



PATIENT SAFETY EQUALS:

# Aseptic Technique, Surgical Conscience and Time Out

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Healthcare in the United States is thought to be safe and effective. However, medical errors of all types occur every year. The Department of Health and Human Services' Office of Inspector General conducted a study November 2010 concluding one in seven Medicare patients experience serious harm because of medical errors and hospital infections each year, leading to 180,000 patient deaths. These numbers are almost double the 98,000 deaths attributed to preventable errors in the 2000 report "To Err is Human" by the Institute of Medicine.<sup>12</sup>

All personnel involved in the perioperative arena need to possess a keen surgical conscience as well as excellent aseptic technique. Over the years, it has been demonstrated in numerous facilities across our nation that due to lack of proper aseptic technique and a poor surgical conscience, many patients have been at high risk of nosocomial infections along with rising incidences of medical errors.

These problems are not isolated by any means. In another survey conducted among physicians, 92% of them said they had experienced a near miss, a minor error or a serious error and 57% confessed to a serious mistake. Of all of these, two-thirds of the physicians reported anxiety about future errors and a half reported decreased job confidence and satisfaction.<sup>3</sup>

Medical errors have caused many to take a closer look at their facilities, practices and ethical behavior along with the changes in

## LEARNING OBJECTIVES

- ▲ Identify the barriers that can play a role in causing patient harm during surgical procedures
- ▲ Define surgical conscience and aseptic technique
- ▲ Learn which items are the most commonly retained
- ▲ Evaluate the role each surgical team member plays in preventing medical errors
- ▲ Read about some of the various safety systems developed to help sites reduce surgical errors

structure, culture and social responsibility to prevent them from happening again. The operating room consists of individuals working and collaborating together as a team. The importance of the topic of asepsis, surgical conscience and a time out has a direct effect on all personnel in that theatre we refer to as an operating room.

### THE TEAM

The first assistant and scrub assistant may be either a nurse or surgical technologists, who are responsible for assisting the surgeon and assist with instrumentation, set ups, suture presentation and sponges while maintaining the sterility of the surgical field through aseptic practice.

A circulating nurse must be an RN, who after additional education and training is specialized in perioperative nursing practices, is a patient advocate, teacher, is responsible and accountable for all activities occurring during surgical procedures and is responsible for monitoring the patient during the procedure.

Orderlies and nursing attendants are the paraprofessionals support team, along with the sterilization technicians, and they are responsible to provide support services when required in an operating room.

Sterilization technicians are responsible to routinely test the sterilization equipment by conducting biological and chemical testing, which will provide an assurance that the items processed have gone through the sterilization process. Detailed records (some in the form of bar coding) are maintained in the event a patient returns to the facility with an infection.

### TERMS DEFINED

Surgical conscience by definition is a 360-degree awareness of everything within a healthcare worker's sterile and

unsterile environment. Asepsis is how this awareness is incorporated into their daily activities. Bacteria in general are opportunistic living creatures, and will take an opportunity to infect when presented. Healthcare workers are subject to vector, fomite, blood and air as modes of transmission, which is why the OR team needs to ensure the sterile field boundaries are maintained and respected. Donning of the OR attire, learning open and closed gloving techniques are some of the key components with the goal of practicing aseptic technique.

Many supplies used during a surgical procedure are used incorporating the principles of asepsis. Surgical drapes are



place over the patient, preventing any cross contamination from occurring. Different pieces of equipment are used during a procedure, and they need to be placed strategically where they will not come in contact with anything that is considered to be sterile. During a surgical procedure, within the trays of instrumentation, there is an indicator strip that should change color indicating these instruments have gone through the sterile process.

### MEASUREMENTS

Surgical procedures are an essential element of health care. Surgeries help save lives; however, improperly prepared

surgical care causes considerable harm to patients. Several measurements are established for organizations to use as guidelines to help prevent medical errors before they occur. Communication among surgical team members is the most important factor in reducing medical errors. Protocol checklists are established for organizations to aid in eliminating, and correcting errors before there is harm to the patient.

The Joint Commission has developed the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery. These are areas of concern to help provide patient safety.<sup>5</sup> Wrong patient errors occur in any stage of care since the new national patient safety goals that went into effect January 2012 will help healthcare providers reduce chances of medical errors. Organizations must use at least two patient identifiers,<sup>10</sup> such as a name and date of birth as reliable measures of identifying the correct patient and that the correct patient receives the proper treatment or service. Other patient safety measures include the pre-procedure marking, and time out measurements required before the start of any procedure. This process should occur more than once and be completed by more than one person

To prevent wrong site, wrong procedure and wrong person errors, healthcare organizations should develop strategies to meet regulatory standards to ensure the safety of their patients.

before the start of any procedure. The purpose is to ensure that relevant documents, information and equipment are correct and current prior to the start of the procedure.<sup>10</sup> This collection of information and documentation is done with the patient present.

The World Health Organization (WHO) initiated the Global Patient Safety Challenge: Safe Surgery Saves Lives in January 2007. These measurements were instituted to improve and provide safe surgical care by using the core safety standards.<sup>19</sup> This set of safety standards was put into place to reduce deaths and complications by the expectations and model of surgical safety. When using a set of con-

sistent measures (essential statistics) and the surgical safety standard checklist in pre-operative and the operating room, a safe standard of patient safety is established. Organizations should implement and follow the surgical checklist measures established by the Joint Commission and WHO; therefore, surgical teams around the world will know exactly what is done every time, thus preventing medical errors from occurring.

#### REGULATORY AND ACCREDITATION STANDARDS

The Joint Commission for Accreditation of Healthcare Organizations (JCAHO) values patient safety and rates America's healthcare organizations based on the quality of care received by patients.<sup>16</sup> JCAHO conducts on-site tours every three years in healthcare organizations. The results of these evaluations can help patients and their families select the healthcare organization that provides the highest quality of service.<sup>18</sup> Patients and families will have the information necessary to avoid healthcare organizations that have received fines or scored poorly on these evaluations.

JCAHO's Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery is critical to patient safety. This became initiative began July 1, 2004. One portion of this protocol is the time out or surgical pause that involves communication between all surgical team members in the operating room prior to the surgery.<sup>5</sup> The other two portions of the protocol occur before the surgical pause and include verification of the patient, site and procedure prior to surgery in addition to marking of the surgical site.<sup>1</sup>

A variety of organizations also have established guidelines, checklists or protocols regarding patient safety during surgical procedures. The American College of Surgeons (ACS) has guidelines for surgeons to use to protect patient safety and eliminate improper procedures. In this case study, the New York State Department of Health is noted for establishing protocol to stress the importance of communication between all members of the surgical team. The Agency for Healthcare Research and Quality (AHRQ) developed a surgical fact sheet for patients to review prior to surgery in an effort to prevent wrong-site surgery. The World Health Organization and the Association of Operating Room Nurs-

# When Accidents Happen

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## WHO SHOULD DO THE REPORTING?

According to the American College of Physicians, physicians are obligated to report information about errors made while caring for a patient, which has or could subsequently jeopardize the patient's well-being. The American Medical Association Council on Ethical and Judicial Affairs makes it clear that physicians have a responsibility to ethically inform the patients of any facts pertaining to the error and provide the patient with an adequate understanding of the incident. In line with what is expected, patients should gain compensation for any kind of suffering incurred because of the error.

## SHOULD THERE BE PUBLIC DISCLOSURE OF THE MEDICAL ERROR REPORT?

There are suggestions made from many of the medical journals, which provide physicians to disclose and published medical errors confidentially. Of course, physicians don't wish to jeopardize their reputations, since like the example used in the main article, the nurse had been practicing for years, and the incident was unintentional and a true mistake. Although there are some physicians and healthcare providers who contribute to these errors, there needs to be some legal protection for those who submit and publish this information in a medical journal. Peer reviewed journals and professional societies also could provide a forum to address such reports toward reduction of patient risk.

## SHOULD THERE BE LEGAL DISCOVERY OF A MEDICAL ERROR REPORT?

In the event of a malpractice lawsuit due to negligence, should the attorneys representing the plaintiff uncover evidence of reported medical errors committed by the same institution or healthcare professional being sued, then those medical error reports should become admissible as evidence of a pattern. If

in fact the mission of the Joint Commission is to continuously improve the safety and quality of care provided to the public, then any organization or individual who breaches that should be held accountable and any evidence of there being a repeat occurrence should be shared.<sup>10</sup>

## WHO SHOULD REGULATE MEDICAL ERROR REPORTING?

The organizations mentioned in the To Whom Medical Errors Should be Reported are the entities that need to regulate medical error reporting. As an example of a response to retained items, the organization NoThing Left Behind® has embarked on a mission of enlisting hospitals around the country to review their policies, evaluate technology and test new practices and processes of how they track surgical items. Because of this endeavor, many hospitals developed a manual that delineates counting practices, along with a system called Sponge ACCOUNTing.

The Institute of Medicine's report concentrated on the three areas of care:

- Customized Care
- Safe Care
- Standardized Care

Application of standardized processes of care would assist with the prevention of medical errors.

## WHAT SHOULD BE THE SPECIFICITY OF MEDICAL ERROR REPORTING?

With the goal of improving patient safety, the specifics of each occurrence, an analysis conducted by a risk management department analyzing the cause and the factors surrounding the error would be the precursors in attempting to develop a strategic plan of action to prevent a similar error in the future. By detailing the specifics and publicizing the facilities where these

errors occurred, it would help change the culture of the healthcare professionals at those establishments.

Many times when errors take place employees tend to view them as an individual occurrence; however, in reality it is a culmination of the whole, and efforts need to be in place focusing on how to be more careful, preventing recurrence. The questions about reporting specifics bring to mind a recent finding by the Joint Commission at 13 surgery centers in the State of New Jersey. They discovered upon their inspection that their sterilization processes were far below standard, and cited the facilities for the same. Sterilization of instrumentation used on patients is a potential culprit in causing infections. This became public knowledge, the names of the facilities were named in the local papers, which subsequently awakened and alerted the public, but also were a huge wake up call for the facilities CEO. Since, all of these 13 centers improved their processes.<sup>10</sup>

Patient safety has a direct association with medical errors, lack of adequate aseptic technique and a poor surgical conscience. This has become one of the biggest controversies in health care today. Changes do not occur quickly. Healthcare providers need to initiate the changes needed in their individual departments and facilities as the advocates for patients. All healthcare professionals have an ethical obligation to make changes, fix processes, work together to eliminate infections and improve as a team. Every patient who seeks medical care should be able to have an expectation that they will receive safe care regardless of circumstance each time they are seen by a healthcare professional.

es (AORN) also have developed surgical safety checklists to protect patients. The establishment of all these guidelines, protocols and checklists proves that surgical errors are avoidable and patient safety is a priority.

## STRATEGIES

To prevent wrong site, wrong procedure and wrong person errors, healthcare organizations should develop strategies to meet regulatory standards to ensure the safety of their patients. The Joint Commission has created what is known as the Check Site System. This system involves a preoperative verification process, marking of the operative site and initiating a time out for a final check prior to starting the procedure. The preoperative process takes place at the hospital bedside. The nurse and physician would match the arm band with the chart and confirm with the patient, or family member, who he or she is and what procedure he or she is about to undertake. The nurse would mark the operative site after confirmation and have another nurse co-sign that the checks are done. The final strategy is for doctors and nurses to take a time out for every patient prior to conducting a procedure. Taking a few brief minutes to check and recheck charts, patient arm bracelets and the patients themselves could prove to be a lifesaving event.

Another strategy is to increase communication among surgeons and other staff members. For many years surgeons expected staff to follow orders and not question what took place in the operating room. Today, more hospitals are encouraging open communication among staff and a cultural change is taking place. According to Williamson, "Communication breakdown and cultural shift including intimidation by surgeons — are at the root of most surgical errors."<sup>20</sup> Surgeons are human and prone to mistakes. Developing the eyes and ears of other staff members will help to reduce mistakes and help other staff members feel more comfortable about speaking up if he or she finds something wrong.

Hospitals that have adopted the check site system and created a more open environment may also want to invest in equipment or devices to assist with the prevention of surgical errors. One such device is called the smart wristband. The smart wristband forces staff to make marks on patients. Inside the wristband is an electronic device that is activated by a sticker in a marking pen. When a staff member marks the surgical site after confirming with the patient or family member, the sticker is removed from the pen, which deacti-



## BARRIERS

The Universal Protocol for preventing wrong site, wrong procedure, and wrong person became effective in 2004 for hospitals accredited by JCAHO. The three principle components of the protocol are site marking, pre-procedure verification and a time out. Although this protocol was to improve patient safety, there was still only a 79% compliance rate for the time out before surgery four years later in 2008. Facilities throughout the United States have met barriers in implementing quality measures to be compliant with the Universal Protocols including communication breakdown, physician noncompliance, process failure and lack of support from leadership.<sup>4</sup>

For communication to be effective in the operating room, it must be effective and clear and concise because there are many people who make up the team to perform surgery. Although many facilities have written policies that address effective communication, this barrier continues to be a problem in many facilities. Another barrier that facilities are facing is physician noncompliance. An example is site marking. Many physicians think that an assistant should be able to mark the site prior to the procedure, even though “the requirement spells out that the delegated individual must be involved in the entire procedure.”<sup>4</sup>

Two additional barriers that interfere with implementation of quality measures are process failure and no supportive leadership. Process failure occurs when the original process was not developed in accordance with a solid quality improvement (QI) model such as PDCA. Many facilities want to blame an individual for an error, when in fact it is the process that failed. Leadership support is vital when implementing a new or revised quality measure. If the leadership team does not support change, the clinical team will not support change either.

vates the wristband. If the wristband is not deactivated, an alarm will sound to remind staff that the checks have not taken place.

Hospitals and surgical centers have an obligation to ensure the safety of patients. There are many strategies to avoid tragedies such as using the Check Site System, creating an environment of open communication or purchasing new technology. Regardless of which strategy is chosen, staff members must take measures to prevent mistakes as much as possible to prevent the loss of a wrong limb or even a life.

## OVERCOMING BARRIERS

For an organization to overcome barriers that interfere with implementation or revision of quality measures, they first must have strong leadership. In the book by Ransom, leaders are initiators that “develop and test change, persuade others, are not daunted by the loud, negative voices, and are not afraid to think and work outside their immediate areas of responsibility.”<sup>18</sup> These leaders are willing to break down the barriers to ensure the changes to improve quality will be possible.

It is the responsibility of the leadership team to develop the culture of patient safety. This message should come from the Chief Executive Officer, medical staff leaders and the board of directors and be consistent throughout the facility. This culture will include a nonpunitive approach to reporting errors, increased communication and adopting a QI model such as PDCA to design and improve processes and prevent potential errors. The ideal culture is “one in which errors are anticipated to occur, processes are designed and improved with human factors and safety in mind, and reporting is encouraged and rewarded.”<sup>18</sup>

## THE MAGNITUDE

Because a keen surgical conscience incorporates a 360-degree awareness of all that is being used during a surgical procedure, the incidence of retained items should not reach the number of occurrences it has. Because of this problem, a national surgical patient safety project to prevent retained surgical items has evolved. This problem has been around since the practice of surgery began. Retained Surgical Items (RSI) is the preferred term. Surgical items fall under four groups: sponges, instruments, needles and miscellaneous small items. There are a minimum of 1,500 to 2,000 cases of reported RSI in the United States each year.

The most frequently retained items are sponges, which vary in size. There also have been cases of retained towels. The most common sites of these items left behind are the chest, abdomen, pelvis and the vagina. The NoThing Left Behind® organization has embarked on a mission of enlisting hospitals around the country to review their policies, evaluate technology and test new practices and processes of how they track surgical items. Because of this endeavor,

many hospitals developed a manual that delineates counting practices, along with a system called Sponge ACCOUNTing.

The Institute of Medicine’s report *To Err is Human* spoke on three domains of care: safe care, standardized care and customized care. Traditionally, most hospitals in the US functioned under the customized care. Since this report, there has been an increased effort to institute safe care and standardized care.

NoThing Left Behind® is a project that was born in October of 2004. The project works together with healthcare facilities to make sure that retained surgical items become a thing of the past. This organization helps develop different processes, provides different tools to be implemented within a hospital’s or surgery center’s policies and that procedures are adhered to by anesthesiologists, surgeons, nurses, surgical technologists and radiologists.

Additionally, the organization works with the members of the legal community and risk managers to information available to provide adequate counsel. It works with the business community as well to come up with ideas for the products used in the operating room so that the products become more reliable.

As of 2010, most operating rooms have placed a standardized process of accountability of surgical items upon everyone on that surgical team.

## RETAINED ITEMS

### *Sponges*

Previously mentioned, surgical sponges are one of the biggest culprits being retained. The prevention of retained items requires excellent communication between the nursing staff, the surgical technologists and the surgeon during the surgical procedure. The application of standardized processes of care would assist in the prevention of retained items. Most hospitals have a surgical count policy that addresses the counts performed by the nurses and the scrub techs, but there are no policies in place to address the behavior of the surgeon and anesthesiologists. Many times, if an individual is new to a particular healthcare facility, the staff will hone in on the “my





way” of doing a count is as follows; which most likely is not following a standardized process.

As of 2010, most operating rooms have placed a standardized process of accountability of surgical items upon everyone on that surgical team. This organization has shared various different methods of Sponge ACCOUTing that have been evaluated and have been found to be highly effective in reducing considerably the number of incidences in an operating room.

Different systems have been incorporated whereas the surgeons, nurses and scrub techs all have the responsibility of ensuring that nothing is left behind. The idea is centered on the questions: *Where are the sponges?* instead of *Is the count correct?*

Other systems have been devised to help with the prevention of retained sponges. Computer Assisted Sponge Count consists of a 2D matrix labeled sponges that performs much like a bar code. Each sponge has its own unique code and can be tracked within the cavity. Another system consists of sponges that have a small radiofrequency tag sewn into a pocket on each sponge. This is known as the RFID system.

Whatever appropriate practice a healthcare center implements, it should incorporate all of the following: the nurses and the scrub tech have an ethical responsibility to be truthful when counting and if the count is incorrect, they need to advise the surgeon to stop closing the wound, remove

the fascia sutures, place a retractor in the cavity and actively search for the missing sponge. If the missing sponge still cannot be found, then the radiologist needs to be summoned to take an X-ray. The patient’s wound should not be closed until the missing sponge is located. Studies have shown that 20% of retained sponges are due to an incorrect sponge count in the operating room.

#### *Needles*

Suture needles of different sizes are often used during a surgical case and can easily become lost. Needle counter boxes should always be incorporated

into a safe practice and a clear policy that X-rays will be required only when large needles are missing. A well-defined policy of what constitutes a large needle should be documented and easily accessible. A possible needle protocol might look something like the following:

- Disclose this information to the patient
- Document the incorrect needle count
- If a miscount occurs, look for the needle
- If large needle, X-ray
- Keep a low number of needles on back table
- Separate small needles from large needles
- Use needle counter box

#### **INSTRUMENTS/MISCELLANEOUS ITEMS**

The most frequently reported retained instrument is a malleable or ribbon retractor. Traditionally, this is used at the end of the case. All techs should know what each instrument looks like so they can quickly identify that all items are accounted for.

While retained surgical items is a problem that affects healthcare facilities across the nation, most of these facilities have already or are in the process of incorporating new policies, procedures and guidelines to ensure that the employees provide optimal patient care. All healthcare employees have an ethical obligation to do what is right, and take the extra steps required to ensure patient safety. Organizations

such as NoThing Left Behind® are taking the stand so that everyone can take an active role in eliminating retained items during surgery.



#### AUTHOR'S BIO

Karen L Chambers, CST, MHA/Ed, began her medical career as a paramedic in NYC working for the 911/EMS system. Upon becoming a

Certified Surgical Technologist, her passion of healthcare grew, guiding her to author various articles, a textbook and become a healthcare educator/program director. Currently, she works as the program director at Eastwick College in Ramsey, New Jersey, where she and her faculty share their knowledge, integrity and compassion needed to deliver utmost patient care with their students. With encouragement and guidance from some of her mentors, she enrolled at the University of Phoenix in 2008 to begin her pursuit of an associate degree, never realizing it would lead her to completion of her MHA/Ed. She is now enrolled in a doctoral program pursuing her PhD.

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