7. Surgical Timeout and Retained Foreign Bodies – Patient Safety in the Operating Room

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There has been much debate about patient safety after the release of the landmark report *To Err is Human: Building a Safer Health System* in 1999 by the Institute of Medicine (IOM) [1]. The authors report 44,000–98,000 deaths per year due to medical errors in the United States. The IOM called for more than 50% decrease in the number of deaths within the 5 years following that publication establishing goals and strategies to achieve this result. These goals include: (1) Establishing a national focus to create leadership, research, tools, and protocols to enhance knowledge. (2) Identifying and learning from errors by developing a nationwide, public, mandatory reporting system, and by encouraging healthcare organizations and practitioners to develop and participate in voluntary reporting systems. (3) Raising performance standards and expectations for improvements in safety through the actions of oversight organizations, professional groups, and group purchasers of healthcare. (4) Implementing safety systems in healthcare organizations to ensure safe practices at the delivery level.

As surgeons, we are potentially intimately involved in some of the errors that are among the most costly to individual morbidity and mortality. More globally, there are institutional and healthcare costs, societal losses of productivity, and other factors due to medical errors. Patient care in any setting from outpatient clinic encounters to ambulatory care centers to intensive care units can be subject to medical errors. The hospital units where errors are *most* likely to occur, and to cause an adverse event, are the intensive care units, the emergency room, and the operating room [1]. In the operating room, these errors include wrong site surgery and retained surgical foreign bodies. Although there are other possible errors such as lack of equipment availability, equipment failure, poor knowledge of patient history, lack of surgeon preparation, fire, medication administration errors, and others, they are beyond the focus of this chapter [2].

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Wrong Site Surgery and the Universal Protocol

What is wrong site surgery? In the literature, the term *wrong site surgery* usually encompasses the breadth of wrong patient, wrong site, and wrong side surgery. A procedure is considered wrong site surgery if the operation begins at the wrong site, even if the error is identified and corrected by the end of the operation without apparent injury. For example making an incision on the opposite side, even if only through the skin and recognizing this and then performing the correct surgery is still considered wrong site surgery. Wrong site surgery has been included in the list of "Serious Reportable Events"(SRE) (Table 7.1) by the

Table 7.1. Serious Reportable Events, National Healthcare Quality Report, Agency for Healthcare Research and Quality, 2007.

Surgical Events
Surgery performed on the wrong body part
Surgery performed on the wrong patient
Wrong surgical procedure performed on a patient
Unintended retention of a foreign object in a patient after surgery or other procedure
Intraoperative or immediately postoperative death in an ASA Class I patient
Product or Device Events
Patient death or serious disability associated with the use of contaminated drugs, devices or biologics provided by the healthcare facility
Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than is intended
Patient death or serious disability associated with the intravascular air embolism that occurs while being cared for in a healthcare facility
Patient Protection Events
Infant discharged to the wrong person
Patient death or serious disability associated with patient elopement (disappearance)
Patient suicide, or attempted suicide, resulting in serious disability while being cared for in a healthcare facility
Care Management Events
Patient death or serious disability associated with a medication error
Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA incompatible blood or blood products
Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility
Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility

(continued)

Table 7.1. (continued)

Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates
Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility
Patient death or serious disability due to spinal manipulative therapy
Artificial insemination with the wrong donor sperm or wrong egg
Criminal Events
Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
Abduction of a patient of any age
Sexual assault on a patient within or on the grounds of a healthcare facility
Death or significant injury of a patient or staff member resulting from a physical assault (i.e., Battery) that occurs within or on the grounds of a healthcare facility
Environmental Events
Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility
Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances
Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility
Patient death or serious disability associated with a fall while being cared for in a healthcare facility
Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility

National Quality Forum, a nonprofit organization composed of public and private healthcare consumers, hospitals, physicians, nurses, healthcare technology companies and other quality research groups with the goal of improving healthcare [3, 4]. Beginning in 2003, The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has required reporting of SRE or sentinel events for root cause analysis. Root cause analysis is a method of thoroughly investigating all of the thoughts and actions which preceded the adverse event to identify the true underlying cause, which if corrected may prevent the event in the future. Although there are several methods to complete an analysis or investigation, the analysis is typically conducted *after* an adverse event. When used appropriately by a team experienced in these methods, it can also be an important *preventive* tool that a healthcare system must utilize to mitigate hazards and prevent recurrence.

The Universal Protocol was initiated by the Joint Commission Board of Commissioners to prevent wrong site, wrong procedure, and wrong patient procedures. This was in response to continuing and increasing occurrences of wrong site, wrong procedure, wrong patient surgery as well as several high visibility cases [5]. The protocol was created in 2003 and implemented in 2004. It was further revised in 2009 after obtaining endorsement and consensus from groups including the American Medical Association, American Hospital Association, American College of Physicians, American College of Surgeons, American Dental Association, and the American Academy of Orthopaedic Surgeons and other leading professional associations [6]. The three principle components of the Universal Protocol are conducting a pre-procedure verification process, marking the procedure site, and performing a time out before the procedure [6].

The incidence of wrong site surgery is unknown. Due to the concerns for litigation and inconsistent reporting, current national estimates probably underestimate the true occurrence of wrong site surgery. Near misses and wrong site surgeries without drastic consequences are also unlikely to be included in these estimates. Yet extrapolated data from malpractice claims during a 20-year period estimate that one wrong site procedure occurs in 112,994 total procedures performed, while other studies estimate one in every 15,000–30,000 procedures performed [3], or in busy hospitals one case in every 5–10 years [7]. The most described wrong site surgery is actually wrong side surgery. Reports demonstrate 50% or more of wrong site surgeries are performed on the incorrect side, only 11–15% of procedures are the wrong procedure, and only 3–13% of procedures are performed on the wrong patient [3, 7]. It is estimated that a surgeon who operates on bilateral structures has an almost 25% lifetime risk of wrong site surgery in their career [3, 8].

Numerous factors have been identified that may increase the risk of wrong site surgery. These frequently include multiple surgeons participating in the same operation. Also, multiple procedures during one operation, or other factors such as time pressures, emergency surgery, abnormal anatomy, and morbid obesity increase the risk of wrong site surgery [9]. An inordinately large number of insurance claims have been identified with orthopedic cases, but this percentage must be weighed with the volume of cases and frequent laterality of procedures. Additionally, wrong site surgery occurs with some frequency in spine cases where the wrong vertebral level is operated on. This has prompted specific protocols to properly identify the proposed vertebral level in spine surgery [10]. This is particularly germane to minimally invasive

surgeons who provided laparoscopic access to the chest or retroperitoneum for spine surgery. Other cited factors identified in individual root cause analyses include poor communication, competing tasks assigned to OR personnel, unusual equipment or setup, staffing problems, and changes in nursing staff during the case, all of which underscore the importance of the accurate flow of information [4, 5, 11].

In the ensuing years after implementation of the Universal Protocol, and particularly the surgical timeout, evidence of decreased medical errors and decreased patient deaths has not been realized to the extent the authors of the IOM report required [2, 3, 9, 10]. There have been various degrees and inconsistent implementation of the IOM recommended strategies to achieve their stated goals and there has been little evidence that the goals have been achieved. Much speculation is published about the reasons for failure; inaccurate reporting systems, infrequent occurrence of such events and others. Gawande et al. [2] believe that we are not using the appropriate tools to evaluate success. In an effort to interpret currently published data the authors explain that if one looks only at the absolute decrease in number of individual deaths or decrease in preventable injuries, implementation of the Universal Protocol has not been effective. The success, however, of the Universal Protocol, may be better appreciated if you evaluate additional important outcomes, such as evidence-based improvement in quality and performance of the healthcare system as a whole or improvements in statistical lives saved, a method of looking at improved outcomes in a broad population. This may be more difficult to measure in a quantitative way, and the outcomes will not necessarily be observed immediately, but there is some evidence already that these outcomes are improving.

In 2008, in an effort to further improve patient safety and postoperative outcomes the World Health Organization (WHO) expanded upon the Universal Protocol. A 19-point checklist was suggested in their Safe Surgery Saves Lives Campaign/Global Patient Safety Challenge. Briefly, the checklist includes three portions: (1) a surgical *sign in* prior to the induction of anesthesia where the patient's identity is confirmed and the patient risk is assessed and the perioperative plan is discussed, (2) a *time-out* prior to incision confirming patient identity, team member identification, antibiotic administration, critical events, and (3) a *sign-out* before the patient leaves the operating room which discusses handling of the specimen, correct documentation of the procedure performed and key findings. In an effort to validate the WHO recommendations, the Safe Surgery Saves Lives Study Group designed a study to evaluate the effectiveness of the checklist. This was a multi-institutional, multinational

study set in eight cities with prospectively collected data on processes and outcomes. The primary endpoints included the rate of complications and death during hospitalization and over the following 30 days. The study found an average of 36% decrease in postoperative complications and deaths over all of the sites [12, 13]. This expanded checklist is not yet a JCAHO requirement, but many institutions such as the Cleveland Clinic Florida have begun using the checklist in the operating rooms.

As the name implies, Universal Protocol is applicable to all surgical procedures. How the protocol is implemented depends on the nature of the surgery and the institution's regulations. For laparoscopic and endoscopic surgeons, there are many opportunities to observe the surgical timeout and implement changes which may improve patient safety and eliminate wrong site surgery. These may range from reviewing operative strategy with OR staff preoperatively reviewing pertinent radiography and running through the operative procedure with the other operating staff and assistants. Additionally, discussing equipment needs preoperatively is particularly important in laparoscopic procedures which require very specialized equipment, e.g., energy devices, staplers, assistant requirements, etc. Confirming tumor location and preoperative endoscopic marking in patients with colon cancers or polyps, and requiring the primary surgeon to be present for and to assist with patient positioning may be other strategies to consider. The post-procedure time-out or debriefing is another important opportunity in laparoscopy. During this time, the team has the assignment to review equipment malfunctions, inspect the instruments that were used and discuss any events or near misses which delayed, complicated or improved the case. It is important to foster an environment in the operating room of patient safety above all else. This process levels the traditional hierarchies to create an environment where any team member is encouraged and expected to speak up and appropriately discuss any concerns he or she may have about patient safety and specifically wrong site surgery. This must be a top-down process in order for it to be effective and requires the surgeons to champion this process.

Retained Foreign Bodies

Another important patient safety issue that involves surgical patients is postoperatively retained foreign bodies. Retained foreign bodies have long been described in medical literature, including instruments,

retractors, needles, and laparotomy pads in any and all cavities. The first case reported was a lost "sea sponge" in 1859 [14]. Since then this topic has been the subject of much debate, literature, and litigation. The most commonly reported retained foreign body is either a 4×4 gauze sponge or a laparotomy pad. No surgical specialty and no operative field are without risk for retained foreign bodies. There have been reports of sponges found years after spine surgery, as well as retained foreign bodies in the eye, the mandible, the chest, and most commonly the abdomen and pelvis, including the vagina.

Retained foreign bodies can manifest in many different ways depending on the object left behind and the cavity or site in which it is retained. Given that more than half of foreign bodies are left in the abdomen, abdominal pain and or mass is the most common presentation. About 50% of abdominal retained foreign bodies become symptomatic, with symptoms including the aforementioned abdominal pain, erosion into the bowel or vessels, abscess formation, fistula formation, obstruction, or bleeding. [15]. Needles and sharps may also be retained in the patient, but there are fewer reported cases. Needles smaller than 13 mm are difficult to identify on plain radiographs; however, it has been suggested that needles of this size are rarely symptomatic and clinically relevant. [14]. Although foreign bodies have been found up to 30 years after being left in the patient, or even at autopsy, the median time to discovery is less than 1 month after surgery [16].

Since 2005, JCAHO mandates reporting of retained foreign bodies. It requires hospitals to perform a root cause analysis after each sentinel event. The incidence of retained foreign bodies is reported at approximately one case per 8,000–18,000 operations, or about one case per year in a busy institution [7, 10, 14]. As with wrong site surgery, the actual incidence is likely much higher in reality for the following reasons. Despite the JCAHO reporting mandate, many retained foreign bodies are either not discovered, discovered much later or are not reported due to fear of litigation or loss of public confidence and lost revenue. That is why it is important to maintain a certain level of suspicion if a patient has unexplained complaints after an operation, even after many years. Currently, computerized tomography (CT) is the best imaging method to detect items inadvertently left behind [14, 15]. It is not, however, without its limitations. Sponges or needles can be mistaken for calcifications, wires, or surgical clips. Surgical instruments are retained less frequently, but can be more easily identified on plain radiographs or other imaging.

After the 1999 IOM report *To Err is Human* and the increased awareness about patient safety, there has been a lot of effort placed on

determining the factors that increase the risk of leaving a surgical foreign body in a patient. Many factors have been suggested to contribute to the risk. Those factors identified most consistently in the literature include emergency operations, unplanned changes in the operative plan, and increased body mass index of the patient or poor communication. Other studies identify multiple procedures at one time, multiple surgical teams, and an incorrect sponge count [11, 14–17]. Other factors considered important but not identified as statistically significant include changes in nursing staff, increased blood loss, and fatigue of the surgical team [13]. It should be noted, however, that a falsely correct count is identified in 88% of cases. The surgical count, therefore, is unfortunately not enough to prevent these occurrences and relies heavily on human performance and is, as such, subject to error.

Strategies to prevent retained foreign bodies will need to be applicable across a wide variety of situations. As one review points out, there is no mandatory method of performing surgical counts or any other method to prevent retaining surgical items. The only standard is that no item be left unintentionally in the patient [16]. Performing needle, instrument and sponge counts as mentioned earlier may be subject to many errors of miscounts which include counting items more than once, not at all, or just errors in addition. Other factors that distract the count process include frequent interruptions and time constraints. In addition, the failure of the surgeon to appropriately address incorrect counts can lead to retained foreign bodies. In many institutions, not all operations even require counts, despite published data showing retained foreign bodies in nearly all procedures large or small.

Although imperfect, the surgical count is an important process in the frontline of preventing retained objects. Improvements can be made by standardizing the way the count is performed, and specifically requiring it be performed for every procedure performed, including gynecologic procedures and vaginal deliveries. A hospital should be obligated to provide the appropriate personnel, funds, and policy enforcement needed to carry out surgical counts in a responsible manner. In addition to improving the performance of counts, the surgeon should make a focused effort to methodically evaluate the cavity prior to closing. One proposed strategy to prevent retained objects, Gibbs et al. suggest a technique which emphasizes using both sight and touch to thoroughly investigate major cavities in a standardized fashion [13]. The surgeon should also require the use of only those sponges and products which are appropriate for use in the designated cavity. For example, by limiting or altogether avoiding the use of small 4×4 gauzes in an open abdomen, or choosing

only towels with radio-opaque markers instead of draping towels if such an item must be used. Additionally, the surgeon should be aware of when the count is being performed, accept the time commitment required to complete this thoroughly and accurately, minimize interruptions or requests for instruments and make every effort to have completed at least one correct count prior to closure of the cavity. Another proposed strategy which should be strongly considered by each institution is developing an institutional policy to address incorrect counts. We have created a sample algorithm to address this (see Fig. 7.1). This will decrease the potential for variability or conflict when an incorrect count is identified.

To overcome human error, other strategies for preventing retained foreign bodies prior to closing or leaving the OR have been suggested. One good strategy that has been implemented by some institutions is selectively requiring plain radiographs prior to leaving the OR (closing films), while others mandate radiographs with every surgical procedure. These techniques are not fail-proof either. It is important to recognize that the interpretation of radiographs can be faulty as well. Films should be reviewed by the operating surgeon along and a radiologist, as it has been shown to be statistically less likely to retain a surgical foreign body when films are read by the radiologist rather than relying only on the surgeon. Film quality varies, objects can be misinterpreted, and thus radiographic imaging cannot be the sole method relied upon for detecting or preventing retained foreign bodies. When used in conjunction with a well-performed count, radiography should prove cost-effective and the benefits provided will outweigh the negligible radiation exposure to the patient and OR personnel. This is particularly true in high risk situations, such as those patients with a high body mass index, emergency operations, those with intra-operative changes in procedure, or procedures with an incorrect count.

The need for patient safety has spurred the adaptation of existing technologies and invention of new technologies with remarkably good results. Some that deserve mentioning are the electronic article surveillance, use of two-dimensional bar codes on sponges, and radiofrequency identification tags [14]. Electronic Article Surveillance adapts current technology used in video stores and other places. The target, specifically the sponge is specifically tagged with a magnetic marker, and a portable detecting device is swept over the cavity. A sound is emitted when a retained marker is identified. Similarly, a radiofrequency identification tag may be incorporated into sponges and detected with a handheld wand. These chips are smaller and act as transponders, receiving and sending signals from the scanner. Both systems were found to have

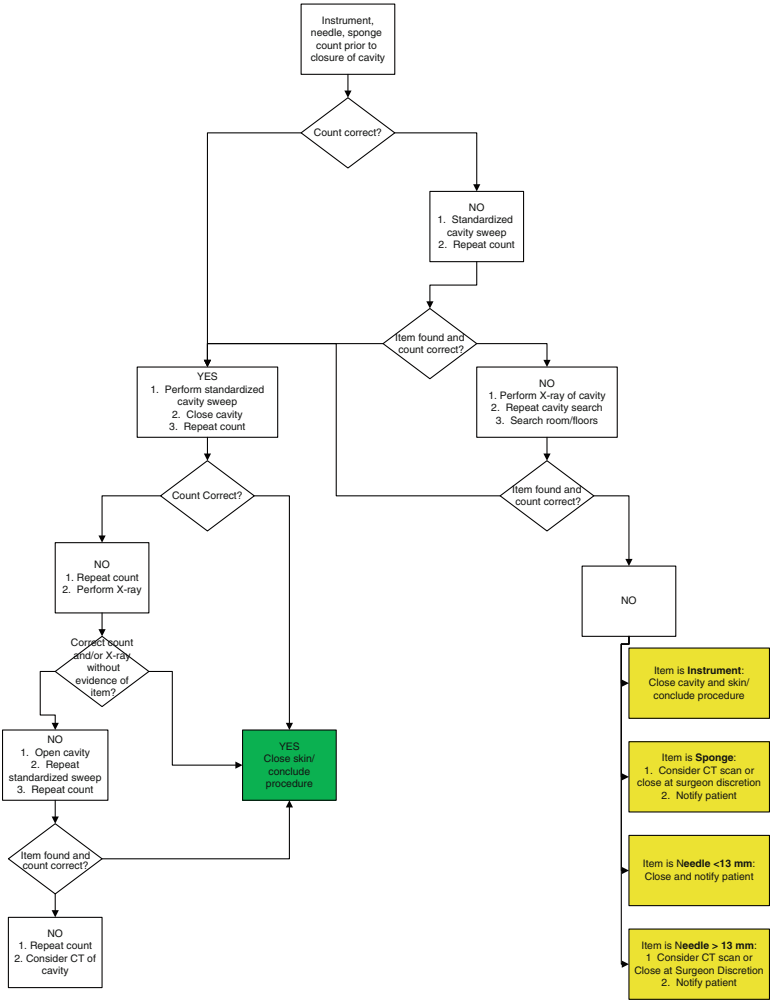

Fig. 7.1. Incorrect Count Algorithm.

nearly 100% sensitivity and specificity in cadaver studies. The bar code system also involves labeling sponges. The item with a bar code is scanned using an electronic scanner similar to that in a department store. Sponges are scanned prior to being placed on the instrument table and after coming off the back table. The device records which items are

scanned in and out, identifies if one is left behind at the end of the case, and can print out a "receipt" at the end of the case. Some of these technologies are already in use at various hospitals across the country. It is important to remember that these tools can be used in conjunction with the previously mentioned efforts at preventing retained foreign bodies. Accuracy should be dramatically improved when responsible counts are performed, appropriate techniques and items are used during the operation, and new technologies are applied appropriately.

Minimally invasive surgeries present a unique set of circumstances for inadvertently leaving behind a foreign body. Although used less frequently, surgical sponges can be introduced into the operative cavity and must be accurately accounted for prior to and after the case. The field of vision is limited and the possibilities of retaining a surgical instrument or part of an instrument, sponge, or needle are potentially increased. The use of trocars and other instruments with multiple parts provides the opportunity to retain an item which might be difficult to detect radiographically. There are multiple reports of fragments of trocars, instrument tips, and surgical needles breaking off and being left within the abdomen after laparoscopic surgeries. Specimens intended for removal are frequently set aside, either in a collection bag or unmarked and can easily be forgotten. In addition to performing the surgical counts, it would be wise to inspect laparoscopic instruments and trocars as part of the count or include this inspection as part of the sign-out as described earlier in the chapter. The sign-out should also include instructions to the nursing team on how to handle the specimen. If the specimen remains in the patient, it should be identified at this time, prior to end of anesthesia and leaving the operating room. Despite the unique risk they present for leaving behind a foreign body, minimally invasive techniques have been just as widely described in the literature for retrieving retained foreign bodies. Typically this is better accomplished early in the postoperative course and is not accomplished as easily with retained sponges, however, laparoscopy and thoracoscopy have been used as late as 14 years after the original procedure with good success.

The best detection method is prevention. Communication with OR staff, anesthesiologist and radiologists is important and cannot be overemphasized. If an object is left behind, the surgeon should avoid delay in diagnosis to the best of his or her ability. Be upfront and honest about the event and accept responsibility for remedying the problem. With heightened awareness and rapidly emerging techniques and technologies, the goal of completely eliminating these "never events" becomes more achievable.

Selected Readings

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