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Committee on Patient Safety and Quality Improvement

This document reflects emerging concepts on patient safety and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed.

Patient Safety in the Surgical Environment

ABSTRACT: Ensuring patient safety in the operating room begins before the patient enters the operative suite and includes attention to all applicable types of preventable medical errors (including, for example, medication errors), but surgical errors are unique to this environment. Steps to prevent wrong-site, wrong-person, wrong-procedure errors, or retained foreign objects have been recommended, starting with structured communication between the patient, the surgeon(s), and other members of the health care team. Prevention of surgical errors requires the attention of all personnel involved in the patient's care.

Potentially preventable surgical errors have received increasing attention in recent years, although they appear to occur relatively infrequently compared with other types of medical errors. The Joint Commission has collected data on reported sentinel events since 1995 with wrong-site surgery consistently ranked as the most frequently cited reason (1). In 2008, the year for which most recent data are available, there were 116 wrong-site surgery sentinel events reviewed. Although specialty specific statistics are not included on the Joint Commission's web site, no surgical specialty is immune from surgical errors (1). Classic examples in the specialty of obstetrics and gynecology include wrong procedures, such as tubal ligation without consent.

Terminology

The term *wrong-site surgery* is used to refer to any surgical procedure performed on the wrong patient, wrong body part, wrong side of the body, or at the wrong level of the correctly identified anatomic site (2). The following terms can be used to describe the various specific errors:

- Wrong-patient surgery describes a surgical procedure performed on a different patient than the one intended to receive the operation.
- Wrong-side surgery indicates a surgical procedure performed on the wrong extremity or side of the patient's body (eg, the left ovary rather than the right ovary).
- Wrong-level surgery and wrong-part surgery are used to indicate surgical procedures that are performed at the correct operative site, but at the wrong level or part of the operative field or patient's anatomy.

Systems Approach

Particularly because of the potential for serious harm from surgical errors, vigorous efforts are required to eliminate or reduce their frequency. Preventing a surgical error appears to be amenable to a systems approach involving a team effort by all individuals participating in the surgical process. Although all members of the surgical team share this responsibility, the primary surgeon should oversee these efforts. The Joint Commission has identified the following factors that may contribute to an increased risk of wrong-site surgery:

- Multiple surgeons involved in the case
- Multiple procedures during a single surgical visit
- Unusual time pressures to start or complete the procedure
- Unusual physical characteristics, including morbid obesity or physical deformity

A common theme in cases of wrong-site surgery involves failed communication between the surgeon(s), the other members of the health care team, and the patient. Communication is crucial throughout the surgical process, particularly during the preoperative assessment of the patient and the procedures used to verify the operative site. Effective preoperative patient assessment includes a review of the medical record or imaging studies immediately before starting surgery. To facilitate this step, all relevant information sources, verified by a predetermined checklist, should be available in the operating room and rechecked by the entire surgical team before the operation begins. A briefing is important for assigning

essential roles and establishing expectations. Introduction of each person in the operating room by name and role, even if team members are familiar, is recommended for improved communication. Whenever possible, the patient (or the patient's designee) should be involved in the process of identifying the correct surgical site, both during the informed consent process and in the physical act of marking the intended surgical site in the preoperative area. A formal procedure for final confirmation of the correct patient and surgical site (a "time out") that requires the participation of all members of the surgical team may be helpful. Time outs may include not only verification of the patient and the surgical site, but also relevant medical history, allergies, administration of appropriate preoperative antibiotics, and deep vein thrombosis prophylaxis.

Improving Patient Safety in the Surgical Environment

The Universal Protocol

In 2003, the Joint Commission published "Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery" (2). The universal protocol, now included in the chapter on national patient safety goals in the Joint Commission's accreditation manual, involves the completion of three principal components before initiation of any surgical procedure (3):

1. Preprocedure verification process

The health care team ensures that all relevant documents and related information or equipment are

- available before the start of the procedure;
- correctly identified, labeled, and matched to the patient's identifiers; and
- reviewed and are consistent with the patient's expectations and with the team's understanding of the intended patient, procedure, and site.

The team must address missing information or discrepancies before starting the procedure.

2. Marking the operative site

Procedures that require marking of the incision or insertion site include those where there is more than one possible location for the procedure or when performing the procedure would negatively affect quality or safety. According to the Joint Commission, the site does not need to be marked in cases where bilateral structures (such as ovaries) are removed (3). Although the Joint Commission does not require a specific site marking method, each facility should be consistent in the method it uses ensuring that the mark is unambiguous. Only the correct site should be marked; an "X" or "No" should never be used on the wrong site.

3. Performing a "time out" before the procedure

The operative team conducts a final assessment that the correct patient, site, and procedure are identified, recog-

nizing that this is problematic in emergency situations, such as an emergency cesarean delivery.

World Health Organization Surgical Safety Checklist

Another useful tool to promote patient safety in the surgical setting is the surgical safety checklist published by the World Health Organization. The checklist is based on the successful international program "Safe Surgery Saves Lives," which incorporates validated checklists to be reviewed by the surgical team before induction of anesthesia, before skin incision, and before the patient leaves the operating room (4). It is inappropriate to place total reliance on the surgeon to identify the correct surgical site or to assume that the surgeon should never be questioned. The risk of error may be reduced by involving the entire surgical team in the site verification process and encouraging any member of that team to point out a possible error without fear of ridicule or reprimand.

Patient Involvement

A relatively new but essential element of the overall process is the formal enlistment of the patient in the effort to avert errors in the operative arena. Involving the patient in this manner requires personal effort by the surgeon to educate the patient during the preoperative evaluation process. The patient, who has the greatest stake in avoiding errors, thus becomes integrally involved in helping ensure that errors are avoided.

Granting Privileges for New Procedures

New techniques and new equipment are important components for developing and delivering the best quality care in the operating room, but they also represent sources of potential surgical error. Whenever possible, a surgeon who is incorporating a new surgical technique should be proctored or supervised by a colleague more experienced in the technique until competency has been satisfactorily demonstrated. In some circumstances, however, a technique may be so innovative that no other surgeon at that facility has more experience. In such situations, it may be necessary to require reciprocal proctoring at another hospital or grant temporary privileges to someone from another hospital to supervise the applicant. The surgeon performing the procedure should have already documented skills and experience in the related surgical arena.

When new equipment is introduced, all members of the surgical team must be trained on and practice with the new equipment as appropriate for the extent of their involvement, and all personnel involved must be aware of all safety features, warnings, and alarms of the device. Whenever possible, the institution's medical engineering department should inspect the equipment and verify that it is functioning properly before the equipment is put into clinical use. Any informational material (eg, user manu-

als, operating instructions) provided by the manufacturer of the equipment should be carefully reviewed by the principal users and should be familiar to anyone using the equipment. Labels attached to the device or plastic cards summarizing instructions for proper use may be helpful until everyone involved is comfortable with the new equipment. All necessary adaptors, attachments, and supplies should be in the room or readily available before beginning surgery with the new equipment. Any recommended protective devices, such as eye shields or special draping material, should be used for the safety of all concerned. The lead surgeon using the new equipment should have demonstrated competency in the use of the device, resulting in the granting of privileges. Leaders of each surgically oriented department will determine the specific requirements for granting privileges to their members for the use of new techniques or equipment. It is never appropriate for nonmedical, noncredentialed individuals, such as industry representatives, to perform the actual surgery. Such individuals should be excluded from the operating room if their presence would present a distraction or discomfort for any member of the essential operating room team. Additional information on requests for new privileges can be found in *Quality and Safety in Women's Health Care*, 2nd edition.

Stress and Fatigue

A well-recognized source of human error is excessive stress and fatigue. According to the Health and Safety Laboratory, Britain's leading industrial health and safety facility and an agency of the British Health and Safety Executive, disrupted sleep patterns and inadequate sleep can result in fatigue and reduced levels of cognitive performance thus increasing the risk of an accident. Human error arising from fatigue may have catastrophic results in safety critical environments (5). Sleep deprivation can cause errors in performing even the most familiar tasks; for example, the National Highway Traffic Safety Administration reports that sleepy drivers cause at least 100,000 automobile accidents annually in the United States, resulting in approximately 40,000 injuries and 1,500 deaths (6). For this reason, many industries have already imposed strict limitations on working hours for individuals in vulnerable occupations, such as truck drivers, airline pilots and crew members, air traffic controllers, and power plant personnel. The Accreditation Council on Graduate Medical Education has enacted restrictions on resident work hours to prevent sleep deprivation, stress, and fatigue that might increase the risk of error (7, 8). Although no legal restrictions have yet been imposed on the work hours of physicians in clinical practice, common sense dictates that the surgeon and the surgical team should be alert and well rested when initiating major surgical procedures. Emergency situations may be particularly hazardous as an environment for error, especially if the surgical team is stressed and fatigued already. A recent study that examined the risk of

complications by attending physicians after performing nighttime procedures found an increased rate of surgical complications when physicians had slept less than 6 hours (9). Adequate backup personnel should be available to relieve individuals who detect diminished performance in themselves or others due to fatigue, so that the risk of error is not increased.

Medication Errors

The surgical environment deserves heightened vigilance to prevent medication errors because medication orders often are given verbally rather than in writing, making such orders particularly vulnerable to misinterpretation or misapplication. Increased stress or confusion during urgent situations in the operating room may increase the possibility of error in prescribing, administering, or monitoring medications. For these reasons, medication error in the surgical arena may not be addressed by the safety measures (eg, electronic order entry) proved effective in other environments. It may be wise for the surgical team to agree on protocols for administering commonly used medications or treatments and to practice their implementation. Timely and effective communication between the surgical and anesthesia teams, including read backs as necessary, during the entire procedure may help avoid errors that could result from misunderstanding.

Retained Foreign Objects

The Joint Commission includes unintended retention of a foreign object in a patient after surgery or other procedure as a reviewable sentinel event (10). In its statement on the prevention of retained foreign objects after surgery, the American College of Surgeons recommends consistent application and adherence to standardized counting procedures and documentation of the surgical counts, instruments or items intentionally left as packing, and actions taken if count discrepancies occur (11). Other protocols to prevent unintentional retention of foreign objects during surgery and vaginal delivery have been developed. For example, the Institute for Clinical Systems Improvement's protocol suggests that sponges, needles, and sharp instruments are counted before and after surgery and vaginal delivery. Only radiopaque sponges and soft goods should be placed on surgical trays or delivery fields. If the counts at the end of the case are either incorrect or compromised, then an abdominal or vaginal examination must be performed. If the counts are still not reconciled, radiographic imaging for retained foreign objects will need to be obtained (12).

Teaching

Trainees, such as obstetric–gynecologic residents, surgical residents, anesthesiology residents, medical students, nursing students, and operating room technician students, may be part of the surgical environment in the operating room or labor and delivery suite. The education process in these environments presents special challenges

in protecting patient safety. It is a fundamental principle that all trainees must be meticulously supervised and assisted when participating in surgery. Both the trainee and the supervisor should be alert, well rested, and well prepared in advance for the surgical procedure being performed. Because patient safety depends on effective communication among all members of the health care team, trainees should be conversant in the pertinent terminology before starting the procedure. The presence of noninvolved individuals as observers in the operating room or delivery suite may be a distraction to the surgical team and, therefore, should receive careful consideration before they are admitted. The current development of virtual surgery training techniques may become useful for students to learn and practice surgical skills before attempting procedures in the operating room.

Obstetric Surgery

Operating on pregnant patients creates unique responsibilities in ensuring patient safety because two or more patients are involved simultaneously—the woman and the fetus(es)—each with different needs. Adequate personnel who will ensure proper attention to the condition of each patient must be present. Particular attention is needed to address administration of the different medications appropriate for the pregnant patient and her fetus(es) or the newborn patient(s), such as dosage and timing of antibiotics or analgesics for mother or newborn(s) or both. The obstetric surgeon also needs to communicate with a pediatrics team in a timely and effective manner to reduce the possibility of error in care of the neonate. The occasional use of blood transfusion opens another potential avenue for introduction of error because calling for the administration of blood products may take place under especially stressful and hectic conditions. Checklists and protocols for massive transfusion in the event of significant obstetric hemorrhage are recommended for labor and delivery units. Much obstetric surgery is by nature unplanned as the course of the delivery unfolds, and obstetric emergencies can progress rapidly, increasing the possibility of error if protocols and standardized procedures are skipped or abbreviated.

Freestanding Surgical Units

In recent years, many surgical procedures traditionally performed only in hospitals or similar institutions have increasingly been performed in physicians' offices or freestanding surgical facilities. This trend has produced cost savings and convenience for patients as well as health care providers and will likely continue. However, because these facilities may not be subject to the same level of scrutiny or administrative oversight as hospitals, surgeons who use these facilities must be particularly vigilant against inadequate training of personnel, inappropriate or poorly maintained equipment and instruments, and ineffective protocols or practices, all of which may increase the likelihood of medical error and jeopardy

to patient safety. According to the American College of Obstetricians and Gynecologists' Presidential Task Force on Patient Safety in the Office Setting, patients have the right to expect the same level of safety regardless of where they seek treatment (13). This task force also notes that 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 surgical center—typically moderate sedation or deeper anesthesia will trigger this requirement (13). Such requirements will likely improve the quality and safety of care provided in these settings.

Distractions

Beepers, radios, telephone calls, and other potential nonessential activities and distractions in the surgical environment should be kept to a minimum, if allowed at all, especially during critical stages of the operation. Just as pilots maintain "sterile cockpits," a Federal Aviation Administration regulation requiring pilots to refrain from nonessential activities during critical parts of a flight, all members of the operating room team also should postpone nonessential conversation until surgery is finished (14). Similarly, it may be preferable to ask nonessential personnel to remain outside the operating room while surgery is being performed. Everyone on the team is mutually accountable for minimizing distractions.

Conclusion

Although medical errors can occur in any aspect of medicine, the surgical environment presents additional, special challenges to safeguarding patient safety. Because these injuries can be serious, particular care is appropriate in creating checklists, systems, and routines that reduce the likelihood of wrong-patient, wrong-side, wrong-part surgical errors, and retained foreign objects. Along with these tools, communication among members of the surgical team is crucial throughout the surgical process, particularly during the preoperative phase. The wide variety of techniques, instruments, and technology used for surgical procedures makes granting privileges of surgeons critically important. Freestanding surgical units may need to be particularly vigilant in ensuring that personnel and equipment are in good condition for surgery. Protocols and procedures to identify and manage stress and fatigue in surgical personnel may help to avoid surgical errors and patient injuries. The operating room is an appropriate educational environment, but the presence of observers at any level must not be allowed to compromise patient safety. Patient safety in surgery demands the full attention of skilled individuals using well-functioning equipment under adequate supervision.

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