Building a Better Safety Net

Taking the Safety Agenda to Office-Based Women's Health

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The recent focus on health care safety is a response to the central ethical tenet of medicine—to do no harm. The delivery of safe hospital care has led to demonstrable reductions in medical errors, adverse events, and patient injuries. These improvements have led to a commensurate reduction of legal risk and the emotional toll on caregivers as well as families. It also has reinvigorated the reason many physicians went into medicine—to make a difference for women's health. The new, voluntary Safety Certification in Outpatient Practice Excellence (SCOPE) for Women's Health program of the American Congress of Obstetricians and Gynecologists is a means to both evaluate and recognize work in a critical but often neglected arena—the outpatient setting. It builds on infrastructure created for safety programs in hospital settings. Strong physician leadership, the development of an office culture committed to safety, communication and teamwork skills, safety programs for office-based surgery, medication safety, and tracking systems are all important for safe treatment of our patients in the office setting. The SCOPE Program defines the necessary safety goals for ambulatory women's health care and provides an educational pathway to reach those goals. SCOPE certification is an achievement recognizing the commitment of physicians and their staff to the health and safety of their patients.

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The duty to "first, do no harm," a fundamental tenet of medicine, requires that we protect our patients from medical errors and preventable injury. After the publication of the Institute of Medicine report "To Err Is Human,"[1] hospitals implemented sweeping changes that improved the safety of women's health care in labor rooms and surgical suites across the country. However, patient-safety initiatives have received remarkably little attention in office practice, where physicians possess significant clinical autonomy and administrative control. The amount of care provided in physicians' offices is staggering: almost 1 billion ambulatory encounters occurred in U.S. physician offices in 2007.[2] Forty-eight percent of medical liability claims involve care within the office setting, a risk not fully appreciated by many physicians.[3] Patients, however, are cognizant of the frequency of office-based medical errors. The National Patient Safety Foundation reported in their patient survey that 22% of respondents believed a mistake had happened to themselves, a family member, or a close friend while in a physician's office.[4] The experience of a medical error can be damaging to a patient's trust in her physician and health care team. A survey of ambulatory care practices in North Carolina found that 14% of patients changed physicians after they believed a medical error had been made.[5]

Not only are our patients vulnerable to harm, but we are as well. When injuries inevitably occur–especially those that could have been prevented–we suffer from guilt, loss of confidence, and the stress of legal liability. It is time to define safety in office practice and begin implementing safety processes to prevent or mitigate adverse events. Until now, there have been no comprehensive safety programs that address the diverse clinical spectrum of ambulatory women's health.

SAFETY CERTIFICATION IN OUTPATIENT PRACTICE EXCELLENCE FOR WOMEN'S HEALTH

Safety Certification in Outpatient Practice Excellence (SCOPE) for Women's Health is a new, voluntary

program of the American Congress of Obstetricians and Gynecologists (ACOG) that evaluates safety processes within the outpatient setting. It was designed through the combined effort and review of many Fellows from diverse practice settings over a number of years. Direct pilot testing occurred in rural and urban practice sites and in solo and large group practices. The result is a certification program that sets office practice in obstetrics and gynecology ahead of other disciplines in the safety curve.

Certification is a two-step process, beginning with submission of a detailed written inventory of the office's existing safety program. This inventory reviews each of seven safety domains outlined by SCOPE for Women's Health (see Box 1), allowing the site an opportunity to self-correct any identified deficiencies. The second phase of the program sends trained reviewers onsite to validate the effectiveness of the office-safety program through interviews with office and medical staff, inspection of facilities and equipment, review of policy manuals and medical records, and education targeted to safety opportunities identified by the reviewer. The onsite review focuses on the office team and their consistent use of processes and procedures that enhance safety and is not intended to assess the clinical quality of individual patient care. Patient-safety deficiencies that are identified by the review must be corrected within a defined time period to achieve and maintain certification. Practice sites that successfully complete both phases are awarded a 3-year certification and are publically recognized by ACOG.

Box 1. Requirements for an Office-Safety Program

1. Designation of a medical director
2. Defining patient safety goals
3. Establishment of a culture of safety
4. Communication and teamwork
5. Surgical safety
6. Medication safety
7. Tracking test results and referrals

There is no cookie cutter approach to building a successful office-safety program. Although SCOPE for Women's Health specifies the essential elements needed to promote patient safety, it allows for flexibility in addressing the specific needs of each office practice. For example, a practice with a large nonnative English–speaking population may require an established onsite language interpreter program, whereas another practice may use a language line to fill the occasional need. A rural health clinic in a small community may use a manual tracking system to monitor laboratory tests, whereas a large multispecialty practice may have access to health information technology that will track laboratory tests electronically. However, each practice should be able to identify the individuals responsible for tracking test results and should have an established procedure to contact patients with normal or abnormal test results.

Designation of a Medical Director

There are seven clinical areas that are central to creating an effective office-safety program. A critical component of any program is the identification of a medical director. This individual is usually a key physician in the practice who is responsible for overall patient safety and should be identified clearly with that role. The medical director should be notified of all adverse events and should review each case to determine whether a preventable injury has occurred. Root-cause analysis and peer review are widely used in hospitals to identify the human and system issues involved in adverse events, and these processes also should be a part of the office-safety program. Another important responsibility of the medical director is completion of periodic audits to confirm that all office staff are compliant with established safety policies and procedures.

The increasing number of in-office gynecologic procedures requires that the medical director carefully review each physician's training and experience before the practitioner is allowed to perform them. A practice should have policies to grant surgical privileges using the same criteria that would be used in a hospital setting. Privileges should be granted for a limited time period, and periodic reviews of each physician's surgical volume, complications, and outcomes should be performed. The practice also may require a period of clinical observation or formal mentoring if a physician has little or no experience performing a procedure. Clinical privileges and ongoing competency evaluation should be granted for simple procedures such as intrauterine device insertion as well as more complex procedures such as hysteroscopic sterilizations. The privileging policies also should extend to advanced cognitive services, such as the interpretation of midtrimester ultrasound examinations, where the level of training and experience are important predictors of the frequency of diagnostic errors.

Defining Patient-Safety Goals

Physicians should cultivate an office environment in which concern for patient safety permeates all clinical interactions. The process of defining formal office-safety goals can promote a culture of safety by

identifying clinical objectives that are shared by all members of the team. Safety goals can be adopted from publications of national organizations such as the Joint Commission's Ambulatory Care National Patient Safety Goals.[6] These goals are applicable to most practice settings and have been shown to improve safety. Preventing infections by frequent handwashing and preventing mistakes during office procedures by performing "time outs" are examples of safety goals that are applicable to all obstetrician–gynecologist (ob-gyn) offices.

Establishment of a Culture of Safety

In an office that supports safe patient care, every member of the team should be able to report near misses and adverse events without blame.[7] "Just culture" acknowledges that competent and caring professionals make mistakes and may even develop "shortcuts" or routine "rules" or procedural violations in their practices. Most office-based medical errors are system failures, not individual failures, and a nonpunitive approach encourages staff members to report unsafe practices. The Agency for Healthcare Research and Quality Medical Office Survey on Patient Safety is a useful survey that can be completed by office staff in a confidential manner.[8] Patient satisfaction surveys also can provide valuable information about patients' perceptions of office safety and medical errors.

Communication and Teamwork

Communication errors are a leading cause of serious errors in all health care settings, and the medical office is no exception. A study of physician–patient communication conducted in office encounters demonstrated that patients were unable to completely articulate their chief complaint 72% of the time and spoke for an average of only 23 seconds before being interrupted by their physicians.[9] This breakdown in communication can lead to misdiagnoses and omissions of care. Miscommunication between physicians and their staff also can result in harm to patients. Examples of effective office communication include telephone messages that are dated, timed, and legible and documentation of a verbal verification of a medication order given during an office procedure. Training in Situation Background Assessment Recommendation (SBAR)[10] communication is another proven method of conveying clear and complete medical information among team members.

Patient care is a team endeavor. Teams make fewer mistakes than individuals, especially when every member of the team is aware of their responsibilities and the responsibilities of their teammates. The Joint Commission, the Institute for Healthcare Improvement, and the Agency for Healthcare Research and Quality encourage practice drills to promote teamwork and enhance communication among health care providers. TeamSTEPPS and Crew Resource Management are two examples of effective formal training programs.[11,12] Regardless of the method of training, practice drills and simulations can ensure that the entire team is ready when there is heavy bleeding after a biopsy, a surprise delivery in an examination room, or fainting during a blood draw. Practice simulations also may identify significant safety issues that might not be readily apparent under normal circumstances. For example, a mock drill of a syncopal episode may reveal that the office staff cannot locate the oxygen tank or cannot recline the phlebotomy chair. Corrective actions after mock drills can improve outcomes when the office staff is faced with a future emergency.

Office-Based Surgery

Office-based surgery offers convenience for both physicians and patients and has a lower cost when compared with a hospital or ambulatory surgery center. However, a 2003 study to evaluate the safety of office-based cosmetic surgery exposed the risks to patients when appropriate safeguards were not in place. The study identified a 10-fold increased risk of adverse events, including death, in the office setting compared with an ambulatory surgery center.[13] These findings resulted in a practice advisory that outlined office-surgery standards for patient selection, provider qualifications, surgical-facility requirements, and anesthesia guidelines for liposuction and other cosmetic procedures.[14] In 2010, ACOG recognized the growing interest by ob-gyns in office-based gynecologic procedures and published the "Report of the Presidential Task Force on Patient Safety in the Office Setting."[15] The report delineates guidelines that serve as a framework for conducting gynecologic surgery in an office setting. It includes specific recommendations on resuscitative equipment, anesthesia, equipment maintenance, preoperative checklists, and the universal protocol. All of these measures have reduced medical errors in hospitals and ambulatory centers and can be expected to promote an equally safe environment for office-based procedures. These are essential elements of the SCOPE for Women's Health program if office-based surgery is being performed in the office setting.

Medication Safety

Medications are dispensed or prescribed in 73% of all office visits.[2] Prescription medications are a common source of medical errors that can result in serious harm. A retrospective review of hospital admissions revealed that medication errors were associated with 13.1% of all preventable ambulatory adverse events.[16] A prospective study of ambulatory patients in a primary care clinic found that 25% experienced adverse drug events over a 6-month period.[17] Medication management in a medical practice is a highly complex activity, requiring transfer of information among patients, office staff, and pharmacies by fax, e-mail, electronic medical record, or phone. Errors in medication therapy can occur when there is a failure to document the medication usage or respond to a patient's reported adverse effects or when the medication is inadequately monitored.[18] Physician handwriting, a longstanding cause of prescription medication errors, can result in dispensing incorrect dosages or different medications altogether.[19] The office practice of dispensing medication samples is another potential cause of medication errors. In the absence of pharmacist involvement, the prescribing physician is responsible for identification of drug interactions and for providing written patient education to the patient. The office also is responsible for keeping a log of prescribed samples so that, in the event of a drug recall, patients at risk can be identified and contacted.

A number of electronic tools recently have been shown to reduce the risk of prescription-related adverse events. The use of e-prescribing systems within electronic health records has been shown to reduce the frequency of ambulatory prescribing errors by almost 50%.[20] These systems offer the advantages of online clinical support tools, improved legibility, and a reduction in "handoffs"–all of which can contribute to improving medication safety. Electronic prescribing systems also increase the accuracy of medication lists, which may reduce medication errors and adverse drug events. Written patient materials are readily available in an electronic health record and can improve patient compliance with prescription medications. Because the potential for medication errors exists in every women's health office, medication safety is an important component of a SCOPE for Women's Health review and should be a focus of attention in all office-safety programs.

Tracking Test Results and Referrals

An evaluation of the office tracking process is part of every review and represents a potentially serious gap in the office safety net. Although patients have a right to participate and make choices about their own medical care (autonomy), the physician has a responsibility to remind patients of recommended tests, treatments, and referrals[21] and to notify patients of test results. Tracking systems are essential office-safety tools that assist the physician in fulfilling this responsibility. A tracking system can be manual or electronic. It should have the date of a test or referral, a tickler system to confirm that the test was completed, a way to confirm that results were provided to the patient, and the ability to recommend additional tests or treatment if necessary. Tracking systems are also critical for monitoring time-sensitive diagnostic testing in obstetrics, including first-trimester genetic screening.

Patients should be notified of all laboratory results, not only abnormal results.[22] From the patient's point of view, a personal phone call from the physician is the preferred method of notification for abnormal test results. "No news is good news" is no longer acceptable. The medical–legal landscape is littered with examples of diagnostic delays and errors of omission resulting from this policy. Studies of closed malpractice claims listed "failure to diagnose breast cancer" as one of the three leading causes of claims in the office setting.[23,24] In one study, system errors involving failure to track diagnostic tests, call or monitor patients, and notify patients of abnormal results occurred in 27% of all diagnosis-related malpractice cases. Failure to notify patients regarding the need for cervical screening is also a potential source of error. Effective tracking systems will become even more critical as clinicians adopt the recently published recommendations for less frequent cervical cancer screening.

SUMMARY

Physicians have the responsibility to provide the same level of safety in an office setting as in a hospital setting. Although the medical conditions and the style of care may differ in each location, our obligation is equally firm regardless of the venue. Patients expect that their physicians and the care team that surrounds them will protect them from both human and systems errors. Breaches in medication safety, lapses in tracking of test results, and impaired communication can endanger patients as significantly as breaches in a surgical procedure. The office setting provides an ideal opportunity to integrate hospital-based safety-culture initiatives that can reduce the risk of adverse events and avoid malpractice claims.[25,26] These improvements will benefit not only our patients but also physicians and their staff. Engaging in activities that promote safety allows all members of the health team

to improve care creatively. Certification by SCOPE for Women's Health provides the ob-gyn with an opportunity to use a road map for office safety. Using this structured and educational approach, the office can achieve a level of safety that might be otherwise difficult to attain. Safety certification is an achievement that generates an increased sense of pride in our office practice by re-asserting our commitment to provide the safest care possible for the women we serve. It is time for all of us, as women's health providers, to take the lead in the effort to improve health safety continually in the office setting.

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