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WOMEN'S HEALTH CARE PHYSICIANS

COMMITTEE OPINION

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Committee on Patient Safety and Quality Improvement

This Committee Opinion was developed by the American College of Obstetricians and Gynecologists' Committee on Patient Safety and Quality Improvement in collaboration with committee members Mark C. Genesen, MD, and Victor M. Feldbaum, MD.

This document reflects emerging concepts on patient safety and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed.

Guiding Principles for Privileging of Innovative Procedures in Gynecologic Surgery

ABSTRACT: New or emerging surgical procedures and technologies continue to be developed at a rapid rate and must be implemented safely into clinical practice. Additional privileging may be required if substantively new technical or cognitive skills are required to implement an innovative procedure or technology. Guiding principles for privileging should include cognitive and technical assessment to ensure appropriate patient selection and performance of the new procedure. Implementation also should include pertinent institutional and staff support as needed. A dynamic process for assessment and maintenance of current competency will enhance the safety of implementation and continued application of emerging procedures and technologies. The number of cases needed to demonstrate cognitive and technical proficiency will vary depending on many factors, including the health care provider's baseline expertise and technical acumen.

Recommendations

The American College of Obstetricians and Gynecologists makes the following recommendations regarding privileging for emerging procedures and technologies:

- New or emerging surgical procedures and technologies must be implemented safely into clinical practice.
- Additional privileging may be required if substantively new technical or cognitive skills are required to implement an innovative procedure or technology.
- Guiding principles for privileging should include cognitive and technical assessment to ensure appropriate patient selection and performance of the new procedure.
- As with all facility privileging, systems to ensure current and ongoing clinical competence and, thus, patient safety, should be developed and implemented.
- Proctoring should be conducted to evaluate the skill set of individual surgeons to determine their ability to perform new procedures or use new technologies independently.
- Criteria for determining competency should be established in advance of the proctoring. The number

of cases needed to demonstrate cognitive and technical proficiency will vary depending on many factors, including the health care provider's baseline expertise and technical acumen.

Introduction

New or emerging surgical procedures and technologies continue to be developed at a rapid rate and must be implemented safely into clinical practice. Procedures that require the development of new multifaceted components, especially new technical or cognitive skills, may entail additional privileging. Guiding principles leading to independent use of a new procedure or technology should facilitate a multifaceted privileging process that addresses education, training, and experience. As with all facility privileging, systems to ensure current and ongoing clinical competence and, thus, patient safety, should be developed and implemented.

Granting Privileges

Before proceeding with privileging for emerging procedures and technologies, each institution should consider whether appropriate studies have adequately supported

the proposed new approach (1). The goals of the new procedure or technology should be identified clearly (2). Adoption of new surgical approaches should be driven by what is best for the patient rather than by external pressures (3). The proper indications and appropriate patient selection should be considered (4). Any significant financial implications also should be considered. After the aforementioned issues have been adequately addressed (Box 1), a multifaceted process should be developed to identify specific criteria to be completed for attaining and maintaining competence in the new procedure. Guidance can be obtained from requirements already in place for analogous procedures or from specialty and subspecialty organizations. These criteria should assess training, experience, and methods to demonstrate current clinical competence. Although education and documentation of training can be performed by medical specialty organizations, educational institutions, and other entities in the health care industry, only the institution where the procedures are to be performed has the authority to approve credentialing or privileging.

Each institution should have a method to assess pertinent technical and cognitive skill sets needed to perform a new procedure or to use a new technology. In addition, broader issues such as changes to patient selection, preoperative assessment, informed consent, intraoperative care, postoperative care, and counseling also should be addressed.

For new procedures and technologies, the process should assess new skill-set requirements related to equipment and technology for physicians (eg, gynecologists and anesthesiologists), hospitals, staff, and other health care providers who are involved. It is essential that a hospital mechanism be in place to provide necessary support for new equipment or technology, including installation, maintenance, and repair. This mechanism may entail several specific items, such as training appropriate team members to troubleshoot equipment malfunctions and ensuring the capability to convert from the new procedure to traditional technology for the completion of the

procedure in the event of unresolvable technical failure, as indicated (eg, convert from robotic-assisted to conventional laparoscopy or laparotomy). Additional training and maintenance of new skills for operating room staff should be considered as well. Box 2 summarizes some of the key items to consider before granting hospital privileges.

Physician-Specific Issues

Fundamental competency and skill prerequisites should be delineated, including competency in relevant fundamental basic and needed advanced skill sets. Accredited courses should include education on equipment and safety factors. The institution's precepting and proctoring requirements should be followed (Table 1). Proctoring should be conducted to evaluate the skill set of individual surgeons to determine their ability to perform new procedures or use new technologies independently. Consideration may be given to using surgical experience from other institutions in lieu of the aforementioned criteria. This experience could include case lists with preoperative and postoperative diagnosis, procedures performed, the physician's role (eg, primary, cosurgeon, assistant), outcome, and any complications. New privileges should be granted only when appropriate training has been completed and documented and competency levels have been demonstrated. This process should be followed by an ongoing review of outcomes.

When a health care provider has not received residency or fellowship training in the new approach, arrangements can be made for a preceptorship with a physician who is already privileged to perform the procedure; the preceptorship may require the applicant to perform the designated surgery with the preceptor acting as first assistant. This may or may not be used as a proctored case depending on institutional policy. Proctoring should be conducted to determine evidence of competency. Criteria for determining competency should be established in advance of the proctoring. The number of cases needed to demonstrate cognitive and technical

Box 1. Institutional Considerations ↵

- Has efficacy and safety of the procedure or technology been vetted properly?
- Has the patient population that will benefit from the new modality been established?
- What are reasonable risks and complications for the procedure, and what risks and complications would trigger reassessment of the technology or require additional training or remediation for the surgeon?
- What educational resources should be available to institutions for surgeons, members of the surgical team, patients, and hospital administrators?
- What are the pertinent financial considerations?

Box 2. Items to Consider Before Granting Hospital Privileges ↵

- Identify specific additional technical or cognitive skill sets needed for the new procedure.
- Delineate relevant education and training.
- Review the number of surgical cases performed with new and similar technology.
- Review letters describing the surgeon's proficiency (preceptored/proctored cases).
- Review the surgeon's performance and outcomes with current technology.
- Review recommendations from peers.

Table 1. Advantages, Disadvantages, and Roles of the Proctor and Preceptor ↩

	Proctor	Preceptor
Goal	Assesses learner’s knowledge and skill	Helps learner acquire new skills and knowledge
Feedback	May provide feedback to learner	Always provides feedback to learner
Expertise	Expertise desirable but not necessary	Must be an expert
Role	Serves as an observer	Assists and can scrub and take charge if needed
Expense	Associated with lower cost	Associated with higher cost
Legal Risk	Assumes less legal risk	Assumes greater risk

proficiency will vary depending on many factors, including the health care provider’s baseline expertise and technical acumen; there may be a steeper learning curve for less-experienced surgeons. The proctor should submit documentation that the applicant is competent to perform the procedures independently at the designated skill level. The proctors should be free from pressure to approve competency, regardless of the minimum requirements, until they are comfortable that the surgeon is competent. The proctor should not perform any of the key components of the procedure. If there is no experienced surgeon on the hospital staff who is able to serve as a proctor, one may be arranged by inviting a credentialed surgeon from another institution to serve as a surgical consultant in this capacity. The proctor should be free from any substantive conflicts of interest and, if not, those conflicts should be disclosed.

Current Available Training Options

Training should be tailored to the particular procedure or technology. Educational options may include classroom or online didactics. Various online training tools also may be useful. Dry lab or animal training may be mandated. Case observation also may provide important benefits. When warranted, simulation training may be required (eg, for robotic-assisted laparoscopy). Preceptorships also may play a role in certain circumstances. Regardless of the procedure, training courses and venues ideally should be free from industry bias.

Measuring Initial and Ongoing Competency and Proficiency

The number of cases needed will be variable depending on inherent skill level, previous relevant experience, simulation experience, frequency of cases, complexity of cases, and availability of peer-supported training systems. Specific minimal numbers required before safe and independent performance of specific procedures is deter-

mined by each institution and ideally will be supported by evidence-based literature. Guidance from evidence-based “learning curves” and available surgeon feedback may be of value (5). A multidisciplinary, institution-based committee for monitoring evolving surgical practices and outcomes may provide useful guidance for developing and refining hospital-specific requirements. Reasonable requirements for demonstrating maintenance of skills and competency should be developed and implemented. Methods other than minimum number of cases per credentialing cycle should be considered if indicated.

Informed Consent

Informed consent should include full disclosure of pertinent issues attributable to the new technology or procedure. An evidence-based presentation of potential risks, benefits, and alternatives should be free of unfounded marketing bias (6). Surgeons should disclose their experience to patients, especially if the surgeon is on the early or steep part of a learning curve (7). If use of a proctor or preceptor is contemplated, this also should be disclosed as part of the informed consent process. Box 3 summarizes recommended consent components.

Conclusion

New procedures and technologies continue to be developed at a rapid rate and must be implemented safely into clinical practice. Additional privileging may be required if substantively new technical or cognitive skills are required to implement an innovative procedure or technology. The application of these innovations may require the development of enhanced, new, or more complex skill sets. Additional training and assessment may be needed before safe and independent implementation by the practitioner. Accordingly, a multifaceted privileging approach is recommended to ensure the development, application, and competency assessment of pertinent new perioperative skill sets. This process should address technical and cognitive components of care. Implementation also should include pertinent institutional and staff support as needed. A dynamic process for assessment and maintenance of current competency will enhance the safety of implementation and continued application of emerging procedures and technologies.

Box 3. Recommended Informed Consent Components ↩

- Description of pertinent risks, complications, benefits, and alternatives
- Disclosure regarding current understanding of the safety and efficacy of new technology
- Disclosure of the surgeon’s experience with the new technology
- Freedom from commercial bias

For More Information

The American College of Obstetricians and Gynecologists has identified additional resources on topics related to this document that may be helpful for ob-gyns, other health care providers, and patients. You may view these resources at www.acog.org/More-Info/PrivilegingInnovativeProcedures.

These resources are for information only and are not meant to be comprehensive. Referral to these resources does not imply the American College of Obstetricians and Gynecologists' endorsement of the organization, the organization's web site, or the content of the resource. The resources may change without notice.

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