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Committee on Reproductive Health Services: Assessing the Safety and Quality of Abortion Care

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Charge to the Committee

In 1975, the Institute of Medicine (IOM) issued the report, *Legalized Abortion and the Public Health: Report of a Study*. The report contained a comprehensive analysis of the then available scientific evidence on the impact of abortion on the health of the public. Since 1975, there have been substantial changes in the U.S. healthcare delivery system and in medical science. In addition, practices for abortion care have changed, including the introduction of new techniques and technologies. An updated systematic and independent analysis of today’s available evidence has not been conducted. An ad hoc consensus committee of the Health and Medicine Division (HMD), which as of March 2016 continues the consensus studies and convening activities previously carried out by the IOM, will produce a comprehensive report on the current state of the science related to the provision of safe, high quality abortion services in the United States.
Research Questions

The committee will consider the following eight questions:

1. What types of legal abortion services are available in the United States? What is the evidence regarding which services are appropriate under different clinical circumstances (e.g., based on patient medical conditions such as previous cesarean section, obesity, gestational age)?

2. What is the evidence on the physical and mental health risks of these different abortion interventions?

3. What is the evidence on the safety and quality of medical and surgical abortion care?

4. What is the evidence on the minimum characteristics of clinical facilities necessary to effectively and safely provide the different types of abortion interventions?
5. What is the evidence on what clinical skills are necessary for health care providers to safely perform the various components of abortion care, including pregnancy determination, counseling, and gestational age assessment, medication dispensing, procedure performance, patient monitoring, and follow-up assessment and care?

6. What safeguards are necessary to manage medical emergencies arising from abortion interventions?

7. What is the evidence on the safe provision of pain management for abortion care?

8. What are the research gaps associated with the provision of safe, high quality care from pre-to post-abortion?
ANALYTIC APPROACH
Six Dimensions of Health Care Quality

Crossing the Quality Chasm: A New Health System for the 21st Century

• **Safety**—avoiding injuries to patients from the care that is intended to help them

• **Effectiveness**—providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and overuse respectively).

• **Patient-centeredness**—providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.

• **Timeliness**—reducing waits and sometimes harmful delays for both those who receive and those who give care.

• **Efficiency**—avoiding waste, including waste of equipment, supplies, ideas, and energy.

• **Equity**—providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.

SOURCE: IOM, 2001
Analytic Framework for Assessing the Quality of Abortion Care

Dimensions of Health Care Quality

- SAFE
- EFFECTIVE
- PATIENT-CENTERED
- TIMELY
- EFFICIENT
- EQUITABLE

POPsULATION: Women seeking abortion

FACTORS DETERMINING PROCEDURE OPTIONS:
- Patient Characteristics:
  - Health status
  - Weeks of gestation
  - Personal preferences
- Availability of Procedures:
  - Regulations
  - Available providers and services
  - Health insurance

INTERVENTION: Abortion

Preabortion
- Clinical assessment
- Informed consent
- Patient counseling
- Contraceptive counseling

Abortion Procedure
- Medication
- Aspiration
- Dilatation and evacuation
- Induction

Postabortion
- Follow-up care
- Contraceptive services (referral or provision)

DESired OUTCOME: Successful abortion, which is safe, effective, patient-centered, timely, efficient, and equitable

FACTORS INFLUENCING SAFETY AND QUALITY:

Type of Facility
- Specialty clinic
- Other clinic
- Physician office
- Ambulatory surgery center
- Hospital

Provider Skills and Training
- OB/GYN
- Family medicine physician
- Advanced practice clinician
- Other physicians

Pain Management
- Analgesia
- Minimal sedation
- Moderate sedation
- Deep sedation
- General anesthesia

NEGATIVE OUTCOMES:

Expected Side Effects
- Pain
- Bleeding

Risk of Complications
- Hemorrhage
- Infection
- Retained products of conception
- Cervical laceration
- Uterine perforation
- Uterine rupture
- Respiratory compromise

Putative Risks
- Reproductive health outcomes
- Breast cancer
- Mental health outcomes
- Premature death
Finding and Assessing Evidence

- Searched for peer-reviewed scientific research and clinical practice guidelines on contemporary U.S. abortion practices and health outcomes

- Conducted systematic bibliographic search for evidence from
  - randomized controlled trials,
  - systematic reviews and meta-analyses,
  - retrospective and prospective cohort studies,
  - case control studies,
  - patient and provider surveys, and
  - other types of observational research

- Only included studies that met scientific standards (using comparable study populations, controls for confounding variables, objective documentation of abortion history, other methods to reduce risk of bias)
TRENDS
Since 1980, the abortion rate has dropped from 29.3 to 14.6 per 1,000 in 2014

The total number of abortions is declining—reaching a low of 926,190 in 2014

Decline has been attributed to historic decline in unintended pregnancies, increasing use of contraception, and restrictions affecting access
Vast Majority of Abortions Performed Early in Pregnancy

In 2014:

- 50% by 7 weeks’ gestation
- 90% by 12 weeks’ gestation
- Medication abortions were ~45% of abortions <9 weeks’ gestation and are likely to increase in number and proportion in the future

SOURCE: Adapted from Jones and Jerman, 2017. Characteristics and circumstances of U.S. women who obtain very early and second trimester abortions.
NOTE: n = 8,105.
Characteristics of Women Who Have Abortions

- Disproportionately lower-income (75%)
  - 49% have family incomes below the federal poverty level (FPL)
  - 26% have family incomes between 100 - 200% of the FPL

- Disproportionately women of color (61%)
  - ~25% Black
  - ~25% Hispanic
  - ~5% Asian/Pacific Islander
  - ~5% Multiracial
  - ~3% Other women of color

- Most are:
  - <age 30 (72%)
  - unmarried (86%)

- 17 percent of women travel more than 50 miles to obtain an abortion
CONTEMPORARY U.S. ABORTION CARE
Medication Abortion

- Mifepristone (Mifeprex) is the only medication specifically approved for medication abortions
  - FDA-approved up to 10 weeks (200 mg mifepristone followed by 800 mcg misoprostol 24 to 48 hours later)
  - Mifepristone distribution is restricted to certified prescribers (FDA REMS program)
- Overall, 22% of abortions are medication abortions (in 2013); up to 9 weeks gestation, 45% are medication abortions (in 2014)
- Although mifepristone is taken at clinic, the abortion occurs at home
Aspiration

- Most common method (68% of all abortions in 2013)
- May be performed up to 14-16 weeks
- Minimally invasive, 10-minute procedure
- Common gynecological procedure (e.g. used for miscarriage management)
Dilation and Evacuation (D&E)

- Fewer than 9% of abortions are performed after 13 weeks (in 2013)
  - Most of these later procedures are by D&E

- D&E is used when the aspiration method is not appropriate
  - It is the preferred method for later abortions (fewer complications, and less time, pain, and expense than induction)

- D&E is banned in two states, and there is limited access elsewhere due to limited access to training
Induction Abortion

- Inductions are rarely performed
  - ~2% of abortions performed at 14 weeks gestation or later (in 2013)
  - ~.02% of all abortions
Women with Obesity or History of Caesarean Section

- Obesity is not a risk factor for women who undergo medication or aspiration abortions.

- Research on the association of obesity and complications during a D&E abortion is less certain—particularly for obese women (BMI 40 or greater) after 14 weeks’ gestation.

- A history of prior Caesarean section is not a risk factor for complications for medication, aspiration, or inductions.

- Women with multiple Caesarean deliveries may be at increased risk of complications during D&E abortions.
Pain Management

- Medication abortion
  - NSAIDs are used to reduce the discomfort of pain and cramping. However, women still report high levels of pain.

- Pain management for other abortion methods range from local anesthesia to minimal, moderate, or deep sedation to general anesthesia.
  - Moderate sedation requires nurse or other qualified staff to monitor the patient (in addition to the clinician performing the abortion)
  - Deep sedation/general anesthesia: requires expertise of an anesthesiologist or certified registered nurse anesthetist
CLINICAL SETTINGS
Vast Majority of Abortions Are Performed in Office-Based Settings

- 95% of abortions are provided in office-based settings

- Overall number of nonhospital facilities providing abortions is declining
  - Greatest proportional decline in states with abortion-specific regulations

- 40% of women aged 15-44 reside in a county without an abortion provider

- 25 states have five or fewer abortion clinics; five states have one clinic

SOURCE: Jones and Jerman, 2017. Abortion incidence and service availability in the United States, 2014; Bearak et al., 2017. Disparities and change over time in distance women would need to travel to have an abortion in the USA: A spatial analysis.
Minimum Characteristics of Clinical Facilities

- Most abortions can be safely provided in office-based settings.
  - For medication abortion, no special equipment or emergency arrangements are required
    - The abortion occurs after a woman leaves the clinical facility
  - For aspiration, D&E, and induction abortions, the minimum facility characteristics depend on the level of sedation:
    - Moderate sedation requires emergency resuscitation equipment, emergency transfer plan, equipment to monitor oxygen saturation, heart rate, and blood pressure.
    - Deep sedation has the same requirements and also equipment to provide general anesthesia and monitor ventilation.
Necessary Safeguards to Manage Medical Emergencies

- The facility should have the appropriate equipment, personnel, and emergency transfer plan to address the complications that might occur.

- Providers should be able to provide or arrange patient access or transfer to facilities equipped to provide emergency intervention, if necessary.
  - Clinicians that perform abortions do not require hospital privileges to ensure safe outcomes for the patient.
CLINICAL SKILLS AND TRAINING
Clinical Skills

- Abortion care requires clinical competency in
  - patient preparation and clinical assessment,
  - pain management,
  - identification and management of side effects and serious complications,
  - contraceptive counseling and provision

- Medication abortion can be provided by physicians, nurse practitioners, physician assistants, and certified nurse-midwives

- Aspiration: requires technical aspects of an aspiration procedure
  - Trained physicians, nurse practitioners, physician assistants, and certified nurse-midwives

- D&E: requires surgical expertise and sufficient caseload to maintain surgical skills
  - OB/GYNs, family medicine, and other physicians with appropriate training and experience

- Induction: requires skills needed for managing labor and delivery
  - OB/GYNs, family medicine physicians, and certified nurse-midwives
Availability of Providers

- The safety and quality of abortion services is contingent on the availability of skilled providers
  - Numerous factors influence availability: declining number of abortion-providing facilities, geographic maldistribution of providers, and legal restrictions on training and provision

- Access to clinical education and training in abortion care is highly variable in the U.S.
  - Some residents and trainees must seek out abortion training and experience outside their educational program
  - Training opportunities are particularly limited in the Southern and Midwestern states and rural areas throughout the country
Selected Residencies and Fellowships Offering Abortion Training the U.S.

LONG-TERM HEALTH EFFECTS
Future Childbearing and Pregnancy Outcomes

- Having an abortion does not increase a woman’s risk of
  - secondary infertility,
  - pregnancy-related hypertensive disorders,
  - abnormal placentation (after a D&E abortion), or
  - preterm birth (<37 weeks)

- Although rare, the risk of very preterm birth (<28 weeks’ gestation) in a woman’s first birth has been associated with the number of prior abortions (Klemetti et al., 2012):
  - No abortion: 0.3%
  - 1 prior abortion: 0.4%
  - 2 prior abortions: 0.6%
  - 3 or more prior abortions: 1.1%
Long-Term Physical Health Effects

- Having an abortion does not increase a woman’s risk of breast cancer.
Long-Term Mental Health Effects

- Having an abortion does not increase a woman’s risk of:
  - depression,
  - anxiety, or
  - posttraumatic stress disorder (PTSD)
State Regulations
State Regulations

Abortion is among the most regulated procedures in the U.S.

- Great amount of state variability. Regulations may:
  - prohibit qualified providers from performing abortions,
  - require medically unnecessary services
  - require an in-person counseling visit
  - mandate a waiting period
  - require facilities to meet the structural standards typical of ambulatory surgical centers
  - Specify procedure room size, corridor width, or maximum distance from a hospital
  - limit private and public health insurance
  - restrict facilities receiving state funds from providing abortion services
  - prohibit abortion based on weeks’ gestation
  - require providers to have hospital admitting privileges or an agreement with a local hospital
DOES ABORTION CARE IN THE UNITED STATES MEET THE SIX ATTRIBUTES OF QUALITY HEALTH CARE?
#1 Safety: Avoiding injuries to patients from the care that is intended to help them

Legal abortions in the United States are safe whether by medication, aspiration, D&E, or induction.

- Serious complications are rare.
  - In most studies, complications occurred in <1 percent of abortions; complications are not >5 percent in any rigorous studies.

- Safety is enhanced when the abortion is performed as early in pregnancy as possible.

- Current pain management methods are safe when appropriate precautions are followed.
Legal abortions in the United States are effective.

- Whether women receive the abortion care that best meets their needs depends on where they live because, in many states, abortion regulations:
  - prohibit abortion care in safe and clinically appropriate settings (doctors’ offices and clinics);
  - prohibit qualified clinicians (family medicine physicians, certified nurse-midwives, nurse practitioners, and physician assistants) from performing abortions;
  - require the informed consent process to include inaccurate information on abortion’s long-term physical and mental health effects;
  - require clinically unnecessary services and delays (e.g., preabortion ultrasound, in-person counseling, waiting periods);
  - require clinicians to have hospital privileges
  - overrule women’s and clinician’s medical decisions
#3 Patient-centeredness: Providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.

- Patients’ personal circumstances and individual preferences (including preferred abortion method), needs, and values may be disregarded depending on where they live.

- Women’s decisions are impeded if they are required to receive
  - inaccurate or misleading information on abortion’s potential harms;
  - clinically unnecessary services and delays (e.g., preabortion ultrasound, in-person counseling, waiting periods).
#4 Timeliness: Reducing waits and sometimes harmful delays for both those who receive and those who give care.

- The timeliness of an abortion depends on a variety of local factors such as:
  - the availability of care;
  - affordability;
  - distance from the provider;
  - state requirements for an in-person counseling appointment; and
  - waiting periods

- Waiting periods may delay the abortion beyond the mandatory waiting period because of the logistical challenges of arranging and getting to a second appointment

- Delays put the patient at greater risk of an adverse event
#5 **Efficiency:** Avoiding waste, including waste of equipment, supplies, ideas, and energy.

- Regulations that require medically unnecessary equipment, services, and/or additional patient visits increase cost, and decrease the efficiency of abortion care.
#6 Equity: Providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.

- Lack of insurance coverage, waiting periods, limits on qualified providers, and requirements for multiple appointments are more burdensome for women who reside far from providers and/or have limited resources.
Research Gaps
Research Gaps

- The committee did not identify gaps in research that raise concerns about the safety and quality of abortion care.

- Questions that merit further investigation:
  - How do the FDA restrictions on mifepristone distribution affect the quality of care?
  - Can the pain of medication abortions be managed prophylactically?
  - What is the best approach to managing pain during aspiration procedures, without sedation?
  - Can advanced clinical practitioners (NPs, CNMs, PAs) be trained to perform D&Es safely and effectively?
  - Do lower income women receive the support services they need? What are the best practices for providing social support services?
Questions?
Thank you

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Download the report for free at:
www.nationalacademies.org/ReproductiveHealth