Consensus Guidelines for Facilities Performing Outpatient Procedures

Evidence Over Ideology

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In policy and law, regulation of abortion is frequently treated differently from other health services. The safety of abortion is similar to that of other types of office- and clinic-based procedures, and facility requirements should be based on assuring high-quality, safe performance of all such procedures. False concerns for patient safety are being used as a justification for promoting regulations that specifically target abortion. The Project on Facility Guidelines for the Safe Performance of Primary Care and Gynecology Procedures in Offices and Clinics was undertaken by clinicians, consumers, and representatives from accrediting bodies to review the available evidence and guidelines that inform safe delivery of outpatient care. Our overall objective was to develop evidence-informed consensus guidelines to promote health care quality, safety, and accessibility. Our consensus determined that requiring facilities performing office-based procedures, including abortion, to meet standards beyond those currently in effect for all general medical offices and clinics is unjustified based on an analysis of available evidence. No safety concerns were identified.

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Government has a legitimate role in protecting the public by establishing standards and requirements for health care provider licensure. However, many proposed laws and regulations at both the state and national levels lack scientific evidence to support any safety concerns defining a need or benefit to patients resulting from those requirements.[1] Some of these laws apply broadly to outpatient settings in which surgery, procedures, or certain levels of sedation are offered; others apply specifically to abortion. They target clinics and facilities that provide medication-induced as well as procedural abortion services. Currently, 16 states have requirements for licensing abortion clinics similar to those for ambulatory surgical centers, whereas 19 require specific dimensions for procedure rooms and corridors.[2] Additionally, 21 states require abortion clinic providers to maintain a relationship with a local hospital.[2] Laws of this nature can have a profound effect on access to abortion, as exhibited by the decline in Texas from 46 clinics in 2011 to 28 clinics in 2014 after passage of onerous facility restrictions.[3] By 2014, 90% of U. S. counties, in which 39% of reproductive age women live, had no clinics providing abortion care.[3]

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The Procedures Working Group list is in Appendix 1, available online at http://links.lww.com/AOG/B234.

Each author has confirmed compliance with the journal's requirements for authorship.

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Procedures are a critical part of both primary care and gynecologic care. Offering procedures in office and clinic settings has the potential to significantly improve patient care, access, affordability, and experience. The American College of Obstetricians and Gynecologists defines a procedure as "a short interventional technique that includes the following general categories:[4]

- Nonincisional diagnostic or therapeutic intervention through a natural body cavity or orifice
- Superficial incisional or excisional diagnostic or therapeutic intervention that does not involve repair or significantly alter morphology
- Device placement into a natural cavity
- Subcutaneous implant
- Injections

The American College of Obstetricians and Gynecologists states that the classification of an intervention as a "procedure" should be based on the nature of the intervention itself and not on the location at which the procedure is performed.

The Project on Facility Guidelines for the Safe Performance of Primary Care and Gynecology Procedures in Offices and Clinics (the Project) was undertaken to support evidence-informed policy regarding the provision of procedures in primary care and gynecology offices and clinics. The Project brought together a broad group of clinicians, consumers, and representatives from accrediting bodies to review available evidence and clinical practices. The goal of the Project was to articulate evidence-informed facility guidelines that would further health care quality, safety, affordability, and patient experience without imposing unjustified burdens on patients' access to care or on clinicians' ability to provide care within their scope of practice.

The Project was led by a planning committee made up of representatives from the American College of Obstetricians and Gynecologists, the National Partnership for Women & Families, the American College of Physicians, the American Academy of Family Physicians, the American College of Nurse-Midwives, Nurse Practitioners in Women's Health, and the Society of Family Planning. Participants in the Project included health care professionals, advocates, and experts in care quality, accreditation, and the provision of primary and gynecologic care in office and clinic settings. From September 26, 2016, to July 11, 2018, the planning committee defined the scope of the Project, recruited a working group of experts and stakeholders ("Procedures Working Group"), and gathered and reviewed evidence. The Procedures Working Group then convened to discuss research evidence, provide expert opinion, and consider appropriate guidelines and practices. They engaged in an iterative, virtual drafting process for crafting a consensus document, solicited and considered public comments, and finalized the consensus guidelines (Fig. 1).

The planning committee defined the Project scope to address only facility factors (those relating to physical environment or office and clinic operations); it did not delve into matters of clinical practice or scope of practice. The Procedures Working Group then sought to define guidelines and accepted practices for facilities in which procedures are performed and to articulate new guidelines where appropriate, given the best available evidence. It did not seek to define which procedures may appropriately be performed in offices and clinics. The Procedures Working Group considered only offices and clinics providing procedures within primary care or gynecology; it did not consider facilities providing procedures in other practice areas. Further, it did not seek to articulate guidelines and accepted practices for the provision of sedation and anesthesia; the American

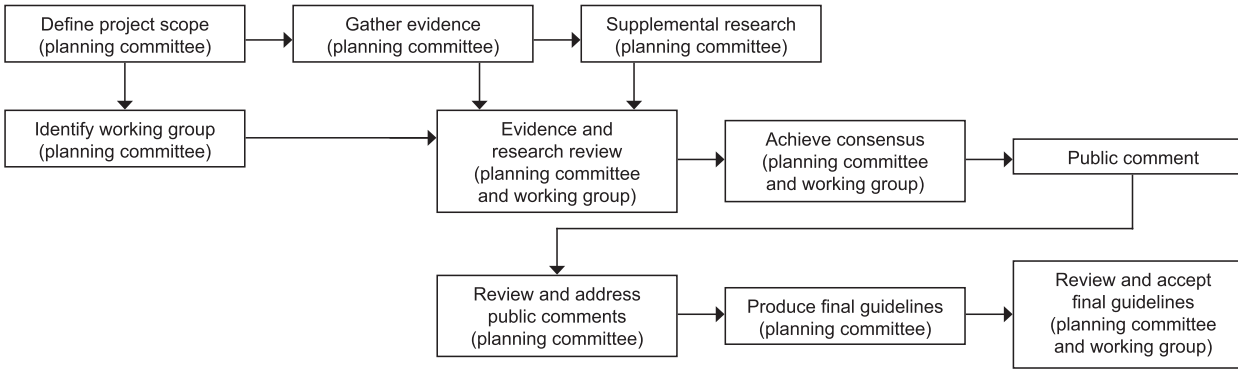

Fig. 1. Project flow.

Levy. Guidelines for Facilities Performing Outpatient Procedures. Obstet Gynecol 2019.

Society of Anesthesiologists has developed widely accepted guidelines in this area. The Procedures Working Group presumed that the applicable portions of those guidelines are followed by clinicians providing sedation and anesthesia in this setting.

The planning committee gathered available evidence regarding the effect of select facility factors on patient safety, care quality, and service availability for review by the Procedures Working Group. The facility factors selected by the planning committee (listed in Box 1) were chosen based on occurrence in existing laws and guidelines governing outpatient surgeries and procedures. The planning committee began the evidence-gathering process by seeking verbal input from a diverse set of experts about relevant evidence to consider. The individuals consulted by the planning committee (see list in Appendix 1, available online at http://links.lww.com/AOG/B234) in this regard included experts in patient safety, health service delivery and access, health care disparities, and health care facility design and construction. Because very little research exists regarding outpatient facility factors, the planning committee cast a wide net in gathering potentially relevant research; thus, some of the research considered comes from outside the area of primary care and gynecology procedures.

A systematic review undertaken by independent researchers served as the foundational research for the Project.[5] This study, which was conducted according to established systematic review standards and published in a peer-reviewed journal, examined the effects of outpatient facility type and specific facility characteristics on patient safety, patient experience, and service availability outcomes in non–hospital-affiliated outpatient settings. The systematic review sought to address two questions: 1) What is the effect of outpatient setting (ambulatory surgery center compared with office) on patient safety, experience, and service availability for outpatient procedures; and 2) What are the effects of particular facility characteristics (facility accreditation, emergency response protocols, clinician qualifications, physical plant specifications, and other policies) on those same outcomes? The authors concluded that existing evidence does not indicate a difference in patient safety for procedures across ambulatory surgery centers and offices. On the second question, the researchers concluded that there was not enough research on any of the facility characteristics to draw conclusions across studies but that there was a suggestion that requiring abortion providers to have hospital admitting privileges may result in decreased service availability for women seeking abortion.

The planning committee supplemented these existing studies with three less formal research inquiries undertaken specifically for the Project.

1. First, the planning committee enlisted a researcher to review the literature for information about how facility laws affect access to health care services in offices and clinics. The researcher found limited published research on the topic, the bulk of which addressed three policy areas (the Mammography Quality Standards Act, the Clinical Laboratory Improvement Amendments, and state-level facility requirements governing the provision of abortion). The limited evidence available suggests that the effect of new facility regulation on patients' access to care depends largely on whether such regulation is attuned to patient and facility needs and includes measures to support facilities as they seek to come into compliance.
2. Second, to gain information about existing facility guidelines for outpatient facilities, researchers conducted a review and appraisal of existing facility guidelines. As few such guidelines exist, the researchers broadly surveyed guidelines for outpatient provision of any surgeries or procedures. The researchers evaluated the quality of guidelines they reviewed using both the Appraisal of Guidelines for Research & Evaluation II tool[6] and the Non-Research Evidence Appraisal Tool from the Association of periOperative Registered Nurses.[7] They then reviewed and summarized the contents of the five guidelines with the highest quality assessment scores.

Box 1. Facility Factor

- Emergency preparedness
  - Facility emergencies
  - Patient emergencies
- Biological material handling
- Physical plant specifications
  - Hall and doorway widths
  - Operating rooms
  - Procedure rooms
  - Separate clean and soiled sterilization rooms
  - Temperature and ventilation
- Clinician qualifications beyond licensing
- Other policies and procedures
  - Infection control
  - Patient satisfaction assessment
  - Peer review of clinicians
  - Preventive maintenance
  - Quality assurance
- Facility accreditation, licensing, or faculty accreditation and licensing

3. Third, to determine whether any relevant public health or patient safety issues related to facility factors had been documented, research was undertaken to examine press releases, published guidance, and opinions from state medical boards and selected health professional organizations. This research found no documentation of any public health or patient safety issues related to facility factors in offices or clinics providing primary care or gynecology procedures.

At an in-person meeting, participants analyzed the available evidence, shared current accepted practices, and discussed whether any evidence of potential harms exists in six areas: emergency preparedness, biological material handling, physical plant specifications, facility accreditation and licensing, clinician qualifications beyond licensing, and other policies and procedures. Researchers examined outpatient accrediting body requirements and state facility laws for office and clinic settings to ensure inclusion. An iterative process then was used to reach consensus among Procedures Working Group members about current accepted practices, areas of possible concern, and the potential need for changes to current accepted practices in each area.

The Project produced consensus guidelines (Box 2) that will further evidence-informed facility practices and policies for primary care and gynecology procedures, including abortion. Feedback on the draft guidelines was solicited from stakeholders and members of the public via a public comment process from April 17, 2018 to May 13, 2018. The draft was posted on an interactive, public website that allowed for submission of comments, proposed edits, and additional evidence. Announcements of the public comment period were sent to health professional and health care organizations according to outreach processes commonly used in the development of clinical guidelines. The feedback provided during the public comment process was thoroughly reviewed and considered by the planning committee. Overall, the comments were supportive and indicated the guidelines were appropriate as written. In some cases, the planning committee made minor revisions or clarifications to the draft guidelines as appropriate and justified by the evidence. The Procedures Working Group reviewed the revised guidelines, gave feedback as necessary, and came to consensus on the content of the final guidelines.

Participants found no evidence of any patient safety or quality-of-care problems related to the examined facility factors in offices or clinics that

Box 2. Facility Guidelines

Facilities' policies, procedures, and supplies should be suited to the nature of the practice and procedures performed. In some facilities, appropriate policies, procedures, and supplies will be minimal. Solo or small practices that perform only occasional, limited procedures should assess which of the guidelines are appropriate to the practice given the procedures performed at the site.

Emergency Preparedness

- Facilities should establish written policies and procedures for managing facility emergencies (eg, natural disaster, fire) and patient emergencies (eg, vasovagal reaction, hemorrhage) and should conduct periodic drills and staff trainings on those policies and procedures. A formal transfer agreement with a hospital is not required because transfers are rare and hospitals are required to accept patients with emergent needs. Good communications in the event of a transfer and working relationships with facilities that may receive or refer patients are encouraged.
- Facilities should have a staff person trained in basic life support onsite when procedures are performed and have a person other than the clinician performing the procedure onsite to provide assistance, call for additional assistance, or transport to a hospital in an emergency.
- Facilities should maintain adequate supplies for basic life support and medications and equipment needed to treat emergencies that may occur with the procedures performed.
- Facilities should provide basic emergency lighting (eg, battery backup lighting, flashlights).
- Facilities should keep doorways and hallways free of obstructions that could impede exit by patients and staff or ingress by emergency personnel. Where the types and risks of procedures performed at the facility create a reasonable likelihood that patient transfer by stretcher may be needed, doorways and hallways in the path of egress should be sufficiently wide to permit passage by stretcher (note that this term includes chair stretchers, which can be maneuvered through typical office doorways and hallways).
- Facilities should provide wayfinding signage that is understandable to the patient population served.

Biological Material Handling

- Facilities should establish written policies and procedures for properly labeling, handling, and storing biological specimens to be sent to pathology or other laboratory. The decision of whether to send specimens for pathology evaluation is made by the clinician or on the basis of facility policies.
- Facilities should establish written policies and procedures for handling, storing, and disposing of hazardous materials in a manner that minimizes the risk of exposure and for reducing the risk of harm to individuals involved, should exposure occur. Tissue not sent to pathology should be disposed of in the same manner as other biological materials. Tissue used in research or commercial endeavors is subject to separate requirements not addressed in this document.

Box 2. Facility Guidelines

Biological Material Handling (*continued*)

- Facilities should conduct periodic staff training on the policies and procedures described.

Physical Plant Specifications*

- Facilities should consider patient privacy, confidentiality, and comfort in the design and flow of the facility.
- Facilities should perform procedures in examination rooms or procedure rooms adequate to accommodate the equipment and personnel involved in the procedure. Typical examination rooms are an adequate size for most procedures; a room larger than needed to accommodate the equipment and personnel involved in the procedure is neither necessary nor desirable.
- Facilities should have patients recover in the room in which the procedure was performed or in a separate recovery room or area. A separate recovery room is not required. Some procedures require no recovery time.
- Facilities should provide separate storage for clean and dirty supplies.
- If instruments are sterilized onsite, facilities should provide separate marked areas for soiled and clean instrument processing. Separate rooms for those functions are not required. Offsite sterilization services may also be used.
- Facilities should provide a source of emergency power for equipment if any of the procedures performed in the facility are ones in which a power loss during the procedure would threaten patient safety.
- Facilities should have onsite, and maintain in good condition, the equipment needed for the procedures performed.
- Facilities should use adequate heating, ventilation, and cooling systems. Systems typical for offices are adequate in this context; no special heating, ventilation, or cooling systems are needed.
- Facilities that store specimens or medications requiring refrigeration should provide separate refrigerated storage for each.

Facility Accreditation and Licensing

- Procedures should be provided in facilities that meet current accepted practices. Such accepted practices do not require facility accreditation or facility licensing.

Clinician Qualifications Beyond Licensing

- Facilities should ensure that clinical staff are trained in the procedures performed, equipment used in the facility, basic life support, cultural sensitivity, and any requirements governing the facility with regard to accommodations to facilitate safe and appropriate access to health services for individuals with disabilities or other conditions, including limited English proficiency. Although some facilities will have no need for nursing staff, facilities should ensure that any clinical duties requiring nursing care are staffed appropriately.

Box 2. Facility Guidelines

Clinical Qualifications Beyond Licensing (*continued*)

- Facilities should designate a clinician responsible for ensuring that clinicians who perform procedures at the facility have established competence in those procedures. Such competence may be established through any of a variety of training, education, and assessment activities (which may be specified by the facility, a professional organization, or specialty). Neither board certification nor hospital privileges are required.

Other Policies and Procedures

- Facilities should establish written policies and procedures for infection control, conduct periodic staff training on those policies and procedures, and implement a plan to monitor compliance.
- Facilities that perform procedures on more than an occasional basis should establish a written quality improvement plan that includes recording and reviewing available facility data on select adverse outcomes related to procedures performed and ways to act on information gained.
- Facilities should establish a written policy and schedule for checking equipment functioning.
- Facilities should establish a written policy and schedule for managing medication inventory.

*We have included some physical plant–related matters in the guidelines for emergency preparedness.

provide primary care and gynecology procedures. Given the available evidence, the Procedures Working Group concluded that there is insufficient research to find that particular facility factors have either a positive or negative effect on patient safety or experience (very little research has been conducted in these areas, and the findings from that limited research are not definitive). The Procedures Working Group also noted that research suggests the possibility that some facility requirements may result in decreased service availability.[5] These findings mirror those of the National Academies of Sciences, Engineering, and Medicine, which recently published their report, "The Safety and Quality of Abortion Care in the United States." They, too, conducted a comprehensive literature review. Using a quality lens and the six dimensions of care quality–safety, effectiveness, efficiency, timeliness, equity, and patient-centered care–the authors found no evidence that regulations targeted at abortion care improved safety. They did find that other aspects of quality care delivery were negatively affected by those regulations–specifically, access to care, timeliness, and the availability of local, qualified providers.[8,9]

CONCLUSIONS

Requiring facilities that perform office-based procedures, including abortion, to meet standards beyond those currently in effect for all general medical offices and clinics is unjustified based on this thorough review and analysis of available evidence; safety concerns were not identified in any area of study.

The consensus guidelines developed by committee experts and stakeholders through systematic review of the literature, provide an evidence-informed basis for evaluating legislation and regulations that use patient safety as a justification for restrictive and ideologically driven policies. This research provides the evidence base to conclude that additional regulation for outpatient procedures, including abortion, has no documented necessity. Targeting specific procedures based on ideology rather than evidence sets a dangerous precedent for the regulation of medicine. It is essential for all health care providers and advocates to evaluate new and proposed facility requirements according to available evidence as outlined in this document. When such regulations are deemed unnecessary, it is incumbent on these same experts to oppose them. Enacting superfluous facility requirements is politics, not public safety.

REFERENCES

1. Weinberger SE, Lawrence HC, III, Henley DE, Alden ER, Hoyt DB. Legislative interference with the patient-physician relationship. N Engl J Med 2012;367:1557–9.
2. Guttmacher Institute. Targeted regulation of abortion providers. Available at: https://www.guttmacher.org/state-policy/explore/targeted-regulation-abortion-providers. Retrieved September 20, 2018.
3. Guttmacher Institute. State facts about abortion. Texas. Available at: https://www.guttmacher.org/fact-sheet/state-facts-about-abortion-texas. Retrieved September 20, 2018.
4. American College of Obstetricians and Gynecologists. Definition of "procedures" related to obstetrics and gynecology: position statement. Available at: https://www.acog.org/Clinical-Guidance-and-Publications/Position-Statements/Definition-of-Procedures-Related-to-Ob-Gyn. Retrieved September 20, 2018.
5. Berglas NF, Battistelli MF, Nicholson WK, Sobota M, Urman RD, Roberts SCM. The effect of facility characteristics on patient safety, patient experience, and service availability for procedures in non-hospital-affiliated outpatient settings: a systematic review. PLoS One 2018;13:e0190975.
6. Brouwers MC, Kho ME, Browman GP, Burgers JS, Cluzeau F, Feder G, et al. AGREE II: advancing guideline development, reporting and evaluation in health care. Can Med Assoc J 2010;182:E839–42.
7. Spruce L, Van Wicklin SA, Hicks RW, Conner R, Dunn D. Introducing AORN's new model for evidence rating. AORN J 2014;99:243–55.
8. National Academies of Sciences, Engineering, and Medicine. The safety and quality of abortion care in the United States. Washington, DC: The National Academies Press, 2018. Available at: https://www.nap.edu/read/24950/chapter/1. Retrieved September 20, 2018.
9. Calonge BN, Gayle HD. The safety and quality of abortion services in the United States: what does the evidence indicate. Ann Intern Med 2018;168:878–80.

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