

Report from the Project on Facility Guidelines for the Safe Performance of Primary Care and Gynecology Procedures in Offices and Clinics

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Introduction

Due to advances in technology and the demand for both affordability and quality in healthcare, an increasing number of surgeries and procedures are performed in office settings.ⁱⁱ In 2003, the American Medical Association and American College of Surgeons convened a working group to articulate principles for high-quality office-based surgery.² Similar attention has not yet been paid by the health professions to appropriate guidelinesⁱⁱⁱ for office-based procedures.

At the same time, an increasing number of states have passed laws regulating offices and clinics. Some of these laws broadly apply to outpatient settings in which surgery, procedures, or certain levels of sedation are offered; others specifically apply to settings in which particular procedures are offered (e.g., termination of pregnancy). Significant questions exist about the research evidence underlying some of these laws and about the laws' effects on patient safety, quality, costs, and the availability of care. Importantly, many of these laws do not distinguish between facilities performing surgeries and those performing procedures.

Procedures are a critical part of primary care and gynecological care, and the performance of procedures in offices and clinics has the potential to significantly improve patient care, access, affordability, and experience.

ⁱ The authors wish to acknowledge Bonnie Scott Jones and Molly Battistelli, of Advancing New Standards in Reproductive Health (ANSIRH), University of California, San Francisco, for their assistance in the drafting process.

ⁱⁱ This document distinguishes procedures from surgeries using the following definition from a position statement of the American College of Obstetricians and Gynecologists:¹

A procedure is a short interventional technique that includes the following general categories:

- non-incisional 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

ⁱⁱⁱ As used in this document, the term “guidelines” means evidence-based recommendations for practice. To avoid confusion, the document does not use the term “standards” in this regard; however, the authors recognize that the two terms are often used interchangeably.

Aims

The Project on Facility Guidelines for the Safe Performance of Primary Care and Gynecology Procedures in Offices and Clinics (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 experts and stakeholders to review available evidence and clinical practices and to produce an evidence-informed statement of facility guidelines and practices in this area. The goal of the Project was to articulate evidence-informed facility guidelines that would further healthcare 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.

Methods

The Project was led by a planning committee made up of representatives from the American College of Obstetricians and Gynecologists, National Partnership for Women & Families, American College of Physicians, American Academy of Family Physicians, American College of Nurse-Midwives, Nurse Practitioners in Women's Health, and the Society of Family Planning. From September 26, 2016, to July 11, 2018, the planning committee: (1) defined the scope of the Project; (2) recruited a working group of experts and stakeholders, many of whom were also representatives of other health care organizations ("Procedures Working Group"); (3) gathered and reviewed evidence; (4) hosted an in-person meeting of the Procedures Working Group to discuss research evidence, provide expert opinion, and consider appropriate guidelines and/or practices; (5) engaged in an iterative, virtual drafting process for crafting, and reaching agreement on, a final consensus document; (6) solicited and considered public comments; and (7) finalized the consensus guidelines.

(1) Project Scope

The planning committee defined the Project scope. Based on that scope, the Procedures Working Group:

- addressed only facility factors (those relating to physical environment and/or office and clinic operations); it did not delve into matters of clinical practice or scope of practice;
- sought to articulate new guidelines where appropriate, given the best available evidence;
- did not seek to define which procedures may appropriately be performed in offices and clinics; rather, it sought to define guidelines and accepted practices for facilities in which such procedures are performed (to provide context, Appendix A lists *examples* of procedures that the Procedures Working Group agreed are currently and appropriately performed within primary care and/or gynecology in offices and clinics);
- considered only offices and clinics providing procedures within primary care and/or gynecology; it did not consider facilities providing procedures in other practice areas;^{iv} and

^{iv}We recognize that many other types of office-based procedures are performed. We hope this document may be useful for procedures in other areas of practice, but we do not intend the document to apply to those other areas.

- did not seek to articulate guidelines and accepted practices for sedation/anesthesia provision; the American Society of Anesthesiologists has developed widely-accepted guidelines in this area,³ and the Procedures Working Group presumed that the applicable portions of those guidelines are followed by clinicians providing sedation/anesthesia in connection with primary care and gynecology procedures in offices and clinics.

(2) Recruitment of Participants

The planning committee developed a working group invitation list based on the need to include persons with diverse expertise and experience relevant to the work of the Project. The persons invited to participate in the Project included healthcare professionals, members of the patient advocacy community, and experts in care quality, accreditation, and other areas relevant to the provision of primary and gynecological care in office and clinic settings. A list of the participants in the Procedures Working Group is attached as Appendix B.

(3) Evidence Gathering and Review

The planning committee gathered available evidence regarding the impact 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 Appendix C) were chosen based on recurrence 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 in this regard included experts in patient safety, health service delivery and access, healthcare disparities, and healthcare 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.

Systematic Literature Review

A systematic review undertaken by independent researchers served as the foundational research for the Project.⁴ 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.^v The systematic review sought to address two questions: (1) What is the effect of outpatient setting (ambulatory surgery center (ASC) vs. 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? On the first question, regarding the impacts of facility type, more than 1000 abstracts were identified, and 10 full-text articles were included in the synthesis. The researchers found significant methodological weaknesses across

^v The systematic review may be accessed online without charge at the following URL: <http://journals.plos.org/plosone/article/authors?id=10.1371/journal.pone.0190975>

this body of literature and no consistent pattern to the results. However, based on seven studies meeting the study’s quality criteria, the authors concluded that existing evidence does not indicate a difference in patient safety for procedures across ASCs and offices. On the second question, regarding the impact of particular facility characteristics, nearly 1900 abstracts and titles were reviewed and 12 full-text studies were included in the synthesis; three of those studies met the researchers’ quality criteria. 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.

Other Research Studies

In addition to the systematic review, the planning committee provided the Procedures Working Group with drafts or preliminary findings from three studies that were in progress or recently submitted for publication. Although some of the research covers procedures outside the scope of this project, the planning committee determined that the results of this research was important to inform the work of the Procedures Working Group.

(1) The first of these was a manuscript under review of a study of facility guideline development efforts previously undertaken in endoscopy, oral surgery, gynecology, and plastic surgery (the manuscript has since been published, and the published paper is listed in the references).⁵ The study examined the processes used to develop facility guidelines and the extent to which research evidence was incorporated into those processes. The study found that facility guidelines processes typically involve a group of volunteer clinicians with relevant expertise who review existing guidelines, search and review published literature, assess the quality of the evidence and describe what it indicates, and make recommendations. The study further found that facility guideline development processes do not typically include a systematic review or formal assessment of evidence quality.

(2) The second consisted of preliminary findings from a retrospective cohort study that examined the safety of miscarriage treatment across hospitals, ASCs, and offices or office-based settings using a national private insurance claims database.⁶ Preliminary results from the comparison between ASCs and offices found lower odds of overall miscarriage treatment-related incidents^{vi} in ASCs than offices but no statistically significant differences when miscarriage treatments were stratified by type (first trimester, second trimester or medical) and no statistically significant difference between ASCs or offices in the odds of major incidents or infections. With respect to the comparison between hospitals and offices, preliminary results found no statistically significant differences in odds of overall incidents but higher odds of major incident or infection for hospital-based treatment than for office-based. When miscarriage treatments were stratified by type, the odds of incident were higher for hospitals than offices for first trimester procedures and for procedures for incomplete and septic miscarriages; odds of an incident were lower for hospitals than offices for medication treatment, and no difference in odds of incident existed between hospitals and offices for procedures in the second trimester.

^{vi} The study defined “incidents” as “miscarriage treatment-related morbidities and adverse events” and “major incidents” as “incidents requiring overnight hospital admission, surgery, or blood transfusion.”

(3) The third was a submitted draft of a retrospective cohort study comparing the safety of abortion in ASCs vs. offices or office-based settings using a national private insurance claims database.⁷ That study found, in adjusted analyses, no statistically significant differences in overall abortion-related incidents^{vii} between ASCs and office-based settings overall, nor for first trimester aspiration abortion or second trimester and later abortion, nor any statistically significant differences in major abortion-related incidents or infections across facility type.

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 impact access to healthcare 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).⁸ The researcher found that the limited evidence available suggests that the impact 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.^{9,10} As few such guidelines exist, the researchers cast a wide net and 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 (AGREE) II tool¹¹ and the Non-Research Evidence Appraisal Tool from the Association of periOperative Registered Nurses (AORN).¹² They then reviewed and summarized the contents of the five guidelines with the highest quality assessment scores.

(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.¹³ 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.

Finally, the planning committee wanted to make certain that information was available to the Procedures Working Group regarding accrediting body requirements and state facility laws for office and clinic settings. To this end, researchers examined select outpatient accreditation requirements and created a summary for the Procedures Working Group.¹⁴ An existing paper submitted for publication examined facility laws governing office- and clinic-based procedures.¹⁵ A draft of that paper was provided for reference to the Procedures Working Group.

^{vii} The study defined “incidents” as “abortion-related morbidities and adverse events” and “major incidents” as “incidents requiring overnight hospital admission, surgery, or blood transfusion.”

(4) Expert and Stakeholder Meeting

An in-person meeting of the Procedures Working Group was held in Washington, DC on December 13 and 14, 2017 (Summit) to review and discuss the research evidence and to share and discuss participants' expert opinions, regarding the impact of various aspects of facility environment and operations on patient safety, experience, and access to primary care and gynecology procedures in offices and clinics. During the Summit, the Procedures Working Group reviewed and analyzed the available evidence, shared current accepted practices, and discussed whether any evidence of potential harms or problems exists.

An iterative process was used during the Summit 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.

(5) Drafting Process

An initial draft of this document was prepared by the planning committee and staff based on conclusions reached during the Summit. A companion document containing just the guidelines and brief introductory material was also prepared. The Procedures Working Group provided written feedback and edits on the draft documents until full consensus was reached. After receiving public comment on the guidelines, participants will again provide written feedback and edits on the documents until full consensus is reached.

(6) Public Comment

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 (facilityguidelines.org) 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.

(7) Finalization

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.

Updates

The planning committee will meet to review new evidence and consider revisions to the guidelines document five years from publication date (if not convened earlier). Two and a half years and five years following initial publication, a search of the literature will be conducted to identify new relevant research, and the results of that search will be reviewed by the project chairs. If it is determined that new evidence necessitates revision or further inquiry prior to five years, the planning committee will convene earlier.

Project Support

The work of the Project was supported by staff at the American College of Obstetricians and Gynecologists, the Advancing New Standards in Reproductive Health (ANSIRH) program at the University of California, San Francisco, and the National Partnership for Women & Families. Support for the costs of the Project was provided by these organizations, as well as by an anonymous U.S.-based, 501(c)(3), charitable foundation. The foundation had no influence on, or involvement in, the Project process, meeting, document creation, or other activities. In-kind support for the Project was provided by the members of the Procedures Working Group and the organizations represented on the planning committee.

Project Findings

The Procedures Working Group concluded that very little research evidence exists in this area, specifically on the impact of outpatient facility factors on patient safety and patient experience and service availability. The Procedures Working Group found no evidence of any patient safety or quality of care problem related to the examined facility factors (see Appendix C) in offices or clinics that 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 impact 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.⁴

Given this evidence base, the Procedures Working Group determined that facility guidelines requiring measures beyond current accepted practices would be unjustified. The Project had intended to articulate such measures for areas of facility operations or environment where available evidence identified potential problems arising from existing accepted practices. However, based upon thorough review and analysis of the available evidence, safety concerns were not identified in any area of study. Therefore, the Procedures Working Group concluded that requiring changes to current accepted practices was unwarranted, and it sought to articulate guidelines reflecting those current accepted practices.

The Procedures Working Group also noted the absence of evidence regarding the extent to which offices and clinics already comply with such accepted practices. This is another area for future research. By incorporating the current accepted practices into these guidelines, the Procedures Working Group strongly urges all offices and clinics providing procedures within primary care or gynecology to comply with those practices.

The guidelines produced by the project are set forth below.

Guidelines^{viii}

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 (e.g., natural disaster, fire) and patient emergencies (e.g., 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 as 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 (e.g., 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.

^{viii} Note that there exist a variety of federal, state, and local laws (e.g., the Americans with Disabilities Act, state health care facility regulations) that may be pertinent to facility topics discussed in this document. This document does not attempt to assess or describe those laws. Providers should be aware of relevant laws applicable to their facilities.

- 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.
- 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 exam rooms or procedure rooms adequate to accommodate the equipment and personnel involved in the procedure. Typical exam 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 where 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 utilize 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.

(Note: We have included some physical plant-related matters in the guidelines for emergency preparedness.)

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. While some facilities will have no need for nursing staff, facilities should ensure that any clinical duties requiring nursing care are staffed appropriately.
- 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 is 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.

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Appendix A - Procedure Examples

The following is an *illustrative* list of procedures that are performed within primary care and/or gynecology in offices and clinics and are within the purview of the guidelines. This list provides examples; it is not an exhaustive list of such procedures.

Abdomen

- Abdominal Paracentesis

Anal canal

- Excision of thrombosed hemorrhoid

Bladder, urethra

- Cystoscopy

Cervix, vagina, vulva

- Colposcopy with biopsies

- Large-loop excision of the transformation zone (LETZ) / Loop electrosurgical excision procedure (LEEP)

Colon, rectum

- Sigmoidoscopy

Joints

- Joint aspiration and injection

Pleural space

- Thoracentesis

Skin

- Punch biopsy

- Incision and drainage of abscess

Spine

- Lumbar puncture

Testicles

- Vasectomy

Uterus

- Endometrial biopsy

- Uterine aspiration

- Dilation and evacuation (D&E)

- Intrauterine device (IUD) insertion

- Intrauterine insemination (IUI)

- Saline infusion sonogram (SIS)

- Hysterosalpingogram (HSG)

Other

- Immunization

- Allergy desensitization

- Contraceptive implant insertion

Appendix B – Procedures Working Group

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Note: Participation in the working group and/or planning committee does not constitute organizational endorsement of the guidelines

Appendix C – Facility Factors

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 and/or licensing