Chapter 1

Office Safety

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The clinician's office has continued to evolve in scope and complexity – both increase the risk of failed systems and reduced patient safety. The growth in office-based invasive procedures has resulted from a number of variables including technology innovation, economic and time pressures, and patient convenience. However, clinicians need not fail to provide a safe environment. Consider the following scenario.

> *After a careful history, physical and imaging workup for a patient with menometrorrhagia you elect, with the patient's consent, to proceed with an endometrial ablative technique. You discuss the options of an in-office versus hospital setting and the patient elects for the office procedure. The following week she arrives at the office and your staff prepares her and the procedure room for the ablation. You have administered an oral anxiolytic, NSAID, and an intramuscular injection of a narcotic. This "cocktail" template was provided by the representative from the equipment manufacturer for your procedure; you were told that the template is being used by many offices. You administer a paracervical block while waiting for the equipment to be prepared. Shortly thereafter the patient has a seizure, respiratory arrest, and codes. Mayhem erupts and people scramble to find the crash cart. Someone yells to call 911. You are in the middle of the procedure and are asking a medical assistant to find the oxygen tank for the patient, while you try to remove the equipment and move the patient from the lithotomy position to supine. No one is managing the airway.*

This scenario identifies core concerns in the following areas relating to in-office procedures: economic incentives, leadership, competency and assessment, anesthesia safety, and teamwork. A scenario such as this introduces the opportunity to emphasize practical corrective measures in advance, such as checklists, timeouts, and mock drills.

Why did you decide to perform the ablation in the office? Common responses could include patient familiarity, cost savings for the patient and her insurance company, or time savings in avoiding the hassles of checking into the hospital with its attendant inefficiencies. However, the most likely but often less-discussed reason for providing more in-office procedures is the financial incentive to you and your practice; the fee is not distributed to the hospital. This financial incentive for in-office procedures should be disclosed to the patient, and ethically your practice should not drive procedures to your office merely for economic gain.

Carefully select the right setting for the patient, taking into consideration risk elements such as health history, BMI, airway management risk, pain tolerance, etc. What governance do you have in your practice to determine the protocols and procedures you plan to incorporate in your office? Have you considered formal certification such as the American College of Obstetricians and Gynecologists Safety Certification in Outpatient Practice Excellence (SCOPE) program? This voluntary certification process, which can be reviewed at www.scopeforwomenshealth.org, has a robust pre- and post-evaluation of your office systems to assure improved safety with opportunities to have outside independent review. Another excellent opportunity to increase patient safety during in-office procedures is available at www.aaahc.org/en/accreditation. The Accreditation Association for Ambulatory Health Care has published a tool kit available for purchase titled "Accreditation Guidebook for Office-Based Surgery." As the leader in your practice, you should recommend accreditation from an outside body. Visit with your insurance carrier, as they may provide financial support with premium discounts to offset the cost. Also consider reinvesting some of the additional profit from performing the procedure in the office to accreditation, staff training, upgrading safety equipment (e.g., monitoring capabilities), updating your crash cart, and other safety initiatives.

The scenario above also demonstrates concerns regarding the competency of you and your staff. As

you integrate more invasive procedures into the office setting, safety initiatives must include the promotion of training and teamwork. Before bringing new technology into your office, verify individual competency by performing enough of the cases in the hospital environment under more careful supervision. A weekend course is simply not sufficient for your own credentialing. State regulatory agencies will continue to encroach on your office domain as more complications surface in the mass introduction of more and more invasive procedures. Create a core team of staff who understand the procedure you plan to perform. Even though they are not the actual clinician performing the procedure, they will be of greater value as a team if they have been instructed in the pathophysiology of the disease process, the actual equipment being utilized, and most importantly the risks of complications and how to mobilize as a team to manage such complications. Enlist assistance from the scheduling team to assure that all patients are advised of an absolute need for a driver with any procedure requiring sedation. By the same token, engage the manufacturer's representative to provide ongoing in-service on the equipment, maintenance, sterilization techniques, troubleshooting unusual case reports, etc. The company generally receives revenue from the disposables and they should be expected to become more engaged with your office training as part of their relationship with you. Leadership also includes the facilitation of an internal credentialing process for clinicians in your office with the same rigor a hospital medical staff would require.

Anesthesia risks are critical in the office environment. Oral administration of agents can create the same levels of patient anesthesia as parenteral usage. It is unethical to try and circumvent conscious sedation policies with an attempt at an oral cocktail. A decision tree allows you essentially two options. Door number one: choose to become fully competent in administration of anesthetics to your patients through training including comprehensive airway management, advanced cardiovascular life support (ACLS), and other specific pathways. Examine the elements that anesthesia personnel use in their profession including monitoring equipment, emergency medications, and ongoing training, and verify that you can provide comparable care. Door number two: create a collaborative relationship with an anesthesia group with experience in the office setting. These individuals often will bring all the equipment to your office and provide a full service program. This allows you as the surgeon to perform your procedure knowing a second individual is managing the airway, pain control, and providing a second eyes and ears to your team, helping to avoid any catastrophes. They can often bill the insurance company separately while still keeping rates below hospital costs.

Finally, how do you avoid the tension, yelling, and disorder when an emergency arises? Two extremely important tools are available – checklists and mock drills. The lead author of this article has extensive experience with checklists as a general aviation pilot. Prior to every flight a checklist must be followed to evaluate all the elements for a safe flight. This checklist is followed every time, and every element of the list must be checked off prior to flight. There are checklists for routine flight and in-flight emergencies and even the airplane has its own annual checklist for the mechanic. These checklists reduce the risk of a disaster in the air. Comparatively, clinicians will stave off numerous disasters and near-misses with the utilization of checklists for seemingly routine processes in the office. A critical component of the checklist is a timeout; pause and review identification of the correct patient with the correct procedure. Review consents, pertinent labs and diagnostics to assure safety and accuracy before beginning the procedure. For a complete source of checklist components, go to ACOG.org and review, under the heading Task Force and Work Group Reports, 2010 Report of the Presidential Task force on Patient Safety in the Office Setting. Mock drills are discussed later in the chapter.

Consider the following scenario.

A 25-year-old female presents for her routine OB appointment. While speaking to billing personnel, she develops chest pain and shortness of breath. She states she is just having an anxiety attack. The patient returns to the waiting room. Minutes later, the receptionist hears a call for help from another patron. The staff walks to the waiting room and finds the pregnant patient lying on the floor in respiratory arrest. After a rocky hospital course she finally recovers. Your malpractice company completes a risk-assessment profile of your office and identifies you need to establish an emergency response protocol. In particular, the protocol needs to guide staff on how to proceed in a medical emergency and specifically on the use of a crash cart and automated external defibrillator (AED). It is also recommended that periodic emergency drills be conducted and documented.

Emergency response protocols in the office setting are imperative to patient safety. Patients perceive

the office setting to be a safe environment where all personnel, both clinical and non-clinical, will have knowledge of how to handle any medical situation. Any delays in emergency treatment may be perceived as negligence. When performing in-hospital surgical procedures, clinicians are much more prepared to handle emergencies with clinical personnel at the bedside to respond. In contrast, an office emergency could be witnessed by any employee, including the receptionist or billing staff.

The roles and expectations of members in the response team are important. Empower staff to identify signs of impending emergency. Post signs at the check-in area for staff to identify common emergency symptoms including chest pain, shortness of breath or changes in breathing, pale skin, sweating, or profuse bleeding.

An overhead intercom system may be utilized to announce the location of the emergency. The clinic may want to apply a unique phrase to an emergency to reduce distress and flow amongst the other patrons in the clinic. Utilization of an emergency button, a simple doorbell installed at the receptionist's desk, may also aid in the early recognition of an emergency.

Basic CPR is a simple tool you can provide to your staff that provides extraordinary rewards. Not only will your staff be more empowered on how to respond to an emergency in the office, they can utilize those tools on a personal level when responding to emergencies in their homes and community settings. Other more advanced practitioners including physicians should be current in ACLS.

Keep a 911 card present at each work station or post information on the back of the employee badge. This emergency information should have the address and phone number of your clinic and the number of the nearest Emergency Department (ED). When calling 911, it is important to identify local landmarks by your location. For instance, "Our address is 101 Lincoln Ave; we are the first turn after the bridge on the right side of the road. We will meet you at the back of the building." When activating 911, the operator asks a list of standard questions which may include the name and age of the patient, the problem, and any current set of vital signs. Make your office staff aware of those questions and how to answer them accurately and quickly.

Develop a more integrative relationship with acute care facilities including the Emergency Department as a safety net for emergencies. Authorize the phone scheduler to routinely educate patients: "If your symptoms worsen or change prior to your appointment, please do not hesitate to go to the Emergency Department." Encourage your patients to be proactive in an emergency situation. For instance, when we review the acronym ACHES (abdominal pain, chest pain, headache, eye changes, shortness of breath) after starting women on oral contraceptives, for any positive response we advise the patient to go to the ED or contact EMS immediately rather than have them wait two days until an appointment is available. New federal meaningful-use standards encourage patients to receive a care summary. Encourage patients to carry portions of their healthcare record to improve safety particularly regarding medication concerns. A portable healthcare record or "passport" (even a simple note card) may be provided with update capabilities for an ongoing list of medical problems, medications, allergies, etc.

The goal of the written Emergency Response Protocol must describe the expected roles of each of the team members. Ideally, these expectations would be utilized and reviewed during a regular mock drill. Mock drills in the hospital setting have helped improve the handling of emergencies. Integrating such drills in the office is a natural extension of this tool. Develop an in-office protocol and conduct mock drills so the staff has clear expectations of their role during an emergency. Utilize the guidelines from www.justculture.org, which promote a workforce culture with a safe atmosphere [1]. Practice simulations will enhance team confidence and improve performance during office emergencies.

Practical suggestions on development of drills include focusing on a single issue such as respiratory arrest. Multiple system failures will be identified. Conduct drills in a limited time (e.g., 10–30 minutes). Have outside members of the staff, not included in the drill, take notes for debriefing and consider multimedia devices to record the event for playback. Emphasize learning and process analysis rather than criticizing team members. Allow time for feedback and discussion by all participants. The protocol will also vary depending on the amount of support staff available. Finally, the protocol will depend on environmental factors such as locale of the office to the ED. Many offices become complacent about their emergency response plan because of their close proximity to the ED or rapid EMS response times. The assignment of roles during an emergency will aid in the execution of an organized emergency response team.

Therefore, the following roles are suggested.

- **Reporter**: The person who initially identifies the emergency and verifies 911 has been called either directly or through the designated personnel.
- **Leader**: Designated clinical team member (usually a clinician). Each clinician within the practice must respond to the emergency. One will be designated as the leader. Each provider may be able to provide additional assistance including patient history and advanced skill sets including ACLS.
- **Nursing staff**: Obtains emergency kit, supplemental oxygen supply, AED, assists with CPR, acquires vital signs, prepares drugs for administration and completes Emergency Occurrence Report.
- **Recorder**: Keeps chronological log of events.
- **Runner**: Traffic control of other patients and responders within the clinic. Meets EMS and escorts them to patient.

Clear communication amongst the team members is crucial for success and cannot be understated. Guidelines from ACOG's Report of the Presidential Task Force on Patient Safety in the Office Setting outline each member's duty to call out their assumed roles and responsibilities [2]. After the emergency is recognized, call for help, and notify the front desk about the incident. Identify who will call 911, and who will meet EMS at the door. Often times, the person who has identified the emergency has the most information about the patient (reporter); however, they are usually the best suited to be at the site of the emergency. Have that person specifically give report to the runner to notify EMS personnel of the situation.

One of the authors of this article worked at a hospital with the addition of a new Emergency Department and Intensive Care Unit. The remodel also included a medical office building (MOB). Physicians were incentivized to move their practices. One day, a code blue was called on the overhead system in the MOB. There was no emergency response protocol established so EMS was activated and hospital staff attempted to respond to the emergency. Many problems ensued during the course of this incident. The hospital staff was not familiar with the layout and did not know where to go. EMS arrived and attempted to take the elevator. However, the gurney would only fit if the head of the bed was elevated, but the patient was not stable enough to elevate the head of the bed. A mock drill done prior to the incident would have easily identified these problems.

Review the Emergency Occurrence Form at the end of the drill. Components of the Emergency Occurrence Form include review of roles assigned to each of the members who respond to the emergency and assessment of clear communication amongst them. Was there any confusion or panic over roles and responsibilities assigned? Was equipment available to handle the emergency? Are there any modifications to the plan that would have assisted in the emergency?

Create a specific Emergency Response Kit. Simply having the medications and supplies available is not sufficient. The inherent increase in situational anxiety when an emergency occurs can contribute to disorganization. A regular review of the contents and use of mock drills is imperative. A checklist format including contents and expiration dates will make staff more familiar with the kit and will ease use during an emergency. The checklist should also include reporting on the functionality of equipment. When considering the contents of the kit, never include instruments or medications that the provider is not comfortable using. By the same token, never include medications within the kit for which you cannot monitor or manage the potential side effects. Store supplies in a central location. Depending on the size of the clinic, a single room may be designated for procedures. Ideally, however, the emergency kit must be as mobile as the emergency itself, as they may occur at various locations within the office.

Consider the following scenario.

> *A patient presents to the office with suboptimal rise of HCG levels from 5700 mIU/ml to 5800 mIU/ml over a 48-hour time interval. A transvaginal ultrasound is negative for an intrauterine pregnancy. You elect to use an injection of methotrexate. The patient signs a consent form and the nurse injects the dose. Fourteen days later the patient arrives in the ER in hypovolemic shock with a ruptured ectopic pregnancy. A root-cause analysis is performed at your office and you detect that an adequate medical history was not taken. You also identify that your new nurse had misread the label on the methotrexate bottle and had administered an excessive dose of methotrexate. You promptly fire the nurse and remind the remaining staff that such gross negligence will not be tolerated.*

A key safety discussion from this scenario centers on the process of patient tracking and follow-up. The use of methotrexate is off-label but appropriate for ectopic pregnancy. Patient follow-up is a subset of

the more global discussion regarding tickler files and data tracking. A robust tickler file system must be in place to track data and patient appointment follow-up including referrals to specialists. This process may be either physical or a computer system; the filing system must manage all paper or electronic inputs from internal and outside sources. If an "in basket" is utilized, time should be allocated for placement into the chart or scanned electronically. Reminder systems for appointments or follow-up test results should have elements such as pop-up windows or built in alarms. They may also include auto-generated email or text capability. If such automatic reminders are not available, then an external calendar and time clock reminder system should be established. The office should task a specific individual to monitor the tracking system. There should also be a back-up individual when someone is on vacation or leave. The delay of a week or even a long weekend may result in patient harm if someone is not clearly assigned to review the tickler files in the absence of the primary responsible party. This core concept holds particular validity with providers. Notification of a partner concerning a patient being treated for an ectopic and as in this case with levels that would suggest a higher than average failure rate is important to prevent the patient from hitting the ER with a ruptured ectopic. The responsibility of scheduling a follow-up visit rested not solely with the nurse but also with the clinician and checkout team, who should routinely verify if a follow-up visit is indicated. Additional elements of the data-tracking system should include:

- Sign-offs: All results including consults should be reviewed, initialed, and dated by the designated provider. Electronic medical records have capabilities to auto-perform this function; however, there is a risk of an electronic signature being completed without a follow-up assignment for an abnormal result.
- Verification of file management: Office managers should monitor the process and timely execution of the tickler system. You cannot simply assume once a process is memorialized that it will flow according to design. The oversight personnel should frequently review the tickler file and assign staff to verify timely and accurate handling of the data.
- Documentation evidence of patient contact: Always remember the end of the chain is the patient. Not only should they be contacted, but clear evidence of their understanding of the action plan and a method to verify compliance until resolution of all elements of the tracked data.

During your root-cause analysis you review the consent form that your staff had the patient sign. You observe it was hand-written on a generic form but did not include elements specific to the risk of off-label use of methotrexate. The consent process (we use the word *process* not *form*) is an important educational tool for your patients. This process helps define specifically the purpose of proposed intervention in your patient's life and well-being. Invasive procedures are planned, and a thorough review of all the pertinent elements in an understandable format will help the patient not only give consent but also become a part of the procedure including the recovery; for example, have the patient circle a mole on their body that they want you to remove. Review the purpose of the in-office sterilization or ablative procedure you propose with a robust dialogue of permanency. The educational steps you utilize (e.g., handouts, drawings, video or internet media) all contribute to the consent process. Memorializing this in written form protects you against future liability risks, but the process is more important than the form. It is imperative that you, the provider, engage in this process. Some elements can be delegated to staff, but the core discussion must come from the provider who will perform the invasive procedure or authorize the methotrexate injection as in this case.

It was noble that you used a root-cause analysis to evaluate where the system failed. A root-cause analysis includes the following elements:

- Intensely analyze the error
- Redesign system
- Test new design
- Educate staff on changes
- Follow-up on the new design
- Monitor over time as the staff and processes change in the office

Most errors in patient safety can be identified through effective examination such as a root-cause analysis. The primary purpose centers on identification of process or systems-level error and using the team approach to identify and implement changes going forward. This will provide a more permanent behavior change and will lead to improved safety practices

[3]. However, you failed to establish a just culture for your office. Unfortunately, we live in a society where people look to blame others for failures. The media screams "who is to blame?" Our world is filled with short sound bites; we live in a quick-paced environment wherein people want the blame to happen immediately – even before a thorough analysis of the problems emerges. You must restrain this temptation in your office. Teams will get nowhere with this culture of blame. A careful and thorough analysis with all members of the team will lead to a correct understanding of the process failure. Each office personnel should feel safe to honestly express their thoughts and concerns against a backdrop of protection for expression.

Beginning in 1976, as a result of a fatal accident in Washington, DC, the United States via the Aviation Safe Reporting System (ASRS) has been collecting confidential voluntary reports of near-misses from pilots, flight attendants, and air traffic controllers. The reports are provided to NASA, which acts as a neutral body with no enforcement power. An important cornerstone of this safety reporting system is the immunity and confidentiality provided to the person generating a report. This allows the aviation industry to review safety trends and create better systems for the aviation community. The Association of Perioperative Registered Nurses has implemented a similar concept called Safety Net covering near-miss reporting of medication, wrong site, communication, technology and consent issues. The Patient Safety Reporting System (PSRS) developed by the Department of Veterans Affairs encourages patient safety through voluntary confidential reports to NASA similar to the aviation industry.

In your office you need to create such a just culture of safety where your staff can report near-misses in a confidential protected environment [1]. As you collect near-miss data you will observe trends of risk and adapt processes to change the methods that will improve the safe transit of a patient through your office. We encourage you and your team to review the power of a just culture. ACOG's December 2009 *Committee Opinion 447* [4] discusses the importance of a just culture where mistakes may be admitted and corrected with an emphasis on non-punitive action. There will be the rare exception where an office employee harms a patient with disregard or has multiple near-misses that may require termination inasmuch as there is zero tolerance for reckless actions. Yet the primary emphasis centers on systems-thinking rather than attempting to assign individual blame.

Patient safety in the office or any setting requires the full cooperation of the entire team, but ultimately, you the reader of this book must light the torch and lead the way through the dark abyss ahead.

References

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