CREATING A POLICY AND PROCEDURE MANUAL FOR AMBULATORY WOMEN'S HEALTH

TABLE OF CONTENTS	

To ensure a safe environment for the outpatient care of women, the principles of patient safety and quality care must extend into all services that a clinician provides in the office. Major elements of office setting safety include effective communication, staff competency, medication error avoidance, accurate patient tracking mechanisms, anesthesia safety, and general procedural safety.

Office based surgery has become increasingly common in ob-gyn practices in recent years. The office setting offers convenience for both physicians and patients, and can reduce the cost of surgical procedures traditionally performed in hospitals or outpatient surgery centers. However, regardless of location, it is the physician's responsibility to provide the same level of quality and safety when performing these procedures in the ambulatory office setting.

The purpose of this guide is to assist in the development of a policy and procedure manual for office based practice. This guide uses step by step directives to build a manual that can assist the office to define, monitor, and improve quality and safety within an office setting.

THE ROLE OF THE MEDICAL DIRECTOR

The Medical Director is responsible for the overall quality and safety of clinical care within the office setting and should be a key physician in the practice. The Medical Director is responsible for the overall clinical activities of the practice. The general responsibilities of the Medical Director in oversight of office based surgery are listed below:

- Credentialing providers within the practice
- Privileging providers for specific surgical procedures
- Development of clinical policies and procedures for office based surgery
- Development of quality outcome measures for surgical procedures
- Conducting quality improvement activities to monitor, measure, and improve the quality of office based surgery, which should include both process and outcome measures
- Peer review and procedural performance evaluation
- Review of adverse surgical events
- Development of a culture of safety for the office staff and health care providers

When creating your own policies and procedures manual, this section should contain:

- A written list of responsibilities of the Medical Director

CREDENTIALING, PRIVILEGING, AND SCOPE OF PRACTICE

All providers in a medical office should undergo a *credentialing* process that verifies their education, training, and work experience. Guidelines on credentialing can be found in the *ACOG Report of the Presidential Task Force on Patient Safety in the Office Setting*. All medical and non-medical staff should have a clear delineation of their scope of practice in their job description, and their credentialing files should reflect this scope of practice and skills competencies.

Staff providing assistance in clinical care (such as drawing blood, assisting with procedures, managing equipment-- including cleaning, etc.) should have a skills assessment and verification plan in their privileging file.

Physicians performing office based surgery should be granted *privileges* for specific procedures. Documentation of these privileges should include the date that privileges were granted, the number of cases performed during the past year for each surgical procedure, and the time period for which privileges will be granted. It is the responsibility of the medical director to periodically review the privileging status of each physician. Criteria to continue procedural privileges should take into account the number of procedures performed, any continuing education that may be required, and any adverse events that occurred during the observed time period.

This section of the procedure manual should contain:

- How the credentials of each health professional will be documented, updated, and available in the office
- Educational and/or training requirements for each surgical procedure performed in the office setting
- A *Delineation of Privileges* Form for each physician, documenting the privileges that have been requested and granted
- A skills competency form for each clinical staff member that details within their area of competency that they have fulfilled criteria for performance and/or assistance of specific procedures (blood drawing, assisting with LEEP, use of equipment, etc.)

QUALITY IMPROVEMENT AND PEER REVIEW

Continuous quality assessment and improvement, as well as an ongoing peer review process are vital to assure the professionalism of the office and safety of the patient. Ideally a single individual in the practice will be designated as medical director with ultimate responsibility for quality improvement and peer review activities. Larger group practices, in order to optimize engagement and broaden input into the program, should consider including several individuals to be responsible for parts of the program under the medical director. A recommended approach in these larger practices is to form a Quality Improvement/Peer Review Committee consisting of physicians as well as other clinical staff.

This section of the procedure manual should contain:

- Important quality indicators, which should be selected and monitored. Examples of such indicators might include (but not be limited to) process measures such as compliance with check lists, proper follow up on lab results and recalls, and other such processes. In addition, quality indicators can and should track outcomes to the extent possible. These may include intra-operative and post-operative complications as well as infection. Patient satisfaction is also an important outcome measure that can be monitored and may give insight to areas for improvement.

- A process for reviewing and developing new quality indicators periodically, and eliminating any which are no longer leading to improvements in outcomes in order to ensure that the quality improvement program is a continuous process.

- A process for tracking all significant complications as well as near misses (also known as "good catches") and a process by which they are subject to careful analysis to determine and remediate any latent system errors.

- A process for recording and reviewing results of all quality assessment measures (monthly or quarterly based on the volume of activity) in order to evaluate trends that may suggest potential areas for improvement.

- A process for discussing and implementing a plan for improvement, and then tracking results to be certain the problem has been adequately addressed.

- A process for communicating what has been learned through this process to all staff ("closing the loop").

- A process to review the activities of all providers on a regular basis (usually with re-credentialing, unless sentinel events or serious complications necessitate an interim review).

- A process whereby the results of the peer review process should be included in any re-credentialing decisions.

GENERAL POLICIES AND PROCEDURES FOR OFFICE BASED SURGERY

This section of the procedure manual should contain the policies, procedures, and supporting documentation to ensure a safe environment for all office based surgery.

This section of the procedure manual should contain:

- A **Compendium of Office Based Surgery** that lists the surgical procedures that may be performed in the office and the inclusion and exclusion criteria for each procedure
- A **Surgical Procedure Form** containing a detailed description of the equipment and supplies required for each office based surgical procedure
- A **Support Staff Roster** listing the nurses and medical assistants who have received training and demonstrated proficiency in assisting physicians in specific office based surgery
- A sample **Medication Log** to record medications that are dispensed for all office procedures. The log should document the date the medication was dispensed, the lot number and the expiration date for each medication.
- A sample **Equipment Maintenance Log** to record the dates that surgical, monitoring or resuscitative equipment was inspected and/or repaired
- An **Adverse Event Form** used to document any complications, near misses, or deviations from the safe performance of a surgical procedure
- The universal **Consent Form** used for all procedures
- The **Surgery Time Out Checklist**
- The **Postoperative Phone call Protocol**
- A description of the **Emergency Plan** for the office procedure for responding to surgical or medication emergencies, including roles and responsibilities of staff members
- Copies of a **Transfer Agreement** with a nearby hospital

SCHEDULING PROCEDURE

The practice should develop a scheduling procedure that is performed for all office based surgery. The following information should be submitted by the physician to the scheduler:

- Patient Name and at least two unique identifiers (e.g., date of birth and medical record number)
- Diagnosis
- Procedure (the description should be site specific)
- Any special equipment required
- Patient allergies

This section of the procedure manual should contain:

- Surgical Scheduling Form
  [If an outside anesthesiologist will be used, consider making this available]

PERIOPERATIVE NOTIFICATION AND PERIOPERATIVE INSTRUCTIONS

Each patient should receive written notification, describing the planned procedure and preoperative instructions. The patient should be given contact information so that they can ask questions about the planned procedure.

This section of the procedure manual should contain:

- **Preoperative Notification Form**
- **Preoperative Instruction Form** provided by the surgeon and documentation standards
- **Preoperative Anesthesia or Sedation Instructions** provided by the anesthesiology provider and documentation standards (if anesthesiology is involved)
- **Postoperative/ Post Anesthesia Instruction Form** and documentation standards including requirements for escort if appropriate and emergency contact phone numbers should complications ensue

INFORMED CONSENT

Informed consent is a process, not a document. It requires a review between the patient and the provider regarding the procedure, the risks and benefits, and the alternatives to this procedure. The provider should document that they have discussed the details of the procedure with the patient, as well as the risks, potential complications, alternatives and potential side effects. The patient acknowledges her understanding of this discussion by signing a written consent form relevant to that discussion.

This section of the procedure manual should contain:

- The general **Consent Form** and policies for completion
- Any standard patient information literature customarily provided to the patient (can be a **list of documents or pamphlets** available in the office)

ANESTHESIA POLICIES AND PROCEDURES

Depending on the type of procedure and the level of anesthesia required, the individual responsible for the administration of medications and patient monitoring may be a medical assistant, nurse, nurse anesthetist or physician. Unless the anesthesia provider is an anesthesiologist or a physician trained and credentialed for the level of sedation given, these individuals must work under protocols with the surgeon assuming responsibility.

This section of the policy and procedure manual should contain

- A list of individuals granted privileges to administer medications during surgery
- A sample copy of the medication log used to document dispensed anesthetic medications. The log should contain the date that a medications is dispensed, the lot number, and expiration date
- Preoperative Anesthesia or Sedation Instructions
- Protocols for preoperative and intra-operative administration of medications
- Anesthesia record that details the preoperative patient evaluation, intra-operative monitoring and medication administration, and postoperative monitoring
- A list of equipment and supplies required in the operating area for administration of anesthesia and patient monitoring
- A list of resuscitative equipment and supplies required in the postoperative recovery area for response to potential emergencies such as respiratory arrest
- Postoperative anesthesia protocols for monitoring in the recovery area
- Post anesthesia patient instructions

PERIOPERATIVE CHECKLISTS AND PROTOCOLS

I. PROCEDURE ROOM CHECKLIST

A pre-surgical checklist should be completed prior to the patient entering the surgical area. Like a flight checklist, the pre-surgical checklist should confirm that all necessary equipment and supplies are available and in working order and that all necessary medications are available and properly labeled.

II. PREOPERATIVE CHECKLIST (BEFORE ANESTHESIA/ANALGESIA)

Prior to initiation of anesthesia, the following procedures must be performed:

- Time out performed (patient identity, site, procedure, and consent confirmed)
- Confirmation that current History and Physical is on the chart
- All medications taken earlier that day are reviewed and recorded
- Patient's escort driver confirmed
- Confirmation that there have been no change in medical condition since last office visit (any changes should be documented)
- Confirmation of NPO
- Preoperative instructions confirmed by patient
- Known allergies reviewed
- Any indicated lab work reviewed
- Preoperative vital signs documented
- Pulse oximeter placed on patient and monitoring oxygen saturation
- Airway or aspiration risk assessed
- Anesthesia and medication check completed
- Essential imaging displayed

III. PREOPERATIVE (BEFORE INCISION/PROCEDURE)

Prior to incision or procedure, the following must be performed:

- Time out performed (patient identity, site, procedure, and consent confirmed)
- Antibiotic prophylaxis given within 60 minutes of the incision, if appropriate
- Critical events anticipated (see ACOG Office Surgical Safety Checklist)

IV. INTRAOPERATIVE CHECKLIST

During the procedure, the following must be performed:

- Intra-operative medications recorded
- Vital signs, oxygen saturation, and level of alertness monitored and recorded every five minutes

V. POSTOPERATIVE CHECKLIST

After a procedure, the following must be performed:

- Instrument, sponge, and needle counts completed
- Specimen labeling confirmed
- Equipment problems documented
- Key concerns regarding recovery and management of patient documented

VI. DISCHARGE PROTOCOL

Before discharging a patient, the following must be performed and documented:

- Criteria for discharge is established and documented
- Discharge instructions given to the patient
- Acceptable activities, activities to avoid, and warning signs are explained to patient
- Timing and method of patient follow up, including follow up phone contact, is explained to patient
- An escort is confirmed, if appropriate

SAFE CULTURE POLICIES AND PROCEDURES

In order to develop a culture where patient safety is a priority, all those involved in providing health care to women in the outpatient setting should be aware that the potential for errors exists systemically. Women's outpatient health care should be delivered in an environment where disclosure of adverse outcomes and errors is the norm and every person in the health care system strives to prevent these errors from occurring. According to the Agency for Healthcare Research and Quality (AHRQ), a safety culture refers to "a commitment to safety that permeates all levels of an organization, from frontline personnel to executive management. Frontline personnel should feel comfortable disclosing errors—including their own—while maintaining professional accountability". (1)

This section of the manual should contain the following elements:

- A policy describing the process for reporting errors, near misses, and adverse outcomes. The process should be clearly delineated and should involve a description of how to perform root cause analysis of the event. A system should be in place that allows any member of the health care team to report these events.
- A policy describing how the office will ensure a culture of safety through empowering all team members to speak up when they feel a situation is not safe.
- A policy on communication that includes a section on communication among members of the health care team, particularly surrounding patient handoffs, and may include team training to facilitate communication. This policy should also include a section on communication with patients, especially those who experience a medical error. The policy should discuss timing, content, communication, and documentation of this event.
- A policy on timing of regular staff meetings, to include all members of the office health care team, to discuss safety issues including any concerns that anyone wants to express. This should include specifications on how to document and distribute meeting minutes.

References:

ACOG Committee Opinion No. 447, Dec 2009, Reaffirmed 2015, *Patient Safety in Obstetrics and Gynecology*

MEDICATION MANAGEMENT

Outpatient medication errors are of paramount concern similar to the inpatient setting. Adverse events related to medications are common and most are preventable (1).

Offices should focus on the "**Five Rights of Medication Use"**

- Right Drug
- Right Dose
- Right Patient
- Right Route
- Right Time

To help ensure that these 5 rights for commonly used medications in the office as well as for prescriptions, the office may consider including policies concerning the following areas:

- inquiries about medications allergies and current medications (including over the counter medications and supplements) at each encounter
- Drug sample inventory and logging of all information regarding dispensed samples
- Documentation of all information relevant to injectable medications
- Inspection of all emergency medications for expiration date on a regular basis
- Secure locations for all medications
- Proper storage of medications requiring refrigeration or freezing
- Use of teach back techniques when prescribing medications

Clinicians should partner with patients and their families as needed to reduce errors. Verbal, written, and audiovisual methods should be used to provide a clear and simple message. Patients must know what the drug is treating as well as its potential side effects. A "read back policy" should be encouraged to ensure patient understanding of these instructions.

Patients should be encouraged to carry a current medication list and to bring their medications to their appointments. They should not expect all health care providers to share this information. Providers should not hesitate to avoid working in "silos" by communicating with members of the patient's health care team such as pharmacists, nurses, and consultants.

References:

1. Gandhi TK, Weingart SN, Sequist TD, Seger AC, Peterson J, Burdick, E, et al. Patient safety: adverse drug events in ambulatory care. NEJM 2003; 348:1556-64.

PATIENT RIGHTS AND RESPONSIBILITIES, INCLUDING PRIVACY AND COMMUNICATIONS SECURITY

Patients have a fundamental right to be informed of the privacy practices of the office as well as to be informed of their privacy rights with respect to their personal health information. Patients should be provided with a copy of the office Notice of Privacy Practices in accordance with the requirements of the Health Information Portability and Accountability Act. The office should check with their state board of health because some patient rights and responsibilities, including privacy and communication security requirements vary by state. Generally, the policy should contain the elements listed below.

This section of the manual should contain the following elements:

- A definition of confidential patient information such as any type of information- verbal, written, or electronic- that pertains to the treatment or care of an individual. This includes Protected Health Information (PHI)* as defined by the Health Insurance Portability and Accountability Act. The patient has the privilege and the right to confidentiality of medical information.

- The policy should contain a clear explanation of the patient's rights and organizational practices regarding use and disclosure of Protected Health Information.

- A description of the responsibility of each and every member of the office staff who in the course of his/her work is entrusted with patient information to respect patients' right to privacy, as well as a signed acknowledgement to reflect and document their understanding of the confidentiality policy and procedure.

- A description of the office policy and the patient's right as it relates to request for records transfer and to uses and disclosures made to people involved in a patient's care; as well as patient request for restrictions that may be applied to uses and disclosures of PHI that are related to treatment, payment, and health care operations.

- A description of the office procedure for reporting a violation of any of the policies or procedures regarding confidentiality of patient information; as well as any consequence as a result of violating such policy

- A description of the office procedures for communicating and reporting test results, treatment plans, and other general medical information to the patient. This may include a description of the methods of communication used by the office such as mail, e-mail, other electronic format, and telephone. This description should also include the methods used by the office to provide security and confidentiality for this information.

References:
Department of Health and Human Services, Federal Register, 45 CRF parts 160 and 164, Standards for the Privacy of Individually Identifiable Health Information; Final Rule. (HIPAA) 164.520

TRACKING POLICIES AND PROCEDURES

The provision of medical care requires testing and consultation as part of both health screening and diagnostic needs. To track patient compliance with consultations and test results, a practice needs to have a clear policy regarding what activities are tracked and a procedure to insure this is accomplished consistently with patient follow up as indicated.

The effective transmission of vital information between provider and patient is essential to improving patient safety and quality of care. Promptly notifying all patients of all lab, imaging, cytology, and pathology results avoids delayed or missed diagnoses and adverse events. This is true whether the results of any test or procedure were normal or abnormal.

Having a tracking log mechanism in place promotes improved follow-up with patients regarding lab, imaging, cytology, and pathology results, which will minimize the chances of a delayed or missed diagnosis and thereby minimize the possibilities for an adverse outcome, anxiety for the patient, and potential liability for the provider.

Coordination of care among multiple health care providers requires effective provider communication. Given that information can easily fall through the cracks between different outpatient offices, it is important to establish a system which promotes effective communication and therefore decreases the likelihood of an adverse outcome for the patient.

This section of the procedure manual should contain:

- Procedures for, and examples of, log sheets to track all ordered and/or performed testing within a practice. The policy should ensure results are received for all laboratory, pathology, and imaging testing.
- Methods to resolve situations when results have not been received.
- Process for notification of the patient of all test results.
- Policy for documenting patient notification or attempts to notify.
- Reminders procedure for follow up of abnormal results (e.g. pap smear, mammogram)
- Procedures for tracking communication to physicians who patients were referred to, and ensuring receipt of consultation from that physician back to the office.
- Procedures for tracking communication back to physicians who referred patients to the office for consultation or ongoing care.

ACOG Committee Opinion 546, Dec 2012, Reaffirmed 2014, *Tracking and Reminder Systems*

EMERGENCY MANAGEMENT AND DRILLS

The role of clinical emergency drills is to assure that in common or rare office emergencies, all staff are able to perform their roles, and provide the equipment and support needed without hesitation or delay. Clinical emergency drills and simulations often find significant gaps in care that cannot be identified without going through the motions and actions of an office emergency.

Clinical emergency drills should be performed in the office on a quarterly basis. All members of the health care team should participate, including those non-clinical staff that may be needed to communicate with emergency response teams and hospital emergency departments. Participation by all staff members will more likely result in a swift and effective response during a real emergency.

Examples of clinical emergeny drills are the following:

- Vasovagal episode
- Local anesthetic complication
- Allergic reaction
- Uterine hemorrhage (obstetric or gynecological)
- Respiratory arrest
- Excessive sedation
- Cardiac event (myocardial infarction)

Details of these clinical emergency drills are contained in the *ACOG Presidential Task Force on Patient Safety in the Office Setting*[1]

This section of the policy and procedure manual should contain:

- A list of clinical emergency drills that the office may want to practice. The drills that are selected should be relevant to the type of services being provided by the office.
- A log to document the date of drills and participants involved.
- A checklist of the technical and communication skills and procedures that should be demonstrated during each drill.
- A "debriefing" evaluation form to document "what went right, what went wrong, and what we can do better next time." Opportunities for improvement should be discussed by the entire team and followed up by the Medical Director.

In addition to clinical emergencies, office staff should also develop emergency plans for non-clinical emergencies, such as severe weather, electrical outages, and any other events unique to their local environment.

[1] *Presidential Task Force on Patient Safety in the Office Setting, ACOG, 2010*

The purpose of this guide is to assist in the development of a policy and procedure manual for office based practice. This guide uses step by step directives to build a manual that can assist the office to define, monitor, and improve quality and safety within an office setting.

The information contained in this guide should not be construed as an exclusive course of action or procedure to be followed. This manual is neither comprehensive in scope nor exhaustive in detail but rather designed to provide general illustrations. Variations and innovations that improve safety of patient care are encouraged rather than restricted.