Facility Guidelines for the Safe Performance of Primary Care and Gynecology Procedures in Offices and Clinics

These guidelines were produced by the Project on Facility Guidelines for the Safe Performance of Primary Care and Gynecology Procedures in Offices and Clinics (Project). 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. The Project brought together experts and stakeholders (Procedures Working Group, see Appendix A for group members) to review available evidence and clinical practices and to produce an evidence-informed statement of facility guidelines for the provision of primary care and gynecology procedures.[i] 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.

As of January 24, 2019, the following organizations have endorsed these guidelines:

American Academy of Family Physicians (AAFP)
American Academy of Nursing (AAN)
American Academy of Physician Assistants (AAPA)
American College of Nurse-Midwives (ACNM)
American College of Obstetricians and Gynecologists (ACOG)
American College of Osteopathic Obstetricians and Gynecologists (ACOOG)
American College of Physicians (ACP)
American Public Health Association (APHA)
National Hispanic Medical Association (NHMA)
National Partnership for Women & Families (NPWF)
Nurse Practitioners in Women's Health (NPWH)
Planned Parenthood Federation of America (PPFA)
Society of Family Planning (SFP)
Society of General Internal Medicine (SGIM)

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[i] 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:
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> - 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

Appendix B lists examples of primary care and gynecology procedures that the Project participants agreed are currently and appropriately performed in offices and clinics.

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 a 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.[ii]

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[iii]

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.

[ii] 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. http://dx.doi.org/10.1371/journal.pone.0190975.

[iii] 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.

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.
- 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.

Appendix A – Procedures Working Group

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

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

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

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

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

Debra Ness, MS, **National Partnership for Women & Families** (planning committee chair)

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

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

Appendix B – 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 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