The American College of Obstetricians and Gynecologists Presidential Task Force on Patient Safety in the Office Setting was convened to identify patient safety concerns, develop tools, and provide guidance for physicians performing invasive surgical procedures in the office setting. Physicians who serve as office medical directors have a myriad of responsibilities related to clinical and patient safety, including evaluating staff competency, encouraging office team communication, promoting patient partnership, and ensuring safety in the use of analgesia or anesthesia. Activities and tools used in the inpatient setting, such as multidisciplinary team meetings, checklists, time-outs, mock emergency drills, and measurement and reporting systems, can easily be tailored and applied to any office practice. (Obstet Gynecol 2010;115:147–51)

The 2000 report by the Institute of Medicine To Err Is Human refocused national attention on the deficiencies in its fragmented health care system and the serious health consequences that can occur at the sharp end (provider–patient interaction). The seminal report examined the prevention of adverse events and medication-related errors through systems changes, error reporting, and new standards and expectations.1 Marked improvements in awareness, regulation, measurement, information technology, workforce, and training issues have steered the evolution of modern health care.2 Through patient safety and quality improvement activities, hospitals have seen benefits such as increased patient satisfaction and health care team culture, reduced morbidity and mortality, and reductions in liability insurance premiums. However, these advancements in the inpatient environment have not been translated into the outpatient office setting.

In his presidential address to the American College of Obstetricians and Gynecologists (the College), Douglas H. Kirkpatrick, MD, revitalized patient safety as a priority in the obstetrician–gynecologist’s office.3 As his presidential initiative, Kirkpatrick charged the Presidential Task Force on Patient Safety in the Office Setting (Task Force) to assist, inform, and enable Fellows to design and implement processes that will facilitate a safe and effective environment for the more invasive technologies currently being introduced into the office. Task Force members included Ty B. Erickson, MD, as chair, and the following members: Elizabeth A. Buys, MD; Mark S. DeFrancesco, MD, MBA; Joseph C. Gambone, DO, MPH; Paul A. Gluck, MD; Douglas H. Kirkpatrick, MD; Sandra Koch, MD; Hector Vila Jr, MD; Patrice M. Weiss, MD; and Sue Woodson, CNM, MSN.

This article is an executive summary of the meeting proceedings of the Task Force. The comprehensive
report of the Task Force will be disseminated by the College as a monograph and as an appendix in the 2010 manual Quality and Safety in Women’s Health Care.

The Task Force seeks to reinvigorate clinicians’ attention toward patient safety in the office setting. Invasive surgical procedures are increasingly moving out of inpatient operating rooms and ambulatory surgical centers and into the office. Patients have the right to expect the same level of safety regardless of where they seek treatment.

Indeed, technology continues to provide new mechanisms to increase the safety and quality of care, such as e-prescribing, electronic medical records, and clinical decision support tools. However, not all offices have incorporated these tools into their practices. Fortunately, many of the “low-tech” lessons and tools readily associated with the inpatient setting’s culture, organization, and infrastructure can also be easily implemented in the office, such as:

- Leadership
- Competency and assessment
- Teamwork and communication
- Anesthesia safety
- Measurement
- Checklists, time-outs, and drills

On first inspection, there may be a perception on the part of Fellows that the Task Force is asking offices to implement wholly new activities and requirements. Even though most office practices may not formally call someone a medical director, they doubtlessly have a key physician who performs the functions of that position. Furthermore, all practitioners go through the process of credentialing and privileging to perform certain procedures for all of the facilities in which they work. Usually the practice administrator or office manager is involved with accumulating the necessary documentation for credentialing. To adopt this in the office simply requires keeping the relevant information and documentation in a special folder for each provider and then regularly verifying ongoing competence and training.

While most physicians are familiar with elements of the Task Force recommendations as applied in the inpatient setting, this report focuses on implementation within the surgical environment. As the details of this summary are read, it is recommended that the reader pay particular attention to the sections related to analgesia/anesthesia safety, tools such as checklists and drills, and, of course, enhanced quality tracking and measurement. Most of these tools are inexpensive to implement but are critically important to the safe introduction of in-office procedures. The full report will provide much assistance for our members.

**LEADERSHIP**

In addition to department and residency chairs, hospitals often have personnel specified for risk management, quality assurance, credentialing, education, data reporting, health information technology, and case management. However, in the office, many of these responsibilities must fall on one person: the office medical director. In a solo practice, the physician should assume this role; in a group practice, one of the partners should be designated as medical director; and in larger group practices, roles and responsibilities may be divided among several individuals (eg, medical director, credentialing, quality assurance). The role of leadership is essential in facilitating an effective patient safety culture.

Responsibilities of the medical director include, but are not limited to, the following:

- Motivating staff toward a culture of safety, teamwork, and communication
- Credentialing and making sure all staff are qualified
- Developing, updating, and enforcing the policy and procedure manual as a living, vibrant document
- Verifying competency via conducting quarterly mock drills
- Tracking and reporting adverse events and procedure outcomes
- Creating a learning, nonpunitive environment as errors are identified and corrected

**COMPETENCY AND ASSESSMENT**

The process of evaluating the competency to perform office-based procedures should be similar to the process followed for inpatient procedures. Procedures initially performed solely in an inpatient setting should only be converted to the office setting after the provider has demonstrated competency in an accredited operating room setting.

**COMMUNICATION WITH THE OFFICE TEAM**

A culture of safety requires the teamwork of all players in the medical office setting: physicians, nursing staff, midlevel providers, medical assistants, receptionists, office managers, and, of course, patients.

Office clinical staff can collaborate to review and agree on office policies and procedures. Just as grand rounds or quality improvement committees can bring a multidisciplinary team together in a hospital, regular meetings should be held with office staff. The medical
director should work with colleagues and support staff to tailor their practice’s adoption of patient safety and quality improvement principles.

COMMUNICATION WITH PATIENTS
Communication with the patient has paramount importance in the office setting. Because health literacy varies across the population, patients may require written or audiovisual educational materials as well as discussions with appropriate staff to promote engagement in their health care. In addition to the risks, benefits, and alternatives discussed with the patient through the informed consent process, office practices should inform patients of their rights and responsibilities. As part of any informed consent for the provision of general care or treatment, many practices include a patient bill of rights as well as a corresponding list of patient responsibilities.

ANESTHESIA SAFETY
The type and level of anesthesia should be dictated by the procedure with input based on patient preference. The decision regarding type of anesthesia should not be altered based on limitations of equipment or personnel in the office setting; rather, it should be based on patient needs in relation to the planned procedure. Such limitations might necessitate performing the procedure in an outpatient surgical center. Documentation of prescreening or selecting patients as candidates for office-based procedures is a crucial step in the process. Contraindications include, but are not limited to:

- Personal or family history of adverse reaction to a local anesthetic
- History of previous failure with local anesthesia or low pain threshold
- An acute respiratory process
- Substance abuse
- High-risk airway assessment/morbid obesity
- Abnormal blood sugars

The level of anesthesia will dictate the equipment and personnel needed, which can be outlined in the office policies and procedures:

- Level I (mild sedation/anxiolysis): Personnel with training in Basic Life Support should be immediately available until all patients are discharged home. Trained personnel and emergency equipment for cardiorespiratory support and treatment of anaphylaxis must be readily available.
- Level II (moderate sedation/analgesia): A minimum of two staff persons must be on the premises, one of whom shall be a licensed physician or licensed health care professional with current training in advanced resuscitative techniques (eg, Advanced Cardiac Life Support), until all patients are discharged home. Additionally, at least one physician must be present or immediately available any time patients are present. Emergency equipment, Advanced Cardiac Life Support medication, and trained personnel for cardiorespiratory support and treatment of anaphylaxis must be immediately available. Oxygen and suction should be available.4,5

The level of anesthesia achieved, not the agents used, is the primary concern regarding patient safety. Whether given orally or parenterally, narcotics and sedatives pose similar risks. Physicians administering or supervising moderate sedation/analgesia, deep sedation/analgesia, or general anesthesia should have appropriate education and training.

MEASUREMENT
Continuous quality assessment and improvement is essential for ensuring professionalism and patient safety in any setting. A measurement system (eg, written log, registry, database) should be maintained to evaluate processes as well as outcomes. Examples of process measures are in part specific to the procedure and might include equipment malfunction, compliance with checklists, adequacy of anesthesia and postoperative analgesia, and maintenance of sterile technique. Outcome measures should include intraoperative and postoperative complications.

Patient experience is also an important measure that may give insight into areas for improvement. Postoperatively, patients can be asked questions regarding satisfaction with the office personnel and procedures and whether the patient’s outcome and recovery met expectations. Patient satisfaction can also be assessed by a survey completed at the time of the postoperative appointment.

All significant complications should be carefully analyzed to determine and remediate any latent system errors. Results of these quality assessment measures should be recorded and periodically reviewed to evaluate trends that may suggest potential areas for improvement. A plan for improvement should be discussed and implemented, with results tracked to ensure the problem has been adequately addressed.

CHECKLISTS, TIME-OUTS, AND DRILLS
Just as in the aviation industry, checklists have been shown to improve outcomes in the inpatient setting.4,6 They are used for both routine and emergency procedures. Checklists will be based on the office policies...
and procedures that are developed and maintained by the medical director.

Preoperative checklists should include, among other items, a screening of patients for contraindications to specific procedures.

Intraoperative checklists should include documentation of the time-out, intraoperative medications, and alertness every 5 minutes if sedation is used. Postoperative checklists include documentation of vital signs, level of consciousness, pain control, and a discharge instruction sheet.

Drills and simulations are an integral part of high-reliability organizations, such as air traffic control, aircraft carriers, and nuclear power plants. They can be effective in preparing staff for emergencies that, although infrequent, could pose a high risk to the patient. Drills should be conducted at least quarterly so the entire office team can test, improve, and maintain knowledge and skills so that they do not panic during a true emergency.

Drills should focus on each person’s roles and responsibilities regarding their communication and interventions. For each drill, all staff should be present and their roles should be clearly defined. There should be a debriefing after every drill to review what was done well and what could be improved.

**OB-GYN OFFICE PRACTICE EVOLUTION**

The Task Force recognizes the changes necessary for a freestanding ob-gyn office to become able to provide ambulatory surgical procedures in a patient-safe environment. Many factors will influence a practice’s decision to perform ambulatory surgical procedures. The state in which the practice is located will have specific requirements, some of those relating to certificate of need. Accreditation for ambulatory procedures by organizations such as the Accreditation Association for Ambulatory Health Care may be required. The practice’s location and whether ambulatory surgical services are readily available in the community will be a factor. The volume of ambulatory surgery provided by the practice will direct the decision as to whether the practice should incorporate these types of procedures. Smaller 1:3 physician practices will need to evaluate the frequency of ambulatory procedures they currently perform in other settings before initiating surgery in their office setting. Larger practices, by number of providers or frequency of procedures, may find efficiency in developing an ambulatory surgical unit. These practices may evolve into having contracts for on-site anesthesia services. Careful evaluation of patient volumes, space and staff requirements, and potential practice efficiencies will help the practice to define its ambulatory goal or objective. Patients rightfully will expect the same level of service as would be expected at other accredited outpatient surgery centers.

**CONCLUSION**

Ultimately, all providers must incorporate patient safety into every aspect of office-based care. This is not the bar toward which we aspire; rather, it is the bedrock on which we build. It is critical to internalize these principles and express them daily. The Task Force was convened to consider the impact of the evolving health care environment on office-based procedures. The members struggled to create practical relevant methods for true behavioral change—to move from discussion to practice. The fundamental questions are:

- How will this change my office practice?
- What will it cost in time and financial resources?
- What constraints will prevent me and my colleagues from immediate implementation?

The forward pressures of technology and industry will continue to provide more opportunities for procedures to move into the office setting. In the hospital setting, physicians have been supported with institutional resources to create a safe surgical environment. Nevertheless, without a large infrastructure, electronic medical record system, or significant capital investment, office practices can begin with the following seven simple steps:

1. Designate a medical director with specific patient safety responsibilities.
2. Create a specific short training manual for all office staff.
   a. Import local hospital and ambulatory surgery center documents already available.
   b. Contact state and other regulatory bodies for requirements that must be met in your locale.
   c. Make this document available and mandatory reading, with sign-offs by all staff.
3. Create a mock drill and try one. (Don’t worry if it fails. Learn by doing.)
4. Create a checklist for one procedure and follow it closely; revise as indicated.
5. Survey and certify staff. (Who has Basic Life Support or Advanced Cardiac Life Support training?)
6. Carefully reexamine anesthesia methods and compare with published guidelines.
7. Discuss patient safety goals with each patient to create a safer environment for the procedure.
The Task Force hopes this summary increases not just awareness but also action in transforming the office into a safe haven for obstetrician–gynecologists and their patients.

REFERENCES