

*Report of the Presidential
Task Force on Patient Safety
in the Office Setting*



**The American College of
Obstetricians and Gynecologists**
Women's Health Care Physicians



April 2010

Dear Colleague:

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. It is the responsibility of obstetricians and gynecologists to be proactive and to ensure that a patient safety culture is ingrained in an office's daily operations.

The Presidential Task Force on Patient Safety in the Office Setting of the American College of Obstetricians and Gynecologists 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 an office medical director have myriad 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 and anesthesia.

The Report of the Presidential Task Force on Patient Safety in the Office Setting outlines activities and tools such as holding multidisciplinary team meetings, using checklists, conducting mock emergency drills, and implementing measurement and reporting systems that can easily be tailored and applied to any office practice.

The American College of Obstetricians and Gynecologists is pleased to provide this complimentary copy of the task force report. In addition, Office Surgical Safety Checklist tear pads are available for sale under inventory number AA545 from the College bookstore (sales@acog.org or (800) 762-2264).

Sincerely,

A handwritten signature in black ink, appearing to read "Douglas H. Kirkpatrick, MD".

Douglas H. Kirkpatrick, MD,
FACOG
President, 2008–2009

A handwritten signature in black ink, appearing to read "Hal C. Lawrence, MD".

Hal C. Lawrence III, MD,
FACOG
Vice President, Practice Activities

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Presidential Task Force on Patient Safety in the Office Setting (2008–2009)

Ty B. Erickson, MD
Elizabeth A. Buys, MD
Mark S. DeFrancesco, MD
Joseph C. Gambone, DO, MPH
Paul A. Gluck, MD

Douglas H. Kirkpatrick, MD
Sandra Koch, MD
Hector Vila Jr, MD
(American Society of Anesthesiologists)

Patrice M. Weiss, MD
Sue Woodson, CNM, MSN
(Association of Women's Health, Obstetric and Neonatal Nurses)

Staff

Hal C. Lawrence III, MD, Vice President, Practice Activities
Sean M. Curran, MPH, Director, Patient Safety and Quality Improvement
Sara Kline, JD, Deputy General Counsel

The clinical information contained herein is based on a variety of publications of the American College of Obstetricians and Gynecologists, which should not be construed as an exclusive course of treatment or procedure to be followed. The clinical information contained in this report is neither comprehensive in scope nor exhaustive in detail but rather is designed to provide general illustrations. The task force encourages the use of this report as a resource in developing local criteria.

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The American College of Obstetricians and Gynecologists
409 12th Street, SW, PO Box 96920, Washington, DC 20090-6920
www.acog.org

12345/43210

Report of the Presidential Task Force on Patient Safety in the Office Setting

Task Force Charge

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 setting.

Introduction

Patient safety includes activities designed to eliminate or mitigate any harm that could occur during the entire time that a patient remains in the care of a health care provider. Increased attention by educational and regulatory organizations has effectively elevated patient safety activities into the consciousness of all parties and stakeholders, including patients.

This task force seeks to reinvigorate the attention of clinicians on patient safety activities in the office setting. This practice setting has traditionally served as the home base for health care providers. An increasing number of invasive and potentially harmful procedures are migrating from the more highly regulated surgery center or hospital surgery units into the office setting. Regulation of office surgical procedures may be nonexistent, difficult to enforce, or resisted by the physician. It should be obvious, however, that once a patient has been invited into this office setting they have the right to expect the same level of patient safety that occurs in the more regulated hospital setting. Health care providers should expect some regulation and seek the help of all stakeholders to assist in establishing a safe, transparent environment for health care delivery. Major elements of office setting safety include effective communication, staff competency, medication error avoidance, accurate patient tracking mechanisms, anesthesia safety, and general procedural safety. Although all of these elements are important, the primary focus of this task force is on providing information and tools to create a safe environment for the introduction of invasive technologies into the office setting. The task force's highest priority is to assist Fellows in establishing physician and staff competency within an

office setting. In this document, we will define the office level according to the depth of anesthesia:

Level I—Local anesthesia with minimal preoperative oral anxiolytic medication

Level II—Moderate sedation

Level III—Deep sedation or general anesthesia

Rather than creating a finished product that may not apply in all individual office settings, we suggest integrating a patient safety culture into every standing committee, every agenda, and every educational opportunity provided to Fellows. This will allow for customization of safety policies, procedures, and practices in any office setting.

It is now well recognized that due to patient, physician, and payer preferences more invasive procedures will continue to move from the hospital operating room into an office setting. This trend creates the need for more robust and effective patient safety initiatives in the office. Establishing a safe environment for patient care in the office setting will require additional effort, expense, and training. On the other hand, these initiatives will be cost-effective by reducing the expense of correcting errors, increasing efficiency, and improving patient satisfaction.

Office Medical Director

Any facility performing outpatient surgical procedures should have a designated medical director. Similar to a movie director, the office medical director has the responsibility to verify that all participants are qualified and cognizant of their roles. They should assure that the set is prepared properly for any given performance. This requires teamwork from all participants: the receptionist, nursing staff, physicians, midlevel providers, and outside participants such as laboratory, pathology, and vendor services. In a solo practice, the physician should assume the role of medical director. In a group practice, one of the partners should be designated as medical director.

In very large practices, other individuals may assume some of the responsibilities listed below (eg, Director of Quality Assurance). The medical director verifies the qualifications and safety of people, equipment, space, and supplies which requires a full understanding of all elements necessary for the safe completion of a planned procedure. This document outlines many elements vital for safe practices; medical directors should familiarize themselves not only with the content of this document but also should expect to adapt the information and tools to their own needs. Holding regular team meetings and involving the collective efforts of all stakeholders should help ensure a safe environment for the performance of invasive procedures.

Checklists and drills are two vital tools assisting the medical director to ensure the safe practice of invasive procedures. In the next section, examples of both will be provided and each practice may modify the examples according to their unique clinical circumstances. Checklists with a box checked to verify completion of each step should be filled out for each procedure. This checklist format is used in the aviation industry for routine as well as emergency procedures. Emergency drills are done at least quarterly, so people can apply common sense, know their roles, complete their tasks, and not panic during a true emergency.

Checklists

(Italicized bullets are expanded upon further in the document.)

Office Set-Up Checklist

- *Comply with policy and procedure manual* (updated with the College's current *Guidelines for Women's Health Care*)
- *Provide patients' rights handout*
- *Provide informed consent materials and sign forms*
- Arrange for transfer agreement with nearby hospital
- Assure adequate equipment for level of anesthesia and analgesia, examples include:
 - Blood pressure and P/heart rate monitor
 - Pulse oximeter
 - Exhaled carbon dioxide monitoring for deep sedation
 - Reliable oxygen source
 - Suction
 - Resuscitation equipment including defibrillator
 - Cardiac monitor
 - Auxiliary electrical power source
 - Emergency medication

- Maintain, test, and inspect all equipment per manufacturer's recommendations
- *Ability to monitor level of sedation (see Anesthesia)*
- *Ability to rescue patient from excessive sedation (see Anesthesia)*
- *Quarterly mock drill*
- Compliance with state board of pharmacy and Drug Enforcement Administration
- Compliance with local building codes, fire codes, and the Occupational Safety and Health Administration
- Compliance with state and professional guidelines
- An Advanced Cardiac Life Support (ACLS), Pediatric Advanced Life Support (PALS), or Basic Life Support (BLS) certified physician or other health care professional immediately available to provide emergency resuscitation
- *Assure that an office-based surgery procedure record is available*
- *Adverse event reporting system*
- *Procedure outcome reporting system in place*
- *Credentialing and privileging of participating providers*

Preoperative Checklist

- *Meets office-based surgery requirements*
- *Meets American Society of Anesthesiologists (ASA) Physical Status I criteria or medically controlled ASA Physical Status II*
- Prescreening verification that the patient is a candidate for an office-based procedure. Contraindications include but are not limited to:
 - Personal or family history of adverse reaction to local anesthetic
 - History of previous failure with local anesthesia or low pain threshold
 - An acute respiratory process
 - Failure to comply with preoperative dietary restrictions
 - Substance abuse
 - High-risk airway assessment
 - Abnormal blood sugars
 - Pregnancy (unless procedure is pregnancy related)
- Document appropriate workup, patient selection, and informed consent
- No change in medical condition since previous office visit
- Preoperative vital signs
- *Current history and physical*
- Review and record all medications taken previously that day

- Confirm *nil per os* (nothing by mouth—NPO) status
- Confirm preoperative instructions followed
- Review allergies
- Confirm patient has an escort driver
- Document no change in patient's medical condition
- Confirm presence of any indicated lab work (eg, glucose level in a diabetic)

Intraoperative Checklist

- *Time-out* (verify provider, patient, surgical site, and procedure)
- Record intraoperative medications
- If sedation implemented, monitor and document oxygen saturation, blood pressure, pulse, and level of alertness every 5 minutes
- For hysteroscopic procedures, record cavity assessment per manufacturer's guidelines

Postoperative Checklist

- Record vital signs and ensure return to within 20% of baseline
- Document adequate level of consciousness, pain control, ability to tolerate liquids by mouth, and ability to void (if appropriate for the procedure)
- Discharge instruction sheet that includes how to recognize a postoperative emergency and steps to follow should one occur after discharge (eg, hemorrhage)
- Postoperative follow-up call within 48 hours
- Schedule appropriate postoperative follow-up appointment
- Record long-term outcome
- Record complications

Mock Drills

Drills should be conducted quarterly based on possible complications to ensure that all staff members are knowledgeable about their roles. For each drill all staff should be present (others such as front desk personnel are important and would have a role to call 911 or arrange for additional help), and their role should be clearly defined. Examples of mock drills included in this document can be used as templates to practice everyone's response in the event of unanticipated complications. Mock drills are a powerful way to ensure that all members of a patient care team are coordinated in the care of that patient. Each drill can be accomplished quickly. It is effective to have a team member role play a patient and act out the drills to help the entire team

accomplish the goal of handling a potential complication in a standard, step-by-step manner. There should be a debriefing following a drill to review what was done well and what could be improved next time.

Drills should be based on critical or frequent complications, resuscitation, or nonclinical situations (eg, intimate partner violence or environmental disaster). Drills should focus on individual roles and include the following responsibilities specific to each person:

- Communication
 - Call for help (within the office)
 - Notify front desk about incident
 - Front desk should prepare to dial 911 if necessary and wait for ambulance at entrance of building if 911 is called
 - Verbally confirm roles with others ("I will call 911" or "I will go wait outside")
 - Communicate situation with other patients or family members
 - Debrief with all office staff after patient recovers
- Interventions (dependent on the situation)
 - Place patient in supine position and elevate legs
 - Open and support airway
 - Check for pulse and blood pressure
 - Give fluids as tolerated

See "Mock Drills" for specific examples of drills that may be implemented.

Policy and Procedure Manual

The office manual should include all policies and procedures pertaining to office-based surgery.

Informed Consent

Informed consent is a process, not a signed form. Ultimately, the operating physician is responsible for assuring that the patient fully understands the risks and benefits of the proposed procedure as well as alternatives. In addition to discussing the specifics of the procedure in the case of surgery in the office setting, there should also be a discussion about the risks and benefits of performing the procedure in the office versus an ambulatory surgery center or hospital.

Written and audiovisual materials may be used as well as a discussion with a nurse or medical assistant to facilitate the patient's understanding. However, final consent for the procedure and the location must be a shared decision between the physician and the patient.

An additional element of informed consent focuses on the partnership between the patient and the health care

provider. These principles should be integrated into the informed consent process.

Patient Rights

Ideally, a practice should inform all 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.

In the accreditation process of virtually every ambulatory health care facility, the surveyor looks for a written patient's bill of rights including a corresponding list of patient responsibilities. These two documents should clearly inform patients of every right they can enjoy in the practice, as well as what the practice should expect from the patient.

Typical rights of patients include, but are not limited to, the right to:

- Privacy
- Being treated with dignity and respect
- Confidentiality of patient records
- Complete medical information about the patient's condition, prognosis, and treatment options
- Participation in decisions about care
- Fees and payment policies
- Access to services at the practice
- Any advance directive policies of the practice (especially if the practice chooses to not honor them)
- Information about the credentials of their health care providers

Typical patient responsibilities include, but are not limited to:

- Being honest and accurate when providing medical history information and information about the use of any medications, over-the-counter products, allergies, or sensitivities
- Following the treatment plan of the health care provider
- Informing the health care provider of any living will or medical power of attorney that might affect the patient's care
- Being responsible for any charges not covered by insurance
- Being respectful of the health care provider and staff

See "The Universal Patient Compact" for an example.

Anesthesia

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. Such limitations might necessitate performing the procedure in a more acute care facility. The level of anesthesia (light, moderate, or deep sedation or general anesthesia) will dictate the equipment and personnel needed.

All necessary medication should be in the room and immediately available before the onset of the procedure. Controlled drugs should be logged out from a secure location. A medication administration log (including the use of local anesthetic agents) must be maintained during the procedure.

A person responsible for administration of medication and monitoring the patient must be present in the procedure room. Depending on the level of anesthesia, this monitoring function might be assumed by a medical assistant, nurse, certified nurse anesthetist, or anesthesiologist. In all but the last case, these individuals must work under protocols with the surgeon assuming responsibility. Physicians administering or supervising moderate sedation or analgesia, deep sedation or analgesia, or general anesthesia should have appropriate education and training.

There should be a designated recovery area adequately staffed and equipped to assure that the patient has the level of monitoring appropriate for the procedure and anesthesia. For all but light (Level I) sedation, there should be oxygen and suction available.

If it is anticipated that any level of sedation may be needed, staff must confirm that the patient has an escort to drive the patient home before starting the procedure. No patient should leave the office following any level of sedation without an escort.

Please note the level of anesthesia achieved is the primary concern regarding patient safety and not the agents used (ie, oral versus intravenous medications). Whether given orally or parenterally, narcotics and sedatives pose similar risks. The patient should be evaluated for depth of sedation regardless of mode of delivery, including all the recommended monitoring equipment and procedures. Please refer to "Anesthesia" regarding the levels of sedation and anesthesia from the ASA.

In addition, a collaborative practice integrating gynecologic surgeons and anesthesiologists may emerge given the increasing migration of more complex invasive procedures to the office setting.

Procedure Outcome Reporting System

Continuous quality assessment and improvement is vital to assure the professionalism of the office and safety of the patient. A designated individual must be responsible for this activity. This might be the duty of the medical director or in large offices it could be another individual.

A log should be maintained to evaluate processes as well as outcomes. Examples of 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 as well as infection. Patient satisfaction is also an important outcome measure that may give insight to areas for improvement. The patient should be called one to two days following the procedure to assess for delayed complications. In addition, at that time the patient can be asked questions regarding satisfaction with the office personnel and procedures, wait times, and if the patient's outcome and recovery met expectations. Ideally this call should be made by a trusted member of the health care team experienced in patient advocacy, such as a nurse or physician's assistant. Patient satisfaction can also be assessed by a survey filled out at the time of the postoperative appointment.

All significant complications should be carefully analyzed by a multidisciplinary team to determine and remediate any latent system errors.

Results of these quality assessment measures should be recorded and periodically reviewed (monthly or quarterly based on the volume of activity) to evaluate trends that may suggest potential areas for improvement. A plan for improvement should be discussed and implemented, with the results tracked to be certain the problem has been adequately addressed.

Ability to Rescue Patient from Excessive Sedation, Emergency Medication, and Resuscitative Policy

These policies should be based on the ASA levels or other scale according to level of invasiveness.

1. Level I—Personnel with training in BLS should be immediately available until all patients are discharged home. Emergency equipment for cardio-respiratory support and treatment of anaphylaxis must be readily available (and in good working order) for those who are trained to use it.
2. Level II—A minimum of two staff persons must be on the premises, one of whom shall be a licensed physician and surgeon and a licensed health care professional with current training in advanced resuscitative techniques (eg, ACLS, PALS) until all patients are discharged home. Additionally, at least one physician must be present or immediately available any time patients are present. Emergency equipment, ACLS medication and trained personnel for cardio-respiratory support and treatment of anaphylaxis must be immediately available.

Time-Outs

Upon arrival to the office, each patient should provide:

1. Photo identification
2. Relevant insurance information
3. Relevant medical information

Immediately prior to beginning the procedure or administering any anesthesia, a time-out must be observed allowing each member of the medical team to verify:

1. That all relevant documents, imaging results, and lab tests have been reviewed and are consistent with each other
2. That all team members and the patient agree on the procedure to be performed and the exact location for it to be performed
3. That the incision site is marked in a way visible even after the patient is prepped and draped (as indicated by the specific procedure)
4. That this is the
 - a. Correct patient (using two independent identifiers)
 - b. Correct procedure
 - c. Correct site

Credentialing, Privileging, and Accreditation

The process of evaluating the competency to perform office-based procedures should be similar to the process followed for inpatient procedures. Physicians performing office-based procedures and the setting in which they will be performed should be subject to a system ensuring appropriate credentialing, privileging, and, in some cases, accreditation. Further, 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.

Credentialing, privileging, and accreditation—though often used interchangeably and loosely—refer to three very distinct, though related, events. This section will define each of the terms and explain how they interrelate.

Credentialing

Essentially, credentialing involves verifying that people are indeed who they purport to be. It involves:

- Verification of education and training, including medical school, residency, board status, and any other work experience.
- Primary or secondary source verification: relevant schools, hospitals, and agencies can be contacted to verify if the license is in good standing and to

identify any history of disciplinary action. Verification also may rely on accepted secondary sources such as web sites of the American Medical Association (AMA) or even state health departments and national resources like the Office of the Inspector General.

- Ideally, the National Practitioner Data Bank (NPDB) should also be queried since employed or partner physicians may develop unknown claims especially from pre-employment activities.
- There is an ongoing need to recheck the data on a regular basis, usually every 1–3 years. Some items, such as previously verified medical school, residency, and training will not change. However, peer review information, the National Practitioner Data Bank, and liability claims in process may indeed change.
- A credentialing system also should require notification of any material changes in credentialed health care providers' status. For instance, if their privileges are limited at the hospital or surgical center, this must be reported to the practice too. Likewise, a health department investigation of a complaint resulting in anything other than full exculpation needs to be reported.
- Initial credentialing should include at least one or two peer letters of support, indicating perceived skill levels and competence.
- For recredentialing, it is not unreasonable to forgo outside peer assessments if the health care provider does enough activity for the practice's quality assurance and risk management system to oversee the quality of the health care provider's work. This ongoing peer review data should be considered in recredentialing decisions.

Although the foregoing process may appear onerous, many practices are already doing a lot of these tasks, on behalf of hospitals, surgical centers, and managed care companies. Applications for initial credentialing include some or all of the following:

- Copy of current state medical license
- Copy of current Drug Enforcement Administration certificate
- Copy of the current cover letter for liability insurance indicating limits of coverage
- Copy of current delineation of privileges from a local hospital
- Copy of board certification (if applicable)
- Copy of any special certificates held (eg, laser)
- Current curriculum vitae
- Letter of recommendation from the Chief of Surgery or Division Chief

- Letter of recommendation from a surgeon, in the same specialty, who holds staff privileges at the institution
- Signature sheets for institutional policies (eg, Health Insurance Portability and Accountability Act, compliance program, or patient safety)
- Any fees

Privileging

Once the process of credentialing is complete, the health care provider's specific role description must be agreed on by the practice. In small practices, the governing body may be the partners themselves. In larger practices, an executive committee or even a board of directors assumes the role of a governing body. The governing body is responsible for privileging—actually delineating the specific procedures each health care provider may perform. Procedures initially performed solely in an inpatient setting should only be converted to the office setting after the health care provider has demonstrated competency in an accredited operating room setting.

Typically, privileging should entail:

- Verification of specific training in certain areas (especially procedures and skills that may be newer and were acquired postresidency)
- Verifying actual competence in performing those procedures
- Specifying procedures allowed (ablation, loop electrosurgical excision procedures [LEEPs], dilation and curettage [D&C] in detail)
- All procedures must be approved by the practice in order to perform them

A fairly complete list of procedures performed in the office might be found in a privileges list used in a local ambulatory surgery center or hospital outpatient department. See "Sample Privileging Form" for sample forms.

Accreditation

Accreditation refers to the practice or facility. There are several accrediting agencies that can be utilized. The list includes the Accreditation Association for Ambulatory Health Care, the Joint Commission, and the American Association for Accreditation of Ambulatory Surgery Facilities, and several others accepted nationally as bona fide accrediting agencies.

A practice may seek accreditation for various reasons but generally there are internal and external indications to pursue it. Internally, the accreditation process involves and augments a self-assessment process that looks critically at the practice structure and function and provides important consultative advice on how to improve processes to enhance the quality of care provided.

Externally, it is a seal of approval from a recognized authority that the practice meets high quality standards. In an age of increasingly consumer-directed health decisions, having a certificate in a waiting room and on any marketing material will help direct savvy health consumers to the office. Also, with respect to contracting with insurers, an accredited organization may be eligible for an enhanced fee schedule or at least argue successfully against more onerous managed care requirements like precertification of certain procedures.

The steps for the usual accreditation process include the following:

- An accrediting organization is invited to survey a practice or facility, applying its published standards to all aspects of the practice.
- The practice's physical structure, ownership, and legal status are reviewed.
- Policies, procedures, protocols, governance, and overall compliance with its own policies and protocols are examined.

Generally, the surveyor's role is to evaluate systems, point out strengths, as well as opportunities for improvement, and consult on methods for improvement. Sometimes quality of care is excellent, but is not documented properly.

Interrelationship of Credentialing, Privileging, and Accreditation

How do these three activities interrelate with respect to performance of outpatient procedures in the office setting? To a large extent, many practices perform the credentialing and privileging already, albeit informally.

For instance, when new physicians are employed, they must be credentialed by any hospital and outpatient surgical facility in which they will work, and also privileged by those entities to be allowed to do certain procedures.

Most likely, each practice already maintains a file for each physician and other collaborative providers of care like certified nurse-midwives, physician assistants, and advanced practice registered nurses. Those files include a current copy of licenses, continuing medical education certificates, and any additional certificates verifying specialized training (eg, nuchal thickness ultrasound training, tension-free vaginal tape or transobturator tape training, or laser use training) obtained since residency was completed.

To begin internal credentialing and privileging for office procedures, the practice would essentially use this existing information. A formal application process not only credentials the health care providers but also allows them to apply for specific privileges.

Credentials must be verified; this verification can be accomplished from secondary sources. There are web

resources (AMA or state and federal websites) that verify if a license is in good standing as well as show any formal complaints or actions taken against any licensed individual. Verification of credentials can also be done through documented communication with the affiliated hospital's credentialing office.

Once credentialing is done, the practice must decide whether the health care provider can be privileged to perform specific procedures. The acceptance of credentials and granting of privileges must be done by the practice's governing body, which can be the partners in a meeting or the board of directors if it is formally organized. Either way, formal minutes should be kept to document the decision.

Simply put, credentialing verifies that physicians or other health care providers are indeed who they say they are. Formal education, training, licensure, and board certification are verified.

Privileging, on the other hand, is the granting of permission to perform specific procedures in the practice. This should be as inclusive as possible. For instance, endometrial biopsy, colposcopy, ultrasound, LEEPs, endometrial or laser ablations of the cervix, Bartholin's incision and drainage, and anything typically found on a hospital privileging list should be included if it is anticipated to be performed in the office.

Peer review should be included by soliciting peers' opinions of the applicant's competence and should at least be done upon initial application for privileges. If the reappointment process includes ongoing peer review in the practice itself (by tracking outcomes, near misses, or adverse events and watching for outliers) separately polling peers may not be necessary.

Accreditation is something more practices may seek in the future. Many states already require it if certain levels of anesthesia are used in the office or facility—typically moderate sedation or deeper anesthesia will trigger this requirement.

Patient Safety and the Relationship With Industry for Procedures Conducted in the Office Setting

Technology has provided opportunities for minimally invasive procedures to move into the office setting. This requires training of personnel and maintenance of durable equipment involved. Industry should create and sustain a culture of safety for procedures and equipment they develop. Many companies have recognized this need and provide resources to maintain patient safety. This should include but is not limited to the following areas:

1. Training of surgeons to include didactic training and proctoring

2. Assisting surgeons in office set-up including safety protocols for the use of equipment
3. Providing help in credentialing providers in specific techniques
4. Providing requirements for safety protocols of sufficient strength prior to placement of devices into the office
5. Training of support staff that may assist in running equipment
6. Periodic evaluation and maintenance of durable equipment above simple reliance on warranty
7. Providing data sheets for ongoing evaluation of outcomes and safe practices including "near misses"
8. Providing checklists specific to procedures and equipment that are standardized and focused on patient safety
9. Helping offices establish mock drills specific to their procedures and equipment
10. Notifying current users of best practices and improvements as they become available
11. Providing detailed patient information to include relevant preoperative and postoperative care spe-

cifics that focus not only on the procedure but attention on safety

Industry should partner with providers in providing a safe environment for these procedures rather than relying solely on the physician to take the full responsibility.

Conclusion

The Presidential Task Force on Patient Safety in the Office Setting convened to consider the effect of a changing health care environment with specific reference to the increase of invasive procedures performed in the office. This document should be viewed as an attempt to increase the awareness of Fellows of the American College of Obstetricians and Gynecologists in becoming vigilant at creating a culture of safety relating to office practice. It provides suggestions and educational opportunities for improvement but should not be viewed as a standard. The goal should be to create an environment to address the solutions to each specific practice. The medical director should counsel with colleagues and supportive staff to individualize their own adoption of these principles. Ultimately, all health care providers must incorporate patient safety in all aspects of office-based care.

Mock Drills

At least one of these drills should be conducted quarterly, possibly on a rotating basis. They are based on possible complications, and are to ensure that all staff members are knowledgeable about their role should a complication occur. For each drill, all staff who participate in office surgery should be present, and the roles for each aspect of patient care and safety should be clearly defined.

These examples of mock drills can be used as templates for a simulation of an event, which is a powerful tool to ensure that all members of a patient care team are coordinated in the care of that patient. Each drill can be accomplished quickly. It is effective to have a team member role play a patient and act out these drills to help the entire team accomplish the goal of handling a potential complication in a standard, stepwise fashion.

1. Vasovagal episode
2. Local anesthetic complication
3. Cardiac event (myocardial infarction)
4. Allergic reaction
5. Uterine hemorrhage
6. Respiratory arrest
7. Excessive sedation

Vasovagal Episode

Description: Syncope, or fainting, is usually a transient loss of consciousness that can be associated with anxiety, prolonged fasting and dehydration, or allergic reactions to medications or systemic injection of local anesthetics.

Signs and Symptoms:

- Dizziness, light-headed feeling
- Loss of consciousness
- Nausea, vomiting
- Weakness
- Cool, clammy, and pale skin
- Decreased blood pressure and pulse

Treatment:

- Place patient in supine position and elevate legs
- Open and support airway
- Check for pulse and blood pressure
- Give fluids as tolerated
- Assess for possible allergic reaction to medications or systemic administration of local anesthetic and act accordingly (ACLS)
- Assess for level of consciousness then reassure patient

Disposition:

- If the patient can slowly sit then stand without dizziness, she may be discharged and instructed to seek medical follow up.
- Consider evaluation to rule out cardiac or neurological basis if suspected.
- Administer CPR and call 911 if the patient has swelling, loss of consciousness, or convulsions associated with low blood pressure.

Approved by:_____ Date:_____

Local Anesthetic Toxicity Reaction

Description: Toxicity reactions occur when local anesthetic is injected into the circulatory system. This results in cardiac depression, possible convulsions, and can lead to cardiac and respiratory compromise.

Signs and Symptoms:

- Cardiac depression: low blood pressure, slow heart rate (initially a fast heart rate if local anesthetic has epinephrine in it)
- Ringing in ears, metallic taste in mouth

Treatment:

- Place patient in supine position and elevate legs

- Optimize airway with head extension and jaw thrust and give oxygen by bag mask
- Be prepared to treat convulsions
- Monitor oxygen saturation, blood pressure, carotid pulse or listen to heart
- Start basic life support and call 911 if there is no pulse or heart tone

Disposition:

- Minor toxicity reaction:
 - The patient may have minor symptoms with no cardiac compromise
 - Do not give any more local anesthetic
 - The patient will recover without further treatment
- Major toxicity reaction with convulsions or cardiac compromise:
 - Call 911 for assistance with IV, CPR, and transport

Approved by: _____ Date: _____

Myocardial Infarction

Description: Patients with partial blockage of the coronary arteries may experience heart pain or angina pectoris when blood flow to the heart muscle is restricted. Should blood flow to the heart muscle stop completely, muscle damage will result in a heart attack or myocardial infarction.

Signs and Symptoms:

- Pallor, nausea, vomiting
- Weak pulse with irregular rhythm
- Chest pain, arm pain, back pain, or no pain

Treatment:

- Supplemental oxygen
- Monitor electrocardiogram for arrhythmia
- Nitroglycerin, sublingual, one or two pills every five minutes until chest pain relieved or onset of a headache
- Aspirin unless contraindicated

Disposition:

- Call 911. The patient should not exert themselves in any way. They should be transported immediately to the hospital.

Approved by: _____ Date: _____

Allergic Reactions

Description: Severe allergic reactions to drugs are rare. These reactions occur when a patient is given a drug that stimulates the immune system. A tiny amount of the drug may cause a severe allergic reaction or anaphylaxis, which can cause cardiac and respiratory compromise.

Signs and Symptoms:

- Minor: rash, wheals, itching, swelling (face, hands)
- Major: wheezing, if severe can cause respiratory distress
- Hypotension—low blood pressure
- Oxygen desaturation
- Rapid pulse, rapid breathing

Treatment:

- Minor:
 - Give supplemental oxygen and monitor oxygen saturation
 - Give diphenhydramine 1 mg/kg intramuscularly
 - Give albuterol × 3 puffs
- Major:
 - Give epinephrine 0.01 mg/kg intramuscularly
 - Give diphenhydramine 1 mg/kg intramuscularly
 - Give dexamethasone 0.5 mg/kg intramuscularly
 - Administer CPR and call 911

Disposition:

- Minor allergic reactions may be treated with diphenhydramine and albuterol and resolve on their own. The patient should be referred for medical follow up.
- Major allergic reactions are life threatening; administer CPR if required, and call 911 for assistance and transport.

Approved by: _____ Date: _____

Uterine Hemorrhage Causing Hypotension

Description: Blood pressure is more than 20% below baseline. Hypotension can be associated with acute blood loss, prolonged fasting and dehydration, or allergic reactions to medications or systemic injection of local anesthetics. If hypotension is the result of uterine bleeding, immediate action must be taken.

Signs and Symptoms:

- Dizziness, light-headed feeling
- Nausea, vomiting
- Fever, dry mouth
- Excessive vaginal bleeding
- Rapid heart beat

Treatment:

- Place patient in supine position and elevate legs
- Give fluids as tolerated
- Start intravenous line and administer normal saline
- Identify site and attempt to stop source

Disposition:

- If the patient can slowly sit then stand without dizziness and bleeding has stopped, she may be discharged and given follow-up instructions and appointment.
- Evaluate the cervix and vagina to assess for laceration or etiology of vaginal bleeding. If bleeding is uterine in nature and is excessive, immediately transfer to the hospital for further treatment and evaluation must ensue.
- Administer CPR and call 911 if the patient has continued bleeding, loss of consciousness, or convulsions associated with low blood pressure.

Approved by:_____ Date:_____

Respiratory Arrest Caused by Laryngospasm

Description: Laryngospasm is a protective reflex preventing foreign material such as water, saliva, or foreign bodies from entering the lower airway. In patients who are awake, laryngospasm is usually brief followed by vigorous coughing. In sedated patients, laryngospasm can be more prolonged with less coughing.

Signs and Symptoms:

- Increased respiratory effort with difficulty in exchanging air
- Noisy respiration (crowing)
- Respiratory retractions: paradoxical inward movement of the chest with inspiratory effort

Treatment:

- Stop the procedure
- Place head down and turn to side
- Use fingers to clear airway of solid material and suction for liquid material
- Administer positive pressure oxygen by bag and mask
- Optimize the airway with head extension and jaw thrust
 - The pain produced by this maneuver will frequently break the laryngospasm
- If air exchange is not improving, call 911 for assistance

Disposition:

- Temporary oxygen desaturation during laryngospasm is common. The majority of patients will recover without problems. Oxygen saturation should return to pretreatment levels within 10 minutes.
- Persistent oxygen desaturation (less than 90% for over 10 minutes) may indicate aspiration of foreign material or, rarely, negative pressure pulmonary edema. Referral for immediate medical attention is indicated.
- Administer CPR and call 911 if laryngospasm is complicated by seizures or bradycardia (heart rate less than 60 in a child or less than 30 in an adult).

Approved by:_____ Date:_____

Excessive Sedation (Hypoventilation)

Description: Shallow, slow breathing results in inadequate removal of carbon dioxide (CO_2) from the lungs. This is usually caused by sedatives, which depress respiratory effort or can cause partial airway obstruction.

Signs and Symptoms:

- Early symptom is the sedated patient is unresponsive to deep painful stimulation
- Mild accumulation of CO_2 will stimulate respiration back toward normal levels and is usually asymptomatic
- Severe accumulation of CO_2 will result in oxygen desaturation and depression of respiratory effort. It may be associated with labored breathing, sweating, or somnolence.

Treatment:

- Decrease level of sedation (stop sedatives)
- Optimize airway with head extension and jaw thrust
 - The painful stimulus will increase respiration
- Provide oxygen supplement with bag and mask if necessary
- Monitor oxygen saturation
- Give reversal agents naxolone 0.4 mg (for narcotics) or flumazenil 0.2 mg (for midazolam or diazepam)

Disposition:

- Most cases of hypoventilation will resolve without problems if the airway is maintained.
- Administer CPR and call 911 if hypoventilation leads to loss of consciousness or apnea (no respiratory effort).

Approved by:_____ Date:_____

The Universal Patient Compact

Principles for Partnership

As your healthcare partner we pledge to:

- Include you as a member of the team
- Treat you with respect, honesty and compassion
- Always tell you the truth
- Include your family or advocate when you would like us to
- Hold ourselves to the highest quality and safety standards
- Be responsive and timely with our care and information to you
- Help you to set goals for your healthcare and treatment plans
- Listen to you and answer your questions
- Provide information to you in a way you can understand
- Respect your right to your own medical information
- Respect your privacy and the privacy of your medical information
- Communicate openly about benefits and risks associated with any treatments
- Provide you with information to help you make informed decisions about your care and treatment options
- Work with you, and other partners who treat you, in the coordination of your care

As a patient I pledge to:

- Be a responsible and active member of my healthcare team
- Treat you with respect, honesty and consideration
- Always tell you the truth
- Respect the commitment you have made to healthcare and healing
- Give you the information that you need to treat me
- Learn all that I can about my condition
- Participate in decisions about my care
- Understand my care plan to the best of my ability
- Tell you what medications I am taking
- Ask questions when I do not understand and until I do understand
- Communicate any problems I have with the plan for my care
- Tell you if something about my health changes
- Tell you if I have trouble reading
- Let you know if I have family, friends or an advocate to help me with my healthcare

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Anesthesia

Anesthesia Contract Risks and Benefits

A significant element of office-based surgery is anesthesia. As described in the section on anesthesia, the level of anesthesia should be dictated by the type of procedure performed and the comfort of the patient. There is a wide range of options for anesthesia that may vary by patient, procedure, or both. There are many ways to deal with the complexity inherent in office-based surgery anesthesia, and all of them with the primary focus on patient preference, comfort, and safety. Some practices have found it to be advantageous to make use of a contract anesthesiologist. Following is a summary of the benefits and risks of this option.

Benefits

An advantage to having an anesthesia contract is that an anesthesiologist is able to devote full attention to the patient and the patient's anesthetic needs, while the surgeon is able to focus on the procedure.

An anesthesiologist has the ability to provide multiple levels of anesthesia during one procedure and for one patient if required. This allows for the variations in levels of sedation that may be required by different patients despite the procedure remaining unchanged. It would increase the

percentage of patients who would be appropriate for office-based surgery. A contract with an anesthesiologist could include the anesthesiologist's responsibility for the individual patient, monitoring equipment (minimizing start-up and maintenance costs in the practice), medications, and requirement that staff remain up to date with mock drills. This is a model used in other specialties for office-based procedures and may be utilized based on an individual office and community needs and availability.

Risks

The guidelines for the performance of office-based surgery outlined in this document for the administration of moderate sedation anesthesia are adequate to ensure patient safety. The use of an anesthesiologist to administer that standard is not required. Retaining a contract anesthesiologist may have a financial impact on the cost of the office procedure. The availability and need for this relationship will vary based on individual needs, state rules and regulations, and health care provider preference. A contract relationship with an anesthesiologist is not available in every community. There are some health care providers who are able to provide a procedure and uphold excellence in patient safety standards while providing adequate anesthesia in a safe and patient-centered way.

(continued)

Continuum of Depth of Sedation

Definition of General Anesthesia and Levels of Sedation/Analgesia*

(Approved by ASA House of Delegates on October 13, 1999, and amended on October 27, 2004)

	<i>Minimal Sedation (Anxiolysis)</i>	<i>Moderate Sedation/ Analgesia ("Conscious Sedation")</i>	<i>Deep Sedation/ Analgesia</i>	<i>General Anesthesia</i>
<i>Responsiveness</i>	Normal response to verbal stimulation	Purposeful** response to verbal or tactile stimulation	Purposeful** response following repeated or painful stimulation	Unarousable even with painful stimulus
<i>Airway</i>	Unaffected	No intervention required	Intervention may be required	Intervention often required
<i>Spontaneous Ventilation</i>	Unaffected	Adequate	May be inadequate	Frequently inadequate
<i>Cardiovascular Function</i>	Unaffected	Usually maintained	Usually maintained	May be impaired

Minimal Sedation (Anxiolysis) is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

Moderate Sedation/Analgesia ("Conscious Sedation") is a drug-induced depression of consciousness during which patients respond purposefully** to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

Deep Sedation/Analgesia is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully** following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

General Anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue*** patients whose level of sedation becomes deeper than initially intended. Individuals administering moderate sedation/analgesia ("conscious sedation") should be able to rescue*** patients who enter a state of deep sedation/analgesia, while those administering deep sedation/analgesia should be able to rescue*** patients who enter a state of general anesthesia.

*Monitored Anesthesia Care does not describe the continuum of depth of sedation, rather it describes "a specific anesthesia service in which an anesthesiologist has been requested to participate in the care of a patient undergoing a diagnostic or therapeutic procedure."

**Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

***Rescue of a patient from a deeper level of sedation than intended is an intervention by a practitioner proficient in airway management and advanced life support.

The qualified practitioner corrects adverse physiologic consequences of the deeper-than-intended level of sedation (such as hypoventilation, hypoxia, and hypotension) and returns the patient to the originally intended level of sedation.

ASA Levels of Sedation, 2004, is reprinted with permission of the American Society of Anesthesiologists, 520 N. Northwest Highway, Park Ridge, Illinois, 600668-2573.

Sample Privileging Form

(sheet 1)

*This sample application for privileges is provided for educational purposes only.
It may require modification for use in a particular facility.*

Outpatient Privileging

Delineation for Privileges for:	Credentialing Period:					
Practice Name:	Department:	Specialty:				
Clinical Category	Procedure Description	Approximate Volume in Prior Year	Amount Required	Requested	Inpatient Privileges Y N N/A	Medical Director Approval Y N N/A
<i>Cervix</i>						
	LEEP	_____	_____	<input type="checkbox"/>		
	Colposcopy cervix	_____	_____	<input type="checkbox"/>		
	Laser therapy*	_____	_____	<input type="checkbox"/>		
	Other:	_____	_____	<input type="checkbox"/>		
<i>Contraception</i>						
	IUD insertion	_____	_____	<input type="checkbox"/>		
	IUD removal	_____	_____	<input type="checkbox"/>		
	Tubal ligation*	_____	_____	<input type="checkbox"/>		
	Other:	_____	_____	<input type="checkbox"/>		
<i>Diagnostic Gyn ultrasound</i>						
	Gyn U/S	_____	_____	<input type="checkbox"/>		
	Sonohysteroscopy	_____	_____	<input type="checkbox"/>		
	Other:	_____	_____	<input type="checkbox"/>		
<i>Diagnostic Ob ultrasound</i>						
	3rd trimester OB U/S	_____	_____	<input type="checkbox"/>		
	1st trimester OB U/S	_____	_____	<input type="checkbox"/>		
	Other:	_____	_____	<input type="checkbox"/>		
<i>Excision of lesion</i>						
	Excision of lesion trunk or exrm	_____	_____	<input type="checkbox"/>		
	Excision of lesion genitalia	_____	_____	<input type="checkbox"/>		
	Other:	_____	_____	<input type="checkbox"/>		

Abbreviations: LEEP, loop electrosurgical excision procedure; IUD, intrauterine device; U/S, ultrasound; exrm, extremity.

*Denotes that procedure requires documentation of performance competency in an inpatient surgical setting prior to performing in an outpatient office setting.

Sample Privileging Form

(sheet 2)

Outpatient Privileging

Delineation for Privileges for: _____		Credentialing Period: _____								
Practice Name: _____		Department: _____		Specialty: _____						
Clinical Category	Procedure Description	Approximate Volume in Prior Year	Amount Required	Requested	Inpatient Privileges			Medical Director Approval		
					Y	N	N/A	Y	N	N/A
<i>Needle aspiration</i>										
	Needle aspiration of breast cyst	_____	_____	<input type="checkbox"/>						
<i>NST</i>										
	Nonstress test	_____	_____	<input type="checkbox"/>						
<i>Pessary</i>										
	Pessary fitting	_____	_____	<input type="checkbox"/>						
<i>Uterus</i>										
	Endometrial biopsy	_____	_____	<input type="checkbox"/>						
	D&C*	_____	_____	<input type="checkbox"/>						
	Hysterosalpingogram	_____	_____	<input type="checkbox"/>						
	Hysteroscopy*	_____	_____	<input type="checkbox"/>						
	Ablation*	_____	_____	<input type="checkbox"/>						
	Other:	_____	_____	<input type="checkbox"/>						
<i>Vagina</i>										
	Destruction of vaginal lesion	_____	_____	<input type="checkbox"/>						
	Vaginal biopsy	_____	_____	<input type="checkbox"/>						
	Laser therapy*	_____	_____	<input type="checkbox"/>						
	Colposcopy vagina*	_____	_____	<input type="checkbox"/>						
	Other:	_____	_____	<input type="checkbox"/>						
<i>Vulvar</i>										
	Destruction of vulva lesion	_____	_____	<input type="checkbox"/>						
	Vulvar biopsy	_____	_____	<input type="checkbox"/>						
	Laser therapy*	_____	_____	<input type="checkbox"/>						
	Hymenotomy	_____	_____	<input type="checkbox"/>						
	Perineoplasty	_____	_____	<input type="checkbox"/>						
	I&D of vulva or perineal abscess	_____	_____	<input type="checkbox"/>						
	Other:	_____	_____	<input type="checkbox"/>						

Abbreviations: NST, nonstress test; D&C, dilation and curettage; I&D, incision and drainage.

*Denotes that procedure requires documentation of performance competency in an inpatient surgical setting prior to performing in an outpatient office setting.

Office Surgical Safety Checklist

How to Use the Office Surgical Safety Checklist

- Review the checklist with your entire office surgical team. Assign each task to the appropriate staff member (eg, patient's escort driver is confirmed by the front desk staff or the preoperative time-out is performed by the physician). This may vary from office to office.
- Assign one person (ie, physician or nurse) as checklist coordinator to be responsible for confirming the tasks on the list with the assigned individuals.
- The checklist coordinator should confirm each task verbally with the appropriate office team member to ensure the appropriate procedures have been implemented and documented. If necessary, the checklist coordinator also can obtain initials from each of the assigned individuals to confirm completion of their respective tasks.
- If the task does not apply to the patient, the checklist coordinator should confirm this with the physician (eg, the use of imaging may not apply to all patients).
- The checklist coordinator should stop the office surgery team from progressing to the next phase of the operation until all tasks have been appropriately addressed. Ideally, any team member should feel comfortable to stop the procedure if they have safety concerns.
- The office surgery team should debrief to discuss modifications for future uses of the checklist. Removing tasks is not recommended.

Seven Starter Steps to Office Patient Safety

- 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 and perform a mock drill. (Try to do one every quarter, including one for CPR.)
- 4) Create a checklist for one procedure and follow it closely; revise as needed.
- 5) Survey and certify staff. (Who has Basic Life Support or Advanced Cardiac Life Support training?)
- 6) Carefully reexamine anesthesia and analgesia methods and compare with published guidelines.
- 7) Discuss patient safety goals with each patient to create a safer environment for the procedure.

Office Surgical Safety Checklist

Patient Name: _____	Primary Diagnosis: _____	Date: _____
Date of Birth: _____	Procedure: _____	
Preoperative (Before Anesthesia/Analgesia)		
<p><input type="checkbox"/> Patient identity, site (marked), procedure, and consent confirmed <input type="checkbox"/> Current history and physical on chart <input type="checkbox"/> All medications taken previously that day reviewed and recorded <input type="checkbox"/> Patient's escort driver confirmed <input type="checkbox"/> No change in medical condition since last office visit, if changed, indicate here: _____ <input type="checkbox"/> <i>Nil per os</i> (nothing by mouth—NPO) status confirmed <input type="checkbox"/> Preoperative instructions followed confirmed by patient <input type="checkbox"/> Known allergies reviewed <input type="checkbox"/> Any indicated lab work confirmed (eg, glucose level assessment in a diabetic patient or pregnancy test) <input type="checkbox"/> Preoperative vital signs documented <input type="checkbox"/> Pulse oximeter on the patient and functioning <input type="checkbox"/> Airway or aspiration risk assessed <input type="checkbox"/> Anesthesia and medication check is complete <input type="checkbox"/> Essential imaging is displayed</p>		
Preoperative (Before Incision)		
<p><input type="checkbox"/> Time-out (provider/patient/site/procedure) <input type="checkbox"/> Antibiotic prophylaxis given within 60 minutes of incision <input type="checkbox"/> Critical events anticipated: _____ <input type="checkbox"/> Critical or nonroutine steps _____ <input type="checkbox"/> How long case will take _____ <input type="checkbox"/> Anticipated blood loss _____ <input type="checkbox"/> Patient specific concerns _____ <input type="checkbox"/> Sterility _____ <input type="checkbox"/> Equipment issues</p>		
Intraoperative	Postoperative	
<p><input type="checkbox"/> Intraoperative medications recorded <input type="checkbox"/> If sedation implemented, oxygen saturation, blood pressure, pulse, and level of alertness monitored and documented every 5 minutes <input type="checkbox"/> For hysteroscopic procedures: _____ <input type="checkbox"/> Cavity assessment recorded per manufacturer's guidelines _____ <input type="checkbox"/> Fluid balance documented</p>	<p><input type="checkbox"/> Instrument, sponge, and needle counts completed <input type="checkbox"/> Specimen labeling confirmed <input type="checkbox"/> Equipment problems documented <input type="checkbox"/> Key concerns for recovery and management of patient documented</p>	
Discharge		
<p><input type="checkbox"/> Vital signs recorded and returned to within 20% of baseline <input type="checkbox"/> Adequate level of consciousness, pain control, ability to tolerate liquids by mouth, and ability to void (if appropriate for the procedure) documented <input type="checkbox"/> Discharge instruction sheet that includes how to recognize a postoperative emergency and steps to follow should one occur after discharge (eg, hemorrhage) discussed and given to patient <input type="checkbox"/> Appropriate postoperative follow-up appointment scheduled <input type="checkbox"/> Complications recorded <input type="checkbox"/> Follow-up call 24–48 hours after procedure assigned</p>		