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Failure Mode and Effects Analysis (FMEA) for the Surgical Patient**Course Description**

The purpose of the continuing education course is to describe the role and strategies of the risk manager on the use Failure Mode and Effects Analysis (FMEA) within a health care organization to identify potential risk and systems failure that may affect the patients' safety during a surgical procedure. The role and the strategies will include the risk manager taking a proactive approach to include the entire health care team within the health care organization to identify potential risk and systems failure for a patient undergoing a surgical procedure. The risk strategies will examine the universal protocol of the time out process that was approved by the joint commission in July 2004.



Target Audience

Advanced Practice Registered Nurses, Registered Nurses, and Licensed Practical Nurses

Course Objectives

1. Define Failure Mode and Effects Analysis (FMEA).
2. Discuss The Joint Commission's reasons for annual FMEA's in health care.
3. Identify why it is important for health care organizations to prioritize initiatives aimed at FMEA and the safety of the surgical patient.
4. Describe SBAR.
5. Identify how teamwork and communication can improve the overall risk for wrong-site surgery.

Introduction

According to Chan; et al (2010) failure mode and effects analysis (FMEA) is a tool that examines potential product or process failures, evaluates risk priorities and helps determine remedial actions to avoid identified problems. FMEA has been used as a tool for risk management in health-care systems since the 1990s, but initially little attention was paid to its usefulness (Duwe, Fuchs, & Hansen-Flaschen, 2005). The Universal Protocol was created to address the continuing occurrence of wrong site, wrong procedure, and wrong person surgery in The Joint Commission (JC) and finalized in July 2004 (The Joint Commission, 2009). The JC has also mandated that all health care organizations that call themselves an accredited organization conduct at the least one FMEA annually. A FMEA facilitates the health care organizations to



find potential problems that affect patient safety before an incident occurs (Same day Surgery, 2003). When patients arrive at any given health care organization for a surgical procedure an assessment for potential risk should be performed. The risk should be grouped into priority as the health care organization team look at their hospital policies and procedures on the universal protocol that institutes the time out and the patient verification process. "Prioritize the failure modes that you want to target based upon the seriousness of effects associated with the different failure modes, and address the failure modes that have the greatest likelihood of occurring and affecting the patient (Same day Surgery, 2003)."

Accredited organizations are required by The JC to improve a clinical process at least once a year consisting of high risk for errors and causing patient harm. The Joint Commission is trying to convey those performance improvement standards should be used as baseline data clearly to visualize if the health care organizations have any potential risk (Case Management, 2003). The performance improvement standard should be a proactive approach to an FMEA that includes the risk manager and the entire team who will be directly affected by high risk patient errors.

Problem

Richardson (2014) reported that in 2012, the American Board of Orthopedic Surgery (ABOS) reported the results of a database consisting of 9,255 surgeons who applied for certification from 1999 through 2010. Of 1.3 million procedures in the database, 76 wrong-site procedures were reported by a total of 61 surgeons. Although failure mode and effects analysis (FMEA) is normally used for potential risk assessment approaches in health care, FMEA is a tool



required by the JC to be used by accredited organization to improve clinical processes for errors that may cause patient harm.

Health care organizations have chosen to focus on high-risk areas because of an alarming number of wrong site surgical procedures for Stern, & Meinberg, 2003 illustrates “One hundred and seventy-three surgeons (16%) reported that they had prepared to operate on the wrong site but then noticed the error prior to the incision, and 217 (21%) reported performing wrong-site surgery at least once. Of an estimated 6,700,000 surgical procedures, 242 were performed at the wrong site, an incidence of one in 27,686 procedures.” Team performance is crucial for FMEA success (Wetterneck, Hundt, & Carayon, 2009).

Position

In this study conducted in the operating room by Makary, Mukherjee, & Sexton, (2007) the entire operating team were surveyed regarding their perception of the risk of wrong-site surgery before and after institution of timeouts. Respondents thought teamwork improved the overall risk for wrong-site surgery decreased after implementing the protocol. Wrong site surgery can yield grave ramifications health care organization and the patient. Wrong site surgery requires a team approach and is preventable as long as the entire team is involved with the organizations time out policies and procedures. To prevent wrong-site surgeries the entire operating room team must perform a "time out" before beginning surgery to ensure that all operating room personnel are familiar with the patient, the procedure, their role, and how to respond to complications (Makary, Mukherjee, Sexton, 2007). Furthermore, the joint commission for health care accreditation recommends that the surgical site is visible to the entire operating room and that the surgeon mark the surgical site and communicates with his team orally verifying the intended site and



procedure. In the operating suite, the team must routinely verify that it is the correct patient, procedure, and site (Kohn, Corrigan, &, Donaldson). Failure to follow the health care organizations timeout policy and procedure prior to a surgical procedure can result in the occurrence of errors.

Supporting work

Neily, J., et. al, (2009). conducted a study and found that many wrong site surgical cases were attributed poor communication that may not have been addressed by preoperative teams time out procedure, furthermore these authors argue for teamwork training to address the communication errors, which occurs at the time of the universal protocol time-out. Any surgical department that conducts multiple surgeries, the operating room team should evaluate ways to minimize the organizations risk by conducting a failure mode and effects analysis. The risk management process involves two major areas, which are intricately tied to each other the identification and analysis of exposures and treating the exposures through some form of risk management technique (Carroll, & Troyer, 2006).

The vulnerability of critical assets to specific threats and assessment can be examined through the health care organization looking at what is the possible outcomes and risk of wrong site orthopedic surgery and identify ways to reduce those risks. Although conducting root cause analysis after a high alert incident has occurred, the Joint Commission has standards, which recommend that each health care organization conduct a risk assessment failure mode and effects analysis (FMEA) annually to meet the Joint commission requirements. By conducting FMEA health care organizations “uses a systematic approach towards the development and



implementation of a proactive risk assessment and management activities so that patient care, treatment, and service processes can be designed or redesigned to prevent failure (The Joint commission, 2005).”

Counterargument Addressing the Problem

Between the years 1995 and 2007, 691 wrong-site surgeries were reported to the joint commission's sentinel event data repository (Stanton, 2009). The 691 only reflects the wrong site surgeries that were reported. Stanton, (2009) further illustrates the time-out is initiated by a designated member of the team and is performed in a standardized fashion, as defined by the health care organization. At the moment the time out is initiated, the entire operating room team should be silent and involved. The surgical site should then be repeated back to the surgeon by two health care professional to avoid wrong site surgery. The operating room team should develop a systematic mindset that should be performed routinely that will yield success. The operating room staff should also utilize the patient in conjunction as active participant in the safety and quality of his or her health care. Studies show that patients who are actively involved in making decisions about their care are more likely to have good outcomes (Joint commission, 2006).

Communication Addressing the Problem

Communication must be effective amongst the surgical team Richardson, (2014) illustrates that for communication to be effective, it must be complete, clear, brief, and timely. Furthermore it is effective for the surgical team to use situation-back-ground-assessment-recommendation (SBAR), call-out, call-back, and hand-off. SBAR can be used in the surgical procedure to:



- a. S- Situation-Should be Brief and detailed explaining what is going on with the patient.
- b. B-Background- Clinical History of the patient that is pertinent to the surgical procedure.
- c. A-Assessment- Current Pre-operative clinical impression
- d. R-Recommendation-The first of several TIME-OUTS should occur at this time.

Conclusion

The Universal Protocol was created to address the continuing occurrence of wrong site, wrong procedure and wrong person surgery in The Joint Commission and finalized in July 2004 (The Joint commission, 2009). The JC has also mandated that all health care organization conduct at the least one FMEA annually. As health care organizations become “caught up in the whirlwind of standards compliance temptation often exists to execute the FMEA project work without proper training. It's imperative that all health care organizations note that there are many different FMEA models, and no one particular technique is most suitable (Spath, 2004).”

The key to FMEA and patient safety is for accredited organizations to improve clinical processes. The clinical process can be improved by health care organization looking at high risk that may cause harm or errors to the patient. The JC is trying to convey that performance improvement standards should be used as baseline data clearly to visualize if the health care organizations have any potential risk (Case Management, 2003). The performance improvement standard should be a proactive and a proper approach to an FMEA that includes proper training to an effective outcome. The risk manager and the entire team who will be directly affected by high risk patient errors should always be involved when conducting a FMEA.

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