral ingestion of the first medication, there have been no patient complaints out of over 6000 patients who have received this care over the past six years and not a single telemedicine patient has spoken in favor of banning the protocols. Moreover, studies of PPH's program have shown that it has an equally low incidence of complications and high patient satisfaction rate, as compared to PPH's medication abortion services in sites where the physician is physically present. In fact, rates of attendance at follow-up appointments were higher for telemedicine patients. *Effectiveness and Acceptability* at 298. Researchers also found that PPH's program has improved women's health by significantly reducing the incidence of more invasive, surgical second-trimester abortions in Iowa. *Changes in Service Delivery Patterns* at 76. Based on this research, ACOG has publicly stated that PPH's program is a safe and acceptable way to extend care to medically underserved communities. ACOG Bulletin 143 at 11.

VI. Other provisions of the Rule are unclear, and unnecessarily restrictive.

Other provisions of the proposed Rule are confusing and unnecessarily restrictive, and would chill the important practice of telemedicine in Iowa.

Section 13.11(7)(b) lists three appropriate means of establishing a valid physician-patient relationship. Because it provides that the physician "may" use these means, (7)(b) is ambiguous as to whether they are exclusive or whether a physician may use other means that in her best professional judgment are appropriate. Section (7)(b) appears to be based on guidelines by the American Medical Association. American Medical Association, *CMS Report 7-A-14: Coverage of and Payment for Telemedicine* 7 (2014) (Attachment AA). But the AMA's language has been altered. While the AMA guidelines allow for the relationship to be established through "[a] face-to-face examination," terminology that is explicitly used to include remote face-to-face interactions using real-time videoconferencing technology, *id.* at 6, the equivalent provision of the Rule, r. 653-13.11(7)(d)(1), has substituted the phrase "in person medical interview and a physical examination," and defined "in person" only to cover interactions where the parties are physically in the same room.

Also of concern, while the AMA guidelines allow for the relationship to be formed in accordance with guidelines issued by specialty organizations, the Rule would add an additional, restrictive condition: these guidelines must address the "technological aspects of telemedicine" in addition to the clinical aspects, r. 653-13.11(7)(b)(3). Section (b)(3) could have the unfair and arbitrary effect of making it impossible for some physicians to use telemedicine technology simply because no nationally recognized organization in

their specialty has issued guidelines addressing both the clinical and the technological aspects of telemedicine.

Additionally, section 13.11(7)(b) allows for a relationship to be formed through consultation with a "health care provider," without defining this term.

PPH also urges the Board to revise draft 13.11(20). This provision specifies "[c]ircumstances when a physician may not personally examine a patient," again without specifying whether these circumstances are exclusive. PPH asks that the Board clarify that the term "personally" covers situations where a physician interviews the patient and examines her remotely using telemedicine technology. This would be the only interpretation consistent with draft 13.11(8), which recognizes that "the medical interview and physical examination may not be in person if the technology utilized in a telemedicine encounter is sufficient to establish an informed diagnosis as though the medical interview and physical examination had been performed in person." Any blanket requirement that physicians, or licensed staff, examine patients in person, moreover, would be medically unnecessary and inconsistent with AMA guidance, *see* Attachment AA at 7, and could seriously hinder future efforts to expand access to care through telemedicine.

Conclusion

For these reasons, PPH respectfully urge the Board to revise the proposed Rules, and rescind r. 653—13.10(147,148,272C), so that the Iowa Administrative Code does not single out abortion services, and so that the Code gives clear, evidence-based guidance to physicians who provide health care using telemedicine technology.

Date: January 15, 2015

BY: Planned Parenthood of the Heartland

BY: _____

Michael Falkstrom, AT0010207
General Counsel
Planned Parenthood of the Heartland
1171 7th Street
Des Moines, IA 50314
Phone: (515) 280-7000

A

WILLING AND UNABLE

Doctors' Constraints in Abortion Care

LORI FREEDMAN

WILLING AND UNABLE

Doctors' Constraints in Abortion Care

Lori Freedman

Vanderbilt University Press
NASHVILLE

© 2010 by Vanderbilt University Press
Nashville, Tennessee 37235
All rights reserved
First Printing 2010

This book is printed on acid-free paper.
Manufactured in the United States of America

Book design and typesetting by Judy Gilats

Library of Congress Cataloging-in-Publication Data

Freedman, Lori, 1973–
Willing and unable : doctors' constraints in abortion care / Lori Freedman.
p. cm.
Includes bibliographical references and index.
ISBN 978-0-8265-1714-2 (cloth : alk. paper)
ISBN 978-0-8265-1715-9 (pbk. : alk. paper)
1. Abortion—United States—Prevention. 2. Reproductive rights—United States. 3. Hospitals—Medical staff—Clinical privileges—United States. I. Title.
[DNLM: 1. Abortion, Legal—United States. 2. Health Services Accessibility—United States. 3. Physicians—United States. WQ 440 F853w 2010]
HQ767.5.U5.F745 2010
362.19'88802—dc22
2009041258

medicine passed the buck on abortion long ago, and many physicians find it both regrettable and easier that way.

Abortion Stigma, Professional Civility, and Conservative Community Pressure

In many parts of the country, both urban and rural, the legacy of the pre-*Roe* "abortionist" is alive and well. The stigma associated with this label is pervasive yet unusual as far as stigmas go in that this one is associated with an otherwise high-status individual: a physician. Regardless, the label is "deeply discrediting," in the words of Erving Goffman, from his seminal introduction of stigma to the field of sociology (Goffman 1963: 3). The word *abortionist* confers the imagery of a physician who does little else besides abortion and may be not skillful enough to do well in general or mainstream medicine. It also connotes bad intentions. In Carole Joffe's study of doctors who provided abortion before legalization, one physician remembered that " 'abortionist' was such a dirty word, it was just one step above pervert, or child abuser . . . to be called an abortionist in the 1950s, you were the scum of the earth" (Joffe 1995: 76). Also, by the mere association with abortion, especially at that time, doctors were seen as condoning a "sexually immoral" lifestyle. Remarking on how perceptions of physicians providing illegal abortions (and those parading as physicians) affected future generations of abortion providers, Joffe writes, "Abortion practices in the pre-*Roe* period created a complex legacy for physicians active after *Roe*, given the enduring images of inept 'quacks' and 'butchers' and the associations with criminality and greed" (Joffe 1995: 52). After legalization, some of Joffe's abortion providers found that their status increased little and that the label abortionist stuck in certain medical environments, regardless of the legal legitimization. One physician objected, "I'm no more an abortionist than I am an obstetrician or a hysterectomist or any other procedure that I do" (Joffe 1995: 153).

In a review of the sociological literature on stigma since Goffman (1963), Bruce Link and Jo Phelan (2001) found four principles consistent among stigmas. These can be applied neatly to abortion providers. First, Link and Phelan argue that stigmas are widely used to distinguish and

label difference—as in *abortionist* rather than *ob-gyn* or *physician*. Second, the label is associated with a negative attribute, in this case, a morally deficient or technically incompetent physician. Third, the stigma allows the user to separate "us" from "them," much as the "quack" is singled out from legitimate physicians. Finally, status loss and discrimination result—exactly what was feared by several physicians in my study and widely experienced decades ago by Joffe's abortion-providing physicians.

Many physicians I spoke with, like Joffe's physician, regard the idea of being labeled for one of the many surgical procedures they perform as absurd. For those in small-town private practices, however, the prospect of being identified with abortion in this way is profoundly threatening. For example, Dr. Bill Spellman in the Midwest said: "I didn't plan on doing abortions in my private practice for a lot of reasons. It's too small of a community to really do *that* . . . it's tough if you do abortions electively in your own private practice because then you get labeled as an *abortionist*, which, a guy [here], he got labeled like that." Similarly, regarding his small southern town, Dr. Kevin Dougherty remarked, "There's a history in the city that I'm in. There was a practice that did offer abortions and were *run out of town*."

The subjects at the center of this controversy, physicians, are normally high-status individuals; they have a long way to fall from grace. Additionally, the individuals in my study were often new parents, new homeowners, new members of a practice—all, of course, because I selected a group that had graduated only five to ten years before from their residency programs. Therefore, many saw themselves as relatively vulnerable—an unlikely characterization of physicians. These doctors had student loans and mortgages to repay; at the same time, they needed to prove themselves as worthy members of their private-practice groups.

Dr. John Brill wanted to continue providing abortions in his private practice, as he had done in his first job after residency, but after moving to a small, conservative town in the West to be closer to family, he no longer saw it as a possibility. "It's a small town and none of the ob-gyns perform abortions," he said. "There is one abortion clinic in town. And the provider who comes up from [the city two and a half hours away] to perform abortions is *vilified* within the community. To perform abortions in this community means being '*evil*.'"

For Dr. Brill, it was as if he had entered a new world. He recently had come from a western urban area where he was, among other things, an abortion provider. Yet his move placed him in a cultural and political context where he quickly decided he must hide that identity. With the aforementioned commuting provider planning to retire soon, Dr. Brill was contacted by the local abortion clinic in its search for a new physician director: "They called me up and said, 'Hey, we heard that you might be the person.' I was like, 'Well, you know, that's real nice but I don't think I can be the guy running the [abortion] clinic.' . . . I didn't turn them down. I said I'd be happy to have a dialogue, but I don't think I can be, you know, 'Doctor Abortion Provider,' the only one in this town." This was not a simple decision for Dr. Brill. Politically, he is very sympathetic to abortion rights; however, he is deeply concerned that any connection to abortion would undermine him professionally:

> It's frustrating because it's a service that is desperately needed, and it would completely destroy my ability to practice medicine in town. And that's a difficult position to be in. Do I sacrifice myself for the greater good? But then I can't take care of my wife and kids? I don't like thinking about it too much. It sort of burns me when I have to think about it too much . . . It's a real sort of strong Christian community, so a lot of the family practice docs in town, they're strong Christians. And that's your referral base. And so to be labeled as the evil abortion doctor is a great way to make no friends amongst the ob-gyns and to have no family practice docs refer patients to you.

Dr. Brill identified professional failure, and the economic effect of that on his family, as a major risk to providing abortions. He worried that other physicians would not refer their patients to him and his practice would be, in a sense, boycotted by the community. For Dr. Brill and doctors similarly situated, the local stigma of abortion is both palpable and personal.

Some physicians had the unpleasant experience of being screened by patients with strong antiabortion views, further reiterating the sentiment that abortion practice is risky for their reputations in their communities and the financial success of the medical groups with which they practice. Five of the six doctors who shared these stories practice in the Midwest in cities of varying sizes. One such physician, Dr. Stacy Kern, had an uncomfortable encounter with a couple who were looking for a physician who, like themselves, would be opposed to abortion:

> I had a patient who came in for obstetrical care with me as a new ob patient . . . And we had about a forty-minute new [prenatal] visit, which is a long time, because we had a lot of stuff to talk about. And at the very end of the discussion her husband said to me, "Well, we just feel so much more comfortable with you because we've had some experiences where practitioners think it's okay to, like, do abortions or something. And I just don't see how anybody could ever believe that—you know, to deliver babies and then to kill babies and to be okay with that" . . .
>
> Well, first I thought, oh dear . . . And I just sort of looked [at them] and I said, "Well, you're talking to one of those people" . . . Oh my God, the room was just like—there's this deep inhalation . . . I said, "Listen, I'm sorry but, you know, if somebody needs a safe procedure, I feel that you have to offer them a safe procedure . . . I'll step out and you two can talk and I'll be back in a few minutes." And I stepped out and actually had a family practice resident shadowing me that day. When we got through, her eyes were [bulging wide]. And I said, "I don't think she'll be staying with me" . . . Well, about five minutes later I went back, and they're all packed up [and said,] "We'll be going elsewhere."

While disconcerting to Dr. Kern, the interaction ended peacefully. Dr. Bill Spellman was not so lucky, and in his case, the patient was initially deceptive, which eroded his confidence in counseling patients about pregnancy options for the future:

> I got burnt on it once so I'm always leery. A woman came in and started talking to me directly about how she wanted to get a termination. She brought it up, she wanted to talk about it, and so I said, "Well, there's this and this and this available out there." And she says, "Would there be any way that you could perform this? I really think that we have a link here and I really want you to do this." And I felt very bad for her because of the whole story behind it. And I said, "Well," I said, "I've done these before." And right then she stood up and she said, "I knew it. I knew it all along. You're a baby killer," and walked out of the room . . . She wrote this long letter to the people who ran the office that I worked for basically telling them just what an absolute scumbag I was and all these other

> things. So since that point—you know, burned once, I'm not going to do it again—when somebody comes in and wants to talk about [abortion], I talk to them a little bit, I have them leave, and I have them come back for another visit.

Dr. Spellman now gives patients with unwanted pregnancies reading materials about pregnancy options from ACOG, a presumably uncontroversial source of information, and talks to them at the second visit about whether they want a referral to an abortion clinic. He feels this has successfully weeded out one or two similar patients, but he credits the professional embarrassment and personal discomfort of this interaction with making him even more sensitive to the stigma and contention surrounding abortion in his community.

Physicians practicing in small and midsized towns worried significantly about the consequences of involvement with abortion. Most of these doctors practiced in groups where policies on abortion are made for the practice as a whole. Dr. Spellman thinks it would be challenging to persuade the partners of his midwestern group practice to provide abortions in their town even if they did want to:

> If you start doing elective terminations in your practice, then the community will just kind of view you as that one thing. The right-to-life people are really, really, really organized in this and they're very, very good about getting that word out within seconds about somebody. And, you know, it's—you hate to say it—you practice in the real world . . . I think if we were in LA or in Phoenix, Arizona, or something like that, I don't think the partners would give a crap. Because it's such a big place that, you know, who cares if two or three thousand or a hundred thousand people believe that you're an abortion clinic when there's still 2.4 million more people out there? Here we only have a couple hundred thousand people . . . They guard their reputation a lot in these communities. It's one of the things that really makes a practice.

Essentially, he argues that performing abortions means facing professional sanctions such as losing patients and losing business, that the anti-abortion activists will bring so much attention to the matter that the entire ob-gyn practice will be viewed as "an abortion clinic." Whether practicing

solo or in a group, doctors in relatively small or politically conservative communities felt a stigma that made abortion practice seem incompatible with general medical practice.

Most of the physicians in my study feared the social and professional consequences of performing abortions and maintained collegiality and civility by not performing them after residency. Those I spoke with who performed abortions regularly, and not exclusively for genetic or medical indications, lived in areas around the country that were less politically conservative and/or worked in relatively protective university settings where multiple layers of bureaucracy as well as the way that the clinic is physically embedded within a larger medical facility made them less visible to the outside world. Indeed, almost all of the physicians I interviewed trained in such protective university environments. Graduation was a rude awakening for some.

Threats, Intimidation, and Violence

Not all professional sanctions were feared, anticipated, and then avoided. Some physicians reported having direct confrontations with colleagues regarding abortion. An important characteristic of most stigmas is that their subjects must agree to the "rules"; that is, they must recognize that they are stigmatized, and if they do not, there will be consequences for such "deviance" (Goffman 1963).[2] Those with power over the stigmatized may impose the consequences in the form of direct discrimination (Link and Phelan 2001). Physicians encounter various types of intimidation and violence when they provide (or consider providing) abortions. These can be viewed as a type of such stigma enforcement. Several physicians I spoke with who wanted to continue performing abortions met with uncomfortable interactions out in the "real world." Indeed, these interactions were uncomfortable enough to keep them "in line" and to significantly shape their practice patterns.

Many physicians found out at job interviews how abortion would be viewed in the private practices they hoped to join. Some declined job offers because of abortion prohibitions, and some did not. Still others had little choice in the matter given the limited job opportunities in their area. For example, Dr. Kern was tied to the area because of her husband's work.

B

May 2010

Characteristics of U.S. Abortion Patients, 2008

Rachel K. Jones, Lawrence B. Finer and Susheela Singh

HIGHLIGHTS

- In 2008, the majority of women obtaining abortions (58%) were in their 20s; women in their 30s made up the second largest age-group (22%).
- Non-Hispanic white women accounted for 36% of abortions, non-Hispanic black women for 30%, Hispanic women for 25% and non-Hispanic women of other races for 9%. While no group made up the majority of abortion patients, black and Hispanic women were overrepresented.
- The overwhelming majority of women having abortions (85%) were unmarried, including 29% who were cohabiting. Among never-married women obtaining abortions, almost one-half had been in a relationship for a year or longer with the man who had made them pregnant.
- Most women having abortions (61%) already had at least one child, including 34% who had two or more children.
- Some 42% of women having abortions were poor, a substantially greater proportion than were poor in 2000 (27%).
- Women obtaining abortions in 2008 were less likely than their counterparts in 2000 to be married or to have a religious affiliation, and were more likely than the earlier cohort to have a college degree. These patterns largely reflect changes in the population of all women of reproductive age.
- Thirty-three percent of women obtaining abortions lacked health insurance, 30% had private health insurance, 31% were covered by Medicaid and 5% had some other type of health insurance.
- Although 66% of women having abortions had some type of health insurance, 57% paid for their abortion out of pocket. Among women with private health insurance, 63% paid out of pocket.

May 2010

Characteristics of U.S. Abortion Patients, 2008

Rachel K. Jones, Lawrence B. Finer and Susheela Singh

CONTENTS

Background 3

Data Collection and Analytic Strategy 4

Results 5
Characteristics of Women Obtaining Abortions 5
Health Insurance Coverage and Payment for Abortion Services 10

Discussion 12
Limitations 13
Conclusions 13

Appendix I: Methods 15
Data Collection 15
Data Quality and Comparability 16
Analytic Strategy 17

Appendix 2: Questionnaires 18
Module A 18
Module B 22

References 26

ACKNOWLEDGMENTS

This report was written by Rachel K. Jones, Lawrence B. Finer and Susheela Singh, all of the Guttmacher Institute. It was developed with funding from an anonymous donor. The conclusions and opinions expressed in this publication are those of the authors.

The authors thank the following individuals for reviewing an early draft of this report: Kelly Blanchard, Ibis Reproductive Health; Amy Hagstrom Miller, Whole Women's Health; Andrea Miller, NARAL Pro-Choice Massachusetts; James Trussell, Princeton University; and Tracy Weitz, Bixby Center for Global Reproductive Health, University of California, San Francisco.

The authors also thank Guttmacher colleagues Heather Boonstra, Patricia Donovan, Stanley Henshaw, Megan Kavanaugh, Cory Richards, Adam Sonfield and Gustavo Suárez for reviewing drafts of the article, as well as Luciana Hebert, Emily Nell, Sameen Qadir and Corey Westover for providing research assistance.

The Guttmacher Institute gratefully acknowledges the general support it receives from individuals and foundations—including major grants from the William and Flora Hewlett Foundation, the David and Lucile Packard Foundation and the Ford Foundation—which undergirds all of the Institute's work.

© Guttmacher Institute, 2010

Suggested citation: Jones RK, Finer LB and Singh S, *Characteristics of U.S. Abortion Patients, 2008*, New York: Guttmacher Institute, 2010.

To order this report or download an electronic copy, go to www.guttmacher.org.

Background

Abortion is one of the most common medical interventions undergone by U.S. women of reproductive age,[1] and an estimated one in three women have an abortion by age 45.[2] Nationally representative surveys are a primary source of information about many sexual and reproductive behaviors. However, only about one-half of abortions are represented in these types of studies, perhaps because stigma prevents some women from reporting their abortions or because some populations of women who have abortions are underrepresented even in surveys regarded as nationally representative.[3,4]

Additionally, much of what is known about women having abortions is incomplete or out of date. The Centers for Disease Control and Prevention (CDC) compiles and releases annual abortion statistics, including demographic characteristics of women having abortions.[5] However, some states do not require abortion reporting, and the information that is gathered is limited to a few basic demographic characteristics. The Guttmacher Institute periodically conducts nationally representative surveys of women having abortions, collecting information on a wider range of background characteristics. One such survey was conducted in 2000, and a number of societal changes have occurred since that time. For example, the population of women has become more racially and ethnically diverse;[6] more women have college degrees;[7] and fewer women are married and more women are cohabiting.[8] These changes may have affected the need for or use of abortion among different subgroups of women and, in turn, altered the social and demographic composition of the population of abortion patients.

This report draws on data from the latest Guttmacher survey to provide a profile of the population of U.S. women who accessed abortion services in 2008. It includes new information about several previously unexamined characteristics: length of relationship with male partners, foreign-born status, attendance at religious services, health insurance status and payment for abortion services. Information from this report can help identify those groups most likely to be affected when new abortion restrictions are implemented, as well as those most at risk of unintended pregnancy.

Data Collection and Analytic Strategy

This is the Guttmacher Institute's fourth national survey of abortion patients. It uses a design, questionnaire and fieldwork procedure similar to those of earlier studies, which collected information from women obtaining abortions in 1987, 1994–1995 and 2000–2001.[9–11] Between April 2008 and May 2009, we collected information from U.S. abortion patients using a four-page, self-administered survey available in English and Spanish. In all, 12,866 abortions were performed at the 95 participating facilities; we obtained usable surveys from 9,493 women, for a response rate of 74%. We constructed weights to correct for any bias produced by deviation from the original sampling plan and nonresponse, and to produce nationally representative results. Missing information on key demographic variables was imputed on the basis of the responses of women with similar characteristics. For a detailed description of the data collection procedure and copies of the survey instruments, see the appendices.

We present descriptive findings (percentage distributions, means and numbers) on key demographic characteristics of abortion patients: age, union status, race and ethnicity, parity, education, poverty, religious affiliation and participation, and foreign-born status. Confidence intervals are provided to show the level of uncertainty around estimates of each population mean. We assessed changes over the past decade by comparing the demographic profile of abortion patients in 2008 with that of women obtaining abortions in 2000.* All analyses were based on weighted data, and the complex sampling feature of SPSS 13.0 was used for all estimates. We used t tests to assess whether changes in subgroup characteristics between 2000 and 2008 were statistically significant.

We could not estimate the abortion rate (the number of abortions per 1,000 women) by subgroup for 2008, because 2005 is the most recent year for which the total number of abortions is available.[12] As a proxy, we constructed a measure that allows us to compare relative levels of abortion across subgroups, which we refer to as an abortion index or a relative abortion rate. Each abortion index is the proportion of abortion patients who are in a given subgroup (e.g., a particular age-group) relative to the proportion of all U.S. women who are in that same subgroup. If the proportions are the same (indicated by an index of 1.0), the subgroup's relative abortion rate is the same as the overall national rate. If the subgroup is overrepresented among abortion patients (index of greater than 1.0), its relative abortion rate is above average; if it is underrepresented (index of less than 1.0), its relative rate is below average. Notably, an increase in the abortion index for a subgroup over time does not necessarily indicate an increase in the subgroup's abortion rate. If the overall abortion rate decreased between 2000 and 2008, the abortion rate for a subgroup may have fallen, even if that subgroup's abortion index rose. However, an increase in the index would mean that the subgroup's position has shifted relative to that of at least one other subgroup and relative to the national rate.

*The fielding period for the prior survey extended into 2001. However, because the majority of questionnaires for both surveys were gathered in the year in which fielding began—2008 and 2000—we refer to both surveys according to the single year.

Results

Characteristics of Women Obtaining Abortions

Age-Group

Public discussions of abortion and the women who have them often focus on adolescents, which may create the impression that most abortion patients are teenagers. However, the majority of women who had abortions in 2008 (58%—Table 1, page 6) were in their 20s; the second largest age-group was women in their 30s (22%). Adolescents (women younger than 20) accounted for 18% of abortions, including the 7% that were obtained by minors (those younger than 18). Abortion patients in 2000 had a similar age distribution to those in 2008.

Women aged 18–29 were overrepresented among abortion patients. Those in their early 20s had the highest abortion index, and the highest relative abortion rate, of any age-group (2.03); in other words, they were overrepresented by a factor of two relative to the population of all women of reproductive age. Women aged 18–19 and 25–29 also had above-average relative abortion rates (indices, 1.76 and 1.46, respectively). All other age-groups had below-average relative abortion rates. For example, the likelihood of abortion among 15–17-year-olds was 57% of that among all women. Abortion indices changed slightly for all age-groups except women aged 40 and older, but the rank ordering of age-groups according to their abortion indices did not change over time.

Union Status

Women's desires to have children, as well as their ability to negotiate the responsibilities of childrearing, may be influenced by relationships with male partners, and abortion varies substantially by union status. Nearly one-half of women having abortions were living with male partners: Some 15% were married, and an additional 29% had been unmarried but cohabiting with male partners in the month they became pregnant. Fifty-six percent of women had not been living with their partners, and most of these (45% of all women who had abortions) had never been married. Abortion patients were slightly (but significantly) less likely to be married in 2008 than in 2000; however, this drop can be attributed to a decline between survey years in currently married women as a proportion of the general population of women aged 15–44 (from 48% to 44%). The proportion of abortion patients who were cohabiting was significantly higher in 2008 than in 2000. Over the last few decades, cohabitation has become a more common living arrangement,[13] and the change among abortion patients may simply reflect this trend; unfortunately, we lack comparable information about this living arrangement among all women in 2000.

Married women were underrepresented among those who had abortions; their likelihood of having an abortion was one-third that of all women (abortion index, 0.34). Both never-married and previously married women were overrepresented among abortion patients and had relative abortion rates slightly above the national average (1.13 and 1.33, respectively). Cohabiting women were substantially overrepresented among women who had abortions; their relative abortion rate was more than three times that of all women (3.46).

While most women accessing abortion services were unmarried and not cohabiting, many were in relationships at the time of their abortion. Sixty-two percent had been in a relationship with their male partner a year or longer, and only 12% reported that they had not been in a relationship with the man who had gotten them pregnant (Figure 1, page 7). Even among never-married women, almost one-half reported that they had been in a relationship with their male partner for a year or more.

Race and Ethnicity

Abortion patients were diverse in terms of race and ethnicity: Non-Hispanic white women made up 36% of patients, non-Hispanic black women 30%, Hispanic women 25% and non-Hispanic women of other races 9%.* The confidence intervals for these estimates were larger than those for other characteristics (in both 2000 and 2008), meaning that the estimates were less precise.†

*Overall, 7% of women obtaining abortions in 2008 identified themselves as Asian (i.e., South Asian, Native Hawaiian or other Pacific Islander), and 3% as members of another racial group (e.g., American Indian). Because the Asian and "other" racial categories were measured differently in the 2000 and 2008 surveys (see Appendix 1), we could not compare these more detailed categories over time.

†This pattern reflects that women in a given racial or ethnic group tend to be concentrated in particular facilities, and thus the estimates are more dependent on the facilities sampled.

TABLE 1. Percentage distribution of U.S. women obtaining abortions and of all U.S. women aged 15–44, and abortion index, by selected characteristics, 2008 and 2000

Characteristic	Women obtaining abortions		All women aged 15–44		Abortion index	
	2008 (N=9,493)	2000 (N=10,683)	2008	2000	2008	2000
Age-group						
<20	17.6 (16.6–18.7)	19.1 (17.9–20.4)	17.0	16.0	1.04	1.20
<15	0.4 (0.3–0.6)	0.7 (0.5–0.8)	na	na	na	na
15–17	6.2 (5.6–6.8)	6.5 (5.8–7.2)	10.7	9.5	0.57	0.68
18–19	11.0 (10.3–11.8)	12.0 (11.2–12.8)	6.2	6.5	1.76	1.85
20–24	33.4 (32.2–34.6)	33.0 (31.8–34.3)	16.4	15.1	2.03	2.19
25–29	24.4 (23.4–25.4)	23.1 (22.2–24.1)	16.7	15.6	1.46	1.49
30–34	13.5 (12.7–14.3)	13.5 (12.6–14.5)	15.5	16.5	0.87	0.82
35–39	8.2 (7.6–9.0)	8.1 (7.5–8.8)	16.9	18.5	0.49	0.44
≥40	2.9 (2.5–3.4)	3.1 (2.6–3.5)	17.5	18.4	0.17	0.17
Union status						
Married	14.8 (13.5–16.2)	17.0 (15.7–18.5)*	43.6	47.7	0.34	0.36
Cohabiting, not married	29.2 (27.6–30.8)	25.4 (24.3–26.6)***	8.4	na	3.46	na
Never-married, not cohabiting	45.0 (43.0–47.1)	46.6 (44.7–48.5)	39.7	na	1.13	na
Previously married, not cohabiting	11.0 (9.9–12.1)	10.9 (10.1–11.8)	8.2	na	1.33	na
Race and ethnicity						
Non-Hispanic white	36.1 (31.5–40.9)	40.9 (35.5–46.6)	61.5	68.2	0.59	0.60
Non-Hispanic black	29.6 (24.6–35.1)	31.7 (27.0–36.9)	14.4	13.7	2.06	2.31
Non-Hispanic other	9.4 (7.4–11.8)	7.3 (5.6–9.4)	7.1	5.3	1.33	1.38
Hispanic	24.9 (19.8–31.0)	20.1 (15.4–25.7)	17.0	12.8	1.46	1.57
Education†						
<high school	12.3 (10.9–13.9)	12.7 (10.6–15.2)	10.2	11.2	1.21	1.13
High school graduate/GED	28.3 (26.7–30.0)	30.3 (28.6–32.0)	25.9	30.9	1.09	0.98
Some college/associate degree	39.5 (38.1–40.9)	40.6 (39.0–42.2)	32.6	32.5	1.21	1.25
≥college graduate	19.9 (18.3–21.5)	16.4 (14.7–18.1)**	31.3	25.5	0.63	0.64
Prior births						
0	39.1 (37.0–41.2)	39.1 (37.3–41.0)	43.9	42.8	0.89	0.91
1	26.5 (25.2–27.8)	27.4 (26.4–28.4)	17.5	18.0	1.51	1.52
≥2	34.5 (32.8–36.1)	33.5 (31.9–35.2)	38.6	39.2	0.89	0.85
Family income as % of federal poverty level						
<100	42.4 (39.8–45.1)	26.6 (24.2–29.2)***	15.9	12.8	2.66	2.08
100–199	26.5 (25.4–27.7)	30.8 (29.2–32.4)***	18.6	17.5	1.42	1.76
≥200	31.1 (28.7–33.6)	42.6 (39.6–45.7)***	65.4	69.8	0.48	0.61
Religious affiliation‡						
Protestant	37.3 (33.5–41.3)	42.8 (38.4–47.3)	50.0	51.0	0.75	0.84
Roman Catholic	28.1 (24.9–31.5)	27.4 (23.6–31.5)	26.9	27.5	1.04	1.00
Other	7.1 (6.3–8.1)	7.6 (6.9–8.4)	5.8	5.4	1.23	1.41
None	27.5 (25.5–29.5)	22.2 (20.4–24.3)***	17.3	16.2	1.59	1.38
Foreign-born						
No	83.6 (80.8–86.1)	na	82.6	na	1.01	na
Yes	16.4 (13.9–19.2)	na	17.4	na	0.94	na

*p<.05. **p<.01. ***p<.001. †Among women aged 20 and older. ‡Among women aged 18 and older. *Notes:* Ns are unweighted. na=not applicable. Figures in parentheses are 95% confidence intervals. *Sources:* **All percentages, 2000:** reference 11, with special tabulations for union status using the 2000 Abortion Patient Survey. **Percentages by age-group, union status, race and ethnicity, education and foreign-born status, 2008:** Special tabulations of the 2008 Current Population Survey, March Supplement. **Percentages by prior births, 2008:** Special tabulations of the 2008 Current Population Survey, Fertility Supplement. **Percentages by poverty status, 2008:** Special tabulations of the 2009 Current Population Survey, March Supplement. **Percentages by religious affiliation, 2008:** Special tabulations of data on women aged 18–44 in the 2006 and 2008 General Social Survey.

Thus, while some of the changes in the racial and ethnic composition of abortion patients between 2000 and 2008 seem substantial—for example, the decline in the proportion who were white and the increase in the proportion who were Hispanic—they were not statistically significant.

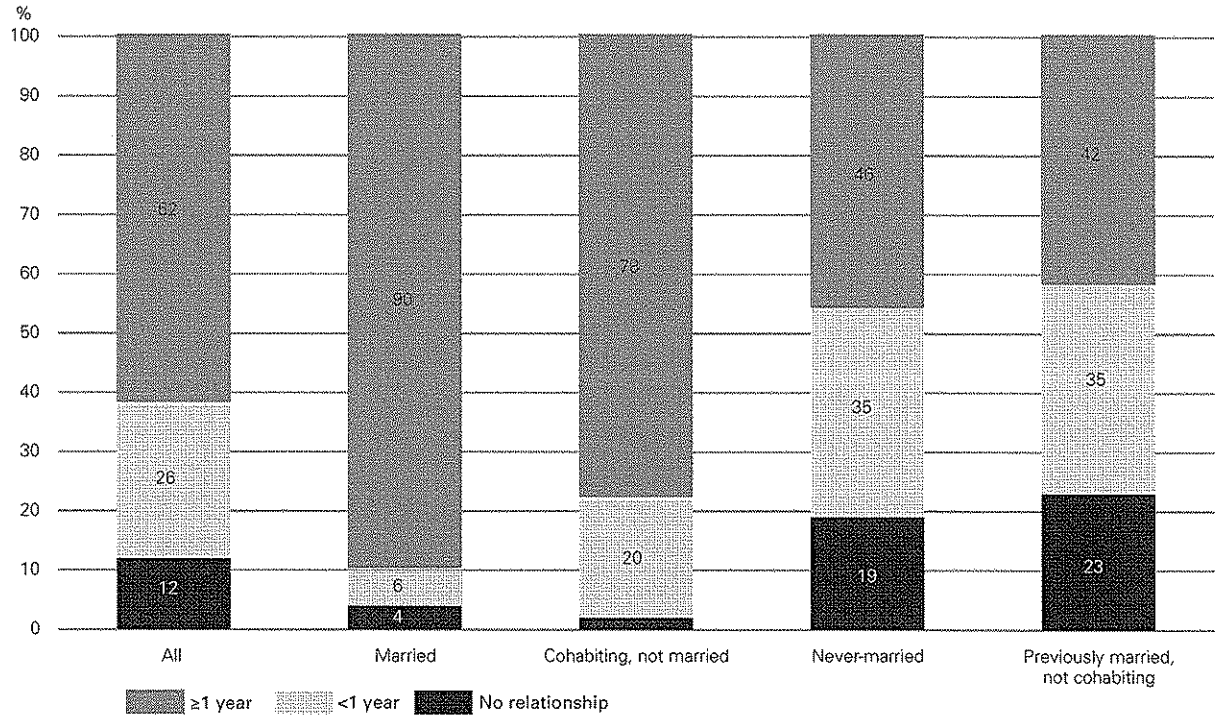
Black and Hispanic women were disproportionately represented among women obtaining abortions and had higher relative abortion rates than all women (abortion indices, 2.06 and 1.46, respectively). The likelihood of abortion among white women was 59% that among all women. Abortion indices were largely unchanged for white women and women of "other" races. Black women's abortion index declined, suggesting that their relative abortion rate was closer to the national average in 2008 than in 2000.

Education

Education can influence fertility intentions in several ways. For young women in particular, the desire to pursue or complete education can provide motivation to delay childbearing, and both attendance and completion of schooling can provide access to information and resources (e.g., sex education, health care) aimed at preventing unintended pregnancies. The overwhelming majority of abortion patients aged 20 and older had graduated from high school—88%, including the 20% who had at least a bachelor's degree. The latter proportion represents a statistically significant increase (from 16%) since 2000, which is largely attributable to an increase in education among all women aged 15–44: Nationwide, 31% had college degrees in 2008, compared with 25% in 2000.

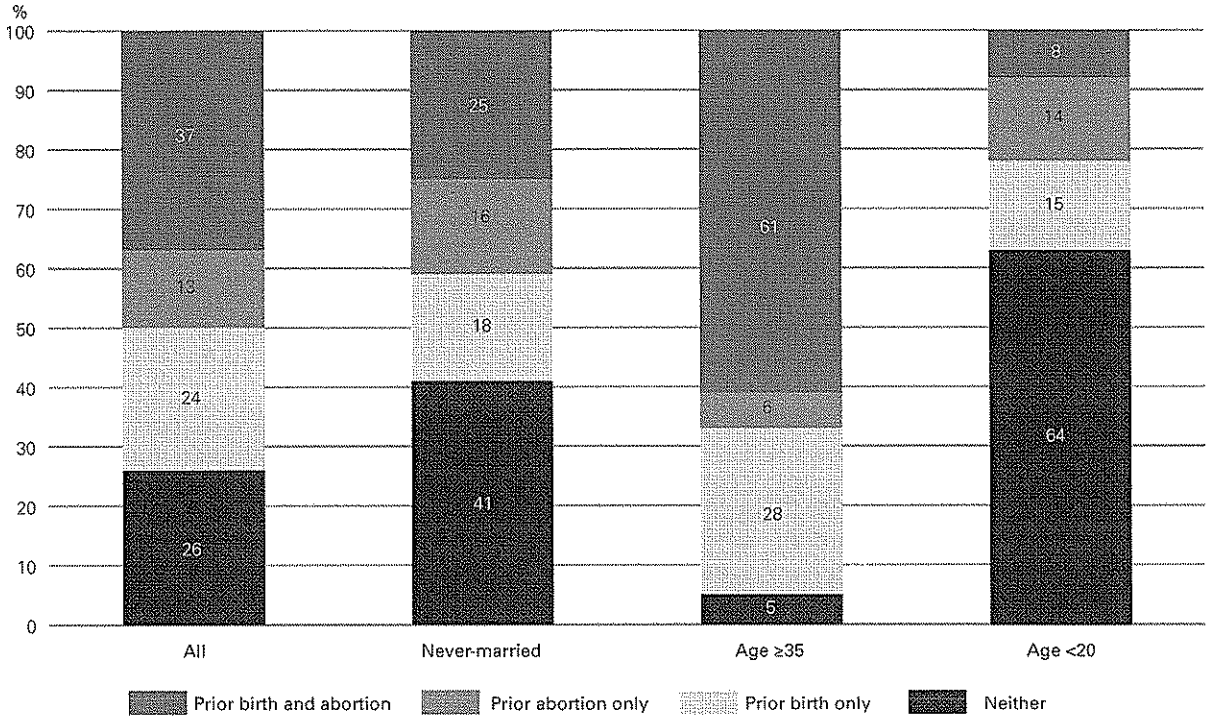
One common reason women give for terminating unintended pregnancies is that having a baby would prevent them from achieving goals such as pursuing an education.[14] Patterns in abortion indices by educational attainment may be due, in part, to educational goals. For example, the fact that women with some college education were more likely than all women to have an abortion (as suggested by an abortion index of 1.21) may reflect that these women were in school or hoping to complete their schooling, and having a baby would have prevented them from achieving this goal. That women with college degrees were less likely than average to have an abortion (as suggested by an index of 0.63) may reflect that higher education provides exposure to information about and access to contraceptives, and perhaps that it offers

FIGURE 1. Percentage distribution of abortion patients, by length of relationship with man responsible for pregnancy, according to union status, 2008



Source: Special tabulations of the 2008 Abortion Provider Survey.

FIGURE 2. Percentage distribution of abortion patients, by pregnancy history, according to selected characteristics



Source: Special tabulations of the 2008 Abortion Provider Survey.

increased motivation to avoid unintended pregnancy in the form of job and career opportunities. Between 2000 and 2008, abortion indices increased for two educational subgroups and decreased for one; all of the changes were relatively small.

Prior Pregnancies

Abortion and motherhood are often regarded as opposing interests, and it is often assumed that women who obtain abortions do not want to be mothers because they are unable or unwilling to assume the responsibilities of raising a child.[15] But 61% of women obtaining abortions in 2008 already had children, including 34% who had two or more. The distribution of abortion patients by number of prior births was virtually unchanged between 2000 and 2008.

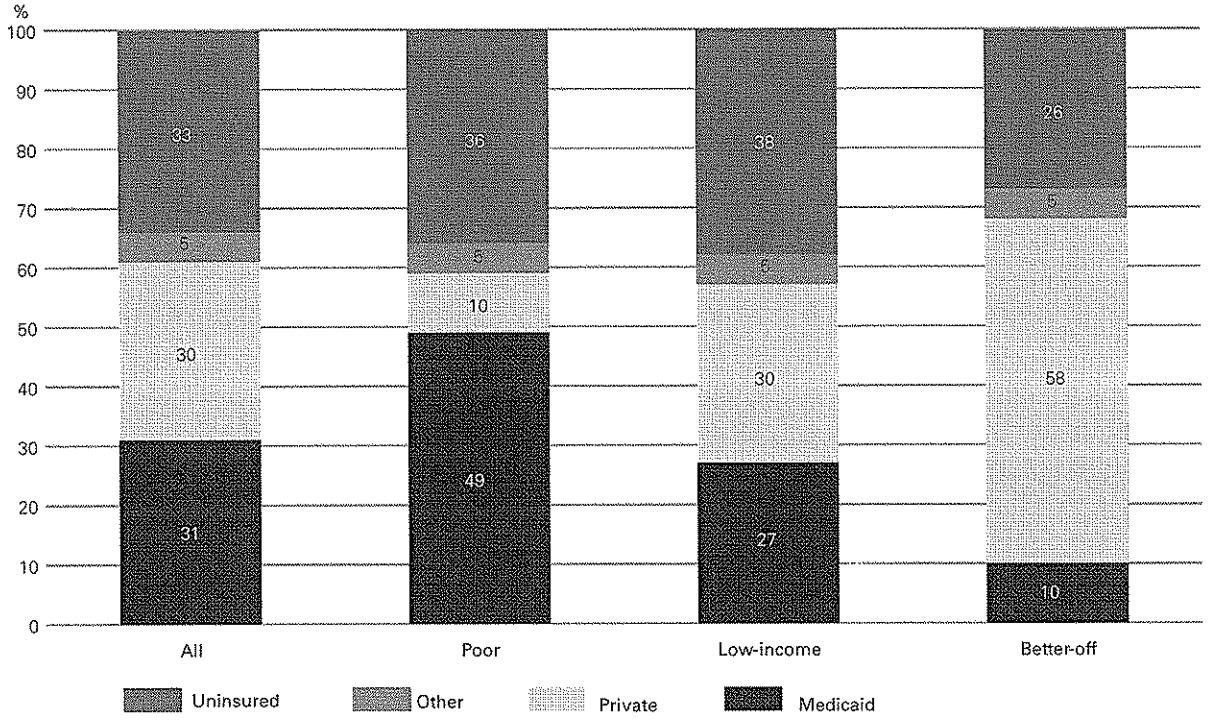
The relative abortion rate for women with no children and with two or more children was lower than the overall average (abortion index, 0.89 for each), while the relative rate for women with one child was 1.5 times that for all women. Between 2000 and 2008, the abortion indices for these subgroups changed little.

Abortion patients in 2008 had quite varied pregnancy histories. Half reported one or more prior abortions; most of these women (37% of all abortion patients) reported both a prior birth and a prior abortion (Figure 2). Multiple abortions are often regarded as a cause for concern, on the assumption that they indicate that women rely on abortion as a means of birth control.[16] However, the occurrence of multiple abortions is strongly associated with age; therefore, multiple abortions may indicate mainly prolonged exposure to the risk of unintended pregnancy. Among abortion patients aged 35 and older, 89% were mothers, and 61% had had a previous abortion as well as a prior birth. By contrast, 64% of abortion patients younger than 20 had had neither a birth nor an abortion before; women in this subgroup were about as likely to be mothers (23%) as to have had a prior abortion (22%).

Poverty Status

Forty-two percent of women obtaining abortions in 2008 reported family incomes that qualified them as poor, and an additional 27% were low-income (i.e., had family incomes of 100–199% of the federal poverty level). By contrast, the proportion who were poor in 2000 was 27%; the increase was statistically significant and continued a trend that had begun between 1994 and 2000.[11] The

FIGURE 3. Percentage distribution of abortion patients, by type of health insurance, according to poverty status



Notes: Poor women are those who reported a family income below the federal poverty level; low-income, those at 100–199% of the poverty level; better-off, those at 200% or more of the poverty level. *Source:* Special tabulations of the 2008 Abortion Provider Survey.

decreases in the proportions who were low-income and better off (i.e., reported family incomes of at least 200% of the poverty level) were also statistically significant.

Poor women were overrepresented among abortion patients. Their relative abortion rate was more than twice that of all women in 2008 (abortion index, 2.66) and more than five times that of women at 200% or more of the poverty level (0.48). The abortion rate for low-income women (1.42) was three times that of better-off women. Not only do poor women have above-average relative abortion rates, the abortion indices suggest that the difference increased between 2000 and 2008 (from 2.08 to 2.66). In contrast, the abortion indices for both low-income and better-off women decreased.

Religious Characteristics

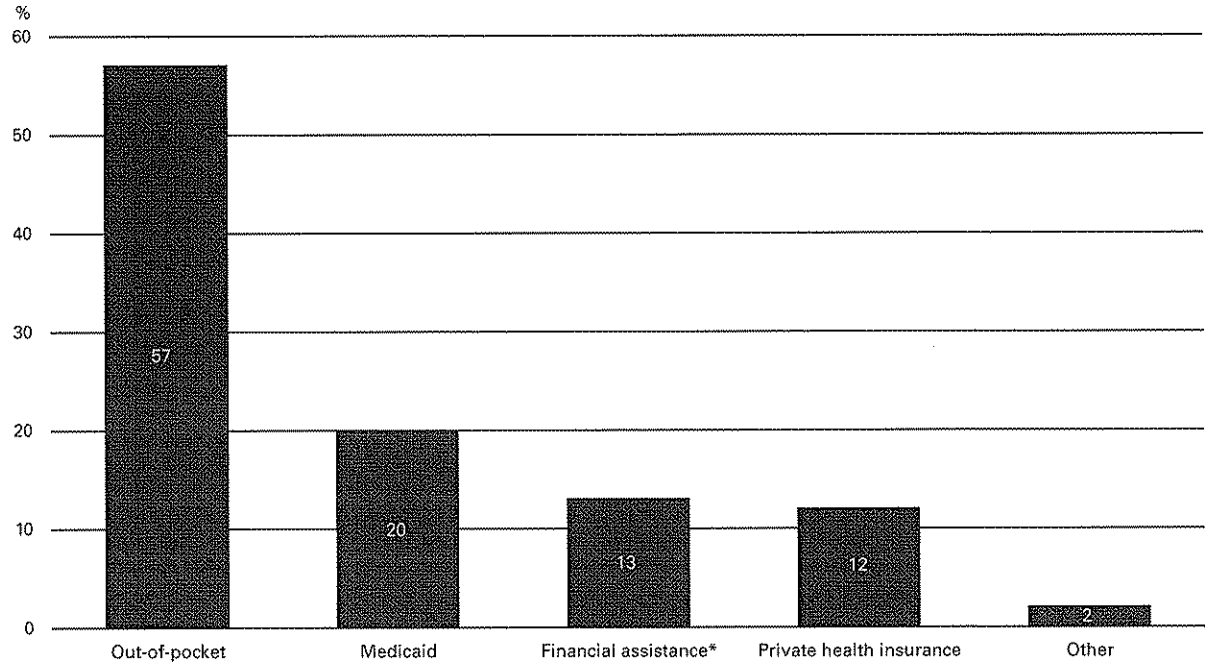
Almost three-quarters of women obtaining abortions in 2008 reported a religious affiliation. The largest proportion were Protestant (37%),* and most of the rest said that they were Catholic (28%) or that they had no religious affiliation (27%). One in five abortion patients identified themselves as born-again, evangelical, charismatic or fundamentalist; 75% of these were Protestant (not shown).† The proportion of abortion patients lacking a religious affiliation increased significantly, from 22%, in 2000.

Protestants were underrepresented among abortion patients, and the relative abortion rate for this group was lower than the rate for all women (abortion index, 0.75). While the Catholic Church has strong proscriptions against abortion, the relative abortion rate for Catholic women was no different from that for all women (1.04). Women with no religious affiliation had a relative abortion rate one and one-half times that of all women (1.59). The abortion indices for Protestant and Catholic women changed little

*As in the previous surveys, Protestants include women who wrote in that they were Christian and did not specify a denomination (8% of abortion patients in 2008).

†In 2000, some 13% of abortion patients aged 18 and older identified as born-again or evangelical. However, the item was reworded slightly for the 2008 survey, and we therefore cannot compare changes according to this characteristic over time.

FIGURE 4. Percentage of abortion patients, by method of payment for abortion



*Private abortion funds or reduced fees. *Note:* Percentages add to more than 100% because women could indicate more than one response. *Source:* Special tabulations of the 2008 Abortion Provider Survey.

between 2000 and 2008.

Attendance at religious services is sometimes regarded as an indicator of an individual's adherence to religious doctrines. In 2008, 15% of women having abortions reported attending religious services once a week or more, 13% attended 1–3 times a month and 32% attended less frequently; 41% never attended religious services (not shown). According to the General Social Survey (see Appendix 1), 23% of U.S. women aged 18–44 in 2006 and 2008 reported that they never attended religious services, and 24% that they attended once a week or more. Thus, tentative evidence suggests that women obtaining abortions attend religious services less frequently than all women.

*Policy or court decisions in 17 states require the use of state funds to cover all or most medically necessary abortions for low-income women enrolled in Medicaid. Nonetheless, two states under court order to fund abortion services (Arizona and Illinois) report very few procedures. (Source: Sonfield A, Alrich C and Gold RB, Public funding for family planning, sterilization and abortion services, FY 1980–2006, *Occasional Report*, New York: Guttmacher Institute, 2008, No. 38, Table 3.9, <http://www.guttmacher.org/pubs/2008/01/28/or38.pdf>, accessed Mar. 16, 2010.) As a result, for analyses that distinguish between abortion patients residing in Medicaid and non-Medicaid coverage states, we do not include Arizona or Illinois in the former.

Foreign-Born Status

Sixteen percent of women obtaining abortions in 2008 were foreign-born. This proportion was similar to the proportion of the larger population of women who were foreign-born; the relative abortion rate for this subgroup was therefore about the same as the overall rate. Women who responded listed more than 70 countries of origin, most commonly Mexico, countries of the West Indies, India and countries of western Europe (not shown). Abortion patients born outside the United States were most likely to identify as Hispanic (49%); 23% were Asian or South Asian, 15% identified as black and 13% were white or reported other racial identities (not shown).

Health Insurance Coverage and Payment For Abortion Services

Although most women in the United States have some type of health insurance,[17,18] poor and low-income women, who make up the majority of abortion patients, are more likely than average to be uninsured.[19] Many of the poorest women qualify for Medicaid, but federal funds are restricted to paying for abortion services only in cases of rape, incest and life endangerment, and only a minority of states uses their own funds to cover abortions for low-income women.*[20] Thus, the 2008 survey attempted

to assess what kind of health insurance coverage women have in general and how they pay for abortion services.

Thirty-three percent of women obtaining abortions in 2008 lacked health insurance (Figure 3, page 9), and comparable proportions had private coverage (30%) or were covered by Medicaid (31%); 5% had some other type of insurance. Not surprisingly, Medicaid coverage differed substantially by poverty status. Forty-nine percent of poor abortion patients were covered by Medicaid for general health care, compared with 27% of low-income women and 10% of those who were better off.* Only 10% of poor women had private insurance, compared with 58% of better-off women. More striking than this difference was the similarity in the proportion uninsured among poor and low-income women (36% and 38%, respectively). Even among women with family incomes of at least 200% of poverty, 26% lacked health insurance.

Although most abortion patients had some type of health insurance, 57% paid out of pocket for this service (Figure 4). The second most common payment method was Medicaid, reported by 20% of abortion patients; in fact, in states that use their own funds to pay for abortions, 92% of patients with Medicaid coverage made use of this payment method (not shown). Thirteen percent of women obtaining abortions relied on financial assistance programs such as private abortion funds and reduced fees to cover some or all of the cost of the service. Another 12% used their private insurance to pay for the procedure,† but 63% of women with private insurance paid out of pocket for the procedure (not shown). Finally, 2% reported using other strategies to pay for their procedures—for example borrowing money from a friend, partner or family member. A small proportion of women reported multiple methods of payment, and almost all of these had both paid out of pocket and received financial assistance or a discount.

*The survey's income question referred to the previous year, so some women may have had a relatively high income that year but been eligible for Medicaid coverage at the time of the survey.

†This figure includes the 4% of all abortion patients who reported paying out of pocket but expected to file for reimbursement by their health insurance companies.

Discussion

The profile of women obtaining abortions in 2008 closely resembled that of abortion patients in 2000. Women who obtain abortions are predominantly poor or low-income, in their 20s and unmarried; black women and Hispanic women continue to be disproportionately represented among abortion patients. Most changes that occurred—abortion patients are now less likely to be married and more likely to have college degrees than they were a decade ago—reflect trends in the larger population of women. The most notable change is that economic disadvantage became increasingly concentrated among abortion patients between 2000 and 2008.

The proportion of abortion patients who were poor increased 59% between surveys, from 27% to 42%. While less accurate measurement of income in the 2008 survey could account for some of the change (see Appendix 1), this shift likely reflects a real increase in poverty among abortion patients. Indeed, unintended pregnancy has become increasingly concentrated among women with the fewest economic resources. Between 1994 and 2000, the proportion of women obtaining abortions who were poor or low-income increased 15%; similarly, while the overall abortion rate declined, the rate for economically disadvantaged women increased.[11] It is important to recognize that poor women were not just having more abortions. Between 1994 and 2001, rates of unintended births increased 45% for this group, but only 10% for all women.[21]

The survey occurred during an economic recession, which may account for some of the substantial increase in poverty among abortion patients between 2000 and 2008. Most directly, the proportion of all women aged 15–44 living in poverty increased 25% during this time (Table 1); thus, we would expect an increase in poverty among women having abortions. More indirectly, recent studies have found that because of financial constraints, women want to delay childbearing or limit the number of children they have, but these same constraints have made it harder for them to access contraceptives and to use them consistently.[22,23] In these situations, poor women may have found it more difficult than better-off women to obtain and use contraceptives and prevent unintended pregnancies. Additionally, when confronted with an unintended pregnancy during the recession, poor women who might have felt equipped to support a child (or another child) in financially stable times may have decided that they simply were not equipped to do so now.

In 2006, the average woman paid $413 for a first-trimester abortion and $1,300 for an abortion at 20 weeks.[12] Although most women obtaining abortions in 2008 had some type of health insurance, the majority paid for abortion services out of pocket. Nearly one in three abortion patients had private health insurance, but two-thirds of this group did not use it to pay for the procedure. We suspect that several factors contributed to the lack of reliance on private insurance among women who had it. First, some may have had health care plans that exclude abortion services—for example, if they were employed by the federal government. Others may have been unaware that their plan covered abortion. Some women may have been reluctant to have the abortion on their insurance records out of concern that an employer, regular health care provider or family member whom they did not want to know about the abortion would have access to this information. Finally, some women with private health insurance have deductibles of several hundred, or even several thousand, dollars that have to be met before they can be reimbursed. Given that most women having abortions are in their 20s, and probably relatively healthy, and that the deductible may have exceeded the cost of abortion, it is quite possible that the deductible prevented these women from using their private insurance for this purpose.

A sizable minority of women (13%) obtained services on a sliding fee scale or relied on outside organizations to cover some or all of the cost of their abortion. We know of several situations that could account for this level of reliance on financial assistance. Some clinics charge reduced fees for women who can demonstrate financial need (for example, women with Medicaid who reside in states where it does not cover abortion services). Additionally, organizations such as the National Abortion Federation and the National Network of Abortion Funds, as well as some Planned Parenthood affiliates, receive charitable donations that are used to help low-income women pay for abortion services. The number of women helped by funds from multiple sources has increased in recent years,[24] and media reports have highlighted the increased demand for such support during the recession.[25,26] The increase in

these types of subsidies may have made abortion services more accessible for poor women and contributed to the increase in the proportion of all abortion patients who were poor. While it is fortunate that some women can take advantage of various forms of financial assistance, women in many parts of the country do not have access to subsidies; moreover, the availability of funds can fluctuate depending on the economy, the generosity of contributors and other factors that are difficult to predict.

Of all the groups examined in this report, cohabiting women had the highest abortion index, suggesting that their rate is more than triple the overall average and is one of the highest relative abortion rates of any subgroup. Cohabiting women also have above-average rates of contraceptive failure[27] and unintended births.[21] Future research might help uncover the relationship dynamics that contribute to these patterns. For example, do cohabiting couples have sex more frequently than other groups, use less effective methods or use their methods less consistently? Does the "less legal" status of the relationship make discussing or agreeing upon childbearing goals harder for cohabiting couples? Are unintended pregnancies more common among cohabiting couples who already have one or more children than among cohabiting couples with no children? At any given point, only a small proportion of women are in cohabiting relationships (8%), but at least half will occupy this relationship status at some point in their lives.[13] Additional information about the dynamics of contraceptive use and pregnancy among this population could identify strategies to help cohabiting women and men avoid unintended pregnancies.

One in six women having abortions in 2008 were foreign-born, and the relative abortion rate for this group apparently is no different from the rate for all women. Notably, information on abortion patients, by definition, does not take into account women who have an unintended pregnancy but are unable to access abortion services. For women of all backgrounds, barriers to abortion services could include money, distance to a provider and inability to travel; these barriers may be especially pronounced for foreign-born women because of difficulties related to language and culture. Undocumented immigrants may have concerns about coming into contact with the health care system, and women from countries where abortion is highly restricted may be unsure if abortion is legal in the United States. Our estimates are a useful first step in documenting the experiences of foreign-born women.

Limitations

This study has several limitations. First, our measure of poverty is imprecise, and levels of poverty among abortion patients in 2008 may be somewhat overestimated (see Appendix 1). If so, the increase in the proportion of abortion patients who were poor is not quite as large as reported. Furthermore, although it is unquestionable that abortion providers in 2008 were serving a population of women who were poorer than the 2000 cohort, we must be careful not to overinterpret these findings, because we lack information about the number of abortions and the abortion rate in 2008. Both the number of abortions and the abortion rate declined every year between 1991 and 2005,[12] but we cannot assume that this trend was sustained between 2005 and 2008. Statistics compiled by the CDC, while incomplete, suggest that both the number and the rate of abortions increased by 3% between 2005 and 2006.[5] This could be a one-year anomaly, or it could be the start of a trend reversal. The current analysis does not allow us to assess differences between 2000 and 2008 in the number of abortions and abortion rates among all poor and low-income women in the United States.

Our measures of insurance status also are imperfect, partly because of the complexity of the U.S. health insurance system and women's uncertainty about what type of health insurance they have. Nonetheless, we expect that the overall patterns in poverty and insurance among abortion patients are real.

The 2008 survey was the first to ask about foreign-born status, but this information may be slightly inaccurate, as the questionnaire was typically available only in English and Spanish (see Appendix 1). Foreign-born women who primarily spoke other languages may have been unable to participate, and foreign-born women may be underrepresented.

Conclusions

While abortion is one of the most common medical interventions undergone by women aged 15–44,[1] it is also one of the most regulated aspects of health care. In 2009 alone, 18 states enacted 34 abortion-related laws, none of which was intended to expand or protect access to abortion.[28] These new laws include mandated information ("counseling") and a waiting period in a state that did not previously have these requirements (Arizona), and the tightening of existing parental consent laws for minors (also in Arizona). One policy implication of this study is that increased restrictions on abortion services would disproportionately affect poor and low-income women, black and Hispanic women, and young adults.

Rather than restricting access to abortion, policy efforts could accomplish more by increasing access to a broad array of reproductive health services, including abortion. Groups overrepresented among abortion patients also have above-average rates of contraceptive failure[27] and unintended birth.[21] Increased public funding to expand access to contraceptive services, particularly for women who are unable to pay, could help reduce levels of unintended pregnancy and improve the lives of many women. Just as essential, access to abortion must be maintained and improved. Given that most women obtaining abortions are poor or low-income, nationwide public funding of abortion for poor women could help reduce the economic burden posed when these services have to be paid for out of pocket, as well as increase access to services for women who are currently unable to afford them.

Appendix 1: Methods

Data Collection

The 2008 survey of abortion patients was the Guttmacher Institute's fourth in a series and used a design and questionnaire similar to those used in the earlier surveys, which were conducted in 1987, 1994–1995 and 2000–2001.[9–11]

We developed a four-page questionnaire to collect information about demographic items contained in prior surveys (e.g., age, race and ethnicity, and educational attainment) and several new issues (e.g., health insurance coverage, how women paid for abortions services and foreign-born status). To keep the questionnaire within four pages and minimize survey administration time, we used a module design to create two versions of the questionnaire. All core demographic and contraceptive methods items were asked of all respondents. Items unique to module A, and asked of only one-half of respondents, included the woman's happiness about the current pregnancy and whether the man who had gotten her pregnant knew about the pregnancy and about the abortion. Items unique to module B included a series of nine questions about abortion stigma. Within each facility, consecutive patients received different modules. Much of the information from the questionnaires not discussed in this report will be summarized in subsequent analyses. The questionnaires are included as Appendix 2.

The facilities in the survey were sampled from all hospitals, clinics and physician's offices where abortions were performed in 2005, according to information from the Guttmacher Institute's 2006 Abortion Provider Census.[12] The universe was stratified by provider type (hospital or nonhospital) and 2005 caseload, rounded to the nearest 10 (30–390 abortions; 400–1,990 abortions; 2,000–4,990 abortions; or 5,000 or more abortions), and then listed by census region and state within each stratum. Facilities that reported fewer than 25 abortions in 2005 were not included because of the high likelihood that they performed few or no abortions during the survey period. Their exclusion caused little bias regarding the representativeness of women obtaining abortions, because these facilities accounted for only 1% of all reported procedures in 2005.[12] Next, we systematically sampled facilities from each stratum by selecting them at specified intervals within the list; the interval varied by stratum. For example, we took every fourth facility that reported 5,000 or more abortions in 2005 and every 21st of those reporting 30–390 abortions. (We oversampled clinics with large caseloads to obtain adequate representation of the variety of facilities in the sample.)

Each facility was assigned a sampling period that was inversely proportional to its probability of being selected. Facilities were asked to administer the questionnaire to all women who obtained an abortion during the specified period, which ranged from two weeks in the largest clinics to 12 weeks in the smallest facilities. Our goal was to recruit 107 facilities; our final sample consisted of 10 hospitals and 85 nonhospital facilities.*

The questionnaire, available in English and Spanish (and, at one facility's request, Portuguese), was distributed to women by facility staff. Participating facilities decided when during the patient's visit to distribute the questionnaire; in most cases, women completed it along with other paperwork while they waited for their procedure. The questionnaire included an introduction explaining the purpose of the survey and informing women that participation was voluntary and anonymous. Nonhospital facilities that served 10–35 abortion patients per week (40% of the sample) were offered the option of using audio computer-assisted self-interviewing; five facilities agreed to this mode of administration, and three of these completed the survey successfully. The questionnaire and procedures were approved by the Guttmacher Institute's federally registered institutional review board.

Participating facilities reported performing 12,866 abortions during the sampling period. Usable questionnaires were obtained from 9,493 patients, for a response rate of 74%. Seventy-three percent of these women obtained abortions during the second half of 2008, and the remaining 27% during the first half of 2009. Facility staff supplied information about age, race, ethnicity, insurance coverage and method of payment for 1,162 of the women who did

*If a facility declined to participate or did not obtain usable questionnaires from at least half of the target women, it was replaced by the next facility listed in its stratum, which in most cases was in the same state or in a neighboring state in the same region. Of the initial 107 providers sampled, 48 participated in the study; 59 had to be replaced, but we succeeded in replacing only 47. Of the 12 facilities that could not be replaced, seven were in the smallest caseload category sampled (30–390 abortions in 2006).

not complete the questionnaire. (Reasons women did not complete the questionnaire included refusal to participate, failure of the clinic to distribute questionnaires and lack of time to complete the questionnaire.) No information was available for the remaining 2,211 women.

As in prior surveys, to correct for any bias produced by deviation from the original sampling plan and nonresponse, we employed a three-stage weighting process. First, individual weights were developed to adjust for the demographic characteristics of the 1,162 nonrespondents for whom the facility staff provided information. Second, facility-level weights adjusted for the 2,211 nonrespondents for whom no demographic data were available. Third, stratum weights were constructed to correct for departures from the number of facilities to be sampled in each grouping by caseload and provider type. With the final weight adjusted to a mean of 1.0, the standard deviation is 0.21, and the range is 0.71–2.37.

Nonresponse was around 2% for most questions, but it ranged from 0.2% (for age) to 15% (for family income). Missing information on key demographic variables was imputed on the basis of the responses of other women with similar characteristics using a "hot-deck" procedure.*

Data Quality and Comparability

While many of the survey items were adopted from the previous patient surveys conducted by the Guttmacher Institute, several were revised to improve accuracy.

Race

The 2000 survey replicated an item on race from the 1995 National Survey of Family Growth (NSFG), which provided four response categories (Alaskan Native/American Indian, Asian/Pacific Islander, black and white) and asked respondents to indicate the one that best described their racial background. The NSFG is administered by a live interviewer, which allows for clarification and "forced categorization" for individuals who are unsure how to classify their race or who identify with more than one race.

We attempted to incorporate greater flexibility into our measurement of race in the 2008 survey. We adopted the item used in the 2006–2008 NSFG, which provided five response categories (American Indian or Alaska Native, Asian, Native Hawaiian/other Pacific Islander, black/African American and white), but made two additional adjustments. We changed the second category to "Asian/South Asian," to make clear for women in the latter group that this racial category was the most appropriate for them (and to better match federal statistics), and we provided an open-ended "other" category, with space for women to write in their race. Hispanic ethnicity was measured as a separate item.

Initially, 15% of women identified with an "other" race; 90% of these also indicated that they were Hispanic, and were coded as such on the combined measure of race and ethnicity used in our analysis. Our coding scheme allowed for only one racial group per respondent.† We do not know how the 2% of women who identified their race as an unspecified non-Hispanic "other" would have been classified, or would have classified themselves, if we had adopted the wording from the 2000 survey. As a result, we are somewhat cautious in our comparisons of race and ethnicity between the 2000 and 2008 surveys.

Health Insurance and Payment for Services

Prior surveys assessed whether women obtaining abortions were covered by Medicaid, but did not distinguish between private health insurance and lack of health insurance among women without Medicaid coverage. For the 2008 survey, we expanded the item to assess whether women had Medicaid, had private health insurance, had some other type of insurance or were uninsured. Because of changes in both the item wording and the response categories, measurement of Medicaid coverage is not comparable across the 2000 and 2008 surveys.

Even with more response categories, our measure of health insurance coverage is imprecise. Some women may be unclear about which kind of health insurance coverage they have. The "other" response category allowed for write-in responses, and some respondents wrote in programs that we identified as state Medicaid programs. (Perhaps because some state programs did not include "Medicaid" in the name, respondents did not identify them as such.) Additionally, a number of insurance programs straddle the state and private realms, providing more affordable coverage to individuals and families whose incomes are too high to qualify for Medicaid. We coded such programs as "other" types of health insurance. The "other" category also includes Indian Health Services, military health plans such as the Civilian Health

*We used cross-tabulations to identify the variables most strongly associated with each item requiring imputation. Respondents were sorted according to these variables in the order of the strength of the item's association with the variable to be imputed, so that similar cases were adjacent to one another in the file. A missing value was then replaced by the value of the preceding case in the file.

†In keeping with coding strategies for prior surveys, women who indicated multiple races were typically classified as belonging to the least common of the racial groups checked off, although women who indicated "other" and a specific race were classified as the specific race. Women who checked off both black and one or more other racial groups were classified as black.

and Medical Program of the Uniformed Services, student health plans and unspecified types of health insurance.

Similar issues pertain to the item collecting information about how women paid for abortion services. For example, 2% of women who indicated that they had private health insurance reported using Medicaid to pay for their abortion. We suspect that such seeming inconsistencies were due to the complexities of the U.S. health care system and respondents' lack of clarity about their type of health insurance coverage.

Income and Poverty

We asked women their total family income, before taxes, in the previous year. We constructed a three-category measure of poverty status based on reported family income and number of family members in the woman's household at the time of the abortion. The three poverty status categories are less than 100%, 100–199%, and 200% or more of the federal poverty threshold; on the basis of these categories, we describe women as poor, low-income or better-off.

Income and, in turn, poverty status are susceptible to higher levels of measurement error than characteristics such as race and age because of lower response rates. In addition, income reporting may have changed between the 2000 and 2008 surveys. In both years, respondents were provided with 11–12 income categories, listed in increments of $5,000 or $10,000 and ranging from "under $9,999" to "$70,000 or more" (in 2000) or "$75,000 or more" (in 2008). For the 2008 survey (but not the prior one), weekly incomes were provided in parentheses. This may have resulted in underreporting of family income, because some women may have a better sense of their weekly income than their yearly income, but the former is more likely to be the posttax figure. Additionally, the 2008 survey was fielded during the recession, and some women likely reported their current (weekly) family income as opposed to family income in the previous year. Women who lived in a household in which one family member had recently become unemployed, or who had otherwise experienced a recent drop in family income, may have reported a lower income than their family had earned in the prior year. Potential changes in reporting of income between 2000 and 2008 may have inflated the number of poor abortion patients in 2008 relative to 2000.

Analytic Strategy

We first performed univariate tabulations of women obtaining abortions in 2008 by age-group, union status, race and ethnicity, parity, education, poverty, religious affiliation and foreign-born status. We provide 95% confidence intervals to show the level of uncertainty around estimates of each population mean. We then compared demographic characteristics of abortion patients in 2008 with those of women obtaining abortions in 2000, and using t tests, we relied on the complex sampling feature of SPSS 13.0 to assess whether changes were statistically significant. All analyses were based on weighted data. As discussed on page 4, we relied on abortion indices to assess relative levels of abortion across subgroups.

Most of the population information used in our calculations comes from the 2008 Current Population Surveys (CPS), usually the March supplement, but we also relied on the fertility supplement for population information on births. Because the CPS uses family income from the prior year to measure poverty status, we use the 2009 CPS to estimate this characteristic. Our survey items on religious affiliation and attendance at religious services were worded to replicate the 2006–2008 NSFG. However, the NSFG data are not yet available. The best available data to estimate religious affiliation and attendance at religious services among all women aged 18–44 was the General Social Surveys for 2006 and 2008. However, these estimates have a margin of error of around three percentage points (for the largest groups) because of the relatively small sample (1,745 for the two years combined). (We will be able to generate more reliable estimates when the 2006–2008 NSFG data are released.) Data on abortion patients in 2000, as well as population data for that year, come from a previously published article on abortion patients in that year.[11]

Appendix 2: Questionnaires

Module A

NATIONAL PATIENT SURVEY

(1-5)

440r (6-9)
a (10)

The Guttmacher Institute
A not-for-profit organization for reproductive health research, policy analysis and public education
125 Maiden Lane, New York, NY 10038 Phone: (800) 355-0244 Fax: (212) 248-1951 Web: www.guttmacher.org

The Guttmacher Institute, a non-profit research organization, is asking abortion patients across the country to provide us with information in order to improve health programs and policies in the United States. Please help by answering the below questions about yourself, your decision to have an abortion and other aspects of your life.

Your participation is voluntary and will not affect the services you receive. There are no direct benefits to participating in this study. While the risks are minimal some of the items are about sensitive issues such as sexual assault and may make you uncomfortable; you can skip these questions as well as any that you are unable to answer. The survey should take 5 to 10 minutes to complete. When you are done with it, place it in the attached envelope and return it to a staff member. **Your name is not requested here.** This survey is confidential and anonymous. The information you provide will be used for research purposes only.

If you would like a copy of the results, ask the clinic for a Guttmacher postcard. You can also contact Dr. Rachel Jones, the survey director, via email (rjones@guttmacher.org) or at the above address and phone number to find out more about the study.

Today's date: ____/____/____ (11-16)
Month Day Year

1. What is your age? _____ (17-18)

2. Are you Hispanic or Latina or of Spanish origin?
   ☐-1 Yes ☐-2 No (19)

3. Which of these groups **best** describes your racial background?

   ☐-1 American Indian
   ☐-2 Asian or South Asian
   ☐-3 Native Hawaiian or other Pacific Islander
   ☐-4 Black or African American
   ☐-5 White
   ☐-6 Other: _____ (20) (21)

4. Which of the following types of health insurance do you currently have? (*check all that apply*)

   ☐-1 Temporary Medicaid coverage (does not cover regular health care) (22)
   ☐-2 Medicaid or another state-run health insurance program (23)
   ☐-3 Private or employee-sponsored health insurance (24)
   ☐-4 Some other type of health insurance: _____ (25)
   ☐-5 I do not have health insurance (26) (27)

5. How are you paying for this abortion? (*check all that apply*)

   ☐-1 I am paying for it out of pocket, but will be reimbursed by my insurance company (28)
   ☐-2 The clinic accepts my private health insurance (29)
   ☐-3 I am using Medicaid (state-sponsored health insurance) (30)
   ☐-4 I am paying for all or part of it out of pocket (includes cash and credit cards) (31)
   ☐-5 I received financial assistance from an outside organization (32)
   ☐-6 I qualified for a price reduction (33)
   ☐-7 Other: _____ (34) (35)

6. Indicate if you experienced any of the following in the LAST 12 MONTHS (*check all that apply*):

- ☐-1 A close friend died (36)
- ☐-2 I fell behind on my rent or mortgage (37)
- ☐-3 I separated from my husband/partner (38)
- ☐-4 I was unemployed and looking for work for a month or more (39)
- ☐-5 I had a serious medical problem (40)
- ☐-6 A dependent or close family member had a serious medical problem (41)
- ☐-7 I had a baby (42)
- ☐-8 I was the victim of a robbery (mugging or stick-up) or personal assault (43)
- ☐-9 My home was burglarized or broken into (44)
- ☐-10 I had a partner who was arrested or incarcerated (45)
- ☐-11 I moved 2 or more times (46)

7. When you made this appointment, had you already made up your mind to have an abortion?
☐-1 Yes ☐-2 No (47)

8. What was the first day of your last menstrual period?

____/____/____ ☐- Don't remember (48-53)
Month Day Year (54)

9. About how many weeks pregnant are you?
_____ weeks (55-56)

10. Before you became pregnant this time, had you stopped using all methods of pregnancy prevention, including condoms, withdrawal, rhythm, etc.?

- ☐-1 Yes
- ☐-2 No
- ☐-3 Never used any pregnancy prevention (67)

11. What was the **LAST** method of pregnancy prevention you used before you found out you were pregnant? *(check all that apply)*

- ☐-1 Pill (58)
- ☐-2 Condom, rubber (for males) (59)
- ☐-3 Depo-Provera, the shot, injectables (60)
- ☐-4 The patch, Ortho Evra (61)
- ☐-5 NuvaRing, vaginal ring (62)
- ☐-6 Implants in arm (63)
- ☐-7 Spermicides (foam/cream/jelly/film/suppositories/inserts) (64)
- ☐-8 Rhythm, natural family planning (65)
- ☐-9 Withdrawal, pulling out (66)
- ☐-10 Other method (specify):_____ (67)
- ☐-11 I never used a method → **SKIP TO Q.14** (68) (69)

12. In what month and year did you stop using that method? ____/____ ☐ Still using method (70-73) (74)
Month Year

13. For about how many months in a row had you been using that method? Please check only one box.

☐-0 Less than 1 month	☐-12 12 months
☐-1 1 month	☐-13 13 months
☐-2 2 months	☐-14 14 months
☐-3 3 months	☐-15 15 months
☐-4 4 months	☐-16 16 months
☐-5 5 months	☐-17 17 months
☐-6 6 months	☐-18 18 months
☐-7 7 months	☐-19 19-21 months
☐-8 8 months	☐-20 22-24 months
☐-9 9 months	☐-21 25-27 months
☐-10 10 months	☐-22 28 or more months
☐-11 11 months	

(75-76)

14. In the month you became pregnant, what was your formal marital status?

- ☐-1 Married
- ☐-2 Divorced
- ☐-3 Widowed
- ☐-4 Separated
- ☐-5 Never married (77)

15. In the month you became pregnant, were you living with your husband or boyfriend?
☐-1 Yes ☐-2 No (78)

16. What is the highest grade of school you have completed?

- ☐-1 0-11th grade
- ☐-2 High school graduate or GED
- ☐-3 Some college or Associate degree
- ☐-4 College graduate or more (79)

17. What religion are you?

- ☐-1 Protestant (for example, Baptist, Methodist, Lutheran, Pentecostal, etc.)
- ☐-2 Catholic
- ☐-3 Jewish
- ☐-4 Other (specify) _____
- ☐-5 None (80) (81)

18. Which of these do you consider yourself to be, if any?

- ☐-1 Born-again Christian
- ☐-2 Charismatic
- ☐-3 Evangelical
- ☐-4 Fundamentalist
- ☐-5 None of the above (82)

19. About how often do you attend religious services?

- ☐-1 More than once a week
- ☐-2 Once a week
- ☐-3 1-3 times a month
- ☐-4 Less than once a month
- ☐-5 Never (83)

20. Including your children, how many family members do you currently live with?

Myself + _____ family members (84-85)
(This includes your husband or boyfriend if you live with him, and any of his family members that live with you.)

21. What was the total household income last year (2007), before taxes, of yourself and all the family members counted in Q.20? Please provide your best estimate if you do not know the exact amount.

- ☐-1 Under $9,999 (less than $192/week)
- ☐-2 $10,000-14,999 ($192-287/week)
- ☐-3 $15,000-19,999 ($288-384/week)
- ☐-4 $20,000-24,999 ($385-480/week)
- ☐-5 $25,000-29,999 ($481-576/week)
- ☐-6 $30,000-34,999 ($577-672/week)
- ☐-7 $35,000-39,999 ($673-768/week)
- ☐-8 $40,000-44,999 ($769-864/week)
- ☐-9 $45,000-49,999 ($865-961/week)
- ☐-10 $50,000-59,999 ($962-1153/week)
- ☐-11 $60,000-74,999 ($1154-1441/week)
- ☐-12 $75,000 or more/year ($1442 or more/week) (86-87)

22. Were you born in the United States?

- ☐-1 Yes → **SKIP TO Q.24**
- ☐-2 No, I was born in _____ (country) (88) (89-90)

23. When did you come to live in the United States?

_____Year (91-92)

24. Where do you currently live?

State _____ (93-94)
ZIP_____ (95-99) (100) (101)

25. How many births have you had? _____ (102-103)

26. How many abortions have you had before this one?

_____ (104-105)

27. Right before you became pregnant, did you want to have a(nother) baby at **any** time in the future?

- ☐-1 Yes
- ☐-2 No → **SKIP TO Q.29**
- ☐-3 Not sure, don't know
- ☐-4 Didn't care (106)

28. So would you say you became pregnant:

- ☐-1 Too soon
- ☐-2 At the right time
- ☐-3 Later than I wanted
- ☐-4 Didn't care (107)

29. On a scale of 1 to 10, circle the number that best describes how you felt when you found out you were pregnant.

1	2	3	4	5	6	7	8	9	10
Very unhappy									Very happy

(108-109)

30. At the time you became pregnant, how long had you been in a relationship with the man with whom you got pregnant?

___-1 Months ___-2 Years (110-111) (112-113)

☐-3 I was not in a relationship with him (114)

31. Does he know that you are pregnant?

- ☐-1 Yes
- ☐-2 No
- ☐-3 I don't know if he knows (115)

32. Does he know that you are choosing to have an abortion?

- ☐-1 Yes
- ☐-2 No
- ☐-3 I don't know if he knows (116)

33. How supportive is he of your decision to have an abortion?

[]-1 He doesn't know I'm having an abortion
[]-2 Very supportive
[]-3 Somewhat supportive
[]-4 Neither
[]-5 Somewhat unsupportive
[]-6 Very unsupportive
[]-7 I'm not sure how supportive he is (117)

34. Has he ever hit, slapped, kicked or otherwise physically hurt you?
[]-1 Yes []-2 No (118)

35. Has he ever forced you to do anything sexual when you didn't want to?
[]-1 Yes []-2 No (119)

36. Is this pregnancy the result of a partner forcing you to have sex when you didn't want to have sex?

[]-1 Yes
[]-2 No
[]-3 Don't know (120)

37. Do you think abortion should be:
[]-1 Legal in all cases
[]-2 Legal in most cases
[]-3 Illegal in most cases
[]-4 Illegal in all cases (121)

38. Did you take any of the following to try to bring back your period or end the CURRENT pregnancy BEFORE you came here?*(check all that apply)*

[]-1 Cytotec, or misoprostol (122)
[]-2 Emergency contraception, also known as EC or the morning-after pill (123)
[]-3 Other:_____ (124)
[]-4 None of the above (125)
(126)

39. Have you EVER taken anything ON YOUR OWN to try to bring back your period or end a pregnancy?*(check all that apply)*

[]-1 Yes, I have taken cytotec, or misoprostol (127)
[]-2 Yes, I have taken emergency contraception, also known as EC or the morning-after pill (128)
[]-3 Yes, I have taken another drug:
_____ _____ (129)
[]-4 None of the above (130)
(131)

Thank you very much for your help.

Module B

NATIONAL PATIENT SURVEY

(1-5)

440r (6-9)
b (10)

The Guttmacher Institute
A not-for-profit organization for reproductive health research, policy analysis and public education
125 Maiden Lane, New York, NY 10038 Phone: (800) 355-0244 Fax: (212) 248-1951 Web: www.guttmacher.org

The Guttmacher Institute, a non-profit research organization, is asking abortion patients across the country to provide us with information in order to improve health programs and policies in the United States. Please help by answering the below questions about yourself, your decision to have an abortion and other aspects of your life.

Your participation is voluntary and will not affect the services you receive. There are no direct benefits to participating in this study. While the risks are minimal some of the items are about sensitive issues such as sexual assault and may make you uncomfortable; you can skip these questions as well as any that you are unable to answer. The survey should take 5 to 10 minutes to complete. When you are done with it, place it in the attached envelope and return it to a staff member. **Your name is not requested here.** This survey is confidential and anonymous. The information you provide will be used for research purposes only.

If you would like a copy of the results, ask the clinic for a Guttmacher postcard. You can also contact Dr. Rachel Jones, the survey director, via email (rjones@guttmacher.org) or at the above address and phone number to find out more about the study.

Today's date: ____/____/____ (11-16)
Month Day Year

1. What is your age? _____ (17-18)

2. Are you Hispanic or Latina or of Spanish origin?
   ☐-1 Yes ☐-2 No (19)

3. Which of these groups **best** describes your racial background?

   ☐-1 American Indian
   ☐-2 Asian or South Asian
   ☐-3 Native Hawaiian or other Pacific Islander
   ☐-4 Black or African American
   ☐-5 White
   ☐-6 Other: _____ (20) (21)

4. Which of the following types of health insurance do you currently have? (*check all that apply*)

   ☐-1 Temporary Medicaid coverage (does not cover regular health care) (22)
   ☐-2 Medicaid or another state-run health insurance program (23)
   ☐-3 Private or employee-sponsored health insurance (24)
   ☐-4 Some other type of health insurance: _____ (25)
   ☐-5 I do not have health insurance (26) (27)

5. How are you paying for this abortion? (*check all that apply*)

   ☐-1 I am paying for it out of pocket, but will be reimbursed by my insurance company (28)
   ☐-2 The clinic accepts my private health insurance (29)
   ☐-3 I am using Medicaid (state-sponsored health insurance) (30)
   ☐-4 I am paying for all or part of it out of pocket (includes cash and credit cards) (31)
   ☐-5 I received financial assistance from an outside organization (32)
   ☐-6 I qualified for a price reduction (33)
   ☐-7 Other: _____ (34) (35)

6. Indicate if you experienced any of the following in the LAST 12 MONTHS (*check all that apply*):

- ☐-1 A close friend died (36)
- ☐-2 I fell behind on my rent or mortgage (37)
- ☐-3 I separated from my husband/partner (38)
- ☐-4 I was unemployed and looking for work for a month or more (39)
- ☐-5 I had a serious medical problem (40)
- ☐-6 A dependent or close family member had a serious medical problem (41)
- ☐-7 I had a baby (42)
- ☐-8 I was the victim of a robbery (mugging or stick-up) or personal assault (43)
- ☐-9 My home was burglarized or broken into (44)
- ☐-10 I had a partner who was arrested or incarcerated (45)
- ☐-11 I moved 2 or more times (46)

7. When you made this appointment, had you already made up your mind to have an abortion?
☐-1 Yes ☐-2 No (47)

8. What was the first day of your last menstrual period?

____/____/____ ☐- Don't remember (48-53)
Month Day Year (54)

9. About how many weeks pregnant are you?
_____ weeks (55-56)

10. Before you became pregnant this time, had you stopped using all methods of pregnancy prevention, including condoms, withdrawal, rhythm, etc.?

- ☐-1 Yes
- ☐-2 No
- ☐-3 Never used any pregnancy prevention (57)

11. What was the **LAST** method of pregnancy prevention you used before you found out you were pregnant? *(check all that apply)*

- ☐-1 Pill (58)
- ☐-2 Condom, rubber (for males) (59)
- ☐-3 Depo-Provera, the shot, injectables (60)
- ☐-4 The patch, Ortho Evra (61)
- ☐-5 NuvaRing, vaginal ring (62)
- ☐-6 Implants in arm (63)
- ☐-7 Spermicides (foam/cream/jelly/film/suppositories/inserts) (64)
- ☐-8 Rhythm, natural family planning (65)
- ☐-9 Withdrawal, pulling out (66)
- ☐-10 Other method (specify):_____ (67)
- ☐-11 I never used a method → **SKIP TO Q.14** (68) (69)

12. In what month and year did you stop using that method? ____/____ ☐ Still using method (70-73) (74)
Month Year

13. For about how many months in a row had you been using that method? Please check only one box.

- ☐-0 Less than 1 month
- ☐-1 1 month
- ☐-2 2 months
- ☐-3 3 months
- ☐-4 4 months
- ☐-5 5 months
- ☐-6 6 months
- ☐-7 7 months
- ☐-8 8 months
- ☐-9 9 months
- ☐-10 10 months
- ☐-11 11 months
- ☐-12 12 months
- ☐-13 13 months
- ☐-14 14 months
- ☐-15 15 months
- ☐-16 16 months
- ☐-17 17 months
- ☐-18 18 months
- ☐-19 19-21 months
- ☐-20 22-24 months
- ☐-21 25-27 months
- ☐-22 28 or more months

(75-76)

14. In the month you became pregnant, what was your formal marital status?

- ☐-1 Married
- ☐-2 Divorced
- ☐-3 Widowed
- ☐-4 Separated
- ☐-5 Never married (77)

15. In the month you became pregnant, were you living with your husband or boyfriend?
☐-1 Yes ☐-2 No (78)

16. What is the highest grade of school you have completed?

- ☐-1 0-11th grade
- ☐-2 High school graduate or GED
- ☐-3 Some college or Associate degree
- ☐-4 College graduate or more (79)

17. What religion are you?

- ☐-1 Protestant (for example, Baptist, Methodist, Lutheran, Pentecostal, etc.)
- ☐-2 Catholic
- ☐-3 Jewish
- ☐-4 Other (specify) _____
- ☐-5 None (80) (81)

18. Which of these do you consider yourself to be, if any?

- ☐-1 Born-again Christian
- ☐-2 Charismatic
- ☐-3 Evangelical
- ☐-4 Fundamentalist
- ☐-5 None of the above (82)

19. About how often do you attend religious services?

- ☐-1 More than once a week
- ☐-2 Once a week
- ☐-3 1-3 times a month
- ☐-4 Less than once a month
- ☐-5 Never (83)

20. Including your children, how many family members do you currently live with?

Myself + _____ family members (84-85)

(This includes your husband or boyfriend if you live with him, and any of his family members that live with you.)

21. What was the total household income last year (2007), before taxes, of yourself and all the family members counted in Q.20? Please provide your best estimate if you do not know the exact amount.

- ☐-1 Under $9,999 (less than $192/week)
- ☐-2 $10,000-14,999 ($192-287/week)
- ☐-3 $15,000-19,999 ($288-384/week)
- ☐-4 $20,000-24,999 ($385-480/week)
- ☐-5 $25,000-29,999 ($481-576/week)
- ☐-6 $30,000-34,999 ($577-672/week)
- ☐-7 $35,000-39,999 ($673-768/week)
- ☐-8 $40,000-44,999 ($769-864/week)
- ☐-9 $45,000-49,999 ($865-961/week)
- ☐-10 $50,000-59,999 ($962-1153/week)
- ☐-11 $60,000-74,999 ($1154-1441/week)
- ☐-12 $75,000 or more/year ($1442 or more/week) (86-87)

22. Were you born in the United States?

- ☐-1 Yes → **SKIP TO Q.24**
- ☐-2 No, I was born in _____ (country) (88) (89-90)

23. When did you come to live in the United States?

_____ Year (91-92)

24. Where do you currently live?

State _____ (93-94)
ZIP_____ (95-99) (100) (101)

25. How many births have you had? _____ (102-103)

26. How many abortions have you had before this one?

_____ (104-105)

27. Right before you became pregnant, did you want to have a(nother) baby at **any** time in the future?

- ☐-1 Yes
- ☐-2 No → **SKIP TO Q.29**
- ☐-3 Not sure, don't know
- ☐-4 Didn't care (106)

28. So would you say you became pregnant:

- ☐-1 Too soon
- ☐-2 At the right time
- ☐-3 Later than I wanted
- ☐-4 Didn't care (107)

29. At the time you became pregnant, how long had you been in a relationship with the man with whom you got pregnant?

___ -1Months ___ -2Years (110-111) (112-113)

☐-3 I was not in a relationship with him (114)

30. How supportive is he of your decision to have an abortion?

- ☐-1 He doesn't know I'm having an abortion
- ☐-2 Very supportive
- ☐-3 Somewhat supportive
- ☐-4 Neither
- ☐-5 Somewhat unsupportive
- ☐-6 Very unsupportive
- ☐-7 I'm not sure how supportive he is (117)

31. Has he ever hit, slapped, kicked or otherwise physically hurt you?

☐-1 Yes ☐-2 No (118)

32. Has he ever forced you to do anything sexual when you didn't want to?

☐-1 Yes ☐-2 No (119)

33. Is this pregnancy the result of a partner forcing you to have sex when you didn't want to have sex?

- ☐-1 Yes
- ☐-2 No
- ☐-3 Don't know (120)

34. Did you take any of the following to try to bring back your period or end the CURRENT pregnancy BEFORE you came here?*(check all that apply)*

- ☐-1 Cytotec, or misoprostol (122)
- ☐-2 Emergency contraception, also known as EC or the morning-after pill (123)
- ☐-3 Other:_____ (124)
- ☐-4 None of the above (125)

(126)

35. Have you EVER taken anything ON YOUR OWN to try to bring back your period or end a pregnancy?*(check all that apply)*

- ☐-1 Yes, I have taken cytotec, or misoprostol (127)
- ☐-2 Yes, I have taken emergency contraception, also known as EC or the morning-after pill (128)
- ☐-3 Yes, I have taken another drug: _____ (129)
- ☐-4 None of the above (130)

(131)

36. The following questions are about how other people's opinions and feelings about abortion may affect you.

Please indicate how much you agree or disagree with the following statements.	Strongly Agree	Agree	Disagree	Strongly Disagree	Not Applicable
a. I would be looked down on by some people if they knew I'd had this abortion. (132)	1	2	3	4	5
b. I need to keep this abortion a secret from my close friends and family. (133)	1	2	3	4	5
c. I can talk openly with people about this abortion. (134)	1	2	3	4	5
d. My friends and family would think less of me if they knew about this abortion. (135)	1	2	3	4	5
e. Having this abortion will **not** cause problems in my relationship with my current partner. (136)	1	2	3	4	5
f. Telling my close friends and family about this abortion would **not** cause problems in our relationships. (137)	1	2	3	4	5
g. My regular health care provider(s) would treat me differently if they knew I'd had this abortion. (138)	1	2	3	4	5
h. I'd be at risk of physical abuse (e.g., being hit, punched or slapped) if I told my current partner or certain family members about this abortion. (139)	1	2	3	4	5
i. What other people think or feel about my decision to have an abortion doesn't matter to me. (140)	1	2	3	4	5

Thank you very much for your help.

References

1. Owings MF and Kozak LJ, Ambulatory and inpatient procedures in the United States, 1996, *Vital and Health Statistics,* 1998, Series 13, No. 139.

2. Guttmacher Institute, State facts about abortion: Texas, 2008, <http://www.guttmacher.org/pubs/sfaa/pdf/texas.pdf>, 2008, accessed Feb. 1, 2010.

3. Fu H et al., Measuring the extent of abortion underreporting in the 1995 National Survey of Family Growth, *Family Planning Perspectives,* 1998, 30(3):128–138.

4. Jones RK and Kost K, Underreporting of induced and spontaneous abortion in the United States: an analysis of the 2002 National Survey of Family Growth, *Studies in Family Planning,* 2007, 38(3):187–197.

5. Pazol K et al. Abortion surveillance, United States—2006, *Morbidity and Mortality Weekly Report,* 2009, Vol. 58, No. SS-8.

6. Frey WH, *Diversity Spreads Out: Metropolitan Shifts in Hispanic, Asian, and Black Populations Since 2000,* Washington, DC: Brookings Institution, 2006.

7. U.S. Census Bureau, Table A-2: percent of people 25 years and over who have completed high school or college, by race, Hispanic origin and sex: selected years 1940 to 2008, 2009, <http://www.census.gov/population/socdemo/education/cps2008/tabA-2.xls>, accessed Feb. 1, 2010.

8. The National Marriage Project, *The State of Our Unions 2007: The Social Health of Marriage in America,* Piscataway, NJ: Rutgers University, 2007.

9. Henshaw SK and Silverman J, The characteristics and prior contraceptive use of U.S. abortion patients, *Family Planning Perspectives,* 1988, 20(4):158–168.

10. Henshaw SK and Kost K, Abortion patients in 1994–1995: characteristics and contraceptive use, *Family Planning Perspectives,* 1996, 28(4):140–147 & 158.

11. Jones RK, Darroch JE and Henshaw SK, Patterns in the socioeconomic characteristics of women obtaining abortions in 2000–2001, *Perspectives on Sexual and Reproductive Health,* 2002, 34(5):226–235.

12. Jones RK et al., Abortion in the United States: incidence and access to services, 2005, *Perspectives on Sexual and Reproductive Health,* 2008, 40(1):6–16.

13. Smock P, Cohabitation in the United States: an appraisal of research themes, findings and implications, *Annual Review of Sociology,* Vol. 26, pp. 1–20.

14. Finer LB et al., Reasons U.S. women have abortions: quantitative and qualitative perspectives, *Perspectives on Sexual and Reproductive Health,* 2005, 37(3):110–118.

15. Jones RK, Frohwirth LF and Moore AM, "I would want to give my child, like, everything in the world": how issues of motherhood influence women who have abortions, *Journal of Family Issues,* 2008, 29(1):79–99.

16. Ludlow J, The things we cannot say: witnessing the traumatization of abortion in the United States, *Women's Studies Quarterly,* 2008, 36(1 & 2):28–41.

17. DeNavas-Walt C, Proctor BD and Smith JC, Income, poverty, and health insurance coverage in the United States: 2008, *Current Population Reports,* 2009, Series P-60, No. 236.

18. The Henry J. Kaiser Family Foundation, Women's health insurance coverage, *Women's Health Policy Facts,* 2009, <http://www.kff.org/womenshealth/upload/6000-08.pdf>, accessed Feb. 1, 2010.

19. Gold RB, Family planning and health care reform: the benefits and challenges of prioritizing prevention, *Guttmacher Policy Review,* 2009, 12(1):19–24.

20. Guttmacher Institute, State funding of abortion under Medicaid, *State Policies in Brief (as of March 2010),* <http://www.guttmacher.org/statecenter/spibs/spib_SFAM.pdf>, accessed Mar. 25, 2010.

21. Finer LB and Henshaw SK, Disparities in rates of unintended pregnancy in the United States, 1994 and 2001, *Perspectives on Sexual and Reproductive Health,* 2006, 38(2):90–96.

22. American College of Obstetricians and Gynecologists, Bad economy blamed for women delaying pregnancy and annual check-up: new Gallup survey reveals disturbing trends, news release, 2010, <http://www acog. org/from_home/publications/press_releases/nr05-05-09-1 cfm>, accessed Feb. 18, 2010.

23. Guttmacher Institute, *A Real-Time Look at the Impact of the Recession on Women's Family Planning and Pregnancy Decisions,* New York: Guttmacher Institute, 2009.

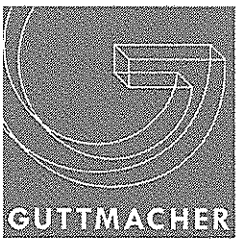
24. National Network of Abortion Funds, Network news, Fall 2008, <http://www nnaf.org/documents/TheNetwork-Fall2008Newsletter.pdf>, accessed Feb. 19, 2010.

25. Harding A, Many women put pregnancy plans on hold in shaky economy, *Health Magazine,* May 28, 2009, <http://news.health.com/2009/05/27/pregnancy-plans-shaky-economy/>, accessed Feb. 1, 2010.

26. Yoshino K, Women's clinics see rise in calls and visits, *Los Angeles Times,* May 20, 2009, <http://articles.latimes.com/2009/may/20/local/me-abortion20>, accessed Feb. 1, 2010.

27. Kost K et al., Estimates of contraceptive failure from the 2002 National Survey of Family Growth, *Contraception,* 2008, 77(1):10–21.

28. Guttmacher Institute, Laws affecting reproductive health and rights: 2009 state policy review, 2010, <http://www.guttmacher.org/statecenter/updates/2009/statetrends42009.html>, accessed Feb. 2, 2010.



Advancing sexual and reproductive health worldwide through research, policy analysis and public education

125 Maiden Lane
New York, NY 10038
(212) 248-1111; fax (212) 248-1951
info@guttmacher.org

1301 Connecticut Avenue NW, Suite 700
Washington, DC 20036
policyinfo@guttmacher.org

www.guttmacher.org

Women's Health Issues 23-2 (2013) e117–e122

WOMEN'S HEALTH ISSUES
www.whijournal.com

Original article

Women's and Providers' Experiences with Medical Abortion Provided Through Telemedicine: A Qualitative Study

Kate Grindlay, MSPH [a,*], Kathleen Lane, CN [b], Daniel Grossman, MD [c]

[a] Ibis Reproductive Health, Cambridge, Massachusetts
[b] Provide, Cedar Rapids, Iowa
[c] Ibis Reproductive Health, Oakland, California; Bixby Center for Global Reproductive Health, Department of Obstetrics, Gynecology and Reproductive Sciences, University of California, San Francisco

Article history: Received 22 August 2012; Received in revised form 4 December 2012; Accepted 6 December 2012

A B S T R A C T

Background: In states requiring physicians to dispense mifepristone, the small number of providers offering the method limits its uptake. In 2008, Planned Parenthood of the Heartland in Iowa began providing medical abortion via telemedicine at clinics without an on-site physician. The purpose of this study was to evaluate patients' and providers' experiences with telemedicine provision of medical abortion.
Methods: Between October 2009 and February 2010, in-depth interviews were conducted at Planned Parenthood clinics with 25 women receiving medical abortion services (20 telemedicine patients and 5 in-person patients) and 15 clinic staff. Data were analyzed qualitatively for themes related to acceptability of the telemedicine service delivery model.
Findings: Patients and providers cited numerous advantages of telemedicine, including decreased travel for patients and physicians and greater availability of locations and appointment times compared with in-person provision. Overall, patients were positive or indifferent about having the conversation with the doctor take place via telemedicine, with most reporting it felt private/secure and in some cases even more comfortable than an in-person visit. However, other women preferred being in the same room with the physician, highlighting the importance of informing women about their options so they can choose their preferred service modality.
Conclusions: The findings from this study indicate that telemedicine can be used to provide medical abortion in a manner that is highly acceptable to patients and providers with minimal impact on the clinic.
Practice Implications: This information demonstrates the feasibility of telemedicine to extend the reach of physicians and improve abortion access in rural settings.
Copyright © 2013 by the Jacobs Institute of Women's Health. Published by Elsevier Inc.

Introduction and Background

The number of abortion providers has declined over the last three decades in the United States (Jones & Kooistra, 2011), resulting in greater distances and higher costs for some women to obtain care. Today, 87% of counties lack an abortion provider, and women in rural areas are the hardest hit by this shortage; 97% of nonmetropolitan counties do not have an abortion provider (Jones & Kooistra, 2011).

When the U.S. Food and Drug Administration approved mifepristone for early medical abortion over a decade ago, many anticipated that it would increase access to abortion because it could be offered by a wide range of providers without the need for surgical facilities (Finer & Wei, 2009; Yarnall, Swica, & Winikoff, 2009). However, only about one quarter of eligible abortions in the United States are medical abortions (Jones & Kooistra, 2011), and the hoped-for increase in provision of the method by family medicine doctors or in private obstetrician–gynecologist offices has not taken place. The majority of states require physicians to dispense mifepristone (Berer, 2009), and the small number of providers offering the method in many of these states limits its uptake.

In rural states, where a single physician may be the only abortion provider within a several hundred mile radius, lack of access to abortion is acutely felt. In Iowa, abortion access for rural women is particularly difficult. Before 2008, physicians at Planned Parenthood of the Heartland in Iowa traveled up to 400

* Correspondence to: Kate Grindlay, MSPH, Ibis Reproductive Health, 17 Dunster Street, Suite 201, Cambridge, MA 02138. Phone: 617-349-0053; Fax: 617-349-0041.
E-mail address: kgrindlay@ibisreproductivehealth.org (K. Grindlay).

1049-3867/$ - see front matter Copyright © 2013 by the Jacobs Institute of Women's Health. Published by Elsevier Inc.
http://dx.doi.org/10.1016/j.whi.2012.12.002

miles roundtrip to provide abortion care at smaller sites, and patients often traveled similar distances from an opposite direction to receive care. Although medical abortion allowed Planned Parenthood to expand the number of locations where patients could obtain an early abortion, limited physician time still restricted the availability of services.

Telemedicine, which involves using information and communication technology to provide a health service or consultation at a distance, has been used in many fields of medicine to improve access to care for rural populations (Wade, Karnon, Elshaug, & Hiller, 2010). In June 2008, Planned Parenthood of the Heartland in Iowa began providing medical abortion via telemedicine at clinics without an on-site physician to improve access to early abortion and reduce physician and patient travel. This telemedicine model providing medical abortion has been described previously, and it was evaluated in a recent prospective cohort study and shown to be equally safe and effective as an in-person physician visit (Grossman, Grindlay, Buchacker, Lane, & Blanchard, 2011). Some measures of acceptability were higher among women who received services via telemedicine, with telemedicine patients having a higher odds of saying they would recommend the service to a friend compared with in-person patients, adjusting for sociodemographic characteristics (odds ratio, 1.72; 95% confidence interval, 1.26–2.34; Grossman, et al., 2011). Another analysis found that after the telemedicine program was launched at Planned Parenthood of the Heartland, women were significantly more likely to have a medical abortion and to have a first-trimester abortion, and women in more rural areas of the state were more likely to access abortion care, especially early medical abortion (Grossman, Grindlay, Buchacker, Potter, & Schmertmann, 2013).

The purpose of this study was to evaluate women's and providers' experiences with telemedicine provision of medical abortion qualitatively. In particular, we aimed to learn more about the acceptability of the telemedicine abortion service and the impact that it has on patients, staff, and clinic operations.

Methods

Between October 2009 and February 2010, in-depth interviews were conducted at Planned Parenthood of the Heartland clinics in Iowa with women receiving telemedicine ($n = 20$) or in-person ($n = 5$) medical abortion services. Women seeking abortion at Planned Parenthood called a central call center, which gave them information about the nearest clinic and soonest appointment and informed them whether the service would be provided by telemedicine or not, and women selected the appointment they preferred. We planned to perform fewer in-depth interviews with women undergoing the standard provision model because of the large amount of published data on women's experiences with this model (Fielding, Edmunds, & Schaff, 2002; Lafaurie, Grossman, Troncoso, Billings, & Chavez, 2005). In addition, we conducted in-depth interviews with 15 clinic staff, including those who were involved with the standard method of providing medical abortion and those involved with the telemedicine model.

Women who chose medical abortion and were eligible for the method (including being pregnant at ≤63 days gestation and not having other standard contraindications), were at least 18 years of age, able to speak English, willing to participate, and able to give informed consent were eligible to participate in the in-depth interviews. The eligibility criteria for clinic staff were that they were a doctor, advanced practice clinician, nurse, medical assistant, or clinic manager on staff at a Planned Parenthood of the Heartland clinic; willing to participate; and able to give informed consent.

At their initial clinic visit, women seeking medical abortion were invited to participate in an in-depth interview about the acceptability of the medical abortion they were undergoing. The interview was performed at the completion of the visit in a private location at the clinic. The interview guide was semi-structured and included open-ended questions about access to health care services generally, decision making about abortion and where to have the procedure, and experience with and opinions of the service. Clinical information was also obtained by the interviewer. Patients received a $25 gift card for their participation.

Clinic staff were invited to participate in the in-depth interview by a study team member, and they were told that their participation was voluntary and confidential. Staff were interviewed in a private location at the clinic or by telephone. No compensation was given to clinic staff for their participation.

All study participants provided written, informed consent to participate in the study and have their interview audio recorded. On average interviews took 45 minutes to 1 hour to complete. The study was approved by Allendale Investigational Review Board.

All interviews were digitally recorded and transcribed verbatim. Data were analyzed qualitatively with inductive coding using grounded theory methods (Charmaz, 2006). All analyses were performed with ATLAS-ti 6.2 (ATLAS-ti GmbH, Berlin, Germany) for themes related to acceptability of the telemedicine service delivery model.

Results

Participant Characteristics

Twenty-five women receiving medical abortion services (20 telemedicine patients and 5 in-person patients) and 15 clinic staff (six medical assistants, five clinic managers, two physicians, and two nurses) participated in the study.

The majority of patients were under 25 years old (64%), had a high school education or less (56%), and were single (68%). Three quarters (76%) identified as White, 12% as African-American/Black, and 12% as other race (Native American, Native American/White, African American/White). Forty-four percent of women had at least one prior birth, and 48% reported at least one prior abortion (Table 1).

Perspectives of Telemedicine Patients before the Visit

When women called to make an appointment, they spoke with a call center that provided information about several clinics that they could choose from, allowing women to weigh their options of whether to have a telemedicine or in-person visit with other considerations such as travel distance, appointment date, or other factors. Women reported having mixed reactions when they first learned about telemedicine. One woman reported initially feeling nervous about telemedicine, but said that it was more important for her to go to the closest clinic. Another woman described thinking that it was "different," but that she had enough trust in the clinic that it would not impact the quality of care.

The telemedicine patients in our sample overwhelmingly selected the clinic based on logistical concerns, citing that even if

Table 1
Participant Characteristics, Patients ($n = 25$)

	n (%)
Telemedicine patient	
Yes	20 (80)
No	5 (20)
Age (yrs)	
18–24	16 (64)
25–29	5 (20)
30–40	4 (16)
Race/ethnicity	
African American/Black, non-Hispanic	3 (12)
Asian-Pacific Islander, non-Hispanic	0 (0)
Hispanic/Latina	0 (0)
White, non-Hispanic	19 (76)
Other (Native American, >1 race)	3 (12)
Education	
High school or less	14 (56)
Some college or college degree	11 (44)
Advanced degree	0 (0)
Student	
Yes	11 (44)
No	14 (56)
Marital status	
Single	17 (68)
Divorced/separated	4 (16)
Married	3 (12)
Partnered	1 (4)
Prior birth	
0	14 (56)
1	4 (16)
≥2	7 (28)
Prior abortion	
0	13 (52)
1	11 (44)
≥2	1 (4)
Participant characteristics, providers ($n = 15$)	
Clinic manager	5 (33)
Medical assistant	6 (40)
Nurse	2 (13)
Physician	2 (13)

they might prefer an in-person visit, other issues took precedence. One dominant factor that drove women to opt for the telemedicine visit was closer proximity, along with the associated considerations of reducing the time they had to take off from work or school, limiting costs associated with travel, and avoiding having to explain the reason for traveling to a more distant location, among others. As a 36-year-old telemedicine patient explained, "I did not want to drive to Iowa City and have it done and then have to drive back.... I didn't want an hour and a half ride home in bad weather. I just figured this would be the easiest way." A 19-year-old woman explained that it was already difficult to get time off from work for the procedure and recovery, and that traveling long distances would further compound the hardship. She elected to be seen via telemedicine closer to her home for a number of interrelated reasons:

> Traveling, that'd be a full tank of gas for me there and back and I don't have money like that to blow around, [I'm] trying to get everything started and get a house and everything. So money's kind of tight.... and then being able to get my mom to have work off so she could go with me 'cause I wanted her to be there with me, and just making sure that I wouldn't have to tell other people, 'Well why are you going to Des Moines?' or something. I wouldn't have had to tell them why I was going there all day. I don't know, [it's] just easier to do it right here in town.

For one woman, choice of clinic was limited because she did not have a driver's license and had to rely on others to get to the clinic.

The other primary reason women opted for the telemedicine visit was that it enabled them to undergo the procedure sooner. Women reported not wanting to wait for an in-person appointment, and that it was important to ensure they would be under the gestational age limit for a medical abortion. Additional factors that women discussed in choosing the clinic included having been there for other reproductive health services or having friends or family members who had been to the clinic, and therefore feeling comfortable and familiar with the services and staff.

No women in our study cited telemedicine—or the greater access to abortion services that it facilitated—as a factor in their decision about whether to have the abortion. Instead, women reported reasons such as financial insecurity, it being a bad time in life for a child, wanting to finish school, being too young, having completed their family, and not having a stable partner as their principal considerations.

Perspectives of Telemedicine Patients after the Visit

Many women in the sample reported feeling indifferent about speaking with the physician via videoconference. Women said things such as, "It didn't affect me at all," and "It was weird at first but pretty simple, easy, quick, nothing special." This was often because they had already had an ultrasound and completed an education and counseling session earlier in the visit with other clinic staff, and they reported having their questions answered by the time they met with the physician. For some women, the doctor's role of reviewing their medical information and ultrasound image, answering questions, and watching them take the pill was something they felt could be done equally well remotely. When asked if they thought it was important to be in the same room with the doctor, many gave comments such as, "I mean, it's pretty self-explanatory, you know, [the doctor] tells you what you've got to do," and "It's something you can do over the phone or a video chat." Other women described it as "almost like being in the room with [the doctor] anyway" and that it was "quick and it's convenient and [the doctor] would be able to answer any questions if I had them." An 18-year-old woman explained,

> I trusted the doctor, that she knew what she was doing and that she was going to give me my medication, I guess. I was already walked through what was going to happen, but she was very direct. She made sure I took my pill, she watched me, and that was about it. I guess another doctor [in person] would sit there and watch me take my pill too.

Some women attributed their comfort in speaking with the doctor via telemedicine to prior experience with webcams and other computer-based communication, such as talking on Skype. A 19-year-old woman commented, "Our generation, we've always done video chat and everything so it's not awkward or anything.... To me it kind of felt like the same thing [as an in-person visit with the doctor] just because I've grown up using computers."

Other women felt more strongly about their preferences, with several stating that they would choose telemedicine over an in-person visit if all other factors were equal. In two cases, this was because of internalized or anticipated stigma related to the abortion that made it feel easier for the women to talk to the

doctor in a more removed manner. A 21-year-old described that, although she never hesitated in her decision to have an abortion, the video interface made her more at ease because, "when you're going to do something like that, it's a little embarrassing. So kind of like, over the computer, it's a little bit easier to just, you know, have a [conversation] than rather like face-to-face." Another woman talked about preferring the video conversation due to anticipated stigma related to the abortion. She explained that she liked that she did not have to be in the same room as the doctor because, as she described,

> Sometimes, you know, you can feel somebody's body language. 'Cause an abortion is a strong, it's a strong thing. People feel certain ways and even if it's their job to give you this medicine, they can still have that 'Well, I don't believe that you should be getting an abortion' body language. So I'd rather do it via that [telemedicine] way.

Another woman who was 18 years old described feeling reticent in general when talking to people face to face, and that she was more comfortable asking questions and speaking to the doctor by video:

> It was cool I think.... I think that's more better than face-to-face. I'm shy so like when I'm face-to-face I'm just more quiet, more like not really want[ing] to say stuff.... But over a computer, you know, she's not standing right there so I could really just say whatever.

For a few women, the feeling of being slightly removed from the doctor made the visit feel less personal and for that reason they said they would have preferred to be with the doctor in-person. A 36-year-old woman described, "[It] just makes me feel a little bit better when they are sitting right in front of me. Eye contact is—I don't know. I'm a big eye contact person. I get eye contact over the conference deal but it's not the same as having them right in front of you." Some women also expressed concerns about privacy related to the video. This included questions about the security of the connection and other people in the room with the doctor that they might not be able to see. One 27-year-old woman said, "Internet is crazy or whatever. I don't even know if it's Internet but.... I just rather have it be face to face. I'm like, it's crazy. People trying to hack in and find out what's going on and being nosy, you know." Another woman said,

> I think you have a certain amount of privacy when you talk to a doctor in a room 'cause it's just you two. But over the webcam she told me or the nurse told me that it was just me and her, that nobody else, it's not broadcast or anything, so that made me feel like privacy was okay.

Despite the concerns raised by these women, their overall perception of the telemedicine service was positive, and all said they would recommend the service at the clinic to a friend.

Perspectives of In-Person Patients

In-person patients reported choosing the clinic for similar reasons to telemedicine patients, prioritizing convenience and appointment times. When asked if their decision would differ if the closest or soonest option were at a clinic that provided services by telemedicine, most said they would choose the telemedicine visit. Only one woman said she would wait or travel further to have an in-person visit with the physician.

These patients had a range of reactions to telemedicine. Only one woman had previously heard about the telemedicine option. One woman was indifferent, stating: "I don't think it really matters [if it's by video or in person]." Others who were in favor of the idea cited the expanded availability of locations and appointment times and said things such as, "the availability of it would be awesome" and "I think that's [more] convenient than having to drive." One woman said that if telemedicine enabled her to get an appointment sooner than a closer clinic, she would choose telemedicine because "in types of situations like this, you don't want to wait." Another woman reflected that it might be less intimidating to speak with the physician by video. Concerns that women had included thinking it might be less personal, or that they might not understand as much if the doctor were not in the same room; one woman said that she just preferred to see the doctor in person.

Staff Perceptions and Impact on Clinic Operations

Staff, like most patients, felt that the procedures for a telemedicine visit were not that different from an in-person visit with the physician. From the clinic operations perspective, they described going through the same processes in both circumstances for the bulk of the visit, with the exception of using a different consent form and the doctor speaking to the patients through the video connection and giving women the medication using a remotely operated lock box.

Staff reported that it was an easy transition for clinics that had previously provided abortion care to begin providing care via telemedicine. For clinics that had previously only provided contraception and other gynecologic services, the primary burdens associated with introducing telemedicine—purchasing ultrasound equipment and training staff on patient education and options counseling and on performing ultrasounds—would not have differed if they were introducing in-person services. Once these were in place, most clinics said it was a fairly quick process to introduce the new model. Most staff were eager to learn about the new technology and saw it as a welcome medical advance.

The biggest challenge with telemedicine introduction that some clinics faced was documentation of patients' Rhesus (Rh) status because a number of them that had not previously provided abortion care did not have on-site testing capabilities. This required back and forth communication with patients to arrange for them to bring in documentation, to visit a third party provider, or to draw the blood sample for Rh at the clinic and send it to an outside lab in advance of their abortion visit—all of which could lead to delays in care. Another challenge noted by some staff was that the call center did not always direct women to the closest clinic. Staff reported doing their best in these circumstances to confirm whether the patient was aware of a closer clinic before their visit, but felt that greater gains from the services might be possible. Lastly, staff noted that most people in the wider community were not aware of the telemedicine services, and that they could potentially help more women get to care earlier if they were better informed of its existence and the local availability.

Clinic staff cited numerous benefits to introducing telemedicine into their clinic system. This included the greater reach of the physicians, who could now be "in three places at once," greater efficiency of resources with women and providers no longer having to travel such long distances, and fewer cancelations and delays related to travel in inclement weather. As one staff member reflected,

> To give choice to a lot more people is exciting, very fulfilling to me personally and professionally. The helplessness you feel about not being able to help people because they can't get here—they don't have a ride, they don't have the money, they don't have whatever, you know—a lot of those problems have gone away so that I'm feeling very pleased.

Another benefit that staff saw was the reduced number of visits that women had to make to outlying clinics. Before telemedicine, women typically had to come to the clinic over the course of 2 days—because the doctor had a limited window in which to see patients at the outlying clinics, women would typically do their "pre-op" activities on one day, and then come back a second day to consult with the doctor. With telemedicine, patients at outlying clinics could typically complete their visit in 1 day.

The greater flexibility of telemedicine also enabled clinics to offer services more frequently and with a wider range of times available to women. Whereas before patients at outlying clinics could only be seen on a particular day of the week or month that the doctor visited the clinic, telemedicine allowed them to potentially schedule any day of the week if needed. Staff found this to be of particular benefit to women who could only take a specific day off from work or school. It also made it possible for clinics to see patients earlier in pregnancy, and to ensure they had access to medical abortion by better accommodating women with a limited timeframe for eligibility. Before telemedicine, a patient might have had to wait up to 2 weeks for an appointment, which could put them out of the window of eligibility. One staff member reflected that the best part of telemedicine for her was, "I think just the feeling of being able to take care of a patient's need when they desperately need you to be there for them."

A few staff members who had not previously been involved in abortion care discussed how introducing these services affected them personally, including that it provided new training opportunities and allowed them to grow professionally. Some staff reflected positively on the experience of providing abortion for the first time as well. One staff member talked about the benefit of allowing her to put her beliefs of supporting abortion rights into practice. A nurse at a telemedicine site said,

> I think it's opened my eyes. I've always kind of had liberal views, but I think it makes it more accessible to the patients and so it's, it puts the compassion and the views all together. It kind of brings, you know, the 'on paper, yes, you support abortion, yes, you support the patients,' that kind of thing, to like, 'here's a patient. They're going through it.' It kind of puts the human touch on what you really support.

Another staff member described having complicated emotions related to abortion, but that she ultimately felt motivated to provide safe medical abortion services to prevent "back alley" abortions from ever happening again.

Discussion

The findings of this study echo prior research highlighting the acceptability among patients and providers of telemedicine use in other medical disciplines (Blackwell, Kelly, & Lenton, 1997; Leggett et al., 2001; Palmas, Teresi, Weinstock, & Shea, 2008). Patients and providers cited numerous advantages of telemedicine, including decreased travel for patients and physicians and greater availability of locations and appointment times compared with in-person provision. Overall, patients were generally positive or indifferent about having the conversation with the doctor take place via telemedicine, with most reporting it felt private and secure, and in some cases even more comfortable than an in-person visit. However, other women preferred being in the same room with the physician, highlighting the importance of informing women about their options so they can choose the service modality with which they feel most comfortable. These qualitative findings complement the results of the larger cohort study from these same clinics, in which 25% of telemedicine patients said they would have preferred to be in the same room with the doctor (Grossman, et al., 2011). In regression analysis, younger and nulliparous women and those with less education were more likely to report preferring an in-person visit (Grossman, et al., 2011). Our qualitative findings, however, suggest this preference may be relative, with considerations about travel distance or wait time to get an appointment taking precedence for many women.

Although women were generally positive about the increased convenience of having the option of telemedicine services, none of the participants said that the ease of access influenced their decision to have the abortion. Instead, it allowed them to obtain the service they needed sooner and closer to home. Our finding that telemedicine did not influence women's decisions to abort is consistent with Iowa vital statistics data, which show that the abortion rate has not increased in Iowa since Planned Parenthood of the Heartland launched the telemedicine service (Iowa Department of Public Health, 2012).

We were surprised to find that internalized abortion stigma seemed to color some women's perceptions of the telemedicine service. For a few women, the anonymity provided by the videoconference communication insulated them from the interaction with the physician, which they anticipated to be negative, and allowed them to maintain a degree of secrecy about the procedure even from their provider. More systematic research using frameworks for understanding abortion stigma (Kumar, Hessini, & Mitchell, 2009; Norris et al., 2011) is needed to examine how telemedicine may mitigate—or perhaps reinforce—these negative internalized feelings.

Clinic staff reported minimal impact on clinic operations as a result of telemedicine introduction, after the initial procurement of equipment and training; the greatest perceived impact was enhanced access for their patients. Interestingly, some staff mentioned personal and professional benefits associated with being a part of this new service, and some took a great deal of pride in the role they played to meet the needs of the community they served. Although abortion clinic doctors and staff may experience personal and professional stigmatization and marginalization in the United States (Norris, et al., 2011), the findings from this study suggest that participating in telemedicine services could possibly help to counter these forces. More research is needed to understand how participation in a novel service delivery model may help abortion clinic staff to resist stigmatization by reframing and recalibrating the role they play as providers (O'Donnell, Weitz, & Freedman, 2011).

This study had several limitations, including that it was conducted with a convenience sample that did not draw from all clinics and may not be representative of all women's and providers' experiences. In addition, the effects of nonparticipation bias are not known. Participants might have associated the interviewer with the clinic, resulting in social desirability bias that censored negative perceptions. However, all women were told the interviewer was not affiliated with the clinic. Finally, we

did not include minors, and therefore cannot reflect on their views or experiences. Despite these limitations, this study provides the first in-depth data on women's and providers' experiences with telemedicine for abortion provision, filling a critical information gap on this service delivery model.

Implications for Practice and Policy

The findings from this study indicate that telemedicine can be used to provide medical abortion in a manner that is highly acceptable to patients and providers with minimal impact on the clinic. In states that require physicians to dispense medical abortion drugs, telemedicine services extend the reach of physicians in rural settings to help women save time and money and access care earlier in pregnancy. This study adds to the evidence documenting the safety, effectiveness and acceptability of providing medical abortion via telemedicine (Grossman, et al., 2011; Grossman, et al., 2013) and should help to motivate providers who serve rural populations to establish telemedicine programs. These data also highlight how efforts by state legislatures to ban the use of telemedicine for abortion run contrary to the medical evidence. Telemedicine is a useful tool to improve access to health care for rural populations, and abortion is another application for this technology.

Acknowledgements

Supported by a grant from an Anonymous Foundation. There are no financial conflicts to disclose. Kate Grindlay had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. The findings and conclusions in this article are those of the authors and do not necessarily represent the views of Planned Parenthood Federation of America, Inc.

The authors thank Todd Buchacker, RN, who was at Planned Parenthood of the Heartland at the time of this study, for his assistance facilitating data collection.

References

Berer, M. (2009). Provision of abortion by mid-level providers: International policy, practice and perspectives. *Bulletin of the World Health Organization*, 87, 58–63.

Blackwell, N. A., Kelly, G. J., & Lenton, L. M. (1997). Telemedicine ophthalmology consultation in remote Queensland. *The Medical Journal of Australia*, 167, 583–586.

Charmaz, K. (2006). *Constructing grounded theory: A practical guide through qualitative analysis*. Thousand Oaks, CA: Sage.

Fielding, S. L., Edmunds, E., & Schaff, E. A. (2002). Having an abortion using mifepristone and home misoprostol: A qualitative analysis of women's experiences. *Perspectives on Sexual and Reproductive Health*, 34, 34–40.

Finer, L. B., & Wei, J. (2009). Effect of mifepristone on abortion access in the United States. *Obstetrics & Gynecology*, 114, 623–630.

Grossman, D., Grindlay, K., Buchacker, T., Lane, K., & Blanchard, K. (2011). Effectiveness and acceptability of medical abortion provided through telemedicine. *Obstetrics & Gynecology*, 118, 296–303.

Grossman, D., Grindlay, K., Buchacker, T., Potter, J. E., & Schmertmann, C. (2013). Changes in service delivery patterns after introduction of telemedicine provision of medical abortion in Iowa. *American Journal of Public Health*, 103, 73–78.

Iowa Department of Public Health. (2012). Vital statistics of Iowa. Retrieved August 15, 2012, from http://www.idph.state.ia.us/.

Jones, R. K., & Kooistra, K. (2011). Abortion incidence and access to services in the United States, 2008. *Perspectives on Sexual and Reproductive Health*, 43, 41–50.

Kumar, A., Hessini, L., & Mitchell, E. M. (2009). Conceptualising abortion stigma. *Culture, Health & Sexuality*, 11, 625–639.

Lafaurie, M. M., Grossman, D., Troncoso, E., Billings, D. L., & Chavez, S. (2005). Women's perspectives on medical abortion in Mexico, Colombia, Ecuador and Peru: A qualitative study. *Reproductive Health Matters*, 13, 75–83.

Leggett, P., Graham, L., Steele, K., Gilliland, A., Stevenson, M., O'Reilly, D., et al. (2001). Telerheumatology–diagnostic accuracy and acceptability to patient, specialist, and general practitioner. *British Journal of General Practice*, 51, 746–748.

Norris, A., Bessett, D., Steinberg, J. R., Kavanaugh, M. L., De Zordo, S., & Becker, D. (2011). Abortion stigma: A reconceptualization of constituents, causes, and consequences. *Women's Health Issues*, 21(3 Suppl.), S49–S54.

O'Donnell, J., Weitz, T. A., & Freedman, L. R. (2011). Resistance and vulnerability to stigmatization in abortion work. *Social Science & Medicine*, 73, 1357–1364.

Palmas, W., Teresi, J., Weinstock, R. S., & Shea, S. (2008). Acceptability to primary care providers of telemedicine in diabetes case management. *Journal of Telemedicine and Telecare*, 14, 306–308.

Wade, V., Karnon, J., Elshaug, A., & Hiller, J. (2010). A systematic review of economic analyses of telehealth services using real time video communication. *BMC Health Services Research*, 10, 233.

Yarnall, J., Swica, Y., & Winikoff, B. (2009). Non-physician clinicians can safely provide first trimester medical abortion. *Reproductive Health Matters*, 17, 61–69.

Author Descriptions

Kate Grindlay, MSPH, is a Senior Project Manager at Ibis Reproductive Health. Her current work focuses on research to expand the availability and accessibility of reproductive health services for women in the U.S. and internationally.

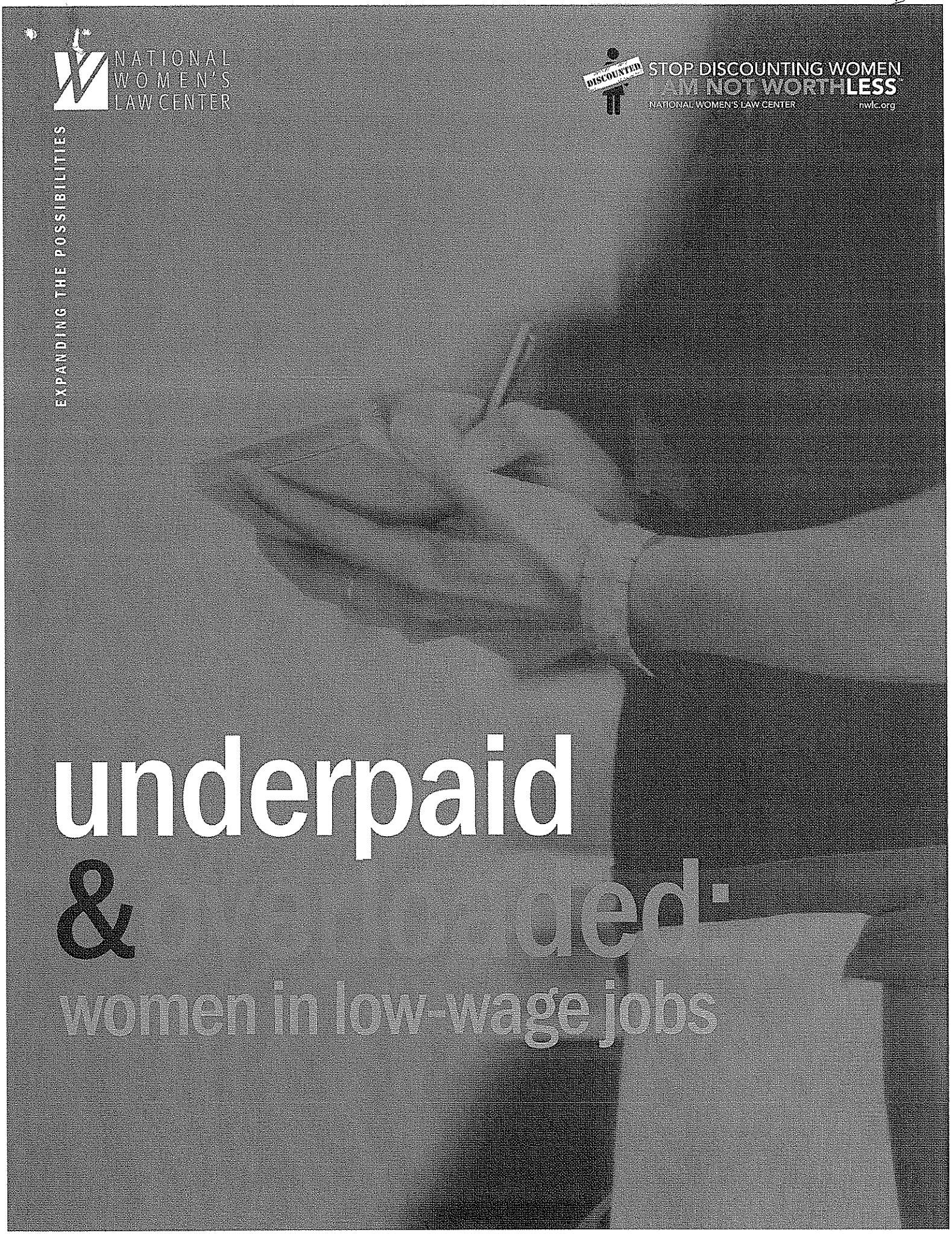
Kathleen Lane, CN, is a consultant at Provide with expertise in reproductive health and field work using qualitative methods.

Daniel Grossman, MD, is the Vice President for Research at Ibis Reproductive Health, an Assistant Clinical Professor at UCSF, and a practicing physician. His current work focuses on improving access to contraception, safe abortion, and HIV services.

D

NATIONAL WOMEN'S LAW CENTER

EXPANDING THE POSSIBILITIES



underpaid & ued:

women in low-wage jobs

ABOUT THE CENTER

The National Women's Law Center is a non-profit organization whose mission is to expand the possibilities for women and their families by working to remove barriers based on gender, open opportunities, and help women and their families lead economically secure, healthy, and fulfilled lives—with special attention to the needs of low-income women and their families.

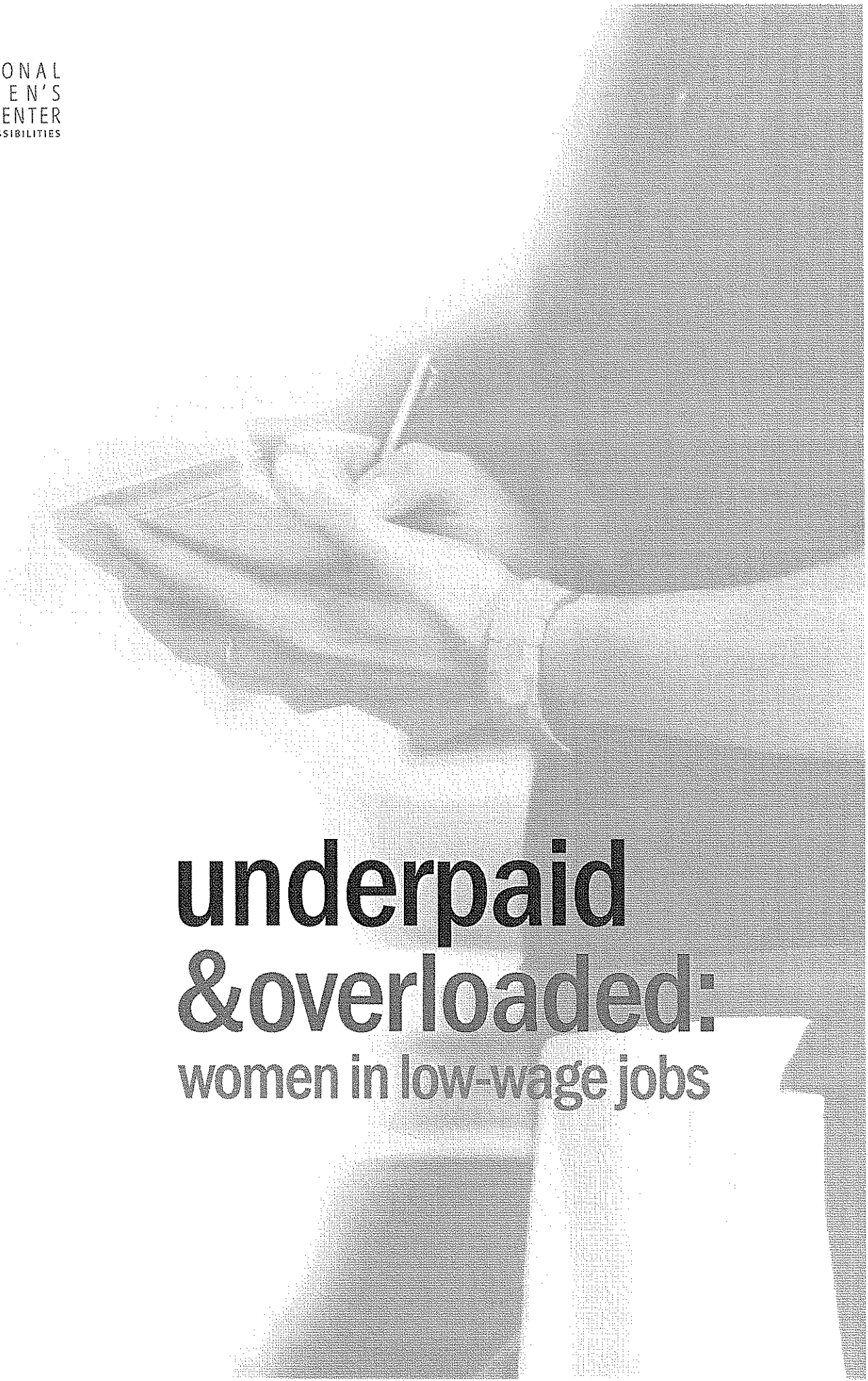
For more information about the National Women's Law Center or to make a tax-deductible contribution to support the Center's work, please visit www.nwlc.org or call the Development office at 202-588-5180.

ACKNOWLEDGMENTS

This report was a collaborative effort that relied upon the work of many individuals. The primary authors are Joan Entmacher, Vice President for Family Economic Security, Lauren Frohlich, Policy Fellow, Katherine Gallagher Robbins, Senior Policy Analyst, Emily Martin, Vice President and General Counsel, and Liz Watson, Senior Counsel and Director of Workplace Justice for Women. They were greatly assisted by other National Women's Law Center staff, including Helen Blank, Nancy Duff Campbell, Karen Davenport, Fatima Goss Graves, Marcia D. Greenberger, Elizabeth Johnston, Karen Schneider, Karen Schulman, Judy Waxman, and Emily Werth. Beth Stover, Graphic and Web Designer, designed the report. The report was made possible by the generous support for the National Women's Law Center's work to address challenges facing women in the low-wage workforce provided by the Annie E. Casey Foundation, Ford Foundation, Moriah Fund, Morningstar Foundation, New Directions Foundation, and an anonymous funder.

© 2014 National Women's Law Center

NATIONAL WOMEN'S LAW CENTER
EXPANDING THE POSSIBILITIES



underpaid &overloaded:

women in low-wage jobs

table of contents

Introduction	1
Women are overrepresented in the low-wage workforce	5
A gender wage gap persists in the low-wage workforce	17
Profile of women in the low-wage workforce	18
Women in the low-wage workforce by state	24
Low-income women and health insurance eligibility through Medicaid under the ACA	26
Addressing the challenges facing women in low-wage jobs	28
Appendix	35

Introduction

OVER THE PAST FOUR DECADES, women's work experience and educational attainment have increased dramatically.[1] Although women have better credentials than ever before,[2] the job and income prospects for many are bleak. Women make up two-thirds of the nearly 20 million workers in low-wage jobs[3]—defined in this report as jobs that typically pay $10.10 per hour or less—although they make up slightly less than half of the workforce as a whole.

The low-wage workforce includes jobs such as home health aides, child care workers, fast food workers, restaurant servers, maids, and cashiers.[4] The work is hard and necessary, but the pay is inadequate. At $10.10 per hour, a full-time, year-round worker earns $20,200 annually—barely above the poverty line for a mother with two children.[5] Many of the workers in these jobs are paid the minimum wage of $7.25 per hour; at that rate, a full-time, year-round worker would earn just $14,500—thousands of dollars below the poverty line for a family of three.[6]

Women's concentration in low-wage jobs has increased in recent years—and the trend is likely to continue. More than one-third (35 percent) of women's net job gains during the recovery from the Great Recession have been in jobs that typically pay $10.10 per hour or less; only 20 percent of men's job gains have been in such low-wage jobs.[7] The share of women workers who hold low-wage jobs increased by more than six percent between 2007, the year before the recession, and 2012,[8] despite women's continued advances in education.[9] And disproportionately strong growth in low-wage, female-dominated jobs is projected for the future. Of the 20 jobs predicted to add the largest numbers of workers between 2012 and 2022, five are low-wage, typically paying less than $10.10 per hour—and all of these low-wage jobs are female-dominated.[10] Another nine of these 20 high-growth jobs pay between $10.10 per hour and the median wage of $16.71 per hour—and five of these jobs are female-dominated.[11]

KEY FACTS

- Women make up two-thirds of the nearly 20 million workers in the low-wage workforce—though they make up less than half of all workers.
- Even in low-wage jobs that typically pay $10.10 per hour or less, women working full time, year round face a 13 percent wage gap—and the gap is even larger for African American and Hispanic women when compared to white, non-Hispanic men.

Women's shares of the low-wage workforce are larger than their male counterparts'—though women's shares of the overall workforce are almost always similar or smaller:

- Women with some college or an associate's degree make up more than twice as large a share of the low-wage workforce as their male counterparts (22 percent v. 10 percent), even though their shares of the overall workforce are similar (15 percent for women v. 14 percent for men).
- Women age 50 and older make up more than three times as large a share of the low-wage workforce as their male counterparts (17 percent v. 5 percent), even though their shares of the overall workforce are similar (16 percent for older women v. 17 percent for older men).
- Mothers make up 3.5 times as large a share of the low-wage workforce as do fathers (21 percent v. 6 percent), even though their shares of the overall workforce are similar (16 percent for mothers v. 17 percent for fathers).

KEY FACTS CONT.

Women's shares of the low-wage workforce are almost always larger than their shares of the overall workforce. For men, this is rarely true:

- Women with only a high school degree are 24 percent of the low-wage workforce, double their share of the overall workforce (12 percent). Men with only a high school degree are underrepresented in the low-wage workforce: they are 12 percent of the low-wage workforce, 0.8 times their share of the overall workforce (15 percent).
- Single women's share of the low-wage workforce (43 percent) is nearly double their share of the overall workforce (23 percent). Single men's share of the low-wage workforce is similar to their share of the overall workforce (25 percent v. 23 percent).
- African American women's share of the low-wage workforce (12 percent) is double their share of the overall workforce (6 percent). African American men's shares of the low-wage and overall workforces are the same at 5 percent.
- The only group of women that is underrepresented in the low-wage workforce is women with a bachelor's degree or higher: they are 5 percent of the low-wage workforce, about one-third of their share of the overall workforce (17 percent). However, men with a bachelor's degree or higher are even more underrepresented in the low-wage workforce: they are 3 percent of the low-wage workforce, about one-sixth of their share of the overall workforce (18 percent).
- In contrast, only a few groups of men, including men without a high school degree, young men (age 16-24), and Hispanic men, are overrepresented in the low-wage workforce compared to their share of the overall workforce—and even in these groups, men are overrepresented to a lesser extent than their female counterparts.

Among women in the low-wage workforce:

- Nearly half are women of color.
- Nearly four out of five have at least a high school degree.
- Half work full time.
- Close to one-third are mothers—and 40 percent of them have family incomes below $25,000.
- More than one-quarter are age 50 and older—about the same share of the female low-wage workforce as women age 16 to 24.

Notes: The "low-wage workforce" is defined here as occupations with median wages of $10.10 or less per hour based on Bureau of Labor Statistics, Occupational Employment Statistics. Worker characteristics are National Women's Law Center calculations based on Current Population Survey (CPS) 2013 using Miriam King et al., *Integrated Public Use Microdata Series (IPUMS), Current Population Survey: Version 3.0* [Machine-readable database] (Minneapolis: University of Minnesota, 2010). Figures are for employed workers unless otherwise noted.

Women's overrepresentation in low-wage jobs is a particular concern today because families' reliance on women's earnings has increased dramatically over the past 40 years.[12] Working mothers are primary breadwinners in 41 percent of families with children, and they are co-breadwinners—bringing in between 25 percent and 50 percent of family earnings—in another 22 percent of these families.[13] At the same time, women still shoulder the majority of caregiving responsibilities.[14] And the characteristics of low-wage jobs pose particular challenges to women as both breadwinners and caregivers.

This analysis focuses on the role of gender in the low-wage workforce, using data on worker characteristics from the Current Population Survey and American Community Survey and data on median hourly wages for occupations from the Bureau of Labor Statistics' Occupational Employment Statistics. It reveals a stark reality: regardless of their education level, age, marital or parental status, race, ethnicity, or national origin, women make up larger shares of the low-wage workforce than do their male counterparts. This pattern holds in each of these groups, even though in virtually all of them women represent a similar or smaller share of the overall workforce than their male counterparts.[15] Looking at the data another way, comparing women's and men's shares of the low-wage workforce to their respective shares of the overall workforce, nearly every group of women is overrepresented in the low-wage workforce; for men, this is rarely true.

The existence of a wage gap between women and men at every education level has been well documented.[16] However, the finding that in this day and age, women need a bachelor's degree to avoid being overrepresented in low-wage jobs—while men only need to finish high school—is startling. Moreover, even in these low-wage jobs, women working full time, year round face a 13 percent wage gap, and the gap is even larger for African American and Hispanic women when compared to white, non-Hispanic men.

The overrepresentation of women in low-wage jobs occurs across the country. In every state, at least six in ten low-wage workers are women, even though women make up half or less of the overall workforce in every state. Women make up at least twice as large a share of the low-wage workforce as men in all but three states and the District of Columbia—and in nine states, women's share of the low-wage workforce is more than 2.5 times that of men.

This report also provides a profile of the women who work in low-wage jobs. Nearly half are women of color. Half work full time—and nearly one in five is poor. Nearly one-third are mothers—and 40 percent of mothers in the low-wage workforce have family incomes below $25,000. More than one-quarter of the women working in low-wage jobs are age 50 and older; they make up nearly the same share of the female low-wage workforce as women age 16 to 24.

Women need a bachelor's degree to avoid being overrepresented in low-wage jobs—while men only need to finish high school.

Low earnings are just one of the challenges workers in low-wage jobs face. These jobs often lack basic benefits such as paid sick leave,[17] and, while the Affordable Care Act (ACA) has significantly improved women's access to affordable health insurance, workers in these jobs may still face barriers to health insurance coverage[18] and services they need, including reproductive health care services. Mothers struggle to afford the safe and stable child care they need to be able to work—much less the high-quality child care their children need to be successful in school.[19] Women working in low-wage jobs, especially women of color, often face discrimination and harassment.[20] They also can be subject to unpredictable and inflexible work schedules, which are particularly difficult for workers balancing family or school responsibilities or trying to hold down a second job to make ends meet.[21] Taken together, these challenges create significant obstacles to moving out of low-wage work and into good jobs that can sustain a family.

The predominance of women in low-wage jobs makes clear that an economic agenda that works for women must address the particular needs of low-wage workers—and an

economic agenda that works for low-wage workers must address the particular needs of women. Moreover, jobs that typically pay low wages, such as home care aides who provide critical services to an expanding elderly population, are a critical and growing part of our economy. Ensuring that workers in those jobs are treated fairly and can provide for their families is vital not only for them, but for the nation as a whole.

THIS REPORT OUTLINES AN AGENDA TO ADDRESS THE NEEDS OF WOMEN IN LOW-WAGE JOBS BY:

- **increasing economic security** through a combination of higher wages—starting with raising the minimum and tipped minimum wages—and other supports, such as the Earned Income Tax Credit, affordable health insurance, nutrition and housing assistance, and removing restrictions on women's access to reproductive health care;
- **supporting workers with family responsibilities** by expanding access to child care assistance and early education, curbing abusive scheduling practices, and ensuring paid sick days and paid family leave;
- **removing barriers to opportunity** by strengthening and enforcing protections against all forms of employment discrimination and providing a path to citizenship for immigrants who are particularly vulnerable to discrimination;
- **creating pathways to opportunity** by making higher education more affordable, enforcing legal protections for pregnant and parenting students and increasing student-parents' access to child care, and expanding women's access to higher-paying, nontraditional fields; and
- **strengthening opportunities for collective action,** including supporting organizing and collective bargaining through traditional unions and collective action by new worker justice organizations.

These policies will not only improve the lives of workers in low-wage jobs—women and men—and their families, but will make our economy stronger for everyone.

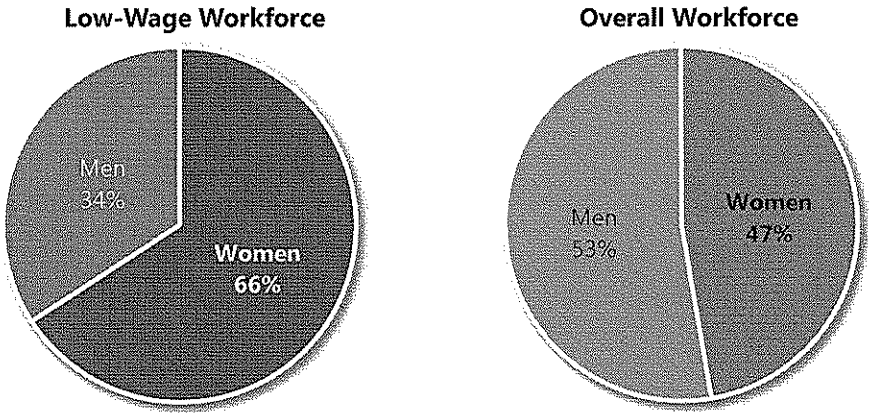
These policies will not only improve the lives of workers in low-wage jobs—women and men—and their families, but will make our economy stronger for everyone.

Women are overrepresented in the low-wage workforce

THERE ARE NEARLY 20 MILLION WORKERS IN THE LOW-WAGE WORKFORCE. Over 13 million of them—two-thirds—are women, even though women are less than half (47.3 percent) of the overall workforce.

Comparing women and men in the low-wage workforce by education level, age, marital and parental status, race, ethnicity, and national origin reveals that in each of these groups women make up larger shares of the low-wage workforce than do their male counterparts, even though women's shares of the overall workforce are almost always similar or smaller. And, for nearly every group of women, their share of the low-wage workforce is larger than their share of the overall workforce. For men, this is rarely true.

FIGURE 1: WOMEN'S SHARES OF THE LOW-WAGE AND OVERALL WORKFORCES



Source: NWLC calculations based on IPUMS-CPS (2013). Figures are for employed workers. The low-wage workforce is defined here as occupations with median wages of $10.10 or less per hour based on BLS, Occupational Employment Statistics.

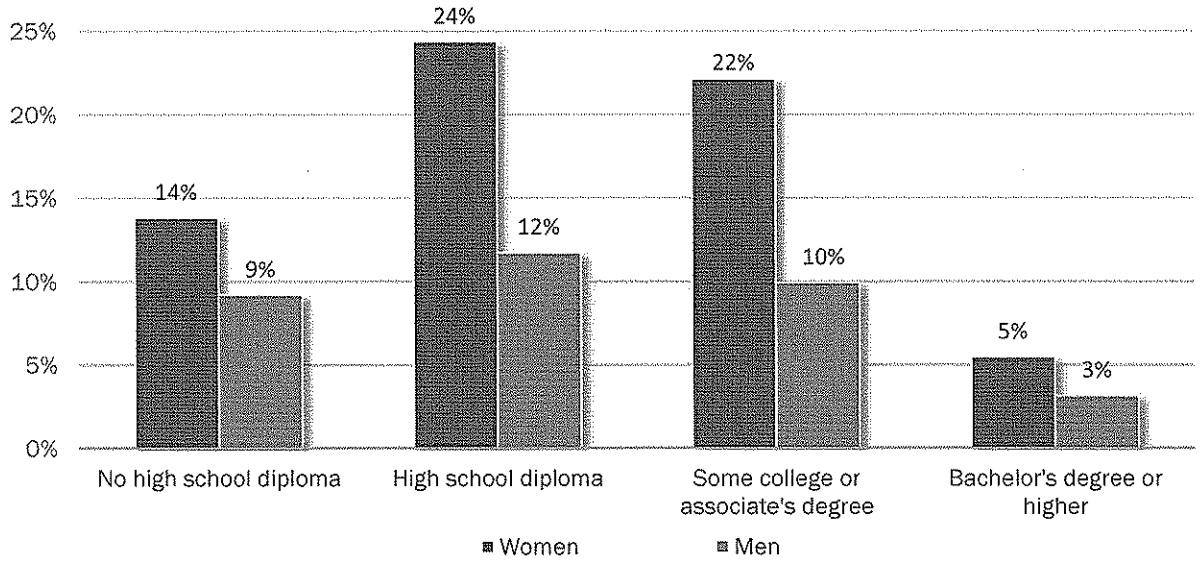
NATIONAL WOMEN'S LAW CENTER
www.nwlc.org

EDUCATIONAL ATTAINMENT

At every education level, women's share of the low-wage workforce is larger than men's, even though women make up a similar or smaller share of the overall workforce compared to their male counterparts.

- Among workers without a high school degree, women's share of the low-wage workforce (13.8 percent) is 1.5 times larger than men's (9.2 percent), even though women without a high school degree account for a smaller share of the overall workforce (3.4 percent) than do their male counterparts (5.5 percent).
- Among workers with only a high school degree, women's share of the low-wage workforce is more than double men's (24.4 percent v. 11.8 percent). This is true even though women with only a high school degree account for a smaller share of the overall workforce (11.5 percent) than do their male counterparts (15.0 percent).
- Among workers with some college or an associate's degree, women's share of the low-wage workforce is more than double men's (22.2 percent v. 10.0 percent), even though their shares of the overall workforce are similar (15.3 percent v. 14.5 percent).
- Among workers with a bachelor's degree or higher, women's share of the low-wage workforce is 1.7 times men's (5.5 percent v. 3.2 percent), even though their shares of the overall workforce are similar (17.1 percent v. 17.8 percent).

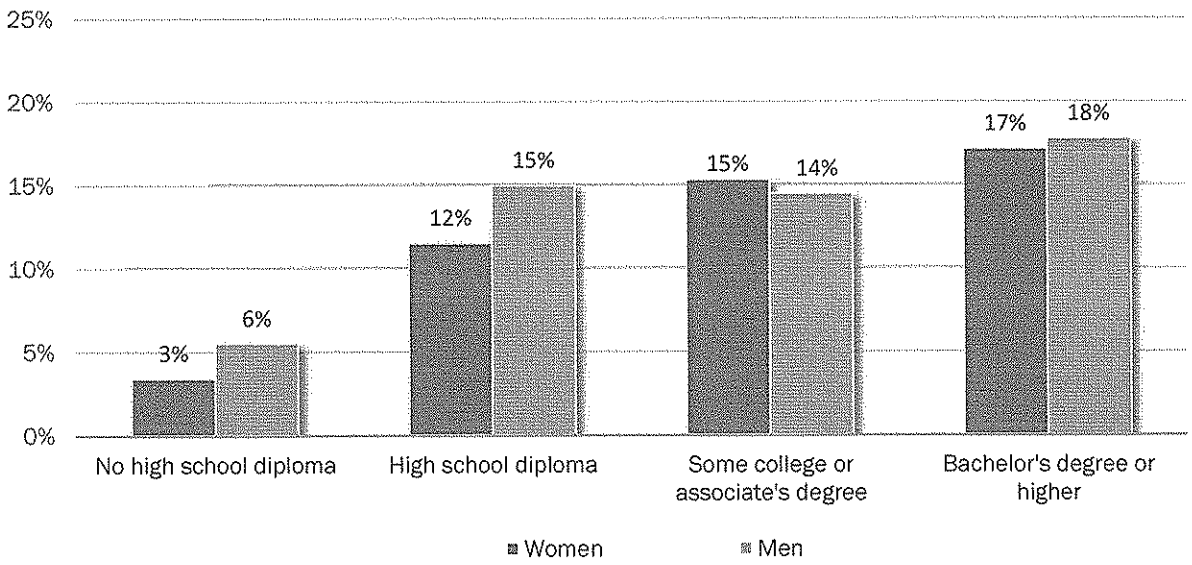
FIGURE 2A: THE LOW-WAGE WORKFORCE BY SEX AND EDUCATIONAL ATTAINMENT



Source: NWLC calculations based on IPUMS-CPS (2013). Figures are for employed workers. The low-wage workforce is defined here as occupations with median wages of $10.10 or less per hour based on BLS, Occupational Employment Statistics.

NATIONAL WOMEN'S LAW CENTER
www.nwlc.org

FIGURE 2B: THE OVERALL WORKFORCE BY SEX AND EDUCATIONAL ATTAINMENT



Source: NWLC calculations based on IPUMS-CPS (2013). Figures are for employed workers.

NATIONAL WOMEN'S LAW CENTER
www.nwlc.org

Relative to their shares of the overall workforce, women are overrepresented in the low-wage workforce at every level of educational attainment except bachelor's degree or higher. Only men without a high school degree are overrepresented in the low-wage workforce.

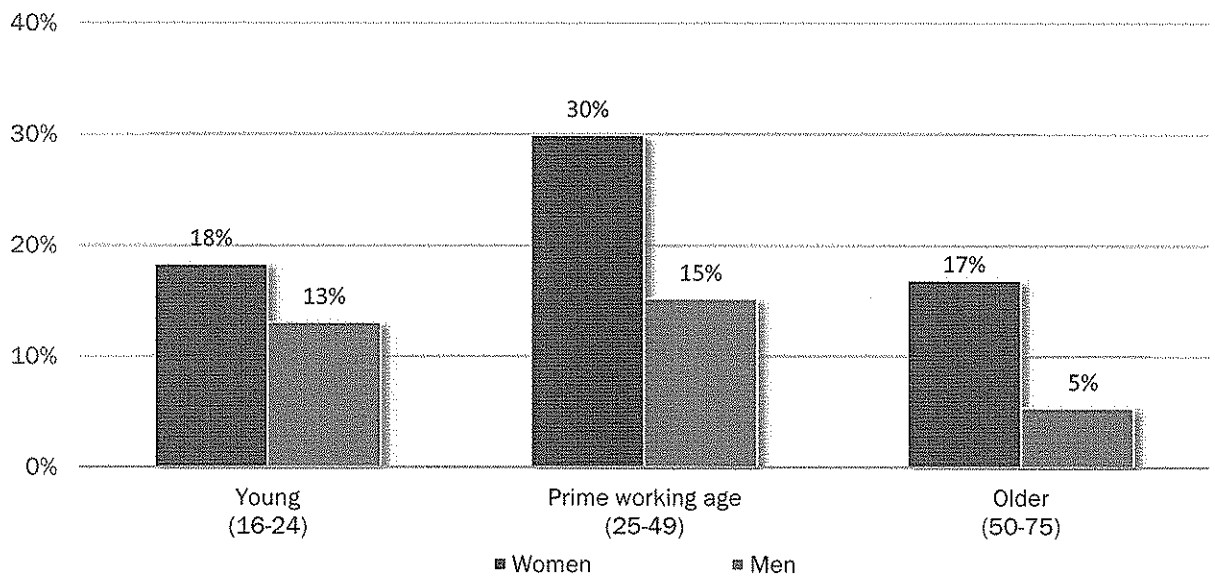
- Women without a high school degree are 13.8 percent of the low-wage workforce, more than four times their share of the overall workforce (3.4 percent). Men without a high school degree are also overrepresented in the low-wage workforce, but to a much lesser extent: they are 9.2 percent of the low-wage workforce, 1.7 times their share of the overall workforce (5.5 percent).
- Women with only a high school degree are 24.4 percent of the low-wage workforce, more than twice their share of the overall workforce (11.5 percent). Men with only a high school degree are underrepresented in the low-wage workforce: they are 11.8 percent of the low-wage workforce, 0.8 times their share of the overall workforce (15.0 percent).
- Women with some college or an associate's degree are 22.2 percent of the low-wage workforce—nearly one-and-a-half times their share of the overall workforce (15.3 percent). Men with some college or an associate's degree are 10.0 percent of the low-wage workforce, 0.7 times their share of the overall workforce.
- Women with a bachelor's degree or higher are 5.5 percent of the low-wage workforce, about one-third of their share of the overall workforce (17.1 percent). Men with a bachelor's degree or higher are even more underrepresented in the low-wage workforce: they are 3.2 percent of the low-wage workforce, about one-sixth of their share of the overall workforce (17.8 percent).

AGE

Women at all ages make up larger shares of the low-wage workforce than do men of the same age group, and the gender disparity worsens with age, even though women at all ages make up similar or smaller shares of the overall workforce compared to their male counterparts.

- Young women's (age 16-24) share of the low-wage workforce (18.3 percent) is 1.4 times that of young men's (13.1 percent), even though their shares of the overall workforce are virtually identical (6.0 percent for young women v. 6.1 percent for young men).
- Among workers in their prime working years (age 25-49), women's share of the low-wage workforce (29.9 percent) is double the size of men's (15.2 percent), even though women's share of the overall workforce (25.2 percent) is similar to men's (29.1 percent).
- Older women's (age 50-75) share of the low-wage workforce (16.9 percent) is more than triple that of older men's (5.4 percent), even though their shares of the overall workforce are similar (15.7 percent for older women v. 16.9 percent for older men).

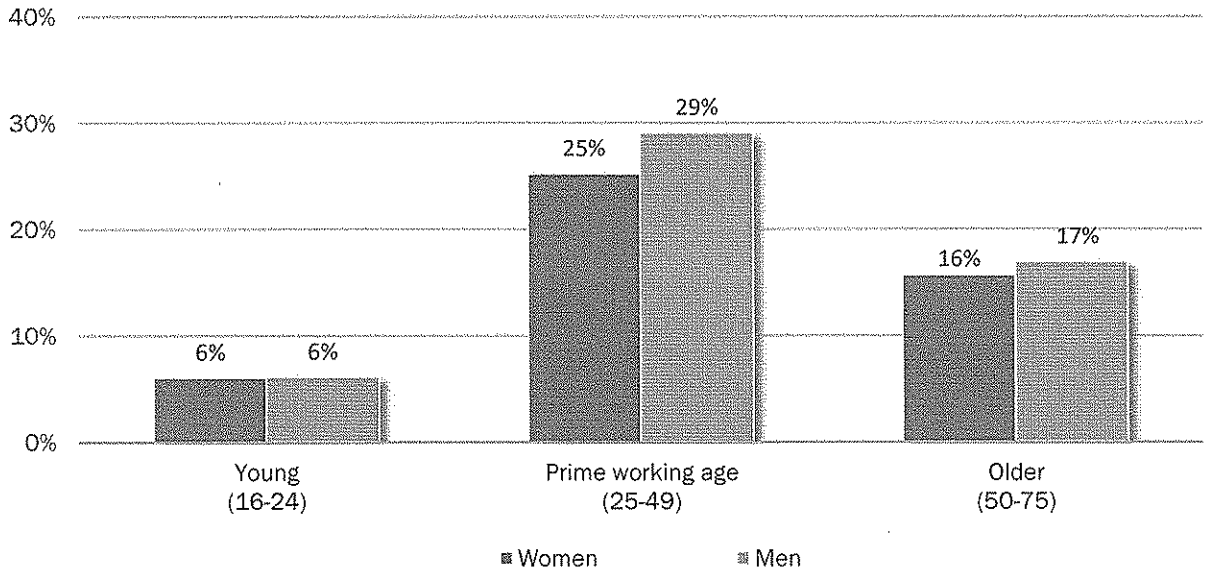
FIGURE 3A: THE LOW-WAGE WORKFORCE BY SEX AND AGE



Source: NWLC calculations based on IPUMS-CPS (2013). Figures are for employed workers. The low-wage workforce is defined here as occupations with median wages of $10.10 or less per hour based on BLS, Occupational Employment Statistics.

NATIONAL WOMEN'S LAW CENTER
www.nwlc.org

FIGURE 3B: THE OVERALL WORKFORCE BY SEX AND AGE



Source: NWLC calculations based on IPUMS-CPS (2013). Figures are for employed workers.

NATIONAL WOMEN'S LAW CENTER
www.nwlc.org

Relative to their shares of the overall workforce, both young women and women in their prime working years are overrepresented in the low-wage workforce. Only young men are overrepresented in the low-wage workforce.

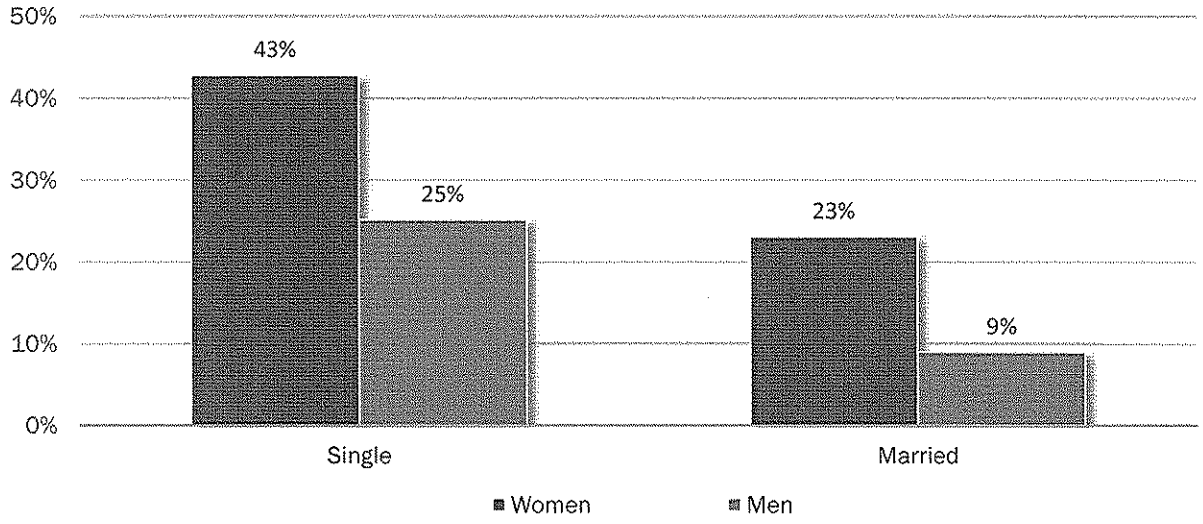
- Young women are 18.3 percent of the low-wage workforce—three times their share of the overall workforce (6.0 percent). Young men are also overrepresented in the low-wage workforce, but to a lesser extent: they are 13.1 percent of the low-wage labor force, twice their share of the overall workforce (6.1 percent).
- Women in their prime working years are 29.9 percent of the low-wage workforce, 1.2 times their share of the overall workforce (25.2 percent). Men in their prime working years are underrepresented in the low-wage workforce: they are 15.2 percent of the low-wage workforce, about half of their share of the overall workforce (29.1 percent).
- Older women are 16.9 percent of the low-wage workforce, similar to their share of the workforce as a whole (15.7 percent). Older men are substantially underrepresented in the low-wage workforce: they are 5.4 percent of the low-wage workforce, about one-third of their share of the overall workforce (16.9 percent).

MARITAL STATUS

Both single and married women account for larger shares of the low-wage workforce than their male counterparts, though their shares of the overall workforce are similar or smaller.[22]

- Single women's share of the low-wage workforce (42.8 percent) is 1.7 times larger than single men's (25.2 percent), even though single women and men make up virtually the same share of the overall workforce—23.1 percent and 22.7 percent, respectively.
- Married women's share of the low-wage workforce (23.1 percent) is 2.6 times larger than married men's (9.0 percent), even though married women make up a smaller share of the overall workforce than married men (24.3 percent v. 30.0 percent).

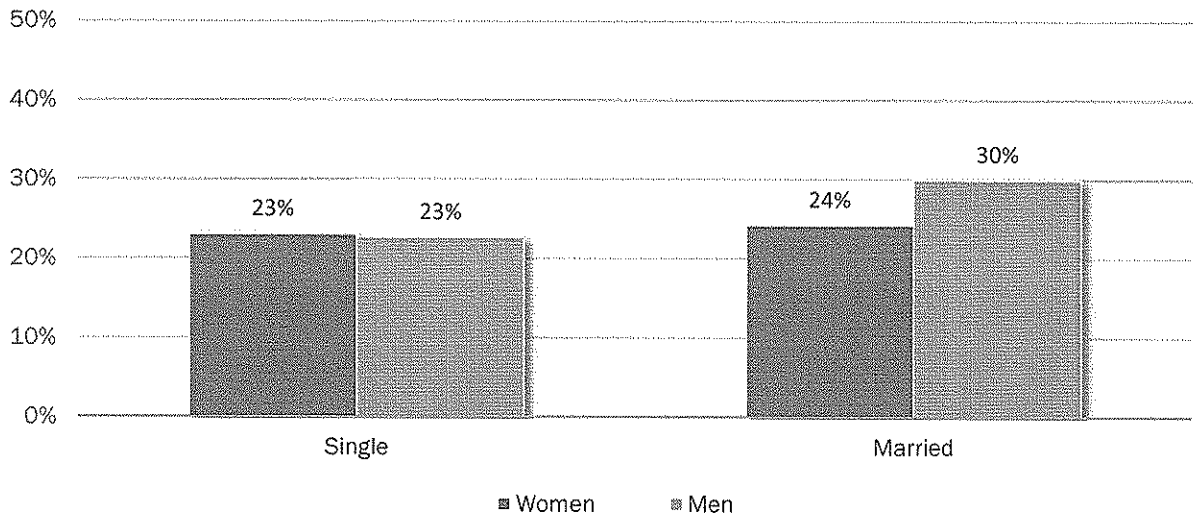
FIGURE 4A: THE LOW-WAGE WORKFORCE BY SEX AND MARITAL STATUS



Source: NWLC calculations based on IPUMS-CPS (2013). Figures are for employed workers. The low-wage workforce is defined here as occupations with median wages of $10.10 or less per hour based on BLS, Occupational Employment Statistics.

NATIONAL WOMEN'S LAW CENTER
www.nwlc.org

FIGURE 4B: THE OVERALL WORKFORCE BY SEX AND MARITAL STATUS



Source: NWLC calculations based on IPUMS-CPS (2013). Figures are for employed workers.

www.nwlc.org

Relative to their shares of the overall workforce, single women are overrepresented in the low-wage workforce while married women make up similar shares of the low-wage and overall workforces. Single men make up similar shares of the low-wage and overall workforces, while married men are underrepresented in the low-wage workforce.

- Single women's share of the low-wage workforce (42.8 percent) is nearly double their share of the overall workforce (23.1 percent). Single men's share of the low-wage workforce is similar to their share of the overall workforce (25.2 percent v. 22.7 percent).
- Married women's shares of the low-wage and overall workforce are similar (23.1 percent v. 24.3 percent). Married men's share of the low-wage workforce (9.0 percent) is less than one-third of their share of the overall workforce (30.0 percent).

PARENTAL STATUS

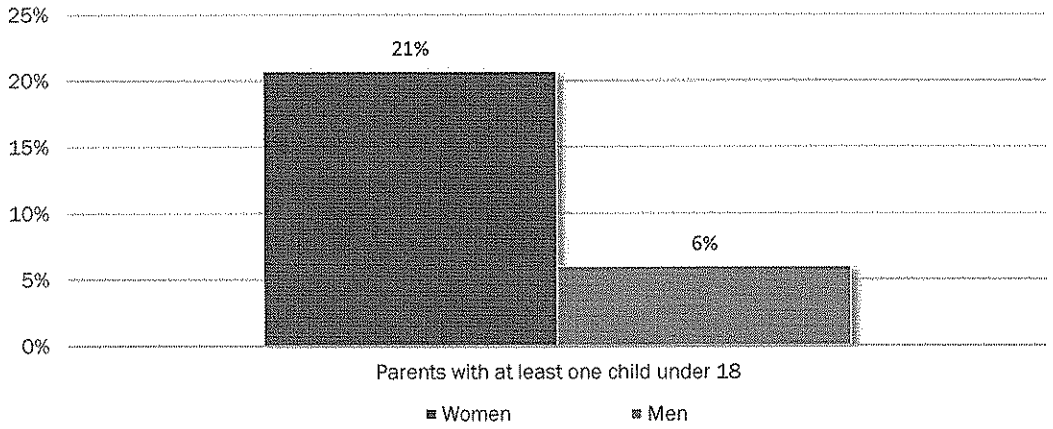
Mothers' share of the low-wage workforce is much larger than fathers', even though their shares of the overall workforce are similar.[23]

- Mothers' share of the low-wage workforce (20.7 percent) is 3.5 times fathers' share (6.0 percent), though their shares of the overall workforce are virtually the same (16.2 percent for mothers v. 16.9 percent for fathers).

Relative to their shares of the overall workforce, mothers are overrepresented in the low-wage workforce, while fathers are underrepresented.

- Mothers' share of the low-wage workforce is 20.7 percent—1.3 times larger than their share of the overall workforce (16.2 percent). Fathers' share of the low-wage workforce is 6.0 percent, about one-third their share of the overall workforce (16.9 percent).

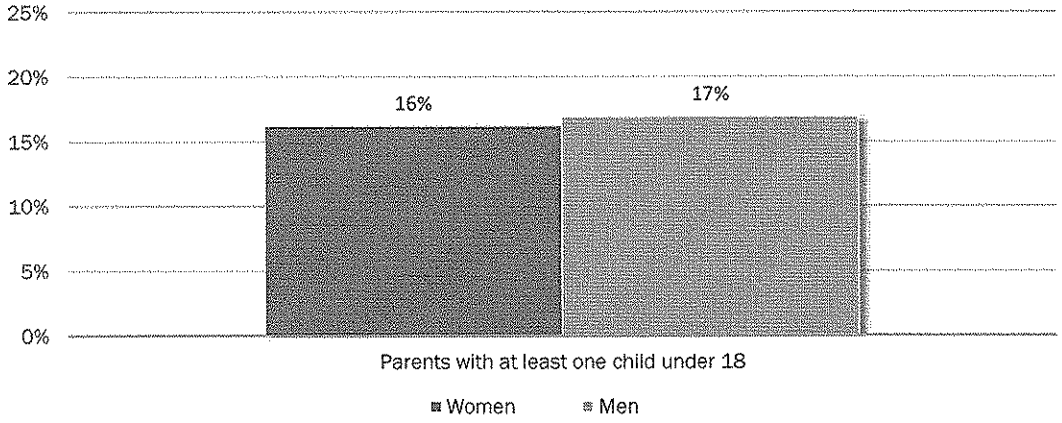
FIGURE 5A: THE LOW-WAGE WORKFORCE BY SEX AND PARENTAL STATUS



Source: NWLC calculations based on IPUMS-CPS (2013). Figures are for employed workers. The low-wage workforce is defined here as occupations with median wages of $10.10 or less per hour based on BLS, Occupational Employment Statistics. "Parents" have related children under 18 in their home.

NATIONAL WOMEN'S LAW CENTER
www.nwlc.org

FIGURE 5B: THE OVERALL WORKFORCE BY SEX AND PARENTAL STATUS



Source: NWLC calculations based on IPUMS-CPS (2013). Figures are for employed workers. "Parents" have related children under 18 in their home.

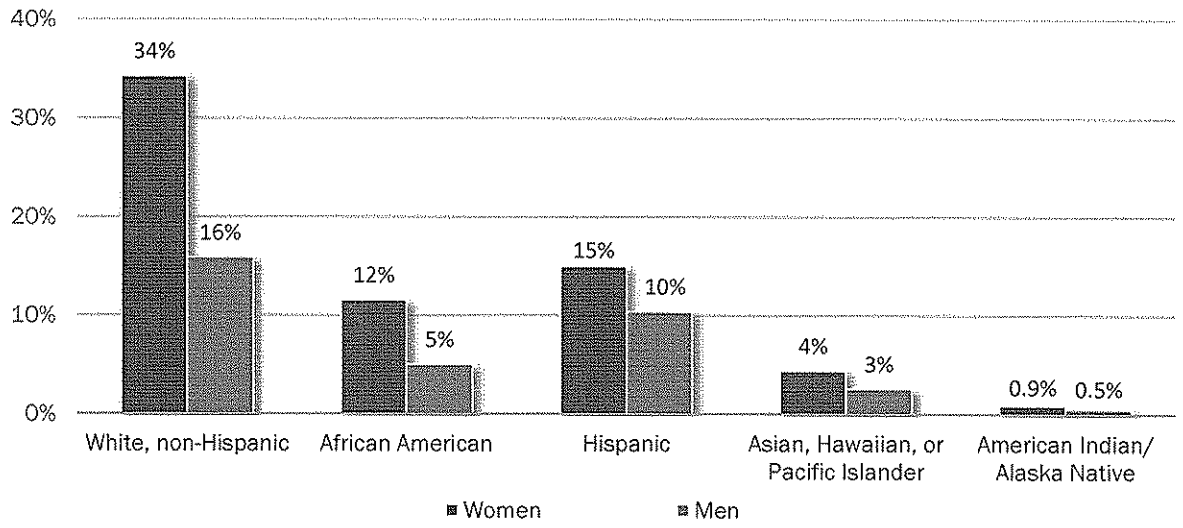
NATIONAL WOMEN'S LAW CENTER
www.nwlc.org

RACE AND ETHNICITY

Across racial and ethnic groups women account for larger shares of the low-wage workforce than their male counterparts, even though women generally make up similar or smaller shares of the overall workforce compared to their male counterparts. However, it is important to note that these comparisons are of workers. People who are not in the workforce, including incarcerated individuals, are not counted in the data. Young, less-educated men of color, especially African American men, are very disproportionately incarcerated, and thus not counted in a comparison of the types of jobs held by people who are in the workforce. This exclusion can create a distorted employment picture for some groups of men of color.[24]

- White, non-Hispanic women's share of the low-wage workforce (34.3 percent) is more than twice as large as white, non-Hispanic men's share of the low-wage workforce (15.9 percent)—though white, non-Hispanic women and men make up similar shares of the overall workforce (31.4 percent and 35.0 percent, respectively).
- African American women's share of the low-wage workforce (11.6 percent) is 2.3 times as large as African American men's share of the low-wage workforce (5.0 percent). African American women are also slightly overrepresented in the overall workforce relative to African American men, though to a much lesser extent: African American women's share of the overall workforce (6.1 percent) is 1.2 times larger than African American men's share (5.1 percent).
- Hispanic women's share of the low-wage workforce (15.0 percent) is 1.4 times as large as Hispanic men's share of the low-wage workforce (10.4 percent)—though Hispanic women make up a smaller share of the overall workforce (6.6 percent) than do Hispanic men (8.9 percent).
- Asian, Hawaiian and/or Pacific Islander women's share of the low-wage workforce (4.4 percent) is 1.7 times larger than Asian, Hawaiian and/or Pacific Islander men's share of the low-wage workforce (2.6 percent)—though Asian, Hawaiian and/or Pacific Islander women and men make up similar shares of the overall workforce (2.9 percent v. 3.2 percent).
- American Indian/Alaska Native women's share of the low-wage workforce (0.9 percent) is 1.6 times larger than American Indian/Alaska Native men's share of the low-wage workforce (0.5 percent)—though American Indian/Alaska Native women and men make up similar shares of the overall workforce (0.4 percent v. 0.5 percent).

FIGURE 6A: THE LOW-WAGE WORKFORCE BY SEX AND RACE/ETHNICITY



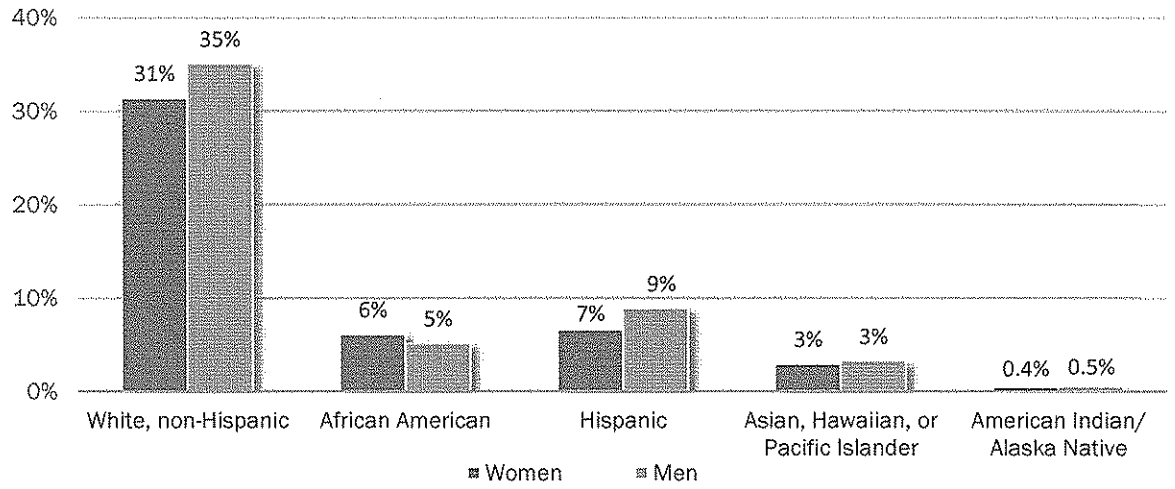
Source: NWLC calculations based on IPUMS-CPS (2013). Figures are for employed workers. The low-wage workforce is defined here as occupations with median wages of $10.10 or less per hour based on BLS, Occupational Employment Statistics.

NATIONAL WOMEN'S LAW CENTER
www.nwlc.org

All groups of women of color are overrepresented in the low-wage workforce. In comparison, only Hispanic men are overrepresented in the low-wage workforce—and they are overrepresented to a lesser extent.

- White, non-Hispanic women's share of the low-wage workforce (34.3 percent) is similar to their share of the overall workforce (31.4 percent). However, white, non-Hispanic men's share of the low-wage workforce (15.9 percent) is half the size of their share of the overall workforce (35.0 percent).
- African American women's share of the low-wage workforce (11.6 percent) is nearly double their share of the overall workforce (6.1 percent). African American men's shares of the low-wage and overall workforces are virtually identical (5.0 percent v. 5.1 percent).
- Hispanic women's share of the low-wage workforce (15.0 percent) is more than double their share of the overall workforce (6.6 percent). Hispanic men are also overrepresented in the low-wage workforce, but to a much lesser extent: Hispanic men's share of the low-wage workforce (10.4 percent) is 1.2 times larger than their share of the overall workforce (8.9 percent).
- Asian, Hawaiian and/or Pacific Islander women's share of the low-wage workforce (4.4 percent) is 1.5 times larger than their share of the overall workforce (2.9 percent). Asian, Hawaiian and/or Pacific Islander men's shares of the low-wage and overall workforces are similar (2.6 percent v. 3.2 percent).
- American Indian/Alaska Native women's share of the low-wage workforce (0.9 percent) is double their share of the overall workforce (0.4 percent). American Indian/Alaska Native men's shares of the low-wage and overall workforces are the same (both 0.5 percent).

FIGURE 6B: THE OVERALL WORKFORCE BY SEX AND RACE/ETHNICITY



Source: NWLC calculations based on IPUMS-CPS (2013). Figures are for employed workers.

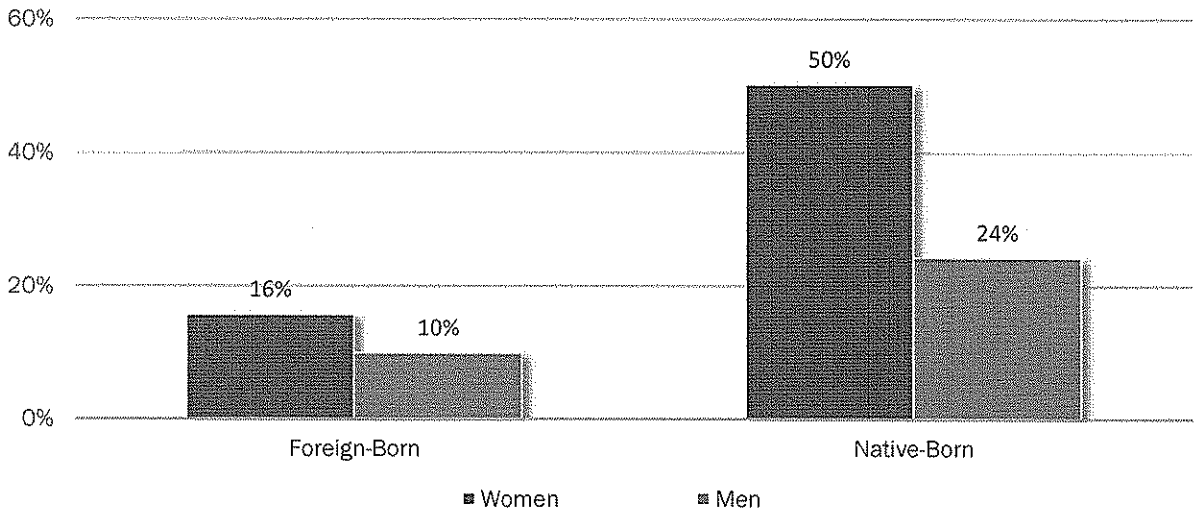
NATIONAL WOMEN'S LAW CENTER
www.nwlc.org

FOREIGN- AND NATIVE-BORN WORKERS

Both foreign-born and native-born women account for larger shares of the low-wage workforce than their male counterparts, even though these women make up similar or smaller shares of the overall workforce than their male counterparts.[25]

- Foreign-born women's share of the low-wage workforce (15.7 percent) is 1.6 times larger than foreign-born men's share of the low-wage workforce (9.9 percent)—though foreign-born women make up a smaller share of the overall workforce (6.9 percent) than do foreign-born men (9.5 percent).
- Native-born women's share of the low-wage workforce (50.2 percent) is double that of native-born men's (24.2 percent)—though native-born women's share of the overall workforce (40.5 percent) is similar to native-born men's (43.2 percent).

FIGURE 7A: THE LOW-WAGE WORKFORCE BY SEX AND FOREIGN-/NATIVE-BORN



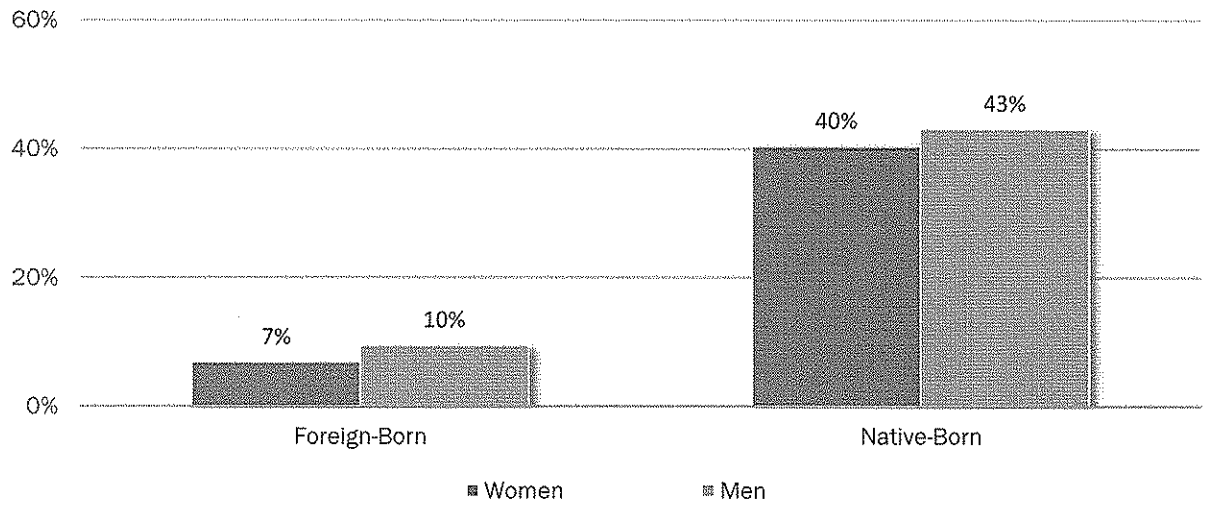
Source: NWLC calculations based on IPUMS-CPS (2013). Figures are for employed workers. The low-wage workforce is defined here as occupations with median wages of $10.10 or less per hour based on BLS, Occupational Employment Statistics.

NATIONAL WOMEN'S LAW CENTER
www.nwlc.org

Relative to their shares of the overall workforce, foreign- and native-born women are both overrepresented in the low-wage workforce, while foreign-born men are equally represented and native-born men are underrepresented.

- Foreign-born women's share of the low-wage workforce (15.7 percent) is more than double their share of the overall workforce (6.9 percent). Foreign-born men's shares of the low-wage and overall workforces are essentially the same (9.9 percent v. 9.5 percent).
- Native-born women's share of the low-wage workforce (50.2 percent) is 1.2 times larger than their share of the overall workforce (40.5 percent). Native-born men are underrepresented in the low-wage workforce: their share of the low-wage workforce (24.2 percent) is about half of their share of the overall workforce (43.2 percent).

FIGURE 7B: THE OVERALL WORKFORCE BY SEX AND FOREIGN-/NATIVE-BORN



Source: NWLC calculations based on IPUMS-CPS (2013). Figures are for employed workers.

NATIONAL WOMEN'S LAW CENTER
www.nwlc.org

A gender wage gap persists in the low-wage workforce

EVEN IN JOBS THAT TYPICALLY PAY JUST $10.10 PER HOUR OR LESS, WOMEN ARE PAID LESS THAN MEN.

- Women working full time, year round in low-wage jobs typically earn just 87 percent of what their male counterparts in the low-wage workforce earn.[26]
- Comparing women working full time, year round in low-wage jobs to white, non-Hispanic men working full time, year round in low-wage jobs:
  - White, non-Hispanic women make 88 percent of what white, non-Hispanic men make in the low-wage workforce.
  - African American women make 84 percent of what white, non-Hispanic men make in the low-wage workforce.
  - Hispanic women make 78 percent of what white, non-Hispanic men make in the low-wage workforce.
  - Asian, Hawaiian and/or Pacific Islander women make 92 percent of what white, non-Hispanic men make in the low-wage workforce.
  - American Indian/Alaska Native women make 92 percent of what white, non-Hispanic men make in the low-wage workforce.

FIGURE 8: GENDER WAGE GAPS IN THE LOW-WAGE WORKFORCE BY RACE AND ETHNICITY

Source: NWLC calculations based on IPUMS-CPS (2013). Figures are for full-time, year-round workers. The low-wage workforce is defined here as occupations with median wages of $10.10 or less per hour based on BLS, Occupational Employment Statistics.

NATIONAL WOMEN'S LAW CENTER
www.nwlc.org

Profile of women in the low-wage workforce

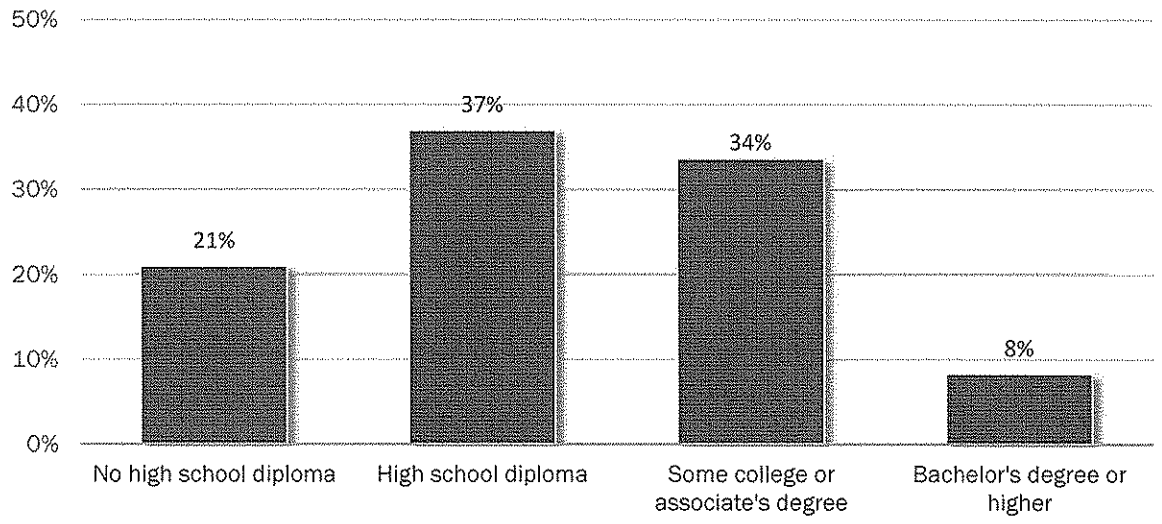
THE WOMEN WHO MAKE UP THE LOW-WAGE WORKFORCE MAY NOT BE WHO YOU THINK.

EDUCATIONAL ATTAINMENT

About four out of five women in the low-wage workforce have a high school degree or higher.

- About one in five (21.0 percent) lack a high school degree.
- Over one-third (37.0 percent) have only a high school degree.
- More than four in ten (42.0 percent) have some college or more.

FIGURE 9: FEMALE LOW-WAGE WORKFORCE BY EDUCATIONAL ATTAINMENT



Source: NWLC calculations based on IPUMS-CPS (2013). Figures are for employed workers. The low-wage workforce is defined here as occupations with median wages of $10.10 or less per hour based on BLS, Occupational Employment Statistics.

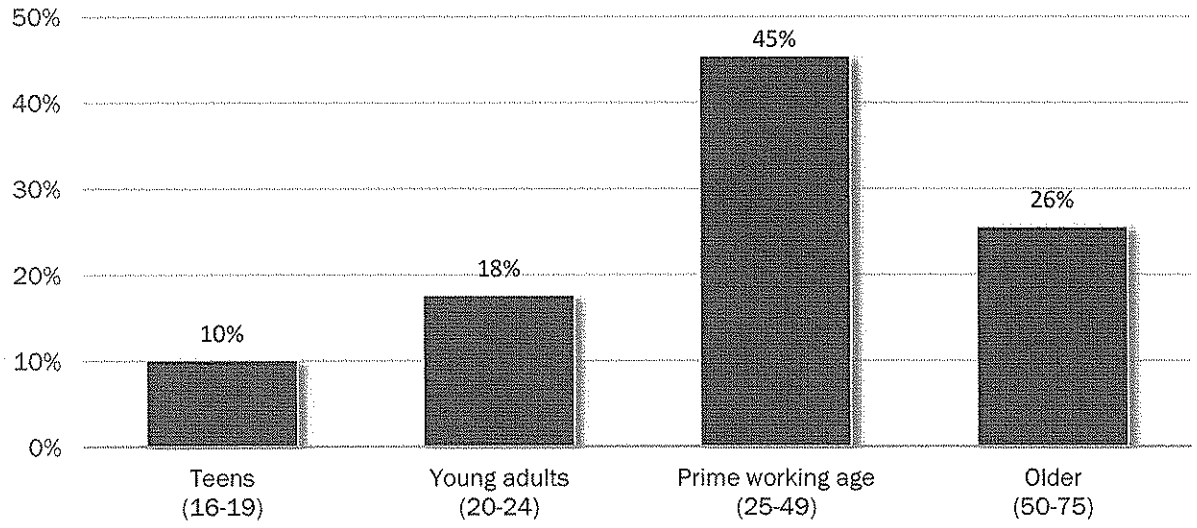
NATIONAL WOMEN'S LAW CENTER
www.nwlc.org

AGE

Nine out of ten women in the low-wage workforce are beyond their teens.

- Only one in ten (10.1 percent) are teens (16-19).
- Close to half (45.4 percent) are age 25-49.
- About one in four (25.6 percent) are age 50-75—about the same share as those age 16-24 (27.8 percent).
- Almost three in four (73.3 percent) are of reproductive age (16-49).

FIGURE 10: FEMALE LOW-WAGE WORKFORCE BY AGE



Source: NWLC calculations based on IPUMS-CPS (2013). Figures are for employed workers. The low-wage workforce is defined here as occupations with median wages of $10.10 or less per hour based on BLS, Occupational Employment Statistics.

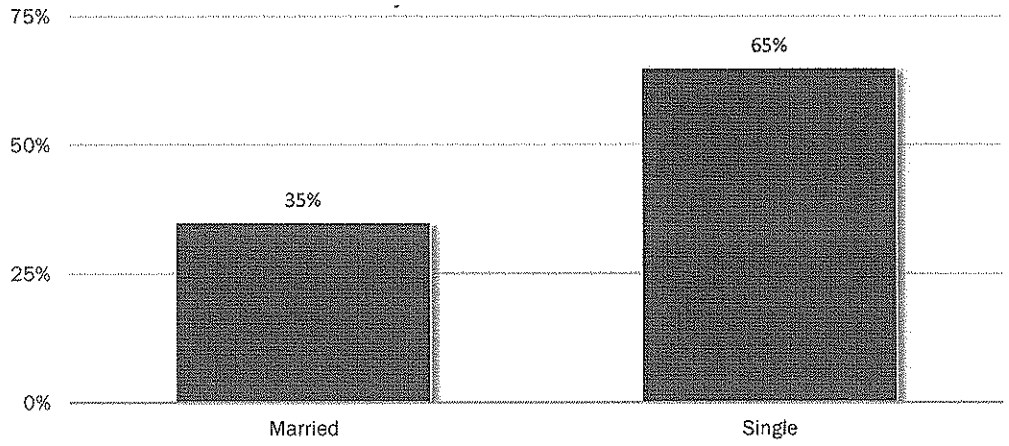
NATIONAL WOMEN'S LAW CENTER
www.nwlc.org

MARITAL STATUS

Most women in the low-wage workforce do not have a spouse's income to rely on.

- Two-thirds (65.0 percent) are single.

FIGURE 11: FEMALE LOW-WAGE WORKFORCE BY MARITAL STATUS



Source: NWLC calculations based on IPUMS-CPS (2013). Figures are for employed workers. The low-wage workforce is defined here as occupations with median wages of $10.10 or less per hour based on BLS, Occupational Employment Statistics.

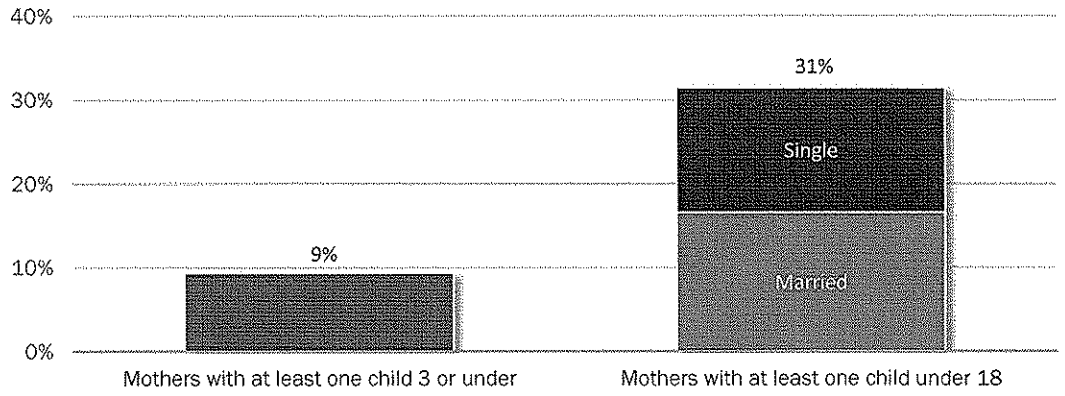
NATIONAL WOMEN'S LAW CENTER
www.nwlc.org

PARENTAL STATUS

Many women working in low-wage jobs are supporting children.

- Nearly one-third (31.5 percent) of women in the low-wage workforce are mothers of children under 18.
- Nearly half of these mothers (47.3 percent) are single.

FIGURE 12: FEMALE LOW-WAGE WORKFORCE BY PARENTAL STATUS



Source: NWLC calculations based on IPUMS-CPS (2013). Figures are for employed workers. The low-wage workforce is defined here as occupations with median wages of $10.10 or less per hour based on BLS, Occupational Employment Statistics. "Mothers" have related children at home.

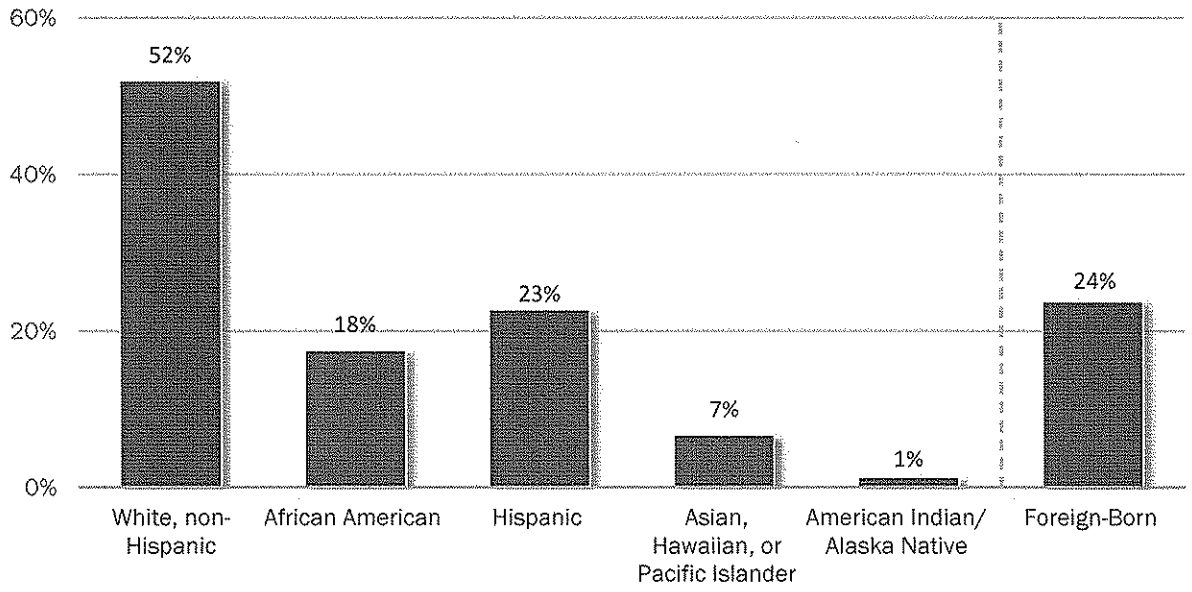
NATIONAL WOMEN'S LAW CENTER
www.nwlc.org

RACE, ETHNICITY, AND ORIGIN

Nearly half (48.0 percent) of women in the low-wage workforce are women of color.

- More than one in six (17.6 percent) are African American.
- Nearly one-quarter (22.8 percent) are Hispanic.
- 6.7 percent are Asian, Hawaiian and/or Pacific Islander.
- 1.3 percent are American Indian or Alaska Native.
- Nearly one-quarter (23.8 percent) are foreign born.[27]

FIGURE 13: FEMALE LOW-WAGE WORKFORCE BY RACE, ETHNICITY, AND ORIGIN



Source: NWLC calculations based on IPUMS-CPS (2013). Figures are for employed workers. The low-wage workforce is defined here as occupations with median wages of $10.10 or less per hour based on BLS, Occupational Employment Statistics.

NATIONAL WOMEN'S LAW CENTER
www.nwlc.org

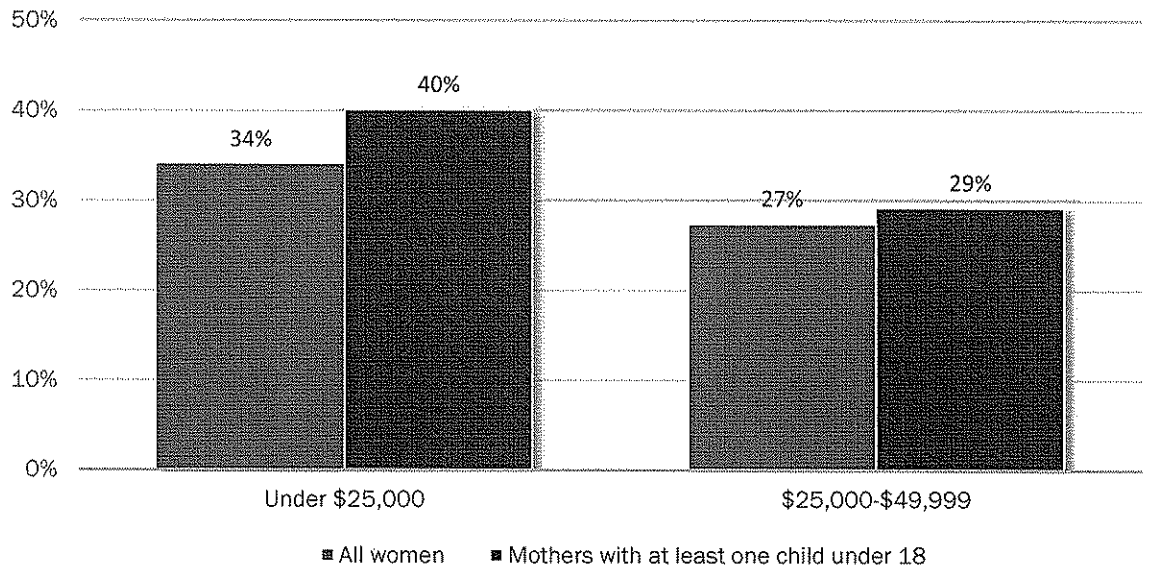
FAMILY INCOME

Nearly one in five women (19.1 percent) in the low-wage workforce is poor,[28] and family income[29] for mothers in the low-wage workforce is even lower than for women working in low-wage jobs overall.

- Among all women in the low-wage workforce:
  - One-third (34.0 percent) live in families with incomes of less than $25,000.
  - Median family income is $37,690.
  - More than six in ten (61.4 percent) live in families with incomes of less than $50,000.

- Among mothers in the low-wage workforce with children under 18:
  - Four in ten (40.1 percent) live in families with incomes of less than $25,000.
  - Median family income is $31,000.
  - Nearly seven in ten (69.3 percent) live in families with incomes of less than $50,000.

FIGURE 14: FEMALE LOW-WAGE WORKFORCE BY FAMILY INCOME



Source: NWLC calculations based on IPUMS-CPS (2013). Figures are for employed workers. The low-wage workforce is defined here as occupations with median wages of $10.10 or less per hour based on BLS, Occupational Employment Statistics. "Mothers" have related children at home.

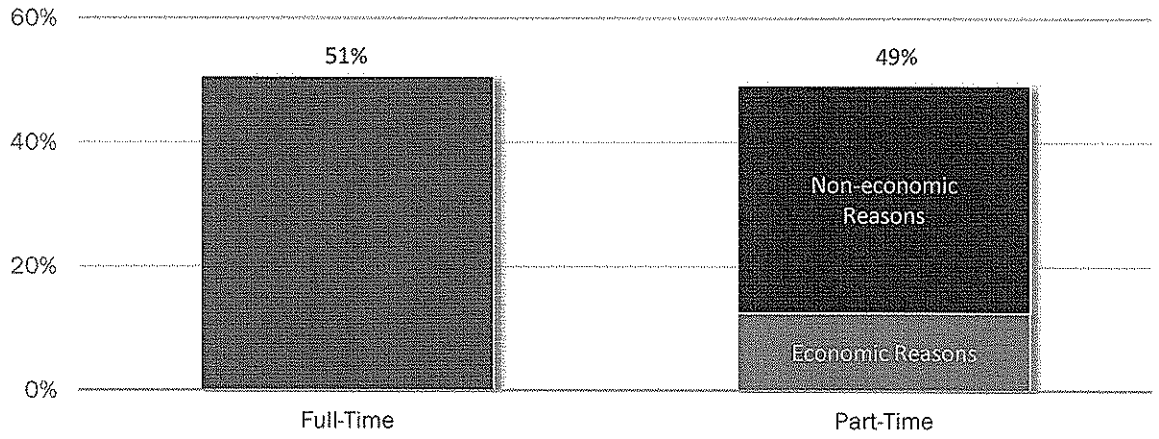
www.nwlc.org

FULL- AND PART-TIME STATUS

Half of women in the low-wage workforce work full time,[30] and a large majority work all year.

- Half (50.7 percent) of women in the low-wage workforce work full time (35 hours per week or more).
- Among the half who work part time:
  - One-quarter (25.5 percent) work part time for economic reasons, including reasons of slack work, current business conditions, and inability to find full-time work.[31]
  - Three-quarters (74.5 percent) work part time for non-economic reasons, including because they are also in school or training, have other family obligations, or have health limitations.[32]
  - Part-time low-wage workers typically work 20 hours per week.
- Among all women in the low-wage workforce, both full-time and part-time workers, the median workweek is 32 hours.

FIGURE 15: FEMALE LOW-WAGE WORKFORCE BY FULL-/PART-TIME STATUS



Source: NWLC calculations based on IPUMS-CPS (2013). Figures are for employed workers. The low-wage workforce is defined here as occupations with median wages of $10.10 or less per hour based on BLS, Occupational Employment Statistics.

NATIONAL WOMEN'S LAW CENTER
www.nwlc.org

Women in the low-wage workforce by state

WOMEN ARE OVERREPRESENTED IN THE LOW-WAGE WORKFORCE IN EVERY STATE.

- Women are a large majority (about six in ten or more) of the low-wage workforce in every state and the District of Columbia, even though they are half or less of the overall workforce in all 50 states.[33]
  - In ten states women are more than 70 percent of the low-wage workforce: Indiana, Wyoming, New Hampshire, Ohio, Alabama, South Carolina, Maine, Louisiana, Mississippi, and West Virginia.

FIGURE 16: WOMEN'S SHARE OF LOW-WAGE WORKFORCE, STATE BY STATE

	Low-Wage Workforce			Overall Workforce		
State	Total Number	Number of Women	Women's Share	Total Number	Number of Women	Women's Share
United States	*19,889,200*	*13,103,500*	*65.9%*	*142,593,300*	*67,486,200*	*47.3%*
Alabama	263,800	188,900	71.6%	2,035,100	962,600	47.3%
Alaska	41,500	28,200	68.0%	359,500	162,800	45.3%
Arizona	381,800	248,600	65.1%	2,755,500	1,280,600	46.5%
Arkansas	178,100	123,200	69.2%	1,258,600	598,600	47.6%
California	2,566,800	1,582,800	61.7%	16,757,200	7,657,200	45.7%
Colorado	317,000	206,000	65.0%	2,534,700	1,170,500	46.2%
Connecticut	228,600	157,800	69.0%	1,771,200	860,600	48.6%
Delaware	55,600	37,500	67.4%	425,200	209,400	49.2%
District of Columbia	33,100	20,000	60.4%	312,000	160,100	51.3%
Florida	1,242,900	815,500	65.6%	8,279,500	3,980,300	48.1%
Georgia	548,600	376,100	68.6%	4,339,800	2,058,300	47.4%
Hawaii	110,300	68,700	62.3%	681,400	317,200	46.6%
Idaho	104,200	65,300	62.7%	703,000	323,600	46.0%
Illinois	802,400	534,100	66.6%	6,043,500	2,890,100	47.8%
Indiana	404,800	283,600	70.1%	2,982,500	1,421,500	47.7%
Iowa	223,700	155,300	69.4%	1,563,800	749,400	47.9%
Kansas	187,900	127,400	67.8%	1,411,700	665,600	47.1%
Kentucky	257,300	176,100	68.4%	1,874,500	892,500	47.6%
Louisiana	289,000	208,800	72.2%	2,011,400	960,600	47.8%
Maine	91,300	65,700	72.0%	650,700	320,400	49.2%
Maryland	341,500	236,000	69.1%	2,951,600	1,460,400	49.5%
Massachusetts	420,300	283,500	67.5%	3,299,000	1,625,500	49.3%
Michigan	630,600	435,400	69.0%	4,274,200	2,089,700	48.9%
Minnesota	371,700	253,000	68.1%	2,751,500	1,330,100	48.3%
Mississippi	171,700	124,100	72.3%	1,216,500	588,000	48.3%
Missouri	386,000	263,400	68.2%	2,796,900	1,356,700	48.5%
Montana	72,700	50,000	68.8%	479,900	228,800	47.7%
Nebraska	135,800	91,100	67.1%	954,300	454,100	47.6%
Nevada	269,000	158,200	58.8%	1,248,700	573,200	45.9%
New Hampshire	81,600	57,200	70.1%	695,800	335,000	48.1%
New Jersey	513,400	332,500	64.8%	4,229,200	2,005,400	47.4%
New Mexico	137,000	89,500	65.3%	891,600	422,700	47.4%
New York	1,333,900	883,600	66.2%	9,098,700	4,413,200	48.5%
North Carolina	583,700	407,200	69.8%	4,339,600	2,069,200	47.7%
North Dakota	57,000	38,400	67.4%	369,100	170,400	46.2%
Ohio	733,400	518,700	70.7%	5,309,100	2,583,100	48.7%
Oklahoma	234,400	163,300	69.7%	1,714,000	794,000	46.3%
Oregon	271,200	176,100	64.9%	1,745,200	835,300	47.9%
Pennsylvania	803,300	561,800	69.9%	5,941,900	2,862,700	48.2%
Rhode Island	76,800	51,500	67.1%	515,100	256,800	49.9%
South Carolina	283,600	203,900	71.9%	2,034,000	978,800	48.1%
South Dakota	61,700	41,300	66.9%	417,400	198,400	47.5%
Tennessee	369,000	255,400	69.2%	2,832,400	1,347,500	47.6%
Texas	1,569,200	1,064,400	67.8%	11,546,900	5,243,800	45.4%
Utah	149,300	97,000	65.0%	1,269,200	563,800	44.4%
Vermont	45,500	30,500	67.0%	330,500	161,300	48.8%
Virginia	470,000	326,600	69.5%	3,987,400	1,898,100	47.6%
Washington	446,200	294,100	65.9%	3,204,700	1,485,900	46.4%
West Virginia	114,100	82,500	72.3%	764,000	361,800	47.4%
Wisconsin	398,400	271,900	68.2%	2,860,000	1,384,000	48.4%
Wyoming	38,100	26,700	70.1%	291,200	131,000	45.0%

Source: NWLC calculations for national data based on IPUMS-CPS (2013) and for state data based on IPUMS-ACS (2008-2012) five-year averages. Figures are for employed workers. The low-wage workforce is defined here as occupations with median wages of $10.10 or less per hour based on BLS, Occupational Employment Statistics.

NATIONAL WOMEN'S LAW CENTER
www.nwlc.org

IN NEARLY ALL STATES, THE LIKELIHOOD THAT A FEMALE WORKER WILL BE IN A LOW-WAGE JOB IS AT LEAST TWICE THAT OF A MALE WORKER.

- The share of women workers who are in the low-wage workforce is at least twice as large as the share of male workers who are in the low-wage workforce in all but three states (Nevada, Hawaii, and California) and the District of Columbia—and even in these jurisdictions, the share of working women in the low-wage workforce is at least 1.5 times that of men.
- The share of working women in the low-wage workforce is more than 2.5 times larger than the share of working men in nine states: Indiana, Maine, Oklahoma, South Carolina, Mississippi, Alabama, Wyoming, Louisiana, and West Virginia.
- The states with the largest gender disparity between women and men in the low-wage workforce are West Virginia and Louisiana. In West Virginia the share of working women who are in low-wage occupations (22.8 percent) is 2.9 times the share of working men in low-wage occupations (7.8 percent).

FIGURE 17: SHARE OF WORKERS WHO ARE LOW-WAGE, STATE BY STATE

	Women			Men			
State	Number Overall	Number Low-Wage	Share Low-Wage	Number Overall	Number Low-Wage	Share Low-Wage	Likelihood a female worker is low-wage compared to a male worker
United States	*67,486,200*	*13,103,500*	*19.4%*	*75,107,200*	*6,785,700*	*9.0%*	*2.1*
Alabama	962,600	188,900	19.6%	1,072,400	75,000	7.0%	2.8
Alaska	162,800	28,200	17.3%	196,700	13,400	6.8%	2.5
Arizona	1,280,600	248,600	19.4%	1,474,800	133,300	9.0%	2.1
Arkansas	598,600	123,200	20.6%	660,000	54,800	8.3%	2.5
California	7,657,200	1,582,800	20.7%	9,100,000	983,900	10.8%	1.9
Colorado	1,170,500	206,000	17.6%	1,364,200	111,000	8.1%	2.2
Connecticut	860,600	157,800	18.3%	910,500	70,800	7.8%	2.4
Delaware	209,400	37,500	17.9%	215,800	18,200	8.4%	2.1
District of Columbia	160,100	20,000	12.5%	151,900	13,000	8.6%	1.5
Florida	3,980,300	815,500	20.5%	4,299,100	427,400	9.9%	2.1
Georgia	2,058,300	376,100	18.3%	2,281,600	172,400	7.6%	2.4
Hawaii	317,200	68,700	21.7%	364,300	41,700	11.4%	1.9
Idaho	323,600	65,300	20.2%	379,500	38,900	10.3%	2.0
Illinois	2,890,100	534,100	18.5%	3,153,400	268,300	8.5%	2.2
Indiana	1,421,500	283,600	20.0%	1,561,000	121,100	7.8%	2.6
Iowa	749,400	155,300	20.7%	814,400	68,400	8.4%	2.5
Kansas	665,600	127,400	19.1%	746,100	60,500	8.1%	2.4
Kentucky	892,500	176,100	19.7%	982,000	81,200	8.3%	2.4
Louisiana	960,600	208,800	21.7%	1,050,800	80,100	7.6%	2.9
Maine	320,400	65,700	20.5%	330,300	25,600	7.8%	2.6
Maryland	1,460,400	236,000	16.2%	1,491,200	105,600	7.1%	2.3
Massachusetts	1,625,500	283,500	17.4%	1,673,400	136,800	8.2%	2.1
Michigan	2,089,700	435,400	20.8%	2,184,500	195,200	8.9%	2.3
Minnesota	1,330,100	253,000	19.0%	1,421,400	118,700	8.4%	2.3
Mississippi	588,000	124,100	21.1%	628,500	47,600	7.6%	2.8
Missouri	1,356,700	263,400	19.4%	1,440,200	122,600	8.5%	2.3
Montana	228,800	50,000	21.9%	251,200	22,800	9.1%	2.4
Nebraska	454,100	91,100	20.1%	500,100	44,700	8.9%	2.2
Nevada	573,200	158,200	27.6%	675,500	110,900	16.4%	1.7
New Hampshire	335,000	57,200	17.1%	360,700	24,400	6.8%	2.5
New Jersey	2,005,400	332,500	16.6%	2,223,800	180,800	8.1%	2.0
New Mexico	422,700	89,500	21.2%	468,900	47,600	10.2%	2.1
New York	4,413,200	883,600	20.0%	4,685,500	450,300	9.6%	2.1
North Carolina	2,069,200	407,200	19.7%	2,270,400	176,600	7.8%	2.5
North Dakota	170,400	38,400	22.5%	198,600	18,600	9.4%	2.4
Ohio	2,583,100	518,700	20.1%	2,726,100	214,700	7.9%	2.5
Oklahoma	794,000	163,300	20.6%	920,000	71,200	7.7%	2.7
Oregon	835,300	176,100	21.1%	909,900	95,100	10.5%	2.0
Pennsylvania	2,862,700	561,800	19.6%	3,079,200	241,500	7.8%	2.5
Rhode Island	256,800	51,500	20.1%	258,300	25,300	9.8%	2.0
South Carolina	978,800	203,900	20.8%	1,055,200	79,700	7.6%	2.8
South Dakota	198,400	41,300	20.8%	219,100	20,400	9.3%	2.2
Tennessee	1,347,500	255,400	19.0%	1,485,000	113,600	7.6%	2.5
Texas	5,243,800	1,064,400	20.3%	6,303,100	504,800	8.0%	2.5
Utah	563,800	97,000	17.2%	705,300	52,300	7.4%	2.3
Vermont	161,300	30,500	18.9%	169,200	14,900	8.8%	2.1
Virginia	1,898,100	326,600	17.2%	2,089,300	143,400	6.9%	2.5
Washington	1,485,900	294,100	19.8%	1,718,900	152,200	8.9%	2.2
West Virginia	361,800	82,500	22.8%	402,200	31,500	7.8%	2.9
Wisconsin	1,384,000	271,900	19.6%	1,476,000	126,500	8.6%	2.3
Wyoming	131,000	26,700	20.4%	160,200	11,500	7.2%	2.8

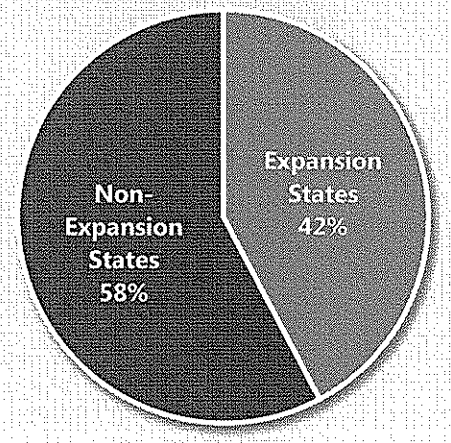
Source: NWLC calculations for national data based on IPUMS-CPS (2013) and for state data based on IPUMS-ACS (2008-2012) five-year averages. Figures are for employed workers. The low-wage workforce is defined here as occupations with median wages of $10.10 or less per hour based on BLS, Occupational Employment Statistics.

NATIONAL WOMEN'S LAW CENTER
www.nwlc.org

Low-income women and health insurance eligibility through Medicaid under the ACA

THE AFFORDABLE CARE ACT (ACA), AS ENACTED, REQUIRED STATES TO EXPAND HEALTH INSURANCE COVERAGE through the Medicaid program by covering all individuals with incomes below 138 percent of the Federal Poverty Level (FPL), with the federal government covering nearly all of the states' costs. This important expansion would have extended health coverage to more than seven million women, including many women working in low-wage jobs, as defined in this report. The Supreme Court, however, determined that states could choose whether or not to expand coverage through Medicaid,[34] with the effect of severely limiting—for now—the ACA's ability to improve low-income women's access to the health and economic security that health insurance provides. As of this writing, the majority of states have chosen to expand coverage, but the majority of low-income women who were not eligible for Medicaid coverage before the ACA live in states that have not yet chosen to expand coverage.

FIGURE 18: WOMEN POTENTIALLY ELIGIBLE FOR MEDICAID



Source: Kaiser Family Foundation and Urban Institute.

NATIONAL WOMEN'S LAW CENTER
www.nwlc.org

FIGURE 19: MEDICAID IN THE STATES*

EXPANSION STATES

State	Number of women newly eligible through Medicaid
Arizona	45,000
Arkansas	106,000
California	856,000
Colorado	98,000
Connecticut	37,000
Delaware	4,000
District of Columbia	7,000
Hawaii	14,000
Illinois	219,000
Iowa	48,000
Kentucky	139,000
Maryland	70,000
Massachusetts	34,000
Michigan	247,000
Minnesota	51,000
Nevada	78,000
New Hampshire	24,000
New Jersey	140,000
New Mexico	61,000
New York	80,000
North Dakota	12,000
Ohio	256,000
Oregon	119,000
Rhode Island	16,000
Vermont	N/A
Washington	134,000
West Virginia	66,000
Wisconsin**	70,000
Total	2,961,000

NON-EXPANSION STATES

State	Number of women potentially newly eligible through Medicaid expansion
Alabama	156,000
Alaska	19,000
Florida	613,000
Georgia	342,000
Idaho	51,000
Indiana	177,000
Kansas	67,000
Louisiana	176,000
Maine	20,000
Mississippi	114,000
Missouri	173,000
Montana	29,000
Nebraska	36,000
North Carolina	277,000
Oklahoma	108,000
Pennsylvania	241,000
South Carolina	140,000
South Dakota	20,000
Tennessee	159,000
Texas	903,000
Utah	46,000
Virginia	169,000
Wyoming	13,000
Total	4,045,000

* "The ACA expands Medicaid to nearly all individuals with incomes at or below 138% FPL ($16,104 for an individual or $27,310 for a family of three in 2014)." THE KAISER COMMISSION ON MEDICAID AND THE UNINSURED, KAISER FAMILY FOUNDATION, WHERE ARE STATES TODAY? MEDICAID AND CHIP ELIGIBILITY LEVELS FOR CHILDREN AND NON-DISABLED ADULTS AS OF APRIL 1, 2014 (June 2014), *available at* http://kaiserfamilyfoundation.files.wordpress.com/2014/06/7993-05-where-are-states-today-fact-sheet-june-2014.pdf.

** Wisconsin has expanded coverage to all individuals with incomes below 138 percent of FPL using different statutory authority.

Source: Kaiser Family Foundation, Status of State Action on the Medicaid Expansion Decision, 2014, http://kff.org/health-reform/state-indicator/state-activity-around-expanding-medicaid-under-the-affordable-care-act/ (as of June 10, 2014); Genevieve M. Kenney et al., Opting in to the Medicaid Expansion under the ACA: Who Are the Uninsured Adults Who Could Gain Health Insurance Coverage?, TIMELY ANALYSIS OF IMMEDIATE HEALTH POL'Y ISSUES, Aug. 2012, *available at* http://www.urban.org/UploadedPDF/412630-opting-in-medicaid.pdf; Kaiser Family Foundation, Adult Income Eligibility Limits at Application as a Percent of the Federal Poverty Level (FPL), January 2013, http://kff.org/medicaid/state-indicator/income-eligibility-low-income-adults/.

www.nwlc.org

Addressing the challenges facing women in low-wage jobs

BECAUSE WOMEN MAKE UP THE LARGE MAJORITY OF WORKERS IN LOW-WAGE JOBS, addressing the needs of low-wage workers requires addressing the needs of women. Moreover, given women's overrepresentation in low-wage jobs, a women's economic agenda must take particular account of low-wage workers' needs for improved pay, working conditions, and work supports. Recent disproportionate growth in low-wage jobs and the economy's increasing reliance on the low-wage workforce adds urgency to these efforts. Public policies that increase wages and economic security, support workers with family responsibilities, remove persistent barriers to opportunity, create pathways to opportunity, and strengthen opportunities for collective action empower workers across the income spectrum, and are especially critical for women in low-wage jobs.

INCREASING WAGES AND ECONOMIC SECURITY

Most women in low-wage jobs struggle to make ends meet. As this report shows, nearly one in five is poor, and more than one in three live in families with incomes below $25,000 a year. For mothers in the low-wage workforce, the situation is worse. Four in ten live in families with incomes of less than $25,000, and nearly seven in ten have family incomes below $50,000 a year.

A survey of workers earning less than $14 per hour found that two-thirds worried about being able to afford housing (67 percent) and healthy food (65 percent). Even larger majorities worried about having health expenses they cannot afford (82 percent) and not having enough money for retirement (83 percent).[35] Despite these challenges, low-wage workers hope for a better future for their children: eight in ten said it is important that their children graduate from college.[36]

However, with wages of $10.10 per hour or less, parents often cannot afford to ensure their children's basic needs are met, much less invest in their children's futures. Indeed, a recent study estimated that two parents must each earn at least $16.79 an hour to provide economic stability in a family with two children.[37] Thus, ensuring basic economic security for low-wage workers and their families will require a combination of higher wages; cash income supports; assistance to meet critical needs such as health insurance, nutrition, and housing; and increased retirement security.

Given women's overrepresentation in low-wage jobs, a women's economic agenda must take particular account of low-wage workers' needs for improved pay, working conditions, and work supports.

Federal, state, and local governments should set reasonable basic labor standards by **raising the minimum wage and the minimum cash wage for tipped workers** (or eliminating the lower minimum cash wage for tipped workers entirely). Employers also have a responsibility to pay fair wages that includes, but goes beyond, compliance with the law; employers should recognize that employees are a resource, not just an expense, and that a fairly compensated workforce is more stable and productive.[38]

Raising the minimum wage—for example, to at least $10.10 per hour—would increase the cash income of low-wage workers and reduce poverty,[39] but still fall short of what families need to achieve real economic security. Protecting and **improving refundable tax credits**, such as the Earned Income Tax Credit (EITC) and Child Tax Credit (CTC), would lift additional families out of poverty.[40] Low-wage work is unstable, and loss of a job can

quickly push a family to the breaking point; **strengthening unemployment insurance and Temporary Assistance for Needy Families** would provide cash support to help families avoid hunger and homelessness when they lose a job or cannot find work.

But low-wage workers need more than cash resources. They also need **affordable, comprehensive health insurance**—a benefit employers rarely provide to low-wage workers.

Firms that employ large shares of low-wage workers are significantly less likely to offer health benefits than other firms, with only 23 percent of firms with large shares of low-wage workers offering health benefits to their employees.[41] Only 29 percent of non-elderly individuals with household incomes below 200 percent of the federal poverty guidelines hold insurance through an employer.[42]

As enacted, the Affordable Care Act (ACA) would have filled this gap for low-income workers through a combination of tax credits to purchase private insurance and expanded Medicaid eligibility. However, in the wake of the Supreme Court decision that allowed states to opt out of expanding Medicaid coverage, the refusal of 24 states to expand coverage has left more than three million low-income women without health insurance.[43] This gap in coverage leaves some low-wage workers without coverage for critical benefits like physician visits, prescription drugs, birth control, and maternity care, which poses real risks for their health and well-being.[44] For example, low-income women without health insurance report going without needed care because of cost 2.5 times as often as low-income women with health insurance.[45]

For those low-wage workers purchasing health insurance, even with the assistance of the ACA's tax credits for health insurance premiums health care costs can be heavy. For example, a woman making $29,000, who qualifies for a premium tax credit, would still pay over eight percent of her income in health care premiums.[46] In addition, she would face the full cost of applicable deductibles, co-payments, and co-insurance, which can amount to thousands of dollars. With plans at the most popular level offering a median annual deductible of $2,500, this woman could pay over 16 percent of her income in health care expenses.[47]

Access to reproductive health care is a critical economic issue for women in low-wage jobs

Women in low-wage jobs need access to affordable health insurance, and roughly 3.5 million women have purchased subsidized coverage in the new health care marketplace.[48] But approximately 3.9 million individuals—largely low-income women and their families—are left without this help, because of a provision known as the "family glitch."[49] Under the Affordable Care Act, as long as required employee contributions for worker-only coverage meet the ACA's affordability test, all members of the family are ineligible for financial assistance in the health insurance marketplace—even if family coverage through the employer costs far more. As a result, family members caught in this "glitch" will have to pay, on average, 14 percent of their income to purchase employer coverage.[50] Ending the "family glitch"—allowing spouses and children to access marketplace subsidies for health insurance—would make it easier for women to maintain health coverage for themselves and their families.

Access to reproductive health care is also a critical economic issue for women in low-wage jobs. The Supreme Court recently ruled that certain companies can refuse to provide insurance coverage of birth control, as otherwise required by federal law.[51] Low-wage workers at these companies may now face a significant barrier to their ability to prevent, plan, or space pregnancies. This not only could mean that low-wage workers miss out on opportunities to advance their education and employment in order to move beyond low-wage jobs,[52] but could also result in an increased need for abortion services, a need already disproportionately high among low-wage workers.[53] Yet accessing abortion is increasingly difficult, since restrictive federal and state laws force women to raise their own money for the procedure and to visit the clinic multiple times, which requires them to arrange time off work, transportation, child care, and lodging.[54] These barriers are difficult for any woman, but especially for low-wage workers who have little control over their work schedules and little ability to absorb extra costs. These barriers can push a low-wage worker seeking an abortion later into pregnancy, increasing risks of complications and threats to her health. Much work remains to ensure that women are able to meet their reproductive

health care needs, including supporting critical publicly funded family planning programs, overturning federal and state restrictions on federal coverage of abortion, and rejecting attempts to restrict women's access to reproductive health care.

To improve affordability of health insurance and health care services for women in low-wage jobs and their families, the 24 states that have not yet expanded coverage through Medicaid must do so immediately so that low-income women can enjoy the financial stability that health insurance confers—and access the health care services they need. Policymakers should also enhance funding for tax credits and cost-sharing reductions for low-income workers and their families and fix the "family glitch."

Health insurance is only one of the basic expenses low-wage workers struggle to meet. Strengthening programs that provide **nutrition and housing assistance** to low-income families would help them afford nutritious food and safe and stable housing.

Retirement security is another serious concern for low-wage workers, who are less likely than other workers to participate in a retirement plan at work. Among workers making less than $10,000 a year, only seven percent participate in an employer-offered plan; among workers earning between $10,000 and $20,000 a year, only 16 percent participate.[55] Nearly half of women working in low-wage jobs work part time, but even employers who offer retirement plans are not required to include part-time workers in the plan.[56] Just 18 percent of part-time, full-year workers participate in employer-offered retirement plans, compared to 51 percent of full-time, full-year workers.[57]

Employers that offer retirement plans should be required to extend coverage to steady part-time workers. For workers whose employers do not offer retirement plans, improving the Saver's tax credit for low- and moderate-income taxpayers who contribute to a retirement plan, making it refundable, and coupling that change with the creation of new, low-cost savings options, would help low-wage workers save for retirement. **Improving Social Security benefits** is also a key strategy to increase low-wage workers' retirement security, because coverage under Social Security is nearly universal, and benefits are secure and life-long.

SUPPORTING WORKERS WITH FAMILY RESPONSIBILITIES

Women's wages are crucial to low-income families. In families in the bottom 20 percent of the income distribution, nearly 70 percent of working wives are either the primary breadwinner or share that responsibility equally with their partners.[58] And nearly half of mothers with at least one child under 18 in the low-wage workforce are single (47.3 percent)—compared to less than one-third of mothers in the overall workforce (31.1 percent).[59] In part because they are less likely to have partners who can share family caregiving responsibilities,[60] women working in low-wage jobs disproportionately shoulder these responsibilities. But for women in low-wage jobs, work and family are often on a collision course. Many struggle with employment practices that shift the risk of doing business onto workers and that make it difficult for workers to meet obligations outside of their jobs. Single mothers not only often experience the crunch between work and family most acutely, but also frequently have very few resources to pay for supports like child care: nearly half of single working mothers have family incomes in the lowest quintile.[61]

Work scheduling practices in many low-wage jobs profoundly complicate caregiving and impose severe stress on families and children.[62] For example, just-in-time scheduling, which involves giving workers their schedules with very little notice to try to match labor costs to consumer demand, results in extreme unpredictability for workers.[63] Unstable work hours in turn result in variable and uncertain incomes.[64] Low-wage jobs often require working evenings, weekends, and even overnight, which can be very hard on families.[65] Yet, many workers are unable to ask for even minor adjustments to their work schedules without suffering retaliation, often in the form of reduced hours.[66]

Workers in low-wage jobs already have difficulty affording **child care**. Nearly one in five working mothers of very young children (age three and under) work in low-wage jobs, and finding and affording care for infants and toddlers is particularly difficult.[67] Scheduling challenges compound the hurdles they confront. Sudden reductions in work hours can leave them with even less income than expected and put the cost of care further out of reach. Child care assistance can help workers afford child care, but is sharply limited—only one in six eligible children

receives federal child care assistance.[68] Some workers may find it particularly difficult to qualify for child care assistance due to fluctuations in work hours that keep them from meeting minimum work requirements. Unpredictable schedules and jobs that often require working evenings, nights, and weekends can also make it difficult to find child care. As a result, many women in low-wage jobs rely on family, friends, and neighbors for child care, because it is often the most affordable, flexible, and accessible option. While parents frequently feel most comfortable with a family member, friend, or neighbor they know and trust, others would prefer another child care option if they could manage it.

Employers should be required to provide advance notice of work schedules, disclose the minimum number of hours that employees can expect to work, and ensure that workers can request schedule changes without fear of retaliation.

Currently, child care investments are sorely insufficient. Increased federal and state investments in child care and early education are essential. In addition, several policy changes and initiatives would better reflect the workplace realities for women in low-wage jobs. Supporting full-day preschool for all children, starting with those in low-income families, would ensure that children have access to high-quality early learning opportunities, regardless of their parents' work schedules. Other policies that would address the needs of these workers include: targeting funding to support child care providers offering care during nights and weekends; allowing families to qualify for child care assistance based on the average number of hours worked over a month or longer period, rather than based on the hours worked during a particular day or week; providing child care assistance to parents who work overnight shifts to cover care for both their work hours and sleep time during the day; allowing parents to maintain child care assistance for slots in child care programs even when their work hours do not precisely match the hours of care; and supporting outreach and quality improvement efforts for informal child care providers.

Abusive scheduling practices that make it difficult to impossible to maintain stable child care must also be curbed. Workers who report to work and are sent home should receive a minimum number of hours of pay. Employers should be required to provide advance notice of work schedules, disclose the minimum number of hours that employees can expect to work, ensure that workers can request schedule changes without fear of retaliation, and provide some premium pay to workers required to work especially onerous shifts—such as split shifts, extremely long shifts, or shifts assigned with little to no notice. In addition, enforcement agencies should better enforce current laws that protect workers from abusive scheduling practices.

A lack of **paid sick days** and **paid family leave** compounds the difficulties faced by workers with family responsibilities. Of workers in occupations that are in the bottom 10 percent of the average wage distribution, only 21 percent have access to paid sick days and a minuscule four percent have access to paid family leave.[69] As a result, taking a day off for a child's doctor's appointment can end up costing a worker her job. Guaranteeing all workers access to paid sick days and paid leave is crucial to ensuring that workers can afford to take time off when they need to care for their families.

States have paved the road forward in many of these areas,[70] and Congress should follow suit. Federal contractors employ a large number of low-wage workers, and the administration should also lead by example by providing a leg up to federal contractors that have strong policies in all of these areas.

REMOVING BARRIERS TO OPPORTUNITY

Women who earn low wages can least afford to have their livelihoods threatened by discrimination. Yet sex discrimination is often particularly blatant in low-wage jobs, precisely because workers in these jobs typically lack power in the workplace and are therefore especially vulnerable to exploitation.[71]

More than 50 years after passage of the Equal Pay Act, **women are still typically paid only 77 cents for every dollar paid to men** for full-time, year-round work.[72] Women continue to be paid less for work in the same jobs as men,[73] and also continue to experience significant barriers to entering higher-paying jobs not traditionally held by women.[74] Instead, as this report shows, women remain clustered in low-paying jobs: the average percentage of

women in the 25 lowest-wage occupations is more than double the average percentage of women in the 25 highest-wage occupations.[75]

While women represent nearly half of the labor force, they remain wholly **underrepresented in traditionally-male occupations** and disproportionately clustered in jobs with lower pay and fewer benefits. For example, women make up only 2.6 percent of all employees in construction and extraction jobs.[76] Women of color are also severely underrepresented. White, non-Hispanic women make up the largest group of women in construction—2.0 percent of all construction workers in the construction industry.[77] Hispanic women constitute the next largest group at 0.4 percent, and then African American women are 0.2 percent.[78]

Some employers discriminate against women with caregiving responsibilities, based on the notion that women who have family responsibilities cannot also be good workers.

Even in the very lowest-paying jobs, two-thirds of which are held by women, women still experience a 13 percent wage gap compared to men in the same jobs.[79] Pay discrimination laws should be strengthened so that it is easier for women to find out when they are being paid less than their male counterparts without suffering retaliation, and to close loopholes that make it very difficult to hold employers responsible for pay discrimination. Comparable worth policies would also go a long way toward rectifying the devaluation of work that is done by women and closing the wage gap, as would raising the minimum wage and tipped minimum wage.

Sexual harassment of women in low-wage jobs runs the gamut from lewd remarks to sexual assault.[80] In one study of predominantly low-income union workers, 26 percent of women and 22 percent of men reported experiencing sexual harassment at work.[81] And women in low-wage jobs are particularly vulnerable to harassment because they especially cannot afford to risk losing their paycheck if they suffer retaliation for reporting the harassment. To address this problem, federal agencies must provide clear and strong guidance on employer obligations to prevent and remedy sexual harassment—including by proactively training all personnel with supervisory authority, routinely monitoring the workplace for any signs of harassment, providing effective complaint mechanisms, responding promptly and thoroughly to all harassment complaints, and addressing any retaliation against workers who report harassment. Legislation restoring protections against harassment by supervisors that were recently weakened by the Supreme Court would also help give women in these jobs tools to fight back.[82]

Women in low-wage jobs often do physically demanding work that may pose challenges for some women at some stages of pregnancy.[83] But these workers often face **discrimination based on pregnancy** if they have a medical need to sit on a stool during a very long shift, to stay off high ladders, or to avoid heavy lifting, for example. Too often when pregnant workers request temporary accommodations due to a medical limitation arising out of pregnancy, they have been fired, forced to quit, or pushed onto unpaid leave, even when their employers provide accommodations for medical limitations arising out of disability or injury.[84] Low-wage workplaces seem particularly likely to apply rigid work rules to force pregnant women off the job.[85] Heightened enforcement of laws prohibiting discrimination on the basis of pregnancy would help these workers, as would enhanced legal protections making it unmistakably clear that pregnant workers who need job modifications have the same rights to reasonable accommodations as workers with disabilities.[86] Additionally, once back at work, nursing mothers need break time and a private space to pump. These accommodations, though required by federal law, are not always available to them. Better enforcement of this requirement is essential.

Some employers **discriminate against women with caregiving responsibilities**, based on the notion that women who have family responsibilities cannot also be good workers.[87] For example, among full-time, year-round workers, mothers typically earn only 69 percent of what fathers earn,[88] and research shows that motherhood is often perceived as rendering a worker less committed and less valuable while fatherhood has the opposite effect.[89] To combat this problem, federal and state agencies must vigorously enforce existing prohibitions on sex-based caregiver discrimination. The federal government should

advise federal contractors on their obligations not to discriminate against workers with caregiving responsibilities based on gender stereotypes. States and localities should also vigorously enforce existing laws prohibiting discrimination on the basis of family responsibilities.

Immigrant women—who are overrepresented in the low-wage workforce—are particularly vulnerable to discrimination and other forms of exploitation, such as wage theft, because immigrant workers who suffer harassment or other forms of discrimination may feel that if they speak up they risk retaliation, including the threat of deportation.[90] As a result, immigrant workers can be trapped in abusive workplaces. The protections of nondiscrimination laws and basic labor standards need to be available to and enforced on behalf of all workers, including immigrants. In addition, immigrants need a path to citizenship. Comprehensive immigration reform is essential to honor the contributions that immigrant women are making to our economy and our nation.

CREATING PATHWAYS TO OPPORTUNITY

For women, it takes a bachelor's degree to avoid overrepresentation in low-wage jobs.[91] This fact highlights the importance of expanding women's access both to college and to higher-paying jobs that are nontraditional for women. But women remain underrepresented in education and workforce training programs that provide pathways to higher-wage jobs, and face many barriers to participation in these programs.[92]

For example, the rising cost of college education coupled with the recession has meant that postsecondary education is out of reach for many students unless they rely on student loans, which can mean taking on massive amounts of debt and devoting high percentages of their earnings to loan repayment.[93] This imposes a particular burden on women, who are paid less than men, even with a college degree.[94] Among full-time workers repaying their loans one year after college graduation, almost half of women were paying more than eight percent of their earnings towards student loan debt compared to about 40 percent of men.[95]

The **student debt crisis** must be addressed to ensure higher education is more accessible for women. Congress should expand Pell grants, which help low-income students attend college without burdening them with debt. In addition, Congress should pass legislation that would allow individuals with outstanding student loan debt to refinance at the lower interest rates currently offered to new borrowers. And federal agencies should simplify the student loan application process to make it more accessible to students.

Student parents face particular barriers to accessing and completing postsecondary education programs. Nearly half of student parents work full time while enrolled, in addition to shouldering caregiving responsibilities, which are heavier for enrolled mothers than for fathers.[96] Pregnant students are routinely denied the opportunity to make up work, forced to drop out of programs, or encouraged to change their plans because their schools refuse to meet even baseline legal requirements to provide accommodations for pregnancy-related medical conditions.[97]

One of the greatest barriers facing student parents is difficulty obtaining affordable, high-quality child care. Unfortunately, the need for child care is much greater than the supply of on-campus child care. Researchers estimate that "only 5 percent of the child care needed by student parents is supplied at on-campus child care centers."[98] It can take months or years on waiting lists to get a spot, especially for infants or toddlers, and centers that are able to provide care during evening or weekend hours are scarce. Parents may also be unable to receive assistance to help pay for off-campus child care. Many states set limits on child care assistance for parents in college, and some states do not provide any assistance for parents working toward a four-year degree.[99]

It does not have to be this way. The federal government should step up enforcement of legal protections for pregnant and parenting students and should increase funding to educational institutions to provide on-site child care, and states should allow parents in college to receive child care assistance.

Nontraditional fields, such as construction, typically offer women the opportunity to earn higher wages than traditionally-female fields.[100] But women's minuscule share in these fields is due in large part to discrimination that blocks women from entering and staying in **nontraditional jobs**. Gender stereotypes, which start in school and continue to plague women on the job, operate as a barrier to entering and succeeding in nontraditional careers. For example, research shows that women are rarely in the pool

of individuals considered for construction apprenticeship opportunities, which offer necessary education and training to access these jobs.[101] And when women participate in construction apprenticeships, they are less likely to complete their apprenticeships than men due to pervasive harassment and lack of child care, among other barriers.[102] Women in these and other nontraditional jobs also often experience extreme hostility on the job. For example, 88 percent of women in construction experience sexual harassment at work,[103] compared to about one-quarter of women in the workforce generally.[104] These roadblocks to higher-wage, higher-skill jobs are detrimental to the economic security of women and their families.

Much work remains to ensure that women have equal access to these higher-wage jobs. Federal agencies charged with enforcing antidiscrimination laws must strengthen their oversight and enforcement in the workplace, and in career and technical education classes and apprenticeships that are the pipeline to these jobs. Federal agencies should also strengthen contractors' affirmative action goals to recruit and retain women in nontraditional jobs and apprenticeships.[105]

STRENGTHENING OPPORTUNITIES FOR COLLECTIVE ACTION

Unionization is particularly important for women in low-wage jobs because the benefits of union membership for women are so pronounced. **Collective bargaining** gives women a seat at the table where important decisions about their working conditions all too often are now made without them. When women workers participate in workplace decision-making through collective bargaining, it dramatically improves their ability to care for themselves and their families. Union members make more than their non-unionized counterparts and the difference is especially pronounced for women, who earn 33 percent more than their non-union counterparts (unionized men, in contrast, earn 19 percent more than their non-union counterparts).[106] And Hispanic women in unions earn a whopping 48 percent more than their non-union counterparts.[107] In addition, women in unions not only earn more, they are paid more equally. Among union members, the wage gap between men and women is half the size of the gap between non-union members.[108]

In addition to promoting higher pay, collective bargaining also empowers women and men to have a voice about hours, scheduling practices, and time off so they can better balance their work and family responsibilities—which is especially critical for workers in low-wage jobs, who are otherwise unlikely to have meaningful leverage to bargain on these matters. In the private sector, union workers are far more likely than non-union workers to have access to paid sick days, paid family leave, vacation, retirement, and comprehensive health insurance that covers all of their needs.[109] For example, women who are union workers are 36 percent more likely to have health insurance with an employer contribution than non-union workers.[110] A woman without a high school diploma is twice as likely to have health insurance with an employer contribution if she is a union worker.[111] Employees of firms with union workers have more generous health benefits than non-unionized workers because their plans have lower deductibles and their employers pay a larger percentage of the premium.[112]

Workers are also using emerging strategies for **collective action outside of traditional unions** to win fights for economic justice.[113] For example, industry-based worker justice organizations have won campaigns for higher pay, used market forces to secure adoption and enforcement of strong policies against discrimination and wage theft, achieved fairer work schedules, and encouraged consumers to patronize high-road employers.[114]

Although collective action is a clear pathway to good jobs, today only 11 percent of employed women are union members.[115] Despite the clear benefits of union membership, some states have enacted so-called right-to-work laws that hinder workers' efforts to organize and bargain collectively.[116] And recently, a 5-to-4 Supreme Court decision limited the rights of home care workers, who provide services to older people and those with disabilities through the Medicaid program, to unionize.[117]

The ability to come together as a group to enforce rights in court is also critical for workers in low-wage jobs, as it gives otherwise vulnerable workers the power to change their workplace.[118] Unfortunately, this right too is under attack in the courts.[119]

For all of these reasons, policies protecting and strengthening collective bargaining rights, new forms of worker organizing, and the ability to come together to enforce employment rights in court are critical for women in low-wage jobs. Giving women a chance to make their voices heard in America's workplaces is key to their economic success.

Appendix

METHODOLOGICAL NOTE

In this analysis, the "low-wage workforce" is comprised of workers in "low-wage occupations," which are detailed occupations with national median hourly wages of $10.10 or less per hour based on the Bureau of Labor Statistics (BLS) Occupational Employment Statistics data from May 2013 (http://www.bls.gov/oes/current/oes_nat.htm). All figures are for employed workers unless otherwise noted. When comparing male and female representation in low-wage and overall workforces, shares are "similar" if their ratio is between 0.9 and 1.1, "underrepresented" if the ratio is 0.8 or less, and "overrepresented" if the ratio is 1.2 or greater. Slight differences in calculations may exist due to rounding. Unless otherwise noted, national data on workforce characteristics are National Women's Law Center calculations based on Current Population Survey (CPS) 2013 using Miriam King et al., *Integrated Public Use Microdata Series (IPUMS), Current Population Survey. Version 3.0* [Machine-readable database] (Minneapolis: University of Minnesota, 2010) and state data on workforce characteristics are National Women's Law Center calculations based on American Community Survey (ACS) 2008-2012 five-year averages using Steven Ruggles, et al., *Integrated Public Use Microdata Series (IPUMS). Version 5.0* [Machine-readable database] (Minneapolis: University of Minnesota, 2010). Some detailed occupations listed in the BLS Occupational Employment Statistics are not available using CPS or ACS data in which case a broader level of occupation is used.

LOW-WAGE OCCUPATIONS (MEDIAN HOURLY WAGES OF $10.10 OR LESS)

Occupation	Median Hourly Wage
Amusement and Recreation Attendants	$9.05
Automotive and Watercraft Service Attendants	$9.84
Baggage Porters and Bellhops	$9.77
Bartenders	$9.09
Cashiers	$9.12
Childcare Workers	$9.42
Cleaners of Vehicles and Equipment	$9.72
Combined Food Preparation and Serving Workers, Including Fast Food	$8.81
Cooks, Fast Food	$8.88
Cooks, Short Order	$9.51
Counter Attendants, Cafeteria, Food Concession, and Coffee Shop	$8.99
Dining Room and Cafeteria Attendants and Bartender Helpers	$8.95
Dishwashers	$8.95
Door-to-Door Sales Workers, News and Street Vendors, and Related Workers	$9.82
Farmworkers and Laborers, Crop, Nursery, and Greenhouse	$9.00
Food Preparation and Serving Related Workers, All Other	$9.94
Food Preparation Workers	$9.35
Food Servers, Nonrestaurant	$9.58
Gaming Dealers	$8.88
Graders and Sorters, Agricultural Products	$9.24
Home Health Aides	$10.10
Hosts and Hostesses, Restaurant, Lounge, and Coffee Shop	$8.96
Hotel, Motel, and Resort Desk Clerks	$9.81
Laundry and Dry-Cleaning Workers	$9.66
Lifeguards, Ski Patrol, and Other Recreational Protective Service Workers	$9.16
Locker Room, Coatroom, and Dressing Room Attendants	$9.42
Maids and Housekeeping Cleaners	$9.51
Manicurists and Pedicurists	$9.30
Models	$9.15
Motion Picture Projectionists	$9.73
Nonfarm Animal Caretakers	$9.57
Packers and Packagers, Hand	$9.60
Parking Lot Attendants	$9.38
Personal Care Aides	$9.67
Personal Care and Service Workers, All Other	$10.04
Pressers, Textile, Garment, and Related Materials	$9.55
Shampooers	$8.90
Ushers, Lobby Attendants, and Ticket Takers	$8.98
Waiters and Waitresses	$8.94

Source: BLS, Occupational Employment Statistics, May 2013, detailed occupations.

NATIONAL WOMEN'S LAW CENTER
www.nwlc.org

Endnotes

1 The share of women in the labor force increased from 43.9 percent in 1972 to 57.7 percent in 2012. U.S. Bureau of Labor Statistics, BLS Reports No. 1049, Women in the Labor Force: A Databook 10-14 (May 2014), *available at* http://www.bls.gov/cps/wlf-databook-2013.pdf. The share of women 25 and older who have completed four years of college or more increased from 9.0 percent in 1972 to 31.4 percent in 2013. U.S. Census Bureau, Educational Attainment, CPS Historical Time Series Tables, Table A-2. Percent of People 25 Years and Over Who Have Completed High School or College, by Race, Hispanic Origin and Sex: Selected Years 1940 to 2013, http://www.census.gov/hhes/socdemo/education/data/cps/historical/.

2 This is based on the share of women 25 and older who have completed four years of college or more. See CPS Historical Time Series Table A-2, *supra* note 1.

3 National Women's Law Center calculations based on Current Population Survey, Annual Social and Economic Supplements (CPS-ASEC) for 2013 using Miriam King et al., *Integrated Public Use Microdata Series, Current Population Survey: Version 3.0* [Machine-readable database] (Minneapolis: University of Minnesota, 2010). The "low-wage workforce" is comprised of workers in "low-wage occupations," which are detailed occupations with median hourly wages of $10.10 per hour or less nationally based on the Bureau of Labor Statistics' Occupational Employment Statistics. Bureau of Labor Statistics, Occupational Employment Statistics, May 2013 National Occupational Employment and Wage Estimates United States, http://www.bls.gov/oes/current/oes_nat.htm. All figures are for all employed workers unless otherwise noted.

4 "Low-wage jobs" and "low-wage workforce" could be defined in different ways; this analysis uses a typical hourly wage of $10.10 or less per hour because $10.10 is the proposed new federal minimum wage in the Fair Minimum Wage Act pending in Congress. S. 460, H.R.1010, 113th Cong. (2013).

5 National Women's Law Center calculation assuming 40 hours per week, 50 weeks per year. The federal poverty level for 2014 for a family of three is $19,790. U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, 2014 Poverty Guidelines, http://aspe.hhs.gov/poverty/14poverty.cfm.

6 *Id.*

7 National Women's Law Center calculations compare women and men in the low-wage workforce in 2009 and 2012 based on Current Population Survey, Annual Social and Economic Supplements (CPS-ASEC) for 2010 and 2013 using Miriam King et al., *Integrated Public Use Microdata Series, Current Population Survey: Version 3.0* [Machine-readable database] (Minneapolis: University of Minnesota, 2010).

8 National Women's Law Center calculations based on Current Population Survey, Annual Social and Economic Supplements (CPS-ASEC) for 2008 through 2013 using Miriam King et al., *Integrated Public Use Microdata Series, Current Population Survey: Version 3.0* [Machine-readable database] (Minneapolis: University of Minnesota, 2010). Low-wage occupations comprised 18.3 percent of the female workforce in 2007, compared to 19.4 percent in 2012.

9 Over the same period, the share of women with a bachelor's degree or higher increased nine percent, the share with only some college or an associate's degree increased two percent, and the share with only a high school diploma or with no high school diploma declined by five percent and eleven percent, respectively. National Women's Law Center calculations based on U.S. Census Bureau, Current Population Survey (CPS), CPS Table Creator, http://www.census.gov/cps/data/cpstablecreator.html. Figures are for individuals 25 and older. Throughout this report "high school diploma" includes its equivalent, passing the General Education Development (GED) tests.

10 National Women's Law Center calculations based on Bureau of Labor Statistics, Employment Projections, Table 1.4: Occupations with the most job growth, 2012 and projected 2022, http://www.bls.gov/emp/ep_table_104.htm (last visited Dec. 19, 2013). Median hourly wages were calculated by dividing median annual salary by 2,080 hours (the number of hours of full-time, year-round work), the same method of calculation used by the Occupational Employment Statistics (OES). Median hourly wages for these positions match those reported by the OES for 2012 when median hourly wages are available. See Bureau of Labor Statistics, Occupational Employment Statistics, May 2012 National Occupational Employment and Wage Estimates United States, http://www.bls.gov/oes/2012/may/oes_nat.htm. For some occupations OES does not publish median hourly wages, in which case they are calculated here by the process described. Female-dominated jobs are defined as occupations in which 60 percent or more of the workers are women. The share of workers who are female comes from Bureau of Labor Statistics, Labor Force Statistics from the Current Population Survey, Household Data, Annual Averages, Table 11: Employed persons by detailed occupation, sex, race, and Hispanic or Latino ethnicity, http://www.bls.gov/cps/cpsaat11.htm (last visited Dec. 19, 2013). In some instances the share of women in a detailed occupation was not available, in which case the broader level of occupation was used.

11 *Id.* In total, 14 of the 20 occupations pay less than the median hourly wage of $16.71 per hour and 13 of the 20 jobs are female-dominated.

12 The share of mothers who are breadwinners or co-breadwinners has increased from 27.5 percent in 1967 to 63.3 percent in 2012. Sarah Jane Glynn, Center for American Progress, Breadwinning Mothers, Then and Now 6 (June 2014), *available at* http://cdn.americanprogress.org/wp-content/uploads/2014/06/Glynn-Breadwinners-report-FINAL.pdf.

13 *Id.*

14 Kenneth Matos & Ellen Galinsky, Families and Work Institute & Society for Human Resource Management, Workplace Flexibility in the United States: A Status Report 1 (2011), *available at* http://familiesandwork.org/downloads/WorkplaceFlexibilityinUS.pdf; *see also* OXFAM America, Hard Work, Hard Lives: Survey Exposes Harsh Reality Faced by Low-Wage Workers in the US 7 (2013), *available at* http://www.oxfamamerica.org/static/oa4/low-wage-worker-report-oxfam-america.pdf. In 2013 women spent nearly twice as much time caregiving as men did: women spent an hour a day on caregiving (55 minutes, on average) compared to about half an hour (32 minutes, on average) for men. National Women's Law Center calculations based on Bureau of Labor Statistics, American Time Use Survey, Table 1. Time spent in primary activities (1) and percent of the civilian population engaging in each activity, averages per day by sex, 2013 annual averages, http://www.bls.gov/news.release/atus.t01.htm. Figures are for all individuals and include caring for and helping household and nonhousehold members.

15 The exception is among African American workers. African American women are slightly overrepresented in the overall workforce compared to African American men, though African American women's overrepresentation in the low-wage workforce is dramatically larger—African American women's share of the overall workforce (6.1 percent) is 1.2 times larger than African American men's (5.1 percent), but their share of the low-wage workforce (11.6 percent) is 2.3 times larger than African American men's share of the low-wage workforce (5.0 percent).

16 National Women's Law Center, 50 Years & Counting: The Unfinished Business of Achieving Fair Pay 2 (2013), *available at* http://www.nwlc.org/sites/default/files/pdfs/final_nwlc_equal_pay_report.pdf.

17 Claudia Williams et al., Institute for Women's Policy Research, 44 Million U.S. Workers Lacked Paid Sick Days in 2010: 77 Percent of Food Service Workers Lacked Access (Jan. 2011), *available at* http://www.iwpr.org/publications/pubs/44-million-u.s.-workers-lacked-paid-sick-days-in-2010-77-percent-of-food-service-workers-lacked-access. Seventy-seven percent of workers in food preparation and service jobs and 62 percent of workers in personal care and service occupations lacked access to paid sick days.

18 Linda J. Blumberg, The Urban Institute, Employer-Sponsored Health Insurance and the Low-Income Workforce: Limitations of the System and Strategies for Increasing Coverage (2007), *available at* http://www.urban.org/UploadedPDF/411536_employer-sponsored_insurance.pdf.

19 U.S. Census Bureau, Child Care, Who's Minding the Kids? Child Care Arrangements: 2011 – Detailed Tables, Table 6. Average Weekly Child Care Expenditures of Families with Employed Mothers that Make Payments, by Age Groups and Selected Characteristics: Spring 2011, http://www.census.gov/hhes/childcare/data/sipp/2011/tables.html. Families in poverty who pay for child care and have working mothers spend nearly a third (30 percent) of their income on that care—and childcare expenditures represent 38 percent of mothers' earnings, on average. Low-income families—between 100 and 200 percent of poverty—who pay for child care and have working mothers spend 18 percent of their income on child care. For these families, childcare expenditures represent 28 percent of mothers' earnings, on average.

20 Fatima Goss Graves et al., National Women's Law Center, Reality Check: Seventeen Million Reasons Low-Wage Workers Need Strong Protections from Harassment (2014), *available at* http://www.nwlc.org/sites/default/files/pdfs/final_nwlc_vancereport2014.pdf.

21 Liz Watson, Lauren Frohlich & Elizabeth Johnston, National Women's Law Center, Collateral Damage: Scheduling Challenges for Workers in Low-Wage Jobs and Their Consequences (Apr. 2014), *available at* http://www.nwlc.org/sites/default/files/pdfs/collateral_damage_scheduling_fact_sheet.pdf.

22 "Single" includes married, spouse absent.

23 "Parents" are defined as having related children under 18 living at home unless otherwise specified.

24 Many surveys of workforce participation, including the Current Population Survey—the source of the national data for this study—exclude incarcerated individuals, who are very disproportionately male, less educated, and African American. See Russell Sage Foundation, *How Incarceration Data Affects Employment Figures* (Sept. 2012), http://www.russellsage.org/blog/how-incarceration-data-affects-employment-figures.

25 "Foreign-born" includes naturalized citizens and non-citizens. "Native-born" includes people born abroad of American parents.

26 Wage gaps are for full-time, year-round workers—most other data in the report are for all employed workers.

27 Foreign-born workers may be of any race or ethnic group.

28 A worker's poverty status is based on whether her family income falls below the official poverty threshold. In 2012, the poverty threshold for one person was $11,720, for one adult and two children under 18 it was $18,498, and for two adults and two children under 18 it was $23,283. U.S. Census Bureau, Current Population Survey (CPS), Annual Social and Economic (ASEC) Supplement, 2012 Poverty Table of Contents, POV35. Poverty Thresholds by Size of Family and Number of Related Children, http://www.census.gov/hhes/www/cpstables/032013/pov/toc.htm.

29 "Family income" represents the total pre-tax cash income from all sources for each family member.

30 "Full-time" refers to working 35 or more hours in the previous week. "Part-time" refers to working between one and 34 hours in the previous week.

31 "Economic reasons" also include seasonal work and the job started or ended during the week.

32 "Non-economic reasons" also include being retired or having a Social Security limit on earnings, having a full-time work week that is under 35 hours, and child care problems.

33 In the District of Columbia women are just over half of the workforce (51.3 percent).

34 See Nat'l Fed'n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566 (2012).

35 OXFAM America, *supra* note 14, at 3.

36 *Id.*

37 Alison Earle et al., *Job characteristics among working parents: differences by race, ethnicity and nativity*, Monthly Lab. Rev., May 2014, at 6, *available at* http://www.bls.gov/opub/mlr/2014/article/pdf/job-characteristics-among-working-parents.pdf.

38 Raise the Minimum Wage, *The Business Case for Raising the Minimum Wage*, http://www.raisetheminimumwage.com/pages/business-case (last visited June 27, 2014).

39 The Fair Minimum Wage Act, S. 460, H.R.1010, 113th Cong. (2013), and Minimum Wage Fairness Act, S. 1737, 113th Cong. (2013), would gradually increase the federal minimum wage from $7.25 per hour to $10.10 per hour and the tipped minimum cash wage from $2.13 per hour to 70 percent of the minimum wage, and index these wages to keep pace with inflation. If these increases were implemented, an estimated 4.6 million non-elderly Americans (workers and their family members) would see their incomes rise above the federal poverty threshold in the short term. Arindrajit Dube, *Minimum Wages and the Distribution of Family Income*, at 34 (Dec. 2013), *available at* https://dl.dropboxusercontent.com/u/15038936/Dube_MinimumWagesFamilyIncomes.pdf.

40 The EITC and CTC lifted almost six million people, over half of whom were children, above the federal poverty threshold in 2011. Thomas L. Hungerford & Rebecca Thiess, Economic Policy Institute, The Earned Income Tax Credit and the Child Tax Credit: History, Purpose, Goals, and Effectiveness 8 (Sept. 25, 2013), *available at* http://www.epi.org/publication/ib370-earned-income-tax-credit-and-the-child-tax-credit-history-purpose-goals-and-effectiveness/.

41 Kaiser Family Foundation & Health Research & Educational Trust, Employer Health Benefits: 2013 Annual Survey 40 (Aug. 2013), *available at* http://kaiserfamilyfoundation.files.wordpress.com/2013/08/8465-employer-health-benefits-20132.pdf. Low-wage firms are defined in this analysis as firms where 35 percent or more of employees earn $23,000 a year or less.

42 State Health Access Data Assistance Center & Robert Wood Johnson Foundation, State-Level Trends in Employer-Sponsored Health Insurance: A State-by-State Analysis 5 (Apr. 2013), *available at* http://www.shadac.org/files/shadac/publications/ESI_Report_2013.pdf.

43 National Women's Law Center, Mind the Gap: Low-Income Women in Dire Need of Health Insurance 1 (Jan. 2014), *available at* http://www.nwlc.org/sites/default/files/pdfs/nwlcmindthegapmedicaidreportfinal_20140122.pdf. At the time of publication of the Mind the Gap report the figure was 25 states. As of July 2014, the number was 24. In addition, the Affordable Care Act allows states to expand Medicaid eligibility to all qualified individuals at or below 138 percent of the Federal Poverty Level. Although 4 million additional women would be eligible for Medicaid coverage if their states accepted the federal money to expand their programs, individuals at or above 100 percent of poverty are also eligible for subsidies for marketplace coverage. This leaves approximately 3 million women with no option for affordable coverage.

44 To date, 11 states have neither expanded their Medicaid program nor provide access to comprehensive family planning services under Medicaid, leaving low-wage workers in those states without this critical coverage. These states are Alaska, Florida, Idaho, Kansas, Maine, Nebraska, South Dakota, Tennessee, Texas, Utah, and Wyoming. In states that have not expanded Medicaid, it also means that the women in those states will not have coverage for abortion. While most of the states that have not expanded Medicaid only provide abortion coverage in cases where the woman's life is endangered or her pregnancy is the result of rape or incest, in seven of the states that have not expanded Medicaid—Alaska, Indiana, Mississippi, Montana, Utah, Virginia, and Wisconsin—women would have coverage beyond those limited circumstances.

45 Mind the Gap, *supra* note 43, at 1.

46 Patient Protection and Affordable Care Act § 1401(a), 26 U.S.C. § 36B.

47 Breakaway Policy Strategies & Robert Wood Johnson Foundation, Eight Million and Counting: A Deeper Look at Premiums, Cost Sharing and Benefit Design in the New Health Insurance Marketplaces (May 2013), *available at* http://www.rwjf.org/en/research-publications/find-rwjf-research/2014/05/eight-million-and-counting.html.

48 U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, Profile of Affordable Care Act Coverage Expansion Enrollment for Medicaid/CHIP and the Health Insurance Marketplace, http://aspe.hhs.gov/health/reports/2014/MarketPlaceEnrollment/Apr2014/pdf/national.pdf.

49 Larry Levitt & Gary Claxton, Kaiser Family Foundation, *Measuring the Affordability of Employer Health Coverage* (Aug. 24, 2011), http://kff.org/health-costs/perspective/measuring-the-affordability-of-employer-health-coverage/.

50 *Id.*
51 Burwell v. Hobby Lobby Stores, Inc., Nos. 13-354, 13-356, 2014 WL 2921709 (U.S. 2014).
52 Studies have shown a clear connection between birth control and increases in women's education, labor force participation, and wages. *See, e.g.*, Jennifer J. Frost & Laura Duberstein Lindberg, *Reasons for using contraception: Perspectives of U.S. women seeking care at specialized family planning clinics*, 87 Contraception 465, 465 (2013); Claudia Goldin & Lawrence F. Katz, *The Power of the Pill: Oral Contraceptives and Women's Career and Marriage Decisions*, 110 J. Pol. Econ. 730, 758-62 (2002).
53 Some groups of women who are overrepresented in the low-wage workforce, including women of color and low-income women, are more likely to be faced with an unintended pregnancy, and are more likely to have an abortion. Susan A. Cohen, *Abortion and Women of Color: The Bigger Picture*, Guttmacher Pol'y Rev. Vol. 11 No. 3, Summer 2008, at 2, 3, *available at* http://www.guttmacher.org/pubs/gpr/11/3/gpr110302.pdf; Heather D. Boonstra et al., Guttmacher Institute, Abortion in Women's Lives 28 (2006), *available at* http://www.guttmacher.org/pubs/2006/05/04/AiWL.pdf.
54 Over the past three years alone, state legislatures have passed an unprecedented number of harsh new restrictions on abortion access. These restrictions include outright bans on abortion, laws that take away insurance coverage of abortion, and laws targeting abortion providers and clinics that have the goal and effect of shutting down providers. In 2013, more than half of women of reproductive age were living in states that were hostile to abortion. Heather D. Boonstra & Elizabeth Nash, *A Surge of State Abortion Restrictions Puts Providers—And the Women They Serve—in the Crosshairs*, Guttmacher Pol'y Rev. Vol. 17 No. 1, Winter 2014, at 9, 13, *available at* http://www.guttmacher.org/pubs/gpr/17/1/gpr170109.pdf.
55 Craig Copeland, Employee Benefit Research Institute, *Employment-Based Retirement Plan Participation: Geographic Differences and Trends*, 2011, Emp. Benefit Res. Inst. Issue Brief No. 378, Nov. 2012, at 11, *available at* http://www.ebri.org/pdf/briefspdf/EBRI_IB_11-2012_No378_RetParticip.pdf.
56 For this purpose, part-time workers are defined as those working fewer than 1,000 hours per year, approximately 20 hours per week. *See* 26 U.S.C. § 410(a)(1)(A), (3)(A); 29 U.S.C. § 1052(a)(1)(A), (3)(A).
57 Copeland, *supra* note 55, at 10.
58 Sarah Jane Glynn, Center for American Progress, The New Breadwinners: 2010 Update 3 (2012), *available at* http://cdn.americanprogress.org/wp-content/uploads/issues/2012/04/pdf/breadwinners.pdf.
59 National Women's Law Center calculations based on Current Population Survey, Annual Social and Economic Supplements (CPS-ASEC) for 2013 using Miriam King et al., *Integrated Public Use Microdata Series, Current Population Survey: Version 3.0* [Machine-readable database] (Minneapolis: University of Minnesota, 2010).
60 Matos & Galinsky, *supra* note 14, at 9.
61 Glynn, *supra* note 12, at 8 (2014).
62 *See, e.g.*, Restaurant Opportunities Centers United, The Third Shift: Child Care Needs and Access for Working Mothers in Restaurants 2, 9-11 (July 2013), *available at* http://www.scribd.com/doc/161943672/The-Third-Shift-Child-Care-Needs-and-Access-for-Working-Mothers-in-Restaurants.
63 *See generally* Nancy C. Cauthen, Demos, Scheduling Hourly Workers: How Last Minute, "Just-In-Time" Scheduling Practices Are Bad for Workers, Families and Business (2011), *available at* http://www.demos.org/sites/default/files/publications/Scheduling_Hourly_Workers_Demos.pdf.
64 *See id.* at 6; Liz Watson & Jennifer E. Swanberg, Workplace Flexibility 2010, Flexible Workplace Solutions for Low-Wage Hourly Workers: A Framework for a National Conversation 6 (May 2011), *available at* http://workplaceflexibility2010.org/images/uploads/whatsnew/Flexible%20Workplace%20Solutions%20for%20Low-Wage%20Hourly%20Workers.pdf.
65 Watson & Swanberg, *supra* note 64, at 12.
66 *See, e.g.*, Stephanie Luce & Naoki Fujita, City University of New York & Retail Action Project, Discounted Jobs: How Retailers Sell Workers Short 9 (2012), *available at* http://retailactionproject.org/wp-content/uploads/2012/01/FINAL_RAP.pdf.
67 Helen Blank, Karen Schulman & Lauren Frohlich, National Women's Law Center, Nearly One in Five Working Mothers of Very Young Children Work in Low-Wage Jobs (Apr. 2014), *available at* http://www.nwlc.org/resource/nearly-one-five-working-mothers-very-young-children-work-low-wage-jobs.
68 U.S. Department of Health and Human Services, Office of Human Services Policy, Office of the Assistant Secretary for Planning and Evaluation, Estimates of Child Care Eligibility and Receipt for Fiscal Year 2009 (Dec. 2012), *available at* http://aspe.hhs.gov/hsp/12/childcareeligibility/ib.pdf.
69 Bureau of Labor Statistics, Employee Benefits Survey, Table 32. Leave benefits: Access, civilian workers, National Compensation Survey, March 2013, http://www.bls.gov/ncs/ebs/benefits/2013/ownership/civilian/table21a.htm. While access to paid family leave is very limited across the workforce overall, low-wage workers are far less likely than other workers to have access to paid family leave: 22 percent of high-wage workers have access to paid leave, as compared to only four percent of low-wage workers. Likewise, access to paid sick leave is also far more limited for low-wage workers: 90 percent of high-wage workers have access to paid sick leave, as compared to only 21 percent of low-wage workers. *Id.* "Low-wage" refers to occupations in the lowest 10 percent of the average wage distribution; "high-wage" refers to occupations in the highest 10 percent.
70 For example, Vermont and San Francisco protect workers' rights to request changes in their schedules, without fear of retaliation. Vt. Stat. tit. 21, § 309; San Francisco Admin. Code Ch. 12Z. Eight states and the District of Columbia require some minimum hours of pay for workers who are called into a shift. Cal. Code Regs. tit. 8, § 11040; Conn. Agencies Regs. § 31-62-D2(d) (mercantile trade); Conn. Agencies Regs. § 31-62-C2 (dry cleaning and dyeing); Conn. Agencies Regs. § 31-62-B2 (laundry); Conn. Agencies Regs. § 31-62-A2 (beauty shops); Conn. Agencies Regs. § 31-62-E1 (hotels, restaurants); D.C. Mun. Regs. tit. 7, § 907; 455 Mass. Code Regs. 2.03; N.H. Rev. Stat. § 275:43-a; N.J. Admin. Code § 12:56-5.5; N.Y. Comp. Codes R. & Regs. tit. 12, § 142-2.3; Or. Admin. R. 839-021-0087; R.I. Gen. Laws § 28-12-3.2. Connecticut, the District of Columbia, and at least six localities have laws requiring that workers be able to earn paid sick days. National Partnership for Women & Families, *Paid Sick Days Statutes* (Mar. 2014), http://www.nationalpartnership.org/research-library/work-family/psd/paid-sick-days-statutes.pdf. And California, New Jersey, Rhode Island and Washington all have laws creating paid family leave insurance programs. National Partnership for Women & Families, *State Paid Family Leave Insurance Laws* (Oct. 2013), http://www.nationalpartnership.org/research-library/work-family/paid-leave/state-paid-family-leave-laws.pdf.
71 *See, e.g.*, National Partnership for Women & Families, The Pregnancy Discrimination Act: Where We Stand 30 Years Later Chart A (Oct. 2008), *available at* http://go.nationalpartnership.org/site/DocServer/Pregnancy_Discrimination_Act_-_Where_We_Stand_30_Years_L.pdf?docID=4281; Restaurant Opportunities Centers United et al., Tipped over the Edge: Gender Inequity in the Restaurant Industry 23 (Feb. 2012), *available at* http://rocunited.org/tipped-over-the-edge-gender-inequity-in-the-restaurant-industry/.
72 National Women's Law Center, The Wage Gap Over Time (Oct. 2013), *available at* http://www.nwlc.org/sites/default/files/pdfs/wage_gap_over_time_overall.pdf.
73 Ariane Hegewisch & Stephanie Keller Hudiburg, Institute for Women's Policy Research, The Gender Wage Gap by Occupation and by Race and Ethnicity, 2013 (Apr. 2013), *available at* http://www.iwpr.org/publications/pubs/the-gender-wage-gap-by-occupation-and-by-race-and-ethnicity-2013.
74 *See* National Women's Law Center, Women in Construction: Still Breaking Ground 2 (June 2014), *available at* http://www.nwlc.org/sites/default/files/pdfs/final_nwlc_womeninconstruction_report.pdf.
75 50 Years & Counting, *supra* note 16, at 5.
76 National Women's Law Center calculations based on Current Population Survey, Annual Social and Economic Supplements (CPS-ASEC) for 2013 using Miriam King et al., *Integrated Public Use Microdata Series, Current Population Survey: Version 3.0* [Machine-readable database] (Minneapolis: University of Minnesota, 2010). *See also* Women in Construction, *supra* note 74.

77 Women in Construction, *supra* note 74, at 2.
78 *Id.* at 2.
79 *See supra* p. 17.
80 *See generally* Reality Check, *supra* note 20.
81 Nancy Krieger et al., *Social Hazards on the Job: Workplace Abuse, Sexual Harassment, and Racial Discrimination*, 36 Int'l J. Health Services 51, 67 (2006).
82 Fair Employment Protection Act, S. 2133, H.R. 4227, 113th Cong. (2014). *See generally* Reality Check, *supra* note 20.
83 National Women's Law Center & A Better Balance, It Shouldn't Be a Heavy Lift: Fair Treatment for Pregnant Workers 5 (Jun. 2013), *available at* http://www.nwlc.org/sites/default/files/pdfs/pregnant_workers.pdf.
84 *See generally id.*
85 *Id.* at 5-7.
86 *See* Pregnant Workers Fairness Act, S. 942, H.R. 1975, 113th Cong. (2013).
87 *See, e.g.*, Shelley J. Correll, Stephan Benard & In Paik, *Getting a Job: Is There a Motherhood Penalty?*, 112 Am. J. Soc. 1297, 1315-17 (2007), *available at* http://gender.stanford.edu/sites/default/files/motherhoodpenalty_0.pdf.
88 National Women's Law Center, How the Wage Gap Hurts Women and Families (Apr. 2014), *available at* http://www.nwlc.org/sites/default/files/pdfs/wage_gap_hurts_women_and_families.pdf.
89 Correll, Benard, & Paik, *supra* note 87, at 1315-17.
90 *See generally* Rebecca Smith & Eunice Hyunhye Cho, National Employment Law Project, Workers' Rights on ICE: How Immigration Reform Can Stop Retaliation and Advance Labor Rights (Feb. 2013), *available at* http://www.nelp.org/page/-/Justice/2013/Workers-Rights-on-ICE-Retaliation-Report.pdf?nocdn=1.
91 *See supra* p. 7.
92 Women in Construction, *supra* note 74, at 7.
93 *See generally* Anne Johnson, Tobin Van Ostern & Abraham White, Center for American Progress, The Student Loan Debt Crisis (Oct. 2012), *available at* http://cdn.americanprogress.org/wp-content/uploads/2012/10/WhiteStudentDebt-5.pdf.
94 *See* Christianne Corbett & Catherine Hill, American Association of University Women, Graduating to a Pay Gap: The Earnings of Women and Men One Year after College Graduation 9 (Feb. 2012), *available at* http://www.aauw.org/files/2013/02/graduating-to-a-pay-gap-the-earnings-of-women-and-men-one-year-after-college-graduation.pdf?_ga=1.223972059.1527543555.1389624091. Female college graduates one year after graduation on average are earning $7,622 less than their male counterparts.
95 *Id.* at 3. These figures are for 2009, up from 38 percent of women and 31 percent of men paying more than eight percent of their earnings toward student loan debt in 2001.
96 Kevin Miller & Barbara Gault, Institute for Women's Policy Research, Improving Child Care Access to Promote Postsecondary Success Among Low-Income Parents 1 (March 2011), *available at* http://www.iwpr.org/publications/pubs/improving-child-care-access-to-promote-postsecondary-success-among-low-income-parents.
97 *See* National Women's Law Center, A Pregnancy Test For Schools: The Impact of Education Laws on Pregnant and Parenting Students 3-6 (Jun. 2012), *available at* http://www.nwlc.org/sites/default/files/final_nwlc_pregnantparenting_report.pdf.
98 Miller & Gault, *supra* note 96, at 1.
99 *See* Sarah Minton et al., The Urban Institute, The CCDF Policies Database Book of Tables: Key Cross-State Variations in CCDF Policies as of October 1, 2012 30-39 (Nov. 2013), *available at* http://www.urban.org/UploadedPDF/412977-the-ccdf-policies-database.pdf.
100 Bureau of Labor Statistics, Labor Force Statistics from the Current Population Survey, Household Data, Annual Averages, Table 11. Employed persons by detailed occupation, sex, race, and Hispanic or Latino ethnicity, http://www.bls.gov/cps/cpsaat11.htm (last visited June 7, 2013); Bureau of Labor Statistics, Labor Force Statistics from the Current Population Survey, Household Data, Annual Averages, Table 39. Median weekly earnings of full-time wage and salary workers by detailed occupation and sex, http://www.bls.gov/cps/cpsaat39.htm (last visited June 7, 2014).
101 *See* Susan Moir et al., Unfinished Business: Building Equality for Women in the Construction Trades 8 (April 2011), *available at* http://scholarworks.umb.edu/cgi/viewcontent.cgi?article=1004&context=lrc_pubs; Women in Construction, *supra* note 74, at 7.
102 *See* Moir et al., *supra* note 101, at 8-9; Women in Construction, *supra* note 74, at 8.
103 *See* U.S. Department of Labor, Advisory Committee on Occupational Safety and Health, Women in the Construction Workplace: Providing Equitable Safety and Health Protection (June 1999), *available at* https://www.osha.gov/doc/accsh/haswicformal.html.
104 ABC News & Washington Post, *One in Four U.S. Women Reports Workplace Harassment* (Nov. 16, 2011), http://www.langerresearch.com/uploads/1130a2WorkplaceHarassment.pdf.
105 *See* Women in Construction, *supra* note 74, at 9.
106 Katherine Gallagher Robbins & Lauren Frohlich, National Women's Law Center, Union Membership is Critical for Women's Wage Equality: Gender Wage Gap for Union Members is Half the Size of Non-Union Workers' Wage Gap (Mar. 2014), *available at* http://www.nwlc.org/sites/default/files/pdfs/unionmembershipcriticalforwomenswageequality.pdf.
107 *Id.*
108 *Id.*
109 Janelle Jones, John Schmitt & Nicole Woo, Center for Economic and Policy Research, Women, Working Families, and Unions (June 2014), *available at* http://www.cepr.net/documents/women-union-2014-06.pdf.
110 *Id.* at 17.
111 *Id.*
112 Lawrence Mishel & Matthew Walters, Economic Policy Institute, How Unions Help All Workers 7 (2003), *available at* http://www.epi.org/publication/briefingpapers_bp143/.
113 *See* Sarita Gupta, *How to Write A New Organizing Playbook*, The Nation, July 7-14, 2014, *available at* http://www.thenation.com/article/180318/how-write-new-organizing-playbook#.
114 *See* Greg Asbed, *Worker-Driven Social Responsibility (WSR): A New Idea for a New Century*, Huffington Post, June 17, 2014, http://www.huffingtonpost.com/greg-asbed/workerdriven-social-respo_b_5500104.html (praising the unprecedented change that the Coalition of Immokalee Workers' "Fair Food Program" has brought to Florida's fields, including wage increases supported by a price premium paid by corporate purchasers of Florida tomatoes and a human-rights-based Code of Conduct); Emily Jane Fox, *Victoria's Secret NY workers win fight for better pay*, CNNMoney, Sept. 11, 2013, http://money.cnn.com/2013/09/11/news/companies/victorias-secret-workers/index.html?iid=HP_LN (describing the campaign organized by members of the Retail Action Project to improve wages and scheduling practices at Victoria's Secret); Dave Jamieson, *In Wake of Protests, Walmart Workers Find More Hours Within Reach*, Huffington Post, Apr. 7, 2014, http://www.huffingtonpost.com/2014/04/07/walmart-hours-part-time_n_5107174.html (detailing the role OUR Walmart members played in Walmart's adoption of the "Access to Open Hours" program, which permits workers to sign up for additional shifts); Lydia DePillis, *Under Pressure, Wal-Mart upgrades its policy for helping pregnant workers*, Washington Post, Apr. 5, 2014, *available at* http://www.washingtonpost.com/blogs/wonkblog/wp/2014/04/05/under-pressure-walmart-upgrades-its-policy-for-helping-pregnant-workers/

(detailing the activism by OUR Walmart members that led to a policy change that could "ease the way for hundreds of thousands of [Walmart's] other female employees who could have babies down the road"); RESTAURANT OPPORTUNITIES CENTERS UNITED & DR. ROSEMARY BATT, TAKING THE HIGH ROAD: A HOW-TO GUIDE FOR SUCCESSFUL RESTAURANT EMPLOYERS (Jan. 2012), *available at* http://rocunited.org/wp-content/uploads/2012/01/ROCGuide_Report_F4.pdf (highlighting "high road employers" and encouraging other employers to take the "high road," defined as providing livable wages, maintaining a healthy workplace through paid sick days, vacation, or health insurance, and creating career ladders for employees through training and internal promotions policies).

115 Gallagher Robbins & Frohlich, *supra* note 106.

116 HEIDI SHIERHOLZ & ELISE GOULD, ECONOMIC POLICY INSTITUTE, THE COMPENSATION PENALTY OF "RIGHT-TO-WORK" LAWS (2011), *available at* http://www.epi.org/publication/bp299/.

117 Harris v. Quinn, 134 S. Ct. 2618 (2014).

118 *See, e.g.*, NATIONAL WOMEN'S LAW CENTER, THE EQUAL EMPLOYMENT OPPORTUNITY RESTORATION ACT OF 2012: WHAT IT MEANS FOR LOW-WAGE WOMEN WORKERS (June 2012), *available at* http://www.nwlc.org/sites/default/files/pdfs/equalemploymentopportunityactlowwageworkers.pdf.

119 *See, e.g.*, Wal-Mart Stores, Inc. v. Dukes, 131 S. Ct. 2541 (2011); AT&T Mobility LLC v. Concepcion, 131 S. Ct. 1740 (2011).

NATIONAL WOMEN'S LAW CENTER

EXPANDING THE POSSIBILITIES

11 Dupont Circle, Suite 800
Washington, DC 20036
202.588.5180 | fax 202.588.5185
www.nwlc.org

E

NATIONAL WOMEN'S LAW CENTER
EXPANDING THE POSSIBILITIES

EMPLOYMENT

Collateral Damage: Scheduling Challenges for Workers in Low-Wage Jobs and Their Consequences

April 2014

Liz Watson, Lauren Frohlich, and Elizabeth Johnston

There are nearly 20 million workers in low-wage jobs (typically paying $10.10 per hour or less),[1] and 76 percent of workers in the ten largest low-wage jobs are women.[2] Low wages can make it hard for workers to support themselves and their families, but wages are not the only problem. Low-wage jobs that are primarily held by women, such as cashiers, maids and housekeepers, and restaurant servers, are marked by work scheduling policies and practices that pose particular challenges for workers with significant responsibilities outside of their job, including caregiving, pursuing education and workforce training, or holding down a second job.[3] The work schedules in these jobs are often unpredictable, unstable and inflexible. Some require working nights, weekends or even overnight, and many offer only part-time work, despite many workers' need for full-time hours.

Women are disproportionately affected by this problem because women hold the majority of low-wage jobs[4] and still shoulder the majority of caregiving responsibilities.[5] And nearly one in five families with children was headed by a single working mother in 2012,[6] a group for whom scheduling challenges pose particularly acute problems. Many of these families struggle financially as well: single mothers make up nearly two-thirds of breadwinning moms today, but this group has a median family income of only $23,000.[7]

Challenging work schedules also cause problems for men working in low-wage jobs who are increasingly assuming a greater role in caring for their families. Between 1977 and 2008, the average workday time fathers spent with their children increased from 2 to 3.1 hours per day.[11] Among both men and women, 75 percent of low-wage workers reported having insufficient time for their children and 61 percent reported having insufficient time to spend on themselves.[12]

This fact sheet outlines five of the most common scheduling challenges faced by workers in low-wage jobs and explains their prevalence and detrimental impact on workers and their families. Understanding the work schedule challenges facing workers in low-wage jobs is an essential first step toward developing solutions to this problem that work for workers, their families, and their employers.

The Rapid Growth in Low-Wage Jobs Held By Women

The dramatic growth in female-dominated low-wage jobs sharpens the need to address work scheduling policies and practices that jeopardize workers' ability to care for their families while holding down their jobs. Mothers with children under 18 make up 24 percent of workers in the ten largest low-wage occupations, compared to just 16 percent of workers overall.[8] In fact, 35 percent of women's job gains during the recovery have been in the ten largest low-wage occupations, as compared to 18 percent of men's.[9]

And these trends are likely to continue. Based on projections from the Bureau of Labor Statistics, over the next decade the economy will continue to add jobs that have historically been low-wage and female-dominated.[10]

STOP DISCOUNTING WOMEN
I AM NOT WORTHLESS.
NATIONAL WOMEN'S LAW CENTER nwlc.org/fairpay

Common Scheduling Challenges

Lack of Control over Work Schedules

Many workers in low-wage jobs have few opportunities for meaningful input into the timing of the hours that they work, and are unable to make even minor adjustments to their work schedules without suffering a penalty.[13] This is true for low-wage workers on both set and variable schedules.[14]

- About half of low-wage workers report having limited control over the timing of their work hours.[15]
- Between two-thirds and three-quarters of full-time low-wage workers report that they are unable to alter the start and end times of their work days.[16]
- Between 40 and 50 percent of low-wage workers have no control over when they take breaks.[17]

Unpredictable Work Schedules

Some employers adopt "just-in-time scheduling" in an effort to minimize labor costs. Just-in-time scheduling bases workers' schedules on perceived consumer demand and often results in workers being given very little advance notice of their work schedules.[18] Scheduling software is frequently used to schedule workers at the last minute, matching the number of workers as closely as possible to retail traffic or other indicators of consumer demand.[19]

- Posting schedules just one week before a worker is expected to work is quite common. In a study of low-skilled, non-production jobs in the hospitality, retail, transportation and financial services industries, only 3 of 17 corporations studied assigned schedules more than a week in advance (one retailer, one hotel, and one bank).[20]
- According to a survey of workers in the retail industry by the Retail Action Project, about a fifth of workers receive their schedules only three days beforehand.[21]
- In another survey of 6,085 workers employed by a major retailer in 388 stores across the country (referred to as "the CitiSales Study"), workers receive notice of their work schedules only seven days in advance, on average.[22]
- Between 19 and 31 percent of low-wage workers are often asked to work extra hours with little or no notice.[23] Roughly 40 to 60 percent of full-time, low-wage workers who are asked to work extra hours with little or no notice say they comply with the request to avoid negative consequences.[24]
- Some retail workers report that they are routinely required to work call-in shifts, which means they must call their employer to find out whether they will be scheduled to work that day, and if they are told to report to work, they often must do so within two hours.[25] In a study of retail workers in New York City, 20 percent of workers surveyed reported that they always or often must be available for call-in shifts.[26]

Unstable Work Schedules

Many workers in low-wage jobs experience unstable schedules with hours that vary from week to week or month to month, or periodic reductions in work hours when work is slow.

- According to the Retail Action Project survey of workers in the retail industry, only 17 percent of all workers surveyed and 10 percent of part-time workers had a set schedule.[27]
- According to the CitiSales Study, for 59 percent of retail employees employed by one major retailer, either the shifts or the days they worked change each week.[28]
- Between 20 and 30 percent of low-wage workers reported a reduction in hours or a layoff when work was slow.[29]

Involuntary Part-Time Work

Workers who want full-time work but are only offered part-time hours—often described as the "underemployed"—struggle to support their families with fewer hours and less pay. The number of workers working part-time involuntarily more than doubled during the recession, growing from 4.4 million prior to the recession 2007 to 8.9 million in 2009, and remains substantially higher than pre-recession levels at 7.9 million workers in 2013.[30]

- In 2013 nearly one-quarter (23 percent) of part-time workers worked part-time involuntarily, including for reasons of slack work or business conditions and because they were unable to find full-time work.[31]
- Low-wage workers are far more likely to work part-time involuntarily than other workers. In 2012, the

rate of involuntary part-time work for employees in low-wage occupations (14 percent) was more than double the rate of involuntary part-time work among employees overall (6 percent).[32]

- Workers in low-wage occupations made up one-third (33 percent) of all involuntary part-time workers in 2012, despite these low-wage workers only making up 14 percent of all workers.[33]

Nonstandard Work Schedules

Workers on nonstandard schedules face unique challenges. "Nonstandard" schedules refers to working evenings, nights, weekends, or working on rotating shifts, irregular schedules, or on call.[34] Nonstandard work is also called "unsocial work" because nonstandard schedules often conflict with family time and make it difficult to maintain other social ties.[35] While the majority of workers on nonstandard schedules do not have these schedules by choice, some workers do choose nonstandard schedules in order to help juggle competing obligations.[36]

- In one study, roughly half of low-wage hourly workers reported working nonstandard schedules.[37] In comparison, an analysis of the American Time Use Survey by the Urban Institute found that 28 percent of workers with very low wages work nonstandard hours, compared to 20 percent of all workers.[38] (The difference in these findings may be accounted for by variations in the way the survey question was asked, as well as differences in the definition of low-wage work.)

- Workers have nonstandard schedules for a variety of reasons. According to the 2004 Current Population Survey Supplement, 55 percent work nonstandard schedules involuntarily because they could not find another job or "it is the nature of the job;" 23 percent work nonstandard schedules for reasons related to family or childcare arrangements or school; 10 percent of nonstandard workers prefer the schedule; and 5 percent gave the reason of better pay.[39]

The Fallout from Challenging Work Schedules

Impact on caregiving responsibilities. Workers in low-wage jobs often face extreme demands at home and work. These workers are more likely to be single parents,[40] more likely to have children with special needs,[41] and more likely to care for elderly or sick relatives.[42] They also have higher rates of illness themselves.[43] At the same time, they have fewer resources to pay for child and elder care than other workers, and they are far less likely to have paid sick and vacation days, or job-protected leave under the Family and Medical Leave Act.[44] For some workers in low-wage jobs who have little to no control over their work schedules, being able to plan for or respond to the exigencies of daily life – for example, ending a shift on time to pick up a child from school or scheduling an afternoon off to take an elderly parent to a doctor's appointment – is simply not an option.

Impact on child care. Low-wage workers' ability to access quality, affordable, and stable child care is often compromised by challenging work schedules.[45] With work schedules and incomes that fluctuate from week to week, many workers have no choice but to cobble together child care at the last minute.[46] Because many centers require caregivers to pay a weekly or monthly fee, regardless of how often the child attends, holding a spot in a child care center is often infeasible for workers who do not know when, or even if, they will work that week. Further, workers with unstable schedules may not qualify for child care subsidies due to fluctuations in income and work hours.[47] Relying on family, friends, and neighbors to provide child care – as most workers in low-wage jobs must do – is complicated by the fact that their child care providers may also be balancing an unpredictable part-time work schedule at their own jobs with providing child care. When workers are unable to find child care or child care falls through, sometimes workers must miss work and lose pay. In one study, 40 to 60 percent of workers who reported missing work due to child care problems also reported losing pay or benefits, or being penalized in some way.[48]

Impact on marriage. Working nonstandard hours has been shown to have negative outcomes for marriages and for children.[49] Research has linked nonstandard hours to higher levels of divorce, less time together as a couple, and lower relationship satisfaction.[50] Although some two-parent families in low-wage jobs cope with the child care problems outlined above by "tag teaming,"—working on opposite schedules so that one parent is available to provide child care—this results in even less time together as a couple.[51]

Impact on children. Workers on nonstandard schedules spend less time with their children,[52] and their children tend to score lower on cognitive tests, have more behavioral problems and poorer mental health.[53] Lesser parental involvement in children's education has consequences for children from low-income families who are three times more likely to drop out of school than children from middle class families.[54]

Impact on education and workforce training. Challenging work schedules can make it nearly impossible to pursue further education or training while holding down a job. One of the most commonly cited challenges to completing a college degree is the inability to balance work and school.[55] Both male and female low-wage workers report a lack of opportunities to pursue additional education and training.[56] In a set of focus groups of students enrolled in community colleges, students identified employers' lack of flexibility with work schedules as a major barrier to pursuing their education.[57]

Impact on transportation. Just-in-time scheduling often complicates transportation for low-wage workers, who may be relying on friends or family to provide a ride to and from work, or public transportation that may run infrequently or erratically.[58] Workers may spend hours and precious resources commuting to and from work, to work a shift lasting only a few hours, or to be sent home unexpectedly when work is slow.[59]

Impact on family economic security. Challenging work schedules make it more difficult to pay the bills. An unexpected reduction in hours means a loss of pay, and it can mean the loss of employer or government benefits that are tied to work hours, including paid and unpaid time off, health insurance, unemployment insurance, public assistance, and work supports.[60] Women working part-time involuntarily are more likely to live in poverty (more than 25 percent) than their counterparts who worked part-time voluntarily (12 percent) or worked full-time (5 percent).[61] Involuntary part-time workers are more likely to have been unemployed for a substantial portion of the previous year (more than 13 weeks)[62] and are less likely to have health care or pension coverage;[63] and part-time positions typically offer less pay pro rata and less job security than full-time positions.[64] Workers report that scheduling and family conflicts are a major reason why they intend to leave their jobs.[65] And spells of unemployment can have disastrous financial consequences for low-income families. In fact, low-wage workers are 2.5 times more likely to be out of work than other workers, but only half as likely to receive unemployment insurance.[66] Workers' inability to pursue or complete education and workforce training programs as a result of work schedule conflict also makes it much more difficult for workers to move up into higher-paying jobs.[67]

Conclusion

The fallout from low-wage jobs characterized by unpredictability, instability, little worker-driven flexibility, nonstandard schedules, and involuntary part-time work is considerable.[68] These challenging work schedules have a cascade of negative consequences for both workers in low-wage jobs and their children.

In contrast, fairer work schedules benefit employees and employers alike. Low-wage workers report that more job autonomy and involvement in management decision-making led to less negative spillover from work to their non-work life.[69] Employees with flexible workplaces are less stressed and have better physical and mental well-being.[70] Less negative spillover from work also leads to greater productivity and job retention: low-wage workers with flexibility are 30 percent less likely than other workers to intend to leave their positions within two years.[71]

Future briefs from NWLC will discuss fair work scheduling policy and practice solutions that are crucial to ensuring that workers can succeed at work and in the rest of their lives.

1 NAT'L WOMEN'S LAW CTR. (NWLC) calculations based on Miriam King et al., Integrated Public Use Microdata Series, CPS: Version 3.0 (IPUMS-CPS), (Univ. of Minn. 2010). Data are for 2012. All figures are for employed workers. Median hourly wages: Bureau of Labor Statistics (BLS), Occupational Employment Statistics (OES), May 2013 National Occupational Employment and Wage Estimates, *available at* http://www.bls.gov/oes/current/oes_nat.htm.

2 NWLC, MINIMUM WAGE: WOMEN ARE 76 PERCENT OF WORKERS IN THE 10 LARGEST LOW-WAGE JOBS AND SUFFER A 10 PERCENT WAGE GAP (Apr. 2014), *available at* http://www.nwlc.org/resource/women-are-76-percent-workers-10-largest-low-wage-jobs-and-suffer-10-percent-wage-gap.

3 *See, e.g.*, RESTAURANT OPPORTUNITIES CENTER UNITED, THE THIRD SHIFT: CHILD CARE NEEDS AND ACCESS FOR LOW-WAGE WORKING MOTHERS IN RESTAURANTS 1-2 (July, 2013), *available at* http://www.scribd.com/doc/161943672/The-Third-Shift-Child-Care-Needs-and-Access-for-Working-Mothers-in-Restaurants.

4 NWLC calculations based on King, *supra* note 1.

5 KENNETH MATOS & ELLEN GALINSKY, WHEN WORK WORKS: WORKPLACE FLEXIBILITY IN THE UNITED STATES, A STATUS REPORT 1 (Families and Work Institute 2011) ("Mothers spend the same number of weekday hours with their children (3.8) in 2008 as they did in 1977 and the majority of married/ partnered women report doing most of the cooking (70%) and cleaning (73%) in their households."), *available at* http://familiesandwork.org/downloads/WorkplaceFlexibilityinUS.pdf; *see also* OXFAM AM., HARD WORK, HARD LIVES: SURVEY EXPOSES HARSH REALITY FACED BY LOW-WAGE WORKERS 7 (OXFAM AM. 2013), *available at* http://www.oxfamamerica.org/static/oa4/low-wage-worker-report-oxfam-america.pdf.

6 NWLC calculations from the Bureau of Labor Statistics (BLS), Current Population Survey (CPS), Annual Social and Economic Supplement, 2013, *available at* http://www.census.gov/cps/data/cpstablecreator.html. 19.1 percent of families with children were headed by working single mothers.
7 Wendy Wang, Kim Parker & Paul Taylor, *Pew Research Social & Demographic Trends: Breadwinner Moms* (May 2013), *available at* http://www.pewsocialtrends.org/2013/05/29/breadwinner-moms/.
8 NWLC, *supra* note 2.
9 *Id.*
10 *See generally* NWLC, Minimum Wage Fact Sheet: Jobs with Largest Project Growth 2012-2011: Almost Half are Low-Wage, Nearly Two-Thirds are Female-Dominated, *available at* http://www.nwlc.org/resource/jobs-largest-projected-growth-2012-2022-almost-half-are-low-wage-nearly-two-thirds-are-fema. Of the 30 occupations that projected to add the largest number of jobs between 2012 and 2022, nearly two-thirds (18) are female-dominated with workforces that are 60 percent or more female, and almost half (13) are low wage, with a median hourly wage less than $13.83 per hour.
11 MATOS & GALINSKY, *supra* note 5 at 1.
12 *Id.* at 13.
13 LIZ WATSON & JENNIFER E. SWANBERG, FLEXIBLE WORKPLACE SOLUTIONS FOR LOW-WAGE HOURLY WORKERS: A FRAMEWORK FOR A NATIONAL CONVERSATION 6 (Workplace Flexibility 2010, May 2011).
14 In this section, "low-wage workers" are defined as those working an hourly job that pays less than two-thirds the median wage for men, unless stated otherwise. This definition of "low-wage" is based WATSON & SWANBERG. Using 2008 National Study of the Changing Workforce data, the sample included workers paid $15.41 or less per hour.
15 WATSON & SWANBERG, *supra* note 13, at 19-20.
16 *Id.*
17 *Id.*
18 *See generally* NANCY C. CAUTHEN, SCHEDULING HOURLY WORKS: HOW LAST MINUTE, JUST-IN-TIME SCHEDULING PRACTICES ARE BAD FOR WORKERS, FAMILIES AND BUSINESS (Demos 2011), *available at* http://www.demos.org/sites/default/files/publications/Scheduling_Hourly_Workers_Demos.pdf.
19 WATSON & SWANBERG, *supra* note 13, at 13.
20 Susan J. Lambert, *Passing the Buck: Labor Flexibility Practices that Transfer Risk onto Hourly Workers*, Human Relations 61(9) 1217 (2008).
21 STEPHANIE LUCE & NAOKI FUJITA, DISCOUNTED JOBS: HOW RETAILERS SELL WORKERS SHORT 8 (Retail Action Project 2012), *available at* http://retailactionproject.org/wp-content/uploads/2012/03/7-75_RAP+cover_lowres.pdf.
22 Jennifer Swanberg et al., Introduction to the CitiSales Study 4 (2009), *available at* http://www.uky.edu/Centers/iwin/citisales/_pdfs/IB1-HourlyWorkers.pdf. *See also* Lambert, *supra* note 20, at 1217.
23 WATSON & SWANBERG, *supra* note 13, at 21.
24 *Id.*
25 LUCE & FUJITA, *supra* note 21, at 13.
26 *Id.*
27 *Id.* at 8, 12.
28 Swanberg et al., *supra* note 22, at 4 ("However, only 41% of employees indicate that they have schedule consistency, i.e., working the same days and the same shift each week.").
29 WATSON & SWANBERG, *supra* note 13, at 22. With the exception of full-time low-wage workers with standard hours, for whom less than 20 percent reported this problem.
30 NWLC calculations based on Bureau of Labor Statistics (BLS) Current Population Survey (CPS) Annual Table 20. Persons at work 1 to 34 hours in all and in nonagricultural industries by reason for working less than 35 hours and usual full- or part-time status, 2007 through 2013, *available at* http://www.bls.gov/cps/tables.htm#annual. Figures are annual averages for those working part-time for economic reasons (also known as involuntarily part-time workers) across all industries.
31 *Id.* Other reasons for working part-time involuntarily include seasonal work (3 percent of all involuntarily part-time workers) and job started or ended during the week (1 percent of all involuntarily part-time workers).
32 NWLC calculations based on King, *supra* note 1. Data are from the Current Population Survey, ASEC 2013, which refers to the reason for working part-time during the week prior to the reference week of the survey. Median hourly wages are from Bureau of Labor Statistics (BLS), Occupational Employment Statistics (OES), May 2013 National Occupational Employment and Wage Estimates (Low-wage occupations are defined here as those typically paying $10.10 per hour or less), *available at* http://www.bls.gov/oes/current/oes_nat.htm.
33 *Id.*
34 Maria E. Enchautegui, *Nonstandard Work Schedules and the Well-Being of Low-Income Families*, Low-Income Working Families Paper 26 1 (Urban Inst. July 2013), *available at* http://www.urban.org/UploadedPDF/412877-nonstandard-work-schedules.pdf.
35 JOAN C. WILLIAMS & HEATHER BOUSHEY, THE THREE FACES OF WORK-FAMILY CONFLICT: THE POOR, THE PROFESSIONALS, AND THE MISSING MIDDLE, CENTER FOR AMERICAN PROGRESS 25 (Work Life Law UC Hastings College of the Law January 2010) (citing Jody Heyman, Inequalities at Work and Home: Social Class and Gender Divides in Unfinished Work: building Equality and Democracy in an Era of Working Families 89, 102 (Jody Heyman & Christopher Bee meds. 2005)), *available at* http://www.americanprogress.org/wp-content/uploads/issues/2010/01/pdf/threefaces.pdf.
36 Terrence M. McMenamin, Shift Work and Flexible Schedules: A Time to Work: Recent Trends in Shift Work and Flexible Schedules, Monthly Labor Review, U.S. DEP'T OF LABOR, MONTHLY LABOR REVIEW (Dec. 2007), available at http://www.bls.gov/opub/mlr/2007/12/art1full.pdf.
37 WATSON & SWANBERG, *supra* note 13, at 5.
38 Enchautegui, *supra* note 34, at 7 ("Very low wages" are defined in the analysis as weekly earnings lower than those of 75 percent of the population who work full time.).
39 NWLC calculations based on McMenamin, *supra* note 36.
40 WILLIAMS & BOUSHEY, *supra* note 35, at 12.
41 Lisa Dodson et al. Keeping Jobs and Raising Families in Low-Income America: It Just Doesn't Work (2002) Radcliffe Public Policy Center and 9to5 National Association of Working Women, at 1.
42 ANNA DANZIGER & SHELLEY WATERS BOOTS, LOWER-WAGE WORKERS AND FLEXIBLE WORK ARRANGEMENTS, Workplace Flexibility 2010 on behalf of the Urban Institute 3 (Georgetown Univ. July 10, 2008).
43 Ellen Galinsky, James T. Bond & Eve Tahmincioglu, *What if Employers Put Women at the Center of Their Workplace Policies? When Businesses Design Workplaces that Support their Employees, Both the Businesses and the Employees Benefit, in* THE SHRIVER REPORT: A WOMAN'S NATION PUSHES BACK FROM THE BRINK (Shriver Center 2014).
44 See NATIONAL P'SHIP FOR WOMEN & FAMILIES, EVERYONE GETS SICK. NOT EVERYONE HAS TIME TO GET BETTER 4 (JULY 2011); FAMILY AND MEDICAL LEAVE IN 2012, *available at* http://go.nationalpartnership.org/site/DocServer/PSD_Briefing_Book.pdf; ABT ASSOCIATES, FAMILY AND MEDICAL LEAVE IN 2012: EXECUTIVE SUMMARY (pre-

pared for the U.S. Dep't of Labor) (Updated Sept. 2013).

45 *See generally* RESTAURANT OPPORTUNITIES CENTER UNITED, *supra* note 3. *See generally* LIZ BEN-ISHAI, HANNAH MATTHEWS, & JODIE LEVIN-EPSTEIN, SCRAMBLING FOR STABILITY: THE CHALLENGES OF JOB SCHEDULE VOLATILITY AND CHILD CARE (Ctr. for Law and Social Policy Mar. 2014), *available at* http://www.clasp.org/resources-and-publications/publication-1/2014-03-27-Scrambling-for-Stability-The-Challenges-of-Job-Schedule-Volat-.pdf.

46 *Id.* at 4.

47 *See generally*, KAREN SCHULMAN & HELEN BLANK, PIVOT POINT: STATE CHILD CARE ASSISTANCE POLICIES 2013 (Nat'l Women's Law Ctr. 2013).

48 WATSON & SWANBERG, *supra* note 13, at 8.

49 *See* Enchautegui, *supra* note 35, at 3-4.

50 Maureen Perry-Jenkins et al., *Shift Work, Role Overload, and the Transition to Parenthood*, 69 J. of Marriage & Family Vol. 1, 123-38 (2007).

51 HEATHER BOUSHEY, TAG-TEAM PARENTING 3 (Ctr, for Econ. & Policy Research Aug. 2005), *available at* http://www.cepr.net/documents/work_schedules_2006_08.pdf.

52 *See* Julia R. Henly, Luke Shaefer & Elaine Waxman, Nonstandard workschedules: Employer- and employee-driven flexibility in retail jobs, 80 SOCIAL SERVICE REVIEW 609-34 (Dec. 2006).

53 Jane Waldfogel and Sara McLanahan, *Work and Family*, FUTURE OF CHILDREN 21 NO. 2 (Fall 2011).

54 Lisa Dodson, et, al, *How Youth are Put at Risk by Parents' Low-Wage Jobs* BOSTON COLLEGE CTR, FOR SOC. POLICY (Fall 2012).

55 EXECUTIVE OFFICE OF THE PRESIDENT, COUNCIL OF ECONOMIC ADVISERS, WORK-LIFE BALANCE AND THE ECONOMICS OF WORKPLACE FLEXIBILITY 3 (Mar. 2010).

56 OXFAM, *supra* note 5, at 4.

57 LISA MATUS-GROSSMAN & SUSAN GOODEN, MDRC, OPENING DOORS: STUDENTS' PERSPECTIVES ON JUGGLING WORK, FAMILY AND COLLEGE 65 (July 2002), *available at* http://www.mdrc.org/sites/default/files/full_466.pdf.

58 JOAN C. WILLIAMS & PENELOPE HUANG, IMPROVING WORK-LIFE FIT IN HOURLY JOBS: AN UNDERUTILIZED COST-CUTTING STRATEGY IN A GLOBALIZED WORLD 13, 15, 57, (Ctr. for Work Life Law 2011); Cauthen, *supra* note 14, at 7.

59 Cauthen, *supra* note 18, at 1, 7.

60 Susan J. Lambert and Julia R. Henly. *Scheduling in Hourly Jobs: Promising Practices for the Twenty-First Century Economy* 9-10 (The Mobility Agenda 2009), *available at* http://ssascholars.uchicago.edu/work-scheduling-study/files/lambert_and_henly_scheduling_policy_brief.pdf; CTR. FOR LAW & SOC. POLICY (CLASP), RETAIL ACTION PROJECT, & WOMEN EMPLOYED, TACKLING UNSTABLE AND UNPREDICTABLE WORK SCHEDULES: A POLICY BRIEF ON GUARANTEED MINIMUM HOURS AND REPORTING PAY POLICIES 4-5 (Mar. 2014), *available at* http://retailactionproject.org/wp-content/uploads/2014/03/Tackling-Unstable-and-Unpredictable-Work-Schedules-3-7-2014-FINAL.pdf.

61 Rebecca Glauber, *Wanting More but Working Less: Involuntary Part-Time Employment and Economic Vulnerability*, Issue Brief No. 64 Carsey Institute 2-3 (Summer 2013), *available at* http://scholars.unh.edu/cgi/viewcontent.cgi?article=1198&context=carsey.

62 *Id.* at 3.

63 H. Luke Shaefer, *Part-Time Workers: Some Key Differences Between Primary and Secondary Earners*, National Poverty Center Working Paper Seiries #09-16 3 (Oct. 2009), *available at* http://npc.umich.edu/publications/u/working_paper09-16.pdf.

64 Rebecca Glauber, *supra* note 61, at 5.

65 LISA DODSON, TIFFANY MANUEL & ELLEN BRAVO, RADCLIFFE INST. FOR ADVANCED STUDY, KEEPING JOBS AND RAISING FAMILIES IN LOW-INCOME AMERICA: IT JUST DOESN'T WORK, AN ACROSS THE BOUNDARIES REPORT 16 (2002), *available at* http://low-wage.wikispaces.com/file/view/keeping+jobs+and+raising+families.pdf.

66 U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-07-2247, UNEMPLOYMENT INSURANCE: LOW-WAGE AND PART-TIME WORKERS CONTINUE TO EXPERIENCE LOW RATES OF RECEIPT 19 (2007), *available at* http://www.gao.gov/new.items/d071147.pdf.

67 *See* Gregory Acs, Katherin Ross Phillips & Daniel McKenzie, *Playing by the Rules but Losing the Game: America's Working Poor*, in LOW-WAGE WORKERS IN THE NEW ECONOMY (Richard Kazis & Marc. S. Miller eds., Urban Inst. Press 2000), *available at* http://www.urban.org/publications/410404.html.

68 *See generally* Dodson, *supra* note 65 (describing in detail the ways having parents in low-wage jobs negatively impacts youth.).

69 James T. Bond and Ellen Galinsky, *How Can Employers Increase the Productivity and Retention of Entry-Level, Hourly Employees?*, Families and Work Institute 12 (Nov. 2006), *available at* http://www.familiesandwork.org/how-can-employers-increase-the-productivity-and-retention-of-entry-level-hourly-employees-brief-2/; *see also* Galinsky, Bond & Tahmincioglu, *supra* note 43 ("Overall, 55 percent of low-income mothers surveyed said it would be "extremely important" to "have the flexibility I need to manage my work and personal or family life...No one surveyed said it was 'not important.'").

70 Sloan Center on Aging and Work at Boston College, *Why Employees Need Workplace Flexibility* (citing sources), *available at* http://workplaceflexibility.bc.edu/need/need_employees.

71 WFD Consulting, *Workplace Flexibility for Lower Wage Workers*, CORP. VOICES FOR WORKING FAMILIES, 17 (Oct. 2006), *available at* http://www.genderprinciples.org/resource_files/Workplace_flexibility_for_lower_wage_workers.pdf.

F

The American College of
Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

COMMITTEE OPINION

Number 554 • February 2013

Committee on Health Care for Underserved Women

This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed.

Reproductive and Sexual Coercion

ABSTRACT: Reproductive and sexual coercion involves behavior intended to maintain power and control in a relationship related to reproductive health by someone who is, was, or wishes to be involved in an intimate or dating relationship with an adult or adolescent. This behavior includes explicit attempts to impregnate a partner against her will, control outcomes of a pregnancy, coerce a partner to have unprotected sex, and interfere with contraceptive methods. Obstetrician–gynecologists are in a unique position to address reproductive and sexual coercion and provide screening and clinical interventions to improve health outcomes. Because of the known link between reproductive health and violence, health care providers should screen women and adolescent girls for intimate partner violence and reproductive and sexual coercion at periodic intervals such as annual examinations, new patient visits, and during obstetric care (at the first prenatal visit, at least once per trimester, and at the postpartum checkup). Interventions include education on the effect of reproductive and sexual coercion and intimate partner violence on patients' health and choices, counseling on harm-reduction strategies, and prevention of unintended pregnancies by offering long-acting methods of contraception that are less detectable to partners.

Background

Reproductive and sexual coercion involves behavior intended to maintain power and control in a relationship related to reproductive health by someone who is, was, or wishes to be involved in an intimate or dating relationship with an adult or adolescent (1). Reproductive coercion is related to behavior that interferes with contraception use and pregnancy (1). The most common forms of reproductive coercion include sabotage of contraceptive methods, pregnancy coercion, and pregnancy pressure. Birth control sabotage is active interference with a partner's contraceptive methods in an attempt to promote pregnancy (1). Examples include hiding, withholding, or destroying a partner's oral contraceptives; breaking or poking holes in a condom on purpose or removing a condom during sex in an attempt to promote pregnancy; not withdrawing when that was the agreed upon method of contraception; and removing vaginal rings, contraceptive patches, or intrauterine devices (IUDs). Pregnancy pressure involves behavior intended to pressure a female partner to become pregnant when she does not wish to become pregnant (1). Pregnancy coercion involves coercive behavior such as threats or acts of violence if a partner does not comply with the perpetrator's wishes regarding the decision to terminate or continue a pregnancy (1). Examples of pregnancy pressure and coercion include threatening to hurt a partner who does not agree to become pregnant, forcing a partner to carry a pregnancy to term against her wishes through threats or acts of violence, forcing a female partner to terminate a pregnancy when she does not want to, or injuring a female partner in a way that may cause a miscarriage (1). Homicide is a leading cause of pregnancy-associated mortality in the United States (2, 3). In one study, the majority of pregnancy-associated homicides were committed by an intimate partner (2).

Sexual coercion includes a range of behavior that a partner may use related to sexual decision making to pressure or coerce a person to have sex without using physical force (1). This behavior includes repeatedly pressuring a partner to have sex, threatening to end a relationship if the person does not have sex, forcing sex without a condom or not allowing other prophylaxis use, intentionally exposing a partner to a sexually transmitted infection (STI), including human immunodeficiency virus (HIV), or threatening retaliation if notified of a positive STI test result (1).

One quarter of adolescent females reported that their abusive male partners were trying to get them pregnant

through interference with planned contraception, forcing the female partners to hide their contraceptive methods (4). In one study of family planning clinic patients, 15% of women experiencing physical violence also reported birth control sabotage (5). Among adolescent mothers on public assistance who experienced recent intimate partner violence (IPV), 66% experienced birth control sabotage by a dating partner (6). Compared with women not experiencing abuse, women experiencing physical abuse and women disclosing psychologic abuse by an intimate partner had an increased risk of developing an STI (7). Based on this information, health care providers should include reproductive and sexual coercion and IPV as part of the differential diagnosis when patients are seen for pregnancy testing or STI testing, emergency contraception, or with unplanned pregnancies because intervention is critical.

Violence and Reproductive Health

Many women who experience reproductive and sexual coercion also experience physical or sexual violence. It may occur independent of physical or sexual violence. Evidence demonstrates that violence and poor reproductive health outcomes are strongly linked. Experiencing violence increases a woman's risk of unintended pregnancies. Women who have experienced IPV are more likely to report a lack of birth control use because of a partner's unwillingness to use birth control or because the partner wants a pregnancy (8). One study found that women with unintended pregnancies were four times more likely to experience IPV than women whose pregnancies were intended (9). In 2007, the prevalence of IPV was nearly three times greater for women seeking an abortion compared with women who were continuing their pregnancies (10). Males who perpetrated IPV in the past year were more likely to report inconsistent or no condom use during vaginal and anal intercourse as well as forced sexual intercourse without a condom, increasing the likelihood of unintended pregnancy (5, 11). A significant portion of women and adolescent girls seeking reproductive health care services have experienced some form of IPV, reproductive and sexual coercion, or both (5). Additional reproductive health issues with long-term implications for women who have experienced violence include earlier initiation of sexual intercourse, alcohol or drug abuse, STIs and HIV, miscarriages, and risky sexual health behavior, such as having unprotected sexual intercourse and having multiple sexual partners (12–14).

Interventions

In contrast to most IPV interventions, which significantly depend on programs or resources outside the clinical setting, health care providers can directly provide interventions that address reproductive and sexual coercion. Interventions can include educating patients about safety planning and support services, offering harm-reduction strategies, and providing discreet and confidential methods of contraception such as IUDs, emergency contraception, depot medroxyprogesterone acetate injections, and etonogestrel implants.

Family planning, clinic-based interventions that focused on awareness of reproductive and sexual coercion and provided harm-reduction strategies to address reproductive and sexual coercion reduced pregnancy coercion by 71% among women who experienced IPV (15). In addition, women in the intervention group were more likely to report ending a relationship because the relationship was unhealthy or because they felt unsafe (15). Integrating assessment and intervention for women who experience reproductive and sexual coercion into standard reproductive health care practices can enhance the quality of care and improve reproductive health outcomes. Because of the known link between reproductive health and violence, health care providers should screen women and adolescent girls for IPV and reproductive and sexual coercion at periodic intervals such as annual examinations, new patient visits, and during obstetric care (at the first prenatal visit, at least once per trimester, and at the postpartum checkup). Some examples of screening questions include the following:

- Has your partner ever forced you to do something sexually that you did not want to do or refused your request to use condoms?
- Has your partner ever tried to get you pregnant when you did not want to be pregnant?
- Are you worried your partner will hurt you if you do not do what he wants with the pregnancy?
- Does your partner support your decision about when or if you want to become pregnant?

Additional questions can be found in Committee Opinion No. 518, *Intimate Partner Violence*, or at www.acog.org/About_ACOG/ACOG_Departments/Health_Care_for_Underserved_Women/~/media/Departments/Violence%20Against%20Women/Reproguidelines.pdf (1, 16).

Helping patients to conceal contraceptive methods may be necessary to help protect the patient. For example, oral emergency contraception is often packaged in a large box with bold labeling, which could easily be discovered by an abusive partner. Health care providers should consider harm-reduction strategies such as giving a patient a plain envelope for the emergency contraceptive pills. This enables her to remove the packaging so the pills will be less likely to be detected by her partner (1). A copper IUD should be considered instead of oral emergency contraception to provide long-term protection given the high frequency of unprotected sex when reproductive or sexual coercion is identified as the reason for requesting emergency contraception.

It is important to be aware that some partners who perpetrate IPV may monitor bleeding patterns and menstrual cycles. For women in this situation, the copper

IUD could be a safe long-term contraceptive option because it does not typically cause amenorrhea. Health care providers should consider trimming IUD strings inside the cervical canal to ensure they are undetectable and to prevent removal by a partner. It should be noted that many women still have misconceptions about IUDs and would benefit from counseling to address these issues (17).

Because STIs and HIV are highly correlated with abusive relationships, it is important to determine whether the patient feels safe and able to make decisions about condom use and partner notification. If a patient has a positive STI test result and is afraid of how a partner may react when she notifies him or her about the STI, it is important to consider requesting anonymous partner notification services through a local health department.

Futures Without Violence, formerly Family Violence Prevention Fund, a U.S.-based nonprofit organization that works to end violence against women and children around the world, developed small, easy to conceal, wallet-sized safety cards in both English and Spanish, that have been cobranded by the American College of Obstetricians and Gynecologists. The safety cards provide information that helps women make the connection between unhealthy relationships and reproductive health concerns such as unintended pregnancies. The safety cards also include self-administered questions for IPV and reproductive and sexual coercion, harm-reduction and safety planning strategies, and information about how to get help and resources.

Health care providers can use the safety card to facilitate screening and educate patients about the effect of IPV and reproductive and sexual coercion on reproductive health. Asking about IPV and reproductive and sexual coercion lets patients know that they are not alone and that it is safe to talk to the health care provider. Use of these cards provides a brief evidenced-based intervention that can be reviewed with a patient in less than 1 minute (15). Cards may be discretely provided at the annual visit or anytime there is a concern regarding reproductive and sexual coercion or IPV. It is important to remember that it still may not be safe for some patients who are currently experiencing abuse to leave the examination room with the safety card. For additional information on using this card in an office setting, refer to, *Addressing Intimate Partner Violence and Reproductive Coercion: A Guide for Obstetric, Gynecologic and Reproductive Health Care Settings*, available at: www.acog.org/About_ACOG/ACOG_Departments/Health_Care_for_Underserved_Women/~/media/Departments/Violence%20Against%20Women/Reproguidelines.pdf (1). To obtain copies of the safety cards, send requests by e-mail to underserved@acog.org.

If a patient responds affirmatively to screening questions, the health care provider should validate her experience and commend her for discussing and evaluating her health and relationships. She should be reassured that the situation is not her fault and further assessment of her safety should be elicited and discreet contraceptive options reviewed. For additional support, patients may be offered hotline numbers, use of the office phone to access suggested care, and referral to a domestic violence advocate for additional resources.

Creating a Safe Environment for Assessment and Disclosure

Health care providers can create a safe and supportive environment for assessing and responding to reproductive and sexual coercion. Practices should have a written policy and provide training to health care providers and employees on IPV and reproductive and sexual coercion, how to offer referrals, and how to establish relationships with women's shelters and state health department violence prevention programs to enhance the services provided (1, 18). Private spaces should be made available to interview women without interruption and where conversations cannot be overheard (1). Having a clearly stated policy in the reception area helps the staff maintain the normal experience of seeing the patient alone without a friend or family member (1). For example, a sign could read, "In this clinic, we respect a patient's right to privacy and always see patients alone for some portion of the visit" (16). Health care providers may display educational posters that address IPV, reproductive and sexual coercion, and healthy relationships that are culturally sensitive, multicultural, and multilingual in bathrooms, reception areas, examination rooms, hallways, and other highly visible areas (1). Having information, including hotline numbers, safety cards, and resources, on display in common areas and in private locations, such as bathrooms and examination rooms, also can be helpful in educating patients who may not be ready to openly discuss their concerns at the present time (1).

Language is important in identifying and assisting patients who have experienced reproductive and sexual coercion. Health care providers must understand the vulnerabilities or triggers, both verbal and physical, that may affect these patients during an examination. Also, when obtaining a medical history, a patient experiencing reproductive and sexual coercion might not respond to the use of the term "rape" because it may occur with her partner and not a stranger. Using a more general term, such as "forced sex," may resonate more with the woman.

Before any assessment, health care providers should inform women about limitations of confidentiality and mandatory reporting legal requirements, which vary by state. A summary of state laws can be found at: www.futureswithoutviolence.org/userfiles/file/HealthCare/MandReport2007FINALMMS.pdf. Opponents of mandatory reporting repeatedly raise concerns for the patient's safety and confidentiality subsequent to reporting, the inadequate infrastructure of services for those who

experience violence, and the lack of data to support the assumed benefits of mandatory reporting. This suggests that mandatory reporting is not yet justified and should not be implemented without provisions that allow women to override or veto reporting requirements. However, some jurisdictions do mandate reporting, and health care providers should be familiar with these requirements. In addition, health care providers need to be familiar with relevant state privacy laws and federal regulations regarding the confidentiality of health information. It is important to note issues related to dating violence that involve a minor can also raise questions about mandatory child abuse reporting requirements and statutory rape laws (19). Child protective services, hospital legal counsel, and state medical societies' legal counsel may be helpful in delineating the requirements.

Recommendations

The American College of Obstetricians and Gynecologists recommends the following for obstetrician–gynecologists to improve the health of women who have been or are experiencing reproductive and sexual coercion:

- Participate in education events regarding reproductive and sexual coercion that covers birth control sabotage, pregnancy pressure and coercion, and the effect of IPV on patients' health and choices.
- Routinely screen women and adolescent girls for reproductive and sexual coercion in a safe and supportive environment that respects confidentiality.
- Counsel patients on harm-reduction strategies and safety planning.
- Offer long-acting methods of contraception that are less detectable to partners, like IUDs and the contraceptive implant or injection.
- Include reproductive and sexual coercion and IPV as part of the differential diagnosis when patients are seen for pregnancy or STI testing, emergency contraception, or with unintended pregnancies.

National Hotlines and Resources

The following resources are for information purposes only. Referral to these sources and web sites does not imply the endorsement of the American College of Obstetricians and Gynecologists. These resources are not meant to be comprehensive. The exclusion of a source or web site does not reflect the quality of that source or web site. Please note that web sites are subject to change without notice.

Hotlines

- National Domestic Violence Hotline
  1-800-799-SAFE (7233)
- Rape Abuse & Incest National Network (RAINN) Hotline
  1-800-656-HOPE (4673)

Web Sites

- Futures Without Violence (previously known as Family Violence Prevention Fund)
  www.futureswithoutviolence.org
- National Coalition Against Domestic Violence
  www.ncadv.org
- National Network to End Domestic Violence
  www.nnedv.org
- National Resource Center on Domestic Violence
  www.nrcdv.org
- Office on Violence Against Women
  (U.S. Department of Justice)
  www.ovw.usdoj.gov

References

1. Chamberlain L, Levenson R. Addressing intimate partner violence, reproductive and sexual coercion: a guide for obstetric, gynecologic and reproductive health care settings. 2nd ed. Washington, DC: American College of Obstetricians and Gynecologists; San Francisco (CA): Futures Without Violence; 2012. Available at: http://www.acog.org/About_ACOG/ACOG_Departments/Health_Care_for_Underserved_Women/~/media/Departments/Violence%20Against%20Women/Reproguidelines.pdf. Retrieved October 2, 2012. ⇦
2. Cheng D, Horon IL. Intimate-partner homicide among pregnant and postpartum women. Obstet Gynecol 2010; 115:1181–6. [PubMed] [*Obstetrics & Gynecology*] ⇦
3. Chang J, Berg CJ, Saltzman LE, Herndon J. Homicide: a leading cause of injury deaths among pregnant and postpartum women in the United States, 1991–1999. Am J Public Health 2005;95:471–7. [PubMed] [Full Text] ⇦
4. Miller E, Decker MR, Reed E, Raj A, Hathaway JE, Silverman JG. Male partner pregnancy-promoting behaviors and adolescent partner violence: findings from a qualitative study with adolescent females. Ambul Pediatr 2007;7:360–6. [PubMed] ⇦
5. Miller E, Decker MR, McCauley HL, Tancredi DJ, Levenson RR, Waldman J, et al. Pregnancy coercion, intimate partner violence and unintended pregnancy. Contraception 2010;81:316–22. [PubMed] [Full Text] ⇦
6. Raphael J. Teens having babies: the unexplored role of domestic violence. Prev Res 2005;12:15–7. ⇦
7. Coker AL, Smith PH, Bethea L, King MR, McKeown RE. Physical health consequences of physical and psychological intimate partner violence. Arch Fam Med 2000;9:451–7. [PubMed] ⇦
8. Gee RE, Mitra N, Wan F, Chavkin DE, Long JA. Power over parity: intimate partner violence and issues of fertility control. Am J Obstet Gynecol 2009;201:148.e1–7. [PubMed] [Full Text] ⇦
9. Gazmararian JA, Adams MM, Saltzman LE, Johnson CH, Bruce FC, Marks JS, et al. The relationship between pregnancy intendedness and physical violence in mothers of newborns. The PRAMS Working Group. Obstet Gynecol 1995;85:1031–8. [PubMed] [*Obstetrics & Gynecology*] ⇦

10. Bourassa D, Berube J. The prevalence of intimate partner violence among women and teenagers seeking abortion compared with those continuing pregnancy. J Obstet Gynaecol Can 2007;29:415–23. [PubMed]⇦

11. Raj A, Reed E, Miller E, Decker MR, Rothman EF, Silverman JG. Contexts of condom use and non-condom use among young adolescent male perpetrators of dating violence. AIDS Care 2007;19:970–3. [PubMed]⇦

12. Kim-Godwin YS, Clements C, McCuiston AM, Fox JA. Dating violence among high school students in southeastern North Carolina. J Sch Nurs 2009;25:141–51. [PubMed] ⇦

13. Silverman JG, Raj A, Mucci LA, Hathaway JE. Dating violence against adolescent girls and associated substance use, unhealthy weight control, sexual risk behavior, pregnancy, and suicidality. JAMA 2001;286:572–9. [PubMed] [Full Text]⇦

14. Fergusson DM, Horwood LJ, Lynskey MT. Childhood sexual abuse, adolescent sexual behaviors and sexual revictimization. Child Abuse Negl 1997;21:789–803. [PubMed]⇦

15. Miller E, Decker MR, McCauley HL, Tancredi DJ, Levenson RR, Waldman J, et al. A family planning clinic partner violence intervention to reduce risk associated with reproductive coercion. Contraception 2011;83:274–80. [PubMed] [Full Text]⇦

16. Intimate partner violence. Committee Opinion No. 518. American College of Obstetricians and Gynecologists. Obstet Gynecol 2012;119:412–7. [PubMed] [*Obstetrics & Gynecology*]⇦

17. Adolescents and long-acting reversible contraception: implants and intrauterine devices. Committee Opinion No. 539. American College of Obstetricians and Gynecologists. Obstet Gynecol 2012;120:983–8. [PubMed] [*Obstetrics & Gynecology*]⇦

18. Miller E, Jordan B, Levenson R, Silverman JG. Reproductive coercion: connecting the dots between partner violence and unintended pregnancy. Contraception 2010;81:457–9. [PubMed] [Full Text]⇦

19. Futures Without Violence. State codes on intimate partner violence victimization reporting requirements for health care providers. San Francisco (CA): FWV; 2007. Available at: http://www.futureswithoutviolence.org/userfiles/file/HealthCare/MandReport2007FINALMMS.pdf. Retrieved October 2, 2012.⇦

Copyright February 2013 by the American College of Obstetricians and Gynecologists, 409 12th Street, SW, PO Box 96920, Washington, DC 20090-6920. All rights reserved.

ISSN 1074-861X

Reproductive and sexual coercion. Committee Opinion No. 554. American College of Obstetricians and Gynecologists. Obstet Gynecol 2013;121:411–5.

Social Science & Medicine 70 (2010) 1737–1744

Contents lists available at ScienceDirect

Social Science & Medicine

journal homepage: www.elsevier.com/locate/socscimed

Male reproductive control of women who have experienced intimate partner violence in the United States

Ann M. Moore [a,*], Lori Frohwirth [a], Elizabeth Miller [b]

[a] Guttmacher Institute, 125 Maiden Lane, 7th Floor, New York, NY 10038, United States
[b] University of California — Davis School of Medicine, United States

ARTICLE INFO

Article history:
Available online 9 March 2010

Keywords:
USA
Reproductive health
Gender-based violence
Pregnancy
Abortion
Birth
Pregnancy promotion
Women

ABSTRACT

Women who have experienced intimate partner violence (IPV) are consistently found to have poor sexual and reproductive health when compared to non-abused women, but the mechanisms through which such associations occur are inadequately defined. Through face-to-face, semi-structured in-depth interviews, we gathered full reproductive histories of 71 women aged 18–49 with a history of IPV recruited from a family planning clinic, an abortion clinic and a domestic violence shelter in the United States. A phenomenon which emerged among 53 respondents (74%) was male reproductive control which encompasses pregnancy-promoting behaviors as well as control and abuse during pregnancy in an attempt to influence the pregnancy outcome. Pregnancy promotion involves male partner attempts to impregnate a woman including verbal threats about getting her pregnant, unprotected forced sex, and contraceptive sabotage. Once pregnant, male partners resort to behaviors that threaten a woman if she does not do what he desires with the pregnancy. Reproductive control was present in violent as well as non-violent relationships. By assessing for male reproductive control among women seeking reproductive health services, including antenatal care, health care providers may be able to provide education, care, and counseling to help women protect their reproductive health and physical safety.
© 2010 Elsevier Ltd. All rights reserved.

Introduction

Intimate partner violence (IPV) is associated with unwanted pregnancy, women not using their preferred contraceptive method, sexually transmitted infections including HIV/AIDS, miscarriages, repeat abortion, a high number of sexual partners, and poor pregnancy outcomes (Alio, Nana, & Salihu, 2009; Center for Impact Research, 2000; Coker, 2007; Fisher et al., 2005; Maman, Campbell, Sweat, & Gielen, 2000; Taggart & Mattson, 1996; Williams, Larsen, & McCloskey, 2008). The proximal determinants of unwanted pregnancy—forced sex and partner's unwillingness to use contraception—have been documented in relationships that include IPV (Campbell, Woods, Chouaf, & Parker, 2000; Lathrop, 1998). Other behaviors that further undermine women's ability to prevent an unwanted pregnancy in abusive relationships include women's lack of negotiating power to insist on contraceptive use, abusive partners' interference with women's use of contraception, and partners' refusal to pay for contraception (Branden, 1998; Heise, Moore, & Toubia, 1995). While these behaviors expose women to the risk of pregnancy, this body of work has not focused on whether men's intentions were to make the woman pregnant.

Pregnancy itself is a vulnerable time for women in abusive relationships. Previous work has documented the increased risk of violence during pregnancy (Gelles, 1988), with unintended pregnancies carrying an even greater risk of violence than intended pregnancies (Gazamararian et al., 1995). This violence may be the result of the partner's jealousy and resentment towards the unborn child (Campbell, Oliver, & Bullock, 1993; Mezey, 1997), and/or the partner's increased feelings of insecurity and possessiveness during the pregnancy (Bacchus, Mezey, & Bewley, 2006). Women report that financial worries and their reduced physical and emotional availability during pregnancy may lead their partners to physical violence (Bacchus et al., 2006). Another reason for violence that has not been systematically explored in the pregnancy and IPV literature is whether the partner may be using violence to make a woman resolve a pregnancy the way that he desires.

While many reproductive health correlates of IPV are known, and male control over various aspects of women's reproductive autonomy have been identified within as well as outside of physically violent relationships, the extent of male involvement in

* Corresponding author. Tel.: +1 212 248 1111; fax: +1 212 248 1951.
E-mail address: amoore@guttmacher.org (A.M. Moore).

0277-9536/$ – see front matter © 2010 Elsevier Ltd. All rights reserved.
doi:10.1016/j.socscimed.2010.02.009

explicitly promoting pregnancies and controlling the outcomes of such pregnancies has not been conceptualized as a type of abuse. We posit that it is ideal for women to have reproductive autonomy which we use to mean a woman's ability to make independent decisions about her reproduction. We define interference with this autonomy *reproductive control*. Reproductive control can be exerted upon women from sources other than their partners including parents, peers, and the medical establishment. Reproductive control by a partner is the present focus of inquiry.

Reproductive control occurs when women's partners demand or enforce their own reproductive intentions whether in direct conflict with or without interest in the woman's intentions, through the use of intimidation, threats, and/or actual violence. It can take numerous forms: economic (not giving the woman money to buy contraception or obtain an abortion), emotional (accusing her of infidelity if she recommends contraception or denying paternity of the pregnancy), as well as physical (beating her up upon finding her contraception or threatening to kill her if she has an abortion). This masculine exercise of power crosses the three main domains of gendered relations as described by Connell (1987): labor, as coerced childbearing reifies women's domestic responsibilities; power, through exerting authority over women's sexual experiences and biologic vulnerability; and cathexis, through men's appropriation of women's sexual, emotional and intimate experiences and mandating child-rearing.

An analysis of violence against women conducted in ten countries by the World Health Organization (WHO) recently defined IPV as physical (having been slapped, pushed, hit, kicked, choked, burned, or threatened with a weapon; singling out violence during pregnancy as having been beaten, punched or kicked in the abdomen while pregnant), sexual (having experienced forced sex, coerced sex out of fear of her partner, or having been forced to do something sexually humiliating), emotional (having been insulted, belittled, scared, intimidated, or threatened), and controlling (isolating, monitoring, ignoring, demonstrating jealousy, acting suspicious, or demanding that the woman need permission to do basic day to day activities) (García-Moreno, Jansen, Ellsberg, Heise, & Watts, 2005). This same study defined poor reproductive health outcomes of IPV to include unsafe sexual behavior, pregnancy complications, unwanted pregnancy and unsafe abortion (Ellsberg et al., 2008). In a summary piece, Coker (2007) reviewed 51 articles published between 1966 and 2006 which examine the association between IPV and sexual health. Based on this body of work, she modeled the direct as well as indirect causal mechanisms through which IPV affects sexual health indicators documented to date in the literature. Identified mechanisms include decreased control over one's sexuality as well as decreased contraceptive use which can lead to increased unplanned pregnancy and increased sexually transmitted infections.

The WHO study and Coker's review treat reproductive correlates of IPV as indirect consequences of abuse rather than as measurable dimensions of abusive behavior. Specifically, their models do not account for pregnancy promotion, birth control sabotage, and coerced abortion. Pregnancy promotion has been defined as messages and behaviors that lead females to believe their partner was actively trying to impregnate them (Miller et al., 2007). The Center for Impact Research has defined birth control sabotage as verbal or behavioral sabotage of the woman's use of birth control by her partner (2000). Other literature has shown that this sabotage can be direct (interfering with her contraceptive use) as well as indirect (causing the woman to fear violence if she does use contraception or even brings up the topic) (Blanc et al., 1996; Clark et al., 2008; Njovana & Watts, 1996; Watts & Mayhew, 2004; Wingood & DiClemente, 1997). Abusive men coercing their partners to have abortions has also been documented (Coggins & Bullock, 2003; Hathaway, Willis, Zimmer, & Silverman, 2005), as has males forcing their partners to become sterilized (Hathaway et al., 2005). As coercive control of women is a central motivation of abuse (Campbell & Humphreys, 1993), we argue that reproductive control is another component of power and control in abusive relationships.

This study adds to previous work on reproductive correlates of IPV by defining the different types of reproductive control perpetrated by men, examining the behaviors along a temporal continuum. Those three temporal periods are before sexual intercourse, during sexual intercourse, and post-conception. Pre-sexual intercourse, women may be subject to verbal pressure and threats from their partner that he intends to make them pregnant. In this same time frame, partners may prevent women's access to and use of effective contraception. During sexual intercourse, which can be forced, men can manipulate contraception to render it ineffective which includes not withdrawing when that was the agreed-upon method of contraception or removing condoms. Post-conception, partners can attempt to influence the outcome of the pregnancy for it to end either in an abortion or a birth. More examples of each type of reproductive control as experienced by our sample are provided in Table 1.

Methods

The study, conducted in 2007, collected the reproductive experiences of women who have ever experienced IPV. We employed a purposive sampling strategy, recruiting 75 women with a history of IPV from three sites: a domestic violence shelter, a freestanding abortion clinic, and a family planning clinic providing a full range of reproductive health services including abortion. All sites were located in large metropolitan areas, one in the Midwest and two on the East Coast approximately 150 miles away from one another. The domestic violence shelter provided a sample of women with a known history of IPV while the clinics provided opportunities to identify women seeking reproductive health care who screened positively for IPV.

Women were eligible to participate if they were between 18 and 49 years of age, spoke English well enough to understand the questions and relate their experiences, and answered either of the following questions affirmatively: "Have you ever been hit, slapped, choked, kicked, physically hurt or threatened by a current or former partner?" or "Has anyone ever made you take part in any sexual activity when you did not want to?" At the domestic violence shelter, we assumed that all women 18–49 were eligible for participation and the interviews were scheduled at a time convenient for the women. At the abortion clinic, patients were screened by clinic staff, while at the reproductive health clinic, patients were screened by the study interviewers. At the abortion clinic, women were interviewed before their surgical abortion or during their follow-up visit; while at the reproductive health clinic, women were interviewed after their medical consultation. Interviews were conducted by female members of the study team who had been trained to ask women about violence and sexual health issues. The interviewers were trained to conduct a safety plan to help any respondent in current danger get to a safe place. As a further protection, all the facilities where the interviews were conducted either had a social worker on staff or had staff who were trained in appropriate referral techniques if the individual demonstrated the need for further counseling. Both the safety plan and appropriate referrals for women in immediate danger were used during the fieldwork. Interviewers obtained written informed consent from each respondent prior to each interview. A Certificate of Confidentiality from the National Institutes of Health was obtained to further protect the respondents. The study protocol was approved by the Institutional Review Board of the Guttmacher Institute.

Table 1
Reproductive control classifications laid out along a temporal continuum.

Classifications	Behavior
Before sexual intercourse	
Pregnancy promotion	Pressuring and coercing a woman to become pregnant; stating intentions to impregnate a woman; closely monitoring a woman for signs of pregnancy; pressuring a woman to become pregnant again immediately after a pregnancy loss; accusing her of being unfaithful if she uses birth control; accusing her of being unfaithful if she wants to abstain from sex as a tactic to get to her to have sex
Contraceptive sabotage	Flushing birth control pills down the toilet; finding hidden birth control pills or emergency contraception in order to destroy them; refusing to withdraw (although that was the agreed-upon method of contraception); refusing to help pay for birth control; forcing sterilization; convincing a woman that birth control has dangerous side effects
During sexual intercourse	
Sexual violence	Rape; forcing unprotected sex; forcing a woman to continue having sex after the condom breaks; having unprotected sex with a woman while she is asleep
Condom manipulation	Surreptitiously removing the condom during sex; compromising the condom (e.g. covertly biting holes in the condom before putting it on); not putting the condom on but saying he did; refusing to use condoms; accusing a woman of being unfaithful if she asks the man to use a condom; forcing a woman to continue having sex after condom breaks
Contraceptive sabotage	Removing the NuvaRing from inside a woman's vagina; refusing to withdraw (although that was the agreed-upon method of contraception); removing the condom during sex; forcing a woman to continue having sex after a condom breaks
Post-conception	
Controlling pregnancy outcome	Refusing to help pay for an abortion; refusing to allow a woman to have an abortion; strongly encouraging or pressuring a woman to have a birth; threatening to end a woman's pregnancy violently if she did not have an abortion; perpetuating violence against her in order to cause a miscarriage or kill the fetus
Interfering with health care	Interrupting, obstructing or sabotaging abortion appointments (sometimes resulting in the woman having an abortion at a later gestation than she desired); sabotaging abortion plans by forcing a woman to be ineligible for an abortion; preventing access to prenatal care

Using a semi-structured set of open-ended questions, participants were asked to describe their relationship histories including all contraceptive use, births, abortions and miscarriages. This technique captured whether each partner had been physically and/or sexually abusive. Interviews covered respondents' abilities to negotiate sexual encounters, contraception, and decisions around pregnancy. The interviews also covered respondents' experiences with health care providers and feelings about their sexuality. Interviews lasted on average 1 h. At the conclusion of the interview, participants were provided a list of local resources for violence-related services and received $40 cash. Final sample size was determined by achieving a balanced number of respondents from the three sites to achieve a total sample that would capture a breadth of diversity and which approached saturation. Four respondents were excluded from this analysis; three had incomplete interviews, and one had a history of only childhood sexual abuse and no IPV (final $N = 71$).

Interviews were digitally recorded without any identifying information and professionally transcribed verbatim. Transcripts were edited for accuracy by members of the research team. The coding structure into which the data were organized, created in N6 (QSR International, Melbourne, Australia), reflected both original research questions in addition to themes and topics that emerged during the interviews. Additions of new codes or changes in code definitions were determined via consensus among the research team. No new codes emerged after coding approximately 30 interviews. The team compared results and checked each other's work to verify agreement in coding. Respondents' reproductive experiences were retrieved within the context of the relevant relationship—physically violent or non-physically violent. This distinction was made according to a combination of the respondent's description of the relationship and the interviewers' understanding of whether any of the abusive behaviors as defined in the screening questions were present in that relationship. The current analysis focuses on experiences of reproductive control across respondents' physically abusive and non-physically abusive relationships. Some respondents experienced various types of reproductive control surrounding one pregnancy (or unsuccessful attempts at making her pregnant) while other respondents experienced various types of reproductive control across different pregnancies (including multiple and varied attempts at making her pregnant).

In the majority of cases where partners attempted to influence the outcome of the pregnancy, partners' desires were in conflict with the respondents'. In a small number of situations included in this analysis, respondents were ambivalent or even in agreement with the pregnancy outcome that her partner wanted, but her desires were irrelevant to her partner and these men still resorted to controlling their partners. All reported experiences with reproductive control qualified for inclusion in our analysis, and were not dependent on the final outcome of the controlling behavior. That is, if a man wanted a woman to get pregnant but she effectively resisted his coercion, she was still categorized as having experienced reproductive control. Women who resisted control are not a separate population of women: some women were able to resist control in one situation but not in others.

Results

Sample characteristics

Sample characteristics are presented in Table 2. Fifty-three respondents (74%) reported ever experiencing some type of reproductive control. The demographic characteristics of the respondents who reported experiencing at least one type of reproductive control did not differ from the rest of the sample. Most respondents were between 20 and 29 years of age, African-American, and had completed at least high school.

Pregnancy promoting behavior (prior to sexual intercourse)

Women who had experienced reproductive control often began their narrative explaining the ways that their partners verbally threatened and coerced them to become pregnant. Verbal threats, such as a man telling his partner he was going to make her pregnant, often took place disconnected from the act of intercourse, sometimes prompted by images on television or other environmental stimuli. Women said that their partners often spoke about wanting to impregnate her to tie her to him forever.

> He was like, "I should just get you pregnant and have a baby with you so that I know you will be in my life forever." ...It's just like, for what, you want me to not go back to school, not go to

Table 2
Demographic characteristics of entire sample ($N = 71$) and those who experienced any reproductive control (RC) ($N = 53$)[a]

	All	%	RC	%
Age				
18–19	7	10%	7	13%
20–24	16	23%	12	23%
25–29	22	31%	18	35%
30–39	15	21%	10	19%
40–49	10	14%	5	10%
Total	70	100%	52	100%
Race				
White/Caucasian	23	33%	14	26%
Black/African-American	37	53%	32	60%
American Indian/Alaska Native	1	1%		0%
Hispanic/Latina	8	11%	6	11%
Other	1	1%	1	2%
Total	70	100%	53	100%
Education				
9–11th grade	9	14%	8	17%
High school graduate/GED	20	30%	18	38%
Some College/Associate's Degree	24	36%	16	33%
College graduate or higher	13	20%	6	13%
Total	66	100%	48	100%
Abortion experience				
Yes	48	68%	40	75%
No	23	32%	13	25%
Total	71	100%	53	100%
Parity				
0	27	38%	17	32%
1	11	15%	9	17%
2	12	17%	10	19%
≥3	21	30%	17	32%
Total	71	100%	53	100%
Have ever had a sexually transmitted infection				
yes	43	61%	34	68%
no	27	39%	16	32%
Total	70	100%	50	100%
# of sexual partners				
2–5	16	23%	13	26%
6–10	18	26%	10	20%
11–20	13	19%	10	20%
20–50	11	16%	9	18%
≥50	10	14%	8	16%
Total	68	98%[b]	50	100%

[a] Ns in the table do not total 53 as some respondents refused to answer some of the demographic characteristic questions.
[b] Does not equal 100% due to rounding.

college, not want me to do anything just sit in the house with a baby while you are out with friends.
–Respondent 1, 19 years of age at time of interview. This partner refused condoms and tried to convince the respondent not to use birth control, accusing her of being unfaithful if she tried. He denied paternity when she became pregnant. She had two abortions with him, both of which he refused to pay for.

In a number of situations, the abusive partner was being sent to prison and his stated reason for wanting to make his partner pregnant was if she were pregnant, he saw less chance of her leaving him while he was imprisoned because she would be seen as less desirable by other men and invested in maintaining a relationship with the father of the child.

Women related these incidents underscoring their partners' blatant disregard for their own pregnancy intentions. When women objected to being told they were going to be impregnated, women reported being ignored, belittled or abused.

We are not ready for kids. You know I already had, at the time I had two children and I told him, like, "We are not ready for kids. Our relationship is not even stable enough." And he would be like, "That's not true. It's never the right time to have a kid. You just don't want to be a part of me. You just don't want me to be around forever." And I will have to, like, coerce him into believing that I wanted to be with him and that wasn't the reason why, to avoid him back lashing with all that extra, "I am not shit," and, "I am a whore," and all that kind of stuff.
–Respondent 2, 28 years of age at time of interview. This partner repeatedly flushed her birth control pills down the toilet and refused to use condoms. When she did become pregnant, she had a miscarriage but her partner accused her of having a covert abortion. Years later he raped her and she became pregnant and did have an abortion.

Since, in some situations, men interpreted women's protests to being made pregnant as emotional rejection, this set into play complex dynamics which often led to the woman reassuring her partner of her feelings for him to avoid abuse and this sometimes included having unprotected sex.

Intentionally trying to impregnate a woman who does not want to become pregnant (during sex)

Threatening women with pregnancy during sex ran a gamut of behaviors ranging from surreptitiously deceptive to violent. Forced sex, as a form of physical violence, has been well documented (Coker, 2007), but forced sex which took place either with the explicit intention of impregnating the woman or with complete indifference to whether the woman was protected from pregnancy, has not been documented. Respondents' experiences of unwanted sex ranged from violent rape to engaging in unwanted sexual intercourse, sometimes only unwanted because it was unprotected.

Respondent (R): I was supposed to go back for my Depo shot [Depo-Provera, an injection to be obtained every three months that hormonally prevents pregnancy] and I missed my appointment and of course, I can't tell him, "No, he can't have any [sex]," you know.
Interviewer (I): Why can't you tell him "no"?
R: Because "no" is not a question, "no" is not, there is no "no" when it comes to sex with him. [...] So regardless of whether I wanted to get pregnant or not, you know, there's, you can't say "no."
–Respondent 3, 25 years of age at time of interview. The respondent was with this abusive man for 8 years. He would make her have sex and not use condoms. Her last two pregnancies with him were unwanted.

While some men, such as the man described above, acted indifferent to their partner's contraceptive use and pregnancy desires, some respondents described their partner's active interception of contraceptive use which left them exposed to the risk of unwanted pregnancy.

The most common ways contraceptive sabotage occurred was either when men failed to withdraw even though it was understood by the woman to be the agreed-upon method of contraception or when men refused to use condoms. When men did consent to use condoms, many respondents said that their partners manipulated the condoms to render them ineffective including taking them off surreptitiously before or during sex, biting holes in them, and not telling their partners when the condom came off or broke. Another

way that respondents experienced contraceptive sabotage was when their partners tried to dissuade them from using hormonal contraception by citing exaggerated side effects that scared the respondent into non-use. This dissuasion often took place in combination with verbal threats of pregnancy or direct physical interference so that there was no doubt about the man's intentions.

> Interviewer (I): Do you feel like he ever tried to control your use of birth control?
> Respondent (R): Yeah.
> I: How so?
> R: By telling me not to use it or like when I had the pill, he used to act out and ask me why I am using them. [...] Then, there was another time I started using the Ring [the NuvaRing, a hormone-releasing ring placed in the vagina to prevent pregnancy that must be changed monthly] and he pulled it out of me. [He asked] "What's this, who be advised you to be using this kind of stuff?" [...] I was like, I thought I could actually hide this one, not knowing you will come up inside of me and pull it out of me.
> – Respondent 4, 24 years of age at time of interview. This partner scared her out of taking birth control pills telling her, ""There is always some kind of harmful side effect...it messes up your inside sometimes, it messes up so bad that you can't even have kids or stuff like that." And I was like, "Okay, well I want to be able to have kids one day." So I stopped it, I got scared of it."" After this incident with the Nuvaring, she got on the Patch [an adhesive patch that one places on one's body and it releases hormones to prevent pregnancy; it must be replaced monthly], which she was able to hide for a while until he found it and told her that someone had died from using the Patch and that it was causing her hair to fall out. She carried one pregnancy to term with this partner and aborted another.

When a pregnancy occurred, women were vulnerable to further reproductive control to bring about the pregnancy outcome he desired.

Attempts at influencing the outcome of the pregnancy (post-conception)

Most women who reported that their partner attempted to control the pregnancy outcome experienced pressure or coercion to resolve the pregnancy the way he wanted; fewer women reported experiencing threats of violence and the use of force.

Among respondents who wanted to terminate the pregnancy, they described abusive partners making them feel bad about their desire to abort using tactics such as begging, badgering and making promises to support the baby to pressure the women into giving birth.

> And I told him—right when I found out I was pregnant, I told him, "You know, I hate to say this, but I want to have an abortion." [...] [He said], "No, you're crazy. How can you say that, [respondent]? You can't just kill your child!" And he was just making me feel so guilty until, finally, I was just, like, "Okay, then. I'll keep the baby."
> –Respondent 5, 19 years old at the time of the interview. This respondent did not want to become pregnant with her violent, much older partner. At that time she was only 16, however, he refused to use condoms. She attempted to use birth control pills, but he would refuse to pay for them and she would run out, and he would accuse her of taking them because she was cheating on him. Right before she delivered the pregnancy described above, he began insisting that the child wasn't his, and kicked her out of the house.

Other men refused to allow their partners to have abortions, denying her access to an abortion. Sometimes this was through men withholding the money to pay for an abortion; some partners sabotaged appointments for abortions by doing things such as making the respondent eat, which prevented her from being able to have the general aesthesia she needed for the abortion; coming into the clinic and "breaking things up" so that the woman left with the man to stop him from making more of a scene; and withholding transportation including bus fare so that she could not get to the clinic for the procedure.

> He kept stopping it [the abortion] [...]. He kept track [of when the appointments were], taking the car, [saying the car] wouldn't work, saying, "I can't come because of this and this but I have to be there [for the abortion], but I have to work this day," so he kept dragging it out, 'cause he wanted me to not be able to have it.
> –Respondent 6, 26 years old at the time of the interview. This partner impregnated her against her will by forcing her to have sex and refusing to withdraw. She ended up aborting at 4 months gestation. She had four other abortions with this partner.

Respondents also described partners who threatened to harm or kill them if they had an abortion:

> He really wanted the baby—he wouldn't let me have—he always said, "If I find out you have an abortion," you know what I mean, "I'm gonna kill you," and so I really was forced into having my son. I didn't want to; I was 18. [...] I was real scared; I didn't wanna have a baby. I just got into [college] on a full scholarship, I just found out, I wanted to go to college and didn't want to have a baby but I was really scared. I was scared of him.
> –same respondent as above in a different abusive relationship. Her partner attended the delivery against her will, and she ran away from him a few days after the birth.

Among women who wanted to have the child, some described experiencing pressure and coercion to terminate a pregnancy. Even when men had not used contraception to avoid an unintended pregnancy, there were situations in which men demanded abortions once their partners became pregnant. Some men threatened to hurt the woman with the intention of bringing about the end of the pregnancy.

> Respondent (R): He sat there and was like, "If you don't get it done, I'm throwing you down the steps, or I'm doing something!"
> Interviewer (I): Did that scare you?
> R: At the same time, yeah, because I probably could believe he would do it. But, because at one time, he was like, "I'll just punch in your stomach," and I am thinking, "Oh yeah, he punched me on my face, he might punch me in my stomach." So just actually feeling, like, the pain because feeling the baby there, it was, like I can't do this, I was like, "This is crazy." I was like, "If it doesn't get done [by a doctor], he's going to do it, and I don't want that to be done. So if it's going to be done, it's going to be done [the] right way, so."
> –Respondent 7, 21 at the time of the interview. She did not want to have this child either but a combination of fear of the procedure and lack of money delayed her from making an appointment. She finally got an abortion in the 5th month of the pregnancy.

Not all women did what their partners wanted them to do—some had abortions when their partners wanted them to have the child; some had children that their partners wanted them to abort. These acts of resistance occurred much less frequently than adherence to partner's demands and in a number of cases led to a high number of abortions: one woman whose partner wanted her to have children, refused condom use, and refused to let her use

contraception, had had eight abortions at the time of the interview, all had been pregnancies with this same partner.

Discussion & implications

These narratives capture the range and intensity of partners' attempts to control women's reproductive lives. Just as other types of abuse are emotional as well as physical, reproductive control was also emotional (through pregnancy promotion, accusing a woman of infidelity if she suggests contraceptive use) as well as physical (through forced sex or physically interfering with a woman's use of contraception). The behaviors presented here do not represent an escalating sequence of events (from promoting a pregnancy, to forced impregnation, to attempting to influence the outcome of a pregnancy) as not everyone in the sample experienced all of the types of control presented. Yet events of reproductive control rarely occurred in isolation of other events of reproductive control. Furthermore, women related experiencing reproductive control within and across their relationships including in non-physically abusive relationships.

In Coker's (2007) review of the literature, she calls for tests of and revisions to the conceptual model that she proposes which summarizes the relationship of IPV and sexual health as documented to date in the literature since at the time she wrote her article, she pointed out that we did not know the mechanisms by which IPV affects sexual health indicators. Based on our findings, this study extends Coker's conceptual model on sexual and reproductive health outcomes of IPV by adding reproductive control as a proximal mechanism linking sexual as well as reproductive outcomes with IPV. The variables that we added to the left-hand side of Coker's conceptual framework—increased pregnancy promotion and decreased reproductive autonomy carried out through unwanted impregnation and partner control over pregnancy resolution—lead to loss of control over one's sexuality, decreased contraceptive use, increased unwanted pregnancy and its concomitant outcomes of increased (unwanted) births and (unwanted) abortions and all the subsequent correlates already included in Coker's model including stress, reproductive health problems, decreased sexual pleasure and physical pain. The addition of the "Reproductive Control" box shows that IPV does not have to precede reproductive control and that reproductive control may occur without IPV but is accompanied by the same sequelae (decreased contraceptive use, increased unplanned pregnancy) as when it is accompanied by IPV.

Throughout Coker's model, we added titles to the boxes to help clarify the categories being captured. We also added greater specificity to relevant Coker categories: under decreased contraceptive use, we add forced (unprotected) sex and contraceptive sabotage. "Unprotected" in parentheses indicates that in some instances, while the sex itself is not unwanted, the fact that it is without contraception makes it unwanted. We added the additional outcomes of an increase in (unwanted) births and an increase in (unwanted) abortions (that is both births and abortions that are wanted by the woman as well as births and abortions that are brought about through coercion by her partner) to the box describing reproductive health outcomes. We changed a number of the arrows to be uni-directional—the modified arrows are circled in the figure. We moved infertility from the box on the reproductive outcomes of IPV and reproductive control to the box on reproductive organ problems. Finally, we added directional arrows on some of the measures of Coker's existing model, e.g. loss of control over one's sexuality increases women's reproductive organ pathologies and increases sexual dysfunction including pain (Fig. 1). Our additions to Coker's (2007) model are bolded to draw attention to them.

This conceptual model will continue to evolve as our lines of inquiry for studying reproductive control become more sophisticated. Further studies will also provide validation of the phenomenon by documenting its occurrence among different populations and with larger samples.

Reproductive control is a heretofore under-explored process that can lead to negative reproductive health outcomes (unintended pregnancy; rapid, repeat pregnancy; sexually transmitted infections; repeat abortion; and women's inability to meet their fertility goals) among women who have experienced IPV. Interventions crafted around mitigating reproductive control could take the form of targeted assessment and prevention strategies in clinical settings. Assessment would allow providers to identify which women may need to hide their contraceptive method from their partners as hidden methods of birth control have the potential of improving the reproductive health outcomes of women who are experiencing reproductive control (Bimla Schwarz, Gerbert, & Gonzales, 2007). Providers should conduct prenatal care and abortion counseling in private, and should ask questions about whether anyone is pressuring the woman either to terminate or to continue the pregnancy. If the woman is being pressured to continue the pregnancy, a medical abortion has the potential of being passed off as a miscarriage which may help her safely terminate a pregnancy her partner wants her to continue. Yet these decisions carry risks for the woman and so a decision-making model that takes into account possible violence she may experience as a result need to be discussed with the woman and factored into the appropriate course of action.

Recent legislative efforts have been introduced across the U.S. aimed at penalizing partners who coerce a woman to have an abortion. Some of these measures attempt to penalize the doctor who provides an abortion taking place under coerced circumstances. While these data include evidence of coerced abortions, they also demonstrate that if women are unable to get an abortion demanded by their partners, some may be at risk of experiencing physical violence from the partner. Some of this violence might be perpetrated with the intention of inducing an abortion. Denying such a woman a safe abortion can therefore endanger her health. Furthermore, these data also highlight the occurrence of coerced births. The one-sided emphasis on only penalizing partners and health care providers involved in coerced abortions does not adequately address the danger a woman is in who is experiencing reproductive control.

These findings should be interpreted in light of the following limitations. The data were gathered after screening women on their experiences of IPV and sexual abuse. This could have led women to overemphasize their abusive relationships so that these data underrepresent women's experiences in non-physically abusive relationships. Another possible bias is that women may have been more likely to talk about reproductive control experiences that resulted in an unintended pregnancy. Both of these possibilities would generate an underestimation of the extent of reproductive control. These findings cannot be generalized to other women experiencing IPV or to women without IPV histories. Since the majority of the sample was African-American, we do not know if comparable results would have emerged among a different sample.

As these data are cross-sectional, we are not able to elucidate the temporal order of reproductive control, i.e. whether experiencing reproductive control comes before experiences of physical violence, occurs concomitantly within physically abusive relationships, or is possibly occurring after physical aggression or perhaps all of the above. We do know that some relationships with reproductive control did not include physical violence as, according to the respondents, those relationships had come to an end. We only have women's responses from a single point in time, even though

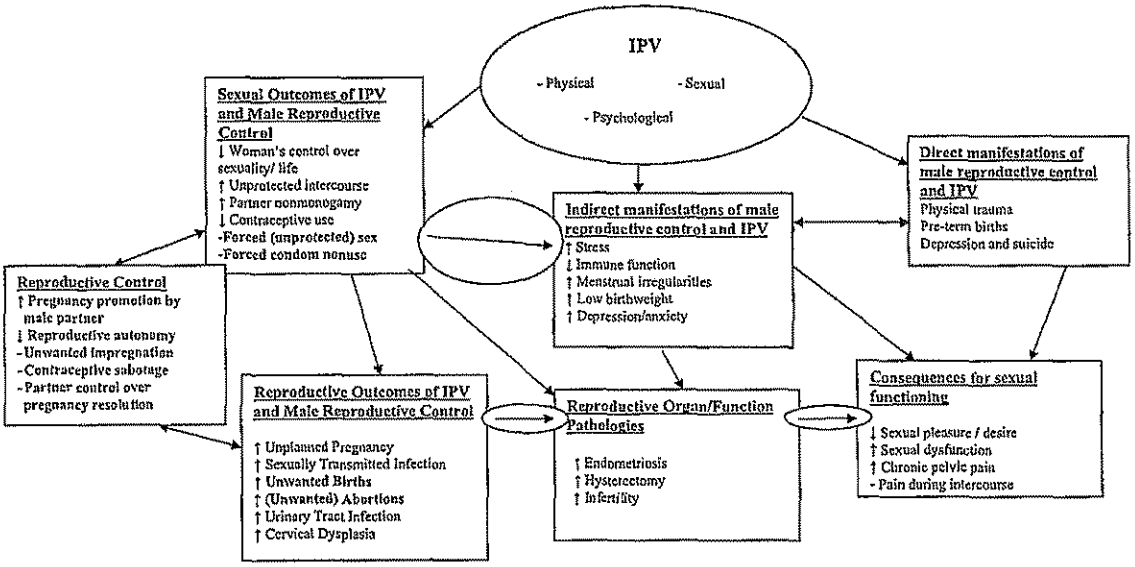


Fig. 1. Expanding Coker's (2007) Model on IPV and Health to Include Mechanisms Through Which Male Reproductive Control and IPV May Affect Women's Reproductive and Sexual Health.

some of these events had happened recently, the narration of those events were likely influenced by recall bias. Had they been asked these same questions on a different day when they were not in a domestic violence shelter or receiving reproductive health care services, women may have answered differently.

Lastly, our understanding of what took place in the reproductive arena is inherently dependent upon the woman's rendition of the experience. A woman may maintain a version of accounts that she finds easier to accept because of what she thinks it says about her, children she may have, and/or her relationship. For example, she may not reveal instances of reproductive control if doing so reduces her feelings of autonomy. Alternatively, she may choose to represent what took place as beyond her control for reasons of self-representation. The biases could work in either direction.

The fact that men are attempting to control women's reproduction is not new. The fact that couples disagree on desired fertility goals is also not new—there are high rates of couple disagreement about their desired number of children worldwide (Voas, 2003). What makes reproductive control something that deserves public health attention is the threats and coercion men enacted on these women to try to get them pregnant and resolve pregnancies in the manner the men wanted, often leaving the women unable to act autonomously.

Due to evolving gender scripts and shifting hierarchies, the enactment of masculinity is no longer as straightforward as it perhaps was in the past. Nor are many of its forms accessible to socially disenfranchised men due to social isolation as a result of race, social status or income, just to name some of the potentially isolating social attributes (Barker, 2005). To the extent that men perceive their roles in society to be in crisis, they may resort to reproductive control through disregard for women's pregnancy preferences, forced pregnancies and mandatory childbearing as a means to keep women in subordinate positions and exert patriarchal power (Connell, 1987). Further examination of men's motivations and actions in the reproductive sphere is needed to allow us to achieve a better theoretical understanding of reproductive control.

More research is needed into effective ways to foster resiliency among women at risk of partner manipulation in the reproductive arena. Prevalence estimates of reproductive control in the population at large would inform the magnitude and breadth of this phenomenon. Further studies are also needed on the multiple ways that women experience constraints on their reproductive autonomy. Examination of longer-term effects of experiencing reproductive control on sexual health is also needed. Beyond reproductive control, research on the other mechanisms through which women with histories of IPV experience reproductive health disadvantages remains critical.

In conclusion, this study identifies a wide range of behaviors in which male partners engage in their efforts to control pregnancy and pregnancy outcomes of their female partners. The experiences of reproductive control identified here help explain the mechanisms through which IPV is correlated with poor reproductive health outcomes including unintended pregnancies that either contribute to the abortion rate or result in mistimed or unwanted births. Public health prevention and intervention efforts to identify reproductive control are needed wherever women receive sexual and reproductive health care so that women can be educated about the impact of such controlling behaviors on their health. Elucidating the breadth and prevalence of reproductive control in previously unrecognized ways may assist in improved service delivery in reproductive health settings as well as engaging reproductive health care providers in assessing for both IPV and reproductive control among their female patients.

Acknowledgements

The authors would like to acknowledge the women we interviewed for this project who shared the most intimate and painful details of their lives in order to help others. We thank you. We also thank Rebecca Levenson and Lisa James for their expertise in the field of family violence and their contribution to the conceptualization, design, implementation and analysis of this project. We would also like to thank Nakeisha Blades, Gabrielle Oestreicher and Ragnar Anderson of the Guttmacher Institute for their help with cleaning and analysis of the data, and Rachel Jones and Heather Boonstra of the Guttmacher Institute for their insightful comments

on the paper. Additionally, we would like to thank the funders of this project, The Wallace Alexander Gerbode Foundation and an anonymous donor.

References

Alio, A. P., Nana, P. N., & Salihu, H. M. (2009). Spousal violence and potentially preventable single and recurrent spontaneous fetal loss in an African setting: cross-sectional study. *The Lancet, 373*, 318–324.

Bacchus, L., Mezey, G., & Bewley, S. (2006). A qualitative exploration of the nature of domestic violence in pregnancy. *Violence Against Women, 12*(6), 588–604.

Barker, G. T. (2005). *Dying to be men: Youth, masculinity and social exclusion*. New York: Taylor and Francis, Inc.

Bimla Schwarz, E., Gerbert, B., & Gonzales, R. (2007). Need for emergency contraception in urgent care settings. *Contraception, 75*, 285–288.

Blanc, A. K., Wolff, B., Gage, A. J., Ezeh, A. C., Neema, S., & Ssekamatte-Ssebuliba, J. (1996). *Negotiating reproductive health outcomes in Uganda*. Calverton, MD: Macro International Inc and Kampala, Uganda: Institute of Statistics and Applied Economics, Makerere University.

Branden, P. S. (1998). Contraceptive choice and patient compliance: the health care provider's challenge. *Journal of Nurse-Midwifery, 43*, 471–482.

Campbell, J. C., & Humphreys, J. (1993). *Nursing care of survivors of family violence*. St. Louis: Mosby.

Campbell, J. C., Oliver, C., & Bullock, L. (1993). Why battering during pregnancy? *AWHONN'S Clinical Issues in Perinatal and Women's Health Nursing, 4*, 343–349.

Campbell, J. C., Woods, A. B., Chouaf, K. L., & Parker, B. (2000). Reproductive health consequences of intimate partner violence: a nursing research review. *Clinical Nursing Research, 9*(3), 217–237.

Center for Impact Research. (2000). *Domestic violence & birth control sabotage: A report from the teen parent project*. Chicago: Center for Impact Research.

Clark, C. J., Silverman, J., Khalaf, I. A., Ra'ad, A. B., Al Sha'ar, Z. A., Al Ata, A. A., et al. (2008). Intimate partner violence and interference with women's efforts to avoid pregnancy in Jordan. *Studies in Family Planning, 39*(2), 123–132.

Coggins, M., & Bullock, L. F. (2003). The wavering line in the sand: the effects of domestic violence and sexual coercion. *Issues in Mental Health Nursing, 24*, 723–738.

Coker, A. L. (2007). Does physical intimate partner violence affect sexual health? A systematic review. *Trauma, Violence & Abuse, 8*(2), 149–177.

Connell, R. W. (1987). *Gender and power: Society, the person and sexual politics*. Stanford: Stanford University Press.

Ellsberg, M., Jansen, H. A. F. M., Heise, L., Watts, C. H., García-Moreno, C., & , the WHO Multi-country Study on Women's Health and Domestic Violence Against Women Study Team. (2008). Intimate partner violence and women's physical and mental health in the WHO multi-country study on women's health and domestic violence: an observational study. *The Lancet, 371*, 1165–1172.

Fisher, W. A., Singh, S. S., Shuper, P. A., Carey, M., Otchet, F., MacLean-Brine, D., et al. (2005). Characteristics of women undergoing repeat induced abortion. *Canadian Medical Association Journal, 172*, 637–641.

García-Moreno, C., Jansen, H. A. F. M., Ellsberg, M., Heise, L., & Watts, C. (2005). *WHO multi-country study on women's health and domestic violence against women*. Geneva: World Health Organization (WHO).

Gazamararian, J. A., Adams, M. M., Saltzman, L. E., Johnson, C. H., Bruce, F. C., Marks, J. S., et al. (1995). The relationship between pregnancy intendedness and physical violence in mothers of newborns. The PRAMS Working Group. *Obstetrics and Gynecology, 85*, 1031–1038.

Gelles, R. (1988). Violence and pregnancy: are pregnant women at greater risk? *Journal of Marriage and Family, 50*, 841–847.

Hathaway, J. E., Willis, G., Zimmer, B., & Silverman, J. G. (2005). Impact of partner abuse on women's reproductive lives. *Journal of the American Medical Women's Association, 60*(1), 42–45.

Heise, L., Moore, K., & Toubia, N. (1995). *Sexual coercion and reproductive health: A focus on research*. New York: Population Council.

Lathrop, A. (1998). Pregnancy resulting from rape. *Journal of Obstetrics, Gynecologic and Neonatal Nursing, 27*(1), 25–31.

Maman, S., Campbell, J. C., Sweat, M. D., & Gielen, A. C. (2000). The intersections of HIV and violence: directions for future research and interventions. *Social Science & Medicine, 50*(4), 459–478.

Mezey, G. C. (1997). Domestic violence in pregnancy. In S. Bewley, J. Friend, & G. C. Mezey (Eds.), *Violence against women* (pp. 191–198). London: RCOG Press.

Miller, E., Decker, M. R., Reed, E., Raj, A., Hathaway, J. E., & Silverman, J. G. (2007). Male partner pregnancy-promoting behaviors and adolescent partner violence: findings from a qualitative study with adolescent females. *Ambulatory Pediatrics, 7*, 360–366.

Njovana, E., & Watts, C. (1996). Gender violence in Zimbabwe: a need for collaborative action. *Reproductive Health Matters, 4*(7), 46–55.

Taggart, L., & Mattson, S. (1996). Delay in prenatal care as a result of battering in pregnancy: cross-cultural implications. *Health Care for Women International, 17*(1), 25–34.

Voas, D. (2003). Conflicting preferences: a reason fertility tends to be too high or too low. *Population and Development Review, 29*(4), 627–646.

Watts, C., & Mayhew, S. (2004). Reproductive health services and intimate partner violence: shaping a pragmatic response in Sub-Saharan Africa. *International Family Planning Perspectives, 30*(4), 207–213.

Williams, C. M., Larsen, U., & McCloskey, L. A. (2008). Intimate partner violence and women's contraceptive use. *Violence Against Women, 14*(12), 1382–1396.

Wingood, G. M., & DiClemente, R. J. (1997). The effects of an abusive primary partner on the condom use and sexual negotiation practices of African-American women. *American Journal of Public Health, 87*(6), 1016–1018.

H

Mandatory Parental Consent to Abortion

Council on Ethical and Judicial Affairs, American Medical Association

This report analyzes the ethical issues raised by requirements that parents be involved when minors seek an abortion. Parents are generally supportive and understanding and can provide helpful guidance to their children. In some cases, however, parents may respond abusively to the knowledge that their minor child is pregnant or is considering an abortion. In addition, privacy in matters of health care is a profound need of minors as well as adults. Accordingly, the Council concludes that, while minors should be encouraged to discuss their pregnancy with their parents and other adults, minors should not be required to involve their parents before deciding whether to undergo an abortion.

(*JAMA*. 1993;269:82-86)

IN A companion report issued by the Council on Ethical and Judicial Affairs,[1] the Council discussed the general importance of confidential health care for minors. The report observed that an assurance of confidentiality may be critical to ensuring that minors are not deterred from seeking medical care, particularly for sensitive problems like mental illness, sexually transmitted diseases, and drug abuse. While parental involvement in the medical care of children is always important and is generally necessary for significant medical procedures, the report concluded that, in certain circumstances, parental involvement can be counterproductive and, unless required by law, should not be mandatory. In this report, the Council on Ethical and Judicial Affairs will examine the sensitive issue of parental involvement when minors seek an abortion. *Parental involvement* is defined as notifying parents, discussing options with them, and/or obtaining their consent.

The Council will not discuss the philosophical, moral, religious, or legal issues surrounding abortion, or examine the appropriateness of abortions for minors. Physicians have widely divergent views on these issues and the Council respects those differences. However, there is a need for guidelines for situations in which a minor is permitted by law to have an abortion without obtaining parental consent. According to Opinion 2.01 of the Council, "[t]he Principles of Medical Ethics of the AMA [American Medical Association] do not prohibit a physician from performing an abortion in accordance with good medical practice and under circumstances that do not violate the law."[2] The purpose of this report is to define ethical medical practice with regard to parental involvement.

ETHICAL CONCERNS

The Council recognizes that, for many physicians and patients, abortion is viewed as wrong except in very limited circumstances, and, where state law mandates parental consent, physicians must respect the law and the position of the public it reflects (*USA Today*. June 30, 1992:1A). Outside of those states, however, it is public policy to permit abortions without parental consent, ie, to treat abortion like other extremely sensitive reproductive choices that minors can make. As federal constitutional law stands today, minors do, in fact, have the right to obtain an abortion without consent unless otherwise provided by state law.[3,4(pp2936-2937),5] The Council knows that, for almost everyone, abortion is qualitatively different from other "reproductive options," but public policy often requires difficult line drawing and those lines exist today.

The issue of confidentiality for minors who seek an abortion implicates competing ethical concerns apart from the abortion issue itself. On the one hand, as with other decisions, minors may not make considered choices about abortion because of immaturity, inexperience, or poor judgment. Parents are generally in the best position to counsel minors about their reproductive options, and they usually have a deep and respected interest in any significant matter involving their children. However, some minors may, in fact, be physically or emotionally harmed if they are required to involve their parents in the decision to have an abortion. In addition, as the AMA Council on Scientific Affairs explained in its report, "Confidential Health Services for Adolescents,"[6] parental involvement could interfere with the minor's need for privacy on matters of sexual intimacy.

BENEFITS OF PARENTAL INVOLVEMENT

The decision to terminate a pregnancy is, of course, an extremely serious

Members of the Council on Ethical and Judicial Affairs include the following: Oscar W. Clarke, MD, Gallipolis, Ohio, Chair; John Glasson, MD, Durham, NC, Vice Chair; Allison M. August, Brookline, Mass; John A. Barrasso, MD, Casper, Wyo; Charles H. Epps, Jr, MD, Washington, DC; Robert McQuillan, MD, Omaha, Neb; Victoria N. Ruff, MD, Columbus, Ohio; Charles W. Plows, MD, Santa Ana, Calif; George T. Wilkins, Jr, MD, Chicago, Ill; and David Orentlicher, MD, JD, Chicago, Ill, Secretary and staff author.

From the Council on Ethical and Judicial Affairs, American Medical Association, Chicago, Ill.

This report was adopted by the House of Delegates of the American Medical Association at the Annual Meeting, June 1992.

Reprint requests to the Council on Ethical and Judicial Affairs, American Medical Association, 515 N State St, Chicago, IL 60610 (David Orentlicher, MD, JD).

Downloaded From: http://jama.jamanetwork.com/ by a Planned Parenthood User on 12/30/2014

one, and minors will often lack the maturity and judgment necessary to reach a sound decision on their own. It is important for minors to receive comprehensive counseling about the issues involved in pregnancy and guidance regarding the different reproductive options.

Moreover, parents are ordinarily the people most concerned with a minor's welfare, and they generally act in their child's best interests. In working through the difficult decision about abortion, minors will generally benefit from the mature advice and emotional support of their parents. Parents will usually be in the best position to understand their children's needs and concerns and to help as the children apply their own values to the abortion decision. Principles of constitutional law have long held that parents should be involved in and responsible for the medical care of their minor children. According to the US Supreme Court, "[I]t is cardinal with us that the custody, care, and nurture of the child reside first in the parents."[7]

Similarly, the common law has long recognized that "natural bonds of affection lead parents to act in the best interests of their children."[8] Parents have traditionally enjoyed a strong presumption under the common law that they are the appropriate medical decision makers for their children.[9] While the state must intervene to protect against abuse, parental decisions are almost never overturned as long as the parents choose from among professionally accepted treatment options.

CONCERNS WITH MANDATORY PARENTAL INVOLVEMENT

For most children, the home is a place of caring, love, and support, a place of safety. For some children, however, the home falls far short of this ideal and may be a place of physical abuse and neglect and psychological maltreatment. On the basis of reports to child protection agencies, the federal government has estimated that there are approximately 1.5 million cases a year of physical abuse and neglect of children.[10] Although no study has specifically dealt with violence as a reaction to minors informing parents about pregnancy, it is reasonable to believe that some minors justifiably fear that they would be treated violently by one or both parents if they had to disclose their pregnancy to their parents.[11] Research on abusive and dysfunctional families has shown that family violence is at its worst during a family member's pregnancy, immediately following childbirth, and during the adolescence of the family's children. Studies of family violence have found that 4% to 17% of women are physically abused during their pregnancy.[12,13] If parental involvement were universally required, some minors might suffer serious physical injury. Disclosure of the pregnancy may also cause serious emotional harm to the minor. Parental notification often precipitates a family crisis, characterized by severe parental anger and rejection of the minor.[14(p1165)]

In addition, like adults, minors have a profound need for privacy in matters of their health care. Privacy may be especially important for minors. Adolescence is a critical period for minors to develop their independent sense of self; the ability to maintain spheres of privacy from parents in areas of personal intimacy is an essential part of that development.[15] The AMA has long recognized this need.

Organized medicine has viewed confidential care for adolescents as essential to their use of health services. As early as 1972, the AMA took the position that to stem the incidence and prevalence of venereal disease, minors needed to receive medical treatment for suspected venereal disease without parental notification.[16] All states subsequently codified this policy, including those without statutory provisions that allowed minors to consent to treatment for other diseases or conditions. The AMA also opposed regulations requiring parental notification for the provision of prescription contraceptives to minors through federally funded programs "since they create a breach of confidentiality in the physician-patient relationship."[17] American Medical Association policy recommendations state that adolescents should have "access to medical consultation and the most effective contraceptive advice and methods,"[18] and physicians should provide contraceptive services on a confidential basis where legally permissible.[17]

Because the need for privacy may be compelling, minors may be driven to desperate measures to maintain the confidentiality of their pregnancies. They may run away from home, obtain a "back-alley" abortion, or resort to self-induced abortion. The desire to maintain secrecy has been one of the leading reasons for illegal abortion deaths since the US Supreme Court decided the existence of a constitutional right to abortion in 1973.[19]

BALANCING THE COMPETING ETHICAL CONCERNS

Provisions should be made to ensure that pregnant minors receive appropriate counseling, support, and advice when deciding among their reproductive options. At the same time, minors should not be forced to undertake measures that may put their health at risk and prevent them from maintaining the necessary degree of privacy in their lives.

As a first step, physicians should strongly encourage minors to discuss their pregnancy and their reproductive options with their parents. Adolescents often underestimate the understanding of their parents and overestimate parental anger.[20(p139)] Physicians should explain how parental involvement can be helpful and that parents are generally very understanding and supportive[20(p139)]—indeed, minors usually discuss their pregnancies with at least one parent.[21] Physicians should also explain that parents are usually in the best position to help the minor consider the issues involved and the way that they will affect the minor's future. If a minor expresses concerns about parental involvement, the physician should try to ensure that the minor's reluctance is not based on any misperceptions about the likely consequences of parental involvement. For example, physicians should try to ensure that the minor is not underestimating parental supportiveness, overestimating parental anger, or failing to appreciate that initial parental disappointment, however profound, will likely moderate.

While minors may not exhibit the same maturity as adults when deciding about abortion, research suggests that the process of medical decision making for adolescents often does not differ from that of adults.[22-25] In one recent study, researchers interviewed 75 females, aged 13 to 21 years, who were visiting a clinic for a pregnancy test because they suspected an unplanned pregnancy. The decision whether to carry the pregnancy to term was examined, and comparisons of the interviewees' decision-making processes were made across the different age groups. Among those who considered abortion, the researchers found no age-related differences for the three measures of cognitive competence studied (thoroughness of consideration of consequences, number of reasons considered, and content of the reasoning about pregnancy).[25]

The expert opinion to date and the available empirical evidence generally support the view that physicians should not require minors to involve their parents before deciding whether to undergo an abortion. In its comprehensive study of adolescent pregnancy, the National Research Council concluded that when considering abortion, "minor adolescents should be encouraged, but not required, to involve their parents and partners in the decision-making process."[26] The American Public Health Association[27] and the Society for Adolescent Medicine[28] have reached the same

Downloaded From: http://jama.jamanetwork.com/ by a Planned Parenthood User on 12/30/2014

conclusion. In a joint statement that addressed the general issue of confidentiality for adolescents, the American College of Obstetricians and Gynecologists, American Academy of Pediatrics, and American Academy of Family Physicians stated that adolescent patients should have the same degree of confidentiality that adult patients have.[29] During the litigation over Minnesota's parental notification statute, the trial court held extensive hearings on the effects of the statute. The statute required, with certain exceptions, that both parents be notified at least 48 hours before an abortion could be performed on a minor.[30] There was considerable expert testimony that the statute was having negative effects on parent-child relationships. Moreover, according to the court, there was no persuasive testimony that the law was enhancing parent-child communications or relationships.[31(p768)] Parental involvement may be harmful to the minor, and the minor is in the best position to assess whether, on balance, parental involvement is advisable.

Accordingly, experts generally conclude that minors should ultimately be allowed to decide whether parental involvement is appropriate, although physicians should provide them with any necessary guidance as they make their decision.

It would not be sufficient to waive a requirement of parental involvement only for those minors who have reported abuse by their parents. Victims of family violence are characteristically secretive about the abuse they have suffered, and minors are particularly reluctant to reveal the existence of abuse in their homes.[31(p769)] In addition, the minor's pregnancy may precipitate the first episode of physical abuse that she suffers. Finally, minors may be psychologically abused to an extent that is serious without the abuse being reportable under state child abuse statutes.[32]

As with adult patients, physicians should try to ensure that their minor patients have made an informed decision after giving careful consideration to the issues involved. They should encourage their minor patients to consult other adults if parents are not going to be involved in the abortion decision. Minors should be urged to seek the advice and counsel of those adults in whom they have confidence, including professional counselors, relatives, friends, teachers, or the clergy.

Counselors should fully explore the alternative choices available to the minor, including carrying the pregnancy to term and keeping the child, carrying the pregnancy to term and placing the child with a relative or with another family through foster care or adoption, or having an abortion. The minor should be told that a decision to have an abortion may be withdrawn at any time before the abortion is performed and that a decision to carry the pregnancy to term may be reconsidered at any time within the time period in which an abortion may be legally performed. Counselors should explain that public and private agencies can provide information about measures to prevent future pregnancies, and the minor should be given a list of such agencies in the local community. But those who counsel must also be objective and not attempt to coerce. The decision is ultimately for the patient to make.

LEGAL CONSIDERATIONS

At least 40 states have enacted statutes that address the issue of parental involvement in a minor's decision to have an abortion (Table). However, many of the statutes either have been enjoined by the courts or are not enforced.[33,34] Parental involvement statutes generally require either that parents be notified about the minor's abortion or that parents give consent to the abortion.[35] However, in order to be valid under the US Constitution, these statutes must include a provision allowing the minor to avoid parental involvement by seeking approval from a judge for the abortion.[4] These provisions are known as *judicial bypass* provisions. In two states, California and Florida, parental involvement statutes have been invalidated under state constitutional provisions, even if the statutes have a judicial bypass option.[36,37] Three states, Connecticut, Maine, and Wisconsin, encourage parental involvement, but only require counseling by the health care provider or another professional counselor before the abortion may be performed.[38-40]

Researchers have attempted to measure the effects of laws requiring parental involvement. In a study of the impact of Massachusetts' parental consent law,[41] researchers found that the law reduced by half the number of minors undergoing abortion in Massachusetts. However, the reduction was explained by a corresponding increase in minor residents of the state traveling to neighboring states for their abortions. There was a small increase in the number of minors who bore children rather than undergo abortion, but the study was not able to determine whether the parental consent law caused the increase.

The impact of Minnesota's parental notification law has also been examined. In one study,[42] researchers found that parental notification was more common after passage of the law than was found in another study conducted before passage of the law. Approximately 65% of minors notified at least one parent about their plans to undergo abortion, and the younger the minor, the more likely she was to notify one of her parents. However, parental notification in Minnesota was no more common than in Wisconsin, a neighboring state that has no law requiring parental involvement. A second study[43] found that after the enactment of Minnesota's law, there was a sharp drop in abortion rates among 15- to 17-year-old girls.

The option of a judicial bypass does not always solve the problems with laws requiring parental involvement. The key to successful counseling of the minor is the minor's ability to seek guidance from individuals with whom she feels most comfortable discussing her pregnancy and her reproductive options. When Minnesota's parental notification statute was reviewed by the courts, the trial court found that many minors were very uncomfortable with judicial hearings.[31] In particular, although the proceedings are confidential, minors are forced to disclose intimate details of their lives before complete strangers. The Council recognizes that judicial bypass may be viewed as an effective compromise for all of the competing concerns, but rather than providing a safeguard to ensure fully considered decisions, judicial proceedings tend to provide cursory review. In Massachusetts, a study[44] found that the average length of time for judicial bypass hearings was 12 minutes. In summary, including a judicial bypass provision does not adequately respond to the problems of statutes that require parental involvement.

RECOMMENDATIONS

With respect to parental involvement (eg, parental notification or consent) when minors seek an abortion, the Council on Ethical and Judicial Affairs believes that the following guidelines constitute good medical practice.

1. Physicians should ascertain the law in their state on parental involvement to ensure that their actions are consistent with their legal obligations.

2. Physicians should strongly encourage minors to discuss their pregnancy with their parents. Physicians should explain how parental involvement can be helpful and that parents are generally very understanding and supportive. If a minor expresses concerns about parental involvement, the physician should ensure that the minor's reluctance is not based on any misperceptions about the likely consequences of parental involvement.

3. Physicians should not feel or be

Downloaded From: http://jama.jamanetwork.com/ by a Planned Parenthood User on 12/30/2014

Restrictions on Minors' Access to Abortion (Prepared by the National Abortion Rights Action League, November 1992)

State	One-Parent	Two-Parent	Consent	Notice	Mandatory Counseling*	Judicial Bypass	Enjoined/ Not Enforced	Enforced
Alabama	X		X			X		X
Alaska	X		X				X†	
Arizona	X		X			X	X†	
Arkansas		X		X		X		X
California	X		X			X	X†	
Colorado	X		X				X†	
Connecticut					X			X
Delaware		X	X				X†	
District of Columbia								
Florida								
Georgia	X			X		X		X
Hawaii								
Idaho		X		X			X	
Illinois		X		X		X	X†	
Illinois‡		X	X				X†	
Indiana	X		X			X		X
Iowa								
Kansas	X			X		X		X
Kentucky		X	X			X	X†	
Louisiana	X		X			X		X
Louisiana‡		X	X				X†	
Maine					X§			X
Maryland	X			X‖				X
Massachusetts		X	X			X		X
Michigan	X		X			X		X¶
Minnesota		X		X		X		X
Mississippi		X	X			X	X†	
Missouri	X		X			X		X
Montana	X			X			X	
Nebraska	X			X		X		X
Nevada	X			X		X	X†	
New Hampshire								
New Jersey								
New Mexico	X		X				X†	
New York								
North Carolina								
North Dakota		X	X			X		X
North Dakota‡	X	X	X#	X			X†	
Ohio	X			X		X		X
Oklahoma								
Oregon								
Pennsylvania	X		X			X	X**	
Rhode Island	X		X			X		X
South Carolina	X††		X			X		X
South Dakota	X		X				X	
Tennessee		X		X			X	
Texas								
Utah		X‡‡		X				X
Vermont								
Virginia								
Washington								
West Virginia	X			X‖		X		X
Wisconsin	X§§		X			X		X
Wyoming	X		X			X		X
Total	**25**	**14**	**24**	**15**	**2**	**25**	**18**	**22**

*Statutes require a minor to receive counseling in which possibility of consulting her parents is discussed.
†Statute has been declared unenforceable by a court or attorney general.
‡State has two different provisions.
§Statute offers mandatory counseling as an alternative to one-parent consent with a judicial bypass.
‖Notice requirement may be waived if a physician determines that the minor is mature enough or that parental notice would not be in the minor's best interest.
¶Statute will be enforceable as of April 1, 1993.
#An unenforced statute requires one-parent consent for a minor's abortion postviability.
**Upheld by the US Supreme Court in *Planned Parenthood v Casey* but is currently unenforced pending further litigation.
††Statute also allows notice to a grandparent.
‡‡Statute is currently applied as requiring notice to one parent.
§§Statute allows consent of an adult family member.

Downloaded From: http://jama.jamanetwork.com/ by a Planned Parenthood User on 12/30/2014

compelled to require minors to involve their parents before deciding whether to undergo an abortion. The patient—even an adolescent—generally must decide whether, on balance, parental involvement is advisable. Accordingly, minors should ultimately be allowed to decide whether parental involvement is appropriate. Physicians should explain under what circumstances (eg, life-threatening emergency) the minor's confidentiality will need to be abrogated.

4. Physicians should try to ensure that minor patients have made an informed decision after giving careful consideration to the issues involved. They should encourage their minor patients to consult alternative sources if parents are not going to be involved in the abortion decision. Minors should be urged to seek the advice and counsel of those adults in whom they have confidence, including professional counselors, relatives, friends, teachers, or the clergy.

References

1. Council on Ethical and Judicial Affairs, American Medical Association. Confidential care for minors. In: Proceedings of the House of Delegates, 141st Annual Meeting; June 21-25, 1992; Chicago, Ill:198-205.
2. Council on Ethical and Judicial Affairs, American Medical Association. *Code of Medical Ethics: Current Opinions.* Chicago, Ill: American Medical Association; 1992:2.
3. *Planned Parenthood of Southeastern Pennsylvania v Casey,* 112 S Ct 2791 (1992).
4. *Hodgson v Minnesota,* 110 S Ct 2926 (1990).
5. *Planned Parenthood of Central Missouri v Danforth,* 428 US 52 (1976).
6. Council on Scientific Affairs, American Medical Association. Confidential health services for adolescents. In: Proceedings of the House of Delegates, 141st Annual Meeting; June 21-25, 1992; Chicago, Ill:289-297.
7. *Prince v Massachusetts,* 321 US 158, 166 (1944).
8. *Parham v JR,* 442 US 584, 602 (1979).
9. *Bowen v American Hospital Association,* 476 US 610, 627 n13 (1986).
10. National Center on Child Abuse and Neglect Information. *Study Findings: Study of National Incidence and Prevalence of Child Abuse and Neglect: 1988.* Washington, DC: US Dept of Health and Human Services; 1988:3-2.
11. Henshaw SK, Kost K. Parental involvement in minors' abortion decisions. *Fam Plann Perspect.* 1992;24:196-207, 213.
12. Amaro H, Fried LE, Cabral H, Zuckerman B. Violence during pregnancy and substance use. *Am J Public Health.* 1990;80:575-579.
13. McFarlane J, Parker B, Soeken K, Bullock L. Assessing for abuse during pregnancy: severity and frequency of injuries and associated entry into prenatal care. *JAMA.* 1992;267:3176-3178.
14. Osofsky JD, Osofsky HJ. Teenage pregnancy: psychosocial considerations. *Clin Obstet Gynecol.* 1978;21:1161-1173.
15. English A. Treating adolescents: legal and ethical considerations. *Med Clin North Am.* 1990;74: 1097-1112.
16. American Medical Association. Policy 440.996: gonorrhea control. In: *Policy Compendium.* Chicago, Ill: American Medical Association; 1992:313.
17. American Medical Association. Policy 75.998: opposition to HHS regulations on contraceptive services for minors. In: *Policy Compendium.* Chicago, Ill: American Medical Association; 1992:55.
18. American Medical Association. Policy 75.999: teenage pregnancy. In: *Policy Compendium.* Chicago, Ill: American Medical Association; 1992:55.
19. Binkin N, Gold J, Cates W. Illegal-abortion deaths in the United States: why are they still occurring? *Fam Plann Perspect.* 1982;14:163-167.
20. Worthington EL, Larson DB, Lyons JS, et al. Mandatory parental involvement prior to adolescent abortion. *J Adolesc Health.* 1991;12:138-142.
21. Zabin LS, Hirsch MB, Emerson MR, Raymond E. To whom do inner-city minors talk about their pregnancies? adolescents' communication with parents and parent surrogates. *Fam Plann Perspect.* 1992;24:148-154, 173.
22. Gittler J, Quigley-Rick M, Saks MJ. Adolescent health care decision making: the law and public policy. In: *Carnegie Council on Adolescent Development: Working Papers.* New York, NY: Carnegie Corp; 1990:37-48.
23. Lewis CC. A comparison of minors' and adults' pregnancy decisions. *Am J Orthopsychiatry.* 1980; 53:446-453.
24. Weithorn LA, Campbell SB. The competency of children and adolescents to make informed treatment decisions. *Child Dev.* 1982;53:1589-1598.
25. Ambuel B, Rappaport J. Development trends in adolescents' psychological and legal competence to consent to abortion. *Law Hum Behav.* 1992;16: 129-154.
26. National Research Council. *Risking the Future: Adolescent Sexuality, Pregnancy, and Childbearing.* Washington, DC: National Academy Press; 1987;1:9-10.
27. American Public Health Association. Resolution 9001: adolescent access to comprehensive, confidential reproductive health care. In: *Public Policy Statements of the American Public Health Association.* Washington, DC: American Public Health Association; 1990:453.
28. Society for Adolescent Medicine. Position statements on reproductive health care for adolescents. *J Adolesc Health.* 1991;12:657-661.
29. Joint Statement of American College of Obstetricians and Gynecologists, American Academy of Family Physicians, American Academy of Pediatrics, Organization for Obstetric, Gynecologic and Neonatal Nurses, National Medical Association. *Confidentiality in Adolescent Health Care.* Washington, DC: American College of Obstetricians and Gynecologists; 1988.
30. Minn Stat Ann §144.343 (West 1989).
31. *Hodgson v Minnesota,* 648 F Supp 756 (D Minn 1986), *aff'd,* 110 S Ct 2926 (1990).
32. Ill Ann Stat ch 23 para 2053, §3 (Smith-Hurd 1992).
33. Greenberger MD, Connor K. Parental notice and consent for abortion: out of step with family law principles and policies. *Fam Plann Perspect.* 1991; 23:31-35.
34. Donovan P. *Our Daughters' Decisions: The Conflict in State Law on Abortion and Other Issues.* New York, NY: Alan Guttmacher Institute; 1992: 14-15.
35. Crosby MC, English A. Mandatory parental involvement/judicial bypass laws: do they promote adolescents' health? *J Adolesc Health.* 1991;12:143-147.
36. *In re TW,* 551 So 2d 1186 (Fla 1989).
37. *American Academy of Pediatrics v Van de Kamp,* 263 Cal Rptr 46 (Cal Ct App 1989).
38. Me Rev Stat Ann tit 22, §1597-A(4) (1992).
39. Conn Gen Stat §19a-601 (1990).
40. Wis Stat §146.78 (1989-90).
41. Cartoof VG, Klerman LV. Parental consent for abortion: impact of the Massachusetts law. *Am J Public Health.* 1986;76:397-400.
42. Blum RW, Resnick MD, Stark TA. The impact of a parental notification law on adolescent abortion decision-making. *Am J Public Health.* 1987;77:619-620.
43. Rogers JL, Boruch RF, Stoms GB, DeMoya D. Impact of the Minnesota parental notification law on abortion and birth. *Am J Public Health.* 1991; 81:294-298.
44. Yates S, Pliner AJ. Judging maturity in the courts: the Massachusetts consent statute. *Am J Public Health.* 1988;78:646-649.

Downloaded From: http://jama.jamanetwork.com/ by a Planned Parenthood User on 12/30/2014

I

Abortion Services in Rural Washington State, 1983–1984 to 1993–1994: Availability and Outcomes

By Sharon A. Dobie, L. Gary Hart, Ann Glusker, David Madigan, Eric H. Larson and Roger A. Rosenblatt

Context: *Fewer rural health providers offer abortion services than a decade ago. It is unknown how the reduction in service availability has affected women's pregnancy outcomes, the extent to which they must travel to obtain an abortion or whether abortions are delayed as a result.*

Methods: *Population, birth and fetal death data, as well as pregnancy termination reports, obtained from Washington State were used to calculate abortion rates and ratios and birthrates for Washington residents in 1983–1984 and in 1993–1994. Residence of abortion patients was classified by county only, and location of providers was recorded as large urban county, small urban county, large rural county or small rural county. Distances that women traveled to obtain an abortion were calculated. Chi-square tests were used to compare urban and rural rates and ratios within time periods, and to compare changes that occurred between time periods.*

Results: *Birthrates and abortion rates decreased for both rural and urban Washington women between 1983–1984 and 1993–1994, but the magnitude of the decrease was greater for rural women. The rural abortion rate fell 27%, from 14.9 abortions per 1,000 women to 10.9 per 1,000, while the urban rate dropped 17%, from 21.8 to 18.2 per 1,000. The decline in the abortion rate was larger for adolescents than it was for other age-groups. In rural areas, the abortion rate decreased from 16.5 per 1,000 adolescents aged 10–19 in 1983–1984 to 10.8 per 1,000 in 1993–1994, while it declined from 23.3 per 1,000 to 16.9 per 1,000 in urban areas. From the earlier to the later time period, rural women traveled on average 12 miles farther each way to obtain an abortion, and the proportion who obtained the procedure in a rural county decreased from 25% to 3%. In the earlier time period, 62% of rural women traveled 50 miles or more to obtain an abortion, compared with 73% in 1993–1994. From 1983–1984 to 1993–1994, the proportion of rural women who traveled out of state for an abortion increased from 8% to 14%. The proportion of rural women terminating their pregnancy after the first trimester increased from 8% in 1983–1984 to 15% in 1993–1994.*

Conclusion: *Rural Washington women are traveling farther and more often to urban and out-of-state locations for abortion services, and are obtaining their abortions at a later gestational age, which is associated with a decade-long decline in the number of abortion providers.*

Family Planning Perspectives, 1999, 31(5):241–245

The availability of abortion services in rural America has declined steadily during the last 20 years. Nationally, the number of nonmetropolitan abortion providers declined 51% from its peak in 1977 to 1988. By 1996, 95% of nonmetropolitan counties had no provider of abortion.[1] This is in sharp contrast to the increased availability of other reproductive health technologies in rural areas.[2] Rural women face considerable barriers when they decide to terminate a pregnancy, including long distances to a provider, harassment, monetary costs and gestational limits.[3] Providers estimate that 8% of women travel more than 100 miles for an abortion,[4] but it is not known whether the distance that women travel has an impact on such issues as when in pregnancy the abortion occurs, the type of procedure performed and the number of abortions that occur.

Seventy-one percent of Washington State's 66,511 square miles is rural. In 1994, there were 1.6 million women aged 10–49 in the state, and 17% of them lived in rural areas.[5] The state has a long history of legal access to abortion, but the number of providers in rural Washington State has always been limited and has declined further in recent years. In 1983, only 10 of the state's 28 rural counties had a provider; there were 19 facilities in these 10 rural counties, staffed by 32 providers. By 1994, the total number of facilities providing abortions throughout Washington State had declined from 88 to 65. The majority of this decline was in rural counties, where only four facilities and six providers still reported providing abortions during the period 1993–1994.[6]

We hypothesize that rural Washington State residents were more likely to have terminated a pregnancy at a later gestational age and were more likely to have traveled farther in 1993–1994 than in 1983–1984. We also hypothesize that there will be higher complication rates (such as bleeding and infections) among rural women, compared with urban residents. Additionally, we explore whether the decline in local access was accompanied by a change in abortion rates, comparing abortion data in Washington State from the period 1983–1984 with those from 1993–1994.

Methods

We used data from several secondary sources. The Washington State Office of Financial Management provided population data for women by age and by county of residence, obtained from intercensal estimates of county population.[7] We obtained birth, fetal death and pregnancy termination data for the years 1983, 1984, 1993 and 1994 from the vital statistics data compiled by the state of Washington.[8]

Data on pregnancy terminations are generated from occurrence reports filed with the State of Washington Department of Health. Through interstate agreements between Washington and most states, occurrence reports are filed for Washington State residents who terminate a pregnancy in these other states. Through an agreement with the State of Washington Department of Health Statistics, data were made available on the individual level. Several variables were eliminated, masked or altered for each occurrence to ensure the anonymity of abortion providers and of women who had elective terminations.

Sharon A. Dobie is associate professor, Ann Glusker is research assistant and Roger A. Rosenblatt is professor and vice chair, Department of Family Medicine, University of Washington School of Medicine, Seattle, WA. L. Gary Hart is professor and director, WWAMI (Washington, Wyoming, Alaska, Montana, Idaho) Rural Health Research Center and WWAMI Center for Health Workforce Studies, Department of Family Medicine, University of Washington School of Medicine. Eric H. Larson is deputy director, WWAMI Rural Health Research Center, and David Madigan is associate professor, Department of Statistics, University of Washington College of Arts and Sciences, Seattle, WA. Funding for this project was provided by the Robert Wood Johnson Generalist Physician Faculty Scholars Program. We wish to thank Sharon Estee and the staff of the State of Washington Department of Health, Center for Health Statistics, for collaborating on the design, data preparation and analysis, and Stanley Henshaw for reviewing and commenting on the manuscript.

Table 1. Annualized abortion rates, abortion ratios and birthrates, by residence and time period, according to age-group

Age	Total		Rural		Urban	
	1983–1984	1993–1994	1983–1984	1993–1994	1983–1984	1993–1994
Total						
Population	1,293,312	1,573,010	231,421	267,028	1,061,891	1,305,982
Abortion rate*	20.6	16.9†	14.9‡	10.9†,‡	21.8	18.2†
Abortion ratio	386.4	341.4†	263.2‡	220.7†,‡	415.4	366.0†
Birthrate*	53.3	49.6†	56.7‡	49.6†	52.5	49.6†
10–19						
Population	316,847	353,550	62,378	68,501	254,469	285,049
Abortion rate	22.0	15.8†	16.5‡	10.8†,‡	23.3	16.9†
Abortion ratio	957.3	641.4†	616.9‡	384.9†,‡	1,058.4	714.4†
Birthrate	23.0	24.6†	26.7‡	28.1‡	22.1	23.7†
20–39						
Population	749,852	830,570	127,673	133,501	622,179	697,069
Abortion rate*	25.8	24.5†	18.7‡	15.8†,‡	27.2	26.2†
Abortion ratio	315.6	300.3†	209.4‡	189.5†,‡	339.9	322.0†
Birthrate*	81.6	81.6	89.1‡	83.2†	80.0	81.3†
40–49						
Population	226,614	388,890	41,370	65,026	185,244	323,864
Abortion rate	1.6	1.8	1.0§	1.2‡	1.7	1.9
Abortion ratio	762.9	459.7†	528.0	373.8	810.7	472.2†
Birthrate	2.1	3.9†	2.0	3.1†,‡	2.1	4.1†

*Rural-urban difference in the change in the rate is significant at p<.01 (by the chi-square test). †Interdecade difference is significant at p<.01 (by the chi-square test). ‡Rural-urban difference is significant at p<.01 (by the chi-square test). §Significant with an assumption of 1 abortion per woman per year, but loses significance under the stricter criterion of 1.5 abortions per woman per year and 1.1 births per woman per year. *Notes:* All rates and ratios are calculated using the mean of population, birth, fetal death and abortion data for each two-year time period. Reports missing age or county of residence are excluded from the analysis. Totals may vary due to rounding.

Address and township of residence were not reported, but county of residence for each occurrence was included. The age of women was entered in five-year aggregates (e.g., 30–34 years of age).

Many rural Washington State counties have few minority women. We protected the anonymity of those who terminated a pregnancy by combining racial and ethnic groups and by masking racial and ethnic identity in counties with few minority women.[9]* We excluded race and ethnicity from our analysis, however, for two reasons. First, a number of the larger abortion providers in the state decline to report race and ethnicity; this information is missing for 24% of cases. Second, although Hispanic ethnicity was reported separately from race in 1993–1994, it was not in 1983–1984, resulting in noncorresponding categories.

We use the terms rural residents and rural providers to refer to those with addresses in counties categorized as nonmetropolitan by the federal Office of Management and Budget. Urban residents and providers are those with addresses classified by the Office of Management and Budget as metropolitan.[10] We masked provider locations, except for the general designation of large urban county, small urban county, large rural county and small rural county. We defined large rural counties as those having a hospital with more than 100 beds; we defined small rural counties as those with no hospital having more than 100 beds.[11] Seven of the 11 metropolitan counties were designated as large urban. With one exception, each was part of a Consolidated Metropolitan Statistical Area (CMSA), which is an area containing one million people or more. Spokane County, while not part of a CMSA, was designated as a large urban county because it has a population of nearly 400,000 and has two large tertiary care hospitals. The remaining four urban counties were classified as small urban because they are not part of a CMSA, have a smaller population than Spokane and do not have a tertiary care hospital.[12]

For each rural resident's report, we constructed a variable for distance traveled to obtain an abortion. The state provided us with a list of location pairs, which included every provider-resident location pair found in the four years of abortion reports. For each, we calculated the distance in miles between the two points.[13] For county locations not in a named township, we used the population centroid for the county.[14] The calculated distances were returned to the state and were then entered as five-mile aggregate distances on each occurrence report. Distance traveled was neither calculated nor entered for rural respondents who obtained an out-of-state abortion or for urban cases.

*Information on this process is available from the authors.

Birth and fetal death reports were masked for the name of the woman only. These data were used to calculate age-specific pregnancy rates, birthrates and abortion rates and ratios, as well as fertility rates. We constructed annualized values by averaging the number of occurrences for each of the two years per decade; we then compared 1983–1984 rates with those of 1993–1994. Denominators for rates and ratios are means from the intercensal data from 1983, 1984, 1993 and 1994.[15] These are population data, not strictly requiring inferential statistics. Nevertheless, we provide inferential statistics as a descriptive device to highlight potentially interesting differences. While we have not made formal adjustments for multiple comparisons, using $p<.01$ as the cutoff rather than $p<.05$ in effect provides some adjustment.

Chi-square tests require that events (births and abortions, in this case) be independent. We cannot ascertain how many women (denominator) had more than one birth or abortion (numerator) for our rates. We adjusted our calculations in the following manner: We assumed a maximum of 1.1 births per year or 1.5 abortions per year per woman, which is an overly conservative estimate, when we performed the chi-square analyses. Had we assumed that each woman had had only one abortion per year, the statistical calculations would gain significance in only one instance, and this is noted in Table 1.

We used chi-square tests to compare urban and rural rates, ratios and outcomes within the same time period, and to compare changes over time between rural residents and between urban residents. Tests on gestational age, type of procedure, location and distance traveled were one-tailed, driven by the directional hypothesis. All others were two-tailed.

Results

Population Characteristics

By 1993–1994, 17% of Washington State's women were rural residents, compared with 18% in 1983–1984. While the absolute number of rural women in the state increased 16%, from 231,000 to 267,000, during the time period, the urban female population increased 23%, from 1.06 million to 1.31 million (Table 1). Statewide, the female population aged between 1983–1984 and 1993–1994, although this aging was of greater magnitude in urban areas. The number of rural women aged 40–49 increased 57%, while the number of urban women in this age-group increased 75%. At the same time, the rural female population aged 20–29 decreased 9%, while the

urban female population aged 20–29 decreased 6% (not shown).

Birthrates and Abortion Rates and Ratios
Birthrates and abortion rates fell throughout the state from 1983–1984 to 1993–1994, with the abortion rate falling more than the birthrate (Table 1). The magnitude of the drop in abortion rates was significantly greater for rural women than for urban women (p<.01). The rural abortion rate fell 27% during the decade (from 14.9 abortions per 1,000 women to 10.9 per 1,000), compared with a 17% drop in the urban rate (from 21.8 to 18.2 per 1,000). As a result, the rural abortion rate was only 60% of the urban rate by 1993–1994. The decrease in abortion rates was greater for teenagers than it was for other age-groups: From 1983–1984 to 1993–1994, the abortion rate for adolescents aged 10–19 dropped 35% in rural areas (from 16.5 to 10.8 per 1,000) and 28% (from 23.3 to 16.9 per 1,000) in urban areas. The difference in the change between urban and rural teenagers was not statistically significant, however.

Overall, abortion ratios declined significantly between time periods within most age-groups, with the exception of rural women aged 40–49. For example, among adolescents, the overall abortion ratio fell from 957 to 641 abortions per 1,000 live births, a decline reflected among both rural and urban teenagers. Statewide, the decline in the abortion ratio also was sizable for the oldest (40–49) age-group.

Gestational Age and Type of Procedure
In both time periods, rural women were significantly more likely to have been parous and not to have had a prior abortion, compared with urban women (Table 2). During 1983–1984, 92% of rural women had their abortions at earlier than 12 weeks of gestation, a proportion equal to that among their urban counterparts. This proportion dropped to 85% in 1993–1994, compared with 89% among urban women. Meanwhile, the proportion of rural women having their abortions at later than 18 weeks more than doubled during the decade, growing from 2% to 5% (p<.01); the proportion for 1993–1994 is significantly higher than that among their urban counterparts (p<.01).

Additionally, from the earlier to the later time period, the proportion of sharp curettage or dilatation and extraction procedures increased from 4% to 9% among rural women (p<.01). In 1983–1984, there was not a significant difference between the proportion of rural women and urban women undergoing these procedures. By 1993–1994, however, this difference had become statistically significant (p<.01). While this may be associated with prenatal diagnosis, women having a prenatal diagnostic procedure revealing a fetal anomaly accounted for less than 1% of all terminations in 1993–1994; this information was not available for 1983–1984. Reported complications were low for both rural and urban women in each time period, with fewer than 1% of women reporting complications in any time period. Differences between rural and urban women and between time periods were not significant.

Table 2. Percentage distribution of women who obtained an abortion, by measure of obstetric history, gestational age and type of abortion procedure, according to residence and time period

Measure	Total		Rural		Urban	
	1983–1984 (N=53,287‡)†	1993–1994 (N=53,662‡)†	1983–1984 (N=6,913§)‡	1993–1994 (N=5,913§)‡	1983–1984 (N=46,374§)‡	1993–1994 (N=47,681§)‡
Prior live birth						
0	59.1	48.7	54.7*	46.6*	59.7	48.9
1–2	34.4	41.7	36.9*	41.5	34.0	41.7
≥3	6.5	9.6	8.4*	11.9*	6.2	9.3
Prior abortion						
0	57.5	52.1	62.8*	59.4*	56.7	51.2
1–2	37.4	39.8	33.7*	35.1*	37.9	40.4
≥3	5.1	8.1	3.5*	5.5*	5.4	8.4
Gestational age						
≤12 weeks	92.3	88.5	91.9	85.3*	92.4	88.9
13–17 weeks	5.8	7.9	6.0	10.1*	5.8	7.7
≥18 weeks	1.9	3.6	2.1	4.7*	1.8	3.5
Procedure						
Suction	94.0	91.9	94.3	90.2*	93.9	92.2
Dilation and extraction/ sharp curettage	4.6	7.8	4.2	9.4*	4.7	7.6
Other	1.4	0.2	1.5	0.4	1.4	0.2
Total	100.0	100.0	100.0	100.0	100.0	100.0

*Rural-urban difference is significant at p<.01 (by chi-square test). †Includes cases with missing age and county. ‡Includes cases with missing age; does not include cases with missing county. *Notes:* All interdecade differences are significant at p<.01 (by chi-square test), except for the percentage of rural women who had had 1–2 prior abortions. Women aged 50–59 are excluded from the analysis. Percentages may not add to 100% due to rounding.

Location of Services
Table 3 shows that the proportion of rural women having abortions in rural Washington locations decreased significantly, from 25% in 1983–1984 to 3% in 1993–1994 (p<.01). Further, the proportion of rural women who went out of state for an abortion increased significantly, from 8% to 14% (p<.01). The majority of out-of-state abortions were obtained in Oregon. (Data on women traveling to British Columbia are not available.)

The mean one-way distance that rural women traveled to obtain an abortion increased by 12 miles from 1983–1984 to

Table 3. Percentage distribution of women who obtained an abortion, by location of provider, according to residence and time period

Provider location	Total		Rural		Urban	
	1983–1984 (N=53,287*)	1993–1994 (N=53,662*)	1983–1984 (N=6,913†)	1993–1994 (N=5,913†)	1983–1984 (N=46,374†)	1993–1994 (N=47,681†)
Urban	**93.6**	**94.5**	**66.9**	**83.2**	**97.5**	**95.9**
Large urban	83.0	84.7	48.4	58.2	88.1	88.0
Small urban	10.6	9.8	18.5	25.0	9.4	7.9
Rural	**3.5**	**0.3**	**24.8**	**2.7**	**0.3**	**0.0**
Large rural	1.7	0.0	12.1	0.1	0.1	0.0
Small rural	1.8	0.3	12.7	2.6	0.2	0.0‡
Out of state	**2.9**	**5.2**	**8.3**	**14.2**	**2.1**	**4.0**
Idaho	0.3	0.1	2.2	0.5	0.0‡	0.0‡
Oregon	2.6	5.1	6.1	13.6	2.1	4.0
Other	0.0‡	0.0‡	0.0‡	0.1	0.0‡	0.0‡
Total	100.0	100.0	100.0	100.0	100.0	100.0

*Includes cases with missing age and county. †Includes cases with missing age; does not include cases with missing county. ‡Less than 0.05%. *Notes:* All rural-urban differences are statistically significant at p<.01 (by the chi-square test), except the differences in the "other" category. All interdecade differences are significant at p<.01 (by chi-square test), except for the "other" category and for urban residents obtaining abortions in large urban counties. Women aged 50–59 are excluded. Percentages may not add to 100 due to rounding.

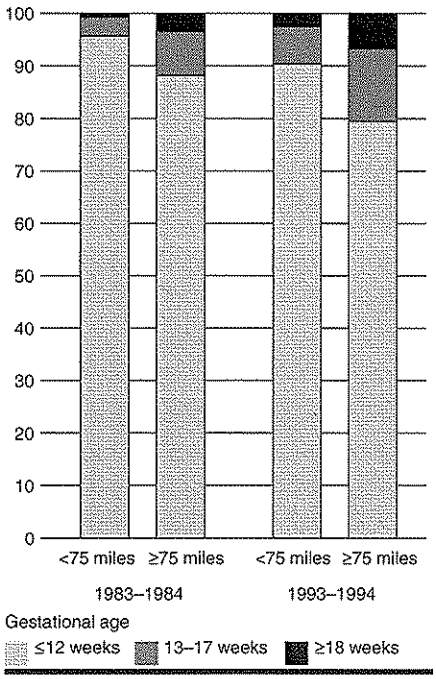
Table 4. Selected measures of travel distance among rural women who had an abortion, according to time period

Measure	1983–1984	1993–1994
% distribution by miles traveled one way†		
<30	24.0	8.0*
30–49	14.2	18.9*
50–99	34.5	42.1*
≥100	27.4	30.9*
Mean distance traveled (miles)	**70.8**	**82.9***
Age 10–19	72.6	83.0*
Age 20–39	70.1	83.0*
Age 40–49	67.0	87.7*
% traveled >50 miles one way		
Age 10–19	61.8	67.2*
Age 20–39	57.3	68.4*
Age 40–49	54.7	72.3*

*Interdecade difference is significant at p<.01 (by the chi-square test). †Information on distance traveled out of state not available.

1993–1994 (95% confidence interval, 10.1–14.2; Table 4). Whereas 24% of rural women traveled less than 30 miles to obtain an abortion in 1983–1984, only 8% did so in 1993–1994. In contrast, 62% traveled 50 miles or more to obtain an abortion in 1983–1984, compared with 73% in 1993–1994. The distance that women traveled ranged from less than five miles to 405 miles each way in 1983–1984, and from less than five miles to 425 miles in 1993–1994 (not shown). During the decade, the proportion of women traveling fewer than 10 miles decreased from 16% to 5%.

Figure 1. Percentage distribution of abortions, by gestational age, according to distance traveled to obtain an abortion and time period



In both time periods, the proportion of rural women who terminated their pregnancy at later than 12 weeks was larger among those who traveled more than 75 miles than among those who traveled less than 75 miles (Figure 1). In 1983–1984, 4% of rural women who traveled less than 75 miles obtained an abortion at later than 12 weeks, compared with 12% of those who traveled 75 miles or more. By comparison, in 1993–1994, 10% of women who traveled less than 75 miles terminated their pregnancy at later than 12 weeks, compared with 21% of those who traveled 75 miles or more.

Age-Specific Differences

Rural women younger than 20 were less likely than older women to have had a prior live birth or an abortion (Table 5). The proportion of rural teenagers who had a prior live birth did not increase significantly during the decade, while the increase was significant for urban adolescents. The proportion of teenagers who had a prior abortion decreased from 16% to 13% in rural areas and remained stable in urban areas, at 21–22%. Among all rural women, the increase in the proportion of abortions terminated after 18 weeks gestational age between time periods was greatest among those younger than 20 (3% vs. 7%).

On average, rural women traveled farther to obtain an abortion in 1993–1994 than they had in the earlier period, but the increase was greatest for women 20 or older (Table 4). In 1983–1984, 55–57% of rural women 20 or older traveled more than 50 miles to terminate a pregnancy, compared with 68–72% in 1993–1994.

Discussion

During the decade studied, pregnancy rates, birthrates, and abortion rates and ratios declined in Washington State. While this occurred among both rural and urban women, the decreases were greater for rural women than for urban women. An aging of the population over the time period accounts for some of the decrease in birthrates and abortion rates for all women. These age shifts, however, are similar in direction and magnitude for both rural and urban women. Therefore, the greater decreases in rural birthrates and abortion rates, compared with urban rates, cannot be attributed solely to changes in population composition.

Overall, health services are readily available throughout Washington State; in particular, prenatal and intrapartum technologies are increasingly available, even in the smallest rural hospitals.[16] This is in sharp contrast to the marked decline in local availability of abortion services. In this study, we found that rural Washington women who terminated a pregnancy in 1993–1994 were almost univer-

Table 5. Percentage of women who had an abortion, by measure of obstetric history, gestational age and percentage having procedure in a rural location, all by age-group and by residence, according to time period

Measure and age-group	1983–1984	1993–1994
TOTAL		
Prior live birth		
10–19	11.9	17.0†
20–39	50.4	59.6†
40–49	88.3	82.6†
Prior abortion		
10–19	21.3	20.1
20–39	50.2	55.3†
40–49	36.9	53.8†
Gestational age >18 weeks		
10–19	2.9	5.1†
20–39	1.5	3.2†
40–49	2.7	2.7
Rural location		
10–19	3.6	0.3†
20–39	3.5	0.3†
40–49	3.7	0.4†
RURAL RESIDENCE		
Prior live birth		
10–19	12.6	14.3*
20–39	58.4*	66.1*,†
40–49	91.4	82.7
Prior abortion		
10–19	16.4*	13.3*
20–39	46.1*	49.8*,†
40–49	34.2	53.3†
Gestational age >18 weeks		
10–19	2.9	6.9*,†
20–39	1.7	4.0*,†
40–49	7.1	3.4
Rural location		
10–19	21.9*	2.1*,†
20–39	25.9*	2.7*,†
40–49	29.4*	4.0*,†
URBAN RESIDENCE		
Prior live birth		
10–19	11.8	17.4†
20–39	49.3	58.9†
40–49	87.9	82.7†
Prior abortion		
10–19	22.1	21.2
20–39	50.8	55.9†
40–49	37.2	53.9†
Gestational age >18 weeks		
10–19	2.9	4.8†
20–39	1.4	3.1†
40–49	2.1	2.6
Rural location		
10–19	0.4	0.0†
20–39	0.3	0.0†,‡
40–49	0.2	0.0

*Rural-urban difference is significant at p<.01 (by chi-square test). †Interdecade difference is significant at p<.01 (by chi-square test). ‡Less than 0.05%. *Notes:* Cases with missing age are not included in the analysis. Percentages may not add to 100 due to rounding.

sally unable to obtain the procedure in their home county. As a result, they traveled greater distances and were more likely to obtain an abortion at a later gestational age than rural women in 1983–1984.

Factors such as confidentiality and comfort may affect the travel decisions of rural women more than urban women. Anonymity is more difficult to achieve locally for a rural woman. For teenagers, this may be even more important; even if the procedure were locally available, they might be more likely to travel than their older counterparts. Notably, the smallest increase in distance traveled during the decade was among women under age 20.

The study reported here has several shortcomings. First, it is based on reports of terminations made by providers, and not all providers file reports. The Alan Guttmacher Institute estimates that over the period 1980–1992, an average of 12% more abortions occurred per year in Washington State than are reported to the state.[17] Furthermore, underreporting from neighboring Oregon and Idaho may have resulted in an overly conservative estimate of the number of women seeking out-of-state abortions. While we know that each year approximately 100 non-Canadian women seek abortions in British Columbia, we do not know these women's country of residence and whether the count is accurate.[18] Thus, rates and ratios may be somewhat higher, while the effect on other variables is not known.

Second, we were unable to analyze the data by race and ethnicity. Women of unknown race and ethnicity had the highest proportion of abortions at a gestational age later than 12 weeks (17% for rural women and 24% for urban women), and 92% of rural women of unknown race and ethnicity traveled more than 50 miles each way to obtain an abortion. Third, these data are from one state, and the degree to which they are generalizable may be limited.

Clearly, the decision-making process for pregnant women considering terminations is multifaceted. The changing patterns we describe may be influenced by a number of variables, including personal beliefs, community attitudes, economics or even increased comfort with the safety of later terminations. The data do not allow us to examine these factors.

These analyses of abortion ratios do show, however, that pregnant rural women in Washington State in the 1990s are more likely to have their babies than to terminate their pregnancy, compared both with urban women and with rural women in the 1980s. More work is needed to understand the relationships among provider availability, other factors influencing decision-making and pregnancy outcomes. Nonetheless, if rural women seek abortions, they are unlikely to find a local provider; they must travel farther and their care is delayed.

References

1. Henshaw SK and Van Vort J, Abortion services in the United States, 1987 and 1988, *Family Planning Perspectives*, 1990, 22(3):102–108 & 142; Henshaw SK, Abortion incidence in the United States, 1995–1996, *Family Planning Perspectives*, 1998, 30(6):263–270 & 287; and Grimes DA, Clinicians who provide abortion: the thinning ranks, *Obstetrics and Gynecology*, 1992, 80(4):719–723.

2. Rosenblatt RA et al., The diffusion of obstetric technology into rural U.S. hospitals, *International Journal of Technology Assessment in Health Care*, 1994, 10(3):479–489; and Rosenblatt RA et al., A comparison of the investment in hospital-based obstetrical ultrasound in Wales and Washington State, *International Journal of Technology Assessment*, 1995, 11(3):571–584.

3. Henshaw SK and Van Vort J, Abortion services in the United States, 1991 and 1992, *Family Planning Perspectives*, 1994, 26(3):100–107; Grimes DA, 1992, op. cit. (see reference 1); Henshaw SK, Factors hindering access to abortion services, *Family Planning Perspectives*, 1995, 27(2):54–59 & 87; Meier KJ and McFarlane DR, State family planning and abortion expenditures: their effect on public health, *American Journal of Public Health*, 1994, 84(9):1468–1472; Kolbert K and Miller A, Government in the examining room: restrictions on the provision of abortion, *Journal of the American Medical Women's Association*, 1994, 49(5):153–155 & 166; and Benshoof J, Planned Parenthood v. Casey: the impact of the new undue burden standard on reproductive health care, *Journal of the American Medical Association*, 1993, 269(17):2249–2257.

4. Henshaw SK, 1995, op. cit. (see reference 3).

5. Washington State Office of Financial Management, Forecasting Division, *Intercensal and Postcensal Estimates of County Population by Age and Sex: 1980–1996*, Olympia, WA: Washington State Office of Financial Management, 1996.

6. Washington State Department of Health (DOH), Center for Health Statistics, Physicians, facilities and abortions by place of occurrence, Washington State, unpublished report of induced terminations of pregnancy, Olympia, WA: Washington State DOH, 1983, 1984, 1993 and 1994.

7. Washington State Office of Financial Management, 1996, op. cit. (see reference 5).

8. Washington State DOH, Center for Health Statistics, Occurrence reports for induced terminations of pregnancy, Olympia, WA: Washington State DOH, 1983, 1984, 1993 and 1994; Washington State DOH, Center for Health Statistics, Occurrence reports for live births, Olympia, WA: Washington State DOH, 1983, 1984, 1993 and 1994; Washington State DOH, Center for Health Statistics, Occurrence reports for fetal deaths, Olympia, WA: Washington State DOH, 1993 and 1994; and Washington State Department of Social and Health Services, *Induced Terminations of Pregnancy in Washington State: 1983–1984*, Olympia, WA: Washington State Department of Social and Health Services, 1986.

9. U.S. Bureau of the Census, *United States Census, 1990*, Washington, DC: U.S. Government Printing Office, STF3A.

10. U.S. Office of Management and Budget (OMB), *Revised Statistical Definitions of Metropolitan Area (MAs) and Guidance on Uses of MA Definitions*, OMB Bulletin Number 95–04, Washington, DC: U.S. OMB, 1995.

11. American Hospital Association (AHA), *Guide to the Health Care Field*, Chicago: AHA, 1994.

12. Washington State Office of Financial Management, Forecasting Division, *Washington State 1993 Data Book*, Olympia, WA: Washington State Office of Financial Management, 1993; and U.S. Bureau of the Census, *Statistical Abstract of the United States: 1995*, 115th ed., Washington, DC: U.S. Government Printing Office, 1995.

13. Washington State Office of Financial Management, 1993, op. cit. (see reference 12); DeLorme Mapping Company, *Washington Atlas and Gazetteer*, Freeport, MN: DeLorme Mapping Company, 1995; and Washington State Department of Transportation (DOT), *Washington: Official State Highway Map*, Olympia, WA: Washington State DOT, 1994.

14. Washington State Office of Financial Management, 1993, op. cit. (see reference 12).

15. Washington State DOH, Center for Health Statistics, *Washington State Pregnancy and Induced Abortion Statistics: 1991–1994*, Olympia, WA: Washington State DOH, 1996.

16. Rosenblatt RA et al., 1994, op. cit. (see reference 2); and Rosenblatt RA et al., 1995, op. cit. (see reference 2).

17. Henshaw SK and Van Vort J, 1994, op. cit. (see reference 1); and Alan Guttmacher Institute (AGI), *Abortion Factbook*, New York: AGI, 1992.

18. Statistics Canada, *Therapeutic Abortions*, Ottawa, Canada: Canadian Center for Health Information, 1983, 1984, 1993 and 1994, selected tables.

Changes in Service Delivery Patterns After Introduction of Telemedicine Provision of Medical Abortion in Iowa

Daniel A. Grossman, MD, Kate Grindlay, MSPH, Todd Buchacker, RN, Joseph E. Potter, PhD, and Carl P. Schmertmann, PhD

Objectives. We assessed the effect of a telemedicine model providing medical abortion on service delivery in a clinic system in Iowa.

Methods. We reviewed Iowa vital statistic data and billing data from the clinic system for all abortion encounters during the 2 years prior to and after the introduction of telemedicine in June 2008 (n = 17 956 encounters). We calculated the distance from the patient's residential zip code to the clinic and to the closest clinic providing surgical abortion.

Results. The abortion rate decreased in Iowa after telemedicine introduction, and the proportion of abortions in the clinics that were medical increased from 46% to 54%. After telemedicine was introduced, and with adjustment for other factors, clinic patients had increased odds of obtaining both medical abortion and abortion before 13 weeks' gestation. Although distance traveled to the clinic decreased only slightly, women living farther than 50 miles from the nearest clinic offering surgical abortion were more likely to obtain an abortion after telemedicine introduction.

Conclusions. Telemedicine could improve access to medical abortion, especially for women living in remote areas, and reduce second-trimester abortion. (*Am J Public Health.* 2013;103:73–78. doi:10.2105/AJPH.2012.301097)

Medical abortion involves the use of medication to induce an abortion nonsurgically, and the regimen used most commonly in the United States involves oral mifepristone followed by misoprostol administered vaginally, orally, buccally, or sublingually.[1] The mifepristone–misoprostol regimen is highly effective up to 9 weeks' gestation and has been found to be very safe.[2,3] Studies in the United States and elsewhere have found that women are very satisfied with this abortion method, and some women prefer it to vacuum aspiration.[4,5] Medical abortion is not a surgical procedure and can be offered by nonphysician clinicians or by physicians who do not perform surgical abortion.[6] However, US clinicians outside of abortion clinics do not appear to have adopted the technology in large numbers. An analysis of data from 2007 found that almost all medical abortion–only providers were located within 50 miles of a large-volume surgical abortion provider.[7]

One factor limiting the uptake of medical abortion is the restriction that most states impose regarding who can provide the service. As of 2009, only 15 states allowed advanced practice clinicians to provide medical abortion; the remainder required that a physician provide the service.[8] Iowa is one such state where a physician must provide medical abortion.

Telemedicine is the delivery of health care services at a distance through information and communication technology. A recent systematic review of economic analyses of telemedicine services found that this care model was cost effective for a range of services.[9] In June 2008, Planned Parenthood of the Heartland in Iowa launched a telemedicine program to allow physicians to provide medical abortion to patients at clinic sites not staffed by a physician to improve access to early abortion and reduce physician travel to outlying clinics. Prior to introducing telemedicine, the network had 17 clinic sites. Two clinics had an on-site physician and offered both medical and surgical abortion, 2 sites offered surgical and medical abortion when a physician traveled there, and 2 additional sites offered only medical abortion when the physician traveled there. The remaining 11 clinics did not provide abortions. A recently published cohort study found that the telemedicine model provided by this clinic system was as effective as a model involving an in-person visit with a physician; telemedicine was also found to be highly acceptable to women, with a low rate of adverse events.[10]

We examined how the clinic system's service delivery patterns changed after the introduction of telemedicine. In particular, we asked whether the proportion of abortions that were medical abortion and second-trimester abortion changed, as well as whether there were changes in the geographical patterns of service delivery.

METHODS

Telemedicine was launched on June 25, 2008, by Planned Parenthood of the Heartland and phased in over the following 21 months. By June 30, 2010, abortion care was being provided at 15 clinic sites. The 4 original surgical abortion sites remained the only sites providing surgical abortion at the end of this period, and all new abortion sites provided medical abortion through telemedicine. The sites to which the physician previously traveled to offer medical abortion began offering telemedicine services after the launch. The telemedicine model used in this clinic system was previously described.[10] For our analysis, we compared data between 2 periods: 2 years prior to telemedicine introduction versus 2 years after.

We used vital statistics records to analyze birth, medical abortion, and surgical abortion data for the state of Iowa during July 2006 to June 2008 versus July 2008 to June 2010.[11] For each period, we calculated the total number of births, abortions, medical abortions, and surgical abortions; the abortion ratio per 100 live births; and the abortion rate per 1000 females aged 15 to 44 years. To calculate the

abortion rate for each period, we averaged the annual number of females aged 15 to 44 years. We performed a χ^2 test to assess statistical differences in the proportion of abortions that were medical versus surgical before and after telemedicine introduction.

We performed a more in-depth analysis on de-identified billing data from all abortion encounters at Planned Parenthood of the Heartland clinics in Iowa between June 20, 2006, and June 30, 2010, (n = 17 956 encounters). This clinic network provided 74% of all abortions in Iowa in 2008.[11] The data set comprised the following variables: date of service; clinic site where abortion was performed; patient age, race and ethnicity, education level, and residential zip code; whether the patient received financial assistance at the clinic to pay for her abortion; gestational age (for surgical abortion gestational age was recorded as ≤13 weeks' or >13 weeks' gestation; by definition, medical abortion was performed at ≤9 weeks' gestation); and type of abortion (medical vs surgical).

We analyzed these data to determine the effect of telemedicine introduction on the following outcomes: the proportion of all abortions that were medical abortion (vs surgical abortion), the proportion of all abortions performed at ≤13 weeks (vs abortion >13 weeks), distance traveled to clinic (approximated with straight-line calculations between clinic and patient residential zip codes), and distance of patient to the nearest clinic that offered surgical abortion, to assess whether women came from more remote areas of the state following the introduction of telemedicine. Women whose reported residential zip code was more than 500 miles from the clinic were excluded from the distance analyses because the location data for these women was assumed to be permanent residence information, such as parents' home address, rather than the woman's local address. After we excluded these cases, the final data set for the geographical analyses comprised 17 801 abortion encounters.

We conducted χ^2 analyses to compare patient characteristics before and after telemedicine introduction. To evaluate the impact of telemedicine on our outcomes of interest, we used the *t* test and linear regression for continuous distance variables and logistic regression for categorical variables (medical abortion provision, abortion ≤13 weeks' gestation, and categorical distance variables). We conducted additional pre–post distance analyses among medical abortion patients only. The predictor variable in each model was telemedicine introduction (1 = patient attended a clinic after telemedicine introduction; 0 = patient attended a clinic before). All sociodemographic covariates from the clinic billing data set were selected a priori in the multivariate models. We performed all statistical tests with Stata 12 (StataCorp LP, College Station, TX).

We matched patients' residential zip codes to polygons in US Census shape files for Iowa and surrounding states. For each zip code, we calculated Z (number of abortion patients before – number of abortion patients after telemedicine introduction). We used the centroids of zip code areas as approximate (X,Y) = (longitude, latitude) locations for patients to produce a set {X,Y,Z} of locations and changes, with zip codes as the unit of observation. We then smoothed this {(X,Y,Z)} map through inverse-distance weighting with the *krige()* function in R's gstat package (R Foundation for Statistical Computing, Vienna, Austria) to find spatial clusters of increased and decreased numbers of abortion cases after the introduction of telemedicine. We performed similar analyses for medical abortions and surgical abortions separately.

RESULTS

Table 1 shows the comparative data on births and abortions for the state of Iowa for the 2-year periods before and after telemedicine was introduced at Planned Parenthood of the Heartland. The number of both births and abortions declined in the state between these periods; however, the reduction in abortions was larger, with a decrease in both abortion ratio and abortion rate for the state. The proportion of medical abortions among all abortions increased significantly, from 33.4% to 45.3% ($P < .001$).

The Planned Parenthood of the Heartland clinic system recorded 8902 abortion encounters during the 2 years before and 9054 abortion encounters during the 2 years after telemedicine was introduced. Demographic characteristics of the Planned Parenthood patients are shown in Table 2. Age and race/ethnicity of abortion patients did not differ in the 2 periods; however, we observed slight differences by education level ($P < .001$). More women received financial assistance during the period after telemedicine was introduced because a new program was started in 2008 to provide such support.[12]

The proportion of abortions that were medical abortion at Planned Parenthood of the Heartland clinics increased from 46% to 54% after telemedicine introduction, and the proportion of abortions performed after 13 weeks' gestation decreased slightly from 3.9% to 3.5% (Table 2). After we controlled for financial assistance, age, race/ethnicity, and education level, we found that women obtaining services after the introduction of telemedicine had a 51% greater likelihood of having a medical abortion (adjusted odds ratio

TABLE 1—Births and Abortions in Iowa Before and After Introduction of Telemedicine Service at Planned Parenthood Clinics in Iowa in June 2008

Variable	July 2006–June 2008	July 2008–June 2010
Average female population aged 15–44 y, no.	583 180	577 876
Births, no.	81 501	79 198
Abortions, no.	13 264	11 762
Abortion type, no. (%)		
Medical	4432 (33.4)	5326 (45.3)*
Surgical	8832 (66.6)	6436 (54.7)
Abortions/100 births	16.3	14.9
Average annual abortions/1000 females aged 15–44 y	11.4	10.2

*$P < .001$. P values were determined by the χ^2 test.

TABLE 2—Abortion Patient Characteristics and Service Delivery Statistics From Planned Parenthood of the Heartland (Iowa) Before and After Introduction of Telemedicine Service in June 2008

Variable	July 2006–June 2008 (n = 8902), No. (%), Mean, or Median	July 2008–June 2010 (n = 9054), No. (%), Mean, or Median	P
Patient characteristics			
Age, y			.53
9–20	2225 (25)	2331 (26)	
21–24	2505 (28)	2475 (27)	
25–29	2085 (23)	2104 (23)	
30–49	2087 (23)	2144 (24)	
Race/ethnicity			.07
Non-Hispanic White	6505 (73)	6583 (73)	
Non-Hispanic Black	826 (9)	922 (10)	
Hispanic	729 (8)	725 (8)	
Asian/Pacific Islander	347 (4)	323 (4)	
> 1 race	144 (2)	178 (2)	
Other race[a] or unknown race	351 (4)	323 (4)	
Highest grade of education completed			<.001
< 9	177 (2)	166 (2)	
9–12	4541 (51)	4711 (52)	
≥ 13	3298 (37)	2827 (31)	
Unknown	886 (10)	1350 (15)	
Received financial assistance to pay for abortion	903 (10)	4506 (50)	<.001
Service delivery statistics			
Abortion type			<.001
Medical	4095 (46)	4850 (54)	
Surgical, ≤ 13 wk	4464 (50)	3886 (43)	
Surgical, > 13 wk	343 (3.9)	318 (3.5)	
Distance traveled by patient from residence to clinic,[b] miles			
Mean	33.2	30.7	<.001
Median	12.6	12.6	
0–25	5271 (60)	5470 (61)	.01
25.1–50	1353 (15)	1454 (16)	
> 50	2184 (25)	2069 (23)	
Distance between residential zip code of patient and nearest clinic providing surgical abortion,[b] miles			
Mean	29.9	31.6	.002
Median	12.6	16.7	
0–25	5287 (60)	5079 (56)	<.001
25.1–50	1437 (16)	1532 (17)	
> 50	2084 (24)	2382 (26)	

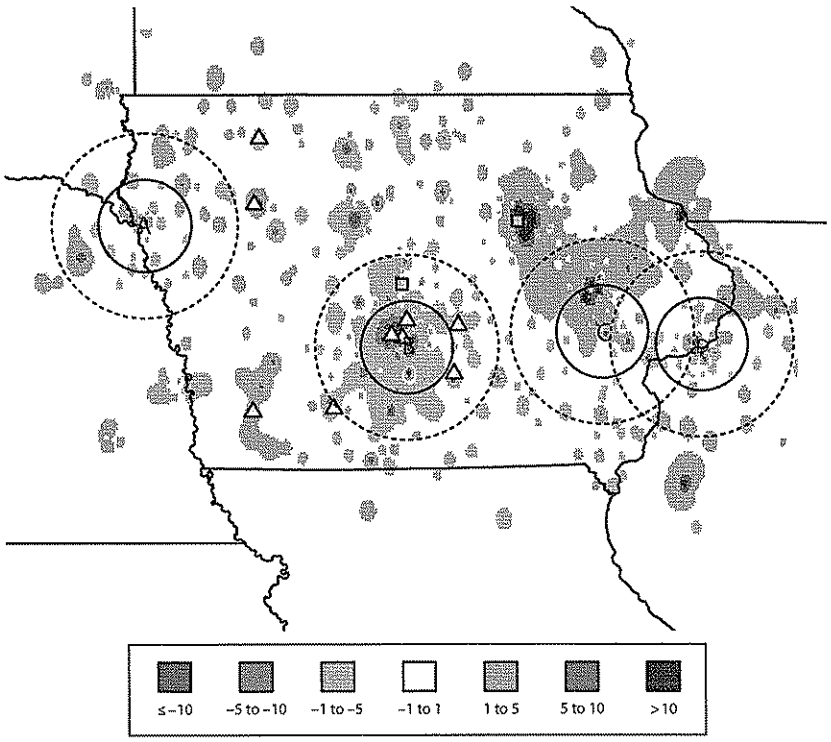
[a]American Indian, Alaskan Native, and other.
[b]Patients who traveled < 500 miles only (n = 17 801; before, n = 8808; after, n = 8993).

[AOR] = 1.51; 95% confidence interval [CI] = 1.41, 1.61). With adjustment for the same covariates, women obtaining services after telemedicine introduction had a 46% greater likelihood of having an abortion at or before 13 weeks' gestation (AOR = 1.46; 95% CI = 1.22, 1.75).

The average distance that women traveled from their home to the clinic decreased slightly, from 33.2 miles before telemedicine introduction to 30.7 miles after ($P < .001$). The proportion of patients who traveled more than 50 miles to the clinic also declined slightly, from 25% to 23% (Table 2). The median distance traveled did not change. In regression analysis, women obtaining services after the introduction of telemedicine had a 3.16-mile decrease in average distance traveled to the clinic, after adjustment for sociodemographic factors (95% CI = −4.51, −1.80). Women presenting after telemedicine introduction also had a 12% reduced likelihood of traveling more than 50 miles to the clinic, after adjustment for sociodemographic factors (AOR = 0.88; 95% CI = 0.81, 0.95). We obtained similar results when we restricted this analysis to medical abortion patients.

Abortion access for women living in more remote parts of the state increased with telemedicine: the proportion of patients who lived more than 25 miles and more than 50 miles from a surgical abortion clinic increased from 40% to 44% and from 24% to 26%, respectively ($P < .001$; Table 2). After adjustment for sociodemographic factors, patients were 12% more likely to reside more than 50 miles from a clinic that provided surgical abortion after than before telemedicine was introduced (AOR = 1.12; 95% CI = 1.03, 1.20). When we restricted this analysis to medical abortion patients (n = 8860) and controlled for sociodemographic factors, we found that after telemedicine introduction, medical abortion patients had a 16% greater likelihood of residing more than 50 miles from a clinic providing surgical abortion (AOR = 1.16; 95% CI = 1.05, 1.28).

Figure 1 shows the smoothed mapping results for the changes in the number of abortions after telemedicine introduction according to patient residential zip code, and Figure 2 shows the same mapping results for surgical abortions (panel a) and for medical abortions (panel b). The data showed a reduction in the number of abortions among women residing around Des Moines and an increase in the number of abortions performed on women living in the western and eastern portions of the state (Figure 1). The number of surgical abortions decreased among women residing throughout the state, but especially for those living in the central and western portions of the state (Figure 2a). The number of medical abortions



Note. Mapping results are smoothed. A, B, C, and D = clinics that provide surgical abortion (solid and broken rings indicate distances of 25 and 50 miles, respectively). Yellow squares = clinics that intermittently offered medical abortion before telemedicine was introduced when a doctor traveled to the clinic and later became telemedicine sites. Yellow triangles = clinics that began offering medical abortion after telemedicine was introduced.

FIGURE 1—Change in total number of abortions by residential zip code for 2 years before (June 20, 2006–June 24, 2008) and after (June 25, 2008–June 30, 2010) telemedicine was introduced in Planned Parenthood of the Heartland clinics in Iowa.

increased among women residing throughout the state, but especially among residents of the western and eastern portions of the state. Most of the increase in the number of medical abortions after telemedicine introduction occurred among women living more than 50 miles from one of the surgical abortion clinics, especially in more remote parts of Iowa, as well as in eastern Nebraska and northwest Illinois. In most cases, the increases occurred in areas surrounding telemedicine sites. The data showed scattered areas where fewer women obtained medical abortions (shown in red), but no clear pattern emerged.

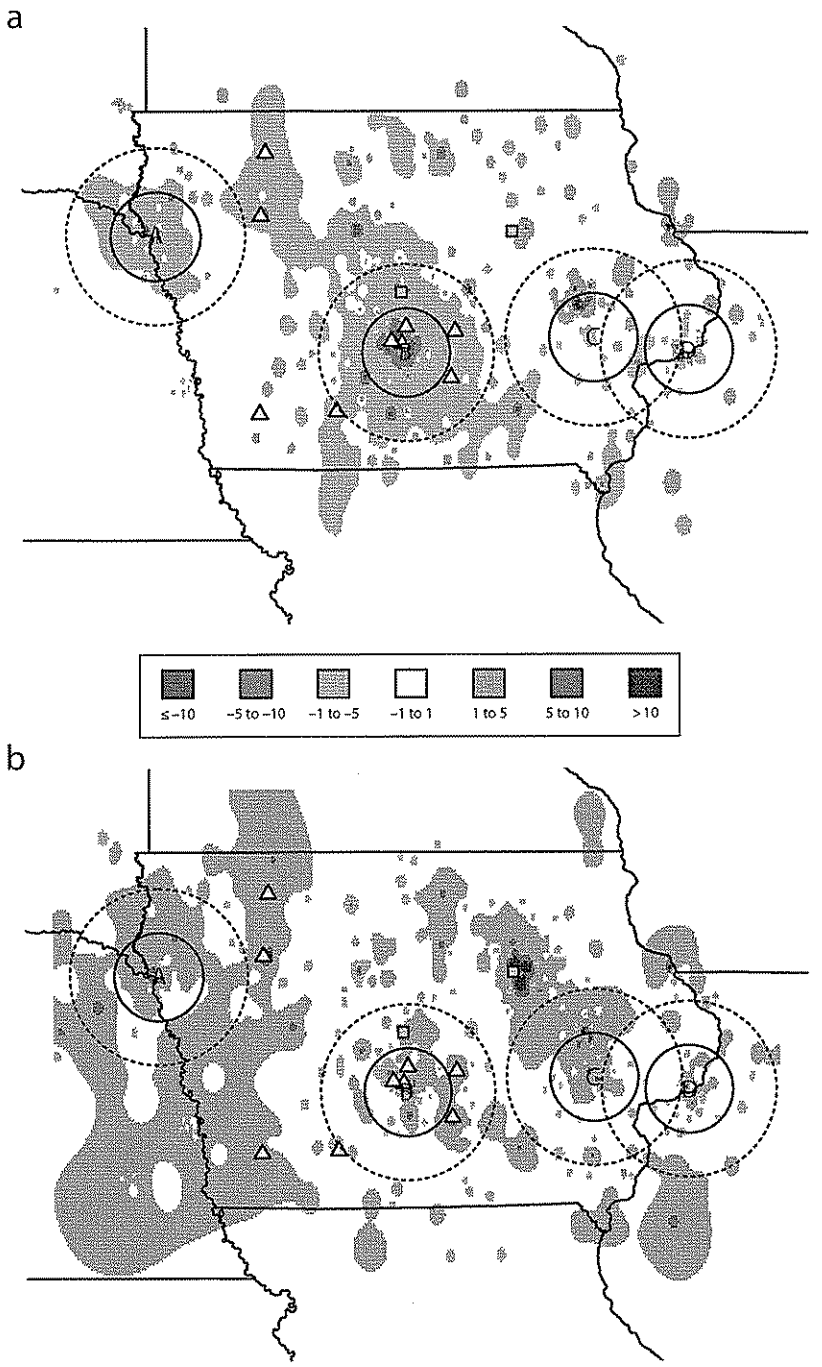
DISCUSSION

After the introduction of telemedicine in a Planned Parenthood clinic system, the proportion of medical abortions performed increased in both the system and the state of Iowa. After adjustment for other factors, including financial assistance, we found that women presenting after telemedicine introduction were significantly more likely to receive a medical abortion. This finding is not surprising because the clinic sites that began offering abortion care after telemedicine introduction only provided medical abortion. Although the increase in medical abortion might be attributable to a time trend unrelated to telemedicine introduction, it is unlikely that the observed increase in medical abortion from 46% to 54% of all Planned Parenthood of the Heartland abortions would have occurred without telemedicine. In a national census of abortion providers, the proportion of nonhospital abortions that were medical abortions only increased from 14% to 17% between 2005 and 2008.[13] It is particularly interesting that the increase in medical abortion occurred in the context of decreasing abortion numbers statewide, reflecting an overall reduction in the number of surgical abortions.

Although the magnitude of the reduction was small, we also found that women were less likely to have a second-trimester abortion in this clinic system after telemedicine introduction. Previous research found that logistical factors, such as difficulty finding a provider, distance from the clinic, and difficulty with transportation, were reported significantly more frequently by women seeking second-trimester abortion than by those seeking first-trimester abortion.[14] Telemedicine may reduce some of these barriers to earlier abortion. In light of the evidence documenting the higher risk of complications and mortality associated with second-trimester than with early first-trimester abortion,[15] the effect of telemedicine on gestational age at time of abortion should be evaluated over a longer period and in other settings to confirm our findings. It would be interesting to evaluate whether telemedicine availability also reduces surgical abortion at 9 to 13 weeks' gestation; unfortunately our data set did not allow us to explore this hypothesis.

Access to care has been defined as the degree of fit between patients and the health care system in 5 specific areas: availability, accessibility, accommodation, affordability, and acceptability.[16] In this clinic system, availability of abortion services certainly increased after telemedicine introduction, because the number of clinics providing abortion care increased. Accessibility is defined as the relationship between the location of supply and the location of patients,[16] and this also clearly increased, as can be seen in Figures 1 and 2. The increase in use of abortion services—especially medical abortion—among women living in more remote parts of Iowa, which we defined as living more than 50 miles from a clinic offering surgical abortion, also suggests that accessibility improved.

Accommodation is the relationship between the way supply resources are organized to accept patients and the patients' ability to accommodate to these factors and their perception of their appropriateness.[16] One measure of accommodation is satisfaction with clinic wait time, which was shown to be significantly higher among telemedicine patients in this system.[10] Affordability was not specifically



Note. Mapping results are smoothed. A, B, C, and D = clinics that provide surgical abortion (solid and broken rings indicate distances of 25 and 50 miles, respectively). Yellow squares = clinics that intermittently offered medical abortion before telemedicine was introduced when a doctor traveled to the clinic and later became telemedicine sites. Yellow triangles = clinics that began offering medical abortion after telemedicine was introduced.

FIGURE 2—Change in number of abortions by residential zip code for 2 years before (June 20, 2006–June 24, 2008) and after (June 25, 2008–June 30, 2010) telemedicine was introduced in Planned Parenthood of the Heartland clinics in Iowa that were (a) surgical and (b) medical.

measured in our study, although it is possible that women's out-of-pocket expenditures related to time away from work, child care, and travel costs may be reduced with telemedicine abortion provision. The final dimension of access—acceptability—has been shown to be significantly higher among telemedicine patients for some measures.[10] Taken together, our analyses suggest that access to abortion care improved after the introduction of telemedicine in this clinic system. They also highlight the need to examine access from a variety of vantage points, including that of patients, rather than simply considering the number and location of service delivery points.

In our geographic analysis, we found an overall reduction in the number of abortions in the central part of the state around Des Moines. The reasons for this decline are not clear. One hypothesis is that a promotional campaign increased uptake of contraception, including long-acting methods, in this area. The reduction in births in Iowa during the same period also supports this hypothesis. In 2009, the Iowa Initiative to Reduce Unintended Pregnancies began several community- and clinic-focused interventions aimed at improving contraceptive use.[17] These interventions may have been particularly effective in urban areas of the state, although additional research would be required to confirm this hypothesis.

Despite this apparent improvement in access to abortion care, we observed a relatively small reduction in the distance women traveled from their home to the clinic. Although this finding may seem surprising, distance to the clinic is only one of several factors women consider when choosing where to obtain the service.[10] Some women may choose to travel farther to get an appointment sooner, and abortion stigma may lead some women in a small community to go to a clinic in another town to avoid being seen by someone they know. Previous research in Iowa found that travel time was not a predictor of women's preference for obtaining abortion services with their regular physician; some women preferred not to obtain care with their regular physician because of concerns about privacy and confidentiality.[18] The decrease in abortion that we observed in the Des Moines area after telemedicine introduction also likely affected distance traveled, because this population lives close to several of

the abortion clinics. It will be interesting to see whether distance traveled by patients in this clinic system continues to decrease in the coming years.

Our study had several limitations. Because it was an observational study, we cannot infer causality from our results, and factors other than telemedicine and the variables we were able to control for may have contributed to our findings. It would be challenging to study the impact of telemedicine with a cluster-randomized design because the clusters would have to be sufficiently far apart to be able to assess distance traveled and to avoid contamination. Another limitation is that we only examined the first 2 years after telemedicine introduction. The telemedicine sites that began offering services later in the study period had small volumes of patients, and these numbers might increase over time. In addition, our findings are specific to the service delivery model implemented in this clinic system and cannot be generalized to other models in other settings. Our study also had several strengths, including the ability to analyze the entire universe of abortion encounters in this clinic system over a 4-year period and the novel spatial mapping techniques we used to determine access to abortion care.

Access to abortion services remains limited in the United States, with 35% of women of reproductive age living in counties without an abortion provider.[13] Telemedicine provision of medical abortion has been shown to be safe, effective, and acceptable to women.[10] Our results suggest that it promotes earlier abortion and improves access to care for rural women. Recent legislation to ban telemedicine abortion[19] may adversely affect public health by preventing women from accessing abortion earlier in pregnancy, when it is safer.[15] ■

About the Authors

Daniel A. Grossman is with Ibis Reproductive Health, Oakland, CA. He is also with the Bixby Center for Global Reproductive Health, Department of Obstetrics, Gynecology, and Reproductive Sciences, University of California, San Francisco. Kate Grindlay is with Ibis Reproductive Health, Cambridge, MA. At the time of the study, Todd Buchacker was with Planned Parenthood of the Heartland, Des Moines, IA. Joseph E. Potter is with the Population Research Center, University of Texas, Austin. Carl P. Schmertmann is with the Center for the Study of Demography and Population Health, Florida State University, Tallahassee.

Correspondence should be sent to Daniel A. Grossman, Ibis Reproductive Health, 1330 Broadway, Suite 1100, Oakland, CA 94612 (e-mail: DGrossman@ibisreproductivehealth.org). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

This article was accepted October 4, 2012.

Contributors

D. A. Grossman originated and supervised the study and led the writing. K. Grindlay performed most of the analyses. T. Buchacker assisted with data collection. J. E. Potter assisted with analyses. C. P. Schmertmann performed the spatial mapping. All authors helped to interpret findings and reviewed and edited drafts of the article.

Acknowledgments

The study was funded by a grant from an anonymous donor.

Note. The findings and conclusions in this article are those of the authors and do not necessarily represent the views of Planned Parenthood Federation of America, Inc.

Human Participant Protection

The study was approved by the Allendale investigational review board.

References

1. Wiegerinck MM, Jones HE, O'Connell K, Lichtenberg ES, Paul M, Westhoff CL. Medical abortion practices: a survey of National Abortion Federation members in the United States. *Contraception.* 2008;78(6):486–491.

2. Kulier R, Kapp N, Gülmezoglu AM, Hofmeyr GJ, Cheng L, Campana A. Medical methods for first trimester abortion. *Cochrane Database Syst Rev.* 2011;(11): CD002855.

3. Fjerstad M, Trussell J, Sivin I, Lichtenberg ES, Cullins V. Rates of serious infection after changes in regimens for medical abortion. *N Engl J Med.* 2009;361(2):145–151.

4. Winikoff B, Ellertson C, Elul B, Sivin I. Acceptability and feasibility of early pregnancy termination by mifepristone-misoprostol. Results of a large multicenter trial in the United States. Mifepristone Clinical Trials Group. *Arch Fam Med.* 1998;7(4):360–366.

5. Ho PC. Women's perceptions on medical abortion. *Contraception.* 2006;74(1):11–15.

6. Yarnall J, Swica Y, Winikoff B. Non-physician clinicians can safely provide first trimester medical abortion. *Reprod Health Matters.* 2009;17(33):61–69.

7. Finer LB, Wei J. Effect of mifepristone on abortion access in the United States. *Obstet Gynecol.* 2009;114(3): 623–630.

8. Berer M. Provision of abortion by mid-level providers: international policy, practice and perspectives. *Bull World Health Organ.* 2009;87(1):58–63.

9. Wade VA, Karnon J, Elshaug AG, Hiller JE. A systematic review of economic analyses of telehealth services using real time video communication. *BMC Health Serv Res.* 2010;10:233.

10. Grossman D, Grindlay K, Buchacker T, Lane K, Blanchard K. Effectiveness and acceptability of medical abortion provided through telemedicine. *Obstet Gynecol.* 2011;118(2 pt 1):296–303.

11. Iowa Department of Public Health, Bureau of Vital Statistics. Vital statistics of Iowa. Available at: http://www.idph.state.ia.us/apl/vital_stats.asp. Accessed May 24, 2012.

12. CAIR Project. Fast facts about abortion funding. Available at: http://www.prochoicewashington.org/assets/files/fastfacts.pdf. Accessed April 4, 2012.

13. Jones RK, Kooistra K. Abortion incidence and access to services in the United States, 2008. *Perspect Sex Reprod Health.* 2011;43(1):41–50.

14. Drey EA, Foster DG, Jackson RA, Lee SJ, Cardenas LH, Darney PD. Risk factors associated with presenting for abortion in the second trimester. *Obstet Gynecol.* 2006;107(1):128–135.

15. Bartlett LA, Berg CJ, Shulman HB, et al. Risk factors for legal induced abortion-related mortality in the United States. *Obstet Gynecol.* 2004;103(4):729–737.

16. Penchansky R, Thomas JW. The concept of access: definition and relationship to consumer satisfaction. *Med Care.* 1981;19(2):127–140.

17. The Iowa Initiative to Reduce Unintended Pregnancies. Available at: http://www.iowainitiative.org/research_program/research_program.php. Accessed April 4, 2012.

18. Shochet T, Trussell J. Determinants of demand: method selection and provider preference among US women seeking abortion services. *Contraception.* 2008; 77(6):397–404.

19. Gold RB, Nash E. Troubling trend: more states hostile to abortion rights as middle ground shrinks. *Guttmacher Pol Rev.* 2012;15(1):14–19.

K

The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

SOCIETY of FAMILY PLANNING
research, education, and leadership

PRACTICE BULLETIN

CLINICAL MANAGEMENT GUIDELINES FOR OBSTETRICIAN–GYNECOLOGISTS

NUMBER 143, MARCH 2014 *(Replaces Practice Bulletin Number 67, October 2005)*

Medical Management of First-Trimester Abortion

Over the past three decades, medical methods of abortion have been developed throughout the world and are now a standard method of providing abortion care in the United States. Medical abortion, which involves the use of medications rather than a surgical procedure to induce an abortion, is an option for women who wish to terminate a first-trimester pregnancy. Although the method is most commonly used up to 63 days of gestation (calculated from the first day of the last menstrual period), the treatment also is effective after 63 days of gestation. The Centers for Disease Control and Prevention estimates that 64% of abortions are performed before 63 days of gestation (1). Medical abortions currently comprise 16.5% of all abortions in the United States and 25.2% of all abortions at or before 9 weeks of gestation (1). Mifepristone, combined with misoprostol, is the most commonly used medical abortion regimen in the United States and Western Europe; however, in parts of the world, mifepristone remains unavailable. This document presents evidence of the effectiveness, benefits, and risks of first-trimester medical abortion and provides a framework for counseling women who are considering medical abortion.

Background

Medications Currently Used for Medical Abortion

Mifepristone

Mifepristone, a derivative of norethindrone, binds to the progesterone receptor with an affinity greater than progesterone itself but does not activate the receptor, thereby acting as an antiprogestin (2). Its known actions on a uterus in pregnant women include decidual necrosis, cervical softening, and increased uterine contractility and prostaglandin sensitivity (3, 4). Human studies have suggested that uterine contractility does not increase until 24–36 hours after mifepristone administration (3). At this point, the sensitivity of the myometrium to the stimulatory effects of exogenous prostaglandins increases fivefold (3). However, more recent studies have shown high efficacy when vaginal misoprostol is administered less than 15 minutes after mifepristone (5). The effectiveness of such a regimen cannot be attributed to the actions of the misoprostol because misoprostol alone has a much lower efficacy than mifepristone. Accordingly, these studies suggest that some or all of these actions occur sooner than previously believed or that the effects of mifepristone that are important and necessary for its abortifacient activity remain incompletely understood.

As a progesterone receptor antagonist, mifepristone also has several other potential medical applications, including emergency contraception; cervical ripening and

Committee on Practice Bulletins—Gynecology and the Society of Family Planning. This Practice Bulletin was developed by the Committee on Practice Bulletins—Gynecology and the Society of Family Planning with the assistance of Mitchell D. Creinin, MD and Daniel A. Grossman, MD. The information is designed to aid practitioners in making decisions about appropriate obstetric and gynecologic care. These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

labor induction; and treatment of symptomatic uterine leiomyomas, endometriosis, Cushing syndrome, breast cancer, early pregnancy loss, and glaucoma (6, 7).

Misoprostol

Misoprostol is an inexpensive prostaglandin E_1 analogue in a tablet form that is stable at room temperature. It is approved by the U.S. Food and Drug Administration (FDA) for oral administration to prevent gastric ulcers in individuals who take antiinflammatory drugs on a long-term basis, and it is included in the FDA-approved labeling of mifepristone for use in abortion. It is used off-label in other regimens for abortion, labor induction, treatment of early pregnancy loss, prevention and treatment of postpartum hemorrhage, and cervical priming before uterine procedures, such as hysteroscopy (8). Pharmacokinetic evaluations of misoprostol absorption when administered by various routes have been performed (9–13). Routes that result in a longer duration of action (ie, buccal and vaginal) also appear to result in greater efficacy compared with oral administration. Similarly, those routes with rapid and significant absorption (ie, sublingual) also have high efficacy, but the greater maximum concentration results in more adverse effects. Misoprostol-only medical abortion regimens are significantly less effective than those that use a combination of mifepristone and misoprostol (14, 15).

Other Agents

Methotrexate in combination with misoprostol was adopted in the United States and Canada as an alternative to mifepristone regimens before mifepristone was available (16, 17). However, methotrexate rarely is used anymore in the United States for medical abortion because of the greater availability and efficacy of mifepristone regimens. Methotrexate blocks dihydrofolate reductase, an enzyme involved in producing thymidine during DNA synthesis. Methotrexate exerts its action primarily on the cytotrophoblast rather than the developing embryo, which inhibits syncytialization of the cytotrophoblast (18). Thus, methotrexate stops the process of implantation rather than weakening the implantation site directly. In contrast, the antiprogestin mifepristone has no direct effect on the trophoblast.

Tamoxifen has been used in some studies of early abortion in combination with misoprostol. However, randomized trials have demonstrated no benefit of using tamoxifen–misoprostol over methotrexate–misoprostol or misoprostol alone regimens (19, 20).

Two small studies from China suggest that multiple daily administrations of letrozole followed by misoprostol, 800 micrograms vaginally, may be another effective option for medical abortion, but more research is needed regarding this regimen (21, 22).

Mifepristone Regimens

Regimen approved by the U.S. Food and Drug Administration

The FDA-approved regimen, as detailed in the mifepristone package labeling, is based on the original regimen registered in France 25 years ago. This regimen includes mifepristone, 600 mg orally, followed approximately 48 hours later by a prostaglandin analogue, usually misoprostol 400 micrograms orally. The FDA-approved regimen includes this treatment with a follow-up visit approximately 14 days after mifepristone administration (23). If clinical history indicates that the woman had a confirmed abortion, a pelvic examination is performed to confirm uterine involution. If clinical history and physical examination do not confirm expulsion, ultrasonography is performed. Suction aspiration at the follow-up evaluation is not specified as necessary unless the pregnancy is ongoing (23).

The efficacy of the FDA-approved regimen is approximately 92% in women with gestations up to 49 days (24, 25). Complete abortion rates are higher with earlier gestations; approximately 96–98% in gestations of up to 42 days, 91–95% in gestations from 43 days to 49 days, and less than 85% in gestations beyond 49 days (24, 26, 27). When abortion does not occur within 3–4 hours after oral misoprostol administration, use of an additional dose does not improve efficacy (26, 28).

Evidence-Based Regimens

Additional "evidence-based" regimens have been developed to improve medical abortion in terms of expense, safety, speed, and adverse effects. Regimens that use low doses of mifepristone (200 mg) have similar efficacy and lower costs compared with those that use mifepristone at 600 mg (29). Based on efficacy and the adverse effect profile, evidence-based protocols for medical abortion are superior to the FDA-approved regimen. Vaginal, buccal, and sublingual routes of misoprostol administration increase efficacy, decrease continuing pregnancy rates, and increase the gestational age range for use as compared with the FDA-approved regimen (30). By changing the route of misoprostol administration, the timing between mifepristone and misoprostol dosing can be varied to allow women more flexibility to accommodate personal situations, such as work and childcare. Regimens that use vaginal misoprostol can be provided simultaneously with mifepristone to terminate gestations of up to 63 days (5). A 6–8-hour interval between mifepristone administration and vaginal misoprostol

administration is as effective as a 24–hour interval and results in significantly fewer adverse effects (31). Buccal and sublingual misoprostol can be administered as early as 24 hours after mifepristone administration (32, 33). Women can safely and effectively self-administer misoprostol at home as part of a medical abortion regimen (32, 34, 35).

Counseling Patients

Medical Abortion Versus Surgical Abortion

Counseling must first emphasize early pregnancy options to ensure that a woman is certain about her decision to have an abortion. If she is uncertain, then the decision about abortion technique must be delayed until she has reached a firm decision, even if the delay means that she will be unable to choose a medical option.

Only when a woman has considered her options and decided to have an abortion does the discussion about the different methods become an issue. Most women who seek early abortion will be eligible for medical and surgical methods. The general advantages and disadvantages of each approach should be explained early in the counseling process (Box 1) (36–38). Even for women who think they are unsure about the method, most will have some preference after counseling (37). Studies that have compared abortion method preferences have included groups of patients who choose their method and those who are randomized to their method. The applicability of these studies to current U.S. medical abortion practice is limited given that no studies included the mifepristone–misoprostol regimen, and in two studies, surgical abortion was performed only under general anesthesia. Generally, women are satisfied with the method they choose but, when randomized, prefer surgical abortion to medical abortion (36–38).

Most women choose medical abortion because of a desire to avoid surgery, a perception that medical abortion is safer than surgical abortion, and a belief that medical abortion is more natural and private than a surgical procedure (39). Compared with surgical abortion, medical abortion takes longer to complete, requires more active patient participation, and is associated with higher reported rates of bleeding and cramping. With medical abortion, expulsion of the products of conception most likely will occur at home, but a few women will still require surgical evacuation to complete the abortion. An early surgical abortion takes place most commonly in one visit and involves less waiting and less doubt about when the abortion occurs compared with medical abortion. In addition, women who undergo surgical abortion will not see any products of conception or blood clots during the procedure.

Box 1. Features of Medical and Surgical Abortion ⇦

Medical Abortion

- Usually avoids invasive procedure
- Usually avoids anesthesia
- Days to weeks to complete
- Available during early pregnancy
- High success rate (approximately 95%)
- Bleeding commonly not perceived as light
- Requires follow-up to ensure completion of abortion
- Patient participation throughout a multiple-step process

Surgical Abortion

- Involves invasive procedure
- Allows use of sedation if desired
- Complete in a predictable period of time
- Available during early pregnancy
- High success rate (99%)
- Bleeding commonly perceived as light
- Does not require follow-up in most cases
- Patient participation in a single-step process

Adverse Effects

Bleeding and cramping will be experienced by most women undergoing medical abortion and are necessary for the process to occur. Adverse effects commonly associated with mifepristone use include nausea, vomiting, diarrhea, headache, dizziness, and thermoregulatory effects (5, 31, 32, 40–42; Table 1). The incidence of each adverse effect is based on the regimen used (especially the prostaglandin analogue), the dose and route of administration of the prostaglandin analogue, and the gestational age. Gastrointestinal adverse effects are less common when misoprostol is administered vaginally as compared with regimens that use oral, buccal, or sublingual misoprostol (29, 43). Buccal and sublingual administration cause similar adverse effects, with the sublingual route associated with a higher rate of chills (44).

Counseling should emphasize that the woman is likely to have bleeding that is much heavier than menses (and potentially with severe cramping) and is best described to patients as comparable with a miscarriage. The woman should understand how much bleeding is considered too much. An easy reference for the patient

Table 1. Adverse Effects in Selected North American Trials of Medical Abortion Regimens ⇦

Trial	Incidence of Adverse Effects (%)											
	Nausea		Vomiting		Diarrhea		Headache		Dizziness		Thermoregulatory Effects*	
	Mifepristone	Misoprostol	Mifepristone	Misoprostol	Mifepristone	Misoprostol	Mifepristone	Misoprostol	Mifepristone	Misoprostol	Mifepristone	Misoprostol
Schaff (1997)†	36	36	14	14	8	22	18	19	22	37	20	37
Schaff (1999)‡	45	43	13	26	11	23	14	13	15	28	14	32
Wiebe (2002)§	45	39	13	15	5	16	19	29	N/R	N/R	N/R	23
Creinin (2004)‖	20	44	5	23	1	27	10	37	12	35	9	56
	39	52	14	30	7	25	20	37	20	37	19	53
Creinin (2007)¶	N/R	58	N/R	31	N/R	35	N/R	40	N/R	39	N/R	69
	29	51	9	31	5	26	18	36	9	37	15	56
Winikoff (2008)#	N/R	64	N/R	40	N/R	35	N/R	31	N/R	30	N/R	33
	N/R	66	N/R	40	N/R	34	N/R	34	N/R	32	N/R	41

Abbreviation: N/R, not reported.

*Fever, warmth, hot flushes, or chills.

†Mifepristone, 600 mg, followed by misoprostol, 800 micrograms vaginally, 36–48 hours later. (Schaff EA, Stadalius LS, Eisinger SH, Franks P. Vaginal misoprostol administered at home after mifepristone (RU486) for abortion. J Fam Pract 1997;44:353–60.)

‡Mifepristone, 200 mg, followed by misoprostol, 800 micrograms vaginally, 48 hours later. (Schaff EA, Eisinger SH, Stadalius LS, Franks P, Gore BZ, Poppema S. Low-dose mifepristone 200 mg and vaginal misoprostol for abortion. Contraception 1999;59:1–6.)

§Mifepristone, 600 mg, followed by misoprostol, 400 micrograms orally, 36–48 hours later. (Wiebe E, Dunn S, Guilbert E, Jacot F, Lugtig L. Comparison of abortions induced by methotrexate or mifepristone followed by misoprostol. Obstet Gynecol 2002;99:813–9.)

‖Mifepristone, 200 mg, followed by misoprostol, 800 micrograms vaginally, 6–8 hours later (first row) or 24 hours later (second row). (Creinin MD, Fox MC, Teal S, Chen A, Schaff EA, Meyn LA. A randomized comparison of misoprostol 6 to 8 hours versus 24 hours after mifepristone for abortion. Obstet Gynecol 2004;103:851–9.)

¶Mifepristone, 200 mg, followed by misoprostol, 800 micrograms vaginally, 0–15 minutes later (first row) or 24 hours later (second row). (Creinin MD, Schreiber CA, Bednarek P, Lintu H, Wagner MS, Meyn L. Mifepristone and misoprostol administered simultaneously compared with 24 hours apart for abortion: a randomized controlled trial. Obstet Gynecol 2007;109:885–94.)

#Mifepristone, 200 mg, followed by misoprostol, 800 micrograms orally (first row) or buccally (second row), 24–36 hours later. (Winikoff B, Dzuba IG, Creinin MD, Crowden WA, Goldberg A, Gonzales J, et al. Two distinct oral routes of misoprostol in mifepristone medical abortion. A randomized controlled trial. Obstet Gynecol 2008;112:1303–10.)

Click for full view.

to use is the soaking of two maxi pads per hour for 2 consecutive hours (45). Patients should be advised to call their health care providers if they experience this level of bleeding. The need for emergency care is based on how the patient is feeling, her baseline hemoglobin (Hb) or hematocrit level, whether the bleeding seems to be slowing, and her distance from an emergency facility. Overall, large series demonstrate that less than 1% of women will need emergency curettage because of excessive bleeding (26, 46–48). Moreover, the risk of clinically significant bleeding and transfusion may be lower in women who undergo medical abortion of gestations up to 49 days compared with those who undergo medical abortion of gestations of more than 49 days (24); this risk will vary based on the regimen used.

Pain management is an important consideration. The woman should be sent home with appropriate instructions for analgesia with over-the-counter medications and can be provided with prescriptions for oral narcotics to use when needed. Nonsteroidal antiinflammatory drugs, such as ibuprofen, are not contraindicated in women who undergo a medical abortion and are appropriate first-line agents for pain management. One randomized trial found that ibuprofen taken when needed was more effective than acetaminophen to reduce pain associated with medical abortion (49). Nonsteroidal antiinflammatory drugs inhibit the synthesis of new prostaglandins, but they do not block the action of prostaglandin receptors and should not inhibit the action of a prostaglandin used for medical abortion. In a retrospective analysis of nonsteroidal antiinflammatory drugs and complete abortion, in 416 women who received misoprostol after methotrexate for medical abortion of gestations up to 56 days, the use of ibuprofen did not interfere with the action of misoprostol to induce uterine contractions and expulsion of the products of conception (50). One randomized trial found that multiple doses of ibuprofen given prophylactically at the time of misoprostol administration did not significantly reduce pain associated with medical abortion compared with ibuprofen taken when needed (51).

Need for Surgical Evacuation

The overall rate of surgical evacuation with medical abortion varies greatly based on the regimen used, the gestational age of the pregnancy, and many other factors. In most studies of medical abortion of gestations up to 63 days with mifepristone 200 mg followed by misoprostol, less than 5% of patients undergo surgical evacuation (52).

To determine whether a surgical evacuation is needed, it is important to distinguish incomplete abortion from the normal course of medical abortion. When an ultrasound examination is performed at the follow-up visit, the sole purpose is to determine whether the gestational sac is present. After surgical or spontaneous expulsion, the uterus will normally contain sonographically hyperechoic tissue that consists of blood, blood clots, and decidua. Rarely does this finding in women who have undergone medical abortion indicate a need for intervention. In the absence of excessive bleeding, health care providers can monitor such patients based on symptoms.

Guidelines for intervention vary for women who have a persistent gestational sac on ultrasonography without evidence of embryonic cardiac activity or continuing development. Patients with a persistent gestational sac 1 week after treatment can safely receive another dose of misoprostol or continue with expectant management (32, 53). Studies indicate that even with a retained sac 2 weeks after mifepristone, intervention is unnecessary and that expulsion will typically occur in the ensuing weeks (45). Women who prefer not to wait longer may choose to have a surgical evacuation at any time. Most commonly, women who are awaiting delayed expulsion will no longer feel pregnant or have medication-induced symptoms; patients will be waiting for the onset of bleeding or cramping similar to anticipating the start of menses (54). Health care providers must differentiate these women from those who have incomplete expulsion of the pregnancy tissue with symptoms, such as prolonged and irregular bleeding episodes.

Continuing pregnancies are typically reported in less than 1% of women who begin medical abortion at or before 63 days of gestation with evidence-based regimens (55). Ongoing pregnancy may be treated with uterine aspiration or a repeat dose of vaginal misoprostol. In an analysis of data from two randomized trials with 14 cases of ongoing pregnancy with gestational cardiac activity, treatment with a repeat dose of misoprostol, 800 micrograms administered vaginally, resulted in expulsion of the products of conception in five cases (36%); in an additional four cases (29%), gestational cardiac activity was no longer present at the next follow-up visit (53). If gestational cardiac activity persists at follow-up after a second dose of misoprostol, uterine aspiration should be performed. Repeat doses of buccal misoprostol to treat ongoing pregnancy have not been studied.

Women who undergo medical abortion may need to access emergency surgical intervention, and it is medically appropriate to provide referral to another health care provider. However, state or local laws may have additional requirements. In women who receive mifepristone and vaginal misoprostol, emergency curettage within the

first 24 hours of treatment is rare, occurring in 0.2% of patients (56). Clinicians who wish to provide medical abortion services either should be trained in surgical abortion or should be able to refer to a clinician trained in surgical abortion.

Clinical Considerations and Recommendations

▶ *Who are candidates for medical abortion with mifepristone and misoprostol?*

Women are candidates for medical abortion with mifepristone and misoprostol if they meet the gestational age criteria for the regimen and have no contraindications to the medical abortion process. Women with twin gestations can be treated with the same regimens as those with singleton gestations (57). Medical contraindications are infrequent.

Most studies exclude women with anemia who have Hb levels of less than 9.5 g/dL or less than 10 g/dL; accordingly, the safety of medical abortion in women with anemia is unknown. Although the transfusion rates associated with medical abortion are low (0.05%), they exceed those reported for surgical abortion in early pregnancy (0.01%) (55, 58).

Other medical contraindications to abortion with mifepristone regimens include confirmed or suspected ectopic pregnancy, intrauterine device (IUD) in place, current long-term systemic corticosteroid therapy, chronic adrenal failure, known coagulopathy or anticoagulant therapy, and intolerance or allergy to mifepristone. Most clinical trials also have excluded women with severe liver, renal, or respiratory disease or uncontrolled hypertension or cardiovascular disease (angina, valvular disease, arrhythmia, or cardiac failure).

Misoprostol should not be used in women who have an allergy or intolerance to misoprostol or other prostaglandins. Asthma is not a contraindication because misoprostol is a weak bronchodilator.

Women are not good candidates for medical abortion if they are unable or unwilling to adhere to care instructions, desire quick completion of the abortion process, are not available for follow-up contact or evaluation or cannot understand the instructions because of language or comprehension barriers.

▶ *Which pretreatment laboratory tests are needed?*

Confirmation of pregnancy is necessary before attempting abortion, regardless of method. Preoperative assessment of Hb or hematocrit is indicated when anemia is suspected. Rh testing is standard of care in the United States, and RhD immunoglobulin should be administered if indicated. Other laboratory evaluations are not indicated but may be required by local and state legislation.

▶ *What is the upper gestational age limit for use of medical abortion?*

The upper gestational age limit at which a medical abortion regimen is still an option varies based on the types, dosages, and routes of administration of the medications. Complete abortion rates with all regimens are highest for women with earlier gestations and are clinically similar in women with pregnancies up to 42 days of gestation. After 49 days of gestation, evidence-based regimens have advantages over the FDA-approved regimen and are medically preferable (Table 2). After 49 days of gestation, the efficacy of the FDA-approved regimen decreases significantly, and the likelihood of continuing pregnancy increases (27). However, regimens using vaginal, sublingual, and buccal misoprostol provide efficacy rates when used up to 63 days of gestation that exceed the approximately 92% efficacy of the FDA-approved regimen when used up to 49 days of gestation (24, 29). Moreover, the continuing pregnancy rates with these alternative methods of administering misoprostol remain low, at approximately 1% or less for vaginal, buccal, and sublingual regimens up to 63 days of gestation (32, 59–61). The amount of published data on sublingual regimens is relatively small compared with vaginal regimens.

The use of the mifepristone–misoprostol regimen has been evaluated for medical abortion in women with pregnancies beyond 9 weeks of gestation, most commonly with regimens that involve the use of vaginal misoprostol and in an in-patient setting (62, 63). In a published review of more than 1,000 women who were observed as inpatients after misoprostol treatment, primarily by the vaginal route, the efficacy rate exceeded 92% for women with pregnancies through 13 weeks of gestation (with a rate of 97% at 9–10 weeks of gestation), steadily decreasing to 92% for those with gestations at 12–13 weeks (64). Continuing pregnancy rates were less than 1% for women with gestations through 11 weeks. The published experience with sublingual misoprostol in this gestational age range is relatively small (62, 64).

A more recent U.S. multicenter trial evaluated 629 women with pregnancies from 57 days of gestation to 70 days of gestation who received mifepristone with buccal misoprostol in an outpatient setting (65). Success rates were 94% for women with gestations from 57 days

Table 2. Comparison of Common Medical Abortion Regimens ⇦

Common Regimens	Overall Success Rate (%)	Advantages and Disadvantages	Gestational Age
Mifepristone 600 mg orally, followed by misoprostol 400 micrograms orally 48 hours later (regimen approved by the U.S. Food and Drug Administration)	92[1]	Must return to office or clinic for misoprostol administration; can be used only up to 49 days of gestation	Up to 49 days
Mifepristone 200 mg orally, followed by misoprostol 800 micrograms vaginally, buccally, or sublingually 24–48 hours later (alternative evidence-based regimens; with vaginal administration, misoprostol may be administered 6 hours or less after mifepristone)	95–99[2–7]	Compared with the regimen approved by the Food and Drug Administration: • More effective • Less time to expulsion • Fewer adverse effects • Lower cost • More convenient because allows home administration of misoprostol	Up to 63 days
Methotrexate, 50 mg/m^2 intramuscularly or 50 mg vaginally plus misoprostol, 800 micrograms vaginally 3–7 days later	92–96[8–10]	Compared with mifepristone–misoprostol regimen: • Takes longer for expulsion in 20–30% of women • Readily available medications • Low drug cost	Up to 49 days
Misoprostol only, 800 micrograms vaginally or sublingually administered every 3 hours for three doses (with vaginal administration, dosing interval may be as long as 12 hours)	84–85[11]	• Significantly higher incidence of adverse effects than other regimens • Readily available medication • Low drug cost	Up to 63 days

[1]Spitz IM, Bardin CW, Benton L, Robbins A. Early pregnancy termination with mifepristone and misoprostol in the United States. N Engl J Med 1998;338:1241–7.

[2]Schaff EA, Eisinger SH, Stadalius LS, Franks P, Gore BZ, Poppema S. Low-dose mifepristone 200 mg and vaginal misoprostol for abortion. Contraception 1999;59:1–6.

[3]Schaff EA, Fielding SL, Westhoff C. Randomized trial of oral versus vaginal misoprostol at one day after mifepristone for early medical abortion. Contraception 2001;64:81–5.

[4]el-Refaey H, Rajasekar D, Abdalla M, Calder L, Templeton A. Induction of abortion with mifepristone (RU 486) and oral or vaginal misoprostol. N Engl J Med 1995; 332:983–7.

[5]von Hertzen H, Honkanen H, Piaggio G, Bartfai G, Erdenetungalag R, Gemzell-Danielsson K, et al. WHO multinational study of three misoprostol regimens after mifepristone for early medical abortion. I: Efficacy. WHO Research Group on Post-Ovulatory Methods for Fertility Regulation. BJOG 2003;110:808–18.

[6]Creinin MD, Fox MC, Teal S, Chen A, Schaff EA, Meyn LA. A randomized comparison of misoprostol 6 to 8 hours versus 24 hours after mifepristone for abortion. MOD Study Trial Group. Obstet Gynecol 2004;103:851–9.

[7]von Hertzen H, Huong NT, Piaggio G, Bayalag M, Cabezas E, Fang AH, et al. Misoprostol dose and route after mifepristone for early medical abortion: a randomised controlled noninferiority trial. WHO Research Group on Postovulatory Methods of Fertility Regulation. BJOG 2010;117:1186–96.

[8]Creinin MD, Vittinghoff E, Schaff E, Klaisle C, Darney PD, Dean C. Medical abortion with oral methotrexate and vaginal misoprostol. Obstet Gynecol 1997;90:611–6.

[9]Creinin MD, Carbonell JL, Schwartz JL, Varela L, Tanda R. A randomized trial of the effect of moistening misoprostol before vaginal administration when used with methotrexate for abortion. Contraception 1999;59:11–6.

[10]Wiebe E, Dunn S, Guilbert E, Jacot F, Lugtig L. Comparison of abortions induced by methotrexate or mifepristone followed by misoprostol. Obstet Gynecol 2002; 99:813–9.

[11]von Hertzen H, Piaggio G, Huong NT, Arustamyan K, Cabezas E, Gomez M, et al. Efficacy of two intervals and two routes of administration of misoprostol for termination of early pregnancy: a randomised controlled equivalence trial. WHO Research Group on Postovulatory Methods of Fertility Regulation. Lancet 2007;369:1938–46.

to 63 days and 93% for those with gestations from 64 days to 70 days, and acceptability was high and similar for both gestational age groups. However, the continuing pregnancy rate was 3% for both groups.

▶ *Should prophylactic antibiotics be used in medical abortion?*

Uterine infection with medical abortion is uncommon, and limited data exist to support the prophylactic use of antibiotics in medical abortion. In a systematic review of 65 studies of heterogeneous design (prospective, retrospective, and randomized), the overall frequency of diagnosed or treated infection after medical abortion in more than 46,000 patients was 0.9% (66). In these studies, as in most surgical abortion studies, the diagnostic criteria for infection were variable, which possibly led to an overestimation of infection.

Although concern regarding serious, rare, and deadly infection with clostridial bacteria in women who undergo medical abortion has been raised, it has since become evident that no specific connection exists between clostridial organisms and medical abortion. Investigations have found these organisms also are associated with other obstetric and gynecologic processes and procedures, including spontaneous abortion, term delivery, surgical abortion, and cervical cone or laser treatment for cervical dysplasia (67, 68). In addition, it is now recognized that clostridial species are a more common cause of pelvic infection than previously believed (68).

Large retrospective analyses of medical abortion safety conducted by Planned Parenthood Federation of America, Inc, since 2001 showed a decrease over time in the *serious infection* rate (defined as receipt of intravenous antibiotics, hospitalization, sepsis, or death) with a change from vaginal to buccal misoprostol (from 0.093% to 0.020%) and a further decrease (to 0.006%) when routine provision of a 1-week treatment course of doxycycline was started on the day of mifepristone administration (69). Because the study used continuous prior time periods as the comparator, the addition of a treatment course of antibiotics cannot be separated from the effect of the switch in the route of misoprostol administration. In a subsequent report, the risk of serious infection in Planned Parenthood clinics increased to 0.013% in 2009 and 0.019% in 2010 (55), a rate equal to the rate noted before routine doxycycline provision. These data indicate that the overall risk of serious infection with medical abortion is very low and that buccal administration of misoprostol may result in a lower risk of serious infection compared with vaginal administration. The benefit suggested by the addition of doxycycline may truly have been a period effect. In addition, adherence to a doxycycline regimen of 14 tablets over 1 week is likely poor such that routine treatment is not beneficial. Accordingly, no strong data exist to support the universal use of prophylactic antibiotics for medical abortion.

Although serious infections occur rarely in patients after medical abortion, health care providers need to be aware of the signs and symptoms. Sustained fever, tachycardia, or severe abdominal pain or general malaise with or without fever that occur more than 24 hours after misoprostol administration should increase suspicion of a serious infection. Clostridial toxic shock often resembles a flu-like illness, so health care providers should have a high level of suspicion for infection when symptoms consistent with flu are present. Women with such infections typically have hemoconcentration and significant leukocytosis without fever and can rapidly progress to refractory hypotension and death.

▶ *Is ultrasonography useful in the medical management of abortion before treatment?*

Before medical abortion is performed, gestational age should be confirmed by clinical evaluation or ultrasound examination. A U.S. study found that women's reported last menstrual period combined with clinical estimation of gestational age was accurate and would have resulted in medical abortion erroneously offered to only 1.6% of women after 63 days of gestation (70). Because efficacy of some regimens decreases significantly with increasing gestational age, the clinical relevance of erroneous gestational age assignment will vary based on the regimen used.

A potential concern when providing early abortion services is the possibility of an undiagnosed extrauterine gestation. The ectopic pregnancy rate in the general population is approximately 19–21 per 1,000 pregnancies and may be slightly higher (21–24 per 1,000 pregnancies) among patients who receive Medicaid (71–73). However, ectopic pregnancy rates in studies of women who seek abortion are consistently lower. A study of surgical abortion in U.S. women with pregnancies less than 6 weeks of gestation found the ectopic pregnancy rate to be 5.9 per 1,000 pregnancies (74). Similarly, the largest study of medical abortion patients published involved 16,369 women with pregnancies of 49 days of gestation or less, 21 of whom were excluded from the analysis because of an ectopic pregnancy, yielding an ectopic pregnancy rate of 1.3 per 1,000 pregnancies (75). Although ectopic pregnancy in a population of women who seek early abortion is rare, women with significant medical risk factors or history (ie, unilateral pain and vaginal bleeding) should have a pretreatment ultrasonography.

If ultrasonography is performed, abdominal ultrasonography is sensitive for diagnosing the presence or absence of a gestational sac in nonobese women (76). Thus, most women can be initially screened with transabdominal ultrasonography, reserving transvaginal ultrasonography for situations in which further clarification is required.

▶ *What methods can be used to confirm complete medical abortion?*

Follow-up evaluation after medical abortion is performed to diagnose and treat complications, including ongoing pregnancy. The introduction of medical abortion into widespread clinical practice has required continued emphasis on follow-up because failure rates for medical abortion are higher than those for surgical techniques, and misoprostol is potentially teratogenic. Initial reports showed that mifepristone and misoprostol can be integrated into clinical practice with low rates of patients lost to follow-up (77, 78). However, further reports reported loss-to-follow-up rates as high as 45% in clinical settings (79).

When the clinician and the patient think that expulsion has occurred based on symptomatology, they are correct 96–99% of the time (80, 81). However, a systematic review found that women's self-assessment alone or combined with clinical assessment had low sensitivity (33–85%) and low positive predictive value (6–66%) to detect ongoing pregnancy (82). Follow-up after receiving mifepristone and misoprostol for medical abortion is important, although an in-clinic evaluation is not always necessary.

The FDA-approved regimen includes an evaluation at 2 weeks after mifepristone administration to assess for history of bleeding and evidence of uterine involution on pelvic examination. However, other options that allow evaluation sooner with a high degree of accuracy to detect ongoing pregnancy include in-clinic transvaginal ultrasound examination 1 week after treatment (83); serum human chorionic gonadotropin (hCG) level measurement before and 1 week after treatment (84); and telephone follow-up at 1 week, with subsequent urine pregnancy testing at 2 weeks or 4 weeks after treatment (81, 85). Although urine pregnancy testing alone with standard high- or low-sensitivity tests has not been shown to be a viable alternative, newer semiquantitative urine hCG tests have shown promise in accurately identifying ongoing pregnancies after medical abortion (86, 87).

Transvaginal ultrasonography is commonly used for follow-up examination after medical abortion, primarily because it provides a definitive assessment of whether or not the products of conception have been expelled. Incorrect interpretation of ultrasound examination results may lead to unnecessary intervention. When an ultrasound examination is performed at follow-up, the sole purpose is to determine whether the gestational sac is present. For patients who are below the threshold for visualization of a gestational sac, follow-up with serum hCG testing is needed. The measurement of endometrial thickness or other findings cannot predict the need for future surgical intervention (83). In research trials, when a transvaginal ultrasound examination shows no evidence of a gestational sac 1 week after mifepristone use, only 1.6% of women will need a subsequent surgical evacuation.

Serum hCG testing is another option for follow-up examination after medical abortion, and it does not require that the patient return to the same facility; she can obtain the test at a location near her home or work. However, a phone call to the patient to discuss the result is still necessary, so the potential for failed follow-up exists in two ways: 1) the patient must present to get a test, and 2) the patient must be reached by phone. A serum hCG level decrease of at least 80% over 6–7 days after initiating treatment with mifepristone and misoprostol indicates a successful abortion (84). In a trial that randomized women to follow-up in the form of in-clinic transvaginal ultrasound examination or serum hCG testing, 24.5% of patients were lost to follow-up, with no significant differences reported in unplanned visits and interventions by 2 weeks (6.6% versus 8.2%, respectively) or in dilation and curettage rates by 4 weeks (4.4% and 1.4%, respectively) (88).

Another study examined follow-up rates for women that chose ultrasound examination or hCG testing (89). The loss-to-follow-up rate was somewhat higher among women who chose hCG testing (33.7% versus 22.9%), but in multivariable analysis, follow-up method was not associated with loss to follow-up. Instead, loss to follow-up was found to be based on patient factors, such as living at least 10 miles from the clinic, prior pregnancy, unemployment, and a history of induced abortion.

When patients are required to go to a facility for assessment of medical abortion outcome, approximately 25% are lost to follow-up, which indicates the need for development of other follow-up methods. Telephone follow-up with subsequent urine pregnancy testing avoids the need for the woman to go to a facility for her initial assessment. A feasibility study of 139 U.S. women had a 100% initial follow-up rate and an overall follow-up of 97% when need for in-person assessment, as determined by telephone contact, was included; a key part of this trial was that the ability to successfully contact the patient by phone was assessed before

medication distribution (81). Another promising method in development is an at-home semiquantitative urine hCG test; in a feasibility study of 394 women who used the product, 1-week posttreatment sensitivity and specificity were 100% and 97%, respectively (90). The study required the participants to return to the clinic on the day they performed the at-home test to review the results, and 20% were lost to follow-up. Thus, combining the semiquantitative urine hCG test with telephone follow-up may hold the most promise.

▶ *Do women have a preference for route of misoprostol administration?*

Many health care providers may offer women only one option for misoprostol administration, even though all routes are not the same. Vaginal routes of administration enable the patients to complete the medical abortion process sooner because of the ability to use the misoprostol 6 hours or less from the time of mifepristone administration (5, 31). Early studies with mifepristone regimens demonstrated that women preferred a shorter interval between medications (91). Other research indicates women prefer oral routes of administration to vaginal administration (11, 92).

A U.S. study with 139 participants allowed the women to choose between buccal and vaginal misoprostol administration (81). The women were fully informed of the efficacy rates, the timing interval allowed for the two routes, and adverse effect rates based on available literature. Almost all women (94%) chose vaginal misoprostol and 74% of these women used the misoprostol at 6 hours or less after the mifepristone, which indicates that timing was a significant factor in their choice.

▶ *How should a patient be counseled about potential teratogenicity if a medical method fails to lead to abortion?*

Because teratogenicity of medical abortifacients becomes an important issue if the pregnancy continues, patients must be counseled before medical abortion treatment of the need for a surgical abortion in the event of a continuing pregnancy. No evidence exists to date of a teratogenic effect of mifepristone. Evidence suggests that misoprostol can result in congenital anomalies when used during the first trimester, possibly because of mild uterine contractions that lead to decreased blood flow during organogenesis (93). Anomalies associated with misoprostol use that have been described in the literature include defects in the frontal or temporal bones and, most commonly, limb abnormalities with or without Möbius syndrome (mask-like facies with bilateral sixth and seventh nerve palsy and frequently coincident micrognathia) (94–98). A case–control study from Brazil compared 96 infants with Möbius syndrome matched with 96 infants with neural tube defects (97). Exposure to misoprostol during the first trimester was 49% and 3%, respectively (odds ratio [OR], 29.7; 95% confidence interval [CI], 11.6–76). Six cases of limb reduction abnormalities in fetuses examined after failed abortion with methotrexate and misoprostol also have been reported (98). Methotrexate exposure also is characterized by a variety of malformations, including growth restriction, limb defects, and craniofacial anomalies, among others (99). Because misoprostol is the common agent used with every medical abortion regimen, health care providers must counsel all women regarding potential teratogenic effects.

▶ *Does medical abortion affect future fertility or pregnancy outcomes?*

Future fertility with medical abortion has been evaluated within only a 1-year period after medical abortion in a group of 93 women who received methotrexate and misoprostol for abortion (100). Although none of the women were actively attempting to achieve pregnancy, 25% became pregnant, a rate higher than the calculated rate expected for this group of women using contraception. By comparison, another report indicated a pregnancy rate of 13% within 1 year after a first surgical abortion (101).

A comparative study from China enrolled more than 14,000 nulliparous women to compare outcomes of pregnancies after medical or surgical abortion and pregnancies in women with no history of abortion (102). Women who had a prior mifepristone abortion were less likely to have preterm birth compared with those women who had never been pregnant (adjusted OR, 0.77; 95% CI, 0.61–0.98), and the frequencies of low birth weight infants and mean lengths of pregnancy were similar in both groups. No significant differences were reported in risk of preterm delivery, frequency of low birth weight infants, or mean infant birth weight in the comparisons of women with previous mifepristone abortion and women with surgical abortion. In a registry-based study from Scotland, no association was found between prior abortion and subsequent preterm birth during the period 2000–2008, when 68% of abortions were medical (103).

▶ *Who is qualified to perform medical abortion?*

In addition to physicians, advanced practice clinicians, such as nurse–midwives, physician assistants, and nurse practitioners, possess the clinical and counseling skills necessary to provide first-trimester medical abortion (104). In a randomized controlled trial in Nepal, women

randomized to receive medical abortion under the care of a staff nurse had a statistically equivalent risk of complete abortion compared with those under the care of a physician, and no serious adverse events were reported (105). This evidence indicates that medical abortion also can be provided safely and effectively by nonphysician clinicians, and in some states, advance practice clinicians are allowed to provide medical abortion. However, many states require that a physician perform an abortion and prohibit provision of medical abortion by nonphysician clinicians.

Telemedicine, which involves the use of video and information technology to provide a medical service at a distance, has been used to extend the reach of physicians to provide medical abortion. In one model, patients seen at a clinic without an on-site physician have a video consultation with a physician located elsewhere. The physician is able to review electronically the patient's medical history, and ultrasonography, if requested, can be performed by a trained technician at the remote clinic. If the patient is eligible for medical abortion, the physician remotely opens a telepharmacy drawer containing the mifepristone and misoprostol and instructs the patient how to use it. This model was evaluated in a nonrandomized study and found to be equally effective when compared with an in-person visit with a physician; adverse events, including ongoing pregnancy, occurred in 1.3% of patients and were not statistically different between the two groups (106). Women who chose telemedicine medical abortion were significantly more likely to say they would recommend the service to a friend compared with women who had an in-person visit with a physician (OR 1.72; 95% CI, 1.26–2.34) (106). In an analysis of this clinic system's service-delivery statistics, after telemedicine was introduced, a significant reduction in second-trimester abortion was reported, and women in remote parts of the state were more likely to obtain an abortion than before (107). Medical abortion can be provided safely and effectively via telemedicine with a high level of patient satisfaction; moreover, the model appears to improve access to early abortion in areas that lack a physician health care provider. Despite the medical evidence, several states have passed legislation that bans the use of telemedicine to provide abortion.

▶ *What is the recommended timing of contraception provision after medical abortion?*

Almost all contraceptive methods can be provided immediately after uncomplicated first-trimester medical abortion, and all are considered Category 1 for provision after first-trimester abortion according to the U.S. Medical Eligibility Criteria (meaning there is no restriction for use) (108). Oral contraceptives, patch, ring, depot medroxyprogesterone acetate, and subdermal implants all may be started on the day of misoprostol administration (109, 110). However, this requires an additional visit to the clinic to start depot medroxyprogesterone acetate and implants, and research is exploring whether these methods can be administered on the day of mifepristone without reducing the efficacy of medical abortion.

The optimal timing of IUD insertion has been evaluated in two randomized studies. One study randomized women to insertion of a copper IUD 1 week after mifepristone versus 4–6 weeks later (111). Significantly more women in the early-insertion group received an IUD (97% versus 76%, $P<.001$). Another study randomized women to insertion of either a copper or levonorgestrel-containing IUD 5–9 days after mifepristone versus 3–4 weeks later (112). Fewer women in the delayed group attended the follow-up visit to insert the IUD (1.5% versus 11%, $P=.03$). In both studies, no significant difference was found in expulsion rates by group; however, the delayed-insertion groups had expulsion rates of 7–11%, which is higher than the expulsion rate noted with immediate IUD insertion after surgical abortion (113). The risk of expulsion of an IUD needs to be weighed against the risk that the patient will not return for a delayed insertion. Sterilization may be performed once abortion is confirmed.

Summary of Recommendations and Conclusions

The following recommendations are based primarily on good and consistent scientific evidence (Level A):

- Based on efficacy and adverse effect profile, evidence-based protocols for medical abortion are superior to the FDA-approved regimen. Vaginal, buccal, and sublingual routes of misoprostol administration increase efficacy, decrease continuing pregnancy rates, and increase the gestational age range for use as compared with the FDA-approved regimen.
- Regimens that use low doses of mifepristone (200 mg) have similar efficacy and lower costs compared with to those that use mifepristone at 600 mg.
- Women can safely and effectively self-administer misoprostol at home as part of a medical abortion regimen.

- Medical abortion also can be provided safely and effectively by nonphysician clinicians.
- Follow-up after receiving mifepristone and misoprostol for medical abortion is important, although an in-clinic evaluation is not always necessary.
- Misoprostol-only medical abortion regimens are significantly less effective than those that use a combination of mifepristone and misoprostol.

The following recommendations are based primarily on limited scientific evidence (Level B):

- Because teratogenicity of medical abortifacients becomes an important issue if the pregnancy continues, patients must be counseled before medical abortion treatment of the need for a surgical abortion in the event of a continuing pregnancy.
- Before medical abortion is performed, gestational age should be confirmed by clinical evaluation or ultrasound examination.
- Nonsteroidal antiinflammatory drugs, such as ibuprofen, are not contraindicated in women who undergo a medical abortion and are appropriate first-line agents for pain management.
- Buccal administration of misoprostol may result in a lower risk of serious infection compared with vaginal administration.
- Medical abortion can be provided safely and effectively via telemedicine with a high level of patient satisfaction; moreover, the model appears to improve access to early abortion in areas that lack a physician health care provider.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- Women who undergo medical abortion may need to access emergency surgical intervention, and it is medically appropriate to provide referral to another health care provider. However, state or local laws may have additional requirements.
- Clinicians who wish to provide medical abortion services either should be trained in surgical abortion or should be able to refer to a clinician trained in surgical abortion.
- No strong data exist to support the universal use of prophylactic antibiotics for medical abortion.
- Rh testing is standard of care in the United States, and RhD immunoglobulin should be administered if indicated.

Proposed Performance Measure

Percentage of patients presenting for abortion before 63 days of gestation who are offered medical management

References

1. Pazol K, Creanga AA, Zane SB, Burley KD, Jamieson DJ. Abortion surveillance--United States, 2009. Centers for Disease Control and Prevention (CDC). MMWR Surveill Summ 2012;61(SS-8):1–44. (Level II-3) [PubMed] [Full Text] ⇦
2. Gravanis A, Schaison G, George M, de Brux J, Satyaswaroop PG, Baulieu EE, et al. Endometrial and pituitary responses to the steroidal antiprogestin RU 486 in postmenopausal women. J Clin Endocrinol Metab 1985;60:156–63. (Level III) [PubMed] ⇦
3. Swahn ML, Bygdeman M. The effect of the antiprogestin RU 486 on uterine contractility and sensitivity to prostaglandin and oxytocin. Br J Obstet Gynaecol 1988;95:126–34. (Level II-3) [PubMed] ⇦
4. Johannisson E, Oberholzer M, Swahn ML, Bygdeman M. Vascular changes in the human endometrium following the administration of the progesterone antagonist RU 486. Contraception 1989;39:103–17. (Level III) [PubMed] [Full Text] ⇦
5. Creinin MD, Schreiber CA, Bednarek P, Lintu H, Wagner MS, Meyn LA. Mifepristone and misoprostol administered simultaneously versus 24 hours apart for abortion: a randomized controlled trial. Medical Abortion at the Same Time (MAST) Study Trial Group. Obstet Gynecol 2007;109:885–94. (Level I) [PubMed] [*Obstetrics & Gynecology*] ⇦
6. Clark RD. Glucocorticoid receptor antagonists. Curr Top Med Chem 2008;8:813–38. (Level III) [PubMed] ⇦
7. Spitz IM. Mifepristone: where do we come from and where are we going? Clinical development over a quarter of a century. Contraception 2010;82:442–52. (Level III) [PubMed] [Full Text] ⇦
8. Allen R, O'Brien BM. Uses of misoprostol in obstetrics and gynecology. Rev Obstet Gynecol 2009;2:159–68. (Level III) [PubMed] [Full Text] ⇦
9. Zieman M, Fong SK, Benowitz NL, Banskter D, Darney PD. Absorption kinetics of misoprostol with oral or vaginal administration. Obstet Gynecol 1997;90:88–92. (Level I) [PubMed] [*Obstetrics & Gynecology*] ⇦
10. Danielsson KG, Marions L, Rodriguez A, Spur BW, Wong PY, Bygdeman M. Comparison between oral and vaginal administration of misoprostol on uterine contractility. Obstet Gynecol 1999;93:275–80. (Level I) [PubMed] [*Obstetrics & Gynecology*] ⇦
11. Tang OS, Schweer H, Seyberth HW, Lee SW, Ho PC. Pharmacokinetics of different routes of administration of misoprostol. Hum Reprod 2002;17:332–6. (Level I) [PubMed] [Full Text] ⇦

12. Schaff EA, DiCenzo R, Fielding SL. Comparison of misoprostol plasma concentrations following buccal and sublingual administration. Contraception 2005;71:22–5. (Level II-3) [PubMed] [Full Text] ⇦

13. Meckstroth KR, Whitaker AK, Bertisch S, Goldberg AB, Darney PD. Misoprostol administered by epithelial routes: Drug absorption and uterine response. Obstet Gynecol 2006;108:582–90. (Level I) [PubMed] [*Obstetrics & Gynecology*] ⇦

14. Jain JK, Dutton C, Harwood B, Meckstroth KR, Mishell DR Jr. A prospective randomized, double-blinded, placebo-controlled trial comparing mifepristone and vaginal misoprostol to vaginal misoprostol alone for elective termination of early pregnancy. Hum Reprod 2002;17:1477–82. (Level I) [PubMed] [Full Text] ⇦

15. Blum J, Raghavan S, Dabash R, Ngoc N, Chelli H, Hajri S, et al. Comparison of misoprostol-only and combined mifepristone-misoprostol regimens for home-based early medical abortion in Tunisia and Vietnam. Int J Gynaecol Obstet 2012;118:166–71. (Level I) [PubMed] [Full Text] ⇦

16. Creinin MD. Medical abortion regimens: historical context and overview. Am J Obstet Gynecol 2000;183:S3–9. (Level III) [PubMed] ⇦

17. Benson J, Clark KA, Gerhardt A, Randall L, Dudley S. Early abortion services in the United States: a provider survey. Contraception 2003;67:287–94. (Level III) [PubMed] [Full Text] ⇦

18. DeLoia JA, Stewart-Akers AM, Creinin MD. Effects of methotrexate on trophoblast proliferation and local immune responses. Hum Reprod 1998;13:1063–9. (Level III) [PubMed] [Full Text] ⇦

19. Wiebe ER. Tamoxifen compared to methotrexate when used with misoprostol for abortion. Contraception 1999; 59:265–70. (Level I) [PubMed] [Full Text] ⇦

20. Jain JK, Meckstroth KR, Park M, Mishell DR, Jr. A comparison of tamoxifen and misoprostol to misoprostol alone for early pregnancy termination. Contraception 1999;60:353–6. (Level I) [PubMed] [Full Text] ⇦

21. Lee VC, Ng EH, Yeung WS, Ho PC. Misoprostol with or without letrozole pretreatment for termination of pregnancy: a randomized controlled trial. Obstet Gynecol 2011;117:317–23. (Level I) [PubMed] [*Obstetrics & Gynecology*] ⇦

22. Yeung TW, Lee VC, Ng EH, Ho PC. A pilot study on the use of a 7-day course of letrozole followed by misoprostol for the termination of early pregnancy up to 63 days. Contraception 2012;86:763–9. (Level III) [PubMed] [Full Text] ⇦

23. Danco Laboratories. Mifeprex® (mifepristone) tablets, 200 mg: prescribing information. New York (NY): Danco Laboratories; 2009. Available at: http://www.earlyoptionpill.com/userfiles/file/Mifeprex%20Labeling%204-22-09_Final_doc.pdf. Retrieved May 16, 2013. (Level III) ⇦

24. Spitz IM, Bardin CW, Benton L, Robbins A. Early pregnancy termination with mifepristone and misoprostol in the United States. N Engl J Med 1998;338:1241–7. (Level II-3) [PubMed] [Full Text] ⇦

25. Comparison of two doses of mifepristone in combination with misoprostol for early medical abortion: a randomised trial. World Health Organisation Task Force on Post-ovulatory Methods of Fertility Regulation. BJOG 2000;107:524–30. (Level I) [PubMed] [Full Text] ⇦

26. Aubeny E, Peyron R, Turpin CL, Renault M, Targosz V, Silvestre L, et al. Termination of early pregnancy (up to 63 days of amenorrhea) with mifepristone and increasing doses of misoprostol [published erratum appears in Int J Fertil Menopausal Stud 1996;41:56]. Int J Fertil Menopausal Stud 1995;40(suppl 2):85–91. (Level II-3) [PubMed] ⇦

27. Creinin MD, Spitz IM. Use of various ultrasonographic criteria to evaluate the efficacy of mifepristone and misoprostol for medical abortion. Am J Obstet Gynecol 1999;181:1419–24. (Level III) [PubMed] ⇦

28. Peyron R, Aubeny E, Targosz V, Silvestre L, Renault M, Elkik F, et al. Early termination of pregnancy with mifepristone (RU 486) and the orally active prostaglandin misoprostol. N Engl J Med 1993;328:1509–13. (Level II-3) [PubMed] [Full Text] ⇦

29. Kulier R, Kapp N, Gulmezoglu AM, Hofmeyr GJ, Cheng L, Campana A. Medical methods for first trimester abortion. Cochrane Database of Systematic Reviews 2011, Issue 11. Art. No.: CD002855. DOI: 10.1002/14651858.CD002855.pub4. (Meta-analysis) [PubMed] [Full Text] ⇦

30. Schaff EA. Mifepristone: ten years later. Contraception 2010;81:1–7. (Level III) [PubMed] [Full Text] ⇦

31. Creinin MD, Fox MC, Teal S, Chen A, Schaff EA, Meyn LA. A randomized comparison of misoprostol 6 to 8 hours versus 24 hours after mifepristone for abortion. MOD Study Trial Group. Obstet Gynecol 2004;103: 851–9. (Level I) [PubMed] [*Obstetrics & Gynecology*] ⇦

32. Winikoff B, Dzuba IG, Creinin MD, Crowden WA, Goldberg AB, Gonzales J, et al. Two distinct oral routes of misoprostol in mifepristone medical abortion: a randomized controlled trial. Obstet Gynecol 2008;112:1303–10. (Level I) [PubMed] [*Obstetrics & Gynecology*] ⇦

33. von Hertzen H, Huong NT, Piaggio G, Bayalag M, Cabezas E, Fang AH, et al. Misoprostol dose and route after mifepristone for early medical abortion: a randomised controlled noninferiority trial. WHO Research Group on Postovulatory Methods of Fertility Regulation. BJOG 2010;117:1186–96. (Level I) [PubMed] [Full Text] ⇦

34. Ngo TD, Park MH, Shakur H, Free C. Comparative effectiveness, safety and acceptability of medical abortion at home and in a clinic: a systematic review. Bull World Health Organ 2011;89:360–70. (Meta-analysis) [PubMed] [Full Text] ⇦

35. Raghavan S, Tsereteli T, Kamilov A, Kurbanbekova D, Yusupov D, Kasimova F, et al. Acceptability and feasibility of the use of 400μg of sublingual misoprostol after mifepristone for medical abortion up to 63 days since the last menstrual period: evidence from Uzbekistan. Eur J Contracept Reprod Health Care 2013;18:104–11. (Level II-3) [PubMed] [Full Text] ⇦

36. Henshaw RC, Naji SA, Russell IT, Templeton AA. Comparison of medical abortion with surgical vacuum aspiration: women's preferences and acceptability of treatment. BMJ 1993;307:714–7. (Level II-3) [PubMed] [Full Text] ⇦

37. Creinin MD. Randomized comparison of efficacy, acceptability and cost of medical versus surgical abortion. Contraception 2000;62:117–24. (Level I) [PubMed] [Full Text] ⇦

38. Rorbye C, Norgaard M, Nilas L. Medical versus surgical abortion: comparing satisfaction and potential confounders in a partly randomized study. Hum Reprod 2005;20:834–8. (Level II-3) [PubMed] [Full Text] ⇦

39. Ho PC. Women's perceptions on medical abortion. Contraception 2006;74:11–5. (Level III) [PubMed] [Full Text] ⇦

40. Schaff EA, Stadalius LS, Eisinger SH, Franks P. Vaginal misoprostol administered at home after mifepristone (RU486) for abortion. J Fam Pract 1997;44:353–60. (Level III) [PubMed] ⇦

41. Schaff EA, Eisinger SH, Stadalius LS, Franks P, Gore BZ, Poppema S. Low-dose mifepristone 200 mg and vaginal misoprostol for abortion. Contraception 1999;59:1–6. (Level II-3) [PubMed] [Full Text] ⇦

42. Wiebe E, Dunn S, Guilbert E, Jacot F, Lugtig L. Comparison of abortions induced by methotrexate or mifepristone followed by misoprostol. Obstet Gynecol 2002;99:813–9. (Level I) [PubMed] [*Obstetrics & Gynecology*] ⇦

43. Honkanen H, Piaggio G, Hertzen H, Bartfai G, Erdenetungalag R, Gemzell-Danielsson K, et al. WHO multinational study of three misoprostol regimens after mifepristone for early medical abortion. WHO Research Group on Post-Ovulatory Methods for Fertility Regulation. BJOG 2004;111:715–25. (Level I) [PubMed] [Full Text] ⇦

44. Chai J, Wong CY, Ho PC. A randomized clinical trial comparing the short-term side effects of sublingual and buccal routes of misoprostol administration for medical abortions up to 63 days' gestation. Contraception 2013;87:480–5. (Level I) [PubMed] [Full Text] ⇦

45. Creinin MD, Danielsson KG. Medical abortion in early pregnancy. In: Paul M, Lichtenberg ES, Borgatta L, Grimes DA, Stubblefield PG, Creinin MD, editors. Management of unintended and abnormal pregnancy: comprehensive abortion care. Hoboken (NJ): Wiley-Blackwell; 2009. p. 111–34. (Level III) ⇦

46. Winikoff B, Sivin I, Coyaji KJ, Cabezas E, Xiao B, Gu S, et al. Safety, efficacy, and acceptability of medical abortion in China, Cuba, and India: a comparative trial of mifepristone-misoprostol versus surgical abortion. Am J Obstet Gynecol 1997;176:431–7. (Level II-3) [PubMed] [Full Text] ⇦

47. Ashok PW, Penney GC, Flett GM, Templeton A. An effective regimen for early medical abortion: a report of 2000 consecutive cases. Hum Reprod 1998;13:2962–5. (Level II-3) [PubMed] [Full Text] ⇦

48. Schaff EA, Eisinger SH, Stadalius LS, Franks P, Gore BZ, Poppema S. Low-dose mifepristone 200 mg and vaginal misoprostol for abortion. Contraception 1999;59:1–6. (Level II-3) [PubMed] [Full Text] ⇦

49. Livshits A, Machtinger R, David LB, Spira M, Moshe-Zahav A, Seidman DS. Ibuprofen and paracetamol for pain relief during medical abortion: a double-blind randomized controlled study. Fertil Steril 2009;91:1877–80. (Level I) [PubMed] [Full Text] ⇦

50. Creinin MD, Shulman T. Effect of nonsteroidal anti-inflammatory drugs on the action of misoprostol in a regimen for early abortion. Contraception 1997;56:165–8. (Level III) [PubMed] [Full Text] ⇦

51. Raymond EG, Weaver MA, Louie KS, Dean G, Porsch L, Lichtenberg ES, et al. Prophylactic compared with therapeutic ibuprofen analgesia in first-trimester medical abortion: a randomized controlled trial. Obstet Gynecol 2013;122:558–64. (Level I) [PubMed] [*Obstetrics & Gynecology*] ⇦

52. Raymond EG, Shannon C, Weaver MA, Winikoff B. First-trimester medical abortion with mifepristone 200 mg and misoprostol: a systematic review. Contraception 2013;87:26–37. (Level III) [PubMed] [Full Text] ⇦

53. Reeves MF, Kudva A, Creinin MD. Medical abortion outcomes after a second dose of misoprostol for persistent gestational sac. Contraception 2008;78:332–5. (Level III) [PubMed] [Full Text] ⇦

54. Creinin MD, Vittinghoff E, Keder L, Darney PD, Tiller G. Methotrexate and misoprostol for early abortion: a multicenter trial. I. Safety and efficacy. Contraception 1996; 53:321–7. (Level II-3) [PubMed] [Full Text] ⇦

55. Cleland K, Creinin MD, Nucatola D, Nshom M, Trussell J. Significant adverse events and outcomes after medical abortion. Obstet Gynecol 2013;121:166–71. (Level III) [PubMed] [*Obstetrics & Gynecology*] ⇦

56. Allen RH, Westhoff C, De Nonno L, Fielding SL, Schaff EA. Curettage after mifepristone-induced abortion: frequency, timing, and indications. Obstet Gynecol 2001;98:101–6. (Level III) [PubMed] [*Obstetrics & Gynecology*] ⇦

57. Hayes JL, Achilles SL, Creinin MD, Reeves MF. Outcomes of medical abortion through 63 days in women with twin gestations. Contraception 2011;84:505–7. (Level III) [PubMed] [Full Text] ⇦

58. Hakim-Elahi E, Tovell HM, Burnhill MS. Complications of first-trimester abortion: a report of 170,000 cases. Obstet Gynecol 1990;76:129–35. (Level II-3) [PubMed] [*Obstetrics & Gynecology*] ⇦

59. Ashok PW, Templeton A, Wagaarachchi PT, Flett GM. Factors affecting the outcome of early medical abortion: a review of 4132 consecutive cases. BJOG 2002;109:1281–9. (Level II-3) [PubMed] [Full Text] ⇦

60. Tang OS, Chan CC, Ng EH, Lee SW, Ho PC. A prospective, randomized, placebo-controlled trial on the use of mifepristone with sublingual or vaginal misoprostol for medical abortions of less than 9 weeks gestation. Hum Reprod 2003;18:2315–8. (Level I) [PubMed] [Full Text] ⇦

61. Chong E, Tsereteli T, Nguyen NN, Winikoff B. A randomized controlled trial of different buccal misoprostol

doses in mifepristone medical abortion. Contraception 2012;86:251–6. (Level I) [PubMed] [Full Text] ⇦

62. Hamoda H, Ashok PW, Flett GM, Templeton A. Medical abortion at 9-13 weeks' gestation: a review of 1076 consecutive cases. Contraception 2005;71:327–32. (Level II-3) [PubMed] [Full Text] ⇦
63. Chen QJ, Hou SP, Meads C, Huang YM, Hong QQ, Zhu HP, et al. Mifepristone in combination with prostaglandins for termination of 10-16 weeks' gestation: a systematic review. EBM-CONNECT Collaboration. Eur J Obstet Gynecol Reprod Biol 2011;159:247–54. (Meta-analysis) [PubMed] [Full Text] ⇦
64. Hamoda H, Ashok PW, Flett GM, Templeton A. A randomised controlled trial of mifepristone in combination with misoprostol administered sublingually or vaginally for medical abortion up to 13 weeks of gestation. BJOG 2005;112:1102–8. (Level I) [PubMed] ⇦
65. Winikoff B, Dzuba IG, Chong E, Goldberg AB, Lichtenberg ES, Ball C, et al. Extending outpatient medical abortion services through 70 days of gestational age. Obstet Gynecol 2012;120:1070–6. (Level II-3) [PubMed] [*Obstetrics & Gynecology*] ⇦
66. Shannon C, Brothers LP, Philip NM, Winikoff B. Infection after medical abortion: a review of the literature. Contraception 2004;70:183–90. (Level III) [PubMed] [Full Text] ⇦
67. Cohen AL, Bhatnagar J, Reagan S, Zane SB, D'Angeli MA, Fischer M, et al. Toxic shock associated with Clostridium sordellii and Clostridium perfringens after medical and spontaneous abortion. Obstet Gynecol 2007;110:1027–33. (Level III) [PubMed] [*Obstetrics & Gynecology*] ⇦
68. Ho CS, Bhatnagar J, Cohen AL, Hacker JK, Zane SB, Reagan S, et al. Undiagnosed cases of fatal Clostridium-associated toxic shock in Californian women of childbearing age. Am J Obstet Gynecol 2009;201:459.e1–7. (Level III) [PubMed] [Full Text] ⇦
69. Fjerstad M, Trussell J, Sivin I, Lichtenberg ES, Cullins V. Rates of serious infection after changes in regimens for medical abortion. N Engl J Med 2009;361:145–51. (Level II-3) [PubMed] [Full Text] ⇦
70. Bracken H, Clark W, Lichtenberg ES, Schweikert SM, Tanenhaus J, Barajas A, et al. Alternatives to routine ultrasound for eligibility assessment prior to early termination of pregnancy with mifepristone-misoprostol. BJOG 2011;118:17–23. (Level II-3) [PubMed] [Full Text] ⇦
71. Ectopic pregnancy--United States, 1988-1989. Centers for Disease Control (CDC). MMWR Morb Mortal Wkly Rep 1992;41:591–4. (Level II-3) [PubMed] ⇦
72. Van Den Eeden SK, Shan J, Bruce C, Glasser M. Ectopic pregnancy rate and treatment utilization in a large managed care organization. Obstet Gynecol 2005;105: 1052–7. (Level II-3) [PubMed] [*Obstetrics & Gynecology*] ⇦
73. Stulberg DB, Cain LR, Dahlquist I, Lauderdale DS. Ectopic pregnancy rates in the Medicaid population. Am J Obstet Gynecol 2013;208:274.e1–7. (Level II-3) [PubMed] [Full Text] ⇦
74. Edwards J, Creinin MD. Surgical abortion for gestations of less than 6 weeks. Curr Probl Obstet Gynecol Fertil 1997;20:11–9. (Level II-2) ⇦
75. Ulmann A, Silvestre L, Chemama L, Rezvani Y, Renault M, Aguillaume CJ, et al. Medical termination of early pregnancy with mifepristone (RU 486) followed by a prostaglandin analogue. Study in 16,369 women. Acta Obstet Gynecol Scand 1992;71:278–83. (Level II-3) [PubMed] ⇦
76. Lohr PA, Reeves MF, Creinin MD. A comparison of transabdominal and transvaginal ultrasonography for determination of gestational age and clinical outcomes in women undergoing early medical abortion. Contraception 2010;81:240–4. (Level II-3) [PubMed] [Full Text] ⇦
77. Creinin MD, Potter C, Holovanisin M, Janczukiewicz L, Pymar HC, Schwartz JL, et al. Mifepristone and misoprostol and methotrexate/misoprostol in clinical practice for abortion. Am J Obstet Gynecol 2003;188:664–9. (Level II-3) [PubMed] [Full Text] ⇦
78. Prine L, Lesnewski R, Berley N, Gold M. Medical abortion in family practice: a case series. J Am Board Fam Pract 2003;16:290–5. (Level III) [PubMed] [Full Text] ⇦
79. Haimov-Kochman R, Arbel R, Sciaky-Tamir Y, Brzezinski A, Laufer N, Yagel S. Risk factors for unsuccessful medical abortion with mifepristone and misoprostol. Acta Obstet Gynecol Scand 2007;86:462–6. (Level II-3) [PubMed] [Full Text] ⇦
80. Rossi B, Creinin MD, Meyn LA. Ability of the clinician and patient to predict the outcome of mifepristone and misoprostol medical abortion. Contraception 2004;70:313–7. (Level II-3) [PubMed] [Full Text] ⇦
81. Perriera LK, Reeves MF, Chen BA, Hohmann HL, Hayes J, Creinin MD. Feasibility of telephone follow-up after medical abortion. Contraception 2010;81:143–9. (Level II-3) [PubMed] [Full Text] ⇦
82. Grossman D, Grindlay K. Alternatives to ultrasound for follow-up after medication abortion: a systematic review. Contraception 2011;83:504–10. (Level III) [PubMed] [Full Text] ⇦
83. Reeves MF, Fox MC, Lohr PA, Creinin MD. Endometrial thickness following medical abortion is not predictive of subsequent surgical intervention. Ultrasound Obstet Gynecol 2009;34:104–9. (Level III) [PubMed] [Full Text] ⇦
84. Fiala C, Safar P, Bygdeman M, Gemzell-Danielsson K. Verifying the effectiveness of medical abortion; ultrasound versus hCG testing. Eur J Obstet Gynecol Reprod Biol 2003;109:190–5. (Level III) [PubMed] [Full Text] ⇦
85. Cameron ST, Glasier A, Dewart H, Johnstone A, Burnside A. Telephone follow-up and self-performed urine pregnancy testing after early medical abortion: a service evaluation. Contraception 2012;86:67–73. (Level II-3) [PubMed] [Full Text] ⇦
86. Godfrey EM, Anderson A, Fielding SL, Meyn L, Creinin MD. Clinical utility of urine pregnancy assays to deter-

mine medical abortion outcome is limited. Contraception 2007;75:378–82. (Level II-3) [PubMed] [Full Text] ⇦

87. Grossman D, Berdichevsky K, Larrea F, Beltran J. Accuracy of a semi-quantitative urine pregnancy test compared to serum beta-hCG measurement: a possible screening tool for ongoing pregnancy after medication abortion. Contraception 2007;76:101–4. (Level II-3) [PubMed] [Full Text] ⇦

88. Dayananda I, Maurer R, Fortin J, Goldberg AB. Medical abortion follow-up with serum human chorionic gonadotropin compared with ultrasonography: a randomized controlled trial. Obstet Gynecol 2013;121:607–13. (Level I) [PubMed] [*Obstetrics & Gynecology*] ⇦

89. Horning EL, Chen BA, Meyn LA, Creinin MD. Comparison of medical abortion follow-up with serum human chorionic gonadotropin testing and in-office assessment. Contraception 2012;85:402–7. (Level II-3) [PubMed] [Full Text] ⇦

90. Blum J, Shochet T, Lynd K, Lichtenberg ES, Fischer D, Arnesen M, et al. Can at-home semi-quantitative pregnancy tests serve as a replacement for clinical follow-up of medical abortion? A US study. Contraception 2012;86:757–62. (Level II-3) [PubMed] [Full Text] ⇦

91. Schaff EA, Fielding SL, Westhoff C, Ellertson C, Eisinger SH, Stadalius LS, et al. Vaginal misoprostol administered 1, 2, or 3 days after mifepristone for early medical abortion: A randomized trial [published erratum appears in JAMA 2000;284:2597]. JAMA 2000;284:1948–53. (Level I) [PubMed] [Full Text] ⇦

92. Arvidsson C, Hellborg M, Gemzell-Danielsson K. Preference and acceptability of oral versus vaginal administration of misoprostol in medical abortion with mifepristone. Eur J Obstet Gynecol Reprod Biol 2005;123:87–91. (Level I) [PubMed] [Full Text] ⇦

93. Yip SK, Tse AO, Haines CJ, Chung TK. Misoprostol's effect on uterine arterial blood flow and fetal heart rate in early pregnancy. Obstet Gynecol 2000;95:232–5. (Level III) [PubMed] [*Obstetrics & Gynecology*] ⇦

94. Fonseca W, Alencar AJ, Mota FS, Coelho HL. Misoprostol and congenital malformations. Lancet 1991;338: 56. (Level III) [PubMed] ⇦

95. Gonzalez CH, Vargas FR, Perez AB, Kim CA, Brunoni D, Marques-Dias MJ, et al. Limb deficiency with or without Mobius sequence in seven Brazilian children associated with misoprostol use in the first trimester of pregnancy. Am J Med Genet 1993;47:59–64. (Level III) [PubMed] ⇦

96. Marques-Dias MJ, Gonzalez CH, Rosemberg S. Mobius sequence in children exposed in utero to misoprostol: neuropathological study of three cases. Birth Defects Res A Clin Mol Teratol 2003;67:1002–7. (Level III) [PubMed] ⇦

97. Pastuszak AL, Schuler L, Speck-Martins CE, Coelho KE, Cordello SM, Vargas F, et al. Use of misoprostol during pregnancy and Mobius' syndrome in infants. N Engl J Med 1998;338:1881–5. (Level II-3) [PubMed] [Full Text] ⇦

98. Wiebe ER. Abortion induced with methotrexate and misoprostol: a comparison of various protocols. Contraception 1997;55:159–63. (Level II-3) [PubMed] [Full Text] ⇦

99. MacDonald K, Norman WV, Popescu O. New anomalies due to methotrexate and misoprostol exposure in early pregnancy. Int J Gynaecol Obstet 2013;122:267–8. (Level III) [PubMed] [Full Text] ⇦

100. Creinin MD. Conception rates after abortion with methotrexate and misoprostol. Int J Gynaecol Obstet 1999;65:183–8. (Level III) [PubMed] [Full Text] ⇦

101. Steinhoff PG, Smith RG, Palmore JA, Diamond M, Chung CS. Women who obtain repeat abortions: a study based on record linkage. Fam Plann Perspect 1979;11:30–8. (Level II-3) [PubMed] ⇦

102. Chen A, Yuan W, Meirik O, Wang X, Wu SZ, Zhou L, et al. Mifepristone-induced early abortion and outcome of subsequent wanted pregnancy. Am J Epidemiol 2004;160:110–7. (Level II-2) [PubMed] [Full Text] ⇦

103. Oliver-Williams C, Fleming M, Monteath K, Wood AM, Smith GC. Changes in association between previous therapeutic abortion and preterm birth in Scotland, 1980 to 2008: a historical cohort study. PLoS Med 2013; 10:e1001481. (Level II-3) [PubMed] [Full Text] ⇦

104. Yarnall J, Swica Y, Winikoff B. Non-physician clinicians can safely provide first trimester medical abortion. Reprod Health Matters 2009;17:61–9. (Level III) [PubMed] [Full Text] ⇦

105. Warriner IK, Wang D, Huong NT, Thapa K, Tamang A, Shah I, et al. Can midlevel health-care providers administer early medical abortion as safely and effectively as doctors? A randomised controlled equivalence trial in Nepal. Lancet 2011;377:1155–61. (Level I) [PubMed] [Full Text] ⇦

106. Grossman D, Grindlay K, Buchacker T, Lane K, Blanchard K. Effectiveness and acceptability of medical abortion provided through telemedicine. Obstet Gynecol 2011;118:296–303. (Level II-3) [PubMed] [*Obstetrics & Gynecology*] ⇦

107. Grossman DA, Grindlay K, Buchacker T, Potter JE, Schmertmann CP. Changes in service delivery patterns after introduction of telemedicine provision of medical abortion in Iowa. Am J Public Health 2013;103:73–8. (Level II-3) [PubMed] [Full Text] ⇦

108. U. S. Medical Eligibility Criteria for Contraceptive Use, 2010. Centers for Disease Control and Prevention (CDC). MMWR Recomm Rep 2010;59(RR-4):1–86. (Level III) [PubMed] [Full Text] ⇦

109. Mittal S. Contraception after medical abortion. Contraception 2006;74:56–60. (Level III) [PubMed] [Full Text] ⇦

110. Understanding and using the U.S. selected practice recommendations for contraceptive use, 2013. Committee Opinion No. 577. American College of Obstetricians and Gynecologists. Obstet Gynecol 2013;122:1132–3. (Level III) [PubMed] [*Obstetrics & Gynecology*] ⇦

111. Shimoni N, Davis A, Ramos ME, Rosario L, Westhoff C. Timing of copper intrauterine device insertion after

medical abortion: a randomized controlled trial. Obstet Gynecol 2011;118:623–8. (Level I) [PubMed] [*Obstetrics & Gynecology*] ⇦

112. Saav I, Stephansson O, Gemzell-Danielsson K. Early versus delayed insertion of intrauterine contraception after medical abortion - a randomized controlled trial. PLoS One 2012;7:e48948. (Level I) [PubMed] [Full Text] ⇦

113. Bednarek PH, Creinin MD, Reeves MF, Cwiak C, Espey E, Jensen JT. Immediate versus delayed IUD insertion after uterine aspiration. Post-Aspiration IUD Randomization (PAIR) Study Trial Group. N Engl J Med 2011;364:2208–17. (Level I) [PubMed] [Full Text] ⇦

The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 2000–November 2013. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles. When reliable research was not available, expert opinions from obstetrician–gynecologists were used.

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

- I Evidence obtained from at least one properly designed randomized controlled trial.
- II-1 Evidence obtained from well-designed controlled trials without randomization.
- II-2 Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A—Recommendations are based on good and consistent scientific evidence.

Level B—Recommendations are based on limited or inconsistent scientific evidence.

Level C—Recommendations are based primarily on consensus and expert opinion.

Published concurrently in the March 2014 issue of *Contraception.*

Copyright March 2014 by the American College of Obstetricians and Gynecologists. All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, posted on the Internet, or transmitted, in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without prior written permission from the publisher.

Requests for authorization to make photocopies should be directed to Copyright Clearance Center, 222 Rosewood Drive, Danvers, MA 01923, (978) 750-8400.

ISSN 1099-3630

The American College of Obstetricians and Gynecologists
409 12th Street, SW, PO Box 96920, Washington, DC 20090-6920

Medical management of first-trimester abortion. Practice Bulletin No. 143. American College of Obstetricians and Gynecologists. Obstet Gynecol 2014;123:676–92.

Table 1. Adverse Effects in Selected North American Trials of Medical Abortion Regimens ⇦

Trial	Incidence of Adverse Effects (%)											
	Nausea		Vomiting		Diarrhea		Headache		Dizziness		Thermoregulatory Effects*	
	Mifepristone	Misoprostol	Mifepristone	Misoprostol	Mifepristone	Misoprostol	Mifepristone	Misoprostol	Mifepristone	Misoprostol	Mifepristone	Misoprostol
Schaff (1997)[†]	36	36	14	14	8	22	18	19	22	37	20	37
Schaff (1999)[‡]	45	43	13	26	11	23	14	13	15	28	14	32
Wiebe (2002)[§]	45	39	13	15	5	16	19	29	N/R	N/R	N/R	23
Creinin (2004)[‖]	20	44	5	23	1	27	10	37	12	35	9	56
	39	52	14	30	7	25	20	37	20	37	19	53
Creinin (2007)[¶]	N/R	58	N/R	31	N/R	35	N/R	40	N/R	39	N/R	69
	29	51	9	31	5	26	18	36	9	37	15	56
Winikoff (2008)[#]	N/R	64	N/R	40	N/R	35	N/R	31	N/R	30	N/R	33
	N/R	66	N/R	40	N/R	34	N/R	34	N/R	32	N/R	41

Abbreviation: N/R, not reported.

*Fever, warmth, hot flushes, or chills.

[†]Mifepristone, 600 mg, followed by misoprostol, 800 micrograms vaginally, 36–48 hours later. (Schaff EA, Stadalius LS, Eisinger SH, Franks P. Vaginal misoprostol administered at home after mifepristone (RU486) for abortion. J Fam Pract 1997;44:353–60.)

[‡]Mifepristone, 200 mg, followed by misoprostol, 800 micrograms vaginally, 48 hours later. (Schaff EA, Eisinger SH, Stadalius LS, Franks P, Gore BZ, Poppema S. Low-dose mifepristone 200 mg and vaginal misoprostol for abortion. Contraception 1999;59:1–6.)

[§]Mifepristone, 600 mg, followed by misoprostol, 400 micrograms orally, 36–48 hours later. (Wiebe E, Dunn S, Guilbert E, Jacot F, Lugtig L. Comparison of abortions induced by methotrexate or mifepristone followed by misoprostol. Obstet Gynecol 2002;99:813–9.)

[‖]Mifepristone, 200 mg, followed by misoprostol, 800 micrograms vaginally, 6–8 hours later (first row) or 24 hours later (second row). (Creinin MD, Fox MC, Teal S, Chen A, Schaff EA, Meyn LA. A randomized comparison of misoprostol 6 to 8 hours versus 24 hours after mifepristone for abortion. Obstet Gynecol 2004;103:851–9.)

[¶]Mifepristone, 200 mg, followed by misoprostol, 800 micrograms vaginally, 0–15 minutes later (first row) or 24 hours later (second row). (Creinin MD, Schreiber CA, Bednarek P, Lintu H, Wagner MS, Meyn L. Mifepristone and misoprostol administered simultaneously compared with 24 hours apart for abortion: a randomized controlled trial. Obstet Gynecol 2007;109:885–94.)

[#]Mifepristone, 200 mg, followed by misoprostol, 800 micrograms orally (first row) or buccally (second row), 24–36 hours later. (Winikoff B, Dzuba IG, Creinin MD, Crowden WA, Goldberg A, Gonzales J, et al. Two distinct oral routes of misoprostol in mifepristone medical abortion. A randomized controlled trial. Obstet Gynecol 2008;112:1303–10.)

to improve on existing device performance while maintaining acceptable economic value. This information could then inform postmarketing surveillance efforts, triggering reviews at prespecified efficacy or complication thresholds and facilitating rapid application of new data as they become available. Manufacturers could use such data to improve device development; researchers could identify target populations for evaluating novel technologies; insurers could identify opportunities for value-based reimbursement; and consumers could be educated about what clinical benefits they are getting for their money. The complex trade-offs between short- and long-term health and economic consequences of technological innovation may not be captured by even the most sophisticated randomized trials. Model-based approaches may provide invaluable insights for evaluating medical device innovation and merit consideration as a standard component of the evaluation process.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

From Yale School of Medicine (L.G.S.) and Yale School of Public Health (A.D.P.) — both in New Haven, CT; the Veterans Affairs Connecticut Healthcare System, West Haven, CT (L.G.S.); and Brigham and Women's Hospital (B.N.R., D.H.S., I.G., H.G., J.N.K., E.L.), Harvard Medical School (D.H.S., E.L.), Harvard School of Public Health (J.N.K.), and Boston University School of Public Health (E.L.) — all in Boston.

1. O'Keeffe K. The rise of Medtech. Medical Device and Diagnostic Industry, June 10, 2011. (http://www.mddionline.com/article/rise-medtech.)
2. Lawrence RC, Felson DT, Helmick CG, et al. Estimates of the prevalence of arthritis and other rheumatic conditions in the United States: part II. Arthritis Rheum 2008; 58:26-35.
3. Paxton EW, Namba RS, Maletis GB, et al. A prospective study of 80,000 total joint and 5000 anterior cruciate ligament reconstruction procedures in a community-based registry in the United States. J Bone Joint Surg Am 2010;92:Suppl 2:117-32.
4. Institute of Medicine. Medical devices and the public's health: the FDA 510(k) clearance process at 35 years. Washington, DC: National Academies Press, 2011. (http://www.iom.edu/Reports/2011/Medical-Devices-and-the-Publics-Health-The-FDA-510k-Clearance-Process-at-35-Years.aspx.)
5. Losina E, Walensky RP, Reichmann WM, et al. Impact of obesity and knee osteoarthritis on morbidity and mortality in older Americans. Ann Intern Med 2011;154:217-26.

Copyright © 2011 Massachusetts Medical Society.

The Supply-Side Economics of Abortion

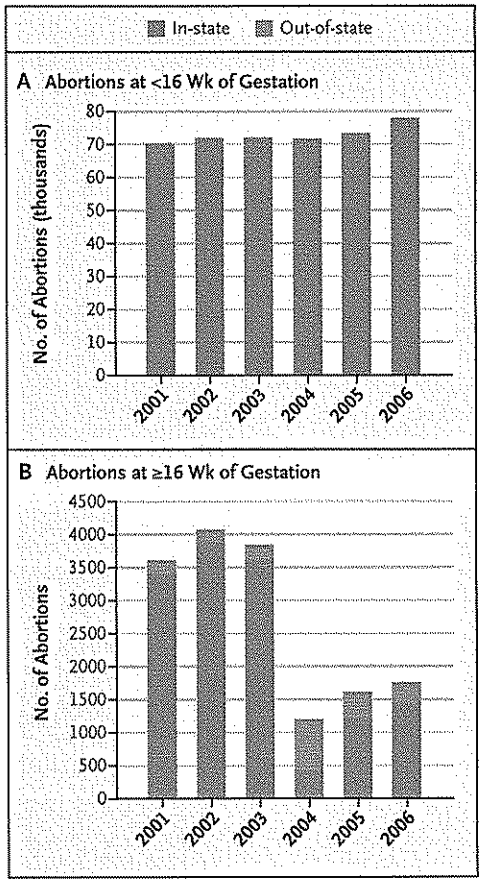
Theodore Joyce, Ph.D.

Under legislation recently signed by Kansas's governor, the Kansas Department of Health and Environment has issued new licensing standards for abortion clinics. The regulations stipulate, among other requirements, that facilities must have procedure rooms of at least 150 ft^2; each procedure room must have janitorial space of at least 50 ft^2; facilities must have designated dressing rooms for patients and separate ones for staff; and each dressing room must have a toilet, a washing station, and storage for clothing.[1] Two physicians who provide abortions in their office-based practice filed suit, stating that the requirements were unnecessary to ensure patient safety and would force them to stop providing abortion services. On July 1, 2011, a federal judge issued a temporary injunction allowing all three providers in Kansas to continue operating for the time being.

Such licensing requirements reflect an aggressive new thrust on the part of abortion opponents. Early approaches to restricting abortion access were directed largely at patients — the demand side of the market. For instance, laws requiring parental involvement in a minor's decision to abort, limiting Medicaid funding of abortion, mandating the provision of information including unfounded claims about risks, and requiring a 24-hour waiting period between receipt of mandated information and an abortion are all efforts to discourage women from terminating their pregnancies. Although these demand-side policies have had relatively little impact on national abortion rates, they have prevented some women from terminating an unwanted pregnancy. Not surprisingly, the women most affected are those without the support and resources to circumvent or comply with these requirements.[2]

Perhaps frustrated by many women's determination to overcome demand-side hurdles, abortion opponents have turned to supply-side restrictions, focusing on providers of abortion services. This strategy is likely to be more effective. In 2004, 12 states had fewer than five non-hospital-based abortion providers and 7 states had one or no provider that performed at least 400 abortions per year. Larger clinics are the mainstay of the service: 94% of all U.S. abortions are performed in

The New England Journal of Medicine
Downloaded from nejm.org at PLANNED PARENTHOOD FED on October 10, 2014. For personal use only. No other uses without permission.
Copyright © 2011 Massachusetts Medical Society. All rights reserved.



Number of Abortions Performed in Residents of Texas, before and after 16 Weeks of Gestation, in and outside Texas, 2001–2006.

Data are from Colman and Joyce.[4]

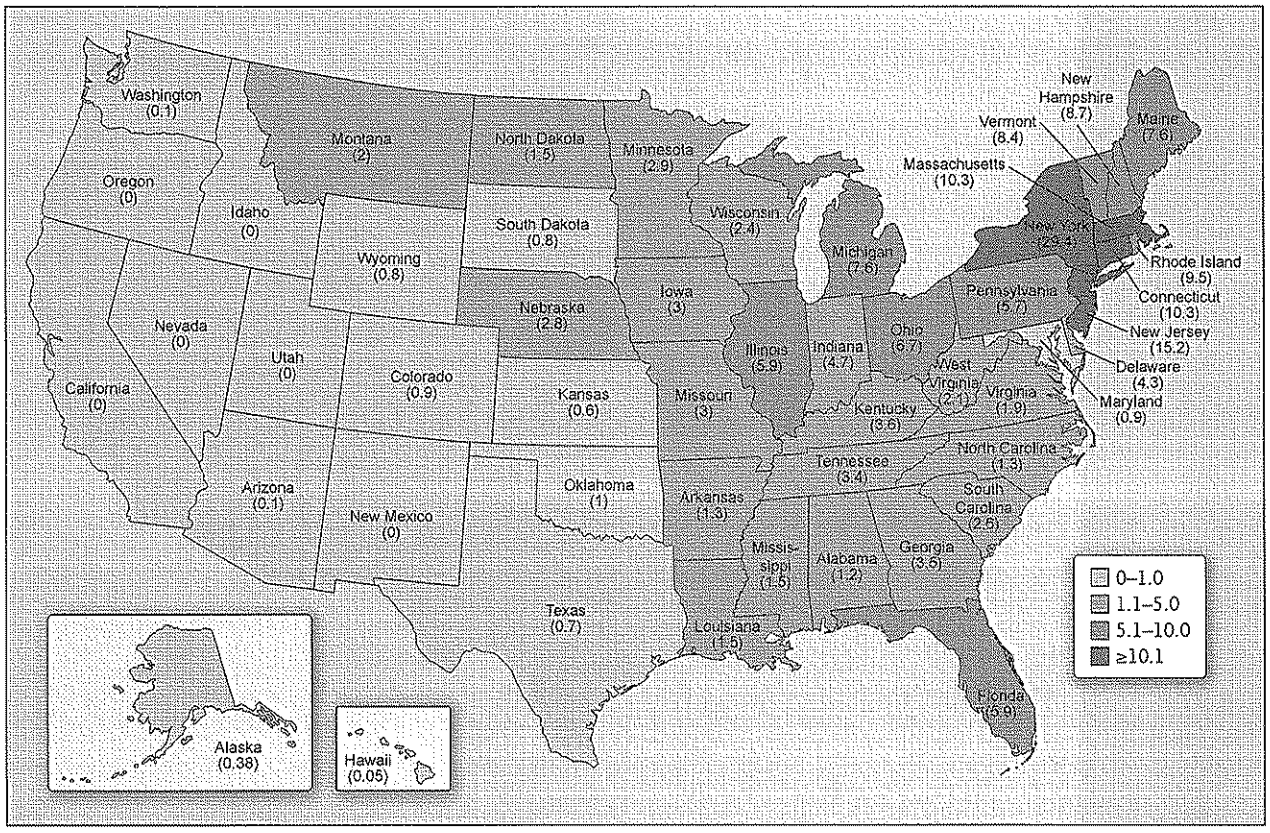
clinics that do 400 or more abortions per year.[3] In Kansas, where more than 10,000 abortions were performed in 2008, the law may reduce the number of providers from three to one.[3] Many Kansas residents would seek abortion services in other states. But the cost of traveling elsewhere for an abortion can be substantial, and travel distance can make compliance with another state's mandatory counseling and waiting periods, or its judicial bypass procedure, more difficult.

Texas's Woman's Right to Know Act provides a natural experiment that permits comparison of the effects of demand-side and supply-side policies. The law, which went into effect in January 2004, has two components. The demand-side element requires that the patient receive information similar to that mandated in other states at least 24 hours before an abortion is performed. The supply-side component requires that all abortions at or after 16 weeks of gestation be performed in a hospital or an ambulatory surgical center. Ambulatory surgical centers must adhere to more demanding staffing, reporting, and facility-structure requirements than free-standing abortion clinics must meet. When the law went into effect, none of Texas's non–hospital-based abortion providers qualified as ambulatory surgical centers, so the average distance to the nearest non–hospital-based abortion provider offering terminations at or after 16 weeks of gestation rose from 33 miles in 2003 to 252 miles in 2004. Hospitals were not a viable alternative, since Texas hospitals perform relatively few abortions.[4]

If Texas's demand-side policies had an impact, there would have been a decrease in abortions at all gestational stages. If only the supply-side policy restricted access, the decrease would be limited to abortions performed at or after 16 weeks. I found that the supply-side policy had dramatic effects, whereas the demand-side policy had none. The number of abortions performed in Texas at or after 16 weeks of gestation dropped by 88%, from 3642 in 2003 to 446 in 2004, while the number of residents who left the state for a late abortion almost quadrupled, from 187 in 2003 to 736 in 2004. Despite this large outflow, there were 2460 fewer abortions at 16 weeks or later in Texas residents 1 year after the law took effect, a 68% decline. By 2006, Austin, Dallas, Houston, and San Antonio had ambulatory surgical centers in which abortions were performed at or after 16 weeks of gestation, but the number of such abortions remained well below the 2003 level.[4] Over the same period there was no meaningful change in the number of abortions before 16 weeks of gestation (see graph). The demand-side policies had no measurable impact.

Even more restrictive supply-side requirements have been enacted in other states. A 2007 Missouri statute mandates that any abortion facility in which five or more first-trimester abortions per month or at least one abortion after 12 weeks of gestation are performed must meet the requirements of an ambulatory surgical center. A state judge issued a temporary restraining order against implementing the statute, largely because of its economic impact.[5] Virginia enacted a similar statute in March 2011. Any abortion facility in which five or more first-trimester abortions per month are performed will be considered a hospital for purposes of the legislation. New regulations from the Virginia Department of Health are scheduled to go into effect on January 1, 2012, after the expected approval of the governor. A new Arizona law requires that only physicians perform medical (as well as surgical) abortions. As a result, Planned Parenthood of Arizona stopped providing abortion services in three clinics, since only nurse practitioners had been available to dispense medication for nonsurgical abortions.

The New England Journal of Medicine
Downloaded from nejm.org at PLANNED PARENTHOOD FED on October 10, 2014. For personal use only. No other uses without permission.
Copyright © 2011 Massachusetts Medical Society. All rights reserved.



Rate of Abortions (per 1000 Women 15 to 44 Years of Age) Performed in New York in Residents of Each State, 1971–1972.
Rates were calculated by the author on the basis of data from the New York State Department of Health.

If policies rendering free-standing abortion clinics economically unviable are allowed to stand, a map of U.S. abortion services will probably resemble the blue-state–red-state configuration after the 2004 presidential election. Services will be readily available in coastal blue states, whereas women in the country's vast middle will have to travel large distances for access. To illustrate the importance of travel distance as a determinant of whether a woman obtains an abortion, consider abortion rates just before *Roe v. Wade.* In 1971–1972, abortion was effectively legal in five states: Alaska, California, Hawaii, New York, and Washington. In 1971–1972, there were 27,793 abortions performed in New York in residents of Illinois, an annual rate of 5.9 abortions per 1000 female Illinois residents 15 to 44 years of age (see map) — but the rate of abortions performed in New York in Connecticut residents was almost twice as high, 10.3 per 1000, and the rate among New Jersey residents was more than 2.5 times as high, 15.2 per 1000.

There were also important differences according to race. The rate of abortions performed in New York in non-white Illinois residents was lower than that among whites (4.5 vs. 6.0 per 1000). The opposite was true for Connecticut and New Jersey. The abortion rate among nonwhite women was 15.8 per 1000 for Connecticut and 23.0 per 1000 for New Jersey, as compared with 9.6 and 13.6 per 1000, respectively, among white residents of those states.

The pre-*Roe* data illustrate that the farther women must travel for an abortion, the lower the abortion rate will be, and that travel distance is a greater obstacle for less-advantaged women. Thus, if a "blue state–red state" distribution of abortion services evolves, the pre-*Roe* racial and socioeconomic patterns will probably reemerge. Women with resources will travel substantial distances for an abortion, whereas less-advantaged women will travel less.

History suggests that there will always be abortions. The goal should be to reduce the abortion rate by reducing unintended pregnancies, while providing safe, legal services for women who need

The New England Journal of Medicine
Downloaded from nejm.org at PLANNED PARENTHOOD FED on October 10, 2014. For personal use only. No other uses without permission.
Copyright © 2011 Massachusetts Medical Society. All rights reserved.

them. Making access to abortion unnecessarily costly will probably result in clandestine abortions and unintended childbearing among families with the least resources and the fewest options.

Disclosure forms provided by the author are available with the full text of this article at NEJM.org.

From Baruch College and Graduate Center, City University of New York, and the National Bureau of Economic Research — both in New York.

1. Hodes & Nauser, MDs, P.a. v. Moser, No. 11-CV-2365 (D. Kan. filed June 28, 2011).
2. Joyce T, Kaestner R, Colman S. Change in abortions and births and the Texas parental notification law. N Engl J Med 2006;354:1031-8.
3. Jones RK, Kooistra K. Abortion ilncidence and access to services in the United States, 2008. Perspect Sex Reprod Health 2011;43:41-50.
4. Colman S, Joyce T. Regulating abortion: impact on patients and providers in Texas. J Policy Anal Manage 2011;30:775-97.
5. Planned Parenthood of Kansas and Mid-Missouri, Inc. v. Drummond, Case No. 07-4164-CV-CODS (W.D. MI. August 27, 2007).

Copyright © 2011 Massachusetts Medical Society.

The New England Journal of Medicine
Downloaded from nejm.org at PLANNED PARENTHOOD FED on October 10, 2014. For personal use only. No other uses without permission.
Copyright © 2011 Massachusetts Medical Society. All rights reserved.

M

IN THE IOWA DISTRICT COURT FOR POLK COUNTY

PLANNED PARENTHOOD OF THE HEARTLAND, INC., and DR. JILL MEADOWS. M.D., Petitioners, v. IOWA BOARD OF MEDICINE, GREG HOVERSTEN, D.O., HAMED TWEFIK, M.D., FRANK BOGNANNO, DIANE CLARK, ROBERT BENDER, M.D., JULIE CARMODY, M.D., JULIE PERKINS, M.D., and ALLISON SCHOENFELDER, M.D., IN THEIR OFFICIAL CAPACITIES AS MEMBERS OF THE BOARD OF MEDICINE AND IN THEIR INDIVIDUAL CAPACITIES, Respondents.	CVCV 046429 AFFIDAVIT OF DANIEL GROSSMAN, M.D.

1. I am Vice President for Research at Ibis Reproductive Health, a nonprofit research organization. I am also Assistant Clinical Professor in the Department of Obstetrics, Gynecology and Reproductive Sciences at the University of California, San Francisco. I am a board-certified obstetrician-gynecologist and a Fellow of the American College of Obstetricians and Gynecologists (ACOG), which I am very active in, most recently serving as the vice chair of the Committee on Practice Bulletins for Gynecology (my term ended in May 2013). I am also a Fellow of the Society of Family Planning and a member of the American Medical Association and the American Public Health Association. I provide clinical services as a consultant to Planned Parenthood Shasta Pacific, and I serve as a liaison member of the Planned Parenthood Federation of America National Medical Committee. My CV is attached hereto as Exhibit A.

2. My research is supported by grants from federal agencies and private foundations, and I have published over 75 articles in peer-reviewed journals.

3. I am very familiar with Planned Parenthood of the Heartland's (PPH) use of telemedicine to provide medication abortion to patients. Between 2008 and 2010, I led a team of researchers that performed an evaluation of PPH's program. Our findings were published in highly respected, peer-reviewed medical journals.[1] The research was funded by a private foundation and was not paid for by Planned Parenthood. We shared these publications with the Iowa Board of Medicine ("Board") when it was considering Adopted and Filed Rule ARC 1034c ("Rule").

4. I submit this affidavit in support of Petitioners' Petition for Judicial Review. In my opinion, and as I testified in person to the Board, the Rule will do nothing to enhance the safety of abortion in Iowa. In fact, the Rule will negatively affect women's health by delaying or preventing women from obtaining an abortion.

5. In its Statement on Adopted and Filed Rule ARC 1034c ("Statement"), the Board asserted or implied the following: 1) that medication abortion is risky; 2) that PPH's telemedicine program is inconsistent with guidelines of the US Food and Drug Administration (FDA); 3) that a physical examination is necessary to screen for ectopic pregnancy and other contraindications; 4) that an in-person meeting between the doctor and the patient "is fundamental to the provision of a safe medical abortion"; and 5) that an in-person meeting will

---

[1] See Daniel Grossman et al., *Changes in Service Delivery Patterns After Introduction of Telemedicine Provision of Medical Abortion in Iowa*, 103(1) AM. J. PUBLIC HEALTH 73-78 (Nov. 2012) ("*Changes in Delivery Patterns*"); Daniel Grossman et al., *Effectiveness and Acceptability of Medical Abortion Provided Through Telemedicine*, 118 OBSTET. GYNECOL. 296-303 (Aug. 2011) ("*Effectiveness and Acceptability*"); Kate Grindlay et al., *Women's and Providers' Experiences with Medical Abortion Provided Through Telemedicine: A Qualitative Study*, 23(2) WOMEN'S HEALTH ISSUES e117-e122 (2013) ("*Qualitative Study*").

result in "increased follow-up care of the patient." Each of these assertions is misleading and/or inaccurate. I will address them in turn.

I. Safety of Medication Abortion

6. Throughout its Statement, the Board implies that the medications used in a medication abortion are particularly high-risk medications. That is not medically accurate.

7. Medication abortion is a method of terminating an early pregnancy by taking medications approved by the Food and Drug Administration that cause the woman to undergo an early miscarriage within a short and predictable period of time. Medication abortion is extremely safe and is associated with few complications or contraindications.

8. I understand that PPH health centers use the most common combination of medications to induce abortion, mifepristone and misoprostol. Mifepristone (also known by its trade name in the USA, Mifeprex) blocks the activity of progesterone, a hormone that prepares the lining of the uterus for a fertilized egg and is necessary to maintain an early pregnancy. Misoprostol is a synthetic prostaglandin used to soften and open the cervix and induce uterine contractions, in order to expel the contents of the uterus. This combination safely and effectively terminates pregnancy through at least 63 days from the first day of the woman's last menstrual period (LMP).

9. Throughout this declaration, when I refer to "medication abortion" I am referring to medication abortions using mifepristone and misoprostol.

10. Prior to a medication abortion, the provider confirms that the woman has an intrauterine pregnancy (that is, a pregnancy that is inside the uterus and not elsewhere) within the 63-day gestational age range, typically by reading an ultrasound; takes the woman's medical

history to ensure that she is not one of a small number of patients with a particular medical condition that makes her an inappropriate candidate for medication abortion (such as having an intrauterine device (IUD) in place; a history of significant cardiovascular, liver or renal disease; chronic adrenal failure; an allergy to mifepristone or misoprostol or other prostaglandins; a known coagulopathy or taking anticoagulant therapy; or undergoing long-term corticosteroid therapy); screens the woman for severe anemia, frequently by measuring hemoglobin or hematocrit in a blood sample; and discusses the medication abortion decision with the woman to ensure that she has made an educated and informed decision and understands what to do and what to expect.

11. The patient then takes mifepristone (which is a pill) orally at the health center. She also is given misoprostol (which is also pills) and instructed to administer them herself twenty-four to forty-eight hours later by placing the pills in her buccal pouch (i.e., between her cheek and gum). The products of conception are passed at home, usually approximately four to six hours after the patient takes the misoprostol. The patient then has follow up within two weeks to confirm that the pregnancy has been safely terminated.

12. Medication abortion requires no anesthesia or sedation. Many women take only over-the-counter medications to control whatever pain or discomfort they have.

13. The June 28, 2013, petition for rulemaking, on which the Rule was based, suggested that medication abortion is unsafe, stating that in July 2011, the FDA reported 14 deaths related to medication abortion. The petition neglected to mention that this statistic covers a period of more than 10 years (from approval of mifepristone in September 2000 through April 2011), during which approximately 1.52 million women chose to have a medication abortion. The FDA data, therefore, reflect that medication abortion is extremely safe, with a mortality rate

of less than 1 per 100,000 abortions, which is comparable to the rate for first-trimester surgical abortion, and lower than the mortality rate associated with penicillin.[2]

14. The petition also neglected to mention that some of those deaths were obviously unrelated to abortion – including two drug/substance abuse overdoses and a suspected homicide.

15. Moreover, the medication abortion regimens used have changed over time, and therefore, the FDA data include regimens that are no longer routinely used, including at PPH. At the end of March 2006, in response to a higher than expected rate of serious infection in the first few years of its providing medication abortion, Planned Parenthood health centers nationwide made two changes to their medication abortion protocols: (1) they discontinued use of vaginal administration of misoprostol and replaced it with buccal administration; and (2) either routine antibiotics were given or all women were tested for chlamydia. In July 2007, Planned Parenthood required all medication abortion patients to receive routine antibiotics.

16. There is now substantial evidence that this new regimen has made an already-safe procedure significantly safer. In a study that is in press at the medical journal *Contraception*, researchers, led by Dr. James Trussell, examined all medication abortions (930,484 abortions) performed at Planned Parenthood health centers nationwide from 2001 through 2012 and analyzed deaths due to infection during two time periods: the period before Planned Parenthood changed its regimen in 2006, and the period since the change.

17. The study showed there were three deaths (out of 218,928 abortions) due to infection before the change, and *none* since (out of 711,556 abortions).[3] By contrast, the mortality rate for childbirth is 8.8 per 100,000.[4]

---

[2] O Idsoe et al., *Nature and Extent of Penicillin Side-reactions, with Particular Reference to Fatalities from Anaphylactic Shock.* 38 World Health Org. Bulletin 159, 175 (1968).

[3] James Trussell et al., *Reduction in Infection-Related Mortality since Modifications in the*

18. In addition to mortality, the complication rate for medication abortions is extremely low. A recent study analyzing complications from medication abortion found a rate of clinically significant adverse events of just 0.16%.[5] Perhaps more importantly here, these are not events for which it would make a difference whether the patient obtained her medication through telemedicine or traveled further to a clinic to meet with a doctor in person. This is because any complications that do arise will always occur after the patient has left the clinic, and most likely at home.[6]

19. For example, if a patient experiences bleeding that requires a transfusion, which is the most common of the rare serious complications from a medication abortion, this can occur up to three weeks after the procedure. In those cases, a physician should refer that patient to the hospital nearest to her to make sure she is treated as quickly as possible. And, whether or not that hospital is familiar with abortion complications, all hospitals are equipped to rapidly diagnose and treat gynecological hemorrhage, as well as any infection, because they routinely see these complications among patients with miscarriage.

II. The Protocol Included in the Mifeprex Labeling

20. The Board's Statement on the Rule states that PPH's telemedicine procedures "are inconsistent with the protocols approved by the Food and Drug Administration (FDA) and

---

Regimen of Medical Abortion, CONTRACEPTION 1, 8 (2013).

[4] Elizabeth Raymond & David Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 OBSTET. GYNECOL. 215, 216 (Feb. 2012).

[5] Kelly Cleland et al., *Clinically Significant Adverse Events and Outcomes after Medical Abortion*, 121 OBSTET. GYNECOL. 166, 168 (Jan. 2013).

[6] The only conceivable complication that could arise at the health center when the woman takes the mifepristone is an allergic reaction, just as could occur in response to any medication, including over-the-counter medications. As with anyone having an allergic reaction (whether an asthma attack, or a reaction to penicillin, for example), it is the standard of care to provide this patient with epinephrine if the reaction is acute enough to warrant it. In my years of providing medication abortion, and of supervising its provision, none of my patients has had an allergic reaction to mifepristone.

the manufacturer of the drugs." Reason 2. This is misleading; nothing that PPH does is prohibited by the FDA or the manufacturer.

21. At the outset, it is important to understand the status of a drug's final printed label (FPL), and specifically to understand that this is not a restriction on physician practice. The FPL approved by the FDA in September 2000, as with FPLs for other medications, is an informational document that provides physicians with guidance about the use for which the drug sponsor requested and received FDA approval. The mifepristone label, therefore, describes the regimen used in the clinical trials upon which the FDA based its approval of the drug. That regimen involved women taking 600 mg of mifepristone orally and returning two days later to the health center to take 400 μg of misoprostol orally. Because the clinical trials (which involved fewer than 3000 women) showed that regimen to be safe and effective through 49 days LMP, the Mifeprex FPL reflects that regimen and gestational age limit.

22. Mifepristone is the only medication that has received FDA approval for marketing as an abortion-inducing drug, and therefore, the only medication with an FPL describing an abortion regimen.

23. By the time that Mifeprex was approved by the FDA in 2000, newer research showed that a lower dosage of mifepristone (200 mg instead of 600 mg), as well as a different dosage and route of administration of self-administered misoprostol, was a safe regimen that had a number of advantages compared to the regimen on the FPL. As explained above, the regimens used over time have changed, but there is no question that the regimen used today by PPH is more effective, can be used later in pregnancy (through at least 63 days LMP), and has fewer side effects. The self-administration of misoprostol eliminates an unnecessary trip to the health center and allows women more control over the timing of the procedure so they can avoid travel

and have the support of loved ones. Eliminating that trip, along with the lower dosage of mifepristone, also lowers the cost of the procedure.

24. The practice of developing new protocols, using different dosages, or using medications for entirely different uses from those for which they were approved by the FDA, when those uses are supported by adequate study, is not unique to mifepristone. This practice is common in medicine and is called "off-label" or "evidence-based" use.

25. The American Medical Association has stated that up to 20 percent of all drugs are prescribed off-label, and among some classes of cardiac drugs, off-label use can be as high as 46 percent.[7] Moreover, the FDA itself has noted that "accepted medical practice often includes drug use that is not reflected in approved drug labeling."[8] For example, this is how aspirin came to be used to prevent heart attacks and Wellbutrin, approved by the FDA as an anti-depressant, came to be used as a smoking cessation drug. Misoprostol, the second drug used in the medication abortion regimen, is another example. It was approved by the FDA as a drug to reduce the incidence of gastric ulcers in patients taking non-steroidal anti-inflammatory drugs such as ibuprofen and is labeled for that use. However, besides being routinely used as part of medication abortion, it is widely used in obstetrics to ripen the cervix for induction of labor and also to prevent and treat postpartum hemorrhage.

26. While the FDA does not require providers to use the regimen on the FPL, it did issue certain requirements for the administration of Mifeprex in its approval letter for the medication, and PPH's program meets these requirements. For example, the letter requires that Mifeprex be "provided by or under the supervision of a physician" who is able to assess the

---

[7] AMA National Task Force on CME Provider/Industry Collaboration, *Fact Sheet: On-Label and Off-Label Usage of Prescription Medicines and Devices*, http://www.ama-assn.org/resources/doc/cme/fact-sheet-4.pdf.

[8] Use of Approved Drugs for Unlabeled Indications, 12 FDA Drug Bulletin 5 (April 1982).

duration of the pregnancy, diagnose ectopic pregnancies, and arrange for the treatment of any complications. PPH's protocol is the same for patients whether they come to a telemedicine site or to a site where the physician is physically present: the physician does not perform the ultrasound or laboratory testing herself but rather reviews the results of these tests, including reviewing the ultrasound images; the physician supervises the provision of the medication by discussing the medication with the patient and observing her take the first dosage; and the physician provides the patient with detailed information about possible complications and the contact information for a 24-hour emergency phone service staffed by Planned Parenthood medical professionals. This protocol is fully consistent with the actual requirements that the FDA placed on prescribers as part of its approval for mifepristone.

III. Safety of Telemedicine Abortion

27. The Statement asserts that an in-person meeting between the doctor and the patient "is fundamental to the provision of a safe medical abortion." This is not true.

28. As explained above, a medication abortion involves screening the woman for contraindications, counseling, and the dispensing of medication. This can be done with equal safety whether or not the physician is physically present in a room with the patient.

29. Telemedicine is widely recognized as an important tool for addressing health care disparities between urban and rural areas and bringing quality medical services to underserved rural communities. The American Medical Association has issued a Resolution recognizing that "[t]he advancement of telemedicine will allow patients . . . to obtain excellence in health care," and that "[t]elemedicine promotes increased access to health care by eliminating travel expenses,

[and] aiding those with impediments to mobility."[9] Similarly, ACOG has voiced concern over the lack of medical services accessible to women in rural communities, and has asked ob-gyns to "[e]ncourage and participate in efforts to utilize effective telemedicine technologies to expand and improve services for rural women."[10]

30. As part of the study I led on PPH's telemedicine abortion program, we reviewed all of the adverse events that occurred after medication abortion during the period between July 1, 2008, shortly after PPH started telemedicine delivery services, and October 31, 2009. During this period, PPH provided 1,172 medication abortions through telemedicine, and 2,384 medication abortions with an in-person physician visit. Consistent with other published literature on medication abortion, adverse events were uncommon, occurring in only 1.3% of medication abortion patients. Most of these adverse events were ongoing pregnancy, which occurred in 0.9% of telemedicine patients and 1% of patients with an in-person visit. Blood transfusion was very rare, occurring in 0.3% of telemedicine patients and 0.1% of patients with an in-person visit. Most importantly, there was no difference in the complication rate between women utilizing telemedicine technology and those who had an in-person visit with a physician. The complication rates were very low in both groups, and they were identical.[11]

31. Our findings reflect that patients who accessed medication abortion through telemedicine reported comparable, and by some measures, greater satisfaction rates. For example, telemedicine patients reported a significantly higher level of satisfaction with their wait

---

[9]American Medical Association House of Delegates Resolution 317, *Telemedicine and Medical Licensure*, http://www.ama-assn.org/resources/doc/council-on-med-ed/res317a08.pdf.

[10]ACOG Committee on Underserved Women, *ACOG Committee Opinion Number 429: Health Disparities for Rural Women* (March 2009), http://www.acog.org/Resources_And_Publications/Committee_Opinions/Committee_on_Health_Care_for_Underserved_Women/Health_Disparities_for_Rural_Women.

[11] *Effectiveness and Acceptability* at 300.

time, and were significantly more likely to say they would recommend the service to a friend.[12] This finding is consistent with the fact that the Board has not reported having received any patient complaints related to this program.

32. The findings also reflect that PPH's telemedicine program has not increased overall abortion rates, but has enabled Iowa women to access abortion earlier in their pregnancy (thereby reducing the incidence of second-trimester abortions).[13] This effect demonstrates an important health improvement for women, because first-trimester abortion is safer than second-trimester abortion.[14] In fact, ACOG has recognized telemedicine provision of medication abortion as a promising strategy to reduce the incidence of second-trimester abortion more widely.[15]

33. These findings are consistent with other studies showing that increased travel times for patients can lead to delay in their obtaining an abortion. For example, a study of abortion in Washington state found that rural women who had to travel more than 75 miles to obtain an abortion were two to three times more likely than women travelling less than 75 miles to terminate after 12 weeks, and that after abortion became less available in Washington, "the proportion of rural women having their abortions at later than 18 weeks more than doubled... growing from 2% to 5%," and the proportion of rural women having abortions after 18 weeks was "significantly higher than that among their urban counterparts."[16]

---

[12] *Effectiveness and Acceptability* at 300.

[13] *Changes in Delivery Patterns* at 76.

[14] Linda A. Bartlett, et al., *Risk Factors for Legal Induced Abortion–Related Mortality in the United States*, 103(4) OBSTET. GYNECOL. 729, 731 (2004).

[15] Committee on Practice Bulletins-Gynecology, American College of Obstetricians and Gynecologists. Practice Bulletin No 135: Second-trimester abortion. 121(6) OBSTET. GYNECOL. 1394, 1400 (2013).

[16] Sharon A. Dobie et al., *Abortion Services in Rural Washington State, 1983-1984 to 1993-1994: Availability and Outcomes*, 31 FAM. PLAN. PERSP. 241, 243 (1999).

34. In addition, PPH staff reported that the telemedicine program, by reducing both patient and physician travel time, has led to fewer cancellations related to inclement weather and has afforded the clinics greater flexibility to accommodate the significant scheduling constraints of their patients.[17]

35. Based on these findings, it is my opinion that the Rule will make abortion less safe in Iowa, by delaying women and preventing some women from accessing medication abortion.

36. The Rule is likely to prevent some women from obtaining a medication abortion because they will not be able to travel to a physician-staffed clinic within the gestational range when medication abortion is available. This will deprive many women of a form of treatment that, in my experience, women often choose for deeply-felt personal reasons. For example, women may choose a medication abortion because they have experienced sexual trauma and wish to avoid a physical procedure that they would experience as re-traumatizing, or because medication abortion allows them to experience the abortion at home, in privacy, among a support system, and at a time of their choosing. Our study reflected that 71 percent of PPH patients who chose medication abortion over the covered time period reported a strong preference for this form of abortion.[18]

37. The Rule will also deprive women of an option that affords significant safety advantages in some cases. Some women have medical conditions that can make first-trimester surgical abortion extremely difficult, and for these women, medication abortion is the preferred method. These circumstances include situations that make it difficult for the provider to access

---

[17] *Qualitative Study* at e121.

[18] *Effectiveness and Acceptability* at 300

the pregnancy inside the uterus. Such cases may include women with cervical abnormalities, women who have been subjected to female genital mutilation, and women who are extremely obese, have uterine fibroids distorting normal anatomy, have a uterus that is very flexed, or have certain uterine anomalies, such as a bicornate uterus (a malformation where the upper portion forms two "horns" making the uterus appear somewhat heart-shaped). For these women, surgical abortion poses significantly higher risks of failed abortion, as well as complications such as perforation of the uterus.

38. Moreover, the Rule may prevent some women from obtaining an abortion altogether, particularly low-income women with limited access to transportation, work-leave and/or childcare. In addition to the other implications, this will expose them to the medical risks associated with continued pregnancy and childbirth, which are substantially greater than the risk associated with abortion.[19]

IV. Physical Exam

39. The Rule requires a "physical examination" by the physician in all cases. *See* § 13.10(2). This requirement is confusing, and in my opinion not medically necessary in any of its possible senses.

40. The phrase "physical examination" is confusing because it could refer to anything from vital signs, to obtaining ultrasound images, to a pelvic examination.

41. If it refers to a pelvic examination, this requirement is medically unnecessary in many cases and, in fact, positively harmful to patients. If a provider performs an ultrasound, as PPH does in every case, there is no medical need to perform a bimanual examination to estimate

[19] Elizabeth Raymond & David Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 OBSTET. GYNECOL. 215, 216 (2012).

uterine size, or palpation of adnexae (that is, a pelvic exam), for every medication abortion patient, because an ultrasound is a more accurate way to determine gestational age.

42. It is bad medicine to inflict an unnecessary, invasive exam on a patient at any time, much less at a time (as when she is having an abortion) when she may already be feeling vulnerable and fragile. A forced pelvic exam would be particularly harmful to patients who are survivors of rape or sexual abuse.

43. If the phrase "physical examination" refers to something else – like the taking of vital signs – this is already done by PPH and it need not be done by a physician. Indeed, such tasks are almost universally performed by non-physicians in all types of medical care. Of course, it is critical for a physician to review the vital signs, and this is done regardless of whether the physician is present with the patient or providing the service by telemedicine.

44. The Statement also states that the Board was motivated by concerns, which it does not specify, about the qualifications of the PPH staff that provide the ultrasound. It is unclear to me whether the Rule would require physicians to perform the ultrasound. If so, that would not be supported by the current standard of care. It is routine in reproductive health centers, including those providing prenatal care, to have ultrasounds performed by staff who have been trained in ultrasonography and who have demonstrated competency, as I understand is the case at PPH's clinics. The ultrasound machine itself (rather than a clinician) calculates gestational age based on measurements taken and documented by the ultrasonographer.

45. Nor is a physical exam necessary, or even helpful, to rule out other contraindications for medication abortion, such as advanced gestational age, ectopic pregnancy, anemia, or history of significant cardiovascular disease or renal failure. PPH already screens for these and other conditions, through: 1) a detailed medical history; 2) laboratory testing; and 3)

ultrasound. It is routine in all fields of medicine for non-physicians to take an initial medical history (to be confirmed by a physician, as PPH does), draw blood, and perform the ultrasound imaging. Requiring the physician to be physically present in the room with the patient would do nothing to improve PPH's patient screening process. What matters is that the physician reviews the laboratory results and ultrasound images, and confirms the patient's medical history, whether in person or by telemedicine.

V. Follow-up Care

46. Finally, the Statement speculates that the physician's physical presence "will strengthen the physician-patient relationship and result in improved and increased follow-up care of the patient." In fact, our research found telemedicine patients were slightly less likely to be lost to follow-up care, although this difference was not significant.[20]

47. PPH's protocol for following up after the patient has taken the medication, whether by telemedicine or otherwise, is to schedule an appointment two weeks later to confirm the termination of the pregnancy by ultrasound and screen for post-pregnancy problems. If the pregnancy has not terminated, the patient is given the option to take an additional dosage of misoprostol or to schedule a surgical completion at another PPH clinic. In my opinion, this is safe, adequate and within the standard of care.

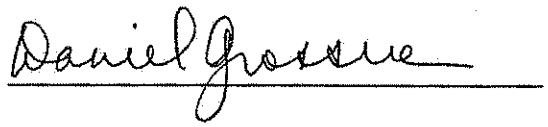
48. In our research, we saw more telemedicine patients returning for these appointments. The higher follow-up rate may be due to the increased convenience of coming to a closer clinic. Of the patients we interviewed in our study, 69 percent of those who chose

[20] *Effectiveness and Acceptability* at 298.

medication abortion via telemedicine reported that having an abortion close to home was very important to them.[21]

49. For all of the foregoing reasons, the Rule does not advance women's health. To the contrary, it harms women's health by imposing unnecessary regulations and banning an extremely safe and effective way of providing medication abortion to women who are underserved by the medical community.

Signed this 15th day of January 2014.



Daniel Grossman, MD

[21] *Effectiveness and Acceptability* at 300.

CALIFORNIA ALL-PURPOSE ACKNOWLEDGMENT

CIVIL CODE § 1189

State of California
County of Alameda

On Jan 15, 2014 (Date) before me, Lorenza G. Sandoval-Essl Notary Public (Here Insert Name and Title of the Officer),

personally appeared Daniel Aaron Grossman (Name(s) of Signer(s)),

LORENZA G. SANDOVAL-ESSL
Commission # 2004784
Notary Public - California
Alameda County
My Comm. Expires Jan 20, 2017

who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

Signature: (Signature of Notary Public)

Place Notary Seal Above

OPTIONAL

Though the information below is not required by law, it may prove valuable to persons relying on the document and could prevent fraudulent removal and reattachment of this form to another document.

Description of Attached Document

Title or Type of Document: Affidavit of Daniel Grossman, MD

Document Date: Jan. 15, 2014 Number of Pages: 16

Signer(s) Other Than Named Above:

Capacity(ies) Claimed by Signer(s)

Signer's Name:	Signer's Name:
☐ Corporate Officer — Title(s):	☐ Corporate Officer — Title(s):
☐ Individual	☐ Individual
☐ Partner — ☐ Limited ☐ General	☐ Partner — ☐ Limited ☐ General
☐ Attorney in Fact	☐ Attorney in Fact
☐ Trustee	☐ Trustee
☐ Guardian or Conservator	☐ Guardian or Conservator
☐ Other:	☐ Other:
Signer Is Representing:	Signer Is Representing:
RIGHT THUMBPRINT OF SIGNER — Top of thumb here	RIGHT THUMBPRINT OF SIGNER — Top of thumb here

© 2010 National Notary Association • NationalNotary.org • 1-800-US NOTARY (1-800-876-6827)

Item #5907

N

Effectiveness and Acceptability of Medical Abortion Provided Through Telemedicine

Daniel Grossman, MD, Kate Grindlay, MSPH, Todd Buchacker, RN, Kathleen Lane, and Kelly Blanchard, MSc

OBJECTIVE: To estimate the effectiveness and acceptability of telemedicine provision of early medical abortion compared with provision with a face-to-face physician visit at a Planned Parenthood affiliate in Iowa.

METHODS: Between November 2008 and October 2009, we conducted a prospective cohort study of women obtaining medical abortion by telemedicine or face-to-face physician visits. We collected clinical data, and women completed a self-administered questionnaire at follow-up. We also compared the prevalence of reportable adverse events between the two service delivery models among all patients seen between July 2008 and October 2009.

RESULTS: Of 578 enrolled participants, follow-up data were obtained for 223 telemedicine patients and 226 face-to-face patients. The proportion with a successful abortion was 99% for telemedicine patients (95% confidence interval [CI] 96–100%) and 97% for face-to-face patients (95% CI 94–99%). Ninety-one percent of all participants were very satisfied with their abortion, although in multivariable analysis, telemedicine patients had a higher odds of saying they would recommend the service to a friend compared with face-to-face patients (odds ratio, 1.72; 95% CI 1.26–2.34). Twenty-five percent of telemedicine patients said they would have preferred being in the same room with the doctor. Younger age, less education, and nulliparity were significantly associated with preferring face-to-face communication. There was no significant difference in the prevalence of adverse events reported during the study period among telemedicine patients (n=1,172) (1.3%; 95% CI 0.8–2.1%) compared with face-to-face patients (n=2,384) (1.3%; 95% CI 0.9–1.8%) (82% power to detect difference of 1.3%).

CONCLUSION: Provision of medical abortion through telemedicine is effective and acceptability is high among women who choose this model.

(Obstet Gynecol 2011;118:296–303)
DOI: 10.1097/AOG.0b013e318224d110

LEVEL OF EVIDENCE: II

Mifepristone was approved by the U.S. Food and Drug Administration in September 2000. Early medical abortion using mifepristone with misoprostol is effective and highly acceptable to U.S. women with some preferring it over vacuum aspiration.[1-3] Medical abortion is not a surgical procedure and can be offered by nonspecialist clinicians,[4] a fact that led some to believe that its availability would improve access to abortion services in the United States. However, a recent analysis found that almost all medical abortion-only providers were located within 50 miles of a large-volume surgical abortion provider.[5]

In approximately 15 states, certified nurse–midwives, physician assistants, and nurse practitioners are permitted to provide medical abortion.[6] In the remaining states, laws that limit provision of abortion to physicians have been applied (or assumed to apply) to medical abortion as well.

Telemedicine, the delivery of health care services at a distance using information and communication technology, has been used in many fields of medicine to improve access to services. For example, telemedicine has been used to provide specialist consultation to primary care services and to deliver rural outpa-

From Ibis Reproductive Health, Oakland, California, and Cambridge, Massachusetts; the Bixby Center for Global Reproductive Health, Department of Obstetrics, Gynecology and Reproductive Sciences, University of California San Francisco, San Francisco, California; Planned Parenthood of the Heartland, Des Moines, Iowa; Abortion Access Project, Cedar Rapids, Iowa.

Funded by a grant from an anonymous donor.

We thank Melanie Zurek for her input on study design as well as the clinic staff at each of the study sites who assisted with data collection.

Corresponding author: Daniel Grossman, MD, Ibis Reproductive Health, 1330 Broadway, Ste 1100, Oakland, CA 94612; e-mail: DGrossman@ibisreproductivehealth.org.

Financial Disclosure
The authors did not report any potential conflicts of interest.

© 2011 by The American College of Obstetricians and Gynecologists. Published by Lippincott Williams & Wilkins.
ISSN: 0029-7844/11

Copyright© American College of Obstetricians and Gynecologists

tient care, generally with patient outcomes that are comparable to in-person treatment.[7] In 2008, Planned Parenthood of the Heartland, a clinic network located in Iowa that provided 74% of all abortions in the state that year,[8] had 17 clinic sites. Three of these clinics had an on-site physician, whereas an additional three sites intermittently offered abortion care when a physician traveled to the clinic; the remaining 11 clinics did not provide abortions. In June 2008, Planned Parenthood of the Heartland launched a program to provide medical abortion using telemedicine at clinic sites not staffed by a physician to improve access to early abortion and reduce physician travel to outlying clinics. The objective of this study was to estimate the effectiveness and acceptability of the telemedicine provision model compared with the standard practice of a face-to-face visit with a physician.

MATERIALS AND METHODS

Between November 2008 and October 2009, women seeking medical abortion at six Planned Parenthood of the Heartland clinics in Iowa were invited to participate in the study. At four sites, medical abortion was offered only through telemedicine; at one site it was offered only with a face-to-face physician visit; and at one site both models were offered, depending on physician availability. Women seeking abortion at Planned Parenthood of the Heartland called a central call center, which gave them information about the nearest clinic and soonest appointment and informed them whether the service would be provided by telemedicine or not, and women selected the appointment they preferred. In the areas served by the telemedicine clinics, there was no other abortion clinic closer than the closest physician-staffed Planned Parenthood clinic. Once at the clinic, women who chose medical abortion and were eligible for the method (including being pregnant at 63 days gestation or less and not having other standard contraindications[9]), were 18 years old or older, able to speak English, and able to give informed consent were eligible to participate in the study.

Clinical information was collected at the participants' first clinic visit, including demographic information and gestational age according to ultrasonography. Participants were given the standard medical abortion regimen at the clinics: 200 mg mifepristone administered orally followed 24–48 hours later by 800 μg misoprostol administered buccally at home.[10] All women had ultrasonography performed by a trained technician, received information about medical abortion, and underwent standard informed consent for the abortion. A physical examination was not routinely done, consistent with the standard of care.[9] For face-to-face visit patients, one of two physicians reviewed the patient's medical history and ultrasonographic images and had a brief discussion with the patient. If the patient was eligible for a medical abortion, the physician handed her the mifepristone and misoprostol tablets, observed her swallow the mifepristone, and gave her final instructions. For those who received services through telemedicine, clinic staff uploaded the patient's medical history and ultrasonographic image to a secure server for the physician to review. One of the same two physicians then had a discussion with the patient using video teleconference equipment that was linked through a dedicated Multiprotocol Label Switching data connection. If the patient was eligible for medical abortion, the physician entered a password into her computer that remotely unlocked a drawer in front of the patient containing the mifepristone and misoprostol tablets. The physician observed her swallow the mifepristone and gave her final instructions through the video teleconference.

Women were scheduled for a follow-up visit within 2 weeks after receiving mifepristone. Pelvic ultrasonography was performed at follow-up to confirm completion of the abortion. If the abortion was incomplete, women were given the option of expectant management, additional misoprostol, or vacuum aspiration; ongoing pregnancies were treated with vacuum aspiration. If a telemedicine patient required a nonemergent vacuum aspiration, she was scheduled at a physician-staffed clinic for the procedure. If the abortion was not complete at the time of this visit, another visit was scheduled. Clinical information was collected at each follow-up visit, including the ultrasonographic result, any medications given, and whether a vacuum aspiration was performed. Effectiveness of medical abortion was defined as the proportion of women with a complete abortion not requiring a surgical procedure, including vacuum aspiration.

Once the abortion was complete, participants were asked to fill out a self-administered questionnaire focusing on their experience with the abortion service, including satisfaction with the service they received. If participants did not return for follow-up, they were contacted at least three times by phone and once by mail to schedule either an in-person follow-up visit or a telephone interview to complete the questionnaire. Information on adverse events was collected from participants at each follow-up visit or

Copyright© American College of Obstetricians and Gynecologists

during the telephone interview, and medical records from other facilities were reviewed when relevant.

All statistical analyses were performed using STATA 10.1. χ^2 analyses and t tests were used to compare study participants to all medical abortion patients aged 18 years or older seen during the study period to assess potential selection bias and to compare demographic, clinical, and acceptability information between telemedicine and face-to-face study participants. All analyses among cohort participants were conducted among women with complete follow-up information.

Univariable and multivariable analyses were conducted to identify potential associations between service delivery model (telemedicine compared with face-to-face) and the primary effectiveness and acceptability outcomes. To account for the possibility that a patient's experience might vary by the clinic she attended, clinic site was introduced into the multivariable model as a random effect, and the standard error was adjusted with a modified-sandwich estimator using STATA's vce (cluster clustervar) option for cluster-correlated data.[11,12] Automated forward selection was used to build the multivariable models with the entry level set at $P<.20$. Demographic and clinical covariates with univariable significance of $P<.20$ not entered during forward selection were next added to the model in order of ascending univariable P value and were included in the final model if their inclusion changed the predictor variable's effect estimate by 10% or more. Gestational age was forced into the multivariable model assessing effectiveness because of evidence that the prevalence of ongoing pregnancy after medical abortion increases with increasing gestational age.[1] Covariates were added using these rules up to the maximum number of allowable covariates in a multivariable model based on the rule: number of events/10.[13]

Sample size was based on the acceptability outcome of overall satisfaction, because we anticipated that effectiveness would be comparable between groups. We also anticipated that acceptability of the telemedicine service would be high but might be somewhat lower than the standard provision model. Assuming 90% of women in the standard provision group reported being satisfied or very satisfied with their experience,[10] a sample of 219 in each group was needed to detect a difference in acceptability among telemedicine patients of 10% or more (two-sided $\alpha=0.05$, power=80%). Recruitment was continued until the desired sample of participants with follow-up data was obtained.

Because of the relatively small sample size of the cohort study, we also analyzed deidentified data on all adverse events after medical abortion reported to the Planned Parenthood Federation of America and Danco Laboratories by Planned Parenthood of the Heartland between July 1, 2008 (shortly after telemedicine was initiated) and October 31, 2009 (shortly after cohort recruitment ended). Planned Parenthood affiliates are required to report the following adverse events: ongoing pregnancy, emergency room treatment, hospitalization, transfusion, unrecognized ectopic pregnancy, allergic reaction, infection requiring intravenous treatment, and death. We calculated the prevalence, 95% confidence intervals (CIs), and χ^2 analyses of any adverse event, ongoing pregnancy, or blood transfusion, comparing telemedicine with face-to-face patients during this period. We also conducted a multivariable analysis of any adverse event comparing telemedicine with face-to-face patients during this period adjusting for possible confounders.

All cohort study participants gave informed consent to participate in the study. They received a $10 gift card for completing the questionnaire. The study was approved by Allendale institutional review board.

RESULTS

The study flow diagram is shown in Figure 1. Fifty-six percent of patients aged 18 years or older seen during the study period were enrolled into the study. Reasons for nonparticipation were not collected, although study staff noted that fewer patients were enrolled on busy clinic days, possibly because staff did not have time to thoroughly explain the study. After excluding seven patients, 578 women were included in the cohort study. Among the 281 telemedicine patients, 205 (73%) had an in-person and 18 (6%) had a phone follow-up interview; 58 (21%) were lost to follow-up. Among the 297 face-to-face patients, 196 (66%) had an in-person and 30 (10%) had a phone follow-up interview; 71 (24%) were lost to follow-up. The proportion of patients that attended an in-person visit was not significantly different between the two groups ($P=.07$).

Age, marital status, and race were similar between cohort study participants and all patients receiving medical abortion aged 18 years or older seen during the study period. A lower proportion of study participants were Latina (4% compared with 7%, $P=.008$) and had a maximum completed education of 12 years or less (52% compared with 58%, $P=.03$). Table 1 shows the enrollment demographic and clinical information for cohort study participants with follow-up data. Among study participants, telemedicine and face-to-face patients were similar in terms of age, marital status, race, ethnicity, parity, and gesta-

Copyright© American College of Obstetricians and Gynecologists

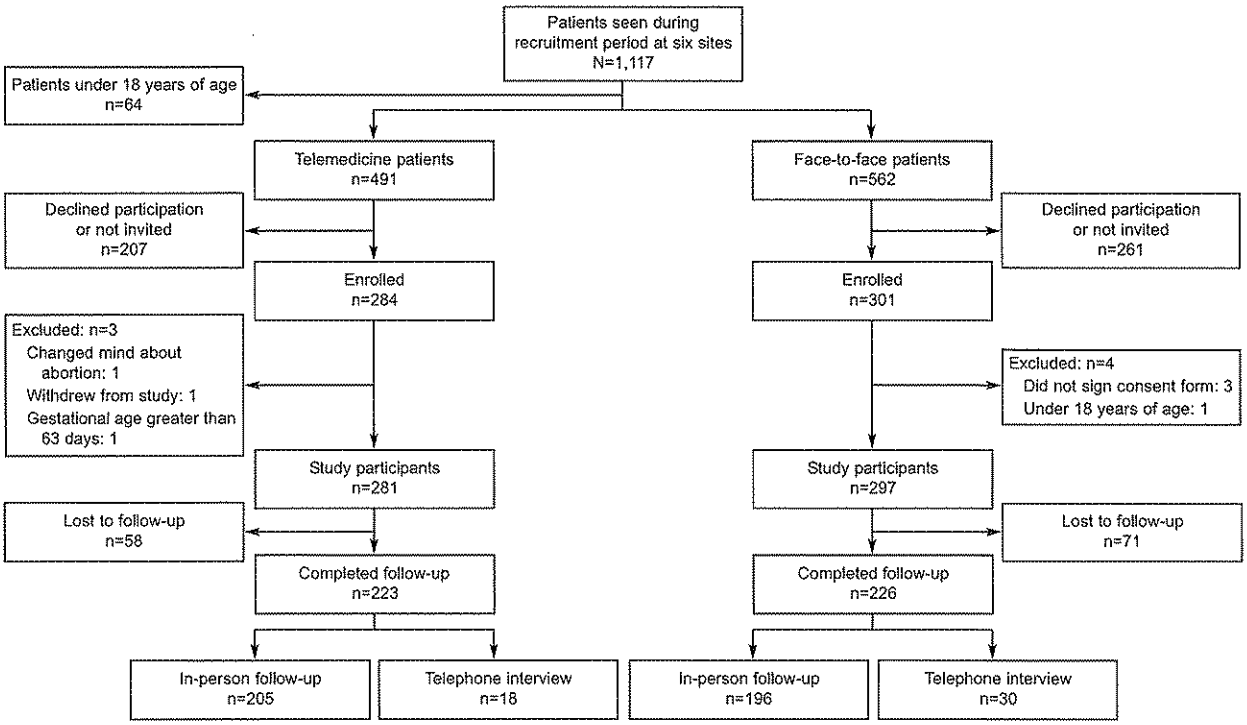


Fig. 1. Flow of patients through the study.
Grossman. Telemedicine Provision of Medical Abortion. Obstet Gynecol 2011.

tional age. Compared with telemedicine participants, more face-to-face participants had a maximum completed education of 12 years or less (58% compared with 46%, $P=.01$) and reported a prior abortion (38% compared with 26%, $P=.006$).

Follow-up information was obtained a median of 15 days after enrollment for those with in-person visits and 27 days after enrollment for those who had phone interviews. At follow-up, eight women (three telemedicine and five face-to-face patients) were given an additional dose of misoprostol and scheduled for a second follow-up visit.

Contraceptive uptake postabortion was slightly higher among participants with a face-to-face visit. Eighty-eight percent (n=199) of face-to-face participants and 80% (n=179) of telemedicine participants were given or had started a contraceptive method by the time of the follow-up visit or phone interview ($P=.02$). Use of specific contraceptive methods was not significantly different between the cohorts, except more face-to-face participants were given condoms (21% compared with 6%, $P<.001$) or had an intrauterine device inserted (23% compared with 12%, $P=.005$) at the follow-up visit.

Two of the 223 telemedicine patients underwent vacuum aspiration for ongoing pregnancy (n=1) or incomplete abortion (n=1), and one woman elected to continue an ongoing pregnancy for a total effectiveness of 98.7% (95% CI 96.1–99.5%). Six of the 226 face-to-face patients underwent vacuum aspiration and one underwent dilation and curettage for ongoing pregnancy (n=2) or incomplete abortion (n=5) for a total effectiveness of 96.9% (95% CI 93.7–98.5%). The odds of successful abortion with telemedicine compared with face-to-face provision was not significantly different in the multivariable model, which adjusted for within-cluster correlation and gestational age (odds ratio [OR] 2.34, 95% CI 0.84–6.55).

There were no deaths or hospitalizations among the cohort study participants. Adverse events, including emergency room visits and visits to other clinics, occurred among 2.5% of participants and were not statistically different between groups ($P=.78$). One telemedicine participant received a blood transfusion in an emergency room. The telemedicine participant who decided to continue with an ongoing pregnancy reported her child was normal at 7 months of age.

Table 2 shows the prevalence of adverse events among all patients undergoing medical abortion from July 1, 2008, to October 31, 2009. A total of 46 adverse events were reported (1.3% of 3,556 medical abortions). No deaths were reported. There was no

Copyright© American College of Obstetricians and Gynecologists

Table 1. Characteristics of Cohort Study Participants

	Telemedicine Cohort (n=223)	Face-to-Face Cohort (n=226)	*P*
Age (y)			.65
18–25	137 (61)	130 (58)	
26–35	71 (32)	77 (34)	
36–45	15 (7)	19 (8)	
Median	23	24	
Mean	24.9	25.7	.11
Marital status			.72
Single	163 (74)	164 (73)	
Married or partnered	35 (16)	42 (19)	
Divorced, widowed, or separated	22 (10)	20 (9)	
Latina or Hispanic	5 (2)	12 (5)	.09
Race			.85
White	179 (82)	182 (85)	
African American	28 (13)	22 (10)	
Asian American	5 (2)	4 (2)	
Other*	6 (3)	6 (3)	
Highest grade completed 12 y or less	102 (46)	130 (58)	.01
Median	13	12	
Mean	13.5	13.1	.01
Parous	112 (50)	133 (59)	.07
Mean	1.01	1.09	.49
Prior abortion	58 (26)	86 (38)	.006
Gestational age (d)			.79
49 or less	141 (63)	142 (63)	
50–56	53 (24)	50 (22)	
57–63	29 (13)	34 (15)	
Median	46	46	
Mean	46.7	47.1	.58

Data are n (%) unless otherwise specified.
* Other race includes women who reported more than one race and women who reported their race as Native American or Alaska Native.

significant difference in the prevalence of any adverse event, ongoing pregnancy, or blood transfusion between women who received services through telemedicine compared with face-to-face provision. With a one-sided α of 0.05, this sample size had 82% power to detect an increase in the prevalence of any adverse event from 1.3% among face-to-face patients to 2.6% among telemedicine patients. The odds of any adverse event among telemedicine compared with face-to-face patients was not significantly different in the multivariable model, which adjusted for within-cluster correlation, marital status, Latina ethnicity, and race (OR 0.96, 95% CI 0.48–1.91).

Table 2. Adverse Events Among All Medical Abortion Patients, July 1, 2008, Through October 31, 2009

	Telemedicine (n=1,172)	Face-to-Face (n=2,384)	*P*
Any adverse event	1.3 (0.8–2.1)	1.3 (0.9–1.8)	.96
Ongoing pregnancy	0.9 (0.5–1.7)	1.0 (0.6–1.4)	.94
Blood transfusion	0.3 (0.1–0.9)	0.1 (0.04–0.4)	.23

Data are % (95% confidence interval) unless otherwise specified.

Table 3 shows information on acceptability of abortion services. Overall satisfaction was very high among participants, although more telemedicine patients (94%) reported being very satisfied compared with face-to-face patients (88%), which was significantly different in the univariable analysis (P=.03). However, when adjusted for within-cluster correlation (no additional covariates met the multivariable model inclusion criteria), this difference was no longer significant (OR 2.10, 95% CI 0.75–5.92).

More telemedicine patients (90%) said they would recommend the medical abortion service to a friend in a similar situation than face-to-face patients (83%, P=.04). In the multivariable model, which adjusted for within-cluster correlation, age, education, and prior abortion, telemedicine patients had greater odds of saying they would recommend the service compared with face-to-face patients (OR 1.72, 95% CI 1.26–2.34).

Patients in both groups reported liking similar aspects of the service, including the staff (58%), information received (30%), and the fact that they did not feel judged (11%). A minority of patients reported dislikes, and a significantly higher proportion of face-to-face patients (32%) complained about the waiting time in the clinic compared with telemedicine patients (7%, P<.001).

We asked women several questions about the factors that influenced their decision about what abortion method to have and which clinic to go to. Seventy-one percent of participants said they strongly wanted medical abortion when they were making their decision (no difference between cohorts), and 94% of participants said having the abortion as early as possible was very important to them (no difference between cohorts). However, 69% of telemedicine patients said having the abortion close to home was very important compared with 58% of face-to-face patients (P=.02).

Three fourths of patients reported being satisfied with the conversation with the doctor (the video teleconference for those receiving telemedicine services), and this did not differ between the two groups (P=.89). Among telemedicine patients, 99% said it was easy to see the doctor, and 99% said it was easy to hear the doctor; 89% said they felt comfortable asking the doctor questions during the video teleconference.

Copyright© American College of Obstetricians and Gynecologists

Table 3. Acceptability of Abortion Services

	Telemedicine Cohort (n=214)	Face-to-Face Cohort (n=217)	*P*
Overall satisfaction			
Very satisfied	201 (94)	191 (88)	.03*
Somewhat satisfied	10 (5)	21 (10)	
Somewhat or very dissatisfied	1 (.5)	1 (.5)	
Not sure or no response	2 (1)	4 (2)	
Would recommend a medical abortion in this clinic to a friend	192 (90)	180 (83)	.04
What liked best (more than one response possible)			
Staff	128 (60)	123 (57)	.51
Information received	67 (31)	61 (28)	.47
Did not feel judged	20 (9)	27 (12)	.30
Other	18 (8)	20 (9)	.77
Felt comfortable	14 (7)	16 (7)	.74
Privacy and confidentiality	14 (7)	11 (5)	.51
Fast	11 (5)	11 (5)	.97
Nothing or no response	10 (5)	8 (4)	.61
What liked least (more than one response possible)			
Nothing or no response	148 (69)	110 (51)	<.001
Waiting time	16 (7)	70 (32)	<.001
Other†	50 (23)	37 (17)	.10
Information received			
Very helpful	195 (91)	202 (93)	.45‡
Somewhat or not helpful	16 (8)	13 (6)	
Not sure or no response	3 (1)	2 (1)	
Satisfaction with conversation with doctor			
Very satisfied	163 (76)	164 (76)	.89*
Somewhat satisfied	34 (16)	36 (17)	
Somewhat or very dissatisfied	11 (5)	6 (3)	
Not sure or no response	6 (3)	11 (5)	
Initial feelings about medical compared with surgical abortion			
Strongly wanted medical abortion	156 (73)	152 (70)	.51§
Leaning toward medical abortion	33 (15)	36 (17)	
Strongly wanted surgical abortion	2 (1)	2 (1)	
Leaning toward surgical abortion	2 (1)	5 (2)	
No strong feeling either way	19 (9)	19 (9)	
No response	2 (1)	3 (1)	
Feelings about importance of having abortion close to home			
Very important	147 (69)	126 (58)	.02‖
Somewhat important	38 (18)	50 (23)	
Not important	21 (10)	31 (14)	
Not sure or no response	8 (4)	10 (5)	
Feelings about importance of having an early abortion			
Very important	202 (94)	202 (93)	.58‖
Somewhat important	8 (4)	10 (5)	
Not important or not sure	4 (2)	5 (2)	
Easy to see doctor during telemedicine encounter			
Yes	211 (99)		
No	3 (1)		
Easy to hear doctor during telemedicine encounter			
Yes	212 (99)		
No	2 (1)		
Comfortable asking questions during telemedicine encounter			
Yes	190 (89)		
No	24 (11)		
Would prefer doctor in room instead of telemedicine			
Yes	53 (25)		
No	154 (73)		
No response	5 (2)		

Data are n (%) unless otherwise specified.

* *P* value for very satisfied compared with not very satisfied.

† Other includes: staff (nine), telemedicine (nine), not enough information received (eight), having abortion (seven), lack of privacy (seven), distance (six), partner could not attend visit (five), and general (36).

‡ *P* value for very helpful compared with not very helpful.

§ *P* value for strongly wanted medical abortion compared with other responses.

‖ *P* value for very important compared with not very important.

Copyright© American College of Obstetricians and Gynecologists

One fourth of telemedicine patients said they would have preferred being in the same room with the doctor. Participants were allowed to write in comments about this response, which generally indicated that although they would have preferred to be in the same room, because that was not an option, they were satisfied with the video teleconference. These open responses are representative of some of the comments participants gave: "I am always generally more comfortable dealing with serious issues in person" and "It was rather irritating, but probably faster/more convenient. (I'm a face to face person)."

In multivariable analysis, the following covariates were associated with a preference for being in the same room with the physician: age 18–25 years (compared with 26 years or older; OR 1.58, 95% CI 1.20–2.09); education 12 years or less (compared with more than 12 years; OR 1.80, 95% CI 1.51–2.14); and nulliparous (compared with parous; OR 1.71, 95% CI 1.15–2.54).

DISCUSSION

We found that provision of medical abortion through telemedicine had comparable clinical outcomes to the face-to-face provision model with equivalent success rates and a low prevalence of adverse events. Both the high success rate and low prevalence of adverse events for the telemedicine service are similar to those reported for medical abortion in the literature.[1,10,14] Although contraceptive uptake was slightly higher among the face-to-face cohort, this was most likely the result of the limited number of providers trained to insert intrauterine devices at telemedicine sites.

Acceptability was high among both groups of women in this study, and these results were similar to other studies on medical abortion with buccal misoprostol.[10,15] We found one measure of acceptability—willingness to recommend the service to a friend—to be significantly higher among telemedicine patients, even after controlling for confounders. The fact that telemedicine patients reported high levels of satisfaction may be related to the convenience of receiving services closer to home or earlier in pregnancy, both of which were important for this group. Our results do not indicate that telemedicine patients were coerced to have a medical abortion despite this being the only method available at the clinics they accessed, because a high proportion reported strongly wanting medical abortion from the outset, and this did not differ from face-to-face patients. The fact that telemedicine patients had a restricted choice at the clinics they attended, if anything, might have biased them to have lower levels of satisfaction compared with face-to-face patients, who also had the option of aspiration abortion.

We found that 25% of telemedicine patients would have preferred a face-to-face visit with the physician, and this was more common among younger, less educated, and nulliparous women. Another study of clinic-based medical abortion found that older age was an independent predictor of a positive experience, whereas education level was not.[16] In our study, participants were told at the time they scheduled their appointment whether they would receive abortion services through telemedicine or not. It seems that some decided to have the abortion through telemedicine perhaps because the clinic was closer to their home or because they could get an appointment sooner, although ideally they would have preferred to be in the same room with the physician. This finding highlights the importance of informing women about what the telemedicine service involves so patients can weigh the options about which service they prefer.

This study has several limitations. Participants were not randomized and instead selected the treatment they received (telemedicine compared with a face-to-face visit), which might have introduced selection bias. However, because this was the first study of telemedicine provision of medical abortion, we felt it was important for women to be well informed of the two provision models and be allowed to choose which they preferred. In the future, a randomized controlled trial might be possible among women who have no real preference between the two models as has been done to compare medical and surgical abortion.[17,18] Overall, 56% of patients aged 18 years or older seen during the study period agreed to participate in the cohort study, and participants were somewhat more educated and less likely to be Latina than the general medical abortion clinic population. This might have introduced selection bias, although the acceptance rate likely affected both cohorts similarly. In addition, 22% of participants were lost to follow-up despite multiple attempts to contact them. Although this loss to follow-up is high, it is similar to proportions reported in the literature[19] and did not differ between cohorts. Finally, our results are specific to the provision models offered in this clinic system, and we cannot generalize our findings to other service delivery settings.

In states where physicians are required to perform medical abortion, the findings from this study indicate that telemedicine can be used to provide medical abortion in an effective and highly acceptable manner. Future research should evaluate whether

Copyright© American College of Obstetricians and Gynecologists

telemedicine provision improves access to services for women in rural areas as well as whether there are cost savings associated with the model. Just as telemedicine has been used to extend the reach of physicians in other disciplines, this provision model has the potential to provide abortion services earlier in pregnancy and closer to a woman's home and to help overcome the barriers to abortion access in the United States.[20]

REFERENCES

1. Spitz IM, Bardin CW, Benton L, Robbins A. Early pregnancy termination with mifepristone and misoprostol in the United States. N Engl J Med 1998;338:1241–7.
2. Winikoff B, Ellertson C, Elul B, Sivin I. Acceptability and feasibility of early pregnancy termination by mifepristone-misoprostol. Results of a large multicenter trial in the United States. Mifepristone Clinical Trials Group. Arch Fam Med 1998;7:360–6.
3. Fjerstad M, Trussell J, Sivin I, Lichtenberg ES, Cullins V. Rates of serious infection after changes in regimens for medical abortion. N Engl J Med 2009;361:145–51.
4. Yarnall J, Swica Y, Winikoff B. Non-physician clinicians can safely provide first trimester medical abortion. Reprod Health Matters 2009;17:61–9.
5. Finer LB, Wei J. Effect of mifepristone on abortion access in the United States. Obstet Gynecol 2009;114:623–30.
6. Berer M. Provision of abortion by mid-level providers: international policy, practice and perspectives. Bull World Health Organ 2009;87:58–63.
7. Wade VA, Karnon J, Elshaug AG, Hiller JE. A systematic review of economic analyses of telehealth services using real time video communication. BMC Health Serv Res 2010;10:233.
8. Iowa Department of Public Health, Bureau of Vital Statistics. 2009 vital statistics of Iowa. Des Moines (IA): Iowa Department of Public Health; 2010.
9. Creinin M, Gemzell Danielsson K. Medical abortion in early pregnancy. In: Paul M, Lichtenberg ES, Borgatta L, Grimes DA, Stubblefield P, Creinin M, eds. Management of unintended and abnormal pregnancy. West Sussex (UK): Blackwell Publishing Ltd; 2009. p. 111–34.
10. Winikoff B, Dzuba IG, Creinin MD, Crowden WA, Goldberg AB, Gonzales J, et al. Two distinct oral routes of misoprostol in mifepristone medical abortion: a randomized controlled trial. Obstet Gynecol 2008;112:1303–10.
11. Williams RL. A note on robust variance estimation for cluster-correlated data. Biometrics 2000;56:645–6.
12. Froot KA. Consistent covariance matrix estimation with cross-sectional dependence and heteroskedasticity in financial data. J Financial Quantitative Anal 1989;24:333–55.
13. Peduzzi P, Concato J, Kemper E, Holford TR, Feinstein AR. A simulation study of the number of events per variable in logistic regression analysis. J Clin Epidemiol 1996;49:1373–9.
14. von Hertzen H, Huong NT, Piaggio G, Bayalag M, Cabezas E, Fang AH, et al; WHO Research Group on Postovulatory Methods of Fertility Regulation. Misoprostol dose and route after mifepristone for early medical abortion: a randomised controlled noninferiority trial. BJOG 2010;117:1186–96.
15. Middleton T, Schaff E, Fielding SL, Scahill M, Shannon C, Westheimer E, et al. Randomized trial of mifepristone and buccal or vaginal misoprostol for abortion through 56 days of last menstrual period. Contraception 2005;72:328–32.
16. Teal SB, Dempsey-Fanning A, Westhoff C. Predictors of acceptability of medication abortion. Contraception 2007;75:224–9.
17. Robson SC, Kelly T, Howel D, Deverill M, Hewison J, Lie ML, et al. Randomised preference trial of medical versus surgical termination of pregnancy less than 14 weeks' gestation (TOPS). Health Technol Assess 2009;13:1–124, iii–iv.
18. Kelly T, Suddes J, Howel D, Hewison J, Robson S. Comparing medical versus surgical termination of pregnancy at 13–20 weeks of gestation: a randomized controlled trial. BJOG 2010;117:1512–20.
19. Clark W, Bracken H, Tanenhaus J, Schweikert S, Lichtenberg ES, Winikoff B. Alternatives to a routine follow-up visit for early medical abortion. Obstet Gynecol 2010;115:264–72.
20. Jones RK, Kooistra K. Abortion incidence and access to services in the United States, 2008. Perspect Sex Reprod Health 2011;43:41–50.

Copyright© American College of Obstetricians and Gynecologists

0

Significant Adverse Events and Outcomes After Medical Abortion

Kelly Cleland, MPA, MPH, Mitchell D. Creinin, MD, Deborah Nucatola, MD, Montsine Nshom, MPH, and James Trussell, PhD

OBJECTIVE: To analyze rates of significant adverse events and outcomes in women having a medical abortion at Planned Parenthood health centers in 2009 and 2010 and to identify changes in the rates of adverse events and outcomes between the 2 years.

METHODS: In this database review we analyzed data from Planned Parenthood affiliates that provided medical abortion in 2009 and 2010 almost exclusively using an evidence-based buccal misoprostol regimen. We evaluated the incidence of six clinically significant adverse events (hospital admission, blood transfusion, emergency department treatment, intravenous antibiotics administration, infection, and death) and two significant outcomes (ongoing pregnancy and ectopic pregnancy diagnosed after medical abortion treatment was initiated). We calculated an overall rate as well as rates for each event and identified changes between the 2 years.

RESULTS: Among 233,805 medical abortions provided in 2009 and 2010, significant adverse events or outcomes were reported in 1,530 cases (0.65%). There was no statistically significant difference in overall rates between years. The most common significant outcome was ongoing intrauterine pregnancy (0.50%); significant adverse events occurred in 0.16% of cases. One patient death occurred as a result of an undiagnosed ectopic pregnancy. Only rates for emergency department treatment and blood transfusion differed by year and were slightly higher in 2010.

CONCLUSION: Review of this large data set reinforces the safety of the evidence-based medical abortion regimen.

(Obstet Gynecol 2013;121:166–71)

DOI: http://10.1097/AOG.0b013e3182755763

LEVEL OF EVIDENCE: III

First-trimester abortion with medications rather than surgery is widely used throughout the world, primarily using a combination of mifepristone and misoprostol. Extensive experience with medical abortion has proven it to be highly effective and safe.[1–6] Like with surgical abortion, complications with medical abortion are relatively infrequent. The low probability of clinically significant adverse events and outcomes and varying protocols make it difficult to estimate these rates without a very large patient population.

Planned Parenthood is a large, multisite provider of women's health care whose health centers have offered medical abortion as an option since 2001.[6] Most Planned Parenthood affiliates (accredited by the Planned Parenthood Federation of America) operate several health centers; some health centers within one affiliate may offer medical abortion services, whereas others may not. At Planned Parenthood health centers that offer medical abortion, this option is available up to and including 63 days of gestation (assuming that state regulations do not restrict health care providers to the U.S. Food and Drug Administration [FDA]–approved regimen).

All Planned Parenthood affiliates are required to follow the Planned Parenthood Federation of America Manual of Medical Standards and Guidelines as a condition of accreditation. The 2009 and 2010 guidelines outlined three acceptable medical abortion regimens using mifepristone and misoprostol (Table 1)

From the Office of Population Research, Princeton University, Princeton, New Jersey; the Department of Obstetrics and Gynecology, University of California, Davis, Sacramento, California; Planned Parenthood Federation of America, New York, New York; and The Hull York Medical School, University of Hull, Hull, United Kingdom.

Supported in part by the Eunice Kennedy Shriver *National Institute of Child Health and Human Development grant for Infrastructure for Population Research at Princeton University, grant R24HD047879 (J.T.).*

The authors thank Mimi Tannen, NP, and Elizabeth Talmont, MSN, NP, of the Planned Parenthood Federation of America (PPFA) for their work related to the medical abortion adverse event reporting system and database.

Corresponding author: Kelly Cleland, MPA, MPH, 218 Wallace Hall, Princeton University, Princeton, NJ 08648; e-mail: kcleland@princeton.edu.

Financial Disclosure

Dr. Creinin receives compensation from Danco Laboratories, LLC, the distributor of mifepristone in the United States, for providing third-party telephone consults to clinicians who call for expert advice on mifepristone. The other authors did not report any potential conflicts of interest.

© 2012 by The American College of Obstetricians and Gynecologists. Published by Lippincott Williams & Wilkins.

ISSN: 0029-7844/13

Copyright© American College of Obstetricians and Gynecologists

Table 1. Medical Abortion Regimens Provided at Planned Parenthood Health Centers in 2009 and 2010*

Regimen†	Gestational Limit (Up to and Including)	Mifepristone	Misoprostol	
			Days After Mifepristone	Dosage
FDA-approved	49 d	Three 200-mg tablets, orally, in office	2 (only if needed)	Two 200-microgram tablets, orally, in office
Evidence-based, oral misoprostol	49 d	One 200-mg tablet, orally, in office	1	Four 200-microgram tablets (split into two doses over 2 h), orally, at home
Evidence-based, buccal misoprostol	63 d	One 200-mg tablet, orally, in office	1 or 2	Four 200-microgram tablets, bucally, at home

FDA, U.S. Food and Drug Administration.
* Follow-up appointment scheduled within 2 weeks of mifepristone ingestion for all regimens.
† All medical abortion regimens required that patients start a course of antibiotics on the day mifepristone was administered. Patients received 100 mg doxycycline orally twice a day for 7 days; if a patient was allergic to doxycycline, acceptable alternatives included 1 g azithromycin orally, 500 mg erythromycin base orally four times a day for 7 days, 800 mg erythromycin ethylsuccinate orally four times a day for 7 days, 300 mg ofloxacin twice a day for 7 days, or 500 mg levofloxacin orally once a day for 7 days.
Data from Planned Parenthood. *Manual of Medical Standards and Guidelines.* New York (NY); 2009 and 2010 (unpublished document).

including the FDA-approved regimen and two evidence-based regimens. All three regimens required that patients start a course of antibiotics the day they took mifepristone and that a follow-up appointment be scheduled within 2 weeks of mifepristone (Planned Parenthood Federation of America Manual of Medical Standards and Guidelines, 2009 and 2010). Planned Parenthood Federation of America internal data from affiliate surveys indicate that at least 99% of the medical abortions performed during 2009 and 2010 followed the evidence-based buccal regimen.

Planned Parenthood Federation of America has a centralized reporting mechanism for significant adverse events and outcomes after medical abortion, which allows a large number of patient outcomes to be assessed through routine reporting. The primary objective of this study was to analyze rates of significant adverse events and outcomes in women having a medical abortion at Planned Parenthood health centers in 2009 and 2010. We also sought to identify changes in the rates of adverse events and outcomes between the 2 years, overall and separately for each event or outcome.

METHODS

This analysis includes data obtained from Planned Parenthood affiliates that provided medical abortion from January 1, 2009, through December 31, 2010. The total number of medical and surgical abortions provided by Planned Parenthood affiliates is collected by the Planned Parenthood Federation of America national office through quarterly and annual summary reports. Abortion in the first trimester is defined as occurring through the 12th week of pregnancy. This study was approved by Allendale investigational review board.

Planned Parenthood health center staff are trained in accurate and complete reporting of significant adverse events and outcomes after medical abortion, and such reporting is centralized through the Planned Parenthood Federation of America national office. Since 2005, the Planned Parenthood Federation of America accreditation process has included auditing to verify that significant adverse events and outcomes related to the use of mifepristone for medical abortion are reported as required. In accordance with the mifepristone prescribing information, Planned Parenthood Federation of America reports all significant adverse events and outcomes to Danco Laboratories, the U.S. distributor of mifepristone, which in turn reports them to the FDA.

Planned Parenthood health center staff collect information about significant adverse events and outcomes after medical abortion from different sources including routine follow-up visits, reports from clinicians providing care at hospital inpatient units or emergency departments, or voluntary reports by patients. The 2009 and 2010 Planned Parenthood Federation of America Manual of Medical Standards and Guidelines included requirements to emphasize the importance of the follow-up visit to all patients, and staff members were required to make three attempts (two in writing) to reach patients who did not return for follow-up. Despite substantial effort to follow up with patients, complete information on the proportion of women who did not return for follow-up as well as any complications they may have experienced is not available.

During the study period, protocols for providing medical abortion and reporting significant adverse

Copyright© American College of Obstetricians and Gynecologists

events and outcomes remained consistent, with the exception that beginning in July 2010, affiliates had the ability to submit reports through a secure web-based system in addition to submitting reports by fax. We analyzed reports of significant adverse events and outcomes after medical abortion, and rates were evaluated for both years together as well as individually for 2009 and 2010. We excluded 2010 data from one affiliate (that had reported only two cases of adverse events or outcomes) which as of September 2010 was no longer a member of Planned Parenthood Federation of America. Because delays in reporting adverse events and outcomes are common, we could not be certain that all adverse events and outcomes that may have occurred at this affiliate during the first 9 months of 2010 had been adequately reported.

Per the Danco Laboratories Mifepristone Prescriber's Agreement, "adverse events, such as hospitalization, blood transfusion, ongoing pregnancy, or other major complications after the use of Mifeprex and misoprostol must be reported to Danco Laboratories."[7] In this report, we evaluate six clinically significant adverse events (hospital admission, blood transfusion, emergency department treatment, intravenous antibiotics administration, infection requiring treatment with intravenous antibiotics or admission to the hospital, and death) and two significant outcomes (ongoing intrauterine pregnancy and ectopic pregnancy diagnosed after medical abortion treatment was initiated) after medical abortion. In this analysis, blood transfusion is binary (whether or not blood products were administered) because not all reports included the specific components or amount.

The Planned Parenthood Federation of America Manual of Medical Standards and Guidelines defined ongoing pregnancy as "a living, viable pregnancy that is growing. For example, the ultrasound scan shows a fetal pole with cardiac activity or a gestational sac that has grown appropriately since mifepristone was given" (Planned Parenthood Federation of America Manual of Medical Standards and Guidelines, 2009 and 2010). The Planned Parenthood Federation of America Manual of Medical Standards and Guidelines permitted use of a repeat dose of misoprostol when the initial follow-up evaluation demonstrated an ongoing pregnancy up to and including 63 days of gestation. In this analysis, if a repeat dose of misoprostol was successful, the case was not included as an ongoing pregnancy.

Categories of significant adverse events and outcomes are not mutually exclusive; in some cases, one problem could be counted as more than one event or outcome. For example, if a patient with a serious infection was admitted to the hospital and treated with intravenous antibiotics, this case would be counted in each of the three outcome categories.

We calculated 95% exact binomial confidence intervals for rates and used Fisher's exact test to test the statistical significance of differences in proportions. Two-sided P values of $<.05$ were considered to be indication of statistical significance. All calculations were performed using Stata SE 11.

RESULTS

As of December 31, 2010, Planned Parenthood Federation of America included 85 independent affiliates operating 810 health centers in 49 states and the District of Columbia; 39% (324) of health centers provided abortion care, and nearly all of these (97.8% [317]) offered medical abortion. In 2009, 314,772 first-trimester abortions were provided by Planned Parenthood Federation of America affiliates, 35% of which were medical abortions. In 2010, medical abortion comprised 38% of the 320,991 first-trimester abortions. Overall, in 2009 and 2010, medical abortion comprised 37% of all first-trimester abortions provided by Planned Parenthood health centers.

Among the 233,805 medical abortions provided at Planned Parenthood health centers in 2009 and 2010, significant adverse events or outcomes were reported in 1,530 (0.65%) cases. There was no statistically significant difference in overall rates between years ($P=.29$). Rates for each significant adverse event and outcome are shown in Table 2. A clinically significant adverse event occurred in 0.16% of cases; this rate did not differ by year. A clinically significant outcome occurred in 0.5% of cases (with no difference by year). Of importance is the rarity of an undiagnosed ectopic pregnancy, which occurred at a rate of 0.7 per 10,000 medical abortions. The most common significant adverse event or outcome after medical abortion during the study period, ongoing intrauterine pregnancy, was reported in 0.50% of cases for both years combined. Among 1,158 ongoing intrauterine pregnancies, 1,095 (94.6%) were known to be terminated surgically, and 63 (5.4%) were either lost to follow-up or patients indicated that they would continue or were considering continuing the pregnancy.

The only adverse event rates that differed in statistical significance in bivariate models between 2009 and 2010 were emergency department treatment (0.07% [n=87] compared with 0.12% [n=151], respectively, $P=.001$) and blood transfusion (0.04% [n=42] compared with 0.06% [n=72], respectively, $P=.024$). There was one death, as a result of an undiagnosed ectopic pregnancy, for a mortality rate of 0.4 per 100,000 over the 2-year study period.

Copyright© American College of Obstetricians and Gynecologists

Table 2. Rates of Significant Adverse Events and Outcomes After Medical Abortion, 2009 and 2010*

Event	No. of Cases	Rate (%)†	95% Confidence Interval	P‡
All significant adverse events and outcomes				
Any significant adverse event or outcome	1,530	0.65	0.62–0.69	.293
2009	706	0.63	0.59–0.68	
2010	824	0.67	0.62–0.72	
Significant adverse events				
Any significant adverse event	385	0.16	0.15–0.18	.092
2009	166	0.15	0.13–0.17	
2010	219	0.18	0.16–0.20	
Emergency department treatment	238	0.10	0.09–0.11	.001
2009	87	0.07	0.06–0.10	
2010	151	0.12	0.10–0.14	
Hospital admission	135	0.06	0.05–0.07	.343
2009	70	0.06	0.05–0.08	
2010	65	0.05	0.04–0.07	
Transfusion§	114	0.05	0.04–0.06	.024
2009	42	0.04	0.03–0.05	
2010	72	0.06	0.05–0.07	
Intravenous antibiotics	57	0.02	0.02–0.03	.292
2009	23	0.02	0.01–0.03	
2010	34	0.03	0.02–0.04	
Infection	37	0.016	0.011–0.021	.254
2009	14	0.013	0.001–0.021	
2010	23	0.019	0.001–0.028	
Significant outcomes				
Any significant outcome	1,174	0.50	0.47–0.53	.953
2009	556	0.50	0.46–0.54	
2010	618	0.50	0.46–0.54	
Ongoing intrauterine pregnancy	1,158	0.50	0.47–0.52	.929
2009	548	0.49	0.45–0.54	
2010	610	0.50	0.46–0.54	
Ectopic pregnancy	16	0.007	0.004–0.011	1.00
2009	8	0.007	0.003–0.014	
2010	8	0.007	0.003–0.013	

* Events are not mutually exclusive.
† Denominator is all medical abortions; n=111,022 in 2009, n=122,783 in 2010, and N=233,805 for 2009 and 2010 combined.
‡ Difference between 2009 and 2010 rates.
§ Transfusion is any blood product transfusion, regardless of the number of units.

DISCUSSION

As the largest provider of abortion care in the United States, Planned Parenthood Federation of America is in a unique position to provide reliable, large-scale data on the efficacy and safety of abortion procedures. The data presented here reinforce the infrequency of clinically significant adverse events and outcomes after medical abortion. The vast majority (99.34%) of medical abortions provided at Planned Parenthood health centers in 2009 and 2010 were completed with no known complications. Clinically significant adverse outcomes were rare, occurring at a rate of 16 per 10,000 medical abortions. The most common significant adverse event or outcome reported was ongoing intrauterine pregnancy, occurring in 0.5% of all medical abortion procedures.

Ongoing pregnancy is reportable to Danco Laboratories per the Mifepristone Prescriber's Agreement. Because it is the efficacy metric for medical abortion, data on ongoing intrauterine pregnancy should be reported and reviewed. However, ongoing intrauterine pregnancy is not a complication that is related to the safety of medical abortion the same way serious infection or blood transfusion is. The risk associated with ongoing pregnancy is tied to the potential teratogenicity of misoprostol.[8,9] Continuing pregnancy is of clinical significance only if it is unrecognized through follow-up and the patient does not have a surgical abortion.

Although we present data for ongoing pregnancy rates, we are unable to assess an overall "failure rate" for the 2-year reporting period. Treatment failure encompasses all reasons for a dilation and curettage,

Copyright© American College of Obstetricians and Gynecologists

including incomplete abortion. Although incomplete abortion managed outside the Planned Parenthood health center is reportable when it is tied to an adverse event (ie, treatment in the emergency department or hospital), incomplete abortion managed at the health center is not. Therefore, we have data only on rates of surgical evacuation for ongoing pregnancy.

Ectopic pregnancy diagnosed after medical abortion treatment was initiated was extremely rare with a rate even lower than the likelihood of maternal death during delivery.[10] Our study includes only ectopic pregnancies that were diagnosed after the medical abortion regimen had begun, not those diagnosed during the initial screening process. One death occurred during the study period as a result of an undiagnosed ectopic pregnancy.

The overall rate for all clinically significant adverse events and outcomes combined did not differ between 2009 and 2010 nor did the rate for most of these events differ by year. Exceptions were emergency department treatment and blood transfusion, both of which were higher in 2010 than in 2009. Because each health center has different local resources available, and patients may travel from more rural areas to some health centers, emergency department treatment may be related to where the original service was provided. Patients who drove for several hours to a health center to obtain care might be more likely to need emergency department treatment for a complication because of less access to a health center for any urgent issue. We do not have any data regarding locale of patients to compare whether emergency department treatment or blood transfusion is related to distance from home to the health center.

The findings in this article are of timely significance because some states in the United States have passed or are considering legislation to restrict mifepristone and misoprostol use to the FDA-approved regimen. The largest U.S. trial of mifepristone and misoprostol using the FDA-approved regimen through 49 days of gestation showed an ongoing pregnancy rate of 1% among 827 women.[11] The 92% efficacy rate of the FDA-approved regimen[11,12] is lower than the 96% efficacy rate for the evidence-based regimen using buccal misoprostol through 63 days of gestation.[13] This current large database analysis reinforces the low ongoing pregnancy rate when using one 200-mg mifepristone tablet and buccal misoprostol.

Potential limitations to this analysis should be considered. The data analyzed in this article are those reported to or received by Planned Parenthood Federation of America; we cannot exclude the possibility that some clinically significant adverse events or outcomes were not included. Some patients may have experienced a significant adverse event or outcome but did not follow up after their medical abortion. Additionally, despite intensive efforts at training affiliate and national office staff in procedures for reporting significant adverse events and outcomes, there remains the potential for human error and omission in the reporting process. Additionally, because experiencing, treating, and reporting an adverse event is subjective, an event may not always reflect the severity of the condition, but rather the concern of the patient. Similarly, treatments with blood products and intravenous antibiotics for the same condition may vary substantially among physicians or institutions.

The last potential limitation to consider is the lack of information available about women who did not experience a significant adverse event or outcome. Detailed information about patient age and gestational age (but no other demographic information) is collected through the Planned Parenthood Federation of America reporting system only for those women with significant adverse events or outcomes after medical abortion. Therefore, we are unable to analyze rates of significant adverse events and outcomes based on patient age, gestational age, or other demographic variables or to identify the exact regimens used in the 232,275 medical abortions with no reported complications. Despite these potential limitations, the findings in this study confirm that evidence-based medical abortion is highly effective and extremely safe.

The FDA allows and encourages off-label use of registered products when existing medical evidence supports such use.[14] The data presented in this article contribute to existing information in the medical literature; all of this evidence, taken together, does not support legislation restricting providers to use of the FDA-approved regimen. Every woman deserves factual medical information whenever she is faced with a decision of whether to terminate her pregnancy.[15] Mandating the FDA-approved regimen, without a scientific basis, does not protect patients from unsafe abortion; it only limits access to safe and effective medical abortion for women desiring a pregnancy termination. This review of Planned Parenthood Federation of America's medical abortion data confirms the safety and efficacy of medical abortion and should be taken into consideration both by clinicians and legislators when considering policy and protocols related to abortion.

REFERENCES

1. Medical management of abortion. ACOG Practice Bulletin No. 67. American College of Obstetricians and Gynecologists. Obstet Gynecol 2005;106:871–82.

Copyright© American College of Obstetricians and Gynecologists

2. Henderson J, Hwang A, Harper C, Stewart F. Safety of mifepristone abortions in clinical use. Contraception 2005;72:175–8.
3. Sitruk-Ware R. Mifepristone and misoprostol sequential regimen side effects, complications and safety. Contraception 2006;74:48–55.
4. Bartz D, Goldberg A. Medication abortion. Clin Obstet Gynecol 2009;52:140–50.
5. Fjerstad M, Sivin I, Lichtenberg ES, Trussell J, Cleland K, Cullins V. Effectiveness of medical abortion with mifepristone and buccal misoprostol through 59 gestational days. Contraception 2009;80:282–6.
6. Fjerstad M, Trussell J, Sivin I, Lichtenberg ES, Cullins V. Rates of serious infection after changes in regimens for medical abortion. N Engl J Med 2009;361:145–51.
7. Mifeprex Prescribing Information. Available at: http://www.earlyoptionpill.com/section/health_professionals/prescribing_information/. Retrieved June 20, 2012.
8. Orioli I, Castilla E. Epidemiological assessment of misoprostol teratogenicity. Br J Obstet Gynaecol 2000;107:519–23.
9. Brasil R, Coelho H, D'Avanzo B, La Vecchia C. Misoprostol and congenital anomalies. Pharmacoepidemiol Drug Saf 2000;9:401–3.
10. Berg CJ, Callaghan WM, Syverson C, Henderson Z. Pregnancy-related mortality in the United States, 1998 to 2005. Obstet Gynecol 2010;116:1302–9.
11. Spitz I, Bardin C, Benton L, Robbins A. Early pregnancy termination with mifepristone and misoprostol in the United States. N Engl J Med 1998;338:1241–7.
12. Comparison of two doses of mifepristone in combination with misoprostol for early medical abortion: a randomised trial. World Health Organisation Task Force on Post-ovulatory Methods of Fertility Regulation. BJOG 2000;107:524–30.
13. Winikoff B, Dzuba IG, Creinin MD, Crowden WA, Goldberg AA, Gonzales J, et al. Two distinct oral routes of misoprostol in mifepristone medical abortion: a randomized controlled trial. Obstet Gynecol 2008;112:1303–10.
14. Use of approved drugs for unlabeled indications. FDA Drug Bull 1982;12:4–5.
15. Creinin MD. Abortion, pregnancy, and public health. Obstet Gynecol 2012;119:212–4.

OBSTETRICS & GYNECOLOGY

Maintenance of Certification Articles

Maintenance of Certification is a program of the American Board of Obstetrics and Gynecology (ABOG; http://www.abog.org). All articles from the reading lists for the current year will be listed on the *Obstetrics & Gynecology* web site at the beginning of January, April, and July.

To access the lists, go to **www.greenjournal.org** and click on the "ABOG MOC II" tab.

Links to content are provided, as well as an indication of the article's status (ie, available by subscription only or open access).

rev 12/2011

Copyright© American College of Obstetricians and Gynecologists

P

Trends in Ectopic Pregnancy Mortality in the United States

1980–2007

Andreea A. Creanga, MD, PhD, Carrie K. Shapiro-Mendoza, PhD, MPH, Connie L. Bish, PhD, MPH, Suzanne Zane, DVM, Cynthia J. Berg, MD, MPH, and William M. Callaghan, MD, MPH

OBJECTIVE: To estimate trends in ectopic pregnancy mortality and examine characteristics of recently hospitalized women who died as a result of ectopic pregnancy in the United States.

METHODS: We used 1980–2007 national birth and death certificate data to calculate ectopic pregnancy mortality ratios (deaths per 100,000 live births) overall and stratified by maternal age and race. We performed nonparametric tests for trend to assess changes in ectopic pregnancy mortality over time and calculated projected mortality ratios for 2013–2017. Ectopic pregnancy deaths among hospitalized women were identified from 1998–2007 Nationwide Inpatient Sample data.

RESULTS: Between 1980 and 2007, 876 deaths were attributed to ectopic pregnancy. The ectopic pregnancy mortality ratio declined by 56.6%, from 1.15 to 0.50 deaths per 100,000 live births between 1980–1984 and 2003–2007; at the current average annual rate of decline, this ratio will further decrease by 28.5% to 0.36 ectopic pregnancy deaths per 100,000 live births by 2013–2017. The ectopic pregnancy mortality ratio was 6.8 times higher for African Americans than whites and 3.5 times higher for women older than 35 years than those younger than 25 years during 2003–2007. Of the 76 deaths among women hospitalized between 1998 and 2007, 70.5% were tubal pregnancies; salpingectomy was performed in 80.6% of cases. Excessive hemorrhage, shock, or renal failure accompanied 67.4% of ectopic pregnancy deaths among hospitalized women.

CONCLUSION: Despite a significant decline in ectopic pregnancy mortality since the 1980s, age disparities, and especially racial disparities, persist. Strategies to ensure timely diagnosis and management of ectopic pregnancies can further reduce related mortality and age and race mortality gaps.

(Obstet Gynecol 2011;117:837–43)
DOI: 10.1097/AOG.0b013e3182113c10

See related articles on pages 828, 850, and 948.

From the Epidemic Intelligence Service, Office of Workforce and Career Development, and the Division of Reproductive Health, Centers for Disease Control and Prevention, Atlanta, Georgia.

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Corresponding author: Andreea A. Creanga, MD, PhD, Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, 4770 Buford Highway, NE, Mail Stop K-23, Atlanta GA 30341-3717; e-mail: acreanga@cdc.gov.

Financial Disclosure
The author did not report any potential conflicts of interest.

© 2011 by The American College of Obstetricians and Gynecologists. Published by Lippincott Williams & Wilkins.
ISSN: 0029-7844/10

An ectopic pregnancy occurs when a fertilized ovum implants outside the endometrial cavity. Although only 1% to 2% of all pregnancies in the United States are ectopic,[1,2] this condition has important health consequences and represents an important cause of morbidity and mortality for women of reproductive age. Specifically, affected women are not only exposed to complications from the ectopic pregnancy itself and the related treatment procedures, but are also at greater risk of another ectopic pregnancy and future infertility.[3,4]

Medical and surgical treatment of ectopic pregnancy is currently provided in both inpatient and outpatient settings. For this reason, obtaining reliable estimates for the incidence of ectopic pregnancy at the national level is difficult.[3] The latest such estimate of 19.7 ectopic pregnancies per 1,000 pregnancies was reported for 1990–1992 using inpatient National Hospital Discharge Survey and outpatient National Hospital Ambulatory Medical Care Survey data.[5] More recent attempts to estimate ectopic pregnancy incidence used data from surveys or administrative databases of public and private insurance and managed care systems.[3,6,7] Although not nationally representative, these data suggest that incidence of ectopic

Copyright© American College of Obstetricians and Gynecologists

pregnancy has not changed substantially in the United States since the early 1990s. Complications of ectopic pregnancy were associated with approximately 13.0% of all maternal deaths between 1970 and 1989[8] and 6.0% of all pregnancy-related deaths between 1991 and 1999.[1] This decline in proportionate mortality is likely attributable to technological advances (eg, more sensitive human chorionic gonadotropin assays, improved ultrasound equipment and techniques) in the diagnosis and treatment of this condition.[4,6,9] Using national vital statistics data from 1991–1999, Grimes estimated an ectopic pregnancy mortality rate of 31.9 per 100,000 ectopic pregnancies and found that relative to a woman's risk of dying after a live birth, a woman with an ectopic pregnancy was 4.5 times more likely to die.[10]

This study's objectives were to: 1) estimate trends in ectopic pregnancy mortality in the United States between 1980 and 2007; 2) estimate age and racial disparities in ectopic pregnancy mortality; and 3) describe sociodemographic and clinical characteristics of recently hospitalized women who died from ectopic pregnancy complications.

MATERIALS AND METHODS

We used national multiple cause-of-death mortality and natality data from death and birth certificates in the National Vital Statistics System to calculate ectopic pregnancy mortality ratios (deaths per 100,000 live births) overall and stratified by maternal age and race. We identified ectopic pregnancy deaths by searching the records for all deaths occurring in the 50 states and the District of Columbia: 1) during 1980–1998 that contained International Classification of Diseases, 9th Revision codes 633.x; and 2) during 1999–2007 that contained International Classification of Diseases, 10th Revision codes O00.x as a contributing cause of death. Codes for ectopic pregnancy included: 633.0 and O00.0 (abdominal pregnancy), 633.1 and O00.1 (tubal pregnancy), 633.2 and O00.2 (ovarian pregnancy), 633.8 and O00.8 (other ectopic pregnancy, ie, cervical, combined, corneal, intraligamentous, mesometric, mural), and 633.9 and O00.9 (unspecified ectopic pregnancy) based on International Classification of Diseases, 9th Revision and International Classification of Diseases, 10th Revision, respectively. Women were grouped into four age categories: younger than 25, 25–29, 30–34, and 35 years or older; for consistency over the entire study period, the race-specific analysis was limited to two race groups: whites and African Americans. Because age- and race-specific annual mortality ratios based on small numbers of deaths (20 or fewer) are considered unreliable,[11] we calculated 5-year moving averages to smooth the data and gain stability with a minimal loss of information. Cuzick nonparametric tests for trend across ordered groups were performed to assess the statistical significance of changes in mortality ratios over time.[12] We used the 5-year moving averages to calculate the average annual percent change in ectopic pregnancy mortality ratios overall and by maternal age and race, and, through linear extrapolation, to project changes in ectopic pregnancy mortality ratios over the next 10 years (ie, by 2013–2017).

To describe characteristics of hospitalized women who died from ectopic pregnancy complications, we used 1998–2007 Nationwide Inpatient Sample hospital discharge data obtained from the Healthcare Cost and Utilization Project.[13] The Nationwide Inpatient Sample is the largest all-payer inpatient care database publicly available in the United States. The sampling "universe" for the Nationwide Inpatient Sample is comprised of US hospitals defined as "nonfederal general and specialty hospitals with average lengths of stay less than 30 days and whose facilities are open to the public."[13] The Nationwide Inpatient Sample sampling frame uses five strata: type of ownership, number of hospital beds, teaching status, urban or rural location, and country region; all hospital discharges are retained in all Nationwide Inpatient Sample sampled hospitals. Each year, the Nationwide Inpatient Sample collects data from a 20% stratified sample of hospitals in the United States; thus, derived analytic weights can be used to provide national-level estimates. Hospital discharge diagnoses and clinical procedures in the Nationwide Inpatient Sample data are classified using the International Classification of Diseases, 9th Revision, Clinical Modification codes.

Using the Nationwide Inpatient Sample data, we identified all records with an ectopic pregnancy discharge diagnosis (633.xx) and at least one corresponding clinical procedural code for operations on fallopian tubes (66.0x, 66.2x, 66.3x, 66.4, 66.5x, 66.6x,), removal of extratubal ectopic pregnancy (74.3), or injection of a cancer chemotherapeutic substance to account for the use of methotrexate (99.25). Of these, records from women who died during their hospitalization for an ectopic pregnancy were included in the analysis. Univariable analyses were conducted to examine women's age, recorded clinical diagnoses and treatment procedures, the length of hospital stay, and the total in-hospital care charges in US dollars.

Both National Vital Statistics System and Nationwide Inpatient Sample data are publicly available and neither source includes personal identifiers. Thus,

Copyright© American College of Obstetricians and Gynecologists

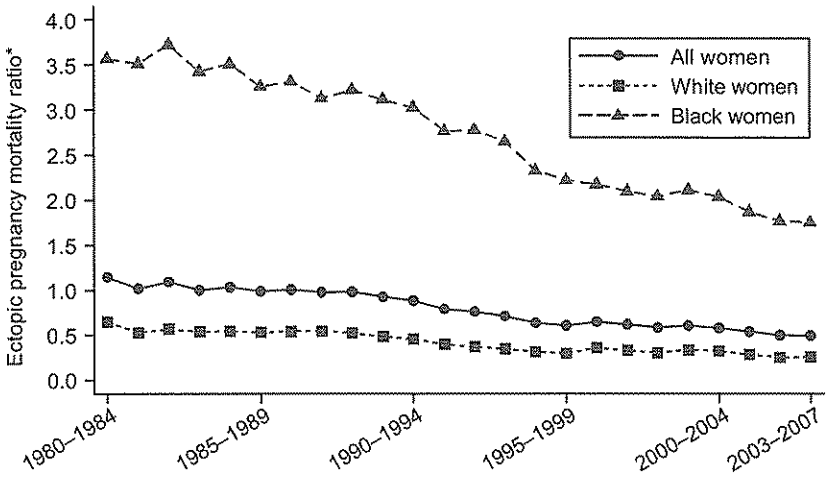


Fig. 1. Trends in ectopic pregnancy mortality for all women and by race: United States, 1980–2007. *Each data point represents a 5-year moving average expressed per 100,000 live births. X-axis labels are shown for every fifth data point and for the last data point.
Creanga. Ectopic Pregnancy Mortality Trends. Obstet Gynecol 2011.

institutional review board approval was not required. All statistical analyses were conducted using STATA 10. The analysis using Nationwide Inpatient Sample data were adjusted for complex survey design using Taylor's linearization method.

RESULTS

According to death certificate data, 876 deaths in the United States were attributable to ectopic pregnancy between 1980 and 2007. The ectopic pregnancy mortality ratio declined significantly by 56.6% during the study period ($P<.001$) from 1.15 to 0.50 deaths per 100,000 live births when comparing 1980–1984 and 2003–2007, respectively (Fig. 1). Although over the same period of time ectopic pregnancy mortality ratio declined by 60.4% ($P<.001$) among white women, the corresponding decrease was 50.8% ($P<.001$) among African American women, from 0.65 to 0.26 deaths per 100,000 live births among whites and from 3.57 to 1.75 deaths per 100,000 live births among African American women. Thus, the ectopic pregnancy mortality ratio was 5.5 (95% confidence interval [CI] 5.3–5.8) times higher for African American compared with white women during 1980–1984 and 6.8 (95% CI 6.5–7.3) times greater during 2003–2007.

By and large, the ectopic pregnancy mortality was higher among older than younger women and declined for women of all ages between 1980–1984 and 2003–2007 (Fig. 2). The pattern of decline also varied with maternal age. We observed an overall continuous decline in mortality resulting from ectopic pregnancy for women younger than 30 years and a less consistent, but, nonetheless, important decline for older women. Of note, women 35 years and older had the highest reduction in ectopic pregnancy mortality between the two time periods (68.8%). Specifically, between 1980–1984 and 2003–2007, the ectopic

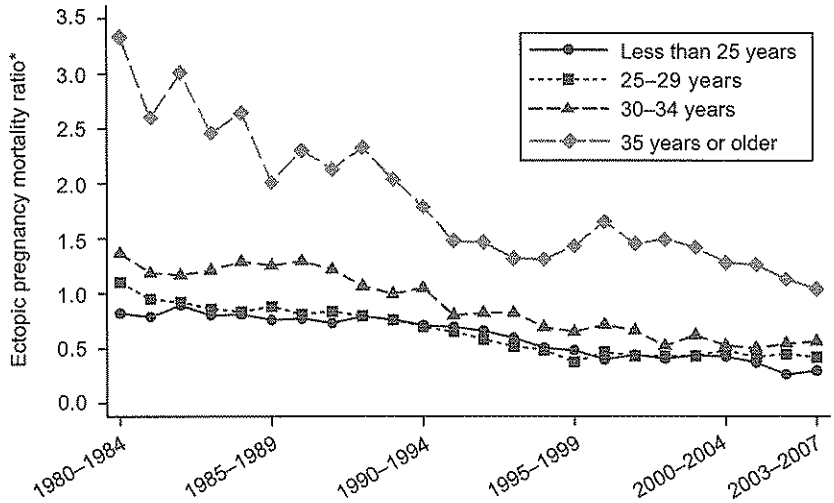


Fig. 2. Trends in ectopic pregnancy mortality by age group: United States, 1980–2007. *Each data point represents a 5-year moving average expressed per 100,000 live births. X-axis labels are shown for every fifth data point and for the last data point.
Creanga. Ectopic Pregnancy Mortality Trends. Obstet Gynecol 2011.

Copyright© American College of Obstetricians and Gynecologists

pregnancy mortality ratio declined from 0.82 deaths to 0.30 deaths per 100,000 live births among women younger than 25 years and from 1.10 deaths to 0.42 deaths per 100,000 live births among women 25–29 years of age. Among women 30–34 years, the level of ectopic pregnancy mortality fluctuated between a maximum ectopic pregnancy mortality ratio of 1.37 deaths per 100,000 live births in 1980–1984 and a minimum of 0.50 deaths per 100,000 live births in 2001–2005, and reached 0.56 deaths per 100,000 live births in 2003–2007. Ectopic pregnancy mortality ratios varied even more among the oldest group of women (35 years and older), from a high 3.33 deaths per 100,000 live births in 1980–1984 to 1.04 deaths per 100,000 live births in 2003–2007. Tests for trend for all trends described here were statistically significant at a level $P<.001$. Based on the most recent point estimate (2003–2007), women 25–29, 30–34, and 35 years or older were 1.4 (95% CI 0.8–2.0; this estimate is not statistically significant but it is clinically important), 1.9 (95% CI 1.3–2.5), and 3.5 (95% CI 3.0–4.1) times more likely to die as a result of complications of ectopic pregnancy than women younger than 25 years.

We calculated the observed (1980–2007) and projected (2013–2017) changes in ectopic pregnancy mortality ratios (Table 1). During the study period, the estimated average annual percent decrease in the ectopic pregnancy mortality ratio was 3.3% for all women, higher for whites (3.5%) than for African Americans (2.8%) and for women in the highest and lowest age groups (4.1% and 3.6%, respectively) than for women 25–29 years (3.5%) and 30–34 years of age (3.1%). If the current average annual rate of decline in ectopic pregnancy mortality ratio in the United States continues, the ratio will further decline by 28.5% by 2013–2017 to 0.36 ectopic pregnancy deaths per 100,000 live births, less so for African Americans (24.9%) and for women 30–34 years (27.1%) but more for whites and for women in the other age groups (29.6–33.9%).

Seventy-six deaths resulting from ectopic pregnancy complications were identified using Nationwide Inpatient Sample hospital discharge data between 1998 and 2007. The median age of the women was 33 years (range 13–43 years). A majority of women (81.8%) were admitted to a hospital from the emergency department. Women were hospitalized for a median of 1 day, with the length of hospital stay ranging from 0 to 74 days. Approximately 7 in 10 women (70.5%) had tubal pregnancies, and salpingectomy was performed in 80.6% of hospitalized patients; of note, no identified patient received treatment with methotrexate. More than two thirds (67.4%) of hospitalized women experienced either excessive hemorrhage, shock, or renal failure.

DISCUSSION

Using the most recent mortality data available, this analysis provides national trends in ectopic pregnancy mortality and describes age- and race-specific mortality patterns for 1980–2007. During this period, ectopic pregnancy mortality declined significantly to a 5-year national average ectopic pregnancy mortality ratio of 0.50 per 100,000 live births and an average of approximately 21 ectopic pregnancy deaths annually between 2003 and 2007. Technologic changes including widespread use of progressively more sensitive pregnancy tests, ultrasound examination, and laparoscopy have likely contributed to an earlier and more accurate diagnosis of ectopic pregnancy,[1,4,6,9] and, in turn, to the observed reduction in ectopic pregnancy mortality. Greater awareness of ectopic pregnancy on the part of women and physicians, earlier intervention, and less invasive treatment for unruptured ectopic pregnancies may be additional contributing factors to this decline in mortality. To the extent that efforts to increase awareness of ectopic pregnancy and knowledge of its risk factors, diagnosis, and treatment, in tandem with access to care and better methods of early treatment, contributed to the observed decrease in ectopic pregnancy mortality, this

Table 1. Observed and Projected Changes in Ectopic Pregnancy Mortality Ratios for All Women and by Race and Age Group: United States

		Race		Age Group (y)			
Indicator	All Women	White	African American	Younger Than 25	25–29	30–34	35 or Older
Average annual decline in EPMR during 1980–2007	3.3	3.5	2.8	3.6	3.5	3.1	4.1
Overall projected decline in EPMR between 2003–2007 and 2013–2017	28.5	29.6	24.9	30.9	30.1	27.1	33.9

EPMR, ectopic pregnancy mortality ratio.
Data are %.

Copyright© American College of Obstetricians and Gynecologists

trend represents a successful integration of public health and clinical medicine.

Despite the general downward trend in ectopic pregnancy mortality, age disparities, and especially racial disparities, persist. Age disparities in ectopic pregnancy mortality are not surprising given that incidence of ectopic pregnancy also increases with age.[7,14] Biologic explanations for such variation in ectopic pregnancy incidence rates are anatomic and functional age-related changes of the fallopian tubes as well as repeated pelvic inflammatory disease that may induce tubal damages and predispose women to ectopic pregnancy[15]; use of assisted reproductive technologies[16] and tubal ligation[17] are also higher among women older than 35 years. Of note, the identified age disparity in ectopic pregnancy mortality is consistent with findings from other studies examining all-cause pregnancy-related deaths in the United States.[1,18] For example, Chang et al[1] report that relative to women in their 20s, those 35–39 and older than 40 years were 2.5 and 5.3 times more likely, respectively to experience a pregnancy-related death between 1991 and 1999.

Like previous ectopic pregnancy mortality trend analyses,[8,14] our results indicate that African American women are more likely to die as a result of ectopic pregnancy complications than white women. Between 2003 and 2007, African American women were approximately 6.8 times more likely than white women to die as a consequence of an ectopic pregnancy, whereas the all-cause maternal mortality rate for the same time period was only 2.7–3.7 times higher for African Americans than for whites.[19–23] Whether this considerable African American–white gap in ectopic pregnancy mortality is the result of an increased ectopic pregnancy incidence or to a higher case-fatality rate among African Americans than whites is unknown. Data from 1986 showed that the risk of ectopic pregnancy among African Americans was 1.6 times higher than among white women.[14] If this difference did not change greatly over time, then it appears that African Americans do have a higher ectopic pregnancy case-fatality rate than whites. Such a conclusion is in line with findings reported by Tucker et al[24]; they used 1988–1999 national data to calculate prevalence and case-fatality rates for preeclampsia, eclampsia, abruptio placentae, placenta previa, and postpartum hemorrhage among African American and white women and found that the higher pregnancy-related mortality from these causes among African American women was largely attributable to higher case-fatality rates. Both the higher ectopic pregnancy mortality and the higher case-fatality rate among African Americans relative to whites might be explained by higher rates of late entry into or no prenatal care,[25,26] lower health insurance coverage,[27] and lower education attainment[28] for African American women compared with white women. All these considered, it is unlikely that a single intervention can eliminate the African American–white gap in ectopic pregnancy mortality, because disparities likely stem from a combination of causes.

The Nationwide Inpatient Sample data add some new information to the limited clinical information on hospitalized women in the United States dying from ectopic pregnancy. Despite the relatively small number of cases identified, we found that complications such as hemorrhage, shock, and renal failure accompanied an important proportion of these cases. Overall, the 76 ectopic pregnancy deaths identified in the 1998–2007 Nationwide Inpatient Sample data represent 34.9% of all ectopic pregnancy deaths captured by national mortality data during the same period. Thus, almost two thirds of all ectopic pregnancy deaths in the United States appear to have occurred in the emergency department, in transit to a hospital, or outside the hospital. Atrash et al[29] examined ectopic pregnancy deaths in the United States between 1970 and 1983 and found that approximately 59% of the women dying did so in a hospital; yet, their analysis preceded the increase in outpatient management of ectopic pregnancy.[30]

Our analysis is not without limitations. First, identification and correct classification of ectopic pregnancy deaths depends on having complete and accurate cause of death information on death certificates. Because maternal death in the United States is a rare event, physicians may not be as familiar with completion of death certificates for women dying as a result of maternal causes.[31] Thus, if not all ectopic pregnancy deaths were identified as such (eg, deaths that occurred without surgical intervention or autopsy were more likely to be missed), our ectopic pregnancy mortality ratios represent underestimates of the true mortality ratios. Comparative analyses using national mortality data and one or more other sources of data on maternal mortality demonstrate that no single data source can capture all maternal deaths.[32] We compared our data against that compiled for the Centers for Disease Control and Prevention's Pregnancy-Related Mortality Surveillance System for the period between 1991 and 1999; whereas 237 ectopic pregnancy deaths were captured through surveillance by the Centers for Disease Control and Prevention,[1] our analysis using multiple cause-of-death data iden-

Copyright© American College of Obstetricians and Gynecologists

tified 257 ectopic pregnancy deaths during the same period of time; both data sources aim to capture deaths at the national level. Second, misclassification of race on death certificates may have resulted in either under- or overestimates of race-specific ectopic pregnancy mortality ratios; moreover, as a result of data limitations, we could not examine ectopic pregnancy mortality among other racial and ethnic groups over the entire study period.

Research has shown that approximately half of all women with an ectopic pregnancy diagnosis do not have any known risk factors.[33] Therefore, early detection and treatment of ectopic pregnancies is, therefore, the most effective way to ensure that outcomes occur at a less severe point along the continuum and to reduce related hospitalization, morbidity, and mortality. Because most ectopic pregnancies are diagnosed during the first trimester of pregnancy,[29] early prenatal care or contact with a physician is highly important in preventing ectopic pregnancy deaths because it provides an opportunity for early diagnosis and treatment of this condition. This aspect appears to be especially important for African American women who tend to have less prenatal care and initiate their antenatal care visits later.[25,26] Thus, measures to educate the public (ie, through media, health education in schools, during patient–clinician interactions) regarding ectopic pregnancy are needed, particularly targeting women at risk of ectopic pregnancy and ectopic pregnancy mortality, including African American and older women of reproductive age. In addition, continued surveillance and studies tracking trends in ectopic pregnancy incidence and mortality should be conducted to monitor the burden from ectopic pregnancy, identify risk factors, and develop strategies to prevent women with ectopic pregnancy from dying.

REFERENCES

1. Chang J, Elam-Evans LD, Berg CJ, Herndon J, Flowers L, Seed KA, Syverson CJ. Pregnancy-related mortality surveillance–United States, 1991–1999. MMWR Surveill Summ 2003;52:1–8.
2. Saraiya M, Berg CJ, Shulman H, Green CA, Atrash HK. Estimates of the annual number of clinically recognized pregnancies in the United States, 1981–1991. Am J Epidemiol 1999;149:1025–9.
3. Zane SB, Kieke BA Jr, Kendrick JS, Bruce C. Surveillance in a time of changing health care practices: estimating ectopic pregnancy incidence in the United States. Matern Child Health J 2002;6:227–36.
4. Barnhart KT. Clinical practice. Ectopic pregnancy. N Engl J Med 2009;361:379–87.
5. Centers for Disease Control and Prevention (CDC). Ectopic pregnancy–United States, 1990–1992. MMWR Morb Mortal Wkly Rep 1995;44:46–8.
6. Van Den Eeden SK, Shan J, Bruce C, Glasser M. Ectopic pregnancy rate and treatment utilization in a large managed care organization. Obstet Gynecol 2005;105:1052–7.
7. Hoover KW, Tao G, Kent CK. Trends in the diagnosis and treatment of ectopic pregnancy in the United States. Obstet Gynecol 2010;115:495–502.
8. Goldner TE, Lawson HW, Xia Z, Atrash HK. Surveillance for ectopic pregnancy–United States, 1970–1989. MMWR CDC Surveill Summ 1993;42:73–85.
9. Anderson FW, Hogan JG, Ansbacher R. Sudden death: ectopic pregnancy mortality. Obstet Gynecol 2004;103:1218–23.
10. Grimes DA. Estimation of pregnancy-related mortality risk by pregnancy outcome, United States, 1991 to 1999. Am J Obstet Gynecol 2006;194:92–4.
11. Hoyert DL. Maternal mortality and related concepts. Vital Health Stat 3 2007;33:1–13. Available at: www.cdc.gov/nchs/data/series/sr_03/sr03_033.pdf.
12. Cuzick J. Wilcoxon-type test for trend. Stat Med 1985;4:87–90.
13. Healthcare Cost and Utilization Project Databases. Rockville (MD): Agency for Healthcare Research and Quality; 2010. Available at: www.hcup-us.ahrq.gov/nisoverview.jsp.
14. Lawson HW, Atrash HK, Saftlas AF, Finch EL. Ectopic pregnancy in the United States, 1970–1986. MMWR CDC Surveill Summ 1989;38:1–10.
15. Soper DE. Pelvic inflammatory disease. Obstet Gynecol 2010;116:419–28.
16. Sunderam S, Chang J, Flowers L, Kulkarni A, Sentelle G, Jeng G, et al; Centers for Disease Control and Prevention (CDC). Assisted reproductive technology surveillance–United States, 2006. MMWR Surveill Summ 2009;58:1–25.
17. Mosher WD, Jones J. Use of contraception in the United States: 1982–2008. Vital Health Stat 23 2010;29:1–44. Available at: www.cdc.gov/nchs/data/series/sr_23/sr23_029.pdf.
18. Callaghan WM, Berg CJ. Pregnancy-related mortality among women 35 years and older, United States, 1991–1997. Obstet Gynecol 2003;102:1015–21.
19. Hoyert DL, Heron MP, Murphy SL, Kung HC. Deaths: final data for 2003. Natl Vital Stat Rep 2006;54:1–120. Available at: www.cdc.gov/nchs/data/nvsr/nvsr54/nvsr54_13.pdf.
20. Miniño AM, Heron MP, Murphy SL, Kochanek KD. Deaths: final data for 2004. Natl Vital Stat Rep 2007;55:1–119. Available at: www.cdc.gov/nchs/data/nvsr/nvsr55/nvsr55_19.pdf.
21. Kung HC, Hoyert DL, Xu J, Murphy SL. Deaths: final data for 2005. Natl Vital Stat Rep 2008;56:1–120. Available at: www.cdc.gov/nchs/data/nvsr/nvsr56/nvsr56_10.pdf.
22. Heron M, Hoyert DL, Murphy SL, Xu J, Kochanek KD, Tejada-Vera B. Deaths: final data for 2006. Natl Vital Stat Rep 2009;57:1–134. Available at: www.cdc.gov/nchs/data/nvsr/nvsr57/nvsr57_14.pdf.
23. Xu J, Kochanek KD, Murphy SL, Tejada-Vera B. Deaths: final data for 2007. Natl Vital Stat Rep 2010;58:1–73. Available at: www.cdc.gov/nchs/data/nvsr/nvsr58/nvsr58_19.pdf.
24. Tucker MJ, Berg CJ, Callaghan WM, Hsia J. The Black–White disparity in pregnancy-related mortality from 5 conditions: differences in prevalence and case-fatality rates. Am J Public Health 2007;97:247–51.
25. Martin JA, Hamilton BE, Sutton PD, Ventura SJ, Mathews TJ, Kirmeyer S, et al. Births: final data for 2007. Natl Vital Stat Rep 2010;58:1–85. Available at: www.cdc.gov/nchs/data/nvsr/nvsr58/nvsr58_24.pdf.
26. National Center for Health Statistics. Health, United States, 2009: With Special Feature on Medical Technology. Hyatts-

Copyright© American College of Obstetricians and Gynecologists

ville (MD): National Center for Health Statistics; 2010. Available at: www.cdc.gov/nchs/data/hus/hus09.pdf.

27. US Census Bureau. Income, Poverty, and Health Insurance Coverage in the United States: 2007. Current Population Reports. 2009. Available at: www.census.gov/prod/2008pubs/p60-235.pdf.
28. US Census Bureau. Educational Attainment in the United States: 2007. Current Population Reports. 2009. Available at: www.census.gov/prod/2009pubs/p20-560.pdf.
29. Atrash HK, Friede A, Hogue CJ. Ectopic pregnancy mortality in the United States, 1970–1983. Obstet Gynecol 1987;70:817–22.
30. Loffer FD. Outpatient management of ectopic pregnancies. Am J Obstet Gynecol 1987;156:1467–72.
31. MacKay AP, Berg CJ, Duran C, Chang J, Rosenberg H. An assessment of pregnancy-related mortality in the United States. Paediatr Perinat Epidemiol 2005;19:206–14.
32. Centers for Disease Control (CDC). Ectopic pregnancy–United States, 1987. MMWR Morb Mortal Wkly Rep 1990;39:401–4.
33. Barnhart KT, Sammel MD, Gracia CR, Chittams J, Hummel AC, Shaunik A. Risk factors for ectopic pregnancy in women with symptomatic first-trimester pregnancies. Fertil Steril 2006;86:36–43.

OBSTETRICS & GYNECOLOGY

Standards for Different Types of Articles

Guidelines for five different types of articles have been adopted by *Obstetrics & Gynecology*:

1. CONSORT (Consolidated Standards of Reporting Trials) standards for reporting randomized trials
2. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines for meta-analyses and systematic reviews of randomized controlled trials
3. MOOSE (Meta-analysis of Observational Studies in Epidemiology) guidelines for meta-analyses and systematic reviews of observational studies
4. STARD (Standards for Reporting of Diagnostic Accuracy) standards for reporting studies of diagnostic accuracy
5. STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines for the reporting of observational studies

Investigators who are planning, conducting, or reporting randomized trials, meta-analyses of randomized trials, meta-analyses of observational studies, studies of diagnostic accuracy, or observational studies should be thoroughly familiar with these sets of standards and follow these guidelines in articles submitted for publication.

NOW AVAILABLE ONLINE - http://ong.editorialmanager.com

rev 12/2010

Copyright© American College of Obstetricians and Gynecologists

Q

Risk Factors for Legal Induced Abortion–Related Mortality in the United States

Linda A. Bartlett, MD, MHSc, Cynthia J. Berg, MD, MPH, Holly B. Shulman, MS, Suzanne B. Zane, DVM, Clarice A. Green, MD, MPH, Sara Whitehead, MD, MPH, and Hani K. Atrash, MD, MPH

OBJECTIVE: To assess risk factors for legal induced abortion–related deaths.

METHODS: This is a descriptive epidemiologic study of women dying of complications of induced abortions. Numerator data are from the Abortion Mortality Surveillance System. Denominator data are from the Abortion Surveillance System, which monitors the number and characteristics of women who have legal induced abortions in the United States. Risk factors examined include age of the woman, gestational length of pregnancy at the time of termination, race, and procedure. Main outcome measures include crude, adjusted, and risk factor–specific mortality rates.

RESULTS: During 1988–1997, the overall death rate for women obtaining legally induced abortions was 0.7 per 100,000 legal induced abortions. The risk of death increased exponentially by 38% for each additional week of gestation. Compared with women whose abortions were performed at or before 8 weeks of gestation, women whose abortions were performed in the second trimester were significantly more likely to die of abortion-related causes. The relative risk (unadjusted) of abortion-related mortality was 14.7 at 13–15 weeks of gestation (95% confidence interval [CI] 6.2, 34.7), 29.5 at 16–20 weeks (95% CI 12.9, 67.4), and 76.6 at or after 21 weeks (95% CI 32.5, 180.8). Up to 87% of deaths in women who chose to terminate their pregnancies after 8 weeks of gestation may have been avoidable if these women had accessed abortion services before 8 weeks of gestation.

CONCLUSION: Although primary prevention of unintended pregnancy is optimal, among women who choose to terminate their pregnancies, increased access to surgical and nonsurgical abortion services may increase the proportion of abortions performed at lower-risk, early gestational ages and help further decrease deaths. (Obstet Gynecol 2004; 103:729–37. © 2004 by The American College of Obstetricians and Gynecologists.)

LEVEL OF EVIDENCE: II-2

From the Maternal and Infant Health Branch, Information Technology, Statistics, and Surveillance Branch, and Applied Sciences Branch, Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, Atlanta, Georgia; and Epidemic Intelligence Service, Division of Applied Public Health Training, Epidemiology Program Office, Atlanta, Georgia. Dr. Green is now with Epidemiology and Drug Safety, Drug Safety and Surveillance, Solvay Pharmaceuticals, Inc. Dr. Whitehead is currently with the Division of STD Prevention, National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention, on station in Chiang Rai, Thailand; and Disease Outbreak and Control Division, Hawaii Department of Health. Dr. Atrash is currently with the National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention, Atlanta, Georgia.

The authors thank Lisa Koonin for leading the collection and maintenance of all abortion-procedure data during 1987–2000, Lisa Flowers for providing assistance with data entry and SAS programming for numerator analyses, and Joy Herndon for providing assistance by coordinating the abortion surveillance system from 2000 through the present.

Legal induced abortion is one of the most frequently performed surgical procedures in the United States. With approximately 1.2 million legal induced abortions performed in 1997,[1] minimizing risk for women who choose to terminate their pregnancies is of clear public health importance.

Pregnancy-related deaths are deaths that occur among women within 1 year of pregnancy from complications of the pregnancy or delivery; deaths associated with complications of induced abortion[2] (ie, abortion-related deaths) also are considered pregnancy related. Previous reports on abortion-related mortality for 1972–1987 have informed abortion policy and practice and improved safety for women. In addition, data on the lower risk of death with certain procedures and anesthetics have guided practice, substantially reducing the number of abortions conducted with methods found to be associated with increased risk.[3–8] However, the medical practice and provision of abortion services continues to change. For example, since the mid-1990s, medical (ie, nonsurgical) regimens using abortifacients within the first 7 weeks of pregnancy have been used to terminate pregnancies.[9] This report provides information on risk factors for abortion-related deaths among women who had abortions in recent years that will help inform and

© 2004 by The American College of Obstetricians and Gynecologists.
Published by Lippincott Williams & Wilkins.
0029-7844/04/$30.00
doi:10.1097/01.AOG.0000116260.81570.60

Copyright© American College of Obstetricians and Gynecologists

update policymakers and practitioners about abortion-related maternal mortality.

MATERIALS AND METHODS

Data for these analyses were derived from 2 data sets from the Centers for Disease Control and Prevention (CDC). Numerator data were obtained from the Abortion Mortality Surveillance System, now a part of the Pregnancy Mortality Surveillance System, which attempts to identify all deaths in the United States caused by pregnancy, including those ending in induced abortion. For abortion mortality rate denominators, we used data from CDC's Induced Abortion Surveillance System, compiled since 1969. From 1973 through 1997, data were received from state health departments or estimated for 52 reporting areas, including 50 states, the District of Columbia, and New York City. Legal induced abortion was defined as "a procedure, performed by a licensed physician or someone acting under the supervision of a licensed physician, that was intended to terminate a suspected or known intrauterine pregnancy and to produce a nonviable fetus at any gestational age." The total number of legal induced abortions was available or estimated from all reporting areas; however, not all of these areas collected information regarding some or all of the characteristics of women who obtained abortions.[1]

The Abortion Mortality Surveillance System defines an abortion-related death is a death resulting from 1) a direct complication of an abortion, 2) an indirect complication caused by the chain of events initiated by the abortion, or 3) an aggravation of a preexisting condition by the physiologic or psychologic effects of the abortion, regardless of the amount of time between the abortion and the death.[10] The inclusion of abortion-related deaths in this surveillance system, regardless of the amount of time between the abortion procedure and the death, is unique and differs from the temporal limit for other pregnancy outcomes in the Pregnancy Mortality Surveillance System. Legal induced abortion–related mortality rate is defined as the number of deaths from legal induced abortion per 100,000 legal induced abortions.

Multiple sources are used in the Abortion Mortality Surveillance System to identify potential cases of abortion-related mortality, including national and state vital records, reports from maternal mortality review committees, private citizens, health care providers, medical examiners, the media, and, more recently, a full-text newspaper database. For each suspected case identified, the Abortion Mortality Surveillance System requests death certificates, clinical records, and autopsy reports. Death certificates were obtained for all cases, but complete clinical records were not always available. Two medical epidemiologists reviewed the available records for each case to determine the cause of death and if it was abortion-related.

Gestational age was defined as the number of completed weeks elapsed from the start of the last menstrual period and was categorized as either 1) 8 weeks or less, 9–10 weeks, 11–12 weeks, 13–15 weeks, 16–20 weeks, and 21 or more weeks or 2) first (12 weeks or less) or second trimester (13 weeks or more). Parity was defined as the number of previous live births and was categorized as 0, 1–2, and 3 or more. When calculating mortality rates specific to parity, gestational age, and marital status, we excluded cases for which the decedent's parity, gestational age, or marital status were unknown, unless specifically noted. Procedures were categorized as curettage, dilatation and evacuation (D&E), instillation, or other. Curettage includes suction or sharp curettage performed at or before 12 weeks of pregnancy. For cases in which the procedure was curettage but the gestational age was unknown, we assumed the procedure occurred at or before 12 weeks of gestation for those analyses that were stratified by trimester of gestation. For those analyses that were performed by weeks of gestation, cases with unknown gestational age were reported separately as unknown gestational age or were excluded. Similarly, when the procedure was unknown and gestational age was recorded as 12 weeks or less, we assumed that curettage was performed. D&E is a combination of suction and sharp curettage performed through a dilated cervix at or after 13 weeks; instillation involves prostaglandin or saline instillation; and "other" associated procedures include hysterectomy, hysterotomy, and use of prostaglandin vaginal suppositories. For the time period of this analysis (1988–1997), approximately 0.10% of legal induced abortions were performed with abortifacients in early pregnancy.[11] No deaths associated with them were identified by the Abortion Mortality Surveillance System during the study period.

Causes of abortion-related deaths included direct causes (eg, vaginal and intraabdominal hemorrhage), infection (including endometritis, septicemia, and other infections), emboli (including thrombotic, amniotic fluid, and air emboli), complications of anesthesia, and indirect causes (categorized as "other"), mainly cardiac, and cerebral vascular events. Women were divided into 2 racial categories: 1) white and 2) black or other. Women who were of black or other races (eg, Asian/Pacific Islander, American Indian) were combined into 1 category because of the difficulty in separating races in the denominator before 1990 and because only 2 cases were reported for a nonwhite, nonblack woman during 1988–1997.

Copyright© American College of Obstetricians and Gynecologists

The crude (unadjusted) legal induced abortion–related mortality rates were calculated for each year from 1972 through 1997. In addition to calculating the crude mortality rate, we stratified the unadjusted mortality rates by various sociodemographic and medical factors, including the type of procedure; woman's race, age, and parity; and gestational age of the pregnancy that was terminated during 1988–1997, the 10 most recent years of data available from the Abortion Mortality Surveillance System. For all rates, the relative risks (RRs) with 95% confidence intervals (CIs) were calculated by using the Taylor series method in Epi-Info 6.04c.[12]

To understand the effect of differences in gestational age distribution on the RR of death for women of different ages and race, we calculated gestational age–adjusted, race-specific, and maternal age–specific mortality rates. For the race-specific analyses, we directly standardized the mortality rates to the gestational age distributions of white women and for the maternal age–specific rates, we used the gestational age distribution of older women as the standard. In these standardized analyses, deaths for which the gestational age at the time of abortion was unknown were assigned a gestational age in proportion to the gestational age distribution of the deceased women where the gestational age was known. To determine whether the shift toward earlier gestation abortions was primarily responsible for the decrease in abortion mortality over time, we calculated and compared gestational age–specific mortality rates over 3 time periods from 1972 through 1997. Because the risk of death with increasing gestational age does not follow a linear distribution, we fit exponential models to assess the relationship between mortality and increasing gestational age.

The project resulting in this manuscript was reviewed for human subjects issues and determined to be in compliance with CDC's guidelines. The analyses used data from the Pregnancy Mortality Surveillance System and Legal Induced Abortion Surveillance System, both housed in the Division of Reproductive Health at CDC.

RESULTS

During 1972–1997, a total of 337 deaths determined to be causally related to legal induced abortions was identified by the Abortion Mortality Surveillance System for an overall legal induced abortion–related mortality rate of 1.1 deaths per 100,000 legal induced abortions (Table 1). From 1972 through 1997, the annual number of legal induced abortion–related deaths decreased from 24 to 7, and the mortality rate decreased from 4.1 to 0.6. Most of the decline occurred early in this time period, from 1972 through 1976; after the legalization of abortion in January of 1973, the mortality rate fell from 4.1 to 1.1 deaths per 100,000 abortions, a reduction of 73% ($P = .001$). Women in the earlier time period (1972–1979) were 3 times (RR 3.1; 95% CI 2.4, 4.1) more likely to die of complications of an abortion than women in the most recent time period (1988–1997) (Table 2 and Figure 1).

We also calculated the gestational age–specific relative risks of dying comparing the earliest (1972–1979) and most recent (1988–1997) time periods using the most recent time period as the referent group. Although the risk of death declined at all gestational ages, the greatest proportion of the decline occurred at earlier gestational ages. Women who had abortions performed in the earlier time period were significantly more likely to die at each gestational age than women who had abortions in the most recent time period; women receiving abortions during 1972–1979 had RRs of 5 (at or before 8 weeks of gestation), 8.6 (at 9–10 weeks), 6.2 (at 13–15 weeks), and 4.1 (at 16–20 weeks), and 1.9 (at or after 21 weeks). These declines are all statistically significant, with the exception of the women who died of complications of abortion at 21 weeks or more of gestation; although their mortality decreased almost 50%, the decrease was not statistically significant. To examine risk factors among women receiving abortions in the most recent time period, we analyzed deaths that occurred during 1988–1997. Gestational age at the time of abortion was the strongest risk factor for abortion-related mortality (Table 2). The lowest rates were among women who had their abortions in the first trimester of pregnancy, particularly within the first 8 weeks of pregnancy. Women whose abortions were performed in the second trimester (at or after 13 weeks of gestation) had abortion-related mortality rates greater than women whose abortions were performed in the first 8 weeks of pregnancy (RR at 13–15 weeks, 14.7 [95% CI 6.2, 34.7]; RR at 16–20 weeks, 29.5 [95% CI 12.9, 67.4]; RR at or after 21 weeks, 76.6 [95% CI 32.5, 180.8]). If women who had abortions after 8 weeks of gestation had obtained abortions during the first 8 weeks of pregnancy, when risk is lowest, 87% of deaths likely could have been prevented.

In addition, we used the data to model the association between the mortality rate and gestational age (Figure 1). We found that for the most recent time period (1988–1997), the risk of death increased exponentially with increasing gestational age. According to this model, there is a 38% increase in risk of death for each additional week of gestation. This implies that the increase in the risk of death due to delaying the procedure by 1 week is much higher at later gestational ages than at earlier gestational ages. For example, applying this model, if an abortion is performed at 9 weeks rather than at 8 weeks of gestation, the estimated absolute increase in the mortality rate is

Copyright© American College of Obstetricians and Gynecologists

Table 1. Legal Induced Abortion–Related Deaths, Legal Induced Abortions, and Abortion Mortality Rates—United States, 1972–1997

Year	Legal induced abortion–related deaths (*n*)*	Legal induced abortions (*n*)	Legal induced abortion mortality rate (per 100,000 legal induced abortions)
1972	24	586,760	4.1
1973	25	615,831	4.1
1974	26	763,476	3.4
1975	29	854,853	3.4
1976	11	988,267	1.1
1977	17	1,079,430	1.6
1978	9	1,157,776	0.8
1979	22	1,251,921	1.8
1980	9	1,297,606	0.7
1981	8	1,300,760	0.6
1982	11	1,303,980	0.8
1983	11	1,268,987	0.9
1984	12	1,333,521	0.9
1985	11	1,328,570	0.8
1986	11	1,328,112	0.8
1987	7	1,353,671	0.5
1988	16	1,371,285	1.2
1989	12	1,396,658	0.9
1990	9	1,429,247	0.6
1991	11	1,388,936	0.8
1992	10	1,359,146	0.7
1993	6	1,330,414	0.5
1994	10	1,267,415	0.8
1995	4	1,210,883	0.3
1996	9	1,221,585	0.7
1997	7	1,186,039	0.6
1972–1979	163	7,298,314	2.2
1980–1987	80	10,515,207	0.8
1988–1997	94	13,161,608	0.7
1972–1997	337	30,975,129	1.1

* For some years, the number of deaths and total legal abortions differ from those in previously published reports to reflect additional information obtained by the Centers for Disease Control and Prevention.

0.05 per 100,000 abortions (from 0.13 to 0.18 deaths per 100,000 abortions). However, if an abortion is performed at 18 weeks of gestation instead of at 17 weeks, the estimated absolute increase is 0.91 (from 2.4 to 3.3 per 100,000 abortions). Thus, the estimated increase in the risk of death due to delaying the procedure by 1 week at 17 weeks of gestation is 18 times greater than the estimated increase in the risk of death by delaying the procedure by 1 week at 8 weeks of gestation.

The second most significant risk factor for death overall was race. Women of black and other races were 2.4 times as likely as white women to die of complications of abortion (Table 2). At all gestational ages, women of black and other races had higher case mortality rates than white women. Because women of black and other races tend to have abortions at later gestational ages,[1,11] we standardized the mortality rates for black women to the gestational age distribution of white women to assess the effect that gestational age may have had on the higher risk of death for women of black and other races. The ratio of the adjusted mortality rates for women of black and other races compared with white women decreased 20% to 1.9. However, this adjusted rate still differs significantly from the rate for white women. No statistically significant differences were observed between crude mortality rates for women of different age or parity. However, data from the Abortion Surveillance System indicate that women younger than 20 years of age had abortions later in gestation than did women aged 20–29 years, and women aged 30 years or older obtained abortions earlier in pregnancy than women in any other age group.[1,11] To determine the impact of these differences on age-specific mortality, we standardized the maternal age–specific mortality rates for gestational age using the gestational age distribution of women aged 30 years or older as the standard. If women younger than 20 years of age who terminated their pregnancies had the same gestational age distribution as women aged 30 years or older, mortality among women younger than 20 years of age would decrease by 32%, and mortality among women aged 20–29 years would decrease by 17%.

Copyright© American College of Obstetricians and Gynecologists

Table 2. Legal Induced Abortion–Related Deaths, Mortality Rates, and Relative Risks, by Selected Characteristics—United States, 1988–1997

Characteristic	1988–1997		
	Legal induced abortion–related deaths (*n*)	Mortality rate*	Relative risk (95% confidence interval)
Gestational age (wk)			
First trimester			
≤ 8	8	0.1	Referent
9–10	5	0.2	1.4 (0.5, 4.2)
11–12	6	0.4	3.4 (1.2, 9.7)
Second trimester			
13–15	15	1.7	14.7 (6.2, 34.7)
16–20	19	3.4	29.5 (12.9, 67.4)
≥ 21	15	8.9	76.6 (32.5, 180.8)
Unknown	26	Not applicable	Not applicable
Race			
White	38	0.5	Referent
Black or other	56	1.1	2.4 (1.6, 3.6)
Time period			
1972–1979	163	2.2	3.1 (2.4, 4.0)
1980–1987	80	0.8	1.1 (0.8, 1.4)
1988–1997	94	0.7	Referent
Age (y)			
≤ 19	20	0.7	1.2 (0.6, 2.2)
20–24	29	0.7	1.1 (0.6, 2.0)
25–29	18	0.6	Referent
30–34	16	0.9	1.5 (0.7, 2.9)
≥ 35	10	0.8	1.3 (0.6, 2.9)
Parity			
0	16	0.3	Referent
1–2	27	0.5	1.9 (1.0, 3.5)
≥ 3	7	0.5	2.1 (0.9, 5.2)
Unknown†	42	Not applicable	Not applicable

* Legal induced abortion mortality rate is the number of legal induced abortion–related deaths per 100,000 legal induced abortions.
† Denominators for calculating rates by parity use previous live births from abortion surveillance data; deaths with unknown parity are excluded.

The procedures that can be used to terminate a pregnancy are determined by the gestational age at the time of the procedure. For the years 1988–1997, more than 99% of abortions in the first trimester were performed by curettage. Therefore, we examined the relationship between abortion procedure and mortality in the second trimester. For women in the second trimester, the mortality rates for D&E were 2.5 times lower than those for instillation and other procedures. These differences were not significant; however, our analysis was limited by very small numbers in some categories and the large number of women who could not be included in this analysis because of unknown procedure or unknown gestational age. No deaths associated with early medical abortion procedures using abortifacients were reported during the study period.

Of abortion-related deaths, 85% were attributable to direct causes and 15% to indirect (ie, "other") causes. Of the direct causes, hemorrhage and infection exceeded any other cause. Overall, each were responsible for approximately one fourth of abortion-related deaths, whereas embolism, anesthetic complications, and other causes were each responsible for about 15% of deaths (Table 3). Cause of death varied by gestational age and procedure type. For example, hemorrhage, a less frequent cause of death at or before 12 weeks of pregnancy, was the most frequent cause of death associated with D&E at 13 weeks or more of gestation.

Among women for whom the interval between the abortion procedure and death was known, 35% of the deaths occurred within 24 hours, and 85% died within 42 days of the procedure, the length of time considered the puerperal period.

DISCUSSION

In the 25 years following the legalization of abortion in 1973 (*Roe v. Wade*, 410 U.S. 113, 1973), the risk of death from legal abortion declined dramatically by 85%, from 4.1 to 0.6, with most of this decline occurring from 1973 through 1976. The number of illegal abortion–related deaths (induced abortions not performed by a licensed

Copyright© American College of Obstetricians and Gynecologists

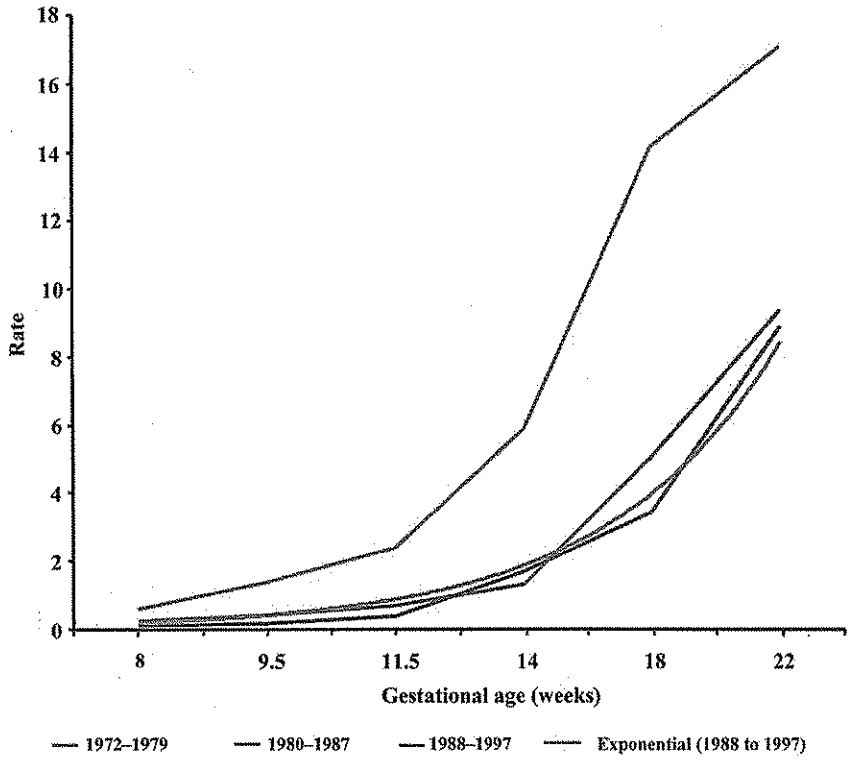


Figure 1. Legal induced abortion mortality rates with plot of exponential model, by gestational age—United States, 1972–1979, 1980–1987, and 1988–1997.

Bartlett. Abortion-Related Mortality. Obstet Gynecol 2004.

physician or a supervised assistant) also declined after legalization of abortion–only 5 deaths associated with illegal abortion were identified during 1988–1997.[1] The initial decrease in legal abortion–related deaths can be largely attributed to an increase in the level of experience and skill of the providers,[7,13] a factor that has reduced the risk of complications with other procedures.[14] Further reductions in the number of deaths and risk of mortality can be attributed to changes in clinical practice–changes made in response to reports that identified procedures with an increased risk of complications. For example, in 1972, approximately 10% of abortions were performed by either saline or prostaglandin instillation procedures. Use of this higher-risk procedure declined through the 1970s to approximately 3% in 1980 and, concurrently, the proportion of providers using dilation and curettage (a procedure associated with lower risk of complications) increased. The heightened risk of death

Table 3. Distribution of Causes of Legal Induced Abortion–Related Deaths,* by Type of Procedure and Trimester of Abortion—United States, 1988–1997

	Cause of death (%)					
Trimester and procedure†	Hemorrhage	Infection	Embolism	Anesthesia complications	Other‡	Unknown
First trimester (< 13 weeks of gestation)						
Curettage	14	31	14	22	17	3
Other§	0	0	0	0	0	0
Second trimester (≥ 13 weeks of gestation)						
Dilatation and evacuation	38	14	19	19	11	
Intrauterine instillation	33	33			33	
Other‡		25	50		25	
Unknown procedure		50			50	
Total for all gestational ages and procedures	24	27	17	16	15	1

Data are presented as percentages only because of small numbers in some cells.

* Excludes 9 women for whom data regarding abortions procedure and gestational age are unknown.

† Women receiving abortions during the first trimester using an unknown procedure were classified as having had a curettage procedure.

‡ Other causes of death include cardiac and cerebrovascular events.

§ Other procedures include hysterectomy, hysterotomy and prostaglandin vaginal suppositories, and medical termination.

Copyright© American College of Obstetricians and Gynecologists

with the use of general anesthetics, in particular fast-acting barbiturates, was also identified in the 1980s; few abortions currently are performed using these substances.[6] As the strong association between gestational age and the risk of complications became more widely known, an increased percentage of abortions were performed early in the first trimester; 34% of abortions were performed before 8 weeks of gestation in 1972 compared with almost 55% in 1997.[1]

The risk factor that continues to be most strongly associated with mortality from legal abortion is gestational age at the time of the abortion. The relationship between gestational age and risk of death has changed over time; currently, the risk of death increases exponentially at all gestational ages, whereas for women obtaining abortions in the earlier time period (1970–1979), the risk of death increased with increasing gestational age but leveled off at the highest gestational ages. The change in models for risk of death by gestational age likely results from the reduction in risk at earlier gestational ages as abortion policy and practice have changed; the risk of death at later gestational ages may be less amenable to reduction because of the inherently greater technical complexity of later abortions related to the anatomical and physiologic changes that occur as pregnancy advances. The increased amount of fetal and placental tissue requires a greater degree of cervical dilation, the increased blood flow predisposes to hemorrhage, and the relaxed myometrium is more subject to mechanical perforation. The technical challenges of the procedure during the second trimester are different from those present in the first trimester, and the inherently greater risk of complications may be less amenable to prevention. However, it is possible that other factors such as exacerbation of a preexisting disease may have also contributed to the greater risk of death for women obtaining abortions at later gestational age, but our ability to determine the potential contribution of other factors is limited because of limited information about the deceased women's medical or social history.

Almost half of abortions still occur after 8 weeks of gestation. Because access to abortions even 1 week earlier reduces the risk of death disproportionately as gestational age increases, addressing this risk factor by further reducing the gestational age at which women have abortions may help to further reduce the risk of death.

Our analysis suggests that almost one fifth of the excess abortion-related mortality among women of black and other races resulted from later gestational age at the time of the abortion. In addition, more than one third of the abortion-related mortality risk for women aged 19 years or younger was due to having an abortion at a later gestational age as compared with women aged 30 years or older.

Because gestational age at the time of abortion is such a strong risk factor for death, factors that can affect access to abortion services deserve examination. First, availability of services influences access to early abortion. Since 1982, the number of abortion providers has decreased by 20%; most of the decline has occurred among hospital-based providers and in nonmetropolitan areas, leading to decreased appointment availability and an increased average distance that women must travel to abortion facilities.[15–17] In addition, many abortion facilities set a gestational age limit after which they will not perform abortions. Consequently, women seeking abortion services after the first trimester may have to travel longer distances, which may lead to even greater delay in obtaining services. Other factors that may also lead to abortions at later gestational ages include failure to recognize a pregnancy or miscalculation of the length of pregnancy; reluctance to tell a partner or parents about a pregnancy; time needed to decide how to resolve the pregnancy; and difficulty in finding a provider, making arrangements for the abortion, obtaining transportation, and being able to afford the procedure.[18–20] In 2001, a total of 33 states required either parental notification or consent or a mandatory waiting period after a woman's initial visit to the abortion provider before the procedure could be performed.[15,19] Both parental notification laws and mandatory waiting periods have been associated with an increase in second-trimester abortions.[21,22] In 1998, only 16 states had Medicaid or other state-supported funding of abortions; thus women in most states must spend time seeking financial resources to pay for an abortion.[15]

Since the mid-1990s, methotrexate with misoprostol and more recently mifepristone have been used for nonsurgical termination of early pregnancies (ie, those up to 7 weeks of gestation).[23] Mifepristone (commonly called RU-486) is approved for such use in most of Europe[24] and has been used for more than a decade in France,[24] Sweden, and Great Britain.[25,26] Before the U.S. Food and Drug Administration approved the drug for use as a medical abortifacient in 2000, it was used in clinical trials in the United States.[9] The CDC's Abortion Surveillance System began to collect data on medical terminations in 1997. In 1999, a total of 25 states reported that 6,278 of these early medical abortions using RU-486 had been performed, which likely is an underestimate.[27] An early medical abortion requires more visits by the woman to her health care provider than are required for a surgical procedure, but acceptability among both providers and patients is reported as being high.[28,29] No deaths determined to be related to use of medical abortifacients were reported in the United States during the study period.

Copyright© American College of Obstetricians and Gynecologists

The number or rate of abortions in European countries where mifepristone is used as an abortifacient has not increased, although the proportion of abortions performed at earlier gestational ages has risen.[25] If the number of abortions remains constant in the United States, increased availability of mifepristone to U.S. women who choose to terminate their pregnancies may increase the proportion of abortions at earlier gestational ages and in turn decrease the risk of abortion-related mortality. Ongoing monitoring of both abortion procedures and abortion-related mortality will help to evaluate the effect of medical abortion regimens.

The United States continues to monitor the number of abortion procedures and abortion-related deaths nationally. Furthermore, CDC's Abortion Mortality Surveillance System uses multiple methods to identify cases of abortion-related mortality, thereby increasing the identification of potential deaths. Cases are confirmed through review of available hospital charts and coroners' reports by clinically experienced epidemiologists. On average, the Abortion Mortality Surveillance System reports more than twice as many deaths related to legal induced abortion than are reported on routine death-certificate data. The completeness of death reporting is difficult to determine; however, an assessment that used multiple methods indicated that both reported numbers and rates of abortion-related deaths was consistent among multiple sources.[30] Surveillance of abortion-related mortality continues to be essential in monitoring trends, evaluating risk factors, and identifying potential clusters of deaths.

Our analyses have several possible limitations. Although state health departments are asked to provide death certificates on all deaths associated with pregnancy and other sources are used to try to ascertain abortion-related deaths, some cases may not be identified. In addition, we were unable to obtain detailed clinical records for all cases, and therefore data on certain factors (eg, gestational age, type of abortion procedure, and other risk factors for death, such as preexisting diseases), were not available for all deaths. In addition, because of the data sources used for this study, we are unable to determine why some women obtain abortions later in their pregnancies. Some of these women may choose to terminate their pregnancies because of a preexisting medical condition or fetal indications (eg, severe fetal anomalies). Thus, our ability to understand all the barriers to early abortion is incomplete. Although determination of the cause of death and relatedness to the abortion procedure is a straightforward process, some misclassification may have occurred. Timeliness in reporting abortion-related deaths is affected by several factors, including delays of up to several years in death notification, difficulty in obtaining clinical information from providers and facilities, and the need to compile multiple years of data before release because of the small number of cases that occur annually and the need to maintain anonymity. In some stratified analyses, abortion-related mortality rates for the different strata may be underestimated, because cases with unknown values for the characteristic of interest could not be included. The aggregate nature of CDC's Abortion Surveillance System also served as a study limitation by preventing multivariable analyses of abortion mortality. Denominator data on abortion procedures is reported univariately, with a subset of states providing bivariate data. Thus, examining the affects of one risk factor while controlling for all other potential risk factors was not feasible.

Legal induced abortion–related deaths occur only rarely. Substantial reduction in the number and risk of deaths caused by complications of abortion can be affected by identification of risk factors for death and use of this evidence to inform policy and practice changes. Currently, gestational age at the time of the abortion is the strongest risk factor for death. If women who terminated their pregnancies after 8 weeks of gestation had accessed abortion services during the first 8 weeks of gestation, up to 87% of deaths might have been avoided. Reasons for delay in accessing services are likely multifactorial; to help guide prevention efforts to reduce mortality from complications of abortion, additional information is needed about the women who access abortion services later during pregnancy and the reasoning behind this decision. Primary prevention of unintended pregnancies is optimal. However, among women who choose to terminate their pregnancies, increased access to early abortion services (including emerging technologies such as early medical abortion regimens) may increase the proportion of abortions performed at the lower-risk, early gestational ages and help reduce maternal deaths.

REFERENCES

1. Koonin LM, Strauss LT, Chrisman CE, Parker WY. Abortion surveillance–United States, 1997. In: CDC Surveillance Summaries, December 8, 2000. MMWR Morb Mortal Wkly Rep 2000;49:1–43.
2. Berg CJ, Chang J, Callaghan W, Whitehead S. Pregnancy-related mortality in the United States, 1991–1997. Obstet Gynecol 2003;101:289–96.
3. Cates WJr, Rochat R, Smith J, Tyler CWJr. Trends in national abortion mortality, United States, 1940–1974: implications for prevention of future abortion deaths. Adv Plan Parent 1976;11:106–13.
4. Centers for Disease Control and Prevention. Abortion surveillance 1976. Atlanta (GA): U.S. Department of

Copyright© American College of Obstetricians and Gynecologists

Health and Human Services, Public Health Service, CDC; 1978.
5. Atrash H, MacKay T, Binkin N, Hogue C. Legal abortion mortality in the United States: 1972 to 1982. Am J Obstet Gynecol 1986;156:605–12.
6. Atrash H, Cheek T, Hogue C. Legal abortion mortality and general anesthesia. Am J Obstet Gynecol 1988;158: 420–4.
7. Council on Scientific Affairs, American Medical Association. Induced termination of pregnancy before and after Roe v Wade. JAMA 1992;268:323–9.
8. Lawson H, Frye A, Atrash H, Smith J, Shulman H, Ramick M. Abortion mortality, United States, 1972 through 1987. Am J Obstet Gynecol 1994;171:1365–72.
9. American College of Obstetricians and Gynecologists. Medical management of abortion. ACOG Practice Bulletin 26; 2001.
10. Centers for Disease Control and Prevention. Abortion surveillance, 1978. Atlanta (GA): U.S. Department of Health, Education and Welfare, Public Health Service, CDC; 1980. p. 6–13.
11. Herndon J, Strauss LT, Whitehead S, Parker WY, Bartlett L, Zane S. Abortion surveillance–United States, 1998. In: CDC Surveillance Summaries, June 7, 2002. MMWR Morb Mortal Wkly Rep 2002;51:1–32.
12. Centers for Disease Control and Prevention. Epi Info version 6: a word processing, data base and statistics system for epidemiology on microcomputers. Available at: http://www.cdc.gov/epiinfo/. Retrieved June 18, 2003.
13. Cates W, Grimes Schulz K. The public health impact of legal abortion: 30 years later. Perspect Sex Reprod Health 2003;35:25–8.
14. Hannan E, Siu A, Kumar D, Kilburn H, Chassin M. The decline in coronary artery bypass graft surgery mortality in New York State: the role of surgeon volume. JAMA 1995;273:209–13.
15. Henshaw SK. Factors hindering access to abortion services. Fam Plann Perspect 1995;27:54–9, 87.
16. Henshaw SK, Van Vort J. Abortion services in the United States, 1987 and 1988. Fam Plann Perspect 1990;22: 102–9.
17. Henshaw SK, Van Vort J. Abortion services in the United States, 1991 and 1992. Fam Plann Perspect 1994;26: 100–6.
18. Alan Guttmacher Institute. State policies in brief. Available at: http://www.agi-usa.org/pubs/spib.html. Retrieved July 11, 2002.
19. Torres A. Forrest JD. Why do women have abortions? Fam Plann Perspect 1988;20:169–76.
20. Henshaw SK. Accessibility of abortion services in the United States. Fam Plann Perspect 1991;23:246–53.
21. Joyce T, Kaestner R. The impact of Mississippi's mandatory delay law on the timing of abortion. Fam Plann Perspect 2000;32:4–13.
22. Henshaw S. The impact of requirements for parental consent on minors' abortions in Mississippi. Fam Plann Perspect 1995;27:120–2.
23. Creinin M, Edwards J. Early abortion: surgical and medical options. Curr Probl Obstet Gynecol Fertil 1997;20: 1–32.
24. Silvestre L, Dubois C, Renault M, Rezvani Y, Baulieu E-E, Ulmann A. Voluntary interruption of pregnancy with mifepristone (RU 486) and a prostaglandin analogue: a large scale French experience. N Engl J Med 1990;322: 645–8.
25. Jones RK, Henshaw SK. Mifepristone for early medical abortion: experiences in France, Great Britain and Sweden. Perspect Sex Reprod 2002;34:154–61.
26. UK Multicentre Trial. The efficacy and tolerance of mifepristone and prostaglandin in first-trimester termination of pregnancy. Br J Obstet Gyneaecol 1990;97:480–6.
27. Koonin LM, Strauss LT, Chrisman CE, Montalbano MA, Bartlett LA, Smith JC. Abortion Surveillance United States, 1996. In: CDC Surveillance Summaries, July 30, 1999. MMWR Morb Mortal Wkly Rep 1999;48:1–42.
28. Creinin MD, Burke AE. Methotrexate and misoprostol for early abortion: a multicenter trial–acceptability. Contraception 1996;54:19–22.
29. Winikoff B, Ellerston C, Elul B, Sivin I. Acceptability and feasibility of early pregnancy termination by mifepristone-misoprostol: results of large multicenter trial in the United States. Arch Family Med 1998;7:360–6.
30. Cates W, Smith J, Rochat R, Grimes D. Mortality from abortion and childbirth: are the statistics biased? JAMA 1982;248:192–6.

Address reprint requests to: L. Bartlett MD, MHSc, Division of Reproductive Health, 4770 Buford Highway NE, MS-K-23, Atlanta, GA 30341; e-mail: LBartlett@CDC.gov.

Received August 25, 2003. Received in revised form December 3, 2003. Accepted December 19, 2003.

Copyright© American College of Obstetricians and Gynecologists

R

Guidelines for Women's Health Care

A Resource Manual

Fourth Edition

The American College of Obstetricians and Gynecologists

WOMEN'S HEALTH CARE PHYSICIANS

Katharine Dexter McCormick
Library
Planned Parenthood Federation of America
434 W. 33rd Street
New York, NY 10001

Guidelines for Women's Health Care

A Resource Manual

Fourth Edition

The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

Guidelines for Women's Health Care: A Resource Manual, Fourth Edition, was developed under the direction of the Editorial Committee for *Guidelines for Women's Health Care* (2009–2014):

Abraham Lichtmacher, MD, Chair
Monica G. Adams, MS, PA-C
Sarah L. Berga, MD
Ann J. Davis, MD
Mitchell I. Edelson, MD
Roxanne M. Jamshidi, MD
Rebecca A. Lehman, PA-C
Jeffrey F. Peipert, MD, PhD
Johanna F. Perlmutter, MD
Holly E. Richter, MD, PhD
Mark D. Walters, MD
Catherine T. Witkop, MD, MPH

The American College of Obstetricians and Gynecologists' Staff:

Gerald F. Joseph Jr, MD
Mary F. Mitchell
Nancy O'Reilly, MHS
Alyssa Politzer, MA
Chuck Emig, MA

The information in *Guidelines for Women's Health Care: A Resource Manual*, Fourth Edition, should not be viewed as a body of rigid rules. The guidelines are general and intended to be adapted to many different situations, taking into account the needs and resources particular to the locality, the institution, or the type of practice. Variations and innovations that improve the quality of patient care are to be encouraged rather than restricted. The purpose of these guidelines will be well served if they provide a firm basis on which local norms may be built.

Library of Congress Cataloging-in-Publication Data

Guidelines for women's health care : a resource manual. -- Fourth edition.
p. ; cm.
Includes bibliographical references and index.
ISBN 978-1-934984-37-6
I. American College of Obstetricians and Gynecologists, issuing body.
[DNLM: 1. Women's Health Services--standards--United States--Guideline. 2. Ambulatory Care Facilities--organization & administration--United States--Guideline. 3. Genital Diseases, Female--therapy--United States--Guideline. WA 309]
RA564.85
362.198002'1873--dc23

2014006171

Copyright 2014 by the American College of Obstetricians and Gynecologists, 409 12th Street, SW, PO Box 96920, Washington, DC 20090-6920. All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, posted on the Internet, or transmitted, in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without the prior written permission from the publisher.

Copies of *Guidelines for Women's Health Care: A Resource Manual*, Fourth Edition, can be ordered by calling toll free 800-762-2264.

12345/87654

INDUCED ABORTION

The medical definition of abortion is the interruption of pregnancy after nidation (the intrauterine implantation of a fertilized egg). According to data compiled by the Guttmacher Institute, approximately 1.21 million legal induced abortions were performed in the United States in 2008, which is 8% fewer than in 2000. The abortion ratio (the number of abortions per 1,000 live births) and the abortion rate (the number of abortions per 1,000 women aged 15–44 years) have decreased from 1990 to 2005 and remained stable through 2008. Women who obtain legal induced abortions are predominantly white, young, and unmarried.

Access to Care

Termination of pregnancy before viability is a medical matter between the patient and the physician, subject to the physician's clinical judgment, the patient's informed consent, relevant state and federal laws, and the availability of appropriate facilities. The American College of Obstetricians and Gynecologists (the College) supports access to care for all individuals and the availability of all reproductive options, irrespective of financial status. If a termination is chosen, it should be performed safely and as early as possible. The College opposes unnecessary regulations that limit or delay access to care (see also the College's Abortion Policy statement at www.acog.org/Resources_And_Publications/Statements_of_Policy_List).

Legal Issues

Induced abortion remains one of the most regulated medical procedures in the United States. Although the U.S. Supreme Court has determined that state bans on abortion are unconstitutional, it has upheld many state laws that make abortion services less accessible. These laws include specific physician and hospital requirements, gestational age limits, restrictions on

use of state funds and private insurance, waiting periods, required parental involvement, specialized facility requirements, and mandatory information requirements. Physicians should be aware of relevant federal and state abortion regulations.

Timing

According to the Centers for Disease Control and Prevention, approximately 64% of abortions are performed before 63 days gestation. Circumstances that can lead to second-trimester abortion include delays in suspecting and testing for pregnancy, delay in obtaining insurance or other funding, and delay in obtaining referral, as well as difficulties in locating and traveling to a health care provider. Poverty, lower education level, and having multiple disruptive life events have been associated with higher rates of seeking second-trimester abortion. In addition, major anatomic or genetic anomalies may be detected in the fetus in the second trimester and women may choose to terminate their pregnancies. Some obstetric and medical indications for second-trimester termination include preeclampsia and preterm premature rupture of membranes, among other conditions.

Methods

Methods of induced abortion include suction (or vacuum) curettage, dilation and evacuation (D&E), medical abortion, and labor-inducing abortion. The type of abortion method chosen depends on several factors, including gestational age, patient health, patient preference, and health care provider experience. Options for first-trimester abortion include suction curettage and medical abortion. Second-trimester abortion methods include D&E, medical abortion, and labor-inducing abortion.

Suction curettage uses cervical dilation (if necessary) followed by a suction device to remove the contents of the uterus. Dilation and evacuation involves cervical dilation followed by the use of grasping forceps to remove the fetus; a final suction curettage often is performed to ensure that the fetus is completely evacuated. Medical abortion involves the use of medications, such as mifepristone and misoprostol, rather than a procedure to induce an abortion. It typically is performed up to 63 days of gestation (calculated from the first day of the last menstrual period), although medical abortion may be used to terminate pregnancies beyond this time. Methods of labor-inducing abortion include the use of one or more of the following: prostaglandin analogues, mifepristone, osmotic cervical dilators, Foley catheters, and oxytocin.

Complications

The mortality rate associated with abortion is low (0.6 per 100,000 legal, induced abortions), and the risk of death associated with childbirth is approximately 14 times higher than that with abortion. Abortion-related mortality increases with each week of gestation, with a rate of 0.1 per 100,000 procedures at 8 weeks of gestation or less, and 8.9 per 100,000 procedures at 21 weeks of gestation or greater. Complications associated with suction curettage, D&E, and medical abortion include infection, hemorrhage, cervical laceration, retained products of conception, and failed abortion (ie, ongoing pregnancy). Uterine perforation can occur with suction curettage and D&E, whereas uterine rupture can occur with medical abortion and labor-inducing abortion.

Patient Counseling

Clinicians are not required to perform abortions. However, they should be prepared to counsel patients fully on their options and to manage complications of induced abortions, as needed. Before an abortion, a patient who is undecided should be counseled on her options for the pregnancy. The patient should be fully informed in a balanced manner about all options, including raising the child herself, placing the child for adoption, and abortion. The information conveyed should be appropriate to the gestational age and must be delivered without personal bias.

The woman should make a firm decision that she wants an abortion before she decides on the abortion technique. Methods that are appropriate based on gestational age and patient health should be discussed, including information about the possible complications associated with each technique. Clinicians should address patient concerns about common misconceptions about abortion. Specifically, patients should be informed

that the available evidence concludes that induced abortion is not associated with an increase in breast cancer risk, nor is a patient at increased risk of regret, depression, or infertility after an abortion. Contraceptive counseling is important. The clinician also should evaluate the patient's available psychosocial support and refer her to counseling or other supportive services, as appropriate.

Evaluation and Management

A comprehensive evaluation should be performed before induced abortion and includes the following:

- Complete medical history
- Thorough physical examination
- Screening for vaginitis and sexually transmitted infections, as indicated
- Appropriate laboratory testing, as indicated
  - — Pregnancy test
  - — Rh determination
  - — Complete blood count
- Ultrasonography, as indicated, to diagnose pregnancy, establish gestational age, and localize the placenta, if indicated
- Consideration for cervical preparation
- Prophylactic antibiotics (for suction curettage or D&E)
- Completion of appropriate paperwork and consent forms, as required by state, hospital, and facility

Clinicians who perform abortions in their offices, clinics, or freestanding ambulatory care facilities should have a plan to provide prompt emergency services if a complication occurs and should establish a mechanism for transferring patients who require emergency treatment. Routine pathologic examination of tissue is not necessary after an induced abortion via suction curettage or D&E in which embryonic or fetal parts can be identified with certainty. In such instances, a description of the gross products of conception should be recorded. The United States has no national system for the

mandatory reporting of induced termination of pregnancy. However, state health departments vary greatly in approaches to the compilation of these data, and clinicians should be aware of any such reporting requirements.

The following postprocedure care should be provided:

- Immunoprophylaxis with anti-D immune globulin for women who are RhD-negative
- Counseling on signs of hemorrhage, uterine perforation, retained tissue, infection, and failed abortion, as appropriate
- Psychologic or other support service consultation, as indicated
- Provision of contraception, if desired; except for hysteroscopic sterilization, diaphragm, or cervical cap, all forms of contraception can be considered after abortion and initiated on the day of the procedure; however, intrauterine devices should not be inserted in the case of immediate postseptic abortion (see also the "Family Planning" section in Part 3).

Clinical training curricula and additional policy guidelines for abortion care are available from the National Abortion Federation (see Resources).

Bibliography

Abortion access and training. ACOG Committee Opinion No. 424. American College of Obstetricians and Gynecologists. Obstet Gynecol 2009;113:247–50.

American College of Obstetricians and Gynecologists. Abortion policy. College Statement of Policy. Washington, DC: American College of Obstetricians and Gynecologists;2011.Availableat:http://www.acog.org/Resources_And_Publications/Statements_of_Policy_List. Retrieved September 24, 2013.

American College of Obstetricians and Gynecologists. Legislative interference with patient care, medical decisions, and the patient–physician relationship. College Statement of Policy. Washington, DC: American College of Obstetricians and Gynecologists;2013.Availableat:http://www.acog.org/Resources_And_Publications/Statements_of_Policy_List. Retrieved September 24, 2013.

Antibiotic prophylaxis for gynecologic procedures. ACOG Practice Bulletin No. 104. American College of Obstetricians and Gynecologists. Obstet Gynecol 2009;113:1180–9.

Bartlett LA, Berg CJ, Shulman HB, Zane SB, Green CA, Whitehead S, et al. Risk factors for legal induced abortion-related mortality in the United States. Obstet Gynecol 2004;103:729–37.

Grimes DA. Risks of mifepristone abortion in context [editorial]. Contraception 2005;71:161.

Guttmacher Institute. Abortion. Available at: http://www.guttmacher.org/sections/abortion.php. Retrieved August 15, 2013.

Induced abortion and breast cancer risk. ACOG Committee Opinion No. 434. American College of Obstetricians and Gynecologists. Obstet Gynecol 2009;113:1417–8.

Jones RK, Kooistra K. Abortion incidence and access to services in the United States, 2008. Perspect Sex Reprod Health 2011;43:41–50.

Jones RK, Zolna MR, Henshaw SK, Finer LB. Abortion in the United States: incidence and access to services, 2005. Perspect Sex Reprod Health 2008;40:6–16.

Medical management of first-trimester abortion. Practice Bulletin No. 143. American College of Obstetricians and Gynecologists. Obstet Gynecol 2014;123:676–92.

Pazol K, Creanga AA, Zane SB, Burley KD, Jamieson DJ. Abortion surveillance—United States, 2009. Centers for Disease Control and Prevention. MMWR Surveill Summ 2012;61:1–44.

Raymond EG, Grimes DA. The comparative safety of legal induced abortion and childbirth in the United States. Obstet Gynecol 2012;119:215–9.

Second-trimester abortion. Practice Bulletin No. 135. American College of Obstetricians and Gynecologists. Obstet Gynecol 2013;121:1394–1406.

U.S. Medical Eligibility Criteria for Contraceptive Use, 2010. Centers for Disease Control and Prevention. MMWR Recomm Rep 2010;59(RR-4):1–86.

Update to CDC's U.S. Medical Eligibility Criteria for Contraceptive Use, 2010: revised recommendations for the use of contraceptive methods during the postpartum period. Centers for Disease Control and Prevention. MMWR Morb Mortal Wkly Rep 2011;60:878–83.

Resources

American College of Obstetricians and Gynecologists. Induced abortion. Patient Education Pamphlet AP043. Washington, DC: American College of Obstetricians and Gynecologists; 2011.

Association of Reproductive Health Professionals. Reproductive health topics: abortion. Available at: http://www.arhp.org/topics/abortion. Retrieved August 15, 2013.

National Abortion Federation. Available at: http://www.prochoice.org. Retrieved August 15, 2013.

Paul M, Lichtenbert ES, Borgatta L, Grimes DA, Stubblefield PG, Creinin MD, editors. Management of unintended and abnormal pregnancy: Comprehensive abortion care. West Sussex: Wiley-Blackwell; 2009.

Physicians for Reproductive Health. Available at: www.prch.org. Retrieved August 15, 2013.

Planned Parenthood Federation of America. Available at: http://www.plannedparenthood.org. Retrieved August 15, 2013.

Society of Family Planning. Clinical guidelines. Available at: http://societyfp.org/resources/guidelines.asp. Retrieved June 28, 2013.

S

Original Research

The Comparative Safety of Legal Induced Abortion and Childbirth in the United States

Elizabeth G. Raymond, MD, MPH, and David A. Grimes, MD

OBJECTIVE: To assess the safety of abortion compared with childbirth.

METHODS: We estimated mortality rates associated with live births and legal induced abortions in the United States in 1998–2005. We used data from the Centers for Disease Control and Prevention's Pregnancy Mortality Surveillance System, birth certificates, and Guttmacher Institute surveys. In addition, we searched for population-based data comparing the morbidity of abortion and childbirth.

RESULTS: The pregnancy-associated mortality rate among women who delivered live neonates was 8.8 deaths per 100,000 live births. The mortality rate related to induced abortion was 0.6 deaths per 100,000 abortions. In the one recent comparative study of pregnancy morbidity in the United States, pregnancy-related complications were more common with childbirth than with abortion.

CONCLUSION: Legal induced abortion is markedly safer than childbirth. The risk of death associated with childbirth is approximately 14 times higher than that with abortion. Similarly, the overall morbidity associated with childbirth exceeds that with abortion.

(Obstet Gynecol 2012;119:215–9)

DOI: 10.1097/AOG.0b013e31823fe923

LEVEL OF EVIDENCE: II

See related editorial on page 212.

From Gynuity Health Projects, New York, New York; and the Department of Obstetrics and Gynecology, University of North Carolina School of Medicine, Chapel Hill, North Carolina.

The authors thank Rachel K. Jones, PhD and Lawrence B. Finer, PhD of the Guttmacher Institute and Suzanne Zane, DVM, of the Division of Reproductive Health, Centers for Disease Control and Prevention, for providing essential input to develop the manuscript.

Corresponding author: Elizabeth G. Raymond, MD, MPH, Gynuity Health Projects, 15 East 26th Street, Suite 801, New York, NY 10010; e-mail: eraymond@gynuity.org.

Financial Disclosure
The authors did not report any potential conflicts of interest.

© 2012 by The American College of Obstetricians and Gynecologists. Published by Lippincott Williams & Wilkins.

ISSN: 0029-7844/12

Decades of research have demonstrated that legal induced abortion is safe. Mortality and serious acute complications are extremely rare.[1–4] Recently, allegations of later sequelae—breast cancer and mental illness—were refuted.[5,6] However, laws in 22 states in the United States now require that before an abortion is performed, the patient must be given detailed, specific verbal or written information about potential risks. In some cases, this material is misleading or patently wrong.[7]

Health policy and medical practice should be based on the best available evidence. In the past 10 years, the introduction of new abortion methods may have affected the overall safety of the procedure. Notably, mifepristone was approved by the U.S. Food and Drug Administration for medical abortion in 2000; by 2008, approximately 17% of all nonhospital abortions were performed medically rather than surgically.[8] In addition, changes in the risk profile of pregnant women—for example, as a result of growing obesity[9] and an upward shift in the maternal age distribution[10]—as well as the rising cesarean delivery rate[10] may have enhanced the risks of the alternative to abortion, childbirth. The objective of this review is to provide an updated assessment[2] of the safety of abortion relative to delivery.

MATERIALS AND METHODS

We estimated mortality rates associated with live births and legal induced abortions in the United States in 1998–2005 by combining published data from several national data sets. For mortality related to live birth, we divided the number of pregnancy-related deaths among women delivering live neonates as reported by the Centers for Disease Control and Prevention's (CDC) Pregnancy Mortality Surveillance System[11] by the number of live births as reported on birth certificates.[10] The Pregnancy Mortality Surveillance System collects and reviews death certificates and other information from deceased women who were recorded as pregnant within a

Copyright© American College of Obstetricians and Gynecologists

specified time period before death in all 50 states and Washington, DC. To estimate abortion-related mortality, we divided the number of legal abortion-related deaths from the 50 states and Washington, DC, reported by the CDC[12] by the number of legal abortions estimated by the Guttmacher Institute from its annual surveys of all U.S. hospitals, clinics, and physician offices known or suspected to have provided abortion services.[8] We did not calculate confidence intervals around mortality rates because these estimates are derived from the full population.

In addition, we searched PubMed for relevant studies for other population-based comparative data on mortality and morbidity of abortion and childbirth in the United States since 2000. We used the following search strategies: (maternal morbidity [MESH] OR maternal mortality [MESH]) AND pregnancy outcome AND United States [MESH] (73 results); pregnancy outcome AND (maternal morbidity [MESH] OR maternal mortality [MESH]) AND United States [tiab] (49 results); pregnancy outcome AND abortion, induced AND morbidity AND United States [MESH] (94 results). We limited our review to reports that included data on both pregnancy outcomes in a single population with contemporaneous, uniform ascertainment of outcomes.

Because women who choose abortion differ in underlying risk for adverse outcomes from women who opt to continue a pregnancy, we also compared the characteristics of each group. We obtained data about characteristics of U.S. women having abortions and live births in 2008 from the Guttmacher Institute 2008 Abortion Patient survey[13] and from birth certificate data[11] (www.cdc.gov/nchs/data_access/vitalstats/VitalStats_Births.htm. Retrieved 28 May 2011).

RESULTS

Between 1998 and 2005, the pregnancy-associated mortality rate among women known to have delivered live neonates in the United States was 8.8 deaths per 100,000 live births (Table 1). Of all pregnancy-associated deaths of women with known pregnancy outcome, 71% occurred after live births[11]; if 71% of women with unknown pregnancy outcome who died of pregnancy-associated causes are also assumed to have had live births, the mortality estimate increases to 10.4 deaths per 100,000 live births. The mortality rate related to legal induced abortion during that same interval was 0.6 deaths per 100,000 abortions. Thus, according to federal statistics, the risk of death associated with childbirth was approximately 14 times higher than that with abortion.

Table 1. Pregnancy-Related Mortality in Women With Live Births or Legal Induced Abortions in the United States, 1998–2005

	Deaths*	Pregnancies†	Deaths per 100,000 Pregnancies
Live birth		32,347,794	
Known live birth	2,856		8.8
Known live births+71% of pregnancies with unknown outcome	3,352		10.4
Legal abortion	64	10,185,100	0.6

* Number of deaths related to live births from Berg et al[11]; number of deaths related to abortion from Pazol et al.[12]

† Number of live births from Martin et al[10]; number of abortions from Jones et al.[8]

Only one recent study provided comparative data on morbidity associated with various pregnancy outcomes in the United States.[14] Epidemiologists at the CDC examined all International Classification of Diseases, 9th Revision, Clinical Modification diagnoses reported during or within 8 weeks after all 24,481 pregnancies among members of the Kaiser Permanente Northwest Health Maintenance Organization between 1998 and 2001. Of these pregnancies, 16,824 ended in live birth, 4,192 in induced abortion, and the rest in spontaneous abortions, stillbirths, or other outcomes. Common maternal morbidities were defined as conditions either unique to pregnancy or potentially exacerbated by pregnancy that occurred in at least 5% of all pregnancies.

Every complication was more common among women having live births than among those having abortions (Fig. 1). The relative risks of morbidity with live birth compared with abortion were 1.3 for mental health conditions, 1.8 for urinary tract infection, 4.4 for postpartum hemorrhage, 5.2 for obstetric infections, 24 for hypertensive disorders of pregnancy, 25 for antepartum hemorrhage, and 26 for anemia.

In 2008, the median age of women having abortions was younger than that of women having live births, but the proportion of women age 40 years or older was comparable (Table 2). Nearly half of women in each group had no education beyond high school. Patients undergoing abortion were twice as likely to be unmarried or non-Hispanic African American women. Nulliparity was equally common in the two groups.

Copyright© American College of Obstetricians and Gynecologists

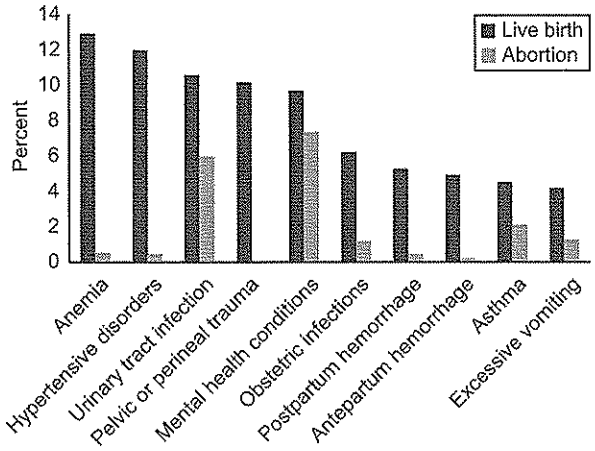


Fig. 1. Common maternal morbidities associated with live birth and abortion, 1998–2001. Common maternal morbidities defined as conditions either unique to pregnancy or potentially exacerbated by pregnancy that occurred in at least 5% of all pregnancies. Data from Bruce FC, Berg CJ, Hornbrook MC, Whitlock EP, Callaghan WM, Bachman DJ, et al. Maternal morbidity rates in a managed care population. Obstet Gynecol 2008;111:1089–95.

Raymond. Safety of Abortion Compared With Childbirth. Obstet Gynecol 2012.

Table 2. Characteristics of Women Having Live Births and Abortions in the United States, 2008

	Live Births*	Abortions†
Age (y)		
Younger than 15	5,764 (0.1)	4,850 (0.4)
15–19	434,758 (10.2)	208,520 (17.2)
20–24	1,052,184 (24.8)	404,920 (33.4)
25–29	1,195,774 (28.2)	295,810 (24.4)
30–34	956,716 (22.5)	163,670 (13.5)
35–39	488,875 (11.5)	99,410 (8.2)
40 or older	113,623 (2.7)	35,160 (2.9)
Total	4,247,694 (100)	1,212,340 (100)
Ethnicity or race		
Hispanic	1,041,239 (24.7)	301,880 (24.9)
Non-Hispanic white	2,267,817 (53.8)	437,660 (36.1)
Non-Hispanic African American	623,029 (14.8)	358,860 (29.6)
Non-Hispanic other	282,783 (6.7)	113,960 (9.4)
Total	4,214,868 (100)	1,212,360 (100)
Marital status		
Married	2,521,128 (59.4)	179,430 (14.8)
Unmarried	1,726,566 (40.6)	1,032,930 (85.2)
Total	4,247,694 (100)	1,212,360 (100)
Education among women aged 20 y and older		
Less than high school	435,462 (18.1)	122,870 (12.3)
High school or GED	630,970 (26.2)	282,710 (28.3)
Some college	685,206 (28.4)	394,590 (39.5)
College graduate	659,044 (27.3)	198,800 (19.9)
Total	2,410,682 (100)	998,970 (100)
Number of prior births		
0	1,703,921 (40.4)	474,030 (39.1)
1	1,330,540 (31.5)	321,270 (26.5)
2 or more	1,186,657 (28.1)	418,260 (34.5)
Total	4,221,118 (100)	1,213,560 (100)

GED, high school equivalency certification.
Data are n (%).
* Data on live births from Martin[10] and the National Center for Health Statistics. Numbers with unknown status are excluded from the table.
† Data on abortion from Jones et al.[13]

DISCUSSION

Legal abortion in the United States remains much safer than childbirth. The difference in risk of death is approximately 14-fold. Abortion also is associated with substantially less pregnancy-related morbidity. These results are consistent with prior analyses of national data.[2] Indeed, the relative safety of abortion has increased substantially since the first decade after nationwide legalization, when child birth-related mortality was approximately seven times the mortality related to abortion.[15] Although we could not find data that allowed comparable calculations of mortality or morbidity associated with surgical and medical abortion, Danco Laboratories, the distributor of mifepristone in the United States, has identified only 11 pregnancy-related deaths among the estimated 1.6 million women who have used the drug in the United States since 2000, which is a mortality rate of 0.7 per 100,000 users (Abigail Long, Danco Laboratories, LLC, personal communication). Clearly, the growing use of medical regimens has not increased relative abortion risk overall.

The disparity between abortion and childbirth safety is not surprising. Pregnancies ending in abortion are substantially shorter than those ending in childbirth and thus entail less time for pregnancy-related problems to occur. Many dangerous pregnancy-related complications such as pregnancy-induced hypertension and placental abnormalities manifest themselves in late pregnancy; early abortion avoids these hazards. Moreover, in the United States in 2008, one third of births occurred by cesarean delivery, an abdominal operation with substantial morbidity.[10,16]

These results may underestimate the relative safety of choosing abortion over continuing a pregnancy for two reasons. First, our comparison was limited to live

Copyright© American College of Obstetricians and Gynecologists

births; we omitted other pregnancy outcomes: spontaneous abortion, stillbirths, ectopic pregnancies, and gestational trophoblastic disease. The number of pregnancies ending in these outcomes was not available. Stillbirths and ectopic pregnancies are associated with higher risks of death than is live birth.[2] We likely therefore underestimated the mortality associated with opting for pregnancy continuation.

Second, patients undergoing abortion appear to be at higher underlying risk than women who opt for delivery. Women who had abortions were more likely to be African American or unmarried, demographic characteristics strongly associated with increased mortality.[11,17] In addition, because comorbidities are sometimes the motivation for abortion, the underlying medical risk of patients undergoing abortion may be higher than that of other pregnant women. Women in good health may be more likely to choose to continue their pregnancies than those who are ill (selection bias termed the "healthy mother" effect[18]). Thus, mortality among patients undergoing abortion may overestimate the mortality risk of the procedure itself.

This study has both strengths and weaknesses. Strengths include the use of the most recent CDC statistics on pregnancy-related mortality for the entire country. Similarly, the cohort study of morbidity had uniform, contemporaneous ascertainment of outcomes in a large health maintenance organization. We systematically reviewed the past decade of PubMed publications for relevant data. Weaknesses include the likely underreporting of deaths, possibly differential by pregnancy outcome (abortion or childbirth).[19] The analytic rules used by the original researchers to handle incomplete or inconsistent data on women's characteristics may have led to errors. Our assessment of women's underlying risk was necessarily incomplete. Moreover, both abortion and childbirth can cause mortality and morbidity long after the end of the pregnancy; these cases are not included in our analysis. However, these weaknesses are unlikely to account for the large differences in mortality and morbidity found in this analysis.

Pregnant women considering their options deserve accurate information about comparative risks. Currently, some state laws and policies violate this standard. In Texas, for example, the mandatory 23-page pamphlet, "A Woman's Right-to-Know," lists 12 potential complications of medical abortion with mifepristone and misoprostol, 12 of suction curettage, and 11 of dilation and evacuation. In contrast, the pamphlet names only six potential complications of vaginal delivery and eight of cesarean delivery.[20] To laypersons who have little understanding of medical risk[21] but can count complications, these tallies may imply that abortion has more complications than does childbirth. Similarly, the mortality statistics are presented as fractions with one in the numerator and with large denominators (eg, 8,475). Empiric evidence[22,23] has demonstrated that women with less formal education than a college degree have trouble comparing risks expressed in this manner. Mortality risk should be expressed as number of deaths per 100,000, which is an easier format to understand.[22,23]

Laws that compel exposure of women to such biased material thwart informed choice and contravene the ethical principle of autonomy.[24] Moreover, they put clinicians in the untenable position of having to be complicit in misleading their patients. Since the early 1970s, the public health evidence has been clear and incontrovertible: induced abortion is safer than childbirth.

REFERENCES

1. Cates W Jr, Rochat RW, Grimes DA, Tyler CW Jr. Legalized abortion: effect on national trends of maternal and abortion-related mortality (1940 through 1976). Am J Obstet Gynecol 1978;132:211–4.
2. Grimes DA. Estimation of pregnancy-related mortality risk by pregnancy outcome, United States, 1991 to 1999. Am J Obstet Gynecol 2006;194:92–4.
3. Hamoda H, Templeton A. Medical and surgical options for induced abortion in first trimester. Best Pract Res Clin Obstet Gynaecol 2010;24:503–16.
4. Grimes DA, Raymond EG. Medical abortion for adolescents. BMJ 2011;342:d2185.
5. Beral V, Bull D, Doll R, Peto R, Reeves G; Collaborative Group on Hormonal Factors in Breast Cancer. Breast cancer and abortion: collaborative reanalysis of data from 53 epidemiological studies, including 83,000 women with breast cancer from 16 countries. Lancet 2004;363:1007–16.
6. Charles VE, Polis CB, Sridhara SK, Blum RW. Abortion and long-term mental health outcomes: a systematic review of the evidence. Contraception 2008;78:436–50.
7. Counseling and waiting periods for abortion. State policies in brief. New York (NY): Guttmacher Institute; 2011.
8. Jones RK, Kooistra K. Abortion incidence and access to services in the United States, 2008. Perspect Sex Reprod Health 2011;43:41–50.
9. Kim SY, Dietz PM, England L, Morrow B, Callaghan WM. Trends in pre-pregnancy obesity in nine states, 1993–2003. Obesity (Silver Spring) 2007;15:986–93.
10. Martin JA, Hamilton BE, Sutton PD, Ventura SJ, Mathews TJ, Osterman MJ. Births: final data for 2008. Hyattsville (MD): National Center for Health Statistics; 2010.
11. Berg CJ, Callaghan WM, Syverson C, Henderson Z. Pregnancy-related mortality in the United States, 1998 to 2005. Obstet Gynecol 2010;116:1302–9.
12. Pazol K, Zane S, Parker WY, Hall LR, Gamble SB, Hamdan S, et al. Abortion surveillance—United States, 2007. MMWR

Copyright© American College of Obstetricians and Gynecologists

Surveill Summ 2011;60:1–42. Erratum in MMWR Surveill Summ 2011;60:315.

13. Jones RK, Kavanaugh ML. Changes in abortion rates between 2000 and 2008 and lifetime incidence of abortion. Obstet Gynecol 2011;117:1358–66.
14. Bruce FC, Berg CJ, Hornbrook MC, et al. Maternal morbidity rates in a managed care population. Obstet Gynecol 2008;111:1089–95.
15. LeBolt SA, Grimes DA, Cates W Jr. Mortality from abortion and childbirth. Are the populations comparable? JAMA 1982;248:188–91.
16. Liu S, Liston RM, Joseph KS, Heaman M, Sauve R, Kramer MS; Maternal Health Study Group of the Canadian Perinatal Surveillance System. Maternal mortality and severe morbidity associated with low-risk planned cesarean delivery versus planned vaginal delivery at term. CMAJ 2007;176:455–60.
17. Bartlett LA, Berg CJ, Shulman HB, Zane SB, Green CA, Whitehead S, et al. Risk factors for legal induced abortion-related mortality in the United States. Obstet Gynecol 2004;103:729–37.
18. Valachis A, Tsali L, Pesce LL, Polyzos NP, Dimitriadis C, Tsalis K, et al. Safety of pregnancy after primary breast carcinoma in young women: a meta-analysis to overcome bias of healthy mother effect studies. Obstet Gynecol Surv 2010;65:786–93.
19. Horon IL. Underreporting of maternal deaths on death certificates and the magnitude of the problem of maternal mortality. Am J Public Health 2005;95:478–82.
20. A woman's right to know. Austin (TX): Texas Department of Health; 2003.
21. Reyna VF, Nelson WL, Han PK, Dieckmann NF. How numeracy influences risk comprehension and medical decision making. Psychol Bull 2009;135:943–73.
22. Grimes DA, Snively GR. Patients' understanding of medical risks: implications for genetic counseling. Obstet Gynecol 1999;93:910–4.
23. van Vliet HA, Grimes DA, Popkin B, Smith U. Lay persons' understanding of the risk of Down's syndrome in genetic counselling. BJOG 2001;108:649–50.
24. Ethical decision making in obstetrics and gynecology. ACOG Committee Opinion No. 390, December 2007. American College of Obstetricians and Gynecologists. Obstet Gynecol 2007;110:1479–87.

BJOG

An International Journal of Obstetrics and Gynaecology

VACANCY: EDITOR-IN-CHIEF

BJOG is inviting applications for the position of Editor-in-Chief as Philip Steer comes to the end of his 7 year term in October 2012.

OVERVIEW OF ROLE

The Editor-in-Chief's role is to lead on the strategic direction of the journal. They must also supervise and coach an excellent team of scientific editors with the support of three deputy editors-in-chief and take final responsibility for all published articles. The role requires a high level of expertise to oversee new developments and to provide intellectual input and experience. The role also requires someone who understands the business side to the extent that they can appreciate the publishing business model and how it is developing. Editorial and strategic experience is essential.

The Editor-in-Chief would need to share the values of BJOG: journal quality (selection, validation and improvement), influence and reputation.

This is a professional role with an annual stipend of £40,000.

Closing date for applications: 17th February 2012
Shortlisted applicants will be invited for interview in March 2012
Start Date as BJOG Scientific Editor: May 2012
Start Date as Editor-in-Chief: November 2012

For more information on this role, a job description and person specification, please visit BJOG's website at **www.BJOG.org** or contact Elizabeth Hay, Managing Editor by email **ehay@rcog.org.uk** or telephone +44 (0) 20 7772 6440

Copyright© American College of Obstetricians and Gynecologists

Access to Obstetric Care in Rural Areas: Effect on Birth Outcomes

THOMAS S. NESBITT, MD, MPH, FREDERICK A. CONNELL, MD, MPH,
L. GARY HART, PHD, AND ROGER A. ROSENBLATT, MD, MPH

Abstract: Hospital discharge data from 33 rural hospital service areas in Washington State were categorized by the extent to which patients left their local communities for obstetrical services. Women from communities with relatively few obstetrical providers in proportion to number of births were less likely to deliver in their local community hospital than women in rural communities with greater numbers of physicians practicing obstetrics in proportion to number of births. Women from these high-outflow communities had a greater proportion of complicated deliveries, higher rates of prematurity, and higher costs of neonatal care than women from communities where most patients delivered in the local hospital. (*Am J Public Health* 1990; 80:814–818.)

Introduction

A fundamental precept of modern obstetrics is that adequate prenatal care leads to improved perinatal outcomes for mothers and infants particularly for high risk populations.[1–3] For pregnant women to obtain timely and appropriate perinatal care, they must establish relationships with individual providers: obstetricians, family physicians, midwives, or public health nurses.

In the rural United States—accounting for 23 percent of the nation's population[5]—two-thirds of the obstetrical providers are family or general practitioners.[6] There has been a precipitous decline over the past several years in the number and proportion of family physicians offering obstetrical services in the United States. In 1988, only 29 percent of the members of the American Academy of Family Physicians were offering routine obstetrical care, down from an estimated 40 percent just two years previously.[7,8] Although approximately 43 percent of *rural* family physicians continued to offer obstetrics, this constitutes a 23 percent decline in their participation since 1980.[7,9] The Institute of Medicine reports that thousands of rural physicians stopped offering obstetrical care, leaving hundreds of rural counties without any local source of obstetrical services.[6] Although the cause of physicians eliminating obstetrical care from their practices is multifactorial, the cost of liability insurance and the fear of suits appear to play a major role in their decisions.[6,8–13]

Even in communities with adequate obstetrical care, a certain proportion of women either choose to leave these communities for obstetrical care, or are referred to different physicians or facilities because of specific complications of pregnancy. However, in towns with little or no obstetrical capacity, most women must travel to secure basic prenatal care as well as delivery. As a consequence it becomes less likely that those women will obtain adequate prenatal care.[14] Delays in care of early labor complications may also result.

This study investigates the extent to which local availability of obstetrics is related to perinatal outcomes. We seek to answer the following questions:

- What are the characteristics of rural communities in which the majority of women deliver at a facility other than their local hospital (outflow)?
- Using outflow as a proxy for access to care, is there any difference in the outcome or cost of care for women living in communities with diminished obstetrical access as compared to women who have ready access to local obstetrical care?

Methods

Population Studied

The study was based on all deliveries of women whose primary residence was in a rural area of Washington State and who gave birth during calendar year 1986. The following definitions were used:

- *Rural hospitals* were defined as all non-federal, short-stay, acute care, inpatient facilities of fewer than 50 beds and located more than 15 miles from a city of 30,000 population or greater. Thirty-three of Washington's 90 hospitals met these criteria.
- A *rural area* was defined as the medical service catchment area served by these hospitals.
- A *catchment area* was the aggregate of all zip code areas whose center was closer to a specific rural hospital by public road than to any other hospital facility.
- Distances were based on figures supplied by the Washington State Department of Transportation.

Stratification of Rural Areas by Location of Delivery

A file of all hospital discharges from non-federal, short-stay hospitals in the State of Washington includes data on the place of residence of the patient, hospital of discharge, the DRG (diagnosis related group), and hospital charges. Maternal residence was used to identify all patients living within the 33 rural medical service catchment areas. By comparing the place of residence with the location of the hospital of delivery, we could determine what proportion of all obstetrical deliveries occurred in facilities outside a woman's local hospital catchment area.

The 33 rural areas were stratified into three groups on the basis of these determinations. Areas in which more than two-thirds of deliveries occurred in the local hospital were designated as "low-outflow" communities. "High-outflow" communities were those in which fewer than one-third of deliveries to local women occurred in the local hospital.

From the Department of Family Practice, University of California, Davis, and the Department of Family Medicine, University of Washington School of Medicine (Nesbitt); the Departments of Pediatrics and Community Medicine, University of Washington (Connell), and the Department of Family Medicine, University of Washington (Hart, Rosenblatt). Address reprint requests to Thomas S. Nesbitt, MD, MPH, Department of Family Practice, University of California-Davis, 2221 Stockton Boulevard, Sacramento, CA 95817. This paper, submitted to the Journal July 25, 1989, was revised and accepted for publication November 8, 1989.

© 1990 American Journal of Public Health 0090-0036/90$1.50

"Medium-outflow" communities were those between these two extremes.

Availability of Obstetrical Services

The availability of obstetrical services in each of the 33 communities was determined through telephone surveys of hospital administrators and directors of nursing. The response rate was 100 percent. Information was obtained as to the number and specialty of all physicians providing obstetrical services in each hospital during the study period (1986), as well as in 1985 and early in 1988. A physician was considered as providing obstetrical services if, in the opinion of the administrator and directors of nursing, the physician was routinely doing deliveries in the hospital; this excluded physicians who delivered only on an emergency basis.

Determining Pregnancy Outcome and Costs

DRGs were used as proxies for obstetrical outcome (Appendix). Maternal complications were defined as all discharges with DRGs 370 or 372. These DRGs are used to designate deliveries—both cesarean section and vaginal—associated with major intrapartum complications, as well as other conditions such as pregnancy-induced hypertension, diabetes, and anemia. The balance of the deliveries were assumed to be uncomplicated for the purposes of this study and included DRG 371 (uncomplicated C-section), 373 (normal vaginal delivery), and 374 and 375 (vaginal delivery with an operating room procedure, such as sterilization). Premature births were defined as babies discharged with DRG codes 386, 387, or 388 all of which referred to premature delivery. DRGs 389, 390, and 391 were defined as full term births.

Hospital charges for neonatal care, as well as source of payment, were also evaluated from the hospital discharge abstracts.

Statistical Analysis

Differences in outcomes between outflow groups were evaluated using chi-square for trend for each outcome measure. Hospital charges for newborns were evaluated by comparing the means of high and low outflow communities, and the confidence interval of the difference between them. In addition, for the same groups, the proportion of newborns with charges greater than $5,000 were compared using the associated 95 percent confidence interval of the difference between those proportions.

Results

Characteristics of Study Communities

Approximately 350,000 people, 8 percent of the population of Washington State, live in the 33 rural medical service areas defined by this study. The 33 hospitals serving these areas represent 37 percent of the 90 acute, short-term, general hospitals in Washington State, but account for only 8 percent of the total licensed acute care beds. These service areas are dispersed throughout the state; 23 of Washington's 39 counties encompass one or more of the study areas. The 5,554 births which occurred to residents of these areas in 1986 represent 8.1 percent of all births to residents of the state during that year. There were 108 physicians practicing obstetrics in the 33 communities during 1986, 93 percent of whom were family or general practitioners; there were eight obstetricians practicing in two low-outflow communities and two medium-outflow communities.

As can be seen from Table 1, both the rural communities and the hospitals that serve them are quite small, with the average service area encompassing 10,592 people and the average hospital having 32 beds. High-outflow communities—those in which more than two-third of all births to local residents did not occur in the local hospital—were smaller than communities where larger proportions of pregnant women delivered in their local community hospital. These high-outflow communities were also somewhat closer to other more sophisticated perinatal facilities, although even for this group the average distance to a Level II facility was 41 miles. Conventional measures of socioeconomic status, such as unemployment rate and the proportion of obstetrical patients enrolled in Medicaid, did not meaningfully differ among the three groups of communities.

The most striking difference between the communities in the outflow groups was the local availability of obstetrical care. By the end of the study period in 1986, only eight of the 13 high-outflow community hospitals still offered routine obstetrical services, with four of the closures occurring since mid-1984. Additionally, three of the eight hospitals which offered obstetrical services in 1986 suspended these services

TABLE 1—Characteristics of Study Communities Stratified by Differential Obstetrical Outflow, Washington State, 1986

Characteristics	Low Outflow (<33%) N = 8	Medium Outflow (33–67%) N = 12	High Outflow (>67%) N = 13	All Communities N = 33
Total number of hospital births to residents of service areas	1,155	2,781	1,618	5,554
Percent of births occurring outside community	19.9	48.8	80	52
Mean miles to Level II nursery	79	63	41	58
Mean beds in local hospital	37	33	27	32
Mean population of hospital service area	11,029	12,318	8,731	10,592
Mean percent of obstetrical patients enrolled in Medicaid	31.3	28	27.4	28.8
Mean percent county unemployment rate (1985)	12.6	11.8	11.1	11.7
Percent of births to women under 18 or over 35 (1986)	9.4	11.0	8.8	9.7
Infant Mortality Rates/1000 births (County rates 1980–83)	11.6	11.8	10.5	11.2

in either 1987 or 1988. The reason given in essentially all of these cases was the decision of local physicians to discontinue offering obstetrics. All of the low and medium-outflow communities continued to offer obstetrics. Figure 1 shows that high-outflow communities had relatively fewer obstetrically active physicians in the year before the study, and that this disparity has become more pronounced during the study year and in the succeeding year. By contrast, there was no significant attrition in obstetric availability in the comparison communities.

Obstetrical Outcomes

Obstetrical outcomes differed systematically across the three groups of communities. As Figure 2 demonstrates, there is a strong association between the proportion of deliveries that occur outside of the community and the rate of complications associated with childbirth. Women living in high-outflow communities were 34 percent more likely to experience birth-associated complications or comorbidity than women from medium-outflow communities, and 67 percent more likely than women from low-outflow communities.

Children of women from high-outflow communities have higher rates of prematurity, a trend significant at the .001 level. Neonatal length of stay—a measure presumably correlated with neonatal outcome—also shows a significant trend across community type.

Access to Care and Perinatal Costs

Table 2 illustrates the difference in hospital charges for newborns used as a proxy for cost for neonatal care across the three community groups. Newborn patients from high-outflow communities have dramatically higher average charges than their counterparts in better served communities.

Although the differences are impressive without regard to insurance type, it appears these differences are mainly the result of patients enrolled in the Medicaid program. It should be noted, however, that infants of lower income women with adverse birth outcomes generating high hospital charges are more likely to be encouraged, and even assisted in enrolling in Medicaid.

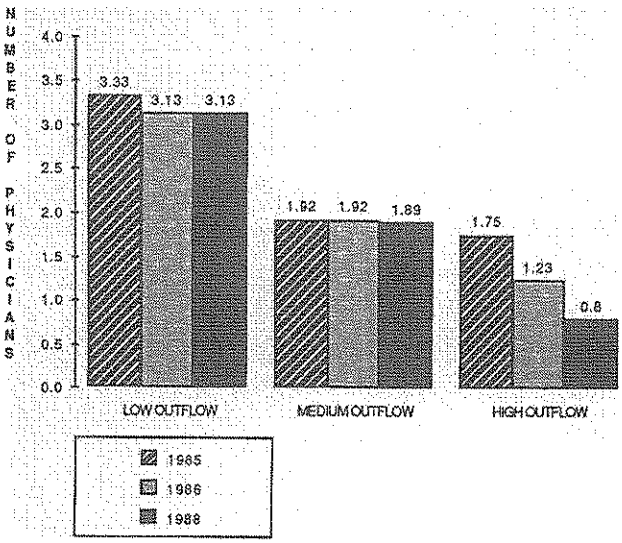


FIGURE 1—Physicians Practicing Obstetrics per 100 Births to Local Women by Community Outflow by Selected Year

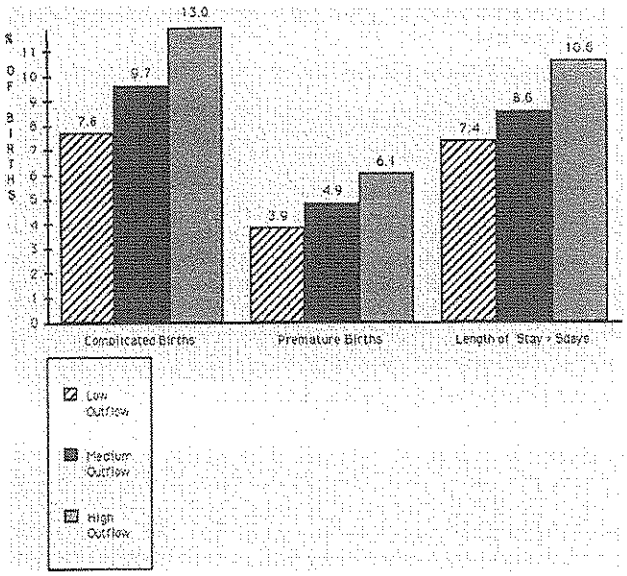


FIGURE 2—Percent of Adverse Birth Outcomes to Rural Washington State Residents by Community Outflow

TABLE 2—Newborn Hospital Charges to Rural Washington Residents Stratified by Community Outflow for Obstetrical Care and Payor Type

	Mean Charges		
	High Outflow N = 1587	Low Outflow N = 1210	Difference (95% CI)
All payors	$2,103	$1,046	$1057 (−$125, $2,239)
Medicaid	$4,627	$1,014	$3613 (−$422, $7,648)
Non-Medicaid	$1,128	$1,061	$67 (−$368, $502)
	Proportion of Newborns with Charges > $5,000		
	High Outflow N = 1587	Low Outflow N = 1210	Difference (95% CI)
All payors	3.6	1.7	1.9 (0.66, 3.14)
Medicaid	6.3	2.1	4.2 (0.54, 7.9)
Non-Medicaid	2.7	1.4	1.3 (−.03, 2.57)

Although a few outliers can generate enormous charges, dramatically increasing the mean, and they undoubtedly had an effect here, newborns with higher charges clearly occurred more frequently in high outflow community populations. As shown in Table 2, there are three times as many babies on Medicaid with charges exceeding $5,000 in the high-outflow communities compared to the low-outflow communities—a measure less affected than average charges by the influence of extreme outliers.

Discussion

The declining proportion of practitioners offering obstetrical services has had a disproportionate impact on rural areas. First, rural areas have fewer physicians per capita than urban regions and thus are more susceptible to changes in the spectrum of clinical services offered by those physicians who

do practice in rural America. Second, a larger proportion of deliveries in rural areas have been provided by general and family physicians, a group that has experienced a high rate of attrition from obstetrics.[6,7–13,15]

Out data demonstrate that women living in rural Washington state communities with little or no obstetrical care available locally tend to deliver in hospitals outside the community. These women are more likely to have complicated labor and premature deliveries, and their infants are more likely to have longer and more expensive hospital stays than the children of their rural counterparts who deliver in local facilities communities with greater access to care.

The design of this study does not permit us to conclude that there is a causal relation between impaired access to rural obstetrical care and adverse perinatal outcome, although this appears to be a tenable hypothesis. There are several possible mechanisms which could account for a causal relation between access to care and outcome, however. First, women living in communities without obstetrical services must travel to obtain routine prenatal care, a barrier associated with poorer prenatal compliance.[14] Women on marginal incomes or women without adequate transportation would be likely to delay or forego prenatal care, and might have more difficulty getting to all their prenatal visits. Even if these patients are able to arrange for transportation to other communities, they may encounter difficulties in obtaining obstetrical care in a state like Washington where most physicians limit the number of pregnant Medicaid patients for whom they will provide care.[10]

Second, obtaining obstetrical care and delivering outside one's local community may in itself constitute a risk factor for adverse outcome, even if obstetrical care has been arranged. Patients from remote, rural communities may have difficulty adhering to prenatal protocols or treatment regimens prescribed by physicians in distant communities. There may be significant delays in presentation to the hospital after the onset of labor. And the increased stress—physiological and psychological—associated with travel and parturition in unfamiliar settings may interfere with the normal process of labor.

Nevertheless, there are alternative explanations for the patterns observed here, the first being the possibility that inappropriate care was delivered by local physicians in high outflow communities. This is an unlikely cause for the results in this study for several reasons. First, there was little care available in these communities; five were without any routine obstetrical services. Second, for the 20 percent of the women from high-outflow communities who did deliver in a local hospital, outcomes were actually superior to local deliveries in medium and low-outflow facilities. Finally, of the non-local complicated births which occurred to women from high outflow communities, less than 5 percent came to those non-local hospitals as the result of a transfer.

A second explanation is that because the data are derived from hospital discharge abstracts, we lack precise information about the prenatal, intrapartum, and neonatal course of the patients in the study. DRGs and costs are used as proxies for outcome, and it is possible that there is a systematic bias in which larger urban hospitals are more likely to intervene medically during the intrapartum period, assign DRG codes denoting increased medical intensity, and keep neonates longer in their nurseries than smaller rural hospitals. Even if such a bias is the cause of the apparent differences in biological outcomes, the increased charges and lengths of stay associated with deliveries outside rural communities are real.

A third alternative explanation for the observed disparities is that women from communities with high-outflow are not comparable to the women living in medium- and low-outflow communities. Perhaps the 13 communities in this group have populations of women with higher risks for adverse perinatal outcomes. However, we found no indications that these high-outflow communities differ systematically from those with lower outflow for obstetrical care. Although the high-outflow communities are slightly smaller than the average rural Washington town or medical service area, the situation regarding previous county infant mortality rates (80–83), county unemployment, and the percent of obstetrical patients on Medicaid from these communities is similar to that of communities with less outflow and better outcomes.

A fourth explanation for these results may be that physicians in communities with increased rates of adverse outcomes transfer those high-risk patients to outside facilities prior to labor, thereby becoming a high-outflow community. However, if one notes that high-outflow communities were those in which more than two-thirds of the patients delivered non-locally, and that these communities had only 13 percent complicated births, it is clear that the transfer of an increased number of complicated patients would not change an otherwise low-outflow community into a high-outflow community.

Despite the limitations of this study, the data suggest that recent declines in the availability of obstetrical care in rural areas are associated with poorer perinatal outcomes. From the experience in Washington State it appears that the pivotal event is the decision by rural family physicians to discontinue providing obstetrical services. In many cases this leads to a substantial curtailment or total discontinuation of obstetrical services in the local hospital, causing women who may have previously delivered in their local hospital to travel to other communities for their obstetric care.

Although in this study loss of local services and associated higher rates of adverse outcomes were observed only in a handful of relatively small communities, this may be the leading edge of a more pervasive phenomenon. Although the problem is more graphic and easily demonstrated in rural populations, impaired obstetrical access may have the same social and biological consequences in urban settings.[16]

This study suggests that programs that maintain local availability of obstetrical care may improve perinatal outcomes in a cost effective fashion, since infants from high-outflow rural communities generated hospital charges twice as high as infants from low- and medium-outflow communities. The excess charges were more than $1.5 million during 1986 alone, most of it paid for by public subsidies through the Medicaid program. This does not include additional costs in the post-hospital period which have been shown to be higher for Medicaid infants whose mothers received inadequate prenatal care.[17]

In conclusion, this study demonstrates an association between diminished rural access to obstetrical care and perinatal outcomes for women who travel outside their local communities for that care. If a causal relationship exists, society would benefit both medically and economically from providing a solution to the problems which stem from a diminishing number of obstetrical providers.

ACKNOWLEDGMENT

The authors would like to thank Joe Campo (Washington State Health Coordinating Council) and Robert Hughes for their assistance with this work.

This study was supported by grant 9353 from the Robert Wood Johnson Foundation to the University of Washington, Department of Family Medicine

and the Office of Rural Health Policy, a component of the Health Resources and Services Administration of the Public Health Service.

APPENDIX

Codification of Diagnosis Related Groups

DRG	Abbreviated Title
Coded as Complicated Birth	
370	Cesarean section with complications or comorbidity
372	Vaginal delivery with complicating diagnosis
Coded as Uncomplicated Birth	
371	Cesarean section without complications or comorbidity
373	Vaginal delivery without complicating diagnoses
374	Vaginal delivery with sterilization and/or D & C
375	Vaginal delivery with operating room procedure except sterilization or D & C
Coded as Premature Neonate	
386	Extremely premature neonate
387	Premature with major complications
388	Premature without major complications
Coded as Term Neonates	
389	Full term neonate with major problems
390	Neonates with other problems
391	Normal newborn

REFERENCES

1. Gortmacher SL: The effect of prenatal care upon the health of the newborn. Am J Public Health 1979; 69:653–657.
2. Moore TR, *et al*: The perinatal and economic impact of prenatal care in a low-socioeconomic population. Am J Obstet Gynecol 1986; 154:29–33.
3. Institute of Medicine: Preventing Low Birthweight. Washington, DC: National Academy Press, 1985.
4. Alan Gutmacher Institute: The Blessed Event and the Bottom Line. New York: Alan Gutmacher Institute, 1987.
5. Rosenblatt RA, Moscovice IS: Rural Health Care. New York: John Wiley and Sons, 1982.
6. Institute of Medicine: The Effects of Medical Professional Liability and the Delivery of Obstetric Care. Washington, DC: National Academy Press, 1989.
7. Schmittling G, Tosu C: Obstetrical privileges for family physicians: A national study. J Fam Pract 1989; 29:179–184.
8. Bredfeldt R: Present status of obstetrics in family practice and the effect of malpractice issues. J Fam Pract 1989; 28:294–297.
9. Clinton C, *et al*: Hospital privileges for family physicians: A national study of office based members of the American Academy of Family Physicians. J Fam Pract 1981; 13:361–371.
10. Rosenblatt RA: The changing pattern of obstetrical practice in Washington State: The impact of tort reform. Fam Med 1988; 20:100–107.
11. Smucker DR: Obstetrics in family practice in the State of Ohio. J Fam Pract 1988; 26:165–167.
12. Smith MA, *et al*: Family practice obstetrics in Michigan: Factors affecting physician participation. J Fam Pract 1989; 28:433–437.
13. Rostow VP, *et al*: Medical professional liability and the delivery of obstetrical care. N Engl J Med 1989; 321:1057–1060.
14. McDonald TP, Coburn AF: Predictors of prenatal care utilization. Soc Sci Med 1988; 27:167–171.
15. Changes in Practice of Obstetrics-Gynecologists ANA's Professional Liability Update. Chicago: American College of Obstetricians and Gynecologists, 1988.
16. Braveman P, *et al*: Adverse outcomes and lack of health insurance among newborns in an eight-county area of California, 1982 to 1986. N Engl J Med 1989; 321:508–513.
17. Maternity Care Access, Division of Medical Assistance, Department of Social and Health Services, Office of Analysis and Review, State of Washington Working Paper, October 13, 1987.

'Late Breaker' Session on Injury Control Invites Abstracts

The Injury Control and Emergency Health Services special primary interest group of the American Public Health Association has announced it will again feature a "late breaker" session during the APHA upcoming 118th annual meeting in New York City. The session will be held on Tuesday, October 2, 8:30 am–10:00 am, and will feature work completed within the last few months—after the deadline for consideration in the regular symposia of the APHA annual meeting.

Abstracts of 250 words or less will be accepted by the Injury Control SPIG until August 15, 1990. Please send the abstract, title of the paper, authors' name, address and telephone number to: Richard Waxweiler, Division of Injury Control, Centers for Disease Control, Mail Stop F-36, Atlanta, GA 30333. Tel: 404/488-4695.

OBSTETRICS

The impact of hospital obstetric volume on maternal outcomes in term, non—low-birthweight pregnancies

Jonathan M. Snowden, PhD; Yvonne W. Cheng, MD, PhD; Cathy L. Emeis, CNM, PhD; Aaron B. Caughey, MD, PhD

OBJECTIVE: The impact of hospital obstetric volume specifically on maternal outcomes remains under studied. We examined the impact of hospital obstetric volume on maternal outcomes in low-risk women who delivered non—low-birthweight infants at term.

STUDY DESIGN: We conducted a retrospective cohort study of term singleton, non—low-birthweight live births from 2007-2008 in California. Deliveries were categorized by hospital obstetric volume categories and separately for nonrural hospitals (category 1: 50-1199 deliveries per year; category 2: 1200-2399; category 3: 2400-3599, and category 4: ≥3600) and rural hospitals (category R1: 50-599 births per year; category R2: 600-1699; category R3: ≥1700). Maternal outcomes were compared with the use of the chi-square test and multivariable logistic regression.

RESULTS: There were 736,643 births in 267 hospitals that met study criteria. After adjustment for confounders, there were higher rates of postpartum hemorrhage in the lowest-volume rural hospitals (category R1 adjusted odds ratio, 3.06; 95% confidence interval, 1.51—6.23). Rates of chorioamnionitis, endometritis, severe perineal lacerations, and wound infection did not differ between volume categories. Longer lengths of stay were observed after maternal complications (eg, chorioamnionitis) in the lowest-volume hospitals (16.9% prolonged length of stay in category 1 hospitals vs 10.5% in category 4 hospitals; adjusted odds ratio, 1.91; 95% confidence interval, 1.01—3.61).

CONCLUSION: After confounder adjustment, few maternal outcomes differed by hospital obstetric volume. However, elevated odds of postpartum hemorrhage in low-volume rural hospitals raises the possibility that maternal outcomes may differ by hospital volume and geography. Further research is needed on maternal outcomes in hospitals of different obstetric volumes.

Key words: maternal complication, obstetric volume, quality, obstetrics

Cite this article as: Snowden JM, Cheng YW, Emeis CL, et al. The impact of hospital obstetric volume on maternal outcomes in term, non—low-birthweight pregnancies. Am J Obstet Gynecol 2014;211:••••.

A wide range of factors likely affect obstetric outcomes for low-risk women who deliver in hospitals.[1,2] For example, hospital-level factors that include ownership, obstetric provider and nursing staffing, and delivery volume are known increasingly to affect perinatal outcomes.[3-7] Hospital obstetric volume is one hospital factor that has received research attention in recent years, with some studies demonstrating increased rates of adverse perinatal outcomes at the extremes of annual delivery volume.[8-13] Several of these studies were conducted outside of the United States, some focused on one or two outcomes (some exclusively neonatal), and some did not stratify by maternal risk profile.

The impact of hospital volume on neonatal outcomes has been well studied in very low-birthweight infants,[14-17] which led to evidence-based recommendations for neonatal regionalization and designated levels of neonatal

From the Department of Obstetrics and Gynecology (Drs Snowden and Caughey) and School of Nursing (Dr Emeis), Oregon Health & Science University, Portland, OR, and Department of Obstetrics, Gynecology, California Pacific Medical Center, San Francisco, CA (Dr Cheng).

Received May 14, 2014; revised Aug. 5, 2014; accepted Sept. 23, 2014.

Supported by grant number R40 MC 25694-01-00 from the Maternal and Child Health Research Program, Maternal and Child Health Bureau (Title V, Social Security Act), Health Resources and Services Administration, Department of Health and Human Services (J.M.S. and A.B.C.), and by the UCSF Women's Reproductive Health Research Career Development Award, NIH, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (K12 HD001262, Y.W.C.).

The content is solely the responsibility of the authors and does not necessarily represent the official views of National Institutes of Health or Health Resources and Services Administration.

The authors report no conflict of interest.

Corresponding author: Jonathan M. Snowden, PhD. snowden@ohsu.edu

0002-9378/$36.00 • © 2014 Elsevier Inc. All rights reserved. • http://dx.doi.org/10.1016/j.ajog.2014.09.026

intensive care.[18] Perinatal regionalization gained widespread attention with the 1976 publication of the landmark March of Dimes report *Toward Improving the Outcome of Pregnancy*[19] and can be defined as "a systematized cohesive regional network in which the complexity of patient needs determines where and by whom care should be provided."[20] In contrast with neonatal outcomes, maternal outcomes have not yet been studied in the same level of detail, particularly in the larger population of pregnant women who deliver non—low-birthweight infants at term.[21] This evidence gap is especially pressing given the increasing prevalence of severe maternal complications (eg, postpartum hemorrhage) and maternal death in the developed world.[22,23] Further, the birth setting and obstetric care that specifically optimize maternal outcomes may not be identical to those that optimize outcomes for their neonates.[24] Because a policy of regionalization must take into account both maternal and fetal/neonatal outcomes, it is crucial to advance our understanding of maternal outcomes across different hospital settings and characteristics that include obstetric volumes. It was our aim to help fill this gap regarding hospital volume for a variety of maternal outcomes in low-risk women.

To address this gap, we analyzed the association between annual hospital obstetric volume and various maternal complications of hospitalization. We conducted a retrospective cohort study of births in the state of California from 2007-2008, analyzing linked vital statistics data and hospital discharge data. We categorized hospitals by annual delivery volume and analyzed rates of maternal outcomes across categories to provide evidence on the impact of hospital obstetric volume, specifically on maternal outcomes. We restricted our sample to the population of women who delivered a non—low-birthweight infant at term without certain preexisting medical conditions to inform the dialogue on optimal birth setting for low-risk women. We hypothesized that obstetric complications would be more frequent in the highest- and lowest-volume hospitals.

Materials and Methods

This was a retrospective cohort study of California deliveries in 2007-2008, with the use of linked vital statistics/patient discharge data. The California Patient Discharge Data, Vital Statistics Birth Certificate Data, and Vital Statistics Death Certificate data are linked and maintained by the Office of Statewide health Planning and Development (OSHPD), Healthcare Information Resource Center, under the California Health and Human Services Agency.[25] The dataset contains patient discharge data (diagnosis and procedure codes) for antepartum admissions in the 9 months before delivery, maternal and infant admissions in the year after delivery, and data from the US Standard Certificate of Live Birth. Maternal and infant records were linked with the record linkage number, which is a unique encrypted alphanumeric code that is specific to each mother/baby pair. Reporting of births in California is almost 100% comprehensive, with California Health and Human Services Agency personnel coding the data according to uniform specifications, performing rigorous quality checks, and reviewing the birth cohort file before it is released. We obtained human subjects approval from the Committee on Human Research at the University of California, San Francisco, the California OSHPD Committee for the Protection of Human Subjects, and the Institutional Review Board at Oregon Health & Science University. The linked dataset did not contain potential patient privacy/identification information, so informed consent was exempted.

Considerations of hospital volume and obstetric regionalization depend on hospital geography.[26] Rural labor and delivery units face a unique set of issues in assuring patient safety, and regionalization/high obstetric volume may not be feasible for such hospitals.[27,28] Rural hospitals account not only for a substantial proportion of hospitals in our study (27%) but also for a small fraction of births (8%). This reflects the marked difference in the distribution of delivery volume for rural vs nonrural hospitals: volumes are lower in rural hospitals (often by a factor of 3-5), with key demographic and health-related differences between populations of the women who are served.[29,30] To reflect these distinct distributions and to assess for effect modification by rurality, we conducted a geography-stratified analysis with a separate definition of 'low rural volume.' Maternity hospital rurality was defined based on OSHPD rural hospital designations, the presence of a California Association of Rural Health Clinics member clinic, and/or a rural zip code according to the Rural-Urban Commuting Area-2 codes.[11]

Annual hospital obstetric volume was categorized with the use of previously published volume categories.[11] For nonrural maternity hospitals, the categories were: 50-1199 deliveries per year (category 1), 1200-2399 deliveries (category 2), 2400-3599 deliveries (category 3), and ≥3600 deliveries per year (category 4). Rural hospitals were divided into separate, previously published volume categories: 50-599 births per year (category R1), 600-1699 births (category R2), and ≥1700 births per year (category R3). Further, we compared outcomes between rural and nonrural hospitals with the lowest obstetric volume (≤1000 annual deliveries) to help tease out the effect of low absolute volume vs geography.

To define a population of relatively low-risk deliveries, we restricted analyses to women who carried a singleton, vertex-presenting fetus at term. We excluded low birthweight infants (birthweight, <2500 g) and fetuses with chromosomal or anatomic anomalies (defined by the birth certificate and *International Classification of Diseases, 9th Revision, Clinical Modification* [ICD-9] codes 740-759.9). Women with preexisting diabetes mellitus and chronic hypertension (as defined by ICD-9 codes) were also excluded, as were women with a previous cesarean delivery. All exclusions were conducted after we calculated hospital obstetric volume.

We compared rates of outcomes across hospital volume categories separately

for rural and nonrural hospitals. The following maternal quality outcomes were analyzed as outcomes: chorioamnionitis, endometritis, postpartum hemorrhage (overall and stratified by spontaneous vaginal delivery, operative vaginal delivery, and cesarean delivery), transfusion of blood products, severe perineal lacerations (3rd and 4th degree) in spontaneous vaginal deliveries, wound infection in cesarean deliveries, and the cesarean delivery rate in the nulliparous, term, singleton, vertex population. The final outcome was prolonged length of stay (LOS; as indicated in the discharge data), which was defined as maternal LOS of >3 days for vaginal deliveries and >5 days for cesarean deliveries. The ICD-9 codes listed in Table 1 were used to define chorioamnionitis, endometritis, postpartum hemorrhage, blood transfusion, severe perineal lacerations, and wound infection. Mode of delivery and parity were derived from birth certificate data. Maternal death was not recorded in the database.

Unadjusted comparisons between volume categories were calculated with the χ^2 test. We used multivariable logistic regression models to assess the association between obstetric volume category and outcomes, controlling for confounding. We adjusted for the following potential confounders: advanced maternal age (≥35 vs <35 years old), maternal education (≥12 vs <12 years), maternal race/ethnicity, maternal public insurance status, prenatal care initiation (first trimester vs later), teaching hospital, and where appropriate, parity (nulliparous vs multiparous). Covariates were selected for inclusion in the model based on a priori subject matter knowledge. Models adjusted for hospital-level clustering of outcomes with the clustered Huber/White variance estimator[31] and calculated robust standard errors.

Finally, we were interested in whether the management of maternal complications differed among hospital volume categories. Therefore, we calculated the rate of prolonged LOS after maternal complications (chorioamnionitis, endometritis, and postpartum hemorrhage). We compared the rates of prolonged LOS after maternal complications across volume categories in nonrural hospitals (cell sizes were too small in rural hospitals). We estimated adjusted associations using multivariable logistic regression, as described earlier. In all analyses, statistical significance was indicated by a probability value of < .05 and/or 95% confidence intervals (CIs).

Power calculations revealed substantial power to detect modest differences (odds ratio [OR], 1.3) in even the rarest outcome (blood transfusion) between volume categories in nonrural hospitals (power, 98%). For outcomes that were stratified by mode of delivery, power was in some cases lower (eg, 77% power to detect an OR of 1.5 for wound infection after cesarean delivery), although still substantial for some outcomes (eg, >99% for postpartum hemorrhage in cesarean deliveries). Power was lower, but still substantial, in the rural analyses (eg, 82% power to detect an OR of 1.5 for transfusion). For rural analysis that was stratified by mode of delivery, we were under-powered for some outcomes (eg, 24% power to detect an OR of 1.5 for wound infection) but not for others (eg, 83% power to detect an OR of 1.5 for postpartum hemorrhage after cesarean delivery). Power was sufficient for prolonged LOS after maternal complications in nonrural hospitals (eg, 82% power to detect an OR of 1.3 for postpartum hemorrhage), but insufficient in rural hospitals (eg, 12% power). We therefore restricted the LOS analyses to nonrural hospitals.

TABLE 1
***International Classification of Diseases, 9th Revision, Clinical Modification* codes for maternal complications**

Outcome	Codes
Chorioamnionitis	658.4, 658.40, 658.41, 658.43, 762.7
Endometritis	670, 670.00, 670.02, 670.04, 670.1, 670.10, 670.12, 670.14, 672, 672.00, 672.02, 672.04
Postpartum hemorrhage	285.1, 666, 666.0, 666.00, 666.02, 666.04, 666.1, 666.10, 666.12, 666.14, 666.2, 666.20, 666.22, 666.24, 666.3, 666.30, 666.32, 666.34
Transfusion of blood products	99.00, 99.01, 99.02, 99.03, 99.04, 99.05, 99.06, 99.07, 99.08, 99.09
Severe perineal lacerations (3rd or 4th degree)	664.2, 664.20, 664.21, 664.24, 664.3, 664.30, 664.31, 664.34, 664.60, 664.61, 664.64
Wound infection	674.3, 674.30, 674.32, 674.34

Snowden. Hospital obstetric volume and maternal outcomes. Am J Obstet Gynecol 2014.

RESULTS

There was a total of 267 maternity hospitals in California that met study criteria, with a total of 736,643 deliveries. Two hundred eleven hospitals with 678,622 deliveries were located in nonrural locations, and 56 hospitals were located in rural locations, with 58,021 deliveries (Table 2). The larger hospitals in categories 3 and 4 cared for more black and Asian American women compared with the smallest hospitals (categories 1 and 2), which cared for a larger share of white women (categories 1 and 2: 30% white; categories 3 and 4: 25% white). In rural hospitals, the higher-volume hospitals (category R3) cared for predominantly Hispanic women with lower educational attainment (73% Hispanic; 22% education ≥12 years), compared with the lowest-volume rural hospitals in category R1 whose patient populations were majority white (55% white; 38% education ≥12 years).

In unadjusted analyses, hospital obstetric volume was associated with multiple outcomes. Rates of chorioamnionitis, endometritis, postpartum hemorrhage, and severe lacerations differed significantly for nonrural hospitals ($P < .001$; Table 3). The magnitude of

TABLE 2
Maternal characteristics by hospital obstetric volume categories

	Nonrural, %					Rural, %			
		Hospital volume category					Hospital volume category		
Characteristic	Overall[a]	1 (50-1199 births per year)[b]	2 (1200-2399 births per year)[c]	3 (2400-3599 births per year)[d]	4 (≥3600 births per year)[e]	Overall[f]	R1 (50-599 births per year)[g]	R2 (600-1699 births per year)[h]	R3 (≥1700 births per year)[i]
Nulliparous	46.8	44.4	47.3	45.6	47.6	43.0	45.4	43.0	41.1
Advanced maternal age	15.1	14.9	15.6	13.4	16.0	8.5	9.1	9.0	7.7
Public insurance	49.2	56.1	45.5	50.4	49.4	69.2	64.1	70.4	71.7
Education ≥12 y	47.2	43.3	48.2	44.4	49.0	30.2	38.1	32.7	22.1
Prenatal care initiated in 1st trimester	83.6	80.2	82.0	83.2	85.5	70.5	73.7	68.2	69.7
Race/ethnicity									
White	26.3	28.1	30.5	24.0	25.1	33.2	55.0	29.3	19.2
Black	4.9	4.0	4.1	5.3	5.2	2.4	2.4	0.8	3.6
Hispanic	54.0	55.6	53.1	56.6	52.5	58.7	34.2	65.2	72.9
Asian-American	12.9	10.2	10.2	12.1	15.3	2.7	3.1	2.0	3.0
Other	2.1	2.1	2.1	1.9	2.0	2.9	5.3	2.7	1.3

[a] n = 678,622 births/n = 211 hospitals; [b] n = 48,450 births/n = 49 hospitals; [c] n = 164,372 births/n = 69 hospitals; [d] n = 183,573 births/n = 48 hospitals; [e] n = 282,722 births/n = 45 hospitals; [f] n = 58,021 births/n = 56 hospitals; [g] n = 17,742 births/n = 35 hospitals; [h] n = 17,699 births/n = 14 hospitals; [i] n = 22,580 births/n = 7 hospitals.

Snowden. Hospital obstetric volume and maternal outcomes. Am J Obstet Gynecol 2014.

these differences was small (frequently <1%) and generally favored lower-volume hospitals when a pattern was apparent (eg, in chorioamnionitis and postpartum hemorrhage after cesarean delivery).

Significant differences were also observed in unadjusted analysis across rural hospital volume categories (Table 4). Postpartum hemorrhage decreased with increasing obstetric volume. The overall hemorrhage rates decreased from 4.5% in category R1 hospitals to 1.7% in category R3 hospitals; for operative vaginal deliveries, the decrease was 6.2-2.6% (both $P < .001$).

After adjustment for confounders, there were few significant differences between volume categories in nonrural hospitals (Table 5). The odds of blood transfusion were significantly higher in category 2 hospitals (OR compared with category 4, 1.30; 95% CI, 1.03–1.66). For all other outcomes, 95% CIs included 1, and effect sizes were generally small (mostly 0.8-1.4). In rural hospitals, odds of postpartum hemorrhage remained elevated in low-volume hospitals after adjustment for confounders in the regression models (Table 6). The overall odds of postpartum hemorrhage was 3-fold higher in the lowest-volume hospitals compared with the highest-volume (category R1 OR, 3.06; 95% CI, 1.51–6.23). Adjusted odds of postpartum hemorrhage were 2-fold higher in medium-volume rural hospitals compared with highest-volume (category R2 OR, 1.95; 95% CI, 1.00–3.81). These increased risks of postpartum hemorrhage were also observed in models that were stratified by mode of delivery. There were no other differences for the other outcomes between rural volume categories.

We compared outcomes across rural vs nonrural hospitals with low obstetric volume (≤1000 annual deliveries; Table 7). In adjusted analyses, rural hospital geography was a risk factor for postpartum hemorrhage overall (OR, 1.96; 95% CI, 1.22–3.17) and when stratified by mode of delivery. Adjusted odds of blood transfusion were also elevated in rural low-volume hospitals, compared with nonrural low-volume hospitals (OR, 1.76; 95% CI, 1.18–2.61). Nulliparous, term, singleton, vertex cesarean delivery was less common in rural hospitals with low volume (OR, 0.73; 95% CI, 0.59–0.92).

When the rate of prolonged LOS after maternal complication in nonrural hospitals was considered, rates generally were increased in the lowest-volume hospitals (category 1). The rate of prolonged LOS after chorioamnionitis was 16.9% in category 1 hospitals, as compared with 10.5% in category 4 hospitals ($P < .001$; Table 8). For prolonged LOS after endometritis, the difference was 30.8% in category 1 hospitals vs 22.8% in category 4 hospitals ($P < .001$). There was no difference in the case of postpartum hemorrhage. These differences persisted after multivariable adjustment in the lowest-volume hospitals (chorioamnionitis OR,

TABLE 3
Rates of maternal outcomes across nonrural hospital volume categories

Variable	Nonrural hospital volume category, %				*P* value
	1 (50-1199 births per year)	2 (1200-2399 births per year)	3 (2400-3599 births per year)	4 (≥3600 births per year)	
Chorioamnionitis	1.8	2.0	2.5	2.2	< .001
Endometritis	0.5	0.5	0.8	0.7	< .001
Postpartum hemorrhage					
Overall	2.9	2.7	2.9	2.8	< .001
Spontaneous vaginal delivery	2.9	2.6	2.7	2.7	< .087
Operative vaginal delivery	3.7	3.3	3.7	3.8	.160
Cesarean delivery	2.6	2.8	4.1	3.1	< .001
Blood transfusion	0.5	0.6	0.6	0.5	< .001
Severe perineal lacerations (spontaneous vaginal delivery)	2.3	2.4	2.6	2.8	< .001
Wound infection (cesarean delivery)	0.7	0.6	0.7	0.6	.268
Prolonged length of stay[a]	2.8	2.7	2.3	2.5	< .001
Nulliparous, term, singleton, vertex cesarean delivery	28.1	26.8	25.1	27.8	< .001

[a] Prolonged length of stay: >3 days for vaginal deliveries; >5 days for cesarean deliveries.

Snowden. Hospital obstetric volume and maternal outcomes. Am J Obstet Gynecol 2014.

TABLE 4
Rates of maternal outcomes across rural hospital volume categories

Variable	Rural hospital volume category, %			*P* value
	R1 (50-599 births per year)	R2 (600-1699 births per year)	R3 (≥1700 births per year)	
Chorioamnionitis	0.7	0.8	0.7	.561
Endometritis	0.5	0.5	0.4	.312
Postpartum hemorrhage				
Overall	4.5	3.3	1.7	< .001
Spontaneous vaginal delivery	4.4	3.3	1.7	< .001
Operative vaginal delivery	6.2	5.2	2.6	< .001
Cesarean delivery	4.1	2.6	2.0	< .001
Blood transfusion	0.7	0.6	0.6	.442
Severe perineal lacerations (spontaneous vaginal delivery)	2.1	1.6	2.3	< .001
Wound infection (cesarean delivery)	0.6	0.9	0.6	.260
Prolonged length of stay[a]	1.8	1.6	1.2	< .001
Nulliparous, term, singleton, vertex cesarean delivery	24.9	26.4	24.0	.003

[a] Prolonged length of stay: >3 days for vaginal deliveries; >5 days for cesarean deliveries.

Snowden. Hospital obstetric volume and maternal outcomes. Am J Obstet Gynecol 2014.

TABLE 5
Logistic regression results[a] of maternal outcomes in nonrural hospitals

Variable	Nonrural hospital volume category, odds ratio (95% confidence interval)			
	1 (50-1199 births per year)	2 (1200-2399 births per year)	3 (2400-3599 births per year)	4 (≥3600 births per year)
Chorioamnionitis	1.13 (0.74–1.74)	1.13 (0.79–1.60)	1.36 (0.94–1.95)	Reference
Endometritis	1.07 (0.73–1.55)	0.94 (0.70–1.26)	1.40 (1.00–1.96)	Reference
Postpartum hemorrhage				
Overall	1.29 (0.92–1.81)	1.14 (0.86–1.52)	1.22 (0.86–1.74)	Reference
Spontaneous vaginal delivery	1.32 (0.95–1.83)	1.15 (0.88–1.52)	1.15 (0.83–1.57)	Reference
Operative vaginal delivery	1.16 (0.81–1.67)	0.94 (0.67–1.32)	1.09 (0.74–1.61)	Reference
Cesarean delivery	1.22 (0.76–1.97)	1.15 (0.75–1.76)	1.62 (0.92–2.83)	Reference
Blood transfusion	1.02 (0.76–1.36)	1.30 (1.03–1.66)	1.19 (0.94–1.51)	Reference
Severe perineal lacerations (spontaneous vaginal delivery)	1.01 (0.83–1.23)	0.94 (0.82–1.09)	1.04 (0.87–1.24)	Reference
Wound infection (cesarean delivery)	1.41 (0.87–2.29)	1.03 (0.75–1.42)	1.28 (0.88–1.84)	Reference
Prolonged length of stay[b]	1.41 (0.94–2.13)	1.27 (0.97–1.66)	1.06 (0.79–1.42)	Reference
Nulliparous, term, singleton, vertex cesarean delivery	1.02 (0.85–1.22)	0.93 (0.81–1.06)	0.88 (0.78–1.00)	Reference

[a] Models were controlled for maternal race/ethnicity, education, age, prenatal care, insurance status, and teaching hospital; where appropriate, models were controlled for parity; models estimated robust standard errors that accounted for hospital-level clustering; [b] Prolonged length of stay: >3 days for vaginal deliveries; >5 days for cesarean deliveries.

Snowden. Hospital obstetric volume and maternal outcomes. Am J Obstet Gynecol 2014.

TABLE 6
Logistic regression results[a] of maternal outcomes in rural hospitals

Variable	Rural hospital volume category, odds ratio (95% confidence interval)		
	R1 (50-599 births per year)	R2 (600-1699 births per year)	R3 (≥1700 births per year)
Chorioamnionitis	1.18 (0.66–2.08)	1.13 (0.58–2.22)	Reference
Endometritis	1.69 (0.99–2.87)	1.36 (0.71–2.58)	Reference
Postpartum hemorrhage			
Overall	3.06 (1.51–6.23)	1.95 (1.00–3.81)	Reference
Spontaneous vaginal delivery	3.17 (1.52–6.62)	2.06 (1.00–4.22)[b]	Reference
Operative vaginal delivery	2.76 (1.17–6.50)	2.12 (1.07–4.23)	Reference
Cesarean delivery	2.65 (1.30–5.43)	1.40 (0.64–3.09)	Reference
Blood transfusion	1.35 (0.91–2.00)	1.00 (0.57–1.74)	Reference
Severe perineal lacerations (spontaneous vaginal delivery)	1.01 (0.68–1.53)	0.67 (0.44–1.01)	Reference
Wound infection (cesarean delivery)	1.41 (0.63–3.15)	1.57 (0.67–3.67)	Reference
Prolonged length of stay[c]	1.20 (0.78–1.86)	1.22 (0.73–2.03)	Reference
Nulliparous, term, singleton, vertex cesarean delivery	1.08 (0.78–1.51)	1.11 (0.76–1.64)	Reference

[a] Models were controlled for maternal race/ethnicity, education, age, prenatal care, and insurance status; where appropriate, models were controlled for parity; models estimated robust standard errors that accounted for hospital-level clustering; [b] Confidence interval includes the null value because of rounding; $P = .049$; [c] Prolonged length of stay: >3 days for vaginal deliveries; >5 days for cesarean deliveries.

Snowden. Hospital obstetric volume and maternal outcomes. Am J Obstet Gynecol 2014.

TABLE 7
Comparison of maternal outcomes by hospital geography (rural vs nonrural) in low-volume hospitals[a]

Maternal outcome	Unadjusted, %			Adjusted, adjusted odds ratio (95% confidence interval)[b]	
	Rural[c]	Nonrural[d]	*P* value	Rural	Nonrural
Chorioamnionitis	0.8	1.3	< .001	0.77 (0.50–1.19)	Reference
Endometritis	0.5	0.4	.142	1.52 (0.97–2.38)	Reference
Postpartum hemorrhage					
Overall	4.4	2.6	< .001	1.96 (1.22–3.17)	Reference
Spontaneous vaginal delivery	4.3	2.7	< .001	1.80 (1.13–2.87)	Reference
Operative vaginal delivery	6.1	3.1	< .001	2.39 (1.21–4.70)	Reference
Cesarean delivery	4.2	2.2	< .001	2.51 (1.34–4.69)	Reference
Blood transfusion	0.7	0.4	< .001	1.76 (1.18–2.61)	Reference
Severe perineal lacerations (spontaneous vaginal delivery)	2.3	2.4	.129	1.00 (0.75–1.31)	Reference
Wound infection (cesarean delivery)	0.7	0.6	.532	1.10 (0.56–2.16)	Reference
Prolonged length of stay[e]	1.8	1.9	.188	0.87 (0.62–1.22)	Reference
Nulliparous, term, singleton, vertex cesarean delivery	23.4	30.3	< .001	0.73 (0.59–0.92)	Reference

[a] Hospitals with annual delivery volume ≤1000; [b] Models were controlled for maternal race/ethnicity, education, age, prenatal care, insurance status, and parity; models estimated robust standard errors that accounted for hospital-level clustering; [c] n = 45 hospitals/n = 28,393 births; [d] n = 38 hospitals/n = 32,811 births; [e] Prolonged length of stay: >3 days for vaginal deliveries; >5 days for cesarean deliveries.

Snowden. Hospital obstetric volume and maternal outcomes. Am J Obstet Gynecol 2014.

1.91; 95% CI, 1.01–3.61; endometritis OR, 1.50; 95% CI, 1.00–2.23).

COMMENT

In this large retrospective cohort of term non–low-birthweight California deliveries, we observed some differences in maternal quality outcomes by hospital volume category. The lowest- and medium-volume rural hospitals exhibited higher rates of postpartum hemorrhage compared with higher-volume rural hospitals, which is a difference that persisted after confounder adjustment. Although most outcomes did not differ in nonrural hospitals, rates of prolonged LOS after chorioamnionitis and endometritis did differ by volume category.

TABLE 8
Prolonged lengths of stay[a] after maternal complications in nonrural hospitals, stratified by volume category

Variable	Category 1 (50-1199 deliveries per day)	Category 2 (1200-2399 deliveries per day)	Category 3 (2400-3599 deliveries per day)	Category 4 (≥3600 deliveries per day)	*P* value
Unadjusted, %					
Chorioamnionitis	16.9	12.1	10.2	10.5	< .001
Endometritis	30.8	23.1	19.7	22.8	.001
Postpartum hemorrhage	10.1	10.2	10.0	9.7	.230
Adjusted, adjusted odds ratio (95% confidence interval)[b]					
Chorioamnionitis	1.91 (1.01–3.61)	1.28 (0.92–1.80)	1.10 (0.79–1.51)	Reference	–
Endometritis	1.50 (1.00–2.23)[c]	1.07 (0.81–1.42)	0.86 (0.67–1.11)	Reference	–
Postpartum hemorrhage	1.30 (0.88–1.91)	1.23 (0.96–1.57)	1.13 (0.88–1.43)	Reference	–

[a] Prolonged length of stay: >3 days for vaginal deliveries; >5 days for cesarean deliveries; [b] Models were controlled for maternal race/ethnicity, education, age, prenatal care, insurance status, parity, and teaching hospital; models estimated robust standard errors that accounted for hospital-level clustering; [c] Confidence interval includes the null value because of rounding; *P* = .048.

Snowden. Hospital obstetric volume and maternal outcomes. Am J Obstet Gynecol 2014.

Specifically, the lowest-volume hospitals exhibited higher rates of prolonged LOS, which suggests that the management of these maternal complications is different in low-volume hospitals. Perhaps these findings reflect different levels of provider coverage, resource availability, and preparedness for unexpected events.[28,32] Future research should further analyze the impact of hospital-level factors on the management of maternal complications and should examine the factors that may explain these differences.

These findings add to the small body of literature on maternal complications and hospital-level factors. One previous study that used the National Inpatient Sample found no consistent association between hospital obstetric volume and maternal complications.[9] In contrast, one study found increased rates of adverse maternal outcomes in very low-volume hospitals and in the highest-volume hospitals for cesarean deliveries;[10] another study found increased rates of obstetric infection in teaching hospitals and hospitals with higher numbers of beds.[7] Several design and analysis differences could explain these differences: different study populations/states, modeling approaches, and outcome definitions. The lack of agreement between studies highlights the importance of additional research on maternal complications that are associated with hospital volume and regionalization.

Our study was not without limitations. We analyzed administrative data, which are not collected for research purposes and are recorded with variable reliability and accuracy.[33,34] Nevertheless, for topics such as this for which randomization is not feasible and large samples are required, administrative data may be the best option. Although California is a large and racially diverse state, these findings may not be generalizable to other regions with different hospital policies, obstetric practice, and populations. We analyzed the most recent data available; however, safety and quality initiatives have been instituted since 2008. Our definition of low-risk excluded low-birthweight and preterm deliveries and women with preexisting medical conditions. There are varying definitions of "low-risk," and seemingly low-risk pregnancies may become high-risk in the prenatal or intrapartum period. The definition of low-risk is an open question in obstetric/perinatal research, and the definitions should continue to be refined as research in this area progresses.[1] Our system of categorizing hospitals relied on arbitrary obstetric volume cutoffs. Cutoffs were chosen to maintain adequate numbers of births and unique hospitals in each category, and using another categorization system may alter results. Last, our database lacks information on the staffing factors, physical space and equipment, and availability of ancillary resources (eg, blood products) that might explain differences between obstetric volumes and geography.

This study adds to the growing literature on hospital obstetric volume and maternal outcomes in low-risk deliveries. We found that most obstetric complications did not differ between hospitals of varying volumes after adjustment for maternal characteristics. However, it is noteworthy that rates of postpartum hemorrhage were elevated in low-volume rural hospitals, especially given that this outcome is a leading cause of preventable maternal death.[35] There is still insufficient evidence to determine whether there are meaningful differences in maternal outcomes by hospital-level factors. Future research should analyze this study question across a variety of populations and hospital settings. Where differences in maternal outcomes exist, it will be important to consider clinical approaches, hospital policies, and potentially systemic strategies (eg, regionalization) to remediate disparities and ensure a universally high quality of maternity care. By furthering our understanding of maternal outcomes and maternal preferences of varying birth settings, we can enable clinicians, hospital administrators, and mothers to make fully informed decisions. ■

REFERENCES

1. IOM (Institute of Medicine) and NRC (National Research Council). An update on research issues in the assessment of birth settings: workshop summary. Washington, DC: The National Academies Press; 2013.
2. Bailit JL, Srinivas SK. Where should I have my baby? Am J Obstet Gynecol 2012;207:1-2.
3. Snyder CC, Wolfe KB, Loftin RW, Tabbah S, Lewis DF, Defranco EA. The influence of hospital type on induction of labor and mode of delivery. Am J Obstet Gynecol 2011;205:346.e1-4.
4. Sherenian M, Profit J, Schmidt B, et al. Nurse-to-patient ratios and neonatal outcomes: a brief systematic review. Neonatology 2013;104:179-83.
5. Srinivas SK, Fager C, Lorch SA. Variations in postdelivery infection and thrombosis by hospital teaching status. Am J Obstet Gynecol 2013;209:567.e1-7.
6. Garcia FA, Miller HB, Huggins GR, Gordon TA. Effect of academic affiliation and obstetric volume on clinical outcome and cost of childbirth. Obstet Gynecol 2001;97:567-76.
7. Goff SL, Pekow PS, Avrunin J, Lagu T, Markenson G, Lindenauer PK. Patterns of obstetric infection rates in a large sample of US hospitals. Am J Obstet Gynecol 2013;208:456.e1-13.
8. Tracy SK, Sullivan E, Dahlen H, Black D, Wang YA, Tracy MB. Does size matter? A population-based study of birth in lower volume maternity hospitals for low risk women. BJOG 2006;113:86-96.
9. Janakiraman V, Lazar J, Joynt KE, Jha AK. Hospital volume, provider volume, and complications after childbirth in U.S. hospitals. Obstet Gynecol 2011;118:521-7.
10. Kyser KL, Lu X, Santillan DA, et al. The association between hospital obstetrical volume and maternal postpartum complications. Am J Obstet Gynecol 2012;207:42.e1-17.
11. Snowden JM, Cheng YW, Kontgis CP, Caughey AB. The association between hospital obstetric volume and perinatal outcomes in California. Am J Obstet Gynecol 2012;207:478.e1-7.
12. Heller G, Richardson DK, Schnell R, Misselwitz B, Kunzel W, Schmidt S. Are we regionalized enough? Early-neonatal deaths in low-risk births by the size of delivery units in Hesse, Germany 1990-1999. Int J Epidemiol 2002;31:1061-8.
13. Hemminki E, Heino A, Gissler M. Should births be centralised in higher level hospitals? Experiences from regionalised health care in Finland. BJOG 2011;118:1186-95.
14. Phibbs CS, Bronstein JM, Buxton E, Phibbs RH. The effects of patient volume and level of care at the hospital of birth on neonatal mortality. JAMA 1996;276:1054-9.
15. Phibbs CS, Baker LC, Caughey AB, Danielsen B, Schmitt SK, Phibbs RH. Level and volume of neonatal intensive care and mortality in very-low-birth-weight infants. N Engl J Med 2007;356:2165-75.
16. Bartels DB, Wypij D, Wenzlaff P, Dammann O, Poets CF. Hospital volume and neonatal mortality among very low birth weight infants. Pediatrics 2006;117:2206-14.

17. Chung JH, Phibbs CS, Boscardin WJ, Kominski GF, Ortega AN, Needleman J. The effect of neonatal intensive care level and hospital volume on mortality of very low birth weight infants. Med Care 2010;48:635-44.
18. Barfield WD; Committee on Fetus and Newborn. Levels of neonatal care. Pediatrics 2012;130:587-97.
19. Committee on Perinatal Health. Toward improving the outcome of pregnancy: recommendations for the regional development of maternal and perinatal health services. White Plains, NY: March of Dimes National Foundation; 1976.
20. Hein HA. Regionalized perinatal care in North America. Semin Neonatol 2004;9:111-6.
21. D'Alton ME, Bonanno CA, Berkowitz RL, et al. Putting the "M" back in maternal-fetal medicine. Am J Obstet Gynecol 2013;208:442-8.
22. Berg CJ, Callaghan WM, Syverson C, Henderson Z. Pregnancy-related mortality in the United States, 1998 to 2005. Obstet Gynecol 2010;116:1302-9.
23. Bateman BT, Berman MF, Riley LE, Leffert LR. The epidemiology of postpartum hemorrhage in a large, nationwide sample of deliveries. Anesth Analg 2010;110:1368-73.
24. Hankins GD, Clark SL, Pacheco LD, O'Keeffe D, D'Alton M, Saade GR. Maternal mortality, near misses, and severe morbidity: lowering rates through designated levels of maternity care. Obstet Gynecol 2012;120:929-34.
25. Danielsen B. Probabilistic record linkages for generating a comprehensive epidemiological research file on maternal and infant health: health information solutions/California Dept of Public Health, 2002. Available at: http://ipodr.org/data%20sources.html. Accessed July 30, 2014.
26. Kozhimannil KB, Hung P, Prasad S, Casey M, Moscovice I. Rural-urban differences in obstetric care, 2002-2010, and implications for the future. Med Care 2014;52:4-9.
27. American College of Obstetricians and Gynecologists. ACOG Committee Opinion no. 429: health disparities for rural women. Obstet Gynecol 2009;113:762-5.
28. Jukkala AM, Kirby RS. Challenges faced in providing safe care in rural perinatal settings. MCN Am J Matern Child Nurs 2009;34:365-71.
29. Kozhimannil K, Hung P, Mcclellan M, Casey M, Prasad S, Moscovice I. Policy brief: obstetric services and quality among critical access, rural, and urban hospitals in nine states. Minneapolis, MN: University of Minnesota Rural Health Research Center, 2013. Available at: http://rhrc.umn.edu/2013/06/ob1/. Accessed July 30, 2014.
30. Simpson KR. An overview of distribution of births in United States hospitals in 2008 with implications for small volume perinatal units in rural hospitals. J Obstet Gynecol Neonatal Nurs 2011;40:432-9.
31. Williams RL. A note on robust variance estimation for cluster-correlated data. Biometrics 2000;56:645-6.
32. American Hospital Association (AHA). The opportunities and challenges for rural hospitals in an era of health reform, 2011. Available at: http://aharesourcecenter.wordpress.com/2011/05/02/opportunites-and-challenges-for-rural-hospitals-in-an-era-of-health-reform/. Accessed Aug. 1, 2014.
33. Goff SL, Pekow PS, Markenson G, Knee A, Chasan-Taber L, Lindenauer PK. Validity of using ICD-9-CM codes to identify selected categories of obstetric complications, procedures and co-morbidities. Paediatr Perinat Epidemiol 2012;26:421-9.
34. Lain SJ, Hadfield RM, Raynes-Greenow CH, et al. Quality of data in perinatal population health databases: a systematic review. Med Care 2012;50:e7-20.
35. Berg CJ, Harper MA, Atkinson SM, et al. Preventability of pregnancy-related deaths: results of a state-wide review. Obstet Gynecol 2005;106:1228-34.

Roberts et al. BMC Medicine 2014, 12:144
http://www.biomedcentral.com/1741-7015/12/144

BMC Medicine

RESEARCH ARTICLE Open Access

Risk of violence from the man involved in the pregnancy after receiving or being denied an abortion

Sarah CM Roberts, M Antonia Biggs*, Karuna S Chibber, Heather Gould, Corinne H Rocca and Diana Greene Foster

Abstract

Background: Intimate partner violence is common among women having abortions, with between 6% and 22% reporting recent violence from an intimate partner. Concern about violence is a reason some pregnant women decide to terminate their pregnancies. Whether risk of violence decreases after having an abortion, remains unknown.

Methods: Data are from the Turnaway Study, a prospective cohort study of women seeking abortions at 30 facilities across the U.S. Participants included women who: presented just prior to a facility's gestational age limit and received abortions (Near Limit Abortion Group, n = 452), presented just beyond the gestational limit and were denied abortions (Turnaways, n = 231), and received first trimester abortions (First Trimester Abortion Group, n = 273). Mixed effects logistic regression was used to assess the relationship between receiving versus being denied abortion and subsequent violence from the man involved in the pregnancy over 2.5 years.

Results: Physical violence decreased for Near Limits (adjusted odds ratios (aOR), 0.93 per month; 95% Confidence Interval (CI) 0.90, 0.96), but not Turnaways who gave birth ($P < .05$ versus Near Limits). The decrease for First Trimesters was similar to Near Limits ($P = .324$). Psychological violence decreased for all groups (aOR, 0.97; CI 0.94, 1.00), with no differential change across groups.

Conclusions: Policies restricting abortion provision may result in more women being unable to terminate unwanted pregnancies, potentially keeping them in contact with violent partners, and putting women and their children at risk.

Keywords: Abortion, Intimate partner violence

Background

Experiencing violence, especially from intimate partners, is common among women having abortions, with 6% to 22% reporting recent violence from an intimate partner [1-5]. Concern about violence is a reason some pregnant women decide to terminate their pregnancies [6-9]. In particular, women who report violence as a reason for abortion describe not wanting to expose children to violence and believing that having the baby will tether them to an abusive partner [6].

Whether having an abortion actually allows women to evade intimate partner violence (IPV) remains unknown. One prospective study in New Zealand found elevated levels of past year IPV among women who had abortions compared to women who gave birth and no differences between women who had abortions and women who had not been pregnant [10]. However, the difference in IPV between women who had an abortion and women who gave birth was no longer statistically significant once confounders were controlled. The New Zealand study assessed IPV from any intimate partner, not necessarily from the man involved in the pregnancy (MIP). Focusing on the MIP is important because this is the person to whom a woman would be linked if she carried the pregnancy to term.

The aim of this paper is to examine changes in violence from the MIP among women receiving versus being denied

* Correspondence: Antonia.Biggs@ucsf.edu
Advancing New Standards in Reproductive Health (ANSIRH), University of California, San Francisco, 1330 Broadway, Suite 1100, Oakland, CA 94612, USA

BioMed Central

© 2014 Roberts et al.; licensee BioMed Central Ltd. This is an Open Access article distributed under the terms of the Creative Commons Attribution License (http://creativecommons.org/licenses/by/4.0), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly credited. The Creative Commons Public Domain Dedication waiver (http://creativecommons.org/publicdomain/zero/1.0/) applies to the data made available in this article, unless otherwise stated.

abortion over 2.5 years after seeking an abortion. Comparing changes in violence over time between women receiving versus denied abortion has the benefit of being able to better match groups of women with respect to important confounding factors, such as pregnancy intentions and violence, that can lead women to become pregnant and also decide to terminate a pregnancy. Thus, women denied abortions better represent what women's experiences would have been had they not terminated the unwanted pregnancy and allow for the possibility of causal inference regarding outcomes subsequent to abortion.

Methods

Data for this paper come from the Turnaway Study, a prospective cohort study of women who all sought, but did not all receive, abortions at 30 abortion facilities in the United States. Women were recruited when they sought abortion and were interviewed by telephone one week later. The Turnaway Study is following participants for five years, interviewing them by telephone biannually. This paper presents findings from the first 2.5 years of data collection. The University of California, San Francisco's Committee for Human Research granted ethical approval for the study. All participants provided written informed consent.

Participants were English- and Spanish-speaking women with no known fetal anomalies or demise, 15-years-old or older, presenting at one of the study facilities between January 2008 and December 2010 (the recruitment period). Facilities with the latest gestational age limit for providing abortion within 150 miles were eligible. All but two facilities approached participated; one was replaced with a facility with a similar catchment area, identical gestational limit and similar patient volume. Participating facility limits ranged from 10 weeks through the end of the second trimester, with four having limits in the first trimester, eight between 14 and less than 20 weeks, and 18 after 20 weeks. Details about the study and facilities have been published previously [11-16].

Women were eligible for the study and assigned to one of three study groups based on their gestational age at abortion-seeking. Women presenting for abortion within two weeks under a facility's gestational age limit and receiving an abortion were assigned to the Near Limit Abortion Group; women presenting for abortion up to three weeks over the limit and denied abortion at that facility were assigned to the Turnaway Group. Near Limit Abortion versus Turnaway is the main comparison in this study. For every Turnaway, we recruited two women for the Near Limit Abortion Group and also one woman receiving an abortion in the first trimester for the First Trimester Abortion Group. The First Trimester Abortion Group was included to assess how the experiences of women in the Near Limit Group compared to the more typical experience of abortion in the U.S., where 90% of abortions occur in the first trimester [17].

Of eligible participants approached, 37.5% consented, with 85% of those consenting (n = 956) completing the baseline interview [16]. Seventy two percent of those completing the baseline interview were retained at the sixth interview (2.5 years). There was no differential participation across the two main study groups (Near Limit Abortion Group and Turnaway Group), but fewer women eligible for the First Trimester Abortion Group participated. There was no differential loss to follow up by study group or by baseline violence over the 2.5 years. Of the 956 who completed a baseline interview, 452 were in the Near Limit Abortion Group, 231 in the Turnaway Group, and 273 in the First Trimester Abortion Group. Some women in the Turnaway Group received an abortion elsewhere or miscarried subsequent to being denied the abortion at the recruitment facility. At one facility with a gestational limit of 10 weeks, 90% of Turnaways received an abortion elsewhere or miscarried. All of the 76 participants from this facility were excluded from analyses. Two Near Limit Abortion Group and one First Trimester Group participants later reported that they had not had the abortion and were excluded from the analyses. Women who did not know who the man involved in the pregnancy was or reported that the pregnancy was a result of rape (n = 15) were not asked questions about the MIP at follow-up interviews and were excluded from the analyses. The sample thus includes 862 participants, with 405 in the Near Limit Abortion Group, 156 Turnaways who had a birth (Turnaway Births), 48 Turnaways who had an abortion (n = 43) or miscarriage (n = 5) (Turnaway No Births), and 253 in the First Trimester Abortion Group.

Two types of violence from the MIP were considered as outcome variables: physical and psychological. These outcome variables were based on questions about physical violence (that is, 'pushed, hit, slapped, kicked, choked, or physically hurt in any way by another person') and psychological violence (that is, 'frightened for your safety as a result of anger or threats made by another person') in the last six months. We also asked whether the perpetrator of the most recent violent episode was the MIP. The violence questions were asked at each biannual interview. Violence questions were modified from California's Maternal and Infant Health Assessment Survey [18]. During the baseline interview, participants were also asked about physical and psychological violence in the year preceding the interview. We used dates of conception and of violence to determine whether the violence occurred during or before pregnancy.

Study group was the main independent variable and included Near Limit Abortion Group (as reference); Turnaway Births (Turnaways with a live birth, including 15 who placed their baby for adoption); Turnaway No

Births (Turnaways who received an abortion elsewhere or miscarried) and First Trimester Abortion Group. Because we were interested in both Near Limit versus Turnaway Birth and Near Limit versus First Trimester comparisons, Near Limit as the reference allowed simultaneous comparisons of both sets of study groups. Months was the time variable and was measured in months since recruitment. Study Group X Months interaction terms allowed examination of group-specific change over time.

Covariables included potential confounders of the relationship between study group and subsequent violence, all measured at baseline. We measured race/ethnicity (White, Black, Hispanic/Latina, Other); age in years; employment (employed full or part time versus unemployed); union status (married, cohabiting, not-cohabiting never married, divorced/widowed); history of child abuse/neglect, or reporting having ever experienced physical abuse, neglect, or sexual abuse during childhood; raising children (no live births, living with all biological children, one or more biological children cared for by someone else); grew up in a household with someone with an alcohol or drug problem; grew up in a household with someone with a psychological disorder; previous depression or anxiety diagnosis; alcohol problem symptom the month before pregnancy recognition, with those reporting having a drink first thing in the morning to steady nerves or get rid of a hangover and those reporting that they were unable to remember what happened the night before because of drinking coded as having a problem symptom; and illicit drug use the month before pregnancy recognition, with any marijuana, heroin, cocaine, methamphetamine use or prescription drug misuse coded as illicit drug use.

We used three analytical approaches. First, we used mixed effects linear, logistic and multinomial logistic regression to compare baseline characteristics of study groups. The mixed effects regression models included random intercepts for facility to account for clustering of participants by site. Second, longitudinal analyses examining associations between study group and violence over time were conducted with mixed effects multivariate logistic regression. Longitudinal analyses included data from the first six interviews, from one week through 2.5 years after abortion-seeking, and included all available data. Random intercepts for facility and for individual were included to account for facility and individual-level clustering. Random slopes for individual did not improve any model fits and, thus, were not included. Third, in the cases where change over time differed between the Near Limit and Turnaway Births groups, a model with Turnaway Births as the reference group was estimated to be able to describe change over time directly for the Turnaway Births group and not describe change solely in relation to the Near Limit Group. All analyses were conducted in Stata 12.0.

Results

Participant baseline characteristics are shown in Table 1. Compared to the Near Limit Abortion Group, the Turnaway Birth Group was younger, less likely to be employed and less likely to be raising children. A smaller proportion of women in the Turnaway No Birth Group than in the Near Limit Abortion Group reported a history of child abuse/neglect and growing up in a household with someone with a drinking or drug problem. Compared to the Near Limit Abortion Group, the First Trimester Abortion Group was more likely to be White, employed and report growing up in a household with someone with a psychological disorder. As expected due to study design, groups differed significantly on gestational age at recruitment.

In the six months prior to baseline (to match the timeframe for subsequent measures of violence), 5% of the participants experienced physical violence from the MIP and 3% reported psychological violence from the MIP (See Table 1). There were no statistically significant differences across study group in either physical or psychological violence from the MIP in the six months prior to baseline.

In the year prior to baseline, violence from the MIP occurred both before and during pregnancy, with about 3% reporting physical violence before pregnancy only, 3% during pregnancy only and 1% both before and during pregnancy (Figure 1, not shown in a table). For psychological violence from the MIP, this was 3% before pregnancy only, 2% during pregnancy only and 2% both before and during pregnancy.

Results of longitudinal analyses are presented in Table 2 and are shown graphically in Figure 2. The adjusted odds ratio (aOR) for Study Group indicates the extent to which violence at baseline for each study group differed from the Near Limit Abortion Group. Months indicates change over time in violence for the Near Limit Abortion Group and the P value for months indicates whether the slope of change over time statistically differed from zero. P values for Study Group X Time interactions indicate whether change over time differed for that study group versus change over time for the Near Limit Abortion group.

Models adjust for: baseline age, race, employment, union status, raising children, depression/anxiety history, child abuse/neglect history, problem alcohol use prior to pregnancy recognition, recent drug use and having a household member with a drinking or drug problem or a psychiatric disorder during childhood.

There were no statistically significant differences in physical violence from the MIP in the six months prior to baseline across study groups. Physical violence from the MIP decreased over time for the Near Limit Group (aOR 0.93, $P < .001$) (See Table 2, Figure 2). Change in physical violence over time was similar in the Turnaway No Births and First Trimester groups as in the Near

Table 1 Baseline characteristics across study group

Participant characteristic	Total	Near limit abortion	Turnaway births	Turnaway no births	First -trimester abortion
	number = 862	number = 405	number = 156	number = 48	number = 253
			mean (SD) or %		
Age, years	24.9 (5.8)	25.0(5.9)	23.5(5.6) **	24.5(6.3)	25.8(5.7) +
Race/ethnicity					*
White	33	32	25	44	39
Black	32	31	35	27	32
Hispanic/Latina	22	21	28	13	21
Other	13	16	13	17	8
Employed	54	55	40 **	50	64 *
Gestational age, weeks	16.9 (7.0)	19.9 (4.0)	23.3 (3.4) ***	18.9 (3.9) ***	7.6 (2.3) ***
Union status					
Married	9	8	10	6	11
Cohabiting	18	18	13	17	21
Not-cohabiting, never married	63	63	72	61	57
Divorced/widowed	10	11	5	17	11
Raising children			*		
No live births	38	34	47	42	38
Living with all biological children	53	56	42	52	55
Has 1+ children cared for by someone else	9	9	11	6	7
History of child abuse/neglect	26	26	26	13*	27
Family history before age 18					
Household member drinking/drug problem	20	21	15	6*	25
Household member psychological disorder	11	8	8	6	18***
Previous depression or anxiety diagnosis	25	23	20	29	30
Alcohol problem symptom	6	4	7	10	7
Recent drug use	14	13	13	8	18
Physical violence from MIP prior six months	5	6	3	4	4
Psychological violence from MIP prior six months	3	3	3	4	4

+$P < .10$, *$P < .05$, **$P < .01$, ***$P < .001$. MIP, man involved in the pregnancy.

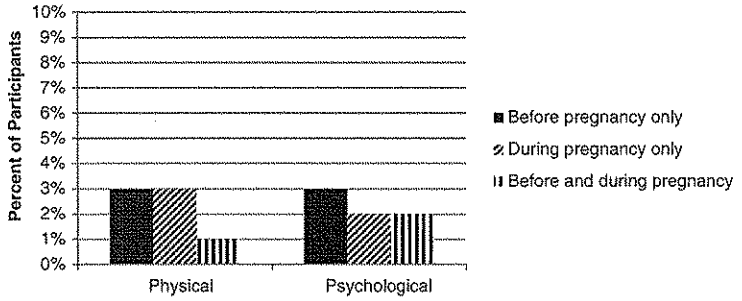


Figure 1 Violence from the man involved in the pregnancy over the past year, baseline.

Table 2 Multivariate mixed effects logistic regressions of physical and psychological violence from the man involved in the pregnancy over 2.5 years

Physical violence (number = 848)				
	aOR	*P* value	95% CI	
Study Group				
Near Limit Abortion Group	ref			
Turnaway Births	0.58	0.288	0.22	1.57
Turnaway No Birth	1.04	0.963	0.20	5.42
First Trimester Abortion Group	1.05	0.895	0.50	2.22
Time				
Months	0.93	<0.001	0.90	0.96
Study Group X Time interactions				
Turnaway Births X months	1.06	0.047	1.00	1.12
Turnaway No Birth X months	0.93	0.406	0.78	1.11
First Trimester X months	1.02	0.324	0.98	1.07
Psychological violence (number = 849)				
	aOR	*P* value	95% CI	
Study Group				
Near Limit Abortion Group	ref			
Turnaway Births	0.97	0.962	0.33	2.85
Turnaway No Birth	2.47	0.290	0.46	13.14
First Trimester Abortion Group	1.28	0.564	0.56	2.91
Time				
Months	0.97	0.043	0.94	1.00
Study Group X Time interactions				
Turnaway Births X months	1.02	0.451	0.97	1.08
Turnaway No Birth X months	0.83	0.126	0.66	1.05
First Trimester X months	1.02	0.394	0.98	1.06

aOR, adjusted odds ratio; CI, confidence interval.

Limit group. However, change in physical violence differed over time between Turnaway Births and the Near Limit Abortion Group (aOR 0.98 for Turnaway Births, $P = .047$ compared to Near Limits). In a model with Turnaway Births as the reference group, the *P*-value for change over time was not significant ($P = 0.396$). This indicates that, unlike the other three groups, the Turnaway Births group did not experience a statistically significant decrease in physical violence from the MIP over time.

Psychological violence from the MIP decreased over time for the Near Limit Abortion Group (aOR = 0.97, $P = .043$) (See Table 2), with no differences at baseline or in change over time by study group; all groups experienced decreased psychological violence from the MIP.

Discussion

Among women seeking abortion, having an abortion was associated with a reduction over time in physical violence from the MIP, while carrying the pregnancy to term was not. Terminating an unwanted pregnancy may allow women to avoid physical violence from the MIP, while having a baby from an unwanted pregnancy appears to result in sustained physical violence over time. This finding is consistent with our hypothesis that having a baby with an abusive man, compared to terminating the unwanted pregnancy, makes it harder to leave the abusive relationship. It is also consistent with findings from analyses of relationship outcomes among women in the Turnaway Study sample [19]. These analyses found that women denied abortions were slower to end their romantic relationships with the MIPs than women having abortions, with differences in romantic involvement disappearing by two years post-abortion seeking. They also found that women denied abortion were more likely to have sustained contact with the MIP over time. Notably, women having first-trimester abortions and women initially denied abortions who did not end up giving birth experienced similar reductions in violence as those having near-limit abortions.

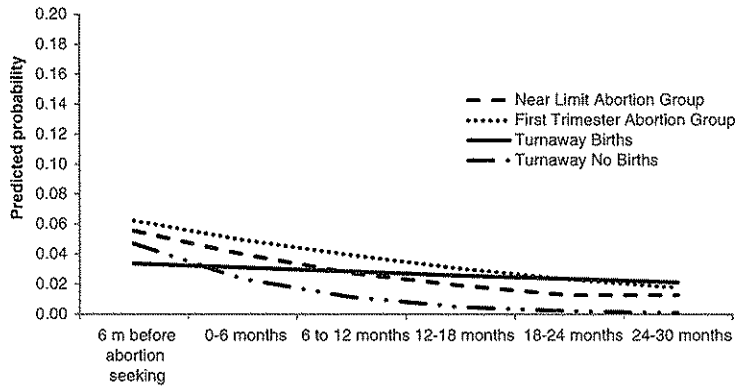


Figure 2 Physical violence from the man involved in the pregnancy.

IPV has serious health consequences for women, including injury, chronic pain, gastrointestinal problems, sexually-transmitted infections, depression and post-traumatic stress disorder [20]. The fact that women who had babies resulting from unwanted pregnancies had more ongoing physical violence is of particular concern, as the violence can also affect their children. Violence during pregnancy is associated with negative birth outcomes, including low birth weight, pre-term delivery and neonatal death [21], and children exposed to IPV are at increased risk of emotional and behavioral problems [22,23]. Ensuring that women unable to terminate unwanted pregnancies receive support and interventions around violence is of utmost importance; guidance is provided in a recent American College of Obstetricians and Gynecologists Opinion [24]. We found no differences in reports of violence prior to abortion seeking by study group; women who sought near-limit abortions did not report more violence than women who sought earlier abortions.

Some limitations are worth noting. First, women in the Near Limit group received abortions later in gestation than typical in the U.S. [17]; thus, it is unclear whether their experiences generalize to the more typical experience. However, when we compared women receiving abortions near gestational limits to women receiving first trimester abortions, we found no differential change over time. Second, violence from the MIP is based on who perpetrated the most recent episode of violence. If women were experiencing violence from multiple sources and the MIP was not the most recent source of violence, this may underestimate violence from the MIP. Third, information about violence from the MIP is based on self-reports by the woman experiencing the violence and may be under-reported. It is worth noting, though, that the proportion reporting violence from the MIP is in the range of estimates of past year intimate partner violence reported in other studies of abortion patients [2,3]. Fourth, the response rate is 37.5% and those who did not participate could differ from those who did participate on key characteristics. A recent review found that most prospective cohort studies published in high impact journals did not report participation information [25], meaning that published response rates for prospective cohort studies may suffer from reporting bias, with only those with higher rates reporting them [26]. The 37.5% response rate for a five year study with biannual interviews of women seeking a stigmatized health service is within the range of other large-scale prospective studies. Importantly, our exposure (receiving versus being denied abortion) was not associated with non-participation. Because the topic of violence was not raised when potential participants were initially informed about the study, non-participation is unlikely to be related to violence outcomes. Fifth, our violence measures did not capture severity or frequency of violence.

This study also has a number of strengths. First, the Turnaway Study is the first study of abortion and subsequent intimate partner violence to use a comparison group for women receiving abortions that best represents what women's experiences would have been had they not been able to terminate their pregnancies. It is also a prospective study that was designed to assess experiences and health subsequent to abortion and, thus, does not rely on retrospective reports of abortion. Second, we found similar proportions experiencing violence from the MIP in the past year to previous studies of IPV among women having abortions, suggesting that the experiences of women in our sample may be typical of those of other women seeking abortion [2,3]. Third, retention was high, with 72% of participants retained at the sixth interview and no differential loss to follow-up by study group.

Conclusions

In summary, physical violence from the MIP decreased over time for women having abortions but not for women denied abortions. This finding is concerning, especially in light of the increasing number of state-based restrictions that limit women's access to abortion care in the U.S. Policies that restrict abortion provision may result in more women being unable to terminate unwanted pregnancies, potentially keeping some women in physically violent relationships, and putting both women and their children at increased risk of violence and other negative health consequences.

Competing interests

The authors declare they have no competing interests.

Authors' contributions

DGF designed and implemented the study and contributed to the interpretation of the statistical results. SCMR guided the data analysis, wrote the first draft of the paper and oversaw the interpretation of the statistical results. KSC conducted preliminary analyses, reviewed the literature and contributed to the interpretation of the statistical results. MAB conducted the final data analyses and contributed to the interpretation of the statistical results. HG reviewed the literature. CHR contributed to the interpretation of the statistical results. All authors contributed to drafting and revising the article. All authors read and approved the final manuscript.

Acknowledgments

Components of this study were funded by the Wallace Alexander Gerbode Foundation, The William and Flora Hewlett Foundation, the David and Lucile Packard Foundation and an anonymous foundation. The authors thank Rana Barar and Sandy Stonesifer for study coordination and management; Janine Carpenter, Undine Darney, Ivette Gomez, Selena Phipps, Claire Schreiber and Danielle Sinkford for conducting interviews; Michaela Ferrari and Elisette Weiss for project support; and Jay Fraser and John Neuhaus for database and statistical assistance. Preliminary findings from this study were presented at the American Public Health Association Conference in San Francisco, CA in October 2012.

Received: 29 May 2014 Accepted: 4 August 2014
Published online: 29 September 2014

References

1. Pallitto CC, Garcia-Moreno C, Jansen HA, Heise L, Ellsberg M, Watts C: Intimate partner violence, abortion, and unintended pregnancy: results from the WHO multi-country study on women's health and domestic violence. *Int J Gynaecol Obstet* 2013, 120:3–9.
2. Saftlas AF, Wallis AB, Shochet T, Harland KK, Dickey P, Peek-Asa C: Prevalence of intimate partner violence among an abortion clinic population. *Am J Public Health* 2010, 100:1412–1415.
3. Jones RK, Moore AM, Frohwirth LF: Perceptions of male knowledge and support among U.S. women obtaining abortions. *Womens Health Issues* 2011, 21:117–123.
4. Evins G, Chescheir N: Prevalence of domestic violence among women seeking abortion services. *Womens Health Issues* 1996, 6:204–210.
5. Glander SS, Moore ML, Michielutte R, Parsons LH: The prevalence of domestic violence among women seeking abortion. *Obstet Gynecol* 1998, 91:1002–1006.
6. Chibber KS, Biggs MA, Roberts SC, Foster DG: The role of intimate partners in women's reasons for seeking abortion. *Womens Health Issues* 2014, 24:e131–138.
7. Biggs MA, Gould H, Foster DG: Understanding why women seek abortions in the US. *BMC Womens Health* 2013, 13:29.
8. Finer LB, Frohwirth LF, Dauphinee LA, Singh S, Moore AM: Reasons U.S. women have abortions: quantitative and qualitative perspectives. *Perspect Sex Reprod Health* 2005, 37:110–118.
9. Kirkman M, Rowe H, Hardiman A, Mallett S, Rosenthal D: Reasons women give for abortion: a review of the literature. *Arch Womens Ment Health* 2009, 12:365–378.
10. Fergusson DM, Boden JM, Horwood LJ: Abortion among young women and subsequent life outcomes. *Perspect Sex Reprod Health* 2007, 39:6–12.
11. Rocca C, Kimport K, Gould H, Foster D: Women's emotional responses to unintended pregnancy, abortion and being denied an abortion in the United States. *Perspect Sex Reprod Health* 2013, 45:122–131.
12. Roberts SC, Avalos LA, Sinkford D, Foster DG: Alcohol, tobacco and drug use as reasons for abortion. *Alcohol Alcohol* 2012, 47:640–648.
13. Gould H, Perrucci A, Barar R, Sinkford D, Foster D: Patient education and emotional support practices in abortion care facilities in the United States. *Womens Health Issues* 2012, 22:e359–e364.
14. Upadhyay UD, Weitz TA, Jones RK, Barar RE, Foster DG: Denial of abortion because of provider gestational age limits in the United States. *Am J Public Health*. in press.
15. Roberts SC, Rocca CH, Foster DG: Receiving versus being denied an abortion and subsequent drug use. *Drug Alcohol Depend* 2014, 134:63–70.
16. Dobkin L, Gould H, Barar R, Ferrari M, Weiss E, Foster DG: Implementing a prospective study of women seeking abortion in the United States: understanding and overcoming barriers to recruitment. *Womens Health Issues* 2014, 24:e115–123.
17. Pazol K, Zane S, Parker WY, Hall LR, Gamble SB, Hamdan S, Berg C, Cook DA, Centers for Disease Control and Prevention (CDC): Abortion surveillance - United States, 2007. *MMWR* 2011, 60:1–42.
18. California Department of Public Health Maternal Child, and Adolescent Health Program: *Maternal and Infant Health Assessment Survey*. 2005. Available at: http://www.cdph.ca.gov/data/surveys/MIHA/Pages/MaternalandInfantHealthAssessment(MIHA)survey.aspx. Accessed January 10, 2014.
19. Mauldon J, Foster DG, Roberts SC: Effect of abortion vs. carrying to term on a woman's relationship with the man involved in the pregnancy. *Perspect Sex Reprod Health*. in press.
20. Campbell JC: Health consequences of intimate partner violence. *Lancet* 2002, 359:1331–1336.
21. Sarkar NN: The impact of intimate partner violence on women's reproductive health and pregnancy outcome. *J Obstet Gynaecol* 2008, 28:266–271.
22. Wolfe DA, Crooks CV, Lee V, McIntyre-Smith A, Jaffe PG: The effects of children's exposure to domestic violence: a meta-analysis and critique. *Clin Child Fam Psychol Rev* 2003, 6:171–187.
23. Evans S, Davies C, DiLillo D: Exposure to domestic violence: a meta-analysis of child and adolescent outcomes. *Aggress Violent Behav* 2008, 13:131–140.
24. ACOG Committee Opinion No. 518: Intimate partner violence. *Obstet Gynecol* 2012, 119:412–417.
25. Morton LM, Cahill J, Hartge P: Reporting participation in epidemiologic studies: a survey of practice. *Am J Epidemiol* 2006, 163:197–203.
26. Galea S, Tracy M: Participation rates in epidemiologic studies. *Ann Epidemiol* 2007, 17:643–653.

doi:10.1186/s12916-014-0144-z
Cite this article as: Roberts *et al.*: Risk of violence from the man involved in the pregnancy after receiving or being denied an abortion. *BMC Medicine* 2014 12:144.

Submit your next manuscript to BioMed Central and take full advantage of:

- Convenient online submission
- Thorough peer review
- No space constraints or color figure charges
- Immediate publication on acceptance
- Inclusion in PubMed, CAS, Scopus and Google Scholar
- Research which is freely available for redistribution

Submit your manuscript at
www.biomedcentral.com/submit

BioMed Central

W

The New York Times | http://nyti.ms/1ue1dET

MAGAZINE

A Mother in Jail for Helping Her Daughter Have an Abortion

By EMILY BAZELON SEPT. 22, 2014

On Sept. 12th, Jennifer Whalen, a 39-year-old mother of three in the rural town of Washingtonville, Pa., went to jail to begin serving a 9-to-18-month sentence. Whalen's crime was, in effect, ordering pills online that her older daughter took in the first several weeks of an unplanned pregnancy, when she was 16, to induce a miscarriage. The medication was a combination of mifepristone (formerly called RU-486) and misoprostol. The drugs have been available from a doctor with a prescription in the United States since 2000 and are used around the world to induce miscarriage.

Recent research increasingly suggests that early in a pregnancy, women can safely use mifepristone and misoprostol to miscarry at home. (Much more about this here, in a story I wrote in August). But if the medical risk of this kind of do-it-yourself abortion is relatively small, the legal risk still looms large.

On the night before Whalen went to jail, I drove to Pennsylvania to meet her. We sat at a conference table in the office of her lawyer, who was present for the 90-minute conversation. For most of the time we spent together, she sat hunched forward, arms wrapped around herself. She was dreading the prospect of leaving her 11-year-old daughter and her husband at home, she said, as well as her older daughter, now 19, who still lives with the family. (The oldest child, a 20-year-old son, lives nearby.) "I'm scared," Whalen said of serving her sentence. "And I'm hurt because I can't be with my family."

In the months since news of Whalen's arrest broke, reporters and bloggers

have been calling her house. Pro-choice activists called, too, saying they wanted to help. But Whalen wouldn't speak to any of them. She doesn't want to be a cause célèbre. The attention, she said, has been excruciating. She agreed to talk publicly for the first time in hopes of correcting errors about the case in the media. She is not a nurse, as some reports stated, and she wishes she could erase every headline that says she performed an illegal abortion. The words, she thinks, made it sound as if she had done back-alley surgery — a disturbing image, especially in the conservative rural area where she has lived her whole life. "That was very upsetting for my family," Whalen said. "It has been awful."

Whalen told me that in the winter of 2012, her daughter came to her and said she was pregnant. Whalen told her she would "support her in any decision she made." Her daughter, who was in high school, took a few days to think and then asked her mother for help ending the pregnancy. "She said, 'I can't have a baby right now,' and she asked me to look up clinics," Whalen said.

Together, they looked online. The closest clinic was about 75 miles away. Pennsylvania requires women seeking abortions to first receive counseling and wait 24 hours before returning for the procedure. The cost of a first-trimester abortion is typically between $300 and $600. Whalen works as a personal-care aide at an assisted-living center for the elderly. She didn't have health insurance for her daughter. And she was worried about taking time away from work and her family to make two trips or to stay overnight. At the time, Whalen and her husband shared one car, which they both used to get to work. And she hadn't told her husband about the pregnancy. "I knew he would be upset, and I was protecting the whole family," she said. (Whalen's husband, who waited outside in the car during our interview, declined to talk to me.)

Whalen called a local women's center on her daughter's behalf but was told no one there could help, she said. She and her daughter did more online searching, and a site popped up with misoprostol and mifepristone for sale for $45. Whalen hadn't heard of the medication before. "I read all the information," she said. "They said these pills would help give a miscarriage, and they were the same ones a doctor would give you." She says she had no

idea that buying them was illegal.

The practical problem with going online to find the pills that cause abortion is that scam sites abound. Women can wind up with fake medication or without all the information they need to take the drugs safely. But that didn't happen in this case. When the drugs arrived, about five days later, Whalen and her daughter read the instructions to make sure of the correct dosage and to know how to look for complications. After her daughter took the pills, she started bleeding, as if she were having her period, Whalen said. "Then she started having stomach pains, and she got scared, so that was when I took her to the hospital. At first, she didn't want me to tell the hospital anything. I told her, 'We have to, so they can take care of you the way they need to.'" In fact, doctors have told me, there is no medical reason for women to tell a health care provider that they've taken the pills, because any treatment they receive is the same as it would be for a spontaneous miscarriage. But the drugs Whalen's daughter took didn't include that information.

At the emergency room of Geisinger Medical Center, Whalen said, hospital personnel checked her daughter and sent her home without any other intervention. (When I called the hospital, a spokeswoman said she could not comment on the case because of patient confidentiality.) The miscarriage was already complete, and Whalen's daughter had no other related symptoms. A few days later, she went back to school.

Whalen says that no one at the hospital mentioned any legal risk. But court documents show that Geisinger reported Whalen to state child-protective services.

Soon after the visit to the emergency room, Whalen woke one morning to a knock on the door. Her husband was still in bed. Whalen got up and found the police outside. They had a warrant to search the house, and they found the empty box for the abortion medication. "They asked me whether I bought the pills online," Whalen said. "I was surprised when they told me I had to have a doctor's scrip. I didn't know that."

After the police left, Whalen heard nothing more from law-enforcement authorities for almost two years. "It was very stressful," she said of that period.

"It's not something you can block out. It was on my mind, in my everyday activities."

In December 2013, the Montour County district attorney, Rebecca Warren, charged Whalen with a felony for offering medical consultation about abortion without a medical license and with three misdemeanors: for endangering the welfare of a child, dispensing drugs without being a pharmacist and assault. I tried to reach Warren, but she didn't return my calls. "This case is not about pro-life or pro-choice," Warren said in a statement last week, responding to criticism of the case from a Pennsylvania state senator. "In actuality, this case is about endangering the welfare of a child through the unauthorized practice of medicine and pharmacy. Allowing individuals to practice medicine or dispense pharmaceuticals without the necessary licenses and knowledge is a blatant violation of the laws of Pennsylvania and a source of great potential harm to our citizens. As such, the existing laws in that regard will continue to be upheld and enforced in Montour County."

Last summer, Whalen's lawyer, Matthew Banks, tried to negotiate a plea deal for her. Banks floated the possibility of pleading guilty to the misdemeanor charges, which carried a significantly lower risk of jail time. But then, Whalen said, she learned that if she pleaded to misdemeanors of assault and endangering the welfare of a child, she would automatically lose her position at the assisted-living facility. "I love my job," she told me, her voice strong with emotion. "I love what I do." Her family also depends on the income she brings in.

And so, Whalen pleaded guilty to the felony charge. Her record was clean — her only other brush with the law was an underage drinking charge in 1994. As a result, the judge could have opted to give her probation rather than jail time.

But at the sentencing, the Montour County judge, Gary Norton, sent Whalen to jail. He granted work-release but made it clear he had little sympathy for her. "What we have here, we can argue until the cows come home of the right to an abortion." Norton said, according to local news reports. "A practitioner might be able to perform this, but a lay person is not permitted

to take this kind of responsibility which is a huge responsibility." The judge went on, "This was somebody taking life and law into their own hands."

Opponents of abortion often dismiss the notion that restricting access to the procedure can lead to prison sentences for women. "The political claim — that women were or will be prosecuted or jailed under abortion laws" is "an urban legend," Clarke D. Forsythe, senior counsel for Americans United for Life, wrote in 2010 on the organization's website. "There is no documented case since 1922 in which a woman has been charged in an abortion in the United States."

It's a useful talking point, because it allows anti-abortion groups to position themselves as the foes only of abortion providers. But it's not true. "Over the years, women have been charged with a range of crimes, from unlawful abortion to failure to report an abortion," Elizabeth Nash, a researcher at the Guttmacher Institute, told me over the phone.

Nash sent me a list of nine cases that she has tracked since 2000, based on court records and media reports. It's incomplete: News stories, she says, include references to several additional cases. Most of these prosecutions have taken place in the last 10 years.

In one sense — Forsythe's dismissals to the contrary — these cases are an inevitable result of criminalizing abortion. In 39 states, it's against the law to perform an abortion if you're not a doctor. In some of the remaining states, you are still required to be a medical professional (a midwife, nurse or physician assistant). In New York, you can do your own abortion in the first two trimesters, but only if you're following a doctor's advice. About a quarter of states also still have old laws that make it a crime to help someone else with a self-induction. In a law passed in 1845, for example, Massachusetts calls for a sentence of up to seven years for assisting.

In the era before Roe v. Wade, the laws against helping with self-induction aimed to protect desperate women from dangerous procedures and unscrupulous providers. But the recent prosecutions of women are about something else. In many of these cases, women were charged after trying to end pregnancies that had advanced far into the second trimester, after fetal

remains were discovered. For example, in a 2011 case from New York, a 20-year-old was charged with the misdemeanor of self-abortion in the first degree when the superintendent of her apartment building found a stillborn fetus in the trash. The district attorney later dropped the case. Nash's list includes one person, other than Whalen, who went to jail: a 22-year-old mother of three in South Carolina who was sentenced to 90 days in 2005 after taking misoprostol about 16 weeks into her pregnancy.

Whalen's case is the only prosecution I could find involving a pregnancy in the first trimester, the early stage at which at least 88 percent of abortions in the United States take place. But it may not be the last. What Whalen did in trying to help her daughter — order pills online — is probably an increasingly common response to the rising wave of abortion restrictions that has rolled across the states in the last four years. "Her situation is very scary legally, because we are seeing the number of clinics dwindle," Nash said. "If women don't have access to abortion clinics, some will turn to the Internet, and then, will they be charged with a crime?"

The grim answer was yes for Jennifer Whalen because of a series of choices made by officials who had the discretion to respond differently. Hospital authorities decided that they were mandated to report Whalen, according to the district attorney, because they made a judgment call that what she did was "suspected or actual child abuse." Warren, the district attorney, could have declined to press charges. And Norton, the judge, could have refrained from sending Whalen to jail.

When I asked Jennifer Whalen whether the case has been especially hard on her older daughter, she didn't want to talk about it. "She's going to college and working two jobs," she said with a bit of pride. It was clear that Whalen is still trying to shield her child. She just wants her to go on and live her life. Emily Bazelon is a staff writer for the magazine.

© 2014 The New York Times Company

The Atlantic

• SUBSCRIBE
• RENEW
• GIVE A GIFT
• DIGITAL EDITION

Print | Close

The Rise of the DIY Abortion in Texas

By Erica Hellerstein

The Alamo flea market sits right off South Texas's lengthy Highway 83; a sprawling, dusty, labyrinth of a place. Under canopies in the converted parking lot, vendors in dark sunglasses stand behind tables heaped with piles of clothing, barking in Spanish and hawking their wares. The air is hot and muggy, thick with the scent of grilled corn and chili.

Customers browse simple items—miracle-diet teas, Barbie dolls or turquoise jeans stretched over curvy mannequins—but there are also shoppers scanning the market for goods that aren't displayed in the stalls. Tables lined with bottles of medicine like Tylenol and NyQuil have double-meanings to those in the know: The over-the-counter drugs on top provide cover for the prescription drugs smuggled over the border from nearby cities in Mexico. Those, the dealer keeps out of sight.

I'm here to look for a small, white, hexagonal pill called misoprostol. Also known as miso or Cytotec, the drug induces an abortion that appears like a miscarriage during the early stages of a woman's pregnancy. For women living in Latin America and other countries that have traditionally outlawed abortion, miso has been a lifeline—it's been called "a noble medication," "world-shaking" and "revolutionary." But now, it's not just an asset of the developing world.

As policies restricting access to abortion roll out in Texas and elsewhere, the use of miso is quickly becoming a part of this country's story. It has already made its way into the black market here in Texas's Rio Grande Valley, where abortion restrictions are tightening, and it is likely to continue its trajectory if anti-abortion legislation does not ease up and clinics continue to be closed.

Over the past several years, dozens of states have restricted abortions. Since 2011, at least 73 abortion clinics in the nation have shut down or stopped providing services; and more than 200 abortion restrictions were legislated throughout the nation. Despite the passage of Roe v. Wade more than 40 years ago, states with pro-life politicians are still gunning to reverse the ruling—in the words of Rick Perry in 2012, "my goal is to make abortion, at any stage, a thing of the past."

Yet these myriad restrictions on women and abortion providers have set the stage for women to skirt medical institutions to take charge of their own health. A similar story has already been written in

many countries around the world, where pro-life legislation has inspired similarly creative solutions. Today, throughout Texas—from the Rio Grande Valley to El Paso—miso's story is being drafted anew. And in this narrative, it is Latin America that has answers for the United States.

* * *

Misoprostol's role as the world's revolutionary abortion pill began by accident, and nobody knows for certain where it all began. Early scientific literature traces the drug's abortion-inducing use to Brazil, but it's possible that it was also being taken—but not documented—in the Caribbean at the same time.

Ironically, misoprostol was never developed to induce abortions: Instead, it was created and marketed as an ulcer medication called Cytotec. The drug, a synthetic prostaglandin E1 analog, has many medical uses: It's taken to prevent and treat ulcers, induce labor, induce abortions, and treat post-partum hemorrhage. In 1986, misoprostol was approved for sale in Brazilian pharmacies as an ulcer medication and was distributed over-the-counter. But its use as an abortion-inducing drug spread rapidly, and slipped below the radar at first. Like many drugs, misoprostol's label had a simple warning: *Do not take if pregnant.*

But not everyone heeded the warning, including a number of Brazilian women who read the drug's packaging and decided to try their luck. Or that's how the story goes. Nobody knows exactly what happened. Some believe that certain Brazilian women made this discovery on their own; others say that a select few pharmacists who knew that Cytotec could induce abortions secretly spread the word. Regardless of who uncovered its power, the pill was precisely what women needed: a magic personal solution to a dreaded problem that dared not be discussed.

In Brazil, as in many parts of the world, Catholicism dominates the abortion debate. Like adultery and murder, it was a mortal sin, worthy of damnation to hell and, according to the country's 1940 Penal Code, a crime against life. Despairing Brazilian women with unwanted pregnancies resorted to drastic and dangerous measures. They listened to old wives tails, ramming sharp objects into their uteruses and guzzling drug cocktails, and visiting clandestine, unsafe abortion clinics. But nothing seemed to reliably work, and all were perilous. That is, until they found the little white pill—that special drug that could, miraculously, "bring the period back."

And so, the whispers circulated and hushed exchanges began. When women searched for the magic drug, they would shield their intentions with coded language: "I need to bring down my period," they would say, or "bring it back." For many Catholic women, describing miso in those terms felt better. It was different than aborting, and far less cognitively dissonant.

As miso became more popular, Latin American doctors from Peru to Brazil started noticing a trend: They were seeing, it seemed, a dramatic decrease in abortion-related complications. Fewer women were carted through hospital doors with gruesome infections from back-alley botched abortions, and ob-gyns saw a reduction in the grisly abortion complications that had so frequently plagued providers, including perforated uteruses, heavy bleeding, and fallen intestines, according to a 2012 study by the global health organization Ipas.

The only explanation "was the mass distribution of miso at the community level," concluded a Colombian ob-gyn in the Ipas study. In the same report, other doctors note that the discovery and

circulation all took place outside hospital walls. Word of misoprostol spread at the grassroots level, working its way up from Brazil and snaking from one Latin American country to another.

In Brazil, an analysis of sales by the company Biolab (which began marketing the drug in 1988) shows a sharp increase beginning in 1989, sometimes exceeding more than 50,000 units per month. In 1991, the company reported that misoprostol's use as an abortion-inducing drug could reach up to 35 percent of its total usage.

Public pressure to regulate the drug in Brazil mounted, and in May 1991, the state of Rio de Janeiro restricted miso's use to hospitals, while the state of Ceara imposed a total ban on its sales. On July 17, 1991, the Ministry of Health required that the purchase of miso had to be accompanied by a prescription from a physician, and made a deal with Biolab Laboratories to reduce the availability of the drug. In 1992, miso's public availability in the State of Sao Paulo was restricted to authorize pharmacies registered with local government authorities. Today, it's difficult—but not impossible—to get the drug in Brazil. Traffickers sell it on the black market and online, but it can be prohibitively expensive (according to a recent *Al Jazeera article*, one pill can cost up to $60), and when it is sold online, it's often counterfeit.

But miso is still commonly used in Brazil, and it accounts for nearly half of the country's one million annual abortions. As these numbers reveal, many of the women in Brazil and Latin America had welcomed miso in the absence of safer options. Now, more than three decades later, the secret has made its way to the United States.

* * *

Texas's Rio Grande Valley—a wide, flat swathe of land straddling the Mexico border—is one of the poorest regions in the country. It's also ground zero for the state's bitter abortion battle.

In the summer of 2013, the Texas legislature passed House Bill 2, a controversial set of abortion restrictions that Wendy Davis famously opposed with a marathon filibuster. The bill bans abortion after 20 weeks, adds restrictions to medication abortions, mandates that abortion providers have hospital-admitting privileges at clinics within 30 miles of where they practice, and requires that abortion clinics comply with ambulatory surgical center requirements by September 2014. Some of these provisions sound sensible, but abortion rights activists believe the intended overall effect is to deny abortions.

The law went into effect last October, and the provisions have since shuttered 12 of the state's 40 abortion providers. Some hospitals refused to grant the privileges because of religious affiliation, while others declined because of the expensive fees associated with the process. Nancy Northrup, the president of the Center for Reproductive Rights, voiced her concerns about the legislation in a statement: "Texas has put the constitutional rights of its women in the hands of biased hospital administrators. As a consequence, the list of high-quality abortion providers forced to turn away patients continues to grow, while reproductive health care options for Texas women continue to shrink."

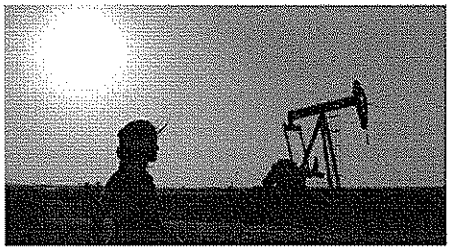
Professional organizations, too, including The American Medical Association and the American College of Obstetricians and Gynecologists, openly opposed the restrictions. A study conducted by the

University of Texas predicted that the law would bar nearly 23,000 Texas women from getting abortions—or almost one in every three women who seeks an abortion.

Many of these women can be found in the Rio Grande Valley, where the admitting privileges provision forced both of the county's abortion clinics to shut down. Now, the closest clinic for the region's one-million-plus residents is 150 miles away. For many poor, uninsured South Texas women, that distance is beyond feasible. Few have access to a set of wheels for the long haul, and others lack the right paperwork to cross immigration checkpoints on highways that run through the state.

Meanwhile, the flea market is close to most people living in the Valley, and the massive Alamo *pulga* looks like just the kind of place to pick up miso. According to several of my local sources, the drug is sold here and it's not difficult to get—you just need to know who to approach and what to ask for.

Related Story



The Difficulty of Getting an Abortion in Texas

In the United States, miso is prescribed and sold legally in combination with another pill called mifepristone (or RU-486) for early nonsurgical abortion. The drug, which is also called Mifeprex, was approved by the U.S. Food and Drug Administration (FDA) in 2000, can only be taken in the early stages of pregnancy (within 49 days of a woman's last menstrual period).

The miso/mife combination is becoming increasingly popular: In 2011, it accounted for 36 percent of all abortions before nine weeks of gestation, and it's often considered the gold standard of medication abortion, with an estimated success rate that is nearly 10 percent higher than using miso alone (92 to 95 percent and 80 to 85 percent, respectively). Because of this, the FDA has never approved the use of misoprostol alone. After all, some say, why promote a silver standard when the gold is available?

Since, unlike miso, mifepristone is only used to induce abortions, it's only available in about 50 countries. In 2007, the Federal District of Mexico City legalized first-trimester abortion, and in 2011 mifepristone was registered in the country. But outside of Mexico City, abortion is only available in the cases of rape or if a woman's life is in danger—and so, mifepristone access is similarly limited.

But the "silver standard" is readily available without a prescription. In Mexico, miso is sold over the counter as an ulcer medication (in the U.S., it's only available with a prescription) creating the perfect conditions for black market sales in the United States. And while no abortion clinics remain in the Valley, the Mexican town of Reynosa is just across the nearby border. There, miso can be bought in bulk at Mexican pharmacies and snuck back over the border into Texas, where it's sold undercover at sprawling flea markets like the one I'm searching in today.

* * *

It's a balmy January morning as I make my way through the aisles of the Valley's Alamo Flea Market, looking for the magic pill. I find a barrel-chested man in a tattered baseball hat who rests his hands on a table displaying an assortment of medicine: Umcka Cold Care, Posture-D Calcium, Anti-Nausea Liquid, and Valerian Root. He leans forward when customers approach the table, a messy mop of curly black hair peeking out from the bottom of his cap. Local sources have said I'll be able to find miso here.

I head towards his booth cautiously, and the mop-haired man (who I later find out goes by Jeff Lopez) eyes me equally warily as I approach the table.

"Ummm," I snatch a bottle of Ibuprofen and squint at the label. "Do you have anything for ulcers?"

Lopez stuffs his hands in his pockets. "We don't have ulcer medicine," he says. "Just the stuff on the table." I'm not surprised he denies it; he may wonder if I'm an undercover agent of the law.

"Ok. Um, do you have something to make your period come back? I need to bring it back," I trail off, scrutinizing his face for expression. "Cytoteca," I say firmly, annunciating the *teca* in the familiar Spanish style. "Do you have it?"

He exhales dramatically.

"Not anymore. I haven't had it since the police came," he huffs, referring to a Valley flea market raid last August in Donna, Texas, where sheriffs uncovered a host of counterfeit drugs, including the diet pill Redotex and Viagra.

Shortly after, a woman was arrested for illegally selling thousands of prescription drugs nearby. (The drugs may be over the counter when bought in Mexico, but they are prescription drugs in the U.S. and illegal to distribute.) Though miso wasn't uncovered in any of the raids, the overall crackdowns—and amped up policing—have made vendors wary of selling the pill. Lopez, who appears to have relaxed his caution, says the market was booming up until those raids.

"When I first found out how many women were asking for it, I couldn't believe it," he recalls. "The market had tons of people selling the pill, and I still got asked for it so many times. Almost every time I was here, someone asked me for it."

Lopez's experience was common. There seemed to be a consensus among nearly everyone I interviewed —from health educators to Valley residents—that if abortion providers remain shut, women will continue to look for miso.

"If a woman wants to abort, she's going to abort," says Lucy Felix, a Valley-based *promotora*, or health educator, at the National Latina Institute for Reproductive Health.

A native of Reynosa, Mexico, Felix has a short brown bob and a bellowing laugh. She wears a thin, gold necklace, a souvenir that a friend brought back from a Catholic trip to Israel. In the middle, a pendant spells out her first name in Hebrew. Blowing on a hot bowl of soup inside a Mexican restaurant in Brownsville, Felix explains the dilemma that many local women face since the crackdown on miso. Now, to get to the nearest abortion providers, they have to pass through *la garita*, or immigration checkpoints.

"So undocumented women, what can they do?" she asks, flinging her hands in the air. "They put things in their vagina. I've heard that women are using coat hangers or some are going to Mexico and getting

clandestine abortions, where it's dirty, unhygienic." Felix gulps down a spoonful of broth. "Other women go to the flea markets. There are still places where you can get pills."

McAllen's Whole Women's Health stopped providing abortion services after the admitting privileges provision went into effect and shut down entirely in March.

"It's just the beginning," the center's former patient advocate, Luzevlia Carreon, observes. "It's in demand right now. It's what our patients are doing and they're going to continue taking it. ... The fact of the matter is that women are going to get pills and are going to figure out ways to have an abortion."

HB2 took the community by surprise, Carreon says. Many had relied on the clinic for years.

"They were so shocked when they found out we weren't offering abortions anymore. I even have patients that call, and after we tell them that we can't offer abortions anymore, they'll just say, 'That's fine. I'm going to figure out a way to do this on my own.' And imagine all the women who don't call us at all, who are still taking [miso]," she sighs. "We have no idea how many are doing this. We just hope for the best."

* * *

In Latin America, miso was a secretive lifeline for many women without means to have other options. Now that the same is happening in the United States, the phenomenon is even more underground here. The networks are just starting to develop and proper information about dosage is not widely available. Moreover, those in the know appear hesitant to distribute material—much of which is circulated around Latin America—about how to safely take the drug.

According to the World Health Organization, more than 21 million women annually have unsafe abortions worldwide, which account for nearly 13 percent of all maternal deaths. Miso is a much safer alternative. If taken in the correct quantities (four to 12 pills over the course of at least nine hours) in a women's first trimester, the drug is 80 to 85 percent effective.

But miso's safety is also a function of the information that comes with it. In Texas's Rio Grande Valley, according to Carreon and others, many women are using the drug improperly because they don't have access to basic facts about the correct dosage. That ignorance can lead to problems.

One woman I interviewed at a Mexican restaurant in Brownsville told me her good friend nearly died after taking pills that her husband bought in Mexico. Instead of ingesting four of the 12 pills every three hours, as is recommended by the World Health Organization, she took two pills under her tongue, then four pills vaginally, then two more under her tongue, then four more vaginally. She began to bleed profusely, doubled over in pain. But because she was undocumented, she was afraid to seek medical help at a nearby hospital or clinic. Instead, she crossed the border to Mexico with her five children—all the while hemorrhaging—in search of medical assistance. She has since recovered but is still in Mexico with her children because she can't cross the border back into the United States.

Carreon says she sees many patients who have taken improper dosages. "A lot of patients said that they would take the whole bottle and they would tell me they took 28 pills," she said. "They're taking maybe four vaginally, two orally. Then an hour later, four more. I hear different ways of using these pills. It's shocking each time."

But strict internal clinic protocol bars Carreon and other employees at Whole Women's Health from answering questions about miso and abortion. And the drug's other distribution channels are similarly mum. Mexican pharmacists can't provide information about the drug and abortion, since it's only sold there as an ulcer medication, and many of the vendors selling miso at flea markets know very little about correct dosage.

Lopez is the first to admit that he knew nothing about the pills when he was selling them. "I'm not a doctor. I sell things," he acknowledges, picking up a medicine bottle. "I don't know anything else."

He adjusts his hat and walks around the table. He's starting to get a little shifty: avoiding eye contact, fidgeting, and giving me short answers. I move a little closer.

"So I'm curious about how many pills you would sell," I start. "Because women are supposed to take 12 pills over nine hours if they're in their first trimester. That's what most doctors recommend."

I glance at Lopez and ask him if he knew this. His answer is a firm no.

When customers came to Lopez looking for the pills, he says he would sell the number they asked for—which often landed in the three or four range—and would charge around $13 per pill. Commonly, buyers didn't know how many to purchase, so Lopez says he would defer to odd numbers and sell them three. Once, he sold a woman 20.

"I didn't know what was right," he says with a shrug.

Now that the vendors throughout South Texas operate in the shadow of the police raid, Lopez says he's not sure if anyone currently sells miso in the *pulgas*.

"The demand is going to be even higher now that the abortion clinics shut down," he speculates. "But if it isn't sold in flea markets, more people are just going to end up going to Mexico."

* * *

The bridge that connects El Paso, Texas, to Juarez, Mexico is surprisingly short—but the two cities on either side look startlingly different. Halfway through my walk to Mexico, I looked to my right. I could see El Paso, neat and carefully assembled, an American flag in the distance slowly swaying with the breeze. And to my left, there was Juarez, dusty and weathered like an old postcard.

Once I crossed over, I stepped inside a yellow building called *Farmacia del Ahorro del Mexico* and asked if I could purchase Cytoteca. "No problem," the pharmacist said, punching a few letters into the keyboard. A couple seconds later, an estimate popped up: $48 U.S. for four pills, or around $150 for the dosage of 12. Down the street, two other pharmacists gave me similar estimates, ranging from $125 to $177, the latter two for a full bottle of 28 pills.

While I didn't take the pharmacists up on their offer, all three were able to dispense the pills for me immediately, though none of the dosages came with instructions about how to use the pills for an abortion. Misoprostol is only sold in Mexican pharmacies as an ulcer medication, and while pharmacists are aware that women are using it for other reasons, they can't provide information about how to terminate a pregnancy with the pill. After all, abortion is restricted outside of Mexico City.

A couple hours later, I hiked across the bridge back to El Paso. After waiting in a brief line at the

checkpoint, I set my bag on the security belt and looked around the room, wondering how many people were slinking over the border with small white hexagonal pills hidden in their belongings.

* * *

In the late '90s, the Internet spread throughout Latin America, ushering in an era of rapid, real-time communication. Suddenly, information about miso was catapulted onto the web. Websites about the drug—where to purchase it, how to use it, and even businesses offering home delivery—began to pop up, but activists wanted to make sure that the information women were getting was correct. So they thought of a practical solution.

Activists, feminists, and abortion advocates grouped together and began creating volunteer-staffed phone hotlines. These small, often DIY networks promoted miso use and distributed information about the drug, and many of them still exist today. They're often run by volunteers who give anonymous callers medical information about miso, like how to take the 12-pill regimen and when to be concerned about adverse reactions to the drug. Hotline workers raise awareness about their services through informal, word-of-mouth networks and social media.

The hotlines have made—and continue to make—an impact on women living in countries with some of the world's strictest abortion legislation. In Chile, where abortion is illegal without exceptions, a hotline called Linea Aborto Libre has had considerable success. It's staffed by a group of young feminists who take turns passing around a compact cellphone. If they're not careful, their work could land them behind bars: Getting an abortion in Chile—or telling a woman how to do so—is a crime punishable by three to five years in jail. To avoid legal prosecution, hotline volunteers read information about misoprostol abortions that's publicly available on the WHO (World Health Organization) website.

Chile's not the only Latin American country with a hotline; similar ones exist in Argentina, Ecuador, Peru and Venezuela. There are well-known websites like Women on Web, an international collective that provides information about self-induction and sends misoprostol to women in countries with restrictive abortion laws. Women on Waves, a Dutch NGO, performs medical abortions on a ship that sails to countries where abortion is illegal.

In Chile and elsewhere, these phone hotlines and other networks were game-changers, because providing information about miso can make the difference between a successful abortion and a botched one that that lands a woman in a hospital or a jail. But given all of the evidence about improper dosages in Texas, why aren't there any hotlines in the United States? How is it that women living in the Valley actually have less access to information than women in Chile—a country with some of the most oppressive abortion policies in the world?

When I told Carreon of McAllen's Whole Women's Health about the phone hotlines, she immediately perked up. "Wow," she exclaimed. "That's so interesting. I think there's a need for that."

But that's where it gets complicated. In the United States, laws related to self-abortion vary by state. In some states, women who induce their own abortions, as well as those who assist them, are subject to criminal liability, and in states like Massachusetts, South Carolina, and Idaho, criminal charges have been brought against women who used miso to end their own pregnancies. In 39 states, it is illegal for

anyone other than a medical provider to perform an abortion. But there is no consistency among states when it comes to the penalties for women inducing abortion without a physician, or for those who help them get information about the medications necessary to self-induce.

Many of the abortion advocates and women's health organizations I talked to were reluctant to even discuss the topic of phone hotlines, concerned that establishing such networks could have serious legal consequences. After all, self-induced abortion is illegal in dozens of states. One reproductive health expert told me that creating phone hotlines, or handing out flyers with information about miso from the WHO is out of the question.

"Giving general information" about where to get an abortion "is never a problem. Helping a woman who wants to end her own pregnancy is a crime," she said firmly.

But others say that setting up and operating a hotline that comes with a recorded disclaimer that it's simply providing scientific information that's already publicly available might be a less risky bet. Francine Coeytaux, a public health specialist and founder of the Pacific Institute for Women's Health, says that reproductive health advocates often have a tendency to self-censor because they've been playing on the defensive against the pro-life movement for so long, and perhaps are overly cautious.

"I don't think we should assume that it's illegal," she said. "It's sharing information and we're not telling them what to do."

* * *

While it appeared that the raids earlier this year had ended miso sales at the flea markets, there are other ways to get it besides crossing the border into Mexico.

Buy-pharma.com, for example, sells one 200-mcg pill for $2 (or a package of eight for $16). On the Facebook page "Cytotec misoprostol," a user can request to buy the pills from the page's administrator, who sells 12 pills for $950 pesos ($73.05).

But often it's nearly impossible to verify the reliability of these pills. Surfing the net for miso through search terms like "abortion pills online" yields pages of results from online pharmacies—some of which are carefully constructed to look like the buyer is in good hands.

Advocates don't promote the use of these sites. A page on the Women on Waves website warns against buying the pills online, and it outlines a long list of doctors and pharmacy websites notorious for selling counterfeit medications.

"The only website we trust to help women gain access to a safe medical abortion is www.womenonweb.org and we cannot guarantee that any other website is trustworthy," the organization writes.

Despite the cautionary advertising, some still choose to purchase medications advertised as miso online. Molly, a feminist abortion advocate who preferred not to use her real name, buys miso and RU-486 (a.k.a "the gold standard") in mass quantities from online pharmacies and sends it to women in the United States who want to use the drugs but don't know how to go about getting them.

"It's incredibly liberating having misoprostol in my bathroom cabinet," she says. "The idea of a pregnancy scare is ... less scary, in a very real way. I wouldn't need to even tell anyone except me, if I

didn't want to."

Molly says that many of the women who contact her are already mothers who live hours away from the nearest clinic. Often, they don't have anyone to watch their children while they go in for the procedure, especially if they have to return for more than one visit and can't afford to take more days off of work.

"They told me they'd try anything: herbs, soaps," she writes in a post that went viral online. "One asked if I knew how, exactly, it was that you went about using a wire hanger to abort. Two or three days later, they would receive a small, unmarked envelope. Inside the envelope were doses of two different drugs that, when used together, will abort nearly any first-trimester pregnancy."

So far, Molly says she has sent the pills out to between 50 and 100 women. Sometimes she receives emails that seem like "suspicious pleas"—messages that sound little too-scripted, like the person behind the keyboard is playing a role to catch Molly at her own game. So now, she's scaling back on sending the drug packages, instead referring women to international pharmacies to buy the medications themselves.

Sending the pills is a risky endeavor. Legally, the process puts her in harm's way, but even more worrisome is the possibility that the medications she sends might seriously jeopardize a woman's health. As many reproductive health experts warn, the pills she buys from the international pharmacies could be counterfeit, or they could be real and still cause complications.

"I know, when I do it, that it could be a devil's bargain," Molly writes in the post. "This could be the envelope that gets traced back to me. This could be the one that lands me in prison. Or, even worse, it could be the one that kills someone. The abortion drugs rarely cause major complications (less often than birth), but they do happen. I don't know what I would do with that on my conscience. I haven't had to find out yet."

* * *

Back in Texas, HB2, the state's strict new abortion law, shows no signs of letting up.

In March, the U.S. 5th Circuit Court ruled unanimously that the admitting privileges provision in HB 2, which led to the closures of clinics in the Valley and elsewhere, "does not impose an undue burden on the life and health of a woman." Since the law went into effect, the state's number of licensed abortion providers dropped from 40 to 28, and only 24 centers still offer the surgical procedure.

And in September, another portion of HB2 will go into effect, which requires all abortion providers to conform to the same standards as ambulatory surgical centers—a costly upgrade that is expected to shut down the majority of the state's remaining clinics. When this portion of the law goes into effect, the number of abortion facilities in the state is expected to drop to six.

Today in Texas things are starting to look a lot like the early years of miso in places like Brazil and Chile: The simple guidelines about miso haven't yet made it to women in the state. But eventually, in those countries, the Internet and the democratization of information prevailed. Unless, and until, abortion restrictions change again, Latin America's DIY-abortion culture might be the future of women in South Texas.

This article available online at:

http://www.theatlantic.com/health/archive/2014/06/the-rise-of-the-diy-abortion-in-texas/373240/

Copyright © 2014 by The Atlantic Monthly Group. All Rights Reserved.

Y

Original Research

Incidence of Emergency Department Visits and Complications After Abortion

Ushma D. Upadhyay, PhD, MPH, Sheila Desai, MPH, Vera Zlidar, MHS, Tracy A. Weitz, PhD, MPA, Daniel Grossman, MD, Patricia Anderson, MPH, and Diana Taylor, PhD, RNP

OBJECTIVE: To conduct a retrospective observational cohort study to estimate the abortion complication rate, including those diagnosed or treated at emergency departments (EDs).

METHODS: Using 2009–2010 abortion data among women covered by the fee-for-service California Medicaid program and all subsequent health care for 6 weeks after having an abortion, we analyzed reasons for ED visits and estimated the abortion-related complication rate and the adjusted relative risk. Complications were defined as receiving an abortion-related diagnosis or treatment at any source of care within 6 weeks after an abortion. Major complications were defined as requiring hospital admission, surgery, or blood transfusion.

RESULTS: A total of 54,911 abortions among 50,273 fee-for-service Medi-Cal beneficiaries were identified. Among all abortions, 1 of 16 (6.4%, n=3,531) was followed by an ED visit within 6 weeks but only 1 of 115 (0.87%, n=478) resulted in an ED visit for an abortion-related complication. Approximately 1 of 5,491 (0.03%, n=15) involved ambulance transfers to EDs on the day of the abortion. The major complication rate was 0.23% (n=126, 1/436): 0.31% (n=35) for medication abortion, 0.16% (n=57) for first-trimester aspiration abortion, and 0.41% (n=34) for second-trimester or later procedures. The total abortion-related complication rate including all sources of care including EDs and the original abortion facility was 2.1% (n=1,156): 5.2% (n=588) for medication abortion, 1.3% (n=438) for first-trimester aspiration abortion, and 1.5% (n=130) for second-trimester or later procedures.

CONCLUSION: Abortion complication rates are comparable to previously published rates even when ED visits are included and there is no loss to follow-up.

(Obstet Gynecol 2015;125:175–83)

DOI: 10.1097/AOG.0000000000000603

LEVEL OF EVIDENCE: II

From the Advancing New Standards in Reproductive Health (ANSIRH), Bixby Center for Global Reproductive Health, Department of Obstetrics, Gynecology and Reproductive Sciences, University of California, San Francisco, San Francisco, California; John Snow, Inc, Arlington, Virginia; and Ibis Reproductive Health, Oakland, California. Ms. Zlidar is currently at the Public Health Institute, Washington, DC.

Supported by a University of California, San Francisco National Center of Excellence in Women's Health RAP Grant from Mount Zion Health Fund of the Jewish Community Endowment Fund and an anonymous foundation.

Presented at the North American Forum on Family Planning, October 6–7, 2013, Seattle, Washington.

The authors thank clinical consultants Kristina Ryan, RN, MSN, FNP, and Yvonne Piper, RN, FNP, MS, for their tireless efforts in coding the data; Diana Greene Foster, PhD, for providing expertise in Medi-Cal data analysis; Janley Hsiao, CPC, Billing Manager at San Francisco General Hospital, for providing expertise in Medi-Cal coding; Philip Darney, MD, MSc, for his critical review of the manuscript; and Shayna Lewis, JD, and Roula AbiSamra, MPH, for administration and coordination of the data.

Corresponding author: Ushma D. Upadhyay, PhD, MPH, Assistant Professor, Advancing New Standards in Reproductive Health (ANSIRH), Bixby Center for Global Reproductive Health, Department of Obstetrics, Gynecology, and Reproductive Sciences, University of California, San Francisco, 1330 Broadway, Suite 1100, Oakland, CA 94612; e-mail: Ushma.Upadhyay@ucsf.edu.

Financial Disclosure
The authors did not report any potential conflicts of interest.

© 2014 by The American College of Obstetricians and Gynecologists. Published by Lippincott Williams & Wilkins.

ISSN: 0029-7844/15

With 1.1 million induced abortions in the United States each year,[1] accurate estimates of abortion complications are paramount to assess and improve quality of care and determine how public policies can most effectively safeguard women's health. Although national abortion-related mortality data exist for the United States,[2] no surveillance system captures abortion-related morbidity. Studies find varying complication rates[3–7] depending on the procedure, weeks of gestation, length of follow-up, and protocols used to detect complications. Furthermore, complication rates are underestimated by low follow-up rates.[5,7–9]

Published complication rates are considered incomplete because they usually do not include those diagnosed at sites other than the original source of care.[10]

Copyright© American College of Obstetricians and Gynecologists

Limited research focuses on emergency department (ED) use when examining postabortion care. Because the abortion care delivery system is concentrated in urban centers maldistributed across states,[1] women often travel to obtain abortion care. Thus, women are likely to seek postabortion care at an ED near their home.

Using state Medicaid data, we examine reasons for postabortion visits, contributing to the literature

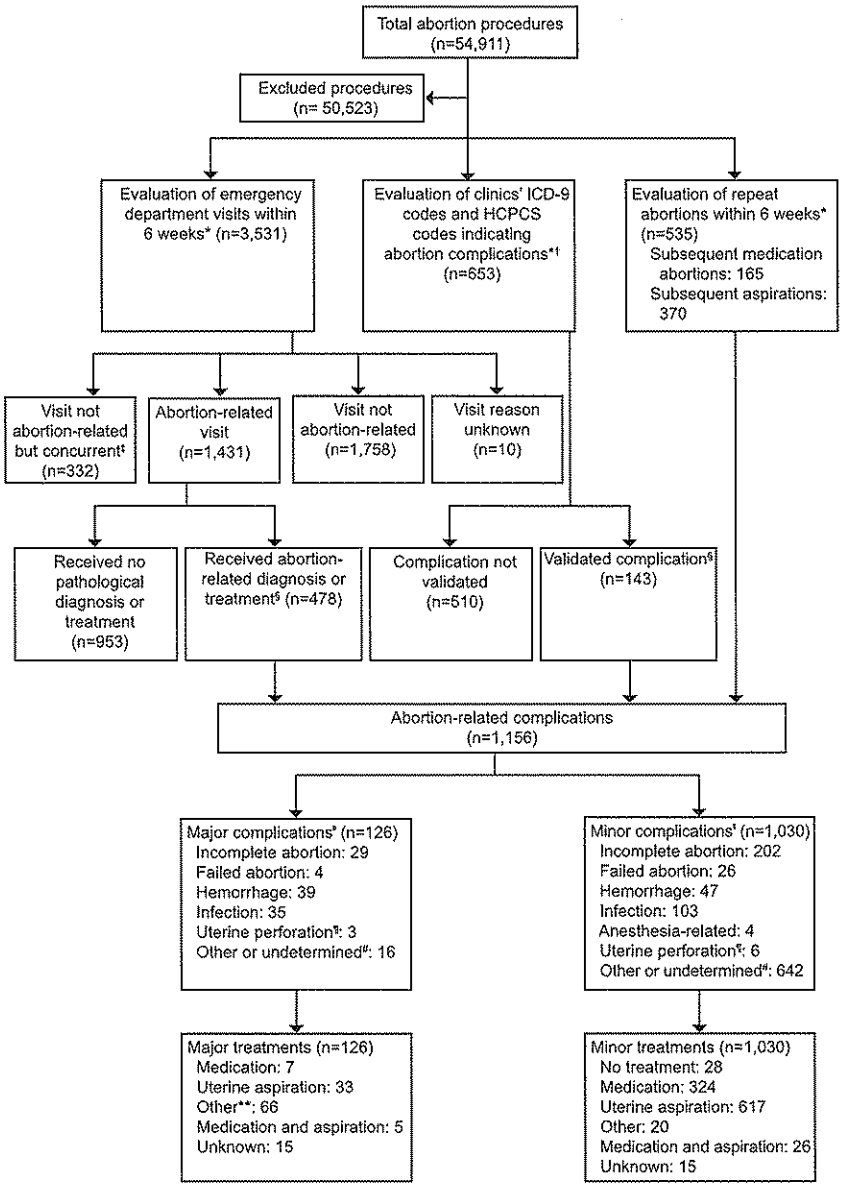


Fig. 1. Process of identification and classification of abortion complications and treatment. ICD-9, International classification of Diseases, 9th Revision; HCPCS, Healthcare Common Procedure Coding System. *Figures presented in the evaluation categories are not mutually exclusive. For example, a complication may have been identified through the evaluation of both emergency department visits and ICD-9 codes and, thus, are represented in both categories. †Includes diagnosis and treatment codes for antibiotics commonly used to treat abortion-related infections, genital tract and pelvic infection, hemorrhage, damage to pelvic organs or tissues, shock, embolism, laparoscopy, laparotomy, and hysterectomy surgeries, and blood transfusions. ‡Includes medical problems that were diagnosed and treated around the time of the abortion procedure such as ectopic pregnancy, molar pregnancy, preexisting medical condition, or concurrent problems present at the time of the procedure. §Confirmed as a complication based on the additional diagnosis or treatment codes, including laboratory tests ordered and medications. ‖Major complications were defined as serious unexpected adverse events requiring hospital admission, surgery, or blood transfusion. Minor complications were all other expected adverse events. ¶Includes one diagnosis of cervical injury requiring suture repair. #For major complications, this diagnosis includes undetermined diagnoses that required blood transfusions and surgery. For minor complications, the majority of this diagnosis consisted of cases treated with repeat abortion, but the exact diagnosis could not be determined. This category also includes diagnoses such as non-anesthesia-related allergic reactions and seizures. **Major treatments include combinations of treatments including blood transfusion (n=50) and surgery (n=13).

Upadhyay. ED Visits and Complications After Abortion. Obstet Gynecol 2015.

Copyright© American College of Obstetricians and Gynecologists

on ED use among patients with public insurance.[11,12] Then, using a standardized methodology for identifying and classifying complications, we estimate the incidence of postabortion complications diagnosed, treated, or diagnosed and treated at all clinical sites to see whether the rate of complications in a closed system with complete follow-up differs from the rates found in other studies.

MATERIALS AND METHODS

We used patient-level billing data from Medi-Cal, California's State Medicaid program. Medi-Cal provides pregnant low-income women immediate, temporary Medicaid coverage. California is one of 17 states that covers abortion and subsequent care for women enrolled in Medicaid. In 2011 an estimated 512 facilities in California performed 181,730 abortions,[1] approximately 51% of which were covered by Medi-Cal.[13]

The study was approved by the institutional review boards of the University of California, San Francisco and the California Health and Human Services Agency.

Medi-Cal is administered on a fee-for-service or managed care arrangement, split approximately in half across the two. Only the fee-for-service billing records contain complete information for care provided to a particular beneficiary; therefore, we received data only for those beneficiaries with fee-for-service coverage. We obtained billing records for every fee-for-service beneficiary who had an abortion

Table 1. Characteristics of Women With Abortions Covered by Medi-Cal, 2009–2010: Abortion-Related Complications, Complication Rates, and Adjusted Relative Risk, by Beneficiary Characteristics

Characteristic	Medi-Cal–Funded Abortions* (N=54,911)	Abortion-Related Complications† (n=1,156)	Abortion-Related Complication Rate/100 Abortions (95% CI)	Adjusted RR‡ (95% CI)	P
Age (y)	25.1±6.5				
19 or younger	11,446 (20.8)	173 (15.0)	1.51 (1.30–1.75)	0.87 (0.71–1.07)	.20
20–24	18,051 (32.9)	371 (32.1)	2.06 (1.86–2.27)	Reference	—
25–29	12,481 (22.7)	290 (25.1)	2.32 (2.07–2.60)	1.07 (0.91–1.26)	.40
30–39	11,508 (21.0)	296 (25.6)	2.57 (2.30–2.88)	1.20 (1.02–1.40)	.03
40 or older	1,400 (2.6)	25 (2.2)	1.79 (1.21–2.63)	0.83 (0.55–1.26)	.55
Race or ethnicity					
Non-Hispanic white	12,614 (23.0)	337 (29.1)	2.67 (2.40–2.97)	Reference	—
Non-Hispanic black	7,144 (13.0)	140 (12.1)	1.96 (1.66–2.31)	0.90 (0.73–1.12)	.35
Hispanic	23,110 (42.1)	471 (40.7)	2.04 (1.86–2.22)	0.76 (0.65–0.89)	<.001
Asian	2,771 (5.1)	62 (5.4)	2.24 (1.75–2.86)	0.87 (0.65–1.16)	.34
Other§	2,602 (4.7)	60 (5.2)	2.31 (1.79–2.96)	0.91 (0.68–1.21)	.50
Abortion procedure type					
Medication	11,319 (20.6)	588 (50.9)	5.19 (4.79–5.60)	5.96 (5.11–6.94)	<.001
1st-trimester aspiration	34,755 (63.3)	438 (37.9)	1.26 (1.14–1.38)	Reference	—
2nd trimester or later	8,837 (16.1)	130 (11.2)	1.47 (1.22–1.72)	0.98 (0.79–1.23)	.88
Site of procedure					
Hospital	1,667 (3.0)	84 (7.3)	5.04 (4.09–6.20)	4.74 (3.40–6.61)	<.001
Outpatient clinic	30,778 (56.1)	583 (50.4)	1.89 (1.75–2.05)	Reference	—
Physician's office or group	22,466 (40.9)	489 (42.3)	2.18 (1.99–2.38)	1.70 (1.32–2.17)	<.001
Residence type					
Urban	43,566 (90.5)	935 (80.9)	2.15 (2.01–2.29)	Reference	—
Rural	4,587 (9.5)	132 (11.4)	2.88 (2.43–3.40)	1.23 (1.00–1.52)	.05
Year of abortion					
2009	28,823 (52.5)	559 (48.4)	1.94 (1.79–2.11)	Reference	—
2010	26,088 (47.5)	597 (51.6)	2.29 (2.11–2.48)	1.03 (0.91–1.16)	.69

CI, confidence interval; RR, relative risk.
Data are mean±standard deviation or n (%) unless otherwise specified.
* The unit of analysis is women's abortions; the same woman may be represented more than once here if she had multiple abortions during the study period. Plus–minus values are mean±standard deviation. Data on age were missing for 25 abortions, data on woman's race or ethnicity were missing for 6,670 women, and data on woman's residence type were missing for 6,758 abortions.
† Cases may not add up to 1,156 as a result of missing data.
‡ Adjusted for age, race or ethnicity, abortion procedure type, site of procedure, residence type, and year of abortion.
§ Other includes Alaskan, American Indian, Hawaiian, Samoan, unknown, or other race or ethnicity.

Copyright© American College of Obstetricians and Gynecologists

Table 2. Reasons for Emergency Department Visits Within 6 Weeks of Initial Abortion

Characteristic of Visit	Total ED Visits (n=3,531)	Proportion of ED Visits (95% CI)
Reason for visit		
Not abortion-related	1,758	49.8 (48.14–51.44)
Abortion-related	1,431	40.5 (38.92–42.15)
Not abortion-related but concurrent*	332	9.4 (8.48–10.41)
Unknown	10	0.3 (0.15–0.53)
Abortion-related ED visit	1,431	40.5 (38.92–42.15)
Received treatment†	478	33.4 (31.00–35.89)
Did not receive treatment‡	953	66.6 (64.11–69.00)
Abortion procedure type		
Medication	770	21.8 (20.47–23.20)
1st-trimester aspiration	2,266	64.2 (62.57–65.74)
2nd trimester or later	495	14.0 (12.91–15.20)

ED, emergency department; CI, confidence interval.

* These are medical problems that were diagnosed, treated, or diagnosed and treated at the time of the abortion procedure (eg, ectopic or molar pregnancy, preexisting medical condition, or concurrent problems present at the time of the procedure).

† These are cases in which a patient received an abortion-related diagnosis or treatment and therefore were considered a complication.

‡ These are cases in which a patient presented with abortion-related symptoms but did not receive a pathologic diagnosis or treatment (eg, observation only).

in 2009 and 2010 and all billing records for all clinical encounters for each of those beneficiaries up to 6 weeks after the abortion. Each clinical encounter results in multiple ($\bar{x}=12$) billing records; thus, we acquired 659,361 records.

Data included an encrypted beneficiary identification number, date of birth, race or ethnicity, city, state, zip code, date(s) of service, type of facility, diagnosis (International Classification of Diseases, 9th Revision [ICD-9] codes), procedure or treatment (Healthcare Common Procedure Coding System, Current Procedural Terminology [CPT] codes), facility type, and amount paid per treatment. For each abortion, we calculated the beneficiary's age and urban or rural residence (determined by zip code).

Abortions were identified using Healthcare Common Procedure Coding System codes (59840–59841, 59850–59852 and 59855–59857, X7724, Z0336); these codes also indicated the abortion type: 1) "medication abortions," which includes use of mifepristone and misoprostol up to 9 weeks of gestation; 2) "first-trimester aspiration," which includes both manual and electric aspiration abortions as well as dilation and curettage "in the first 12–14 weeks of gestation"[14]; and 3) "second-trimester or later procedures." Included in this latter category are medical and surgical abortions performed using multiple abortion techniques such as dilation and evacuation, with or without osmotic dilators and misoprostol as well as full or partial inductions used "after 12–14 weeks of gestation."[14] The billing data that we had did not allow us to make a determination of weeks of gestation nor the specific technique used.

We searched for additional claims made to Medi-Cal up to 6 weeks after the abortion for each abortion identified. Postabortion ED visits (not including urgent care) within 6 weeks were identified using codes associated with ED use (Healthcare Common Procedure Coding System codes: 99281–99285, and Z7502). Clinically trained reviewers evaluated all available billing data (including all ICD-9 and Healthcare Common Procedure Coding System or CPT procedure codes) for each beneficiary who had an ED visit and assigned the visit to one of three categories: 1) not abortion-related; 2) not abortion-related but for a concurrent problem (diagnosed, treated, or diagnosed and treated at the time of the abortion); and 3) abortion-related. An ED visit was classified as abortion-related based on the constellation of ICD-9

Table 3. Major and Minor Abortion-Related Complication Rates by Procedure Type

	Medication Abortion (n=11,319)		1st-Trimester Aspiration (n=34,755)	
Complication Type	Rate/100 (95% CI)	n	Rate/100 (95% CI)	n
Major	0.31 (0.21–0.41)	35	0.16 (0.12–0.21)	57
Minor	4.88 (4.49–5.28)	553	1.10 (0.99–1.21)	381
Total complications	5.19 (4.79–5.60)	588	1.26 (1.14–1.38)	438

CI, confidence interval.

Copyright© American College of Obstetricians and Gynecologists

and Healthcare Common Procedure Coding System or CPT procedure codes for that visit. For example, in many cases, it was a combination of an ICD-9 code for an abortion, postabortion complication, or abdominal pain that indicated that the visit was abortion related along with a Healthcare Common Procedure Coding System or CPT procedure code for a pregnancy test, pelvic examination, transvaginal ultrasonography, abdominal ultrasonography, or dose of misoprostol.

Each abortion-related visit was then classified as 1) woman received an abortion-related diagnosis, treatment, or both; or 2) woman presented with abortion-related symptoms such as abdominal pain or cramping but received no pathologic diagnosis or treatment. When ED visits took place for multiple reasons, only the reason most closely related to the abortion was recorded (Fig. 1).

Additionally, we identified all ambulance transfers (Healthcare Common Procedure Coding System codes: X0030, X0034, X0036, X0400, X0402, X0412) and all self-referred ED visits on the day of the abortion regardless of whether the visit resulted in an abortion-related diagnosis or treatment.

The process of identifying and classifying abortion complications involved several steps. We defined a complication as any postabortion adverse event that received an abortion-related diagnosis or treatment at any source of care, including EDs and the original abortion facility within 6 weeks of an abortion procedure. To identify complications, the clinically trained reviewers evaluated all: 1) abortion-related diagnoses and treatments identified through the ED visit analysis described previously (excluding visits having no pathologic diagnosis or treatment); 2) ICD-9 codes that indicate abortion-related complications (635.00–635.82) and Healthcare Common Procedure Coding System or CPT codes for laparoscopy, laparotomy, and hysterectomy surgeries (49000, 49320, 49329, 58150, 58578, 58960), blood transfusions (86970, P9016–P9021, P9048, 390), and antibiotics commonly used to treat abortion-related infections and sepsis at least 1 day after the abortion; and 3) subsequent medication abortions and aspirations within 6 weeks.

The reviewers examined each case identified through this process and applied a systematic classification scheme developed by several of this study's authors and used in a recent study of abortion safety.[3] The classification system comprised a list of known abortion complications with standard definitions that included specific criteria (signs, symptoms, laboratory findings) to indicate the complication diagnosis. To validate the system, first, outside experts who work with the U.S. Agency for Health Research & Quality Evidence-Based Practice Centers and from abortion-related research or service delivery reviewed the classification system. Second, a Data and Clinical Safety Monitoring Committee reviewed incident data to further clarify complication definitions and criteria.

For this study, the clinician reviewers categorized each identified case into one of seven diagnoses: incomplete abortion, failed abortion, hemorrhage, infection, uterine perforation, anesthesia-related, and other or undetermined. The clinically trained reviewers examined all available billing data for the beneficiary, including laboratory tests ordered and medications, to validate each diagnosis. For example, to confirm a diagnosis of failed abortion, they checked for additional confirmatory evidence such as codes for aspiration or prenatal care. For diagnoses of hemorrhage, the reviewers looked for treatments such as aspiration, Methergine, or blood transfusion. One diagnosis category was assigned per abortion; when the billing records indicated more than one diagnosis, the highest level diagnosis was selected. Cases identified based on subsequent medication abortion, misoprostol dose, or aspiration within 6 weeks of the initial abortion without any ICD-9 code indicating a complication were categorized as "other or undetermined."

2nd Trimester or Later (n=8,837)		Total (N=54,911)		*P*	
Rate/100 (95% CI)	n	Rate/100 (95% CI)	n	Medication Abortion vs 1st-Trimester Abortion	1st-Trimester Abortion vs 2nd Trimester or Later
0.41 (0.27–0.54)	36	0.23 (0.19–0.27)	126	.003	<.001
1.09 (0.87–1.30)	96	1.88 (1.76–1.99)	1,030		
1.47 (1.22–1.72)	130	2.11 (1.99–2.23)	1,156	<.001	.12

Copyright© American College of Obstetricians and Gynecologists

Table 4. Distribution of Abortion-Related Complication Diagnoses by Type of Procedure and Type of Treatment

Characteristic	Complication Diagnosis			
	Incomplete Abortion	Failed Abortion	Hemorrhage	Infection
Abortion procedure type*				
Medication abortion (11,319)	99 (0.87)	15 (0.13)	16 (0.14)	26 (0.23)
1st-trimester aspiration (34,755)	116 (0.33)	14 (0.04)	44 (0.13)	94 (0.27)
2nd trimester or later (8,837)	16 (0.18)	1 (0.01)	26 (0.29)	18 (0.20)
Total (54,911)	231 (0.42)	30 (0.05)	86 (0.16)	138 (0.25)
Type of treatment§				
No treatment	0 (0.00)	5 (16.67)	0 (0.00)	0 (0.00)
Medication	2 (0.87)	0 (0.00)	20 (23.27)	100 (72.46)
Uterine aspiration	198 (85.71)	22 (73.33)	22 (25.58)	8 (5.80)
Both medication and aspiration	18 (7.79)	0 (0.00)	5 (5.81)	8 (5.80)
Other‖	13 (5.63)	3 (10.00)	34 (39.53)	6 (4.35)
Undetermined	0 (0.00)	0 (0.00)	5 (5.81)	16 (11.59)
Total	231 (100.0)	30 (100.0)	86 (100.0)	138 (100.0)

Data are n (%).
* Includes one diagnosis of cervical injury requiring suture repair.
† For major complications, this diagnosis includes undetermined diagnoses that required blood transfusions and surgery. For minor complications, the majority of this diagnosis consisted of cases treated with repeat abortion, but the exact diagnosis could not be determined. This category also includes diagnoses such as nonanesthesia-related allergic reactions and seizures.
‡ Row percentages reported.
§ Column percentages reported.
‖ Includes treatments such as blood transfusion (n=50 for major complications), surgical repair (n=13 for major complications), and tamponade.

Cases with the ICD-9 code "635.8 Abortion with unspecified complication" were also categorized as other or undetermined. To produce the most conservative estimate, we included undetermined diagnoses in the overall complications estimate.

Each complication was then classified as receiving one of six treatment categories: no treatment, medication (including mifepristone and misoprostol, misoprostol alone, or other medications), uterine aspiration, both medication and aspiration, other treatment, or undetermined. Abortion-related complications were classified as major if they required hospital admission (vendor codes 50, 60), surgery, or blood transfusion with all others classified as minor.

The data analysis was done in several steps. Using Stata 13, first we described the sample characteristics: age, race, residence, abortion procedure type, facility type, and year of abortion. Second, we estimated ED visits on the day of the abortion and within 6 weeks and present reasons for visits. Third, we estimated the abortion-related complication rate by the sample characteristics and the relative risk of a complication adjusted for all other characteristics using a generalized linear mixed model that accounts for lack of independence between multiple abortions by the same woman and those performed by the same health care provider; *P* values were determined from z tests derived from the model. Women who had missing data for any characteristic were retained in the model. Fourth, we compared major and minor complications by abortion procedure type using Pearson χ^2 tests. Finally, we described complication diagnoses by abortion procedure type and treatment. The abortion was the unit of analysis because 8.3% (n=4,165) of women in the data set had more than one abortion. Statistical significance was set at $P<.05$ for all comparisons; 95% confidence intervals (CIs) are reported.

RESULTS

Among the 659,361 records received, we identified 54,911 abortions among 50,273 fee-for-service Medi-Cal beneficiaries in 2009 and 2010. The largest proportions of women were ages 20–29 years, Hispanic, urban, had a first-trimester aspiration abortion, and were seen at an outpatient clinic (Table 1).

Among all 54,911 abortions, one in 1,036 (0.10%, n=53) were followed by an ED visit on the day of the abortion, including 1 of 5,491 (0.03%, n=15) transferred by ambulance for immediate care, although not all resulted in an abortion-related diagnosis or treatment.

Among all abortions (N=54,911), 1 of 16 (6.4%, n=3,531) was followed by an ED visit within 6 weeks of the abortion. Of these, 49.8% (n=1,758) were

Copyright© American College of Obstetricians and Gynecologists

Complication Diagnosis			
Uterine Perforation*	Anesthesia-Related	Other or Undetermined†	Total (N=54,911)
0 (0.00)	0 (0.00)	432 (3.82)	588 (5.19)
2 (0.01)	2 (0.01)	166 (0.48)	438 (1.26)
7 (0.08)	2 (0.02)	60 (0.68)	130 (1.47)
9 (0.02)	4 (0.01)	658 (1.20)	1,156 (2.11)
1 (11.11)	0 (0.00)	22 (3.34)	28 (2.42)
0 (0.00)	4 (100.0)	205 (31.16)	331 (28.63)
0 (0.00)	0 (0.00)	400 (60.79)	650 (56.23)
0 (0.00)	0 (0.00)	2 (0.30)	31 (7.44)
5 (55.56)	0 (0.00)	23 (3.50)	86 (2.68)
3 (33.33)	0 (0.00)	6 (0.91)	30 (2.60)
9 (100.0)	4 (100.0)	658 (100.0)	1,156 (100.0)

unrelated to the abortion, 9.4% (n=332) were conditions unrelated to but concurrent with the abortion, and 40.5% (n=1,431) were abortion-related. Among abortion-related visits, two thirds (66.6%, n=953) were cases in which a patient presented with abortion-related symptoms but did not receive a pathologic diagnosis or treatment. Thus, 1 of 115 (0.87%, n=478) abortions resulted in an ED visit receiving a diagnosis, treatment, or diagnosis and treatment. Among all abortion-related ED visits (n=1,431), 21.8% (n=770) followed a medication abortion, 64.2% (n=2,266) followed a first-trimester aspiration abortion, and 14.0% (n=495) followed a second-trimester or later procedure (Table 2).

Among all abortions (N=54,911), 1,156 (2.1%, 95% CI 1.99–2.23) resulted in an abortion-related complication diagnosed or treated at any source of care, including EDs and the original abortion facility. The unadjusted complication rate was 5.2% (n=588) for medication abortions, 1.3% (n=438) for first-trimester aspiration abortions, and 1.5% (n=130) for second-trimester or later procedures. Adjusted results indicate that women ages 30–39 years were 1.20 (95% CI 1.02–1.40) times as likely to have a complication compared with women ages 20–24 years, and Hispanic women were significantly less likely to have a complication compared with white women. Medication abortions were 5.96 (95% CI 5.11–6.94) times as likely to result in a complication as first-trimester aspiration abortions. Women receiving abortion care at hospitals or physician's offices or groups were significantly more likely to have a complication than women receiving care at outpatient clinics (Table 1).

The rate of major complications among all 54,911 abortions was 0.23% (95% CI 0.19–0.27) (n=126, 1/436), 0.31% (n=35) among women who had medication abortions, 0.16% (n=57) among women who had first-trimester aspiration abortions, and 0.41% (n=34) among women who had second-trimester or later procedures (Table 3). Among all women, 0.20% (n=108) were admitted to hospitals, 0.02% (n=13) had surgery, and 0.09% (n=50) received blood transfusions (data not shown). These three categories are not mutually exclusive; some women were admitted to a hospital and had surgery, received a blood transfusion, or had surgery and a blood transfusion.

The most common complications were other or undetermined diagnoses (1.20%, n=658), comprised mostly of undetermined diagnoses that lead to repeat abortion, and incomplete abortions (0.42%, n=231) (Table 4). The majority of incomplete abortions (85.7%, n=198) and failed abortions (73.3%, n=22) were treated with uterine aspiration. The majority of hemorrhage cases were treated by other treatments (including blood transfusion) (39.5%, n=34) or medication (23.3%, n=20). All anesthesia-related cases were treated with medication as were the majority of infections (72.5%, n=100).

DISCUSSION

We observed a 2.1% abortion-related complication rate after nearly 55,000 abortions diagnosed or treated at all sources of care. The majority were minor. Rates of transfers to an ED, hospital admissions, surgeries, and blood transfusions were low. The complication rate is much lower than that found during childbirth[15] and comparable to that found in the literature[3,7] even when ED visits are included and there is no loss to follow-up.

Copyright© American College of Obstetricians and Gynecologists

We observed the highest rate of complications among women obtaining medication abortions (5.2%, n=588), the vast majority of which were minor and expected. This rate may be overestimated with aspirations performed presumptively or to alleviate bleeding or cramping symptoms.[16] Nevertheless, this rate is consistent with intervention rates found in other studies.[17,18]

The complication rate for second-trimester or later procedures is lower than other studies.[4,19] This may be because the second-trimester or later category includes a large number of abortions performed earlier in the second trimester when complication rates are closer to those in the first trimester. Only 1.4% of all abortions nationally occur after 20 weeks of gestation[20]; our data should not be used to make determinations about the complication rate among the small number of procedures performed later in pregnancy.

We found a high rate (6.4%) of ED visits after abortion, half of which were not abortion-related. This finding is consistent with previous research and could reflect Medi-Cal beneficiaries' use of the ED as the health care provider of first resort.[11] Additionally, the Medi-Cal fee-for-service population has been noted as having greater health risks and more costly use compared with the Medi-Cal managed care population.[21]

Two thirds of abortion-related ED visits did not result in a diagnosis or treatment, representing visits primarily for symptoms, not complications. Strategies to reduce ED visits include increasing the number and types of Medi-Cal primary care providers, particularly in underserved areas, who can provide abortion care, postabortion care, or both, and improving health care provider–patient communication on nonurgent postprocedure side effects.

This study examines postabortion ED visits and complications up to 6 weeks and across multiple facilities without loss to follow-up, addressing a common methodologic limitation of other studies. In other studies, follow-up periods ranged from 2 to 4 weeks with most considering follow-up a return visit to the original abortion facility. When reported, loss to follow-up varies widely: 9% at 1 week,[7] 2–34% at 2 weeks,[5,8,9] and between 8 and 65% in studies where duration is not specified.[22,23] Additionally, this study has the sample size necessary to robustly estimate rare events.

Using billing codes to identify complications has methodologic limitations. Administrative data sets often contain erroneous codes[24]; however, our clinical reviewers examined all related billing records for patients with complications for inconsistencies and errors. Also, by relying on Medi-Cal codes, we could not assess whether any of the complications lead to deaths or detect complications not documented by billing codes. It is possible that complications seen or treated at the original abortion facility did not result in any Medi-Cal reimbursements, thereby underestimating the complication rate.

We were unable to determine the exact week of gestation of each abortion, which is known to be a strong predictor of complication risk.[6] Additionally, repeat abortions performed within 6 weeks were assumed to be for the same pregnancy, but they may have been for new pregnancies. This, too, may lead to overestimating the complication rate, although the proportion of new pregnancies is likely too small to have much effect.

Regarding generalizability to the national abortion population, demographically, our sample had higher rates of Hispanics, lower rates of blacks,[25] and presumably higher rates of low-income women. Medi-Cal beneficiaries may have more health problems than the general population[21] and given that the sample had insurance coverage, they may differ from women whose follow-up care is self-pay. These differences would mean that the reported complication rate is overestimated.

These new data can inform policy debates regarding abortion regulation in the United States. State legislatures have passed regulations such as ambulatory surgical center requirements (23 states), transfer agreement laws (eight states), and hospital admitting privileges requirements (13 states)[26] with the stated intent to increase safety. Given that in practice their ultimate effect often is the closure of abortion facilities,[27] there is a need to consider the public health effect of these policies, weighing any theoretical incremental reduction in patient risk that may occur against any increases in risk that may occur with reduced access to abortion care.

REFERENCES

1. Jones RK, Jerman J. Abortion incidence and service availability in the United States, 2011. Perspect Sex Reprod Health 2014; 46:3–14.
2. Bartlett LA, Berg CJ, Shulman HB, Zane SB, Green CA, Whitehead S, et al. Risk factors for legal induced abortion-related mortality in the United States. Obstet Gynecol 2004; 103:729–37.
3. Weitz TA, Taylor D, Desai S, Upadhyay UD, Waldman J, Battistelli MF, et al. Safety of aspiration abortion performed by nurse practitioners, certified nurse midwives, and physician assistants under a California legal waiver. Am J Public Health 2013;103:454–61.
4. Grossman D, Blanchard K, Blumenthal P. Complications after second trimester surgical and medical abortion. Reprod Health Matters 2008;16(suppl):173–82.
5. Paul ME, Mitchell CM, Rogers AJ, Fox MC, Lackie EG. Early surgical abortion: Efficacy and safety. Am J Obstet Gynecol 2002;187:407–11.

Copyright© American College of Obstetricians and Gynecologists

6. Cates W Jr, Schulz KF, Grimes DA, Tyler CW Jr. The effect of delay and method choice on the risk of abortion morbidity. Fam Plann Perspect 1977;9:266–8, 273.

7. Bennett IM, Baylson M, Kalkstein K, Gillespie G, Bellamy SL, Fleischman J. Early abortion in family medicine: clinical outcomes. Ann Fam Med 2009;7:527–33.

8. Meirik O, My Huong NT, Piaggio G, Bergel E, von Hertzen H; WHO Research Group on Postovulatory Methods of Fertility Regulation. Complications of first-trimester abortion by vacuum aspiration after cervical preparation with and without misoprostol: a multicentre randomised trial. Lancet 2012;379:1817–24.

9. Goldman MB, Occhiuto JS, Peterson LE, Zapka JG, Palmer RH. Physician assistants as providers of surgically induced abortion services. Am J Public Health 2004;94:1352–7.

10. Cree D, Jelsema R. The comparative safety of legal induced abortion and childbirth in the United States. Obstet Gynecol 2012;119:1271.

11. McConville S, Lee H. Emergency department care in California: who uses it and why? San Francisco (CA): Public Policy Institute of California; 2008.

12. Hoot NR, Aronsky D. Systematic review of emergency department crowding: causes, effects, and solutions. Ann Emerg Med 2008;52:126–36.

13. California Department of Health Care Services. Medi-Cal funded induced abortions, 2010. Sacramento (CA): California Department of Health Care Services; 2011.

14. California Department of Health Care Services. Medi-cal provider manual. Sacramento (CA): Department of Health Care Services; 2008.

15. Raymond EG, Grimes DA. The comparative safety of legal induced abortion and childbirth in the United States. Obstet Gynecol 2012;119:215–9.

16. Cleland K, Creinin M, Nucatola D, Nshom M, Trussell J. Significant adverse events and outcomes after medical abortion. Obstet Gynecol 2013;121:166–71.

17. Medical management of first-trimester abortion. Practice Bulletin No. 143. American College of Obstetricians and Gynecologists. Obstet Gynecol 2014;123:676–92.

18. Winikoff B, Dzuba IG, Creinin MD, Crowden WA, Goldberg AB, Gonzales J, et al. Two distinct oral routes of misoprostol in mifepristone medical abortion: a randomized controlled trial. Obstet Gynecol 2008;112:1303–10.

19. Peterson WF, Berry FN, Grace MR, Gulbranson CL. Second-trimester abortion by dilatation and evacuation: an analysis of 11,747 cases. Obstet Gynecol 1983;62:185–90.

20. Pazol K, Creanga AA, Burley KD, Hayes B, Jamieson DJ; Centers for Disease Control and Prevention (CDC). Abortion surveillance–United States, 2010. MMWR Surveill Summ 2013;62:1–44.

21. Riner RM. Challenging the cost effectiveness of Medi-Cal managed care. West J Emerg Med 2009;10:124-e8.

22. Hakim-Elahi E, Tovell HM, Burnhill MS. Complications of first-trimester abortion: a report of 170,000 cases. Obstet Gynecol 1990;76:129–35.

23. Westfall JM, Sophocles A, Burggraf H, Ellis S. Manual vacuum aspiration for first-trimester abortion. Arch Fam Med 1998;7:559–62.

24. Fjerstad M, Westhoff C, Lifford KL. Immediate complications after medical compared with surgical termination of pregnancy. Obstet Gynecol 2010;115:660.

25. Jones R, Finer LB, Singh S. Characteristics of US abortion patients, 2008. New York (NY): Guttmacher Institute; 2010.

26. Guttmacher Institute. State policies in brief: targeted regulation of abortion providers. New York City (NY): Guttmacher Institute; 2014.

27. Grossman D, Baum S, Fuentes L, White K, Hopkins K, Stevenson A, et al. Change in abortion services after implementation of a restrictive law in Texas. Contraception 2014;90:496–501.

Copyright© American College of Obstetricians and Gynecologists

Z

MAJOR ARTICLE

Emergency Department Visits for Antibiotic-Associated Adverse Events

Nadine Shehab, Priti R. Patel, Arjun Srinivasan, and Daniel S. Budnitz

Division of Healthcare Quality Promotion, National Center for Detection, Preparedness, and Control of Infectious Diseases, Coordinating Center for Infectious Diseases, Centers for Disease Control and Prevention, Atlanta, Georgia

(See the editorial commentary by Linder on pages 744–6)

Background. Drug-related adverse events are an underappreciated consequence of antibiotic use, and the national magnitude and scope of these events have not been studied. Our objective was to estimate and compare the numbers and rates of emergency department (ED) visits for drug-related adverse events associated with systemic antibiotics in the United States by drug class, individual drug, and event type.

Methods. We analyzed drug-related adverse events from the National Electronic Injury Surveillance System–Cooperative Adverse Drug Event Surveillance project (2004–2006) and outpatient prescriptions from national sample surveys of ambulatory care practices, the National Ambulatory Medical Care Survey and the National Hospital Ambulatory Medical Care Survey (2004–2005).

Results. On the basis of 6614 cases, an estimated 142,505 visits (95% confidence interval [CI], 116,506–168,504 visits) annually were made to US EDs for drug-related adverse events attributable to systemic antibiotics. Antibiotics were implicated in 19.3% of all ED visits for drug-related adverse events. Most ED visits for antibiotic-associated adverse events were for allergic reactions (78.7% of visits; 95% CI, 75.3%–82.1% of visits). One-half of the estimated ED visits were attributable to penicillins (36.9% of visits; 95% CI, 34.7%–39.2% of visits) and cephalosporins (12.2%; 95% CI, 10.9%–13.5%). Among commonly prescribed antibiotics, sulfonamides and clindamycin were associated with the highest rate of ED visits (18.9 ED visits per 10,000 outpatient prescription visits [95% CI, 13.1–24.7 ED visits per 10,000 outpatient prescription visits] and 18.5 ED visits per 10,000 outpatient prescription visits [95% CI, 12.1–25.0 ED visits per 10,000 outpatient prescription visits], respectively). Compared with all other antibiotic classes, sulfonamides were associated with a significantly higher rate of moderate-to-severe allergic reactions (4.3% [95% CI, 2.9%–5.8%] vs. 1.9 % [95% CI, 1.5%–2.3%]), and sulfonamides and fluoroquinolones were associated with a significantly higher rate of neurologic or psychiatric disturbances (1.4% [95% CI, 1.0%–1.7%] vs. 0.5% [95% CI, 0.4%–0.6%]).

Conclusions. Antibiotic-associated adverse events lead to many ED visits, and allergic reactions are the most common events. Minimizing unnecessary antibiotic use by even a small percentage could significantly reduce the immediate and direct risks of drug-related adverse events in individual patients.

Antibiotics are among the most frequently used medications in the United States. Annually, antibiotics are prescribed to an estimated 16% of patients during ambulatory care visits [1], and pharmaceutical manufacturers spend >$1 billion promoting antibiotics [2]. Antibiotic resistance resulting from excessive and injudicious use of antibiotics is perceived to be a serious threat to public health [3–5]. Consequently, efforts to promote judicious antibiotic use have focused largely on the long-term societal impact of antibiotic resistance [5–7]. The more immediate risks of antibiotic use in the community—namely, adverse effects—are generally considered to be infrequent and mild. National campaigns and communication strategies aimed at reducing inappropriate antibiotic use have not traditionally incorporated messages that address these more direct and short-term risks of antibiotic use [8, 9]. To better characterize the scope and burden of serious antibiotic-associated adverse events, we used nationally representative surveillance data from the United States to

Received 11 November 2007; accepted 24 April 2008; electronically published 11 August 2008.

The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the funding agencies.

Reprints or correspondence: Dr. Nadine Shehab, Div. of Healthcare Quality Promotion, Centers for Disease Control and Prevention, 1600 Clifton Rd. NE, Mailstop A-24, Atlanta, GA 30333 (nshehab@cdc.gov).

Clinical Infectious Diseases 2008; 47:735–43
This article is in the public domain, and no copyright is claimed.
1058-4838/2008/4706-0001
DOI: 10.1086/591126

Downloaded from http://cid.oxfordjournals.org/ at Planned Parenthood Federation of America on December 30, 2014

describe the frequency, rate, and nature of emergency department (ED) visits for adverse events caused by systemic antibiotics.

METHODS

National estimates of the number of ED visits for drug-related adverse events were based on data from the National Electronic Injury Surveillance System–Cooperative Adverse Drug Event Surveillance (NEISS-CADES) project, a national stratified probability sample of 63 hospitals with a minimum of 6 beds and a 24-h ED in the United States and its territories [10–12]. The NEISS-CADES project, which has been described in detail elsewhere, is a joint effort of the Centers for Disease Control and Prevention, the US Consumer Product Safety Commission, and the US Food and Drug Administration [11, 12]. In brief, trained coders located at each participating hospital review clinical records of every ED visit to identify physician-diagnosed drug-related adverse events, to report up to 2 medications implicated in each adverse event, and to record narrative descriptions of the incident. We defined a drug-related adverse event as an incident ED visit by a patient from 1 January 2004 through 31 December 2006 for a condition that the treating physician explicitly attributed to the use of an antibiotic or for an antibiotic-specific adverse effect. Topical antibiotics (i.e., dermatologic, ophthalmic, otic, or vaginal formulations) were excluded. Adverse events were categorized as adverse effects (defined as undesirable pharmacologic or idiosyncratic effects, such as diarrhea, dizziness, and headache, while a patient was receiving therapy at recommended doses), allergic reactions (defined as immunologically mediated effects, such as rash and anaphylaxis), unintentional overdoses (defined as toxic effects associated with excess dose, such as effects attributable to unintentionally ingesting more than the prescribed dose), unintentional exposures (defined as unintentional ingestion of a medication, such as a child finding and ingesting an antibiotic), and other effects (defined as adverse events not attributable to allergic reactions, adverse effects, or unintentional overdoses, such as injection site reactions and choking). On the basis of the diagnoses and symptoms provided for each case and with use of methods described elsewhere [12], the manifestations associated with each adverse event were categorized into various conditions. For simplification of presentation, adverse event conditions were assigned in mutually exclusive and hierarchical fashion.

National estimates of the number of outpatient prescription visits (i.e., ambulatory care visits during which an antibiotic was prescribed) were based on the National Ambulatory Medical Care Survey (NAMCS) and the National Hospital Ambulatory Medical Care Survey (NHAMCS) [13–16]. The NAMCS and NHAMCS are national sample surveys that provide information about the provision and use of ambulatory medical care services, including physician office, hospital outpatient department, and ED visits, in the United States and have been used previously for estimates of the frequency of antibiotic prescribing [17–20]. We used public-use data from the period 2004–2005 (the most recent years available) to identify ambulatory care visits at which treatment with a systemic antibiotic was either started or continued by using a combination of the 4-digit National Drug Code Directory class, brand name, generic name (for single-ingredient drug products), and individual active ingredients (for multi-ingredient drug products). We estimated the number of outpatient prescription visits from NAMCS and NHAMCS for all systemic antibiotics that were implicated in an ED visit for a drug-related adverse event in the NEISS-CADES project from 2004 through 2006.

Each NEISS-CADES, NAMCS, and NHAMCS visit was assigned a sample weight on the basis of the inverse probability of selection, adjusted for nonresponse, population changes, and in NAMCS and NHAMCS, weight smoothing (i.e., adjustments for extremes in final weights of visits) [10, 21, 22]. We calculated national estimates of the frequency of ED and prescription visits and corresponding 95% CIs using the Surveymeans procedure in SAS, version 9.1 (SAS), to account for the sample weights and complex sample designs. We divided frequency estimates and 95% CIs by 3 for the period 2004–2006 (NEISS-CADES) and by 2 for the period 2004–2005 (NAMCS, NHAMCS), to obtain annual estimated frequencies. Estimates based on small numbers of cases (<20 cases for NEISS-CADES and <30 cases for NAMCS and NHAMCS) or with a coefficient of variation >30% were considered to be statistically unstable and are not presented here.

We calculated rates by dividing the estimated number of ED visits for drug-related adverse events (from NEISS-CADES) by the estimated number of outpatient visits at which that antibiotic or antibiotic class was prescribed (from NAMCS and NHAMCS). The 95% CI for each rate incorporated variance estimates for both numerator and denominator components of the corresponding rate estimate [23]. Because these components were calculated from separate surveillance systems, they were treated as independent and as having zero covariance [23].

RESULTS

On the basis of 6614 cases, an estimated 142,505 ED visits (95% CI, 116,506-168,504 visits) annually occurred because of antibiotic-associated adverse events from 2004 through 2006 (table 1). Systemic antibiotics were implicated in 19.3% of all ED visits for drug-related adverse events. Persons aged 15–44 years accounted for an estimated 41.2% of ED visits. Infants (age, <1 year) accounted for only an estimated 6.3% of ED visits; however, after accounting for prescription frequency, the estimated rate of ED visits for adverse events attributable to an-

Downloaded from http://cid.oxfordjournals.org/ at Planned Parenthood Federation of America on December 30, 2014

Table 1. Number of cases and national estimates of emergency department (ED) visits for adverse events associated with systemic antibiotics, by patient and case characteristics—United States, 2004–2006.

Characteristic	ED visits for adverse events		
	No. of cases	Estimated annual no. of visits	Estimated annual visits, % (95% CI)
Age, years			
<1	545	8982	6.3 (5.3–7.3)
1–4	976	16,462	11.5 (10.1–13.0)
5–14	656	11,559	8.1 (7.1–9.1)
15–44	2577	58,711	41.2 (38.7–43.7)
45–64	1143	27,607	19.4 (18.0–20.7)
65–79	507	13,546	9.5 (8.4–10.6)
≥80	210	5638	4.0 (3.3–4.7)
Sex			
Female	4263	95,444	67.0 (65.3–68.7)
Male	2351	47,061	33.0 (31.3–34.7)
Mechanism of adverse event[a]			
Adverse effect	1193	27,298	19.2 (15.8–22.6)
Allergic reaction	5265	112,116	78.7 (75.3–82.1)
Unintentional overdose	72	1321	0.9 (0.7–1.2)
Unintentional exposure	32	540	0.4 (0.2–0.6)
Other	52	1231	0.9 (0.7–1.6)
Disposition			
Admitted, observed, or transferred	372	8738	6.1 (4.6–7.7)
Treated and released or left against medical advice	6242	133,767	93.9 (92.3–95.4)
No. of implicated medications			
1	5784	125,882	88.3 (86.5–90.1)
≥2	830	16,623	11.7 (9.9–13.5)
No. of concurrent medications			
None listed	4024	86,904	61.0 (55.0–67.0)
1–3	1907	38,628	27.1 (23.0–31.2)
4–6	477	11,554	8.1 (6.4–9.8)
≥7	206	5419	3.8 (2.8–4.8)
Total	6614	142,505	100

NOTE. Estimates are based on the National Electronic Injury Surveillance System–Cooperative Adverse Drug Event Surveillance project (2004–2006).

[a] Adverse effects refer to undesirable pharmacologic or idiosyncratic effects that occur while the patient is receiving therapy at recommended doses (e.g., diarrhea, dizziness, and headache); allergic reactions refer to immunologically mediated effects (e.g., rash and anaphylaxis); unintentional overdoses refer to toxic effects linked to excess dose (e.g., because of unintentionally ingesting more than the prescribed dose); unintentional exposures (e.g., unintentional ingestion of a medication, such as a child finding and ingesting an antibiotic); and other effects refer to adverse events not associated with allergic reactions, adverse effects, or unintentional overdoses (e.g., injection site reactions and choking).

tibiotics was highest in this age group (15.9 ED visits per 10,000 outpatient prescription visits; 95% CI, 10.6–21.1 ED visits per 10,000 outpatient prescription visits). More than two-thirds of estimated ED visits for antibiotic-associated adverse events were by female patients, and the estimated rate of ED visits was significantly higher among female patients than among male patients (12.5 ED visits per 10,000 outpatient prescription visits [95% CI, 9.9–15.1 ED visits per 10,000 outpatient prescription visits] vs. 7.9 ED visits per 10,000 outpatient prescription visits [95% CI, 6.3–9.5 ED visits per 10,000 outpatient prescription visits]). An estimated 78.7% of drug-related adverse events were attributed to allergic reactions; 6.1% of drug-related adverse events led to hospitalization.

Together, penicillins and cephalosporins were implicated in one-half of the estimated ED visits for antibiotic-associated adverse events (36.9% and 12.2% of visits, respectively) (table 2). Among antibiotics commonly used in the community, the estimated rates of ED visits for drug-related adverse events were

Downloaded from http://cid.oxfordjournals.org/ at Planned Parenthood Federation of America on December 30, 2014

Table 2. Number of cases and national estimates of emergency department (ED) visits for adverse events associated with systemic antibiotics, by drug—United States, 2004–2006.

Drugs class, drug	ED visits for adverse events		Estimated annual outpatient prescription visits, no. in thousands (%)	Estimated annual no. of ED visits per 10,000 outpatient prescription visits (95% CI)
	No. of cases	Estimated annual no. of visits (%)		
Penicillins				
All	2604	52,654 (36.9)	40,653 (29.8)	13.0 (10.3–15.6)
Amoxicillin and penicillin[a]	2130	42,340 (29.7)	27,276 (20.0)	15.5 (12.3–18.7)
Amoxicillin-clavulanate	429	9409 (6.6)	12,002 (8.8)	7.8 (5.5–10.2)
Cephalosporins				
All	801	17,376 (12.2)	28,406 (20.8)	6.1 (4.5–7.7)
Cephalexin	434	9935 (7.0)	12,988 (9.5)	7.6 (5.5–9.8)
Cefdinir	164	2506 (1.8)	4226 (3.1)	5.9 (3.3–8.6)
Ceftriaxone	55[b]	1085 (0.8)	5483 (4.0)	2.0 (1.1–2.9)
Cefuroxime	48[b]	1276 (0.9)	1072 (0.8)	11.9 (4.9–18.9)
Cefprozil	44	1184 (0.8)	1832 (1.3)	6.5 (3.0–10.0)
Fluoroquinolones				
All	791	19,279 (13.5)	20,913 (15.3)	9.2 (7.0–11.5)
Levofloxacin	337	8342 (5.9)	9425 (6.9)	8.9 (6.2–11.5)
Ciprofloxacin	219	4970 (3.5)	7709 (5.7)	6.4 (4.5–8.4)
Moxifloxacin	182	4665 (3.3)	2253 (1.7)	20.7 (11.9–29.5)
Gatifloxacin	38	875 (0.6)	1351 (1.0)	6.5 (2.8–10.2)
Sulfonamides and trimethoprim[c]				
All	756	16,865 (11.8)	8629 (6.5)	18.9 (13.1–24.7)
Sulfamethoxazole-trimethoprim	718	16,068 (11.3)	8577 (6.3)	18.7 (12.9–24.6)
Macrolides and ketolides				
All	602	13,704 (9.6)	26,574 (19.6)	5.1 (3.8–6.4)
Azithromycin	371	8491 (6.0)	18,822 (13.8)	4.5 (3.2–5.8)
Erythromycin	100[b]	2545 (1.8)	2540 (1.9)	10.0 (5.4–14.6)
Clarithromycin	102[b]	2025 (1.4)	5109 (3.7)	4.0 (2.2–5.7)
Lincosamides (clindamycin)	204	4419 (3.1)	2385 (1.8)	18.5 (12.1–25.0)
Tetracyclines				
All	187	4488 (3.1)	8550 (6.3)	5.2 (3.7–6.8)
Doxycycline	131	3209 (2.3)	5543 (4.1)	5.8 (3.9–7.7)
Metronidazole	125	2620 (1.8)	3456 (2.5)	7.6 (5.1–10.1)
Nitrofurans (nitrofurantoin)	96	2226 (1.6)	2306 (1.7)	9.7 (5.8–13.5)
Vancomycin and linezolid				
All	52	1166 (0.8)	484 (0.4)	24.1 (10.9–37.3)
Vancomycin	45	963 (0.7)	444 (0.3)	21.7 (8.9–34.4)
Unspecified and other antibiotics[d]	214	4362 (3.1)	2972 (2.2)	14.7 (9.6–19.8)
Two antibiotics from different drug classes[e]	182	3345 (2.3)	8595	..

NOTE. Estimates of the number of adverse events are based on the National Electronic Injury Surveillance System–Cooperative Adverse Drug Event Surveillance project (2004–2006). Estimates of the number of outpatient prescription visits are based on the National Ambulatory Medical Care Survey and National Hospital Ambulatory Medical Care Survey (2004–2005). Individual drugs are shown in the table only if they were implicated in ≥0.5% of estimated emergency department visits for antibiotic-associated adverse events. For example, cefaclor was counted under cephalosporins but was implicated in only 18 patients (estimated percentage of ED visits, 0.4%) and, therefore, is not shown.

[a] Penicillin includes penicillin V and penicillin G salts.

[b] Because each case was individually weighted, categories with a similar number of cases may not reflect identical national estimates.

[c] Sulfonamides include sulfamethoxazole-trimethoprim, sulfisoxazole, and sulfisoxazole-erythromycin.

[d] For ED visits for adverse events, "other" antibiotics include imipenem-cilastatin (3 cases), ertapenem (1 case), gentamicin (3 cases), tobramycin (1 case), and daptomycin (1 case). For outpatient prescription visits, "other" antibiotics include carbapenems, aminoglycosides (excluding neomycin sulfate), and daptomycin.

[e] Outpatient prescription visits when >1 antibiotic from different drug classes were mentioned were included in the count for each antibiotic class.

Downloaded from http://cid.oxfordjournals.org/ at Planned Parenthood Federation of America on December 30, 2014

highest for sulfonamides (18.9 ED visits per 10,000 outpatient prescription visits) and clindamycin (18.5 ED visits per 10,000 outpatient prescription visits). Within most antibiotic classes, the rates of ED visits for adverse events attributable to individual drugs were similar. However, the rate of ED visits for adverse events attributable to amoxicillin or penicillin was significantly higher than that for adverse events attributable to amoxicillin-clavulanate (15.5 ED visits per 10,000 outpatient prescription visits [95% CI, 12.3–18.7 ED visits per 10,000 outpatient prescription visits] vs. 7.8 ED visits per 10,000 outpatient prescription visits [95% CI, 5.5–10.2 ED visits per 10,000 outpatient prescription visits]), and the rate of ED visits for adverse events attributable to moxifloxacin was significantly higher than that for adverse events attributable to any other fluoroquinolone (table 2). Overall, the rate of ED visits for antibiotic-associated adverse events was 10.5 ED visits per 10,000 outpatient prescription visits (95% CI, 8.3–12.6 ED visits per 10,000 outpatient prescription visits).

Among ED visits for adverse events attributed only to 1 antibiotic or 2 antibiotics from the same class, the most common drug-related adverse event conditions were allergic reactions (table 3). Sulfonamides were associated with a significantly higher rate of moderate-to-severe allergic reactions, compared with all other antibiotic classes combined (4.3% [95% CI, 2.9%–5.8%] vs. 1.9% [95% CI, 1.5%–2.3%]). The rate of mild allergic reactions was significantly higher with penicillins, sulfonamides, and clindamycin than with all other antibiotic classes combined (7.8% [95% CI, 6.2%–9.3%] vs. 2.8% [95% CI, 2.2%–3.4%]). The rate of gastrointestinal disturbances was highest with clindamycin (3.0%; 95% CI, 1.5%–4.6%), but this rate was not significantly different from the rate with all other antibiotic classes. Sulfonamides and fluoroquinolones were associated with significantly higher rates of neurologic or psychiatric effects than were all other antibiotic classes combined (1.4% [95% CI, 1.0%–1.7%] vs. 0.5% [95% CI, 0.4%–0.6%]). Sulfonamides and fluoroquinolones were also associated with the highest rates of hospitalization (1.0% [95% CI, 0.5%–1.6%] and 0.9% [95% CI, 0.5%–1.2%]), but rates of hospitalization were not significantly different among classes.

DISCUSSION

This investigation was the first that we are aware of to use timely, nationally representative surveillance data to estimate and compare the numbers and rates of adverse events attributable to systemic antibiotics by drug class, individual drug, and event type. We estimated that adverse events attributable to antibiotics caused >142,000 ED visits per year, and nearly four-fifths of these events were allergic reactions. The overall rate of ED visits for antibiotic-associated adverse events (10.5 ED visits per 10,000 outpatient prescription visits) was higher than expected. The rate of ED visits for antibiotic-associated adverse events is one-half of the rate of ED visits for adverse events attributable to "high-risk" medications, such as warfarin, insulin, and digoxin (20.6 ED visits per 10,000 outpatient prescription visits); however, the rate of ED visits for antibiotic-associated adverse events is 3 times higher than that for adverse events attributable to some anticoagulant and antiplatelet agents (e.g., aspirin and clopidogrel), oral hypoglycemics (e.g., metformin), and some narrow therapeutic index agents (e.g., phenytoin and lithium; rate for all of these drug classes combined, 3.3 ED visits per 10,000 outpatient prescription visits) [24].

Previous studies using NAMCS, NHAMCS, and NEISS-CADES data have estimated that antibiotics cause ~19% of ambulatory care visits [25] and 18% of ED visits [12] for drug-related adverse events. However, these studies did not provide detailed comparisons among antibiotic classes and drugs, account for antibiotic prescribing frequency, or describe the nature of antibiotic-associated adverse events. More-detailed studies of antibiotic-associated adverse events have been largely limited to studies involving hospitalized patients, spontaneous reports of adverse drug reactions attributable to a single antibiotic or antibiotic class, or studies of specific adverse events [26–30].

We found that nearly 80% of ED visits for antibiotic-associated adverse events among patients receiving ambulatory care were the result of allergic reactions. This finding is in contrast to those for other medication classes that cause many ED visits for drug-related adverse events (e.g., anticoagulants, antidiabetics, and anticonvulsants), which primarily result from medication errors and overdoses [12, 24]. Although medication errors and overdoses can be prevented by improving administration and monitoring, most allergic reactions can only be prevented by avoiding exposure to a drug. We could not assess the appropriateness of antibiotic prescribing from these data; however, more than one-half of the estimated 100 million antibiotic prescriptions written in the community each year for respiratory tract infections may be unnecessary [17, 18, 31]. Although the risk of an ED visit for an antibiotic-associated adverse event is small for an individual patient, when antibiotics are commonly prescribed for indications for which they have no benefit, the burden of preventable adverse events in the population is great. Thus, efforts to mitigate the burden of untoward effects of antibiotics should focus on minimizing excessive use of antibiotics, because decreasing inappropriate antibiotic use by even a small percentage could substantially reduce the number of patients who experience antibiotic-associated adverse events.

Previous studies have found that, when both infectious diseases specialists and general physicians prescribe broad-spectrum antibiotics, such as fluoroquinolones, they often cite perceived advantages of these agents in terms of their safety profiles

Downloaded from http://cid.oxfordjournals.org/ at Planned Parenthood Federation of America on December 30, 2014

Table 3. Number of cases and national estimates of the rate of emergency department (ED) visits for adverse events associated with a single systemic antibiotic class, by adverse event condition—United States, 2004–2006.

	Adverse event condition									
	Moderate-to-severe allergic reaction[b]		Neurologic and/or psychiatric		Gastrointestinal		Mild allergic reaction[c]		Other or unspecified effect	
Drug class[a]	No. of cases	Estimated no. of ED visits per 10,000 OPV (95% CI)	No. of cases	Estimated no. of ED visits per 10,000 OPV (95% CI)	No. of cases	Estimated no. of ED visits per 10,000 OPV (95% CI)	No. of cases	Estimated no. of ED visits per 10,000 OPV (95% CI)	No. of cases	Estimated no. of ED visits per 10,000 OPV (95% CI)
Penicillins	420	2.2 (1.7–2.7)	66	0.4 (0.3–0.6)	212	1.1 (0.6–1.6)	1528	7.6 (6.0–9.1)	175	0.7 (0.4–0.9)
Cephalosporins	184	1.3 (0.9–1.7)	39	0.3 (0.2–0.5)	88	0.7 (0.3–1.0)	357	2.8 (2.0–3.5)	58	0.4 (0.2–0.6)
Fluoroquinolones	212	2.4 (1.8–3.1)	100	1.2 (0.9–1.6)	83	1.1 (0.6–1.5)	228	2.8 (1.9–3.7)	75	0.7 (0.4–0.9)
Sulfonamides and trimethoprim	163	4.3 (2.9–5.8)	55	1.7 (0.9–2.4)	61	2.0 (0.8–3.1)	355	8.3 (5.8–10.7)	57	1.2 (0.6–1.9)
Macrolides and ketolides	120	1.1 (0.7–1.4)	39	0.3 (0.2–0.4)	111	1.0 (0.6–1.4)	190	1.7 (1.2–2.2)	59	0.4 (0.3–0.6)
Lincosamides (clindamycin)	32	2.8 (1.3–4.2)	11	...	34	3.0 (1.5–4.6)	80	8.4 (5.1–11.7)	18	...
Tetracyclines	38	1.2 (0.6–1.8)	11	...	28	0.7 (0.4–1.0)	66	2.0 (1.3–2.6)	22	0.4 (0.2–0.6)
All other antibiotic classes[d]	80	1.9 (1.2–2.7)	52	1.4 (0.8–1.9)	66	1.7 (0.9–2.4)	171	4.0 (2.9–5.1)	58	1.2 (0.6–0.8)

NOTE. Estimates of the number of adverse events are based on the National Electronic Injury Surveillance System–Cooperative Adverse Drug Event Surveillance project (2004–2006). Estimates of the number of outpatient prescription visits (OPV) are based on the National Ambulatory Medical Care Survey and National Hospital Ambulatory Medical Care Survey (2004–2005). Adverse events were categorized into 1 condition. Adverse event conditions are mutually exclusive and were assigned hierarchically (left to right). For example, a case in which a patient experienced both a severe allergic reaction and gastrointestinal effects would be categorized as a moderate-to-severe allergic reaction.

[a] Only cases in which drugs from a single systemic antibiotic class were implicated in the adverse event are included (5802 cases). Estimates with coefficient of variation >30% or based on <20 cases were not calculated.

[b] Includes anaphylaxis, angioedema, erythema multiforme, exfoliative dermatitis, facial-pharyngeal-genital edema, hypersensitivity vasculitis, red man syndrome, respiratory distress or arrest, serum sickness, and Stevens-Johnson syndrome.

[c] Includes dermatitis, drug eruption, erythema, flushing, localized edema, pruritus, rash, rash morbilliform, and urticaria.

[d] Includes metronidazole, nitrofurans, vancomycin, linezolid, unspecified, and other antibiotic classes.

Downloaded from http://cid.oxfordjournals.org/ at Planned Parenthood Federation of America on December 30, 2014

[32, 33]. Although the rate of ED visits for adverse events attributable to fluoroquinolones was lower than the rates of ED visits for adverse events attributable to sulfonamides and clindamycin, it was higher than the rates of ED visits for adverse events attributable to cephalosporins, macrolides, and tetracyclines. In addition, fluoroquinolones were associated with the second highest rates of neurologic or psychiatric effects and hospitalization. The significantly higher rate of adverse events attributable to moxifloxacin, compared with fluoroquinolones, is similar to findings from clinical trials and studies based on spontaneous reporting [28, 34] and is contrary to the perception that "newer" antibiotics have superior adverse effect profiles [32, 33].

Adverse event data cannot be used in isolation to dictate the decision as to whether to prescribe antibiotics or to determine optimal antibiotic selection for individual patients. However, these national surveillance data can be used by clinicians to help assess the validity of their perceptions of the safety profile of various antibiotics and antibiotic classes. These population-based findings are also important, because adverse event data from spontaneous reports cannot provide population rates, and safety data from clinical trials largely reflect adverse events among a small number of highly selected persons relative to those eventually exposed to antibiotics in the community [35].

The infectious diseases and public health communities have long argued for judicious antibiotic use by physicians because of the lack of effectiveness for treating certain conditions (e.g., upper respiratory tract infection caused by a virus) and the threat of antibiotic resistance [5–9]. Nevertheless, unnecessary prescribing of antibiotics in the community remains common [18, 19, 36–38]. In qualitative studies of antibiotic prescribing practices, physicians reported difficulty with communicating information on antibiotic effectiveness and resistance and expressed concerns about the time required for such explanations [39, 40]. Physicians often perceived antibiotic resistance as a societal problem, identified the interests of their individual patients as being more important, and prescribed antibiotics to patients who they believed expected to receive antibiotics [32, 33, 39–41]. National data quantifying the risks of clinically relevant antibiotic-associated adverse events (i.e., those resulting in ED visits) can support a simpler argument for using antibiotics judiciously and one that directly addresses the individual patient and the physician's primary responsibility, primum non nocere, first do no harm.

National antibiotic-associated adverse event data can also be used by campaigns targeted at changing patient expectations of antibiotic therapy. In studies that assessed patients' perceptions of the harmful consequences of antibiotic use, the association between antibiotics and adverse effects (e.g., rash) was almost always mentioned, but the association between antibiotics and resistance was rarely mentioned [39]. Similar research has demonstrated that patients frequently do not understand that antibiotics are ineffective against viral infections [42]. Thus, communicating the risk of serious antibiotic-associated adverse events to patients can add to their existing perceptions of risks of antibiotic therapy and may reduce the amount of requests for antibiotic therapy more than by trying to convey information on antibiotic effectiveness or resistance alone [32, 33, 39, 40]. Because one-quarter of all estimated ED visits for antibiotic-associated adverse events (~37,000 visits) were by children aged <15 years and the highest rate of ED visits was among infants, this message could be targeted at parents of pediatric patients, in particular.

Antibiotic use guidelines are beginning to recognize that the risk of adverse effects in individual patients can outweigh the benefits of antibiotics for certain prophylactic indications. Recently, infective endocarditis prophylaxis guidelines were revised, at least in part, on the basis of the assessment that the risk of antibiotic-associated adverse events exceeds the benefits of prophylactic use for many patients [43, 44]. Future antibiotic use guidelines should incorporate the best available evidence on risk of antibiotic-associated adverse events in individual patients in ways that can be integrated in clinical practice [32, 35, 40].

This investigation focused on drug-related adverse events diagnosed in EDs, and thus, the numbers and rates do not reflect all antibiotic-associated adverse events. Although our data describe clinically relevant drug-related adverse events that warranted medical attention and contributed to health care resource use, we could not account for unreported events and events identified in other health care settings, such as physicians' offices. Because case identification in the NEISS-CADES project relies on the presence of a physician-diagnosed drug-related adverse event in the ED, rare and less well-recognized events and events with subacute onset are less likely to be captured. We limited our analysis of drug-related adverse event conditions and outcomes (table 3) to cases in which only drugs from a single antibiotic class were implicated in the adverse event, to describe only the events that were attributed to antibiotics and not to other types of drugs. In doing so, we may have neglected to describe certain adverse events, such as those resulting from drug-drug interactions (e.g., hemorrhage in a patient receiving warfarin and a fluoroquinolone) [45]. Physicians may also be more likely to recognize certain adverse event conditions associated with a particular antibiotic class than those associated with other classes (e.g., they are more likely to identify allergic reactions associated with β-lactam antibiotics than allergic reactions associated with fluoroquinolones), thus influencing the spectrum of adverse events described in association with each antibiotic class. Similar to most previous studies on antibiotic prescribing [17–20], we used NAMCS and NHAMCS for estimates of the frequency of out-

Downloaded from http://cid.oxfordjournals.org/ at Planned Parenthood Federation of America on December 30, 2014

patient antibiotic prescribing. Our estimates of the frequency of outpatient antibiotic prescribing are similar to those previously reported using NAMCS and NHAMCS [1, 20]. However, different prescription databases may have yielded different estimates of the frequency of outpatient antibiotic prescribing [46], and the frequency of outpatient antibiotic prescribing, when based on NAMCS and NHAMCS, is likely to be underestimated, because these databases exclude telephone and e-mail contacts, antibiotics prescribed in nursing homes or ambulatory surgery centers, and antibiotic courses initiated during hospitalization or provided at hospital discharge.

Antibiotic-associated adverse events lead to many ED visits, and allergic reactions are the most common events. Communicating the risks of antibiotic-associated adverse events can become an important strategy in efforts to promote judicious antibiotic use. Avoiding unnecessary antibiotic use reduces not only the public health threat of antibiotic resistance but also the risk of drug-related adverse events in individual patients.

Acknowledgments

We thank Victor Johnson and Benjamin Kupronis, for programming assistance; Kelly Weidenbach, Cathy Irish, and Joel Friedman, for assistance with data collection; and Linda McCaig and Cindy Friedman, for review of the manuscript.

Financial support. This work was implemented using Centers for Disease Control and Prevention (CDC) funding and was supported in part by an appointment (to N.S.) to the CDC Research Participation Program administered by the Oak Ridge Institute for Science and Education through an interagency agreement between the US Department of Energy and the CDC. None of the funding sources had a role in the in study design; in the collection, analysis, and interpretation of data; in the writing of the report; or in the decision to submit the article for publication.

Potential conflicts of interest. All authors: no conflicts.

References

1. Raofi S, Schappert SM. Medication therapy in ambulatory medical care: United States, 2003–04. Vital Health Stat 13 **2006**; 163:1–40.
2. Ma J, Stafford RS, Cockburn IM, Finkelstein SN. A statistical analysis of the magnitude and composition of drug promotion in the United States in 1998. Clin Ther **2003**; 25:1503–17.
3. Wise R, Hart T, Cars O, et al. Antimicrobial resistance is a major threat to public health. BMJ **1998**; 317:609–10.
4. Harrison PF, Lederberg J, eds. Antimicrobial resistance: issues and options. Washington, DC: National Academy Press, **1998**.
5. Schwartz B, Bell DM, Hughes JM. Preventing the emergence of antimicrobial resistance: a call for action by clinicians, public health officials, and patients. JAMA **1997**; 278:944–5.
6. Low DE, Scheld WM. Strategies for stemming the tide of antimicrobial resistance. JAMA **1998**; 279:394–5.
7. Gould IM. A review of the role of antibiotic policies in the control of antibiotic resistance. J Antimicrob Chemother **1999**; 43:459–65.
8. Alliance for the Prudent Use of Antibiotics. Available at: http://www.tufts.edu/med/apua/. Accessed 11 June 2007.
9. Department of Health and Human Services, Centers for Disease Control and Prevention. Get smart: know when antibiotics work. Available at: http://www.cdc.gov/drugresistance/community/. Accessed 11 June 2007.
10. US Consumer Product Safety Commission. National Electronic Injury Surveillance System all injury program sample design and implementation. Washington, DC: US Consumer Product Safety Commission, **2002**.
11. Jhung MA, Budnitz DS, Mendelsohn AB, et al. Evaluation and overview of the National Electronic Injury Surveillance System–Cooperative Adverse Drug Event Surveillance project (NEISS-CADES). Med Care **2007**; 45(Suppl 2):S96-102.
12. Budnitz DS, Pollock DA, Weidenbach KN, Mendelsohn AB, Schroeder TJ, Annest JL. National surveillance of emergency department visits for outpatient adverse drug events. JAMA **2006**; 296:1858–66.
13. National Center for Health Statistics. National Ambulatory Medical Care Survey: public use data file documentation: 2004. Hyattsville, MD: National Center for Health Statistics, **2006**.
14. National Center for Health Statistics. National Hospital Ambulatory Medical Care Survey: public use data file documentation: 2004. Hyattsville, MD: National Center for Health Statistics, **2006**.
15. National Center for Health Statistics. National Ambulatory Medical Care Survey: public use data file documentation: 2005. Hyattsville, MD: National Center for Health Statistics, **2006**.
16. National Center for Health Statistics. National Hospital Ambulatory Medical Care Survey: public use data file documentation: 2005. Hyattsville, MD: National Center for Health Statistics, **2006**.
17. Nyquist AC, Gonzales R, Steiner JF, Sande MA. Antibiotic prescribing for children with colds, upper respiratory tract infections, and bronchitis. JAMA **1998**; 279:875–7.
18. Gonzales R, Malone DC, Maselli JH, Sande MA. Excessive antibiotic use for acute respiratory infections in the United States. Clin Infect Dis **2001**; 33:757–62.
19. Linder JA, Bates DW, Lee GM, Finkelstein JA. Antibiotic treatment of children with sore throat. JAMA **2005**; 294:2315–22.
20. Roumie CL, Halasa NB, Grijalva CG, et al. Trends in antibiotic prescribing for adults in the United States—1995 to 2002. J Gen Intern Med **2005**; 20:697–702.
21. National Center for Health Statistics, Centers for Disease Control and Prevention. NAMCS estimation procedures. Available at: http://www.cdc.gov/nchs/about/major/ahcd/namcs_est_proc.htm. Accessed 30 May 2007.
22. National Center for Health Statistics, Centers for Disease Control and Prevention. NHAMCS estimation procedures. Available at: http://www.cdc.gov/nchs/about/major/ahcd/nhamcs_est_proc.htm. Accessed 30 May 2007.
23. Kish L. Survey sampling. New York, NY: Wiley Inter-Science, **1995**: 206–9.
24. Budnitz DS, Shehab N, Kegler SR, Richards CL. Emergency department visits for adverse drug events in older adults: the contribution of potentially inappropriate medication use. Ann Intern Med **2007**; 147: 755–65.
25. Zhan C, Arispe I, Kelley E, et al. Ambulatory care visits for treating adverse drug effects in the United States, 1995–2001. Jt Comm J Qual Patient Saf **2005**; 31:372–8.
26. Prescott WA Jr, DePestel DD, Ellis JJ, Regal RE. Incidence of carbapenem-associated allergic-type reactions among patients with versus patients without a reported penicillin allergy. Clin Infect Dis **2004**; 38: 1102–7.
27. Gholami K, Parsa S, Shalviri G, Sharifzadeh M, Assasi N. Anti-infectives–induced adverse drug reactions in hospitalized patients. Pharmacoepidemiol Drug Saf **2005**; 14:501–6.
28. Sachs B, Riegel S, Seebeck J, et al. Fluoroquinolone-associated anaphylaxis in spontaneous adverse drug reaction reports in Germany: differences in reporting rates between individual fluoroquinolones and occurrence after first-ever use. Drug Saf **2006**; 29:1087–100.
29. Lawrence KR, Adra M, Gillman PK. Serotonin toxicity associated with the use of linezolid: a review of postmarketing data. Clin Infect Dis **2006**; 42:1578–83.
30. Park-Wyllie LY, Juurlink DN, Kopp A, et al. Outpatient gatifloxacin therapy and dysglycemia in older adults. N Engl J Med **2006**; 354: 1352–61.
31. Gill JM, Fleischut P, Haas S, Pellini B, Crawford A, Nash DB. Use of

Downloaded from http://cid.oxfordjournals.org/ at Planned Parenthood Federation of America on December 30, 2014

antibiotics for adult respiratory infections in outpatient settings: a national ambulatory network study. Fam Med **2006**; 38:349–54.
32. Metlay JP, Shea JA, Crossette LB, Asch DA. Tensions in antibiotic prescribing: pitting social concerns against the interests of individual patients. J Gen Intern Med **2002**; 17:87–94.
33. Wood F, Simpson S, Butler CC. Socially responsible antibiotic choices in primary care: a qualitative study of GPs' decisions to prescribe broad-spectrum and fluoroquinolone antibiotics. Fam Pract **2007**; 24:427–34.
34. Leone R, Venegoni M, Motola D, et al. Adverse drug reactions related to the use of fluoroquinolone antimicrobials: an analysis of spontaneous reports and fluoroquinolone consumption data from three Italian regions. Drug Saf **2003**; 26:109–20.
35. Powers JH. Increasing the efficiency of clinical trials of antimicrobials: the scientific basis of substantial evidence of effectiveness of drugs. Clin Infect Dis **2007**; 45:S153–62.
36. Hirschmann JV. Antibiotics for common respiratory tract infections in adults. Arch Intern Med **2002**; 162:256–64.
37. Gilberg K, Laouri M, Wade S, Isonaka S. Analysis of medication use patterns: apparent overuse of antibiotics and underuse of prescriptions drugs for asthma, depression, and CHF. J Manag Care Pharm **2003**; 9:232–7.
38. Hickner J. A new look at an old problem: inappropriate antibiotics for acute respiratory tract infections. Ann Fam Med **2006**; 4:484–5.
39. Butler CC, Rollnick S, Pill R, Maggs-Rapport F, Stott N. Understanding the culture of prescribing: qualitative study of general practitioners' and patients' perceptions of antibiotics for sore throats. BMJ **1998**; 317:637–42.
40. Kumar S, Little P, Britten N. Why do general practitioners prescribe antibiotics for sore throat? Grounded theory interview study. BMJ **2003**; 326:138.
41. Linder JA, Singer DE. Desire for antibiotics and antibiotic prescribing for adults with upper respiratory tract infections. J Gen Intern Med **2003**; 18:795–801.
42. Wilson AA, Crane LA, Barrett PH Jr, Gonzales R. Public belief and use of antibiotics for acute respiratory illness. J Gen Intern Med **1999**; 14:658–62.
43. Wilson W, Taubert KA, Gewitz M, et al. Prevention of infective endocarditis: guidelines from the American Heart Association: a guideline from the American Heart Association Rheumatic Fever, Endocarditis, and Kawasaki Disease Committee, Council on Cardiovascular Disease in the Young, and the Council on Clinical Cardiology, Council on Cardiovascular Surgery and Anesthesia, and the Quality of Care and Outcomes Research Interdisciplinary Working Group. J Am Dent Assoc **2008**; 139(Suppl):3S-24S (erratum: J Am Dent Assoc 2008;139:253).
44. Gould FK, Elliott TSJ, Foweraker J, et al. Guidelines for the prevention of endocarditis: report of the Working Party of the British Society of Antimicrobial Chemotherapy. J Antimicrob Chemother **2006**; 57: 1035–42.
45. Glasheen JJ, Fugit RV, Prochazka AV. The risk of overanticoagulation with antibiotic use in outpatients on stable warfarin regimes. J Gen Intern Med **2005**; 20:653–6.
46. Lin SJ, Lambert B, Tan H, Toh S. Frequency estimates from prescription drug datasets. Pharmacoepidemiol Drug Saf **2006**; 15:512–20.

Downloaded from http://cid.oxfordjournals.org/ at Planned Parenthood Federation of America on December 30, 2014

AA

REPORT 7 OF THE COUNCIL ON MEDICAL SERVICE (A-14)
Coverage of and Payment for Telemedicine
(Reference Committee A)

EXECUTIVE SUMMARY

Telemedicine, a key innovation in support of health care delivery reform, is being used in initiatives to improve access to care, care coordination and quality, as well as reduce the rate of growth in health care spending. The evolution of telemedicine impacts all three strategic focus areas of the American Medical Association (AMA): improving health outcomes, accelerating change in medical education, and enhancing physician satisfaction and practice sustainability by shaping delivery and payment models.

The definition of telemedicine, as well as telehealth, has continued to evolve, and there is no consensus on the definition of either of the two terms. Today, there are three broad categories of telemedicine technologies: store-and-forward, remote monitoring, and (real-time) interactive services. The coverage of and payment for telemedicine services vary widely. While public and private payers have continued to develop formal mechanisms to pay for telemedicine services, inconsistencies remain that create barriers to the further adoption of telemedicine.

The standards of care and practice guidelines relevant to telemedicine are evolving and vary based on specialty and service provided. A number of national medical specialty societies have developed clinical guidelines and position statements addressing telemedicine while others have initiated steps to do so. Besides the specialty societies, the American Telemedicine Association (ATA)—an organization comprised of a cross-section of stakeholders including, for example, insurers, telecommunication providers, vendors, and individual physicians and other providers—has spear-headed a guideline development process for telemedicine with varying levels of engagement of medical specialty societies.

With a growing number of services being provided via telemedicine technologies, there is a need for a set of safeguards and standards in AMA policy to support the appropriate coverage of and payment for telemedicine services. In this report, the Council recommends a set of principles to ensure the appropriate coverage of and payment for telemedicine services. These principles aim to support future innovation in the use of telemedicine, while ensuring patient safety, quality of care and the privacy of patient information, as well as protecting the patient-physician relationship and promoting improved care coordination and communication with medical homes. Before physicians provide any telemedicine service, they should verify that their medical liability insurance policy covers telemedicine services, including telemedicine services provided across state lines if applicable.

Because the coverage of and payment for telemedicine services is related to the evidence in support of telemedicine, the report also includes recommendations supporting additional research, pilot programs and demonstration projects regarding telemedicine. In order to ensure quality of care, patient safety, and coordination of care in the provision of telemedicine services, the report's recommendations reiterate the importance of national medical specialty societies continuing to be involved in the development of appropriate and comprehensive practice parameters, standards and guidelines to address the clinical and technological aspects of telemedicine.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 7-A-14

Subject: Coverage of and Payment for Telemedicine

Presented by: Charles F. Willson, MD, Chair

Referred to: Reference Committee A
(Gary L. Bryant, MD, Chair)

Telemedicine, a key innovation in support of health care delivery reform, is being used in initiatives to improve access to care, care coordination and quality, as well as reduce the rate of growth in health care spending. The evolution of telemedicine impacts all three strategic focus areas of the American Medical Association (AMA): improving health outcomes, accelerating change in medical education, and enhancing physician satisfaction and practice sustainability by shaping delivery and payment models. This Council-initiated report provides background on the delivery of telemedicine; outlines coverage and payment rules of public and private payers addressing telemedicine; summarizes specialty society practice guidelines and position statements on telemedicine; highlights case studies on telemedicine; summarizes relevant AMA policy and presents policy recommendations.

BACKGROUND

In 1996, the Institute of Medicine (IOM) released its report "Telemedicine: A Guide to Assessing Telecommunications for Health Care," which defined telemedicine as "the use of electronic information and communications technologies to provide and support health care when distance separates participants." The IOM report on telemedicine also stated that:

> … telemedicine is not a single technology or a discrete set of related technologies; it is, rather, a large and very heterogeneous collection of clinical practices, technologies, and organizational arrangements. In addition, widespread adoption of effective telemedicine applications depends on a complex, broadly distributed technical and human infrastructure that is only partly in place and is being profoundly affected by rapid changes in health care, information, and communications systems.[1]

Since the release of the IOM report, the definition of telemedicine, as well as telehealth, has continued to evolve, and there is no consensus on the definition of either of the two terms. Today, there are three broad categories of telemedicine technologies: store-and-forward, remote monitoring, and (real-time) interactive services.

Store-and-forward telemedicine involves the transmittal of medical data (such as medical images and bio signals) to a physician or medical specialist for assessment. It does not require the presence of both parties at the same time and has thus become popular with specialties such as dermatology, radiology and pathology, which can be conducive to asynchronous telemedicine.

© 2014 American Medical Association. All rights reserved.

Remote monitoring, or self-monitoring or testing, enables medical professionals to monitor a patient remotely using various technological devices. This method is typically used to manage chronic diseases or specific conditions (e.g., heart disease, diabetes mellitus, or asthma), as devices that can be used by patients at home to capture such health indicators as blood pressure, glucose levels, ECG and weight.

Interactive telemedicine services provide real-time, face-to-face interaction between patient and provider (e.g., online "portal" communications). Telemedicine, where the patient and provider are connected through real-time audio and video technology (generally a requirement for payment) has been used as an alternative to the traditional method of care delivery, and in certain circumstances can be used to deliver such care as the diagnosis, consultation, treatment, education, care management and self-management of patients.

COVERAGE OF AND PAYMENT FOR TELEMEDICINE

The coverage of and payment for telemedicine services vary widely. The passage of the Balanced Budget Act of 1997 and the Telemedicine Communications Act of 1996 enabled payment for professional telemedicine consultation in 1999. While public and private payers have continued to develop formal mechanisms to pay for telemedicine services, inconsistencies remain that create barriers to the further adoption of telemedicine.

Medicare

Each year, Medicare pays approximately $6 million for telemedicine services. In 2009, there were approximately 40,000 telemedicine visits, involving some 14,000 Medicare beneficiaries. That same year, 369 practitioners, including physicians, provided 10 or more telemedicine services to Medicare beneficiaries, most of which were mental health services. Psychiatrists, psychologists and clinical social workers comprised 49 percent of the practitioners who provided 10 or more telemedicine services in Medicare. While physician assistants, nurse practitioners and clinical nurse specialists accounted for 19 percent of such practitioners, family medicine and internal medicine physicians accounted for seven percent.[2]

Medicare provides payment to physicians and other health professionals for a relatively narrow list of Part B services that are provided via telemedicine. Eligible services include: initial and follow-up inpatient consultations; office or other outpatient visits; psychiatric diagnostic interview examinations; end-stage renal disease related services; neurobehavioral status exams; screenings for sexually transmitted infections (STIs) and high intensity behavioral counseling to prevent STIs; and intensive behavioral therapy for cardiovascular disease. In its final 2014 Physician Fee Schedule (PFS) rule, the Centers for Medicare & Medicaid Services (CMS) expanded telemedicine service codes that will be paid by Medicare to include transitional care management services (CPT codes 99495 and 99496). There is also an opportunity to request that services be added to the list of telemedicine services covered by Medicare, outlined at www.cms.gov/telehealth.

The originating sites where Medicare beneficiaries receiving services via telemedicine are located are limited to qualified centers in areas defined as rural Health Professional Shortage Areas (HPSAs), counties outside metropolitan statistical areas, and areas approved by the government for demonstration of telemedicine. Of note, in its Medicare 2014 PFS final rule, CMS expanded geographic locations where telemedicine services may be covered by Medicare by changing its definition of rural HPSAs to those located in rural census tracts as determined by the Office of Rural Health Policy.

The telemedicine services covered by Medicare are required to have both interactive audio and video with real-time communication. Coverage of store-and-forward telemedicine services is currently only allowed in Hawaii and Alaska as part of a demonstration program. Additional requirements for in-person visits exist for certain illnesses. Payment modifiers are used to code telemedicine services, and physicians are paid under the PFS. Physicians and other practitioners who provide a service via telemedicine must be paid an amount equal to the amount that the practitioner would have been paid if the service had been provided without the use of telemedicine. If a prescriber has reassigned billing rights to a Critical Access Hospital, payment is 80 percent of the Medicare PFS for telemedicine services.

Medicare Advantage plans are exempt from these limitations placed on telemedicine services provided to Medicare fee-for-service beneficiaries. The Council notes that there is increasing momentum in Congress to also exempt physicians and other health practitioners who participate in alternative payment models from the aforementioned telemedicine limitations that otherwise exist in Medicare.

Other Payers

Forty-six states and the District of Columbia (DC) offer some form of Medicaid payment for telemedicine services. While the Medicaid programs in all of these states and DC pay for some services administered via real-time audio and video technologies, the Medicaid programs in only nine states at some level pay for store-and-forward, and 14 states pay for remote patient monitoring.[3] In addition, 19 states and DC have adopted laws mandating that private payers cover what the states deem as telemedicine services (definitions vary by state).[4] State coverage of and payment for telemedicine services are related to state laws addressing what services providers can and cannot deliver remotely and what requirements need to be met in order to do so. The Council notes that there is little consistency among states in how telemedicine is defined and regulated.

Some of the leading private health insurers provide coverage and payment for telemedicine, with varying approaches to doing so. Some private insurers, including WellPoint, Aetna and Highmark have partnered with telemedicine companies that offer health consultations with very different technology models and standard operating procedures for interactions between patients and the health care providers. Examples of the significant variability in technology platforms and measures to facilitate care coordination include on one end of the spectrum, collaborations which offer two-way interactive video platforms and the ability to interact with a physician, and on the other end, partnerships with companies that primarily offer telephone communications between a patient and a health care provider.

SPECIALTY SOCIETY PRACTICE GUIDELINES AND POSITION STATEMENTS

The standards of care and practice guidelines relevant to telemedicine are evolving and vary based on specialty and service provided. The AMA has surveyed both national medical specialty societies and state medical associations concerning practice guidelines as well as policies broadly governing telemedicine. A number of specialty societies have developed clinical guidelines and position statements addressing telemedicine while others have initiated steps to do so. Examples of clinical guideline development include the American Academy of Child and Adolescent Psychiatry's practice parameter for telepsychiatry with children and adolescents, the Society of American Gastrointestinal and Endoscopic Surgeons' guidelines for the surgical practice of telemedicine, and the American College of Radiology/Society for Imaging Informatics in Medicine's practice guidelines for electronic medical information privacy and security.

Besides medical specialty societies, the American Telemedicine Association (ATA)—an organization comprised of a cross-section of stakeholders including, for example, insurers, telecommunication providers, vendors, and individual physicians and other providers—has spear-headed a guideline development process for telemedicine with varying levels of engagement of medical specialty societies. For example, the American Academy of Dermatology (AAD) provided input on the use of the Practice Guidelines for Teledermatology, developed by the ATA. The ATA also released practice guidelines for video-based online mental health services, which were developed with input from the American Psychiatric Association (APA). It is anticipated that national medical specialty societies will take a greater role in the development and approval of telemedicine clinical practice guidelines.

Along with many other specialty societies, including the American College of Physicians, the American Academy of Family Physicians, the American Osteopathic Association, and AAD, APA also has a position statement on the ethical use of telemedicine. The American College of Radiology also issued a white paper on teleradiology practice, and the Telemedicine Work Group of the American Academy of Neurology issued a report on teleneurology applications.

CASE STUDIES OF TELEMEDICINE

As outlined in the highlighted case studies below, there is a range of medical services being delivered via telemedicine by physicians and other health professionals. Telemedicine services are provided by hospitals, specialty departments, home health agencies and private physician offices. While some telemedicine programs are multispecialty in nature, others are tailored to specific diseases and medical specialties.

University of Virginia (UVA) Center for Telehealth

The UVA Center for Telehealth works across the UVA Telemedicine Partner Networks, which includes 118 sites to offer telemedicine services in more than 40 specialties and sub-specialties. Services provided include single consultations and follow-up visits, emergency consultations, and screenings using store-and-forward technologies, such as mobile digital mammography and retinopathy. Depending on the specialty, the patient may need to have an initial in-person visit with the specialist at UVA and then continue with follow-up appointments via telemedicine. The Center has provided more than 33,000 patient encounters in Virginia, and provides more than 30,000 teleradiology services per year.[5] The Center accepts referrals from other physicians, as well as direct appointments from patients. After the appointment with a physician of the UVA Center for Telehealth, to ensure continuity of care, the referring physician, if any, and/or the patient's primary care physician, is provided a report with follow-up information.

Arkansas ANGELS

The Antenatal & Neonatal Guidelines, Education & Learning System (ANGELS) of the University of Arkansas for Medical Services (UAMS) provides patients with around-the-clock and telemedical support to address high-risk obstetrical care needs. With approximately thirty telemedicine sites, ANGELS delivers subspecialty care services to high-risk mothers and their infants. Notably, UAMS houses many of state's only board-certified maternal-fetal medicine specialists and genetic counselors. ANGELS uses a variety of telemedicine technologies to deliver care, including specialized ultrasound equipment that digitally transfers a sonogram image to UAMS, as well as special devices to perform colposcopies via telemedicine to allow for remote cervical examination and biopsy. In 2012, there were 5,221 telemedicine visits as part of ANGELS, as well as 2,062

telemedicine obstetric ultrasound visits and 130 fetal echocardiogram visits. Also in 2012, 1,629 colposcopy exams were provided, which identified 303 women with high-grade lesions requiring treatment and five diagnosed with cancer.[6]

AccessDerm

AccessDerm is a teledermatology program sponsored by the AAD that provides primary care practitioners working in participating clinics caring for underserved patients with free access to dermatologic consultations of AAD members. The primary care practitioner and participating AAD-member dermatologist use either personal mobile devices or the Internet to transmit the information required for the consultation. AccessDerm consultations comply with HIPAA requirements for the privacy and security of patient information. As of the drafting of this report, 16 states have clinics registered to participate in the program. As of February 18, 2014, AccessDerm has provided more than 960 consultations to underserved patients, which have included diagnoses of a previously undiagnosed melanoma and a Kaposi's sarcoma.[7]

AMA POLICY

Payment

AMA policy states that physicians should uniformly be compensated for their professional services at a fair fee for established patients with whom the physician has had previous face-to-face professional contact, whether the current consultation service is rendered by telephone, fax, electronic mail or other forms of communication (Policy H-390.859). Policy H-390.859 also calls for CMS and other payers to separately recognize and adequately pay for non-face-to-face electronic visits. Likewise, Policy H-480.961 states that CMS should reimburse telemedicine services in a fashion similar to traditional payments for all other forms of consultation, which involves paying the various providers for their individual claims, and not by various "fee splitting" or "fee sharing" payment schemes. Policy H-480.974 states that the AMA will work with CMS and other payers to develop and test appropriate payment mechanisms for telemedicine through demonstration projects aimed at evaluating the effect of care delivered by physicians using telemedicine-related technology on costs, quality, and the patient-physician relationship. Policy H-385.919 supports pilot projects of innovative payment models being structured to include incentive payments for the use of electronic communications such as Web portals, remote patient monitoring, real-time virtual office visits, and email and telephone communications.

Clinical standards

Policies H-480.974, H-480.968 and H-480.969 encourage national specialties to develop appropriate and comprehensive practice parameters, standards and guidelines to address the clinical and technological aspects of telemedicine. Policy H-480.968 urges national private accreditation organizations to require that medical care organizations that establish ongoing arrangements for medical care delivery from remote sites require practitioners at those sites to meet no less stringent credentialing standards and participate in quality review procedures that are at least equivalent to those at the site of care delivery.

Licensure

Policy H-480.969 states that medical boards of states and territories should require a full and unrestricted license in that state for the practice of telemedicine, and outlines principles for any telemedicine license category. Policy D-480.999 opposes a single national federalized system of medical licensure. Policy H-160.937 outlines principles for the supervision of non-physician providers and technicians when telemedicine is used.

Ethical guidance

Opinion E-5.025, issued in 1994, prohibits physicians from providing any clinical services via telecommunications. As stated in Board of Trustees Report 22-A-13, this opinion may no longer be consistent with best ethical analysis or strong practice in the rapidly evolving area of telemedicine. As such, Policy D-480.974 states that the Council on Ethical and Judicial Affairs (CEJA) will review Opinions relating to telemedicine and update the Code of Medical Ethics as appropriate. A CEJA report examining ethical guidance in this area is in development.

DISCUSSION

As telemedicine continues to evolve, with a growing number of services being provided via telemedicine technologies, the Council firmly believes that there is a need for a set of safeguards and standards in AMA policy to support the appropriate coverage of and payment for telemedicine services. Such standards and safeguards need to support future innovation in the use of telemedicine, while ensuring patient safety, quality of care and the privacy of patient information, as well as protecting the patient-physician relationship and promoting improved care coordination and communication with medical homes.

Prior to delivering services via telemedicine, the Council believes a valid patient-physician relationship must be established, through at minimum a face-to-face examination, if a face-to-face encounter would otherwise be required in the provision of the same service not delivered via telemedicine. The face-to-face encounter could occur in person or virtually through real-time audio and video technology. Also, before a telemedicine service is provided, the physician or other health professional must notify the patient of cost-sharing responsibilities and limitations in drugs that can be prescribed via telemedicine. When a service is delivered using telemedicine, mechanisms to ensure continuity of care, follow-up care and referrals for emergency services must be in place.

The Council believes that key tenets in the delivery of in-person services hold true for the delivery of telemedicine services. Notably, physicians and other health practitioners delivering telemedicine services must abide by state licensure laws and requirements as well as state medical practice laws including, for example, laws concerning consent involving minors, prescribing, reproductive rights, end-of-life, and scope. In addition, prior to the delivery of any telemedicine service, physicians need to verify that their medical liability insurance policy covers telemedicine services, including telemedicine services provided across state lines if applicable. It is essential that patients have access to the licensure and board certification qualifications of the health care practitioners who are providing the care in advance of their visit.

The scope of the coverage of and payment for telemedicine services is directly correlated to the strength of the evidence base in support of telemedicine. While there is an emerging body of evidence suggesting that delivering services via telemedicine could contribute to improving patient

health outcomes, additional evidence needs to be compiled to ensure quality of care and patient safety. In addition to investing in research focused on the delivery of care via telemedicine, additional pilot programs and demonstration projects should be supported.

To ensure quality of care, patient safety, and coordination of care in the provision of telemedicine services, the Council believes it is essential for national medical specialty societies to continue to develop appropriate and comprehensive practice parameters, standards and guidelines to address the clinical and technological aspects of telemedicine, as called for in Policies H-480.974, H-480.968 and H-480.969. In addition, the Council notes that it is essential that specialty societies leverage, to the extent practicable, the work of national telemedicine organizations, including the ATA, in the area of technical standards and take the lead in the development of clinical practice guidelines for telemedicine.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted and the remainder of the report be filed:

1. That American Medical Association (AMA) policy be that telemedicine services should be covered and paid for if they abide by the following principles:

    a) A valid patient-physician relationship must be established before the provision of telemedicine services, through:
        - A face-to-face examination, if a face-to-face encounter would otherwise be required in the provision of the same service not delivered via telemedicine;
        - A consultation with another physician who has an ongoing patient-physician relationship with the patient. The physician who has established a valid physician-patient relationship must agree to supervise the patient's care; or
        - Meeting standards of establishing a patient-physician relationship included as part of evidence-based clinical practice guidelines on telemedicine developed by major medical specialty societies, such as those of radiology and pathology.

        Exceptions to the foregoing include on-call, cross coverage situations; emergency medical treatment; and other exceptions that become recognized as meeting or improving the standard of care. If a medical home does not exist, telemedicine providers should facilitate the identification of medical homes and treating physicians where in-person services can be delivered in coordination with the telemedicine services.
    b) Physicians and other health practitioners delivering telemedicine services must abide by state licensure laws and state medical practice laws and requirements in the state in which the patient receives services.
    c) Physicians and other health practitioners delivering telemedicine services must be licensed in the state where the patient receives services, or be providing these services as otherwise authorized by that state's medical board.
    d) Patients seeking care delivered via telemedicine must have a choice of provider, as required for all medical services.
    e) The delivery of telemedicine services must be consistent with state scope of practice laws.
    f) Patients receiving telemedicine services must have access to the licensure and board certification qualifications of the health care practitioners who are providing the care in advance of their visit.

g) The standards and scope of telemedicine services should be consistent with related in-person services.

h) The delivery of telemedicine services must follow evidence-based practice guidelines, to the degree they are available, to ensure patient safety, quality of care and positive health outcomes.

i) The telemedicine service must be delivered in a transparent manner, to include but not be limited to, the identification of the patient and physician in advance of the delivery of the service, as well as patient cost-sharing responsibilities and any limitations in drugs that can be prescribed via telemedicine.

j) The patient's medical history must be collected as part of the provision of any telemedicine service.

k) The provision of telemedicine services must be properly documented and should include providing a visit summary to the patient.

l) The provision of telemedicine services must include care coordination with the patient's medical home and/or existing treating physicians, which includes at a minimum identifying the patient's existing medical home and treating physician(s) and providing to the latter a copy of the medical record.

m) Physicians, health professionals and entities that deliver telemedicine services must establish protocols for referrals for emergency services.

2. That AMA policy be that delivery of telemedicine services must abide by laws addressing the privacy and security of patients' medical information. (New HOD Policy)

3. That our AMA encourage additional research to develop a stronger evidence base for telemedicine. (New HOD Policy)

4. That our AMA support additional pilot programs in the Medicare program to enable coverage of telemedicine services, including, but not limited to store-and-forward telemedicine. (New HOD Policy)

5. That our AMA support demonstration projects under the auspices of the Center for Medicare and Medicaid Innovation to address how telemedicine can be integrated into new payment and delivery models. (New HOD Policy)

6. That our AMA encourage physicians to verify that their medical liability insurance policy covers telemedicine services, including telemedicine services provided across state lines if applicable, prior to the delivery of any telemedicine service. (New HOD Policy)

7. That our AMA encourage national medical specialty societies to leverage and potentially collaborate in the work of national telemedicine organizations, such as the American Telemedicine Association, in the area of telemedicine technical standards, to the extent practicable, and to take the lead in the development of telemedicine clinical practice guidelines. (New HOD Policy)

8. That our AMA reaffirm Policies H-480.974, H-480.968 and H-480.969, which encourage national medical specialty societies to develop appropriate and comprehensive practice parameters, standards and guidelines to address the clinical and technological aspects of telemedicine. (Reaffirm HOD Policy)

Fiscal Note: Less than $500

REFERENCES

[1] Institute of Medicine. Telemedicine: A Guide to Assessing Telecommunications for Health Care. 1996. Available at: http://www.nap.edu/catalog.php?record_id=5296.
[2] Institute of Medicine. The Role of Telehealth in an Evolving Health Care Environment: Workshop Summary. 2012. Available at: http://www.iom.edu/Reports/2012/The-Role-of-Telehealth-in-an-Evolving-Health-Care-Environment.aspx.
[3] National Telehealth Policy Resource Center. State Telehealth Laws and Reimbursement Policies: A Comprehensive Scan of the 50 States and the District of Columbia. February 2014. Available at: http://telehealthpolicy.us/sites/telehealthpolicy.us/files/uploader/50%20State%20Scan%20February%202014%20Final.pdf.
[4] National Conference of State Legislatures. State Coverage for Telehealth Services. Available at: http://www.ncsl.org/research/health/state-coverage-for-telehealth-services.aspx.
[5] Rheuban, K. Telehealth in an Evolving Healthcare Environment. Presentation to AMA Councils. November 15, 2013.
[6] University of Arkansas for Medical Services ANGELS. 2012 Annual Report. Available at: http://angels.uams.edu/files/2010/12/Angels-Annual-report-2012.pdf.
[7] American Academy of Dermatology. AccessDerm Teledermatology Program. Available at http://www.aad.org/members/volunteer-and-mentor-opportunities/accessderm-teledermatology-program.