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CLINICAL PERSPECTIVE

NEVER EVENTS IN THE OPERATING ROOM (OR)

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The term "Never Event" was first introduced in 2001 by the National Quality Forum (NQF), in reference to particularly alarming medical errors that should never occur in health care organizations.[1] Since that time, the list of Never Events has been expanded to denote adverse events that are clearly identifiable and measurable, serious with a result in significant disability or death, and usually preventable.

Definition of Never Events

The list of serious reportable events related to surgical and other invasive procedures include, but are not limited to the following.[2]

- Procedure performed on the wrong site or the wrong patient.
- Wrong procedure performed on a patient.
- Unintended retention of a foreign object in a patient after a procedure.
- Patient death or serious injury associated with a medication error (eg, wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration).

The Joint Commission also considers any wrong-side, -site, or -patient procedure or a patient death, paralysis, coma, or other significant permanent loss of function related to a medication error to be a sentinel event, which is defined as *"an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof."*[3] These types of events are called "sentinel" because they indicate the need for an immediate investigation, analysis, and response.

Based on The Joint Commission's rationale for sentinel events needing immediate investigation, all Never Events should also have a root cause analysis.

Incidence of Never Events

Most Never Events are rare occurrences.[4] In the United States, a 2013 study estimated that over 4,000 surgical Never Events malpractice claims occur annually.[5] An earlier study estimated that a typical large hospital in the United States might

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experience a case of wrong-site surgery serious enough to report to risk managers or result in a lawsuit would occur once every 5 to 10 years.[6] From 2004 to 2014, The Joint Commission reported a total of 1,102 wrong-patient, wrong-site, wrong-procedure and 434 medication error sentinel events.[7]

European data, primarily from the European Union Member States, estimates that among patients who are admitted to the hospital, 8% to 12% of patients experience adverse events while receiving health care, including surgical and medication-related errors.[8]

In Japan, the Japan Council for Quality Health Care collects voluntarily-reported adverse events from Japan health care organizations, in particular sentinel events with root cause analysis.[9] Health care organizations are asked to voluntarily pool their events, which are aggregated and then the results disseminated. The Ministry of Health, Labour and Welfare patient safety committee recommended a national reporting system in 2003.

Over 200 health care organizations or health services in Australia voluntarily send incident reports to the Australian Incident Monitoring System (AIMS); AIMS uses the Healthcare Incident Types classification system, which extracts very detailed data from the reporter in regards to generic incident types, contributing factors, outcomes, actions, and consequences.[10]

Consequences of Never Events

When Never Events do occur, they are devastating to patients; over the past 12 years, 71% of Never Events reported to The Joint Commission were fatal.[11] A recent report estimates that approximately 200,000 patients in the United States die from preventable medical errors.[12]

Surgical Never Events are also quite costly to the health care system. A review of 9,744 paid malpractice judgments and out-of-court settlements for surgical Never Events between 1990 and 2010 found that 59.2% of the patients had a temporary injury, 32.9% had a permanent injury, and 6.6 % of the patients died; the malpractice payments totaled $1.3 billion USD.[13] In this study, higher payments were associated with severe patient outcomes and claims involving a physician with multiple malpractice reports.

For 2008, medical errors in the United States cost $19.5 billion USD; approximately 87% ($17 billion USD) of this total were directly associated with additional medical costs (eg, prescription drugs and inpatient and outpatient care).[14] An additional $1.4 billion USD of costs were related to increased mortality rates, with $1.1 billion USD or 10 million days of lost productivity from missed work.[15]

Because Never Events are often devastating and preventable, health care organizations are under increasing pressure to

eliminate them entirely.[16] In August 2007, the United States Centers for Medicare and Medicaid Services (CMS) announced that Medicare would no longer pay for the additional costs associated with many preventable errors, including those that are considered Never Events.[17] At the time, CMS estimated that this policy would save $21 million USD out of a total of $110 billion USD in inpatient health care costs it expected to pay in 2009.[18] Since February 2009, CMS has not reimbursed hospitals for any costs associated with wrong-site surgeries.[19]

In addition, surgeons involved in a wrong site surgery or unintended retained foreign object event may now have penalties imposed by state licensing boards and are no longer paid by some insurers.[20]

Best Practices for Preventing Never Events in the OR

State Reporting Laws

Never Events are publicly reported, to increase accountability and also improve quality of care. Since the NQF published the original list of Never Events in 2002, 11 states have mandated reporting of these incidents whenever they occur; an additional 16 states mandate reporting of serious adverse events, including several of the NQF Never Events. Health care organizations are accountable for correcting systematic problems that contribute to the events, with some states mandating that a root cause analysis be conducted and the results are reported.[21]

The Joint Commission Universal Protocol

As part of The Joint Commission's National Patient Safety Goals, Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery™ applies to all surgical and nonsurgical invasive procedures.[22] The Universal Protocol consists of three key elements:

- Conduct a preprocedure verification process. This is an ongoing process of information gathering and confirmation to ensure that all relevant documents and related information or equipment are:
  - available before the start of the procedure;
  - correctly labeled, identified, and matched to the patient's unique identifiers;
  - reviewed; and
  - consistent with the patient's expectations as well as the team's understanding of the intended patient, procedure, and site.
- Mark the procedure site. At a minimum, sites are marked when there is more than one possible location for the procedure and also when performing the procedure in a different site would negatively affect safety or quality. The procedure site should be marked before the procedure is performed and, if possible, the patient should be involved.

- Perform and document a time-out before the procedure. During the time-out, the team members agree, at a minimum, on the correct patient identity, correct site, and correct procedure to be performed.

World Health Organization (WHO) Surgical Safety Checklist

The WHO Surgical Safety Checklist was developed to reduce errors and adverse events, and also increase teamwork and communication in surgery.[23] The 19-item checklist consists of selected aspects of care to be assessed documented prior to induction of anesthesia, before the skin incision, and before the patient is transferred out of the OR. The use of this checklist has shown significant reductions in both morbidity and mortality; it is now used by a majority of surgical providers worldwide.

Association of periOperative Registered Nurses (AORN) Position Statement

In its Position Statement: Preventing Wrong-Patient, Wrong-Site, Wrong-Procedure Events, AORN recognizes the need to prevent wrong-patient, wrong-site, wrong- procedure events to promote safe, optimal patient outcomes.[24] Key elements of this statement include multidisciplinary collaboration to develop protocols and standardized processes, and also the completion of a preoperative checklist that includes pre-procedure verification, site marking, and time-out procedures.

American College of Surgeons (ACS) Statement

In 2002, the ACS issued its Statement on Ensuring Correct Patient, Correct Site, and Correct Procedure surgery[25] that included the following guidelines to eliminate wrong site surgery.

- Verify that the correct patient is being transported to the OR.
- Verify that the correct procedure is on the OR schedule.
- Verify with the patient or the patient's representative the procedure that is expected to be performed, including the location of the operation.
- Confirm the consent form with the patient or the patient's representative.
- Reach agreement in the case of a bilateral limb, organ, or anatomic site (eg, hernia). The surgeon and patient should agree and the operating surgeon should mark the site before the patient is given narcotics, sedation, or anesthesia.
- Verify accuracy for multiple procedures. If the patient is scheduled for multiple procedures that will be performed by different surgeons, all the items on the checklist must be verified for each planned procedure.
- Conduct a final verification process with members of the surgical team to confirm the correct patient, procedure, and site.
- Ensure that all relevant records and imaging studies are present in the OR.
- Stop all activities if any verification process fails to identify the correct site. Do not resume activities until accurate verification is obtained.

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Solutions

Today, many tools are available to assist OR personnel in preventing surgical Never Events and complying with professional recommendations, as outlined below.

Checklists

The fast pace and complexity of the OR can distract perioperative teams away from the detail of each patient's specific conditions relative to his or her invasive procedure. The use of a checklist, such as the WHO Surgical Safety Checklist, has been shown to significantly reduce surgical morbidity and mortality because it provides a consistent structure to focus the perioperative team on the priority aspects of the patient's care. Of the 234 million operations performed globally every year, at least half a million deaths would be preventable annually with effective implementation of the WHO Surgical Safety Checklist worldwide.[26] A recent study examining the effects of the use of a comprehensive, multidisciplinary surgical safety checklist on patient outcomes demonstrated that the total number of complications per 100 patients was reduced from 27.3 to 16.7; the percentage of patients with one or more complications decreased from 15.4% to 10.6%; and in-hospital mortality was reduced from 1.5% to 0.8%.[27]

Time-out/Surgical Pause

The whole perioperative team must be clear on the correct patient identity, the correct site, the correct procedure to be performed, and other relevant priority patient information before the surgical incision is made to prevent serious errors from occurring. Today, several products are available to reduce the incidence of never events by reminding the surgical team to take a time-out as recommended by The Joint Commission's Universal Protocol. Various types of disposable, brightly colored time-out reminders are available for insertion in custom procedure kits, examples follow.

- A cloth printed with the words time-out as a prominent reminder to implement the Universal Protocol. This is available as either a non-sterile or sterile product, and therefore can be placed near the surgical site, or over the instrument tray or Mayo stand.
- A sleeve that can be placed over a scalpel, on the Mayo stand, or on the back table during set up to serve as a reminder to implement the Universal Protocol.
- A hood with the words time-out that can be placed over instruments as a reminder of the Universal Protocol.

Marking the Surgical Site

The surgical-site marking on the patient's skin should be visible after the application of the preoperative patient skin antisepsis solution for the time-out verification to be effective. Products to assist with marking the correct surgical site include skin markers, and stickers, or tattoos. Many of these types of markers also include a time-out reminder. Marking the surgical site with a

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marker can be enhanced by using a sticker along with a skin marker; these stickers typically have a signature line for the patient. Tattoos placed on the patient may remain legible for up to a week.

Notifier for QUIET during Surgical Count

The risk of a surgical item being retained is increased when noise, unnecessary activity, or distractions occur while accounting for surgical items that have been opened or used during the invasive procedure. A brightly colored cloth designed by nurses can help reduce the risk of retained surgical items by notifying the surgical team that the count is about to begin, thereby reducing distractions and unnecessary activities while the count is in progress.

Medication Labelling Systems

Errors will occur when medications or solutions are unlabelled on the sterile field. The scrub person can use sterile permanent markers to label medications and solutions on the sterile field, but the risk for error continues if the writing is illegible due to small labels or smudging. Medication labelling systems are available that include:

- a color coded flag system that increases the visibility of the labels and provide a color-coded strip for both medication cup and the syringe,
- labels that are moisture- and smear-resistant and will not tear or fall off when submerged in fluid, or
- labels that are tailored for individual specialties and can be pre-printed with department-specific medication names.

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