SENTINEL EVENT NEWSLETTER

ISSUE 3, DECEMBER, 2014

DIVISION OF LICENSING AND REGULATORY SERVICES,
MAINE DEPARTMENT OF HEALTH AND HUMAN SERVICES

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WRONG SITE SURGERY

Although called 'wrong site' surgery, many organizations, including the Center for Medicare and Medicaid Services (CMS) group wrong site, wrong side, wrong patient and wrong procedure into this one category. Wrong site surgery, as compared to some other adverse events, happens infrequently. Although it is difficult to get an accurate estimate of the number of wrong site surgeries, in large part because of the inconsistency in reporting, studies have shown that the occurrence of wrong site surgery is 1 in 112,994 non-spinal surgeries (Kwaan, et al, 2006). The Joint Commission (TJC) estimates that 40 wrong site surgeries occur each week. In a 2007 article by John R. Clarke, M.D., published in the Annals of Surgery, he estimated that surgeons who work on symmetrical structures may have a 1 in 4 chance to be involved in a wrong-site error during their careers. In 2014, 11 wrong site surgeries were reported (6 wrong site surgeries and 5 wrong procedures), or 6.5% of the total reported sentinel events (168).

Wrong site surgeries receive significant attention because of the devastating effects they can have on patients and their families, as well as the providers involved in the event. One of the most publicized wrong site surgeries occurred in 1995, when the wrong leg of a patient was amputated, and the subsequent, required amputation left the patient a double amputee. Some examples of wrong site surgery in Maine include: procedure scheduled for hip surgery, when it should have been knee surgery (near miss); hand surgery where an extra digit was operated on; wrong site fistula placement for dialysis, and wrong organ biopsied.

There are also significant financial consequences for wrong site surgery. In 2009, CMS stopped paying for wrong site surgeries, stating that, "evidence, or lack of evidence of benefit is not necessary to determine that a surgical procedure on the wrong patient does not improve health outcomes." Wrong site surgery is a true 'never event', and cannot be considered an accepted risk of surgery. The American Academy of Orthopaedic Surgeons (AAOS) reports that, for a 10 year period, 84% of malpractice claims involving wrong site orthopaedic surgery resulted in indemnity payments, compared to other types of orthopaedic surgery claims, where indemnity payments were made only 30% of the time. In some states, administrative penalties are assessed for wrong site surgery – 2 wrong site surgeries in California were assessed penalties of $50,000 and $75,000, respectively. Liability settlements also tend to be high – Medical Liability Mutual Insurance Company provided case examples to its policyholders that ranged from $230,000 in a settlement for a wrong procedure surgery to a $992,000 jury award for a wrong site surgery (Healthcare Finance News, 1/18/12).

Various organizations have been working on tools to assist organizations in prevention of wrong site surgeries. In 2003, TJC approved the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery. This protocol

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WRONG SITE SURGERY (CONTINUED)

included the following requirements:

- Implementing a preoperative verification process of all relevant documents and studies before the starts of the procedure;
- Unambiguously marking the surgical site; and
- Conducting a final verification or time out immediately before starting the procedure

The Association of peri-Operative Nurses (AORN) collaborated with TJC to develop the Correct Site Surgery Tool Kit that contains resources to assist in implementing the protocol. This toolkit is available to AORN members at: http://www.aorn.org/timeout/.

In 2012, TJC's Center for Transforming Healthcare developed the Targeted Solutions Tool (TST) that guides healthcare providers through a step-by-step process to help identify, measure and reduce risks in processes that can contribute to wrong site surgery. TJC has stated that the 8 original participating organizations, using the TST were able to reduce the number of surgical cases with risks by 46%, in the scheduling area; 63%, in the preoperative area; and 51% in the OR. TJC accredited organizations can access the TST at: http://www.centerfortransforminghealthcare.org/ and non-accredited organizations can access the tool of a fee basis.

The state of Pennsylvania, through its Patient Safety Authority, has developed a number of tools to assist healthcare organizations in preventing wrong site surgeries, for example: self-assessment checklists, observational, verification and monitoring tools, and a booklet for surgeons' offices titled, "What You Can Do To Prevent Wrong Site Surgery". These can be found at: http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Pages/home.aspx.

The Institute for Quality Improvement has developed a Patient Safety Toolkit for Ambulatory Surgery, available at: http://www.aahc.org/Global/pdfs/AAAHC%20content/Patient%20Safety%20Toolkets/PST-surgical%20checklists_FINAL.pdf

DISTRACTIONS IN THE OR

Distraction in the OR was identified by the Pennsylvania Patient Safety Reporting System in 304 adverse events occurring between January 2010 and May 2013 (PA Patient Safety Advisory June, 2012). This article discusses the various types of distractions, and provides the following strategies for reducing distractions in the OR setting:

- Assemble multidisciplinary teams to identify critical phases in operative procedures, specific to individual teams and procedure types as necessary, that should not be interrupted;
- Implement a "no interruption zone" (sometimes referred to as a sterile cockpit) protocol during critical phases of operative procedures;
- Use preoperative and procedural checklists;
- Design and implement a multidisciplinary briefing tool.
- Use a structured communication tool, such as SBAR (situation, background, assessment and recommendation), especially during critical phases of a procedure;
- Minimize communication by members of the OR team that is irrelevant to the current procedure, and limit interruptions from outside staff and other visitors to the OR;
- Establish guidelines and expectations, applicable to all members of the surgical team, for the appropriate use of cell phones, pagers, smartphones, and other personal electronic devices (PEDs) in the OR, and monitor for compliance;
- Educate staff about electronic distraction and its potential detrimental effect on patient safety;
- Raise awareness of the addictive component of PEDs and other technologies;
- Reduce noise level in the OR whenever possible, especially during critical phases in the procedure (e.g., limit conversation not relevant to the current procedure, lower the volume of background music, adjust surgical equipment settings to reduce excess noise, as able);
- Customize alarm settings for individual patients, and use smart alarms, when available, to reduce distraction from false or nuisance alarms;
- Provide teamwork training, such as crew resource management (CRM) or TeamSTEPPS, using case studies specific to the OR
- Engage surgeons in patient safety teamwork training and quality improvement projects targeted to reducing distraction.

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THE SECOND VICTIM

A patient harmed as a result of an adverse medical event may, understandably, feel victimized by the provider(s) and/or the organization involved in the event. Patients trust that they will be taken care of appropriately by healthcare providers. A patient entering a hospital for a surgical procedure does not expect that the surgeon will operate on the wrong site, or will perform the wrong procedure. When an adverse event happens in the course of a patient's healthcare, it can have a devastating impact.

The impact on providers involved in an adverse event, particularly if there is bad outcome for a patient, can also be devastating. Patient safety literature has begun to recognize that providers involved in an adverse event are 'second victims'. In his article called, "Addressing the Second Victims of Medical Error – Leaders must support their staff when mistakes occur" (Healthcare Executive Mar/April 2013), Nelson discusses the impact of medical errors on healthcare providers involved in the event:

- Second victims typically experience deep stress that includes physical symptoms, such as sleep disturbances, crying and headaches;
- Emotional stress may be manifested in feelings of sadness, fear, anger, shame and damage to professional self-esteem;
- As the organization reviews the error, the second victim can be plagued by self-doubt and a loss of confidence in the workplace;
- Second victims may experience professional insecurity, fearful that their reputations will continue to suffer as a result of their competence being questioned;
- Non-supportive and negative comments result in further erosion of the second victim's professional and personal integrity.

A Just Culture is supportive of second victims. Some ways of doing this include:

- Developing a formal effort that promotes open discussions of the issues surrounding the event;
- Immediate support for second victims after the event, and continuing for as long as necessary
- Resources trained to respond to second victims in an appropriate and timely manner.

Best practices include Johns Hopkins Hospital that launched a Second Victim Committee aimed at assisting professionals traumatized as a result of unexpected outcomes and errors. University of Missouri Health Center created a "for YOU team", providing one-on-one peer support. Members of the peer support group go through specialized training to learn how to better assist their colleagues. Members work closely with legal counsel.

JUST CULTURE

Traditional hospital culture has looked for causation of errors at those individuals closest to the error, typically frontline staff. In moving from this 'shame and blame' culture, some healthcare organizations have attempted to develop a 'blame free' culture. Current patient safety science recognizes that there are times that individuals are responsible for errors, because of choices they make, and have developed the term, "Just Culture" to describe an environment that holds individuals accountable for those things within their control, and acknowledges that 'human error' is the product of complex systems.

David Marx is a patient safety expert in defining Just Culture and assisting organizations in creating this type of environment. In his book, "Whack-a-Mole, The Price We Pay for Expecting Perfection" (2009), Marx identifies only 2 inputs that impact the ability to avoid adverse events: system design and behavioral choice. Marx categorizes behavior into 3 types:

- Human error – an inadvertent action and the inevitable outcome of the system. In the case of human error, Marx states that there is no wrong-doer – there is only the predictable path that through our shared human fallibility we are someday going to hurt each other.
- At risk behavior – when individuals perceive themselves to be acting in a safe way, while others perceive their actions to be otherwise. Providers tend to drift in their behavioral choices to places they believe are safe through personal experience, yet from a system-level perspective, appear risky.
- Reckless behavior – when individuals choose to consciously disregard a substantial and unjustifiable risk.

Marks describes how a 'Just Culture' addresses these behaviors:

- Console human error – human error is an outcome. Instead of looking at the outcome, we should look to the actions that lead to the outcome.
- Coach at-risk behavior – coaching is a non-punitive, constructive dialogue. Marx acknowledges that coaching makes sense intellectually, but actually changing behaviors in response to coaching is more complex.
- Punish reckless behavior, independent of the outcome. Avoid a 'no-harm, no-foul' approach.

In a Just Culture, organizations learn from mistakes. Transparency and accountability go hand-in-hand.

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SENTINEL EVENT TEAM (SET) UPDATES

Sentinel Event Rules – The Sentinel Event Rules have been finalized, and will be in effect as of 1/1/2015.

Staffing – The Sentinel Event Team welcomes Jennene Murphy, R.N. Jennene has worked in various clinical environments, including critical care/emergency room nursing, and most recently worked as a travel nurse. Jennene is available to assist facilities with sentinel event questions.

Obstetric Events – Infant deaths per 1000 live births increased from 5.5 in 2013 to 6.6 in the 2014 reports from America's Health Rankings. The SET has identified a recent spike in "Death or serious injury of a neonate associated with labor or delivery in a low risk pregnancy". We are gathering data to review and hope to share our findings with facilities in the near future. Please be alert to identified risks, fetal assessments, resources/ability to handle the delivery, timely communication, delay in transfer or delay in C-Section decisions.
Please share this with your OB services.

SENTINEL EVENT TEAM

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Maine People Living Safe, Healthy and Productive Lives

Paul R. LePage, Governor *Mary C. Mayhew, Commissioner*