Facility guidelines for the safe performance of primary care and gynecology procedures in offices and clinics

Barbara Levy, MD, Debra Ness, MS, Steve Weinberger, MD, Valerie King, MD, MPH, Suzanne Wertman, MSN, CNM, Carolyn Sutton, MS, WHNP-BC, Amanda Dennis, DrPh, MBE; on behalf of the Procedures Working Group

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 (this document defines "procedures" in the manner set forth in the January 2018 position statement of the American College of Obstetricians and Gynecologists[1]). 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 guidelines[i] 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). There are significant questions about the research evidence underlying some of these laws and about the laws' impacts 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 practice and the performance of procedures in offices and clinics has the potential to significantly improve patient care, access, affordability and experience.

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 and practice in this area. 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 for this area. The goal of the Project was to articulate evidence-informed 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.

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i 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.

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 TBD, 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 professional 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 (that is determined by applicable standards of care); rather, it sought to define guidelines and accepted practices for facilities in which such procedures are performed (to provide factual context, Appendix A lists *examples* of primary care and gynecology procedures that the Procedures Working Group agrees are currently and appropriately performed in offices and clinics);
- considered only offices and clinics performing primary care and/or ambulatory gynecology procedures; it did not consider facilities providing procedures in other practice areas;[ii] and
- 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.

[ii] We recognize that many other types of office-based procedures are performed and hope this document may be useful for procedures in other areas of practice as well.

(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, a patient representative and 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.

Systematic Literature Review

A systematic review undertaken by independent researchers served as the foundational research for the Project. This study, which was conducted according to established systematic review standards and published in a peer reviewed journal,[4] 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 (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; seven of those studies met the researchers' quality criteria. The researchers found significant methodological weaknesses across this body of literature and no consistent pattern to the results. However, based on the studies meeting formal quality criteria, the authors determined 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.

(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.[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/clinics using a national private insurance claims database.[6] Preliminary results from the comparison between ASCs and offices found lower odds of overall miscarriage-related incidents[iii] 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 there was no difference in odds of an incident between hospitals and offices for procedures in the second trimester.

(3) The third was a submitted draft of a retrospective cohort study comparing the safety of abortion in ASCs vs. offices/clinics using a national private insurance claims database.[7] That study found, in adjusted analyses, no statistically significant differences in overall abortion-related incidents[iv] between ASCs and offices, nor any statistically significant differences in major abortion-related incidents or infections across facility type.

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iii The study defined "incidents" as "receiving miscarriage treatment-related diagnosis or treatment from any source within six weeks;" and "major incidents" as incidents requiring overnight hospital admission, surgery, or blood transfusion.

iv The study defined "incidents" as "receiving an abortion-related diagnosis or treatment from any source within six weeks;" and "major incidents" as "incidents requiring overnight hospital admission, surgery, or blood transfusion.

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 tool[11] 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 sought to have on hand information about 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.

(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.

The Procedures Working Group concluded that there is very little research evidence in this area and that further research is needed, specifically on the impact of outpatient facility factors on patient safety and patient experience and service availability. Given the available evidence, the Procedures Working Group also concluded that there is insufficient research to find that particular facility factors have either a positive or a negative impact on patient safety or experience. The research also suggests the possibility that some facility requirements may result in decreased service availability. [4]

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 guidelines in each area considered.

(5) Drafting Process

An initial draft of the guidelines document was prepared by the Planning Committee and staff based on conclusions reached during the Summit. For each aspect of facility operations and environment considered, the document sets forth the consensus expert opinion of the Procedures Working Group regarding current accepted practices and the potential need to articulate guidelines to change those practices, given the available evidence.

The Procedures Working Group had intended to articulate new guidelines for those 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 new guidelines to change existing accepted practices were unwarranted.[v]

The Procedures Working Group provided written feedback and edits on the draft guidelines document until full consensus on a draft for soliciting public comment was reached. Following the public comment process, participants again provided written feedback and edits until full consensus on a final guidelines document was reached.

(6) Public Comment

Feedback on the draft guidelines was solicited from stakeholders and members of the public via a public comment process. The draft was posted on an interactive, public website (www.fsdinitiative.com) that allowed for submission of comments, proposed edits, and additional evidence. Announcements of the public comment period were sent to TBD # of health professional and health delivery organizations according to outreach processes commonly used in the development of clinical guidelines.

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v Apart from guidelines and practices, there exist a variety of federal, state, and local laws that may be pertinent to the facility topics discussed in this document. We do not attempt to assess or describe those laws. Providers should be aware of relevant laws applicable to their facilities.

(7) Finalization

The feedback provided during the public comment process was reviewed by the Planning Committee, which prepared a synthesis of the comments and proposed responses and revisions. 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 or outcomes (i.e., no foundation representative attended the Summit, participated in the working group selection, or had any role in drafting or reviewing this document).

Guidelines

Emergency Preparedness

Current Accepted Practices

It is current accepted practice for offices and clinics providing primary care or gynecology procedures to:

- Establish written policies and procedures for managing facility emergencies (e.g., natural disaster, fire) and patient emergencies (e.g., vasovagal reaction, hemorrhage) and conduct periodic drills and staff trainings on those policies and procedures;
- 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 or call for transport to a hospital in an emergency;
- Maintain adequate supplies for basic life support, and medicines needed to treat emergencies that may occur with the procedures performed;
- Provide basic emergency lighting (e.g., battery backup lighting or flashlights);
- Keep doorways and hallways free of obstructions that could impede exit by patients and staff or ingress by emergency personnel (where appropriate and proportional to the types and risks of procedures performed at the facility, it is current accepted practice to have doorways and hallways of sufficient width to permit transport by emergency medical services);
- Provide wayfinding signage that is understandable to the patient population served.

New Guidelines

There is no evidence of any patient safety or quality of care problem related to emergency preparedness in offices or clinics that provide primary care and gynecology procedures. Given the current evidence base, changes to these accepted practices are unwarranted. Accordingly, there is no justification for establishing new guidelines regarding emergency preparedness at this time.

Biological Material Handling

Current Accepted Practices

It is current accepted practice for offices and clinics providing primary care or gynecology procedures to:

- 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) and conduct periodic staff training on those policies and procedures;

- Establish written policies and procedures for handling, storing, and disposing of hazardous materials in a manner that minimizes the risk of exposure, and conduct periodic staff training on those policies and procedures; tissue not sent to pathology is 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).

New Guidelines

There is no evidence of any patient safety or quality of care problem related to biological material handling in offices or clinics that provide primary care and gynecology procedures. Given the current evidence base, changes to these accepted practices are unwarranted. Accordingly, there is no justification for establishing new guidelines regarding biological material handling at this time.

Physical Plant Specifications

Current Accepted Practices

It is current accepted practice for offices and clinics providing primary care or gynecology procedures to:

- Consider patient privacy, confidentiality, and comfort in the design and flow of the facility;
- Perform procedures in exam rooms or procedure rooms (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);
- 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; note that some procedures entail no recovery time);
- Provide separate storage for clean and dirty supplies;
- If instruments are sterilized onsite (offsite services may also be used), provide separate marked areas for soiled and clean instrument processing (separate rooms are not required);
- Provide a source of emergency power for equipment if the procedure is one where a power loss during the procedure would threaten patient safety;
- Have onsite, and maintain in good condition, the equipment needed for the procedures performed;
- Utilize heating, ventilation, and cooling systems typical for offices (no special heating, ventilation, or cooling systems are needed);
- Provide separate refrigerated storage for specimens and medications if the facility stores specimens or medications that require refrigeration.

(Note: some physical plant-related matters are described under emergency preparedness)

New Guidelines

There is no evidence of any patient safety or quality of care problem related to physical plant specifications in offices or clinics that provide primary care and gynecology procedures. Given the current evidence base, changes to these accepted practices are unwarranted. Accordingly, there is no justification for establishing new guidelines regarding physical plant specifications at this time.

Clinician Qualifications Beyond Licensing and Competency

Current Accepted Practices

It is current accepted practice for offices and clinics providing primary care or gynecology procedures to:

- Ensure that clinical staff are trained in the procedures performed, equipment used in the facility, basic life support, and cultural sensitivity (Procedures performed in offices or clinics do not require specified levels of nursing staff to assure adequate training).
- Establish competence in the procedures performed through any of a variety of training, education, and assessment activities (neither board certification nor hospital privileges is required).

New Guidelines

There is no evidence of any patient safety or quality of care problem related to clinician qualifications, beyond licensing and competency, in offices or clinics that provide primary care and gynecology procedures. Given the current evidence base, changes to these accepted practices are unwarranted. Accordingly, there is no justification for establishing new guidelines regarding clinician qualifications at this time.

Other Policies and Procedures

Current Accepted Practices

It is current accepted practice for offices and clinics providing primary care or gynecology procedures to:

- Establish written policies and procedures for infection control, conduct periodic staff training on those policies and procedures, and implement a plan to monitor compliance;
- 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.
- Establish a written policy and schedule for checking equipment,
- Establish a written policy and schedule for managing medication inventory.

New Guidelines

There is no evidence of any patient safety or quality of care problem related to other policies and procedures in offices or clinics that provide primary care and gynecology procedures. Given the current evidence base, changes to these accepted practices are unwarranted. Accordingly, there is no justification for establishing new guidelines regarding other policies and procedures at this time.

Facility Accreditation and Licensing

Current Accepted Practices

It is current accepted practice for offices and clinics providing primary care or gynecology procedures to:

- Provide procedures in facilities that may or may not be accredited and/or licensed (neither accreditation nor facility licensing is required).

New Guidelines

There is no evidence of any patient safety or quality of care problem related to accreditation and licensing in offices or clinics that provide primary care and gynecology procedures. Given the current evidence base, changes to these accepted practices are unwarranted. Accordingly, there is no justification for establishing new guidelines regarding accreditation and licensing at this time.

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Appendix A - Procedure Examples

Following is an *illustrative* list of primary care and gynecological procedures that are performed in offices and clinics and within the purview of the Consensus 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)

Other
- Immunization
- Allergy desensitization
- Exercise tolerance testing
- Implant insertion

Appendix B – Procedures Working Group

Michael Barr, MD, MBA, MACP, **National Committee for Quality Assurance**

Linda Blount, MPH, **Black Women's Health Imperative**

Sonya Borrero, MD, MS, **Society of Family Planning**

William Bradford, DO, **American College of Osteopathic Obstetricians and Gynecologists**

Jennifer Brull, MD, FAAFP, Family Medicine Provider

Minerva Campos, MD, MPH, **National Hispanic Medical Association**

Mark DeFrancesco, MD, MBA, **Accreditation Association for Hospitals and Health Systems**

Amanda Dennis, DrPh, MBE, **Society of Family Planning** (Planning Committee member)

Rony Elias, MD, **American Society for Reproductive Medicine**

Daniel Grossman, MD, **Advancing New Standards in Reproductive Health**, University of California, San Francisco

Valerie King, MD, MPH, FAAFP **American Academy of Family Physicians** (Planning Committee member)

Hal Lawrence, MD, **American College of Obstetricians and Gynecologists**

Barbara Levy, MD, **American College of Obstetricians and Gynecologists** (Planning Committee chair)

Denise Link, PhD, WHNP, FAAN, FAANP, **American Academy of Nursing**

Raegan McDonald-Mosley, MD, MPH, **Planned Parenthood Federation of America**

Debra Ness, MS, **National Partnership for Women & Families** (Planning Committee chair)

Abby Norman, Patient Representative

Shirley Orr, MHS, APRN, NEA-BC, **American Public Health Association**

Matthew Reeves, MD, MPH, **National Abortion Federation**

Sara Rosenbaum, JD, **George Washington University**

E. Bimla Schwarz, MD, MS, **Society of General Internal Medicine**

Carolyn Sutton, MS, WHNP-BC, FAANP, **Nurse Practitioners in Women's Health** (Planning Committee member)

Elyse Watkins, DHSc, PA-C, **American Academy of Physician Assistants**

Steven Weinberger, MD, MACP, FRCP, **American College of Physicians** (Planning Committee member)

Suzanne Wertman, MSN, CNM, **American College of Nurse-Midwives** (Planning Committee member)

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 & doorway widths
- Operating rooms
- Procedure rooms
- Separate clean & soiled sterilization rooms
- Temperature & ventilation

Clinician qualifications beyond licensing & competency

Other policies and procedures

- Infection control
- Patient satisfaction assessment
- Peer review of physicians
- Preventive maintenance
- Quality assurance

Facility accreditation and/or licensing