

EVALUATION OF FIRE RISKS TO IMPROVE SAFETY IN THE OPERATING ROOM

by

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Abstract

Background: Patient safety is the cornerstone of high-quality health care, and has become an increasingly important public concern. Surgical fires are a preventable, never event. As with other low incidence but high impact events, solutions to prevent this complication are known and published. However, preventive measures have yet to diffuse sufficiently across professional boundaries. The challenges to preventing fires relate to educating all of the members of the surgical team, and overcoming barriers to intraoperative communication.

Methodology: Through an educational program, the surgical services staff at the selected facility were made aware of the importance of acknowledging fire safety through the implementation of a fire risk assessment with every procedure. Use of the fire safety checklist was monitored for compliance.

Findings: Results showed a 95% compliance rate with checklist completion, and 90% effective communication of the fire risk score to members of the surgical team. Feedback was positive throughout, including making the process concise, quick, and easy to complete, as well as improving communication among team members.

Key Words: Patient safety, surgical fires, surgical safety checklists, preventing OR fires, fire safety, fire risk assessment checklist

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Chapter 1: Introduction

Introduction

Surgical care has been an essential component of health care worldwide for over a century. The World Health Organization (WHO) has been involved in many initiatives to address surgical safety, including the Global Patient Safety Challenge: Safe Surgery Saves Lives, which began in 2007 (WHO, 2008). The focus of this initiative is the WHO Safe Surgery Checklist, which was developed to ensure that the surgery team has completed a timeout prior to proceeding with any surgical procedure. The magnitude of improvement demonstrated by the WHO initiative was surprising, and the initial results have been confirmed by further detailed work demonstrating that surgical checklists, when properly implemented, can make a substantial difference to patient safety (Walker, Reshamwalla, & Wilson, 2012).

Another aspect of safe surgery involves the occurrence of operating room (OR) fires. An incident, such as a surgical fire in the OR, is often referred to as a never event. Never events are described as occurrences that cause patient harm that are completely preventable when reasonable precautions are taken (Yoon, Alaia, Hutzler, & Bosco, 2015). The incidence of OR fires has been estimated to range from 550 to 650 events every year in the United States, which is comparable to that of wrong-site surgery (Mehta, Bhananker, Posner, & Domino, 2013). Patient injuries after a fire in the OR are often severe and may cause death in some cases. The causes of OR fires are multi-factorial, but the main point to understand is that most are completely preventable with the proper communication, appropriate education, and the active management of risk factors (Hart, Yajnik, Ashford, Springer, & Harvey, 2011). Continuing education and communication among OR personnel along with fire prevention protocols in high-fire risk procedures may reduce the occurrence of OR fires (Mehta et al., 2013).

Problem Statement

The potential for operating room fires is present on a daily basis, with every surgical procedure. Every year, there are about 550-650 surgical fires in the United States. About 20-30 surgical fires cause serious injury or disfigurement. One to two fires are fatal, most involving fires in the airway (ERCI Institute, 2016). The causes are multi-factorial, and are often referred to as the fire triad. The fire triad basically states that if there is an oxidizer, a fuel source, and an ignition source, then any spark may result in an eruption of flames (Cowles, Wahr, & Nussmeier, 2016). The awareness of the risk factors for fire is the shared responsibility of all team members. These risks are present at every facility across the country, in every procedural area where the fire triad is present. Although there is a fire safety protocol in place at the facility where the project will be implemented, the fire safety checklist is not being verbalized during the surgical time out; however, the circulating nurse is completing the fire safety checklist in the Electronic Health Record (EHR) as part of required documentation. Essentially, the fire safety check is being completed by one member of the team through documentation in the EHR, but it is not being discussed among all members of the surgical team. The goal of the QI project is to develop, implement, and evaluate a process to ensure that all surgical services staff follow a fire risk assessment checklist and understand the implications. This will be accomplished with the addition and initiation of a fire risk assessment checklist prior to the start of any surgical procedure. This brief checklist will be added to the broader safe surgery checklist within the EHR at the selected facility. By adding this checklist as part of the verbal timeout in the OR, each team member present will have the opportunity to participate in the fire safety checklist, be aware of the risks that are present, and know how to mitigate those risks and follow fire safety protocols. Ultimately, this will help promote patient safety in the operating room.

Theoretical Framework

Healthcare organizations are complex adaptive systems where change is a complicated process with varying degrees of difficulty and agreement among disciplines. Professionals from various disciplines often subscribe to different change management theories for continuous quality improvement. Lewin's Change Theory is a common change theory used by nurses across specialty areas for various quality improvement projects to transform care at the bedside (Wojciechowski, Pearsall, Murphy, & French, 2016).

Kurt Lewin, a German psychologist, outlined a model for change used by industry in the 1940s. Lewin believed that the key to resolving social conflict was to facilitate learning and so enable individuals to understand and restructure their perceptions of the world around them (Burnes, 2004). Lewin's theory proposed that "individuals and groups of individuals are influenced by restraining forces, or obstacles that counter driving forces aimed at keeping the status quo, and driving forces, or positive forces for change that push in the direction that causes change to happen" (Wojciechowski et al., 2016, p. 4). The tension between the driving and restraining forces maintains equilibrium. Lewin believed that group behavior is a set of interactions and forces that not only affect group structures, but can also modify individual behaviors. Because of this, individual behaviors are a function of the group environment, and any changes in behavior will stem from changes, large or small, in the forces within the group environment. Lewin argued that "if one could identify, plot, and establish the potency of driving and restraining forces, then it would be possible not to only understand why individuals, groups, and organizations act as they do, but also what forces need to be diminished or strengthened to bring about change" (Burnes, 2004, p. 981).

In order for an organization to change the status quo, it can execute planned change activities using Lewin's three-step model. The first step is unfreezing, which is the act of destabilizing old behaviors and is necessary for old behaviors to be unlearned and new behavior to be successfully adopted (Bishop, 2015). Schein (1996) comments that unfreezing creates problem awareness, making it possible for people to let go of old ways and patterns through education, challenging status quo, and demonstrating issues or problems. In this stage, a nurse leader may recognize a problem, identify the need for change, and mobilize others to see the need for change. This stage requires identifying the factors for and against change and necessitates strengthening the driving forces and/or weakening the restraining forces. The second step is to consider a method that will result in the least resistance in moving a change forward. Changing enables individuals and groups to switch to more acceptable behaviors (Bishop, 2015). This phase seeks alternatives, demonstrates benefits of change, and decreases forces that may affect change negatively. This stage is often difficult, because there is uncertainty and fear associated with change. It is important to coach to overcome fears and practice clear communication to avoid losing sight of the desired outcome. The third and final step is refreezing, which involves a return of the dynamic force field and a new state of equilibrium (Bishop, 2015). Burnes (2004) describes this step as seeking to stabilize the group at a new equilibrium in order to ensure that the new behaviors are relatively safe from regression. In organizations this would be seen in policies, procedures, and practices as well as norms and culture (McGarry, Cashin, & Fowler, 2012). Unless group norms and routines are transformed, changes to individual behavior will not be sustained. This final stage is important because locking in the change is crucial to its sustainability.

In reviewing the literature, Lewin's Change Theory has been used quite extensively in clinical nursing practice, nursing education, educational administration, nursing research, and healthcare operations. The structure and processes of the theory assist in avoiding the common pitfalls that prevent successful change initiatives, and also offers a framework to guide change (Shirey, 2013). Knowing which driving and restraining forces may affect the proposed change will help in the design of a detailed action plan and encourage success.

Definition of Terms

Safety. Safety can be defined in a very broad context and can apply to many aspects of our daily lives, occupations, and situations. In a general sense, safety can be described as a feeling of well-being and freedom from injury, danger, or loss in our day-to-day activities. Examples include the safety features of our cars, walking in a well-lit parking lot, feeling able to speak up at work without fear of repercussion, using machinery or equipment that has been tested and made safe for use, and being provided the appropriate workplace personal protective equipment, just to name a few. A general definition of safety is the "perspective that acceptable control and management exists over hazards and risks inherent to the tasks being performed" (Lambert, 2009, slide 5).

Patient Safety. This can be described as the prevention of harm to patients. Also, patient safety can be defined as "freedom from accidental injury; ensuring patient safety involves the establishment of operation systems and processes that minimize the likelihood of errors and maximize the likelihood of intercepting them when they occur" (Clancy, Farquhar, & Collins, 2005, p. 194). Emphasis is placed on the system of care delivery that prevents errors, learns from the errors that do occur, and is built on a culture of safety that involves health care professionals, organizations, and patients (Mitchell, 2008). A review of literature results in a

basic common theme of preventing harm to patients. Ultimately, keeping patients free from accidental injury, reducing the likelihood of errors, and correcting the errors before they have a chance to cause harm to a patient is key to patient safety.

Sentinel Event. This is essentially the opposite of patient safety. It is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase “or the risk thereof: includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome” (Watson, 2009, p. 926). Although rare, sentinel events can occur at the best of hospitals with the most skilled staff. No one is immune to the potential risk for an untoward patient outcome that can result in significant injury or death.

Never Event. An incident, such as performing surgery on the incorrect site or an OR fire, is often referred to as a never event. Never events are described as occurrences that cause patient harm that are completely preventable when reasonable precautions are taken (Yoon et al., 2015). Another definition of a never event is “a serious, largely preventable patient safety incident that should not occur if the available preventative measures have been implemented by healthcare providers” (Tichanow, 2016, p. 11).

Chapter 2: Review of the Relevant Literature

Literature Review

The initial literature search strategy was created using the following keywords: surgical fires, surgical safety checklist, sentinel events, surgical fire safety, and never events. When possible, the review was limited to 10 years and to English language research. The review was completed with the use of the electronic bibliographic databases, PubMed, CINAHL, and

Ovid. An additional literature search using the PubMed database resulted in meaningful Medical Subject Headings (MeSH) terms of “medical errors”, “surgical procedures”, “operative”, “safety”, and “checklist”. The initial literature search yielded 2,508 citations after removing duplicates. After applying additional filters of “operating room” and “surgical time out”, 154 of the original citations were retained. Abstracts of the 154 papers were reviewed and 22 manuscripts were found to be potentially significant to the examination of evaluating fire risks to improve safety in the operating room. A Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Flow Diagram was completed showing the literature search strategy (see Appendix L). See Appendix A for a complete literature matrix.

Incidence of OR fires. There is a wealth of knowledge regarding the incidence of fire in the operating room. Of the 22 manuscripts found to be significant to this project, six discussed that fire in the operating room is a relatively rare event, but when it does occur, the medical outcomes are often catastrophic for the injured patient, with severe legal and economic consequences for the surgical team and facility (Choudhry, Haddad, Khasawneh, Cullinane, & Zielinski, 2016; Clarke & Bruley, 2012; Cowles et al., 2016; Hart et al., 2011; Hempel et al., 2015; and Rinder, 2008). Most OR fires are preventable with communication, appropriate education, and management of risks. Since these preventive measures have little cost and are nearly 100 percent effective, they are prioritized in patient safety initiatives. These same manuscripts report the occurrence of OR fires as ranging from 550 to 650 events per year in the United States. However, since half of the states do not have mandatory reporting, the actual number is probably higher (Choudhry et al., 2016; Cowles et al., 2016). Most claims occur in an outpatient setting, involve the upper body, and are cases managed with monitored anesthesia care (MAC), which involves an open oxygen source.

Impact of OR fires. The impact of an OR fire is described in 5 papers. Patient injuries after an OR fire are often severe, including painful and disfiguring burns to the face and neck, or severe airway injury with tracheostomy and permanent lung damage (Cowles et al., 2016; Hart et al., 2011; Rinder, 2008). Typically, a surviving patient must return to the OR many times to treat acute burn injuries and revise scar tissue, causing recurring anxiety, post-traumatic stress, and economic burden (Choudhry et al., 2016; Cowles et al., 2016; Dalal, Saha, & Agarwal, 2010).

Never Events. A systematic review of surgical never events (Hempel et al., 2015) found 138 empirical studies meeting their inclusion criteria. The objective was to examine the incidence, root cause of and interventions to prevent never events like wrong-site surgery, retained surgical items, and surgical fires in the era after the implementation of the Universal Protocol in 2004. This document included international controlled and uncontrolled evaluations of interventions aimed at preventing the mentioned never events during surgical and other invasive procedures that reported on events or near misses. Studies with randomized clinical trials, before-and-after intervention studies, and after-intervention studies were eligible.

Causes of OR fires. Many of the papers reviewed discussed the causes of fires in the OR (Choudhry et al., 2016; Cowles et al., 2016; Hart et al., 2011; Mehta et al., 2013; and Stewart & Bartley 2016). Fire in the OR is often described as containing three components: an oxidizer (oxygen, nitrous oxide), an ignition source (electrosurgery unit [ESU], laser), and a fuel (alcohol-based prep solution, surgical towels and drapes). This combination is commonly referred to as the fire triad, or the fire triangle. Whenever these three items are in close contact under appropriate conditions and proportions, a fire will occur. The key to prevention is altering one or more of these components so combustion is not possible. In the OR, each healthcare worker owns a part of the fire triangle (Hart et al., 2011). The fuel source is typically provided by the

circulating nurse in the form of alcohol-based preps, drapes and towels, ointments, alcohol, patient hair, and dressings. Alcohol-based skin preparations have become more common as a source of fuel since the Centers for Disease Control (CDC) identified them as the preferred method for skin disinfection in most cases (Hart et al., 2011). The surgeon usually supplies the ignition source in the form of electrocautery. Lasers for airway surgeries, fiberoptic light sources, sparks from surgical drills and burrs, and glowing embers of charred tissue are also common sources. The final component is an oxidizer, which is controlled by anesthesia. Most of us realize that oxygen greatly enhances the rate of combustion, but many do not know that nitrous oxide supports combustion in the same manner. Oxidizers lower the temperature at which a fuel will ignite, therefore increasing the chance of a fire.

Surgical Safety Checklists. At least 7 pieces of literature discuss surgical safety checklists, surgical team members' attitudes toward time out protocols, and implementation and compliance with surgical checklists (Alidina et al., 2017; Erestam et al., 2017; Haugen, Muruges, Haaverstad, Eide, & Softeland, 2013; Neuhaus, Spies, Wilk, Weigand, & Lichtenstern, 2017; Stewart et al., 2015; Uppot et al., 2017; and Zingiryan, Paruch, Osler, & Hyman, 2016). Each of these manuscripts describe the use of perioperative checklists as generating a growing body of evidence pointing toward reduction of mortality and morbidity, improved compliance with guidelines, reduction of adverse events, and improvements in human factor-related areas. In particular, an editorial by Stewart et al. (2015) reported that the mandated timeout before each surgical procedure was designed to reduce the risk of wrong-site surgery, but that many may not realize that OR fires occur as frequently. It is estimated that patients are harmed by 20% of the OR fires that are reported each year. OR fires, together with retained surgical sponges and wrong-site surgery, are now classified as "never" events by the Centers for

Medicare and Medicaid Services (CMS). The Joint Commission has expected that fire assessment be included in the preoperative timeout, and as a result, some medical centers have included fire risk assessment in the preoperative timeout. However, it is not widely used at this point, and more attention needs to be drawn to this important component of the timeout.

A cross-sectional study by Haugen et al. (2013) surveyed surgeons, anesthesiologists, nurse anesthetists, and operating room nurses to determine team members' experience of near misses or mistakes, strategies for verifying patient and procedure, whether they believed that these mistakes could be avoided using the time out protocol, and how they would accept the implementation of the protocol in the operating room. Most surgical team members had experienced near misses in the OR. This study advocates that routines for ensuring the correct patient, site, and surgical procedure must involve all surgical team members. This belief could certainly be applied to a fire risk assessment checklist.

Erestam et al. (2017) developed a prospective interventional study to determine the safety climate and teamwork in the operating room before and after the implementation of a revised WHO checklist. Emerging concepts from this study are safety culture and safety climate when discussing safer surgery. Deficiencies in teamwork and communication were found during this study. Also, adherence to the revision of the checklist was insufficient, dominated by a lack of structure.

Another example of surgical checklists and impact on safety culture was developed by Zingiryan et al. (2016). The team created a 28-questions survey to assess perspectives of surgical team members, as well as monitor rates of nine complications before and after Safe Surgery Checklist (SSC) implementation. Significant findings were that although there was no decrease in any of the nine complications two years after the SSC implementation, there was

overall improved communication, safety, and prevented errors in the operating room. It did improve the perception of safety culture by OR staff.

Gaps in the Literature and Limitations

During the synthesis of the available literature for this project, it was discovered that there is a tremendous amount of information and the phenomenon of OR fires is well-documented in the literature. There is a strong theme of education for surgical services staff throughout the pieces of literature that were evaluated. However, a noted gap in the literature includes linking OR fire safety and checklists systems. There are a multitude of published papers on checklists, and also on fire safety, but less on the link between the two. Many of the papers discussed the importance and value of surgical safety checklists on patient safety. Others describe in detail the components of OR fires and how to prevent them. There are very few that link the topic of checklists and OR fire safety. On completion of this project, hopefully a strong link between using a fire safety checklist and the successful prevention of OR fires will be presented.

While the quality of the literature that was collected for this project is informative and supports the goals of the project, the level of evidence for most of the pieces of literature are greater than a level four as described by Melnyk and Fineout-Overholt (2011). None of the papers described randomized controlled trials. Some were pre- or post-test formats. Most were observational study, clinical consensus, systematic reviews, or expert opinions. Still, the literature that was collected is very useful to the completion of this project, providing a foundation for showing the link between OR fire safety and fire safety checklists and aiding in implementing the new protocol in operating rooms.

Chapter 3: Methodology

Needs Assessment

The facility for this project was a 74-bed community hospital offering services in emergency, medical, surgical, imaging, rehabilitation and maternity. It is part of a larger corporate healthcare system with more than 25,000 team members, 14 hospitals, 100 outpatient facilities, and 350 physician practices. Fires in the operating room are an inherent risk at any facility. OR fires, together with retained surgical sponges and wrong-site surgery, are now classified as “never” events by the Centers for Medicare and Medicaid Services (CMS) (Stewart et al., 2014). The Joint Commission (TJC) has expected that fire assessment be included in the preoperative timeout, and as a result, some medical centers have included fire risk assessment in the preoperative timeout (Stewart et al., 2014). However, it is not widely used at this point, and more attention needs to be drawn to this important component of the timeout. The OR staff at the selected facility were performing a surgical timeout, which included identifying the patient, procedure, laterality, allergies, and antibiotic status prior to starting the procedure. It was directly observed that this timeout did not include addressing fire safety, even though there are expectations by TJC and required documentation in the EHR that the RN completes regarding fire safety.

Methodology

The goal was to develop, implement, and evaluate a process to ensure all surgical services members followed a fire risk assessment checklist and understood the implications. The intention was to incorporate a brief three question fire risk assessment into each and every surgical timeout that was completed. Each of the three questions would be assigned a score, and

based on that score, would determine if the patient was at no risk, moderate, or high risk for a surgical fire.

Protection of Human Subjects

This project underwent review by an Institutional Review Board (IRB) at the project site as well as at East Carolina University, who both deemed the project as non-human subject research (see Appendix J and K). The only data collected was the evaluation of staff compliance with the use of a checklist. No data about the staff, including demographics, titles, level of education, etc. was collected. The checklist compliance data was collected by the DNP student and kept in a secure location. The raw Excel data collection file (see Appendix O) was stored electronically on a password protected computer.

Tools

A healthcare system in the United States created a fire risk assessment tool that addresses the potential fire risks present in the operating room (see Appendix C). This particular tool was first published in 2006 by the Christiana Care Health System to assess the range of human factors that contribute to surgical fire risks as a component of the preoperative time out. This tool has become the gold standard in addressing fire safety in the OR (Sanchez, Barach, Johnson, & Jacobs, 2017). It has been published in the Anesthesia Patient Safety Foundation (APSF), and as an algorithm by the American Society of Anesthesiologists (ASA). It is also supported by closed malpractice claims data (Cowles et al., 2016). The tool asks three simple questions. Is there an open oxygen source? Is there an available ignition source? Is the surgical site above the xiphoid or less than 12 inches from the oxygen source? (Townesley, n.d.). If a risk is present, a score of 1 is applied. If no risk is present, then a score of 0 is applied. The risk score therefore would range from 0 (low risk) to 3 (high risk). Based on the score after answering these

questions, certain protocols would be followed to minimize the risk of an OR fire (Townesley, n.d.). There are routine and high-risk protocols (see Appendix C) that address the fire safety concerns and how to minimize the risk factors and be as prepared as possible if a fire were to occur in a high risk situation (Bruley, 2004).

The fire risk assessment tool addresses the potential fire risks present in the OR. The tool is very similar to the documentation that currently exists in the EHR of the project site facility. The benefit of using an existing tool is that it has been validated and has been proven to be a successful tool in the awareness, preparation, and patient safety culture regarding OR fires. Permission was received to use the tool in this QI project (see Appendix G). The initiation of this QI project began with an educational presentation to the surgical services staff at the selected facility to discuss fire in the operating room, statistics, general considerations, causes of OR fires, and stress that all members of the OR team play an integral part in the management and prevention of OR fires. In addition, the educational session explained the key elements of fire prevention in the OR, which are risk assessment, communication between members of the surgical team, and preventive measures based on level of risk. The target audience was the surgical services staff, including anesthesia providers, surgeons, nurses, surgical technicians, and ancillary staff. The ultimate beneficiaries of this program were the surgical patient population at the project site, as the goal was to improve patient safety.

It was important that the staff understood that operating room fires are considered a never event, and that most are completely preventable with the proper precautions. The educational presentation to the surgical services staff explained not only the fire triangle and ways to prevent the three elements from joining, it also described the use of the fire risk assessment tool in the OR. Protocols for each level of risk were provided, describing methods for reducing fire risk,

and how to prepare the OR in case a fire were to occur. This educational program took place during the monthly surgical services staff meeting, where a wide range of team members were included. Additional conversations were required to reach the staff that were not present at the staff meeting. A PowerPoint presentation was developed to include all of the information as described (see Appendix I).

Evaluation Methods

To evaluate whether the fire risk assessment tool was being used, and if it was being used correctly, there was a designated person assigned in each operating room to monitor the use of the fire risk assessment. The designated person was the Certified Registered Nurse Anesthetist (CRNA) assigned to each room. Prior to the start of any data collection, the CRNAs were given instructions on what information was being collected, what the data collection form looked like, and any questions about the process were addressed (see Appendix D). The period of time for data collection was 8 weeks. The data collection included whether the fire safety checklist was completed prior to the procedure, whether the three questions about oxygen, ignition source, and surgical site were asked, and whether the score from the three questions was made clear to the team. If the score was three, or high-risk, were the appropriate protocols discussed and risks addressed? (see Appendix C). These protocols already existed within this facility. The protocols developed by Christiana Care have been widely discussed in the literature and are considered the gold standard for fire safety and prevention (Sanchez et al., 2017). Data collection forms were deposited in a designated, secure location at the end of each day, were hand delivered to the DNP student, or were personally collected from the OR suites by the DNP student. The DNP student obtained data during surgical timeouts to analyze documentation compliance and effectiveness of the process. This did not require any protected health information (PHI) or

identifiers to be collected, and privacy was maintained. Correct use of the fire safety checklist in the OR was the only data of interest.

Feedback from the staff, obtained during periodic huddles in the OR, was used to evaluate the implementation of the project and to determine staff opinions of using the checklist. Additional education and explanation of the project and the intended outcomes was provided as needed, based on feedback, to improve compliance with performing the checklist during surgical timeouts.

Data Analysis

After the 8-week data collection period was complete, 280 evaluation forms were obtained. The data from the evaluation forms was entered into Excel as a spreadsheet for analysis. The collected data was descriptive statistics, and as such, revealed information about the numbers and percentages associated with each of the six questions on the evaluation form (see Appendix D). Data was filtered to determine the number of yes, no, or N/A answers. This data was entered into Table 1 (see Appendix M), and Table 2 (see Appendix N).

Limitations

Some limitations regarding this project were identified after the process of implementation and data analysis was complete. One of the limitations identified was that the data collected during the designated collection timeframe was most likely not completely accurate on the use of the fire risk assessment checklist. For example, data collectors were encouraged to fill out an evaluation form for every single case they were present for to evaluate the time out process and use of the checklist, regardless of if it was done correctly or not. The evaluation process was not done consistently on every timeout prior to a procedure. Also, some of the anesthesia providers present for the timeouts admitted they never filled out an evaluation

form. As a result, the data collected on the correct use of the fire safety checklist may seem falsely high due to missing evaluation forms.

Another limitation identified was the willingness of the staff to participate in the implementation of the fire risk assessment checklist. This was more noticeable at the beginning of the process, as change is difficult for some people. Also, since this was a new process for everyone, another limitation is that it was difficult for some to remember to include the checklist in the timeout. Staff members were encouraged to refer to the laminated copies of the checklist in each OR for reference during timeouts to make the process easier and more complete.

Financial Implications

Patient injuries after a fire in the OR are often severe (e.g. painful and disfiguring burns to the face and neck and/or severe airway injury with permanent lung damage). Typically, a surviving patient must return to the OR many times to treat acute burn injuries and revise scar tissue, which can be a tremendous economic burden on the patient and the facility.

Regarding a fire in the OR, most of the claims occur in an outpatient setting (76%), involve the upper body (85%), and are cases managed with monitored anesthesia care (MAC) (81%) (Mehta et al., 2013). Every member of the surgical team that is involved in an OR fire is usually implicated in some degree of negligence and culpability. Closed claim data shows that payments were made in 78% of claims, and the median settlement value was approximately \$120,000 (Mehta et al., 2013). Estimates are that preventable medical errors, including OR fires, are responsible for between 44,000 and 98,000 of patient deaths in hospitals per year. The cost of errors ranges from \$17 million up to \$29 million annually, and the related emotional costs for patients and their families, as well as caregivers, are incalculable (Clancy et al., 2005).

Patients who are victims of surgical fires often sustain significant physical injuries, resulting in added costs of having to abort the initial procedure, complete the procedure at a later date, and possibly schedule additional surgeries to repair burn injuries. Also, the cost of lawsuits, trials, and resultant settlements for the individual providers and for the facilities and insurance companies are significant. Settlements can range from hundreds of thousands of dollars to well into the millions depending on the injuries sustained by the patient.

The cost to develop and implement this QI project was very minimal, in fact less than 50 dollars. The process of using the checklist and practicing preventative steps to prevent OR fires literally costs nothing. If, through these education and preventive measures, this quality improvement project prevents even one surgical fire, then it was a worthwhile and tremendous cost-saving project.

Chapter 4: Results

Sample

This QI project logged evaluations of the performance of the fire risk assessment checklist by the Registered Nurses (RNs) during surgical timeouts in the OR. Sample characteristics of the RNs using the checklist were of no concern in this project. No demographic data was collected for this reason. The evaluation of the use of the checklist focused specifically on the correct use of the checklist during the surgical timeout.

The data was collected during an 8-week time period on surgical cases performed in the main operating room at the selected facility. The final sample size was 280 evaluations.

Intended Outcome

The intended outcome of the project was to implement the use of a fire risk assessment checklist into every surgical preoperative timeout to improve fire safety in the OR. Through an

educational presentation, the staff was made aware of the risks of OR fires, causes, and preventative measures, as well as what the fire risk assessment checklist was and the safety protocols associated with the checklist. The outcome of the project was evaluated by monitoring staff compliance with the use of the fire risk checklist during preoperative timeouts. Feedback from staff through periodic huddles and one-on-one conversations was utilized to determine the need for further education, encouragement, and discussion about the project to increase awareness of the use of the checklist.

Findings

The sample size was 280 evaluations. The final checklist completion rate during the evaluation period was 95% (n=267).

Figure 1. Percentage of checklist completion rates



The rate of discussion of each of the three risk score questions on the checklist was 82% (n=230). The assignment of a risk score based on the answers to the 3 questions was accomplished in 89% of the evaluated cases (n=250). 90% of the time, the risk score was communicated to members of the surgical team. The use of alcohol-based prep solutions is

common in the OR. If one was used, a required 3-minute dry time must be observed. 57.9% of the cases used this prep solution, and the appropriate dry time was observed. In 39.6% of the cases this prep solution was not used, and in 2.5% of the cases that did use the alcohol-based solution, it was reported that the 3-minute dry time was not observed. And finally, if the case received a score that was considered high risk, there are additional protocols that must be followed. 90.4% of the cases were marked as not high risk (n=253). Out of those that were considered high risk, 5% of the time the additional protocols were discussed, and 4.6% of the time they were not. See Table 1 (Appendix M) and Table 2 (Appendix N) for a breakdown of the data and percentages.

Chapter 5: Discussion

Introduction

Quality improvement projects are important in that they can provide opportunities to improve an area of patient care by either changing an existing process, or creating a new one. QI projects also offer learning opportunities throughout the development and implementation of the project. This chapter will discuss the significance of the findings in this QI project, its strengths and limitations, as well as some benefits to nursing practice, recommendations and lessons learned during this process.

Significance of Findings

The clinical significance of implementing this project in the selected facility showed that the introduction of the fire risk assessment checklist was successful. Staff members in the OR are already very familiar with checklists and their effectiveness in preventing wrong site surgery, procedures done on the wrong patient, and prevention of retained objects after a surgical

procedure. In the cases that were evaluated, 95% of the time the fire risk checklist was completed. The use of the fire risk assessment checklist provided a quick and simple way to assess fire risk for each surgical patient. In addition, communication among surgical team members was improved, as the fire risk was brought to their attention and discussed prior to the initiation of any surgical procedure. Staff members reported that they felt the checklist was very concise, simple, and easy to complete, while making it more likely that the checklist would be completed. Many voiced their appreciation of bringing this patient safety issue to their attention, and awareness of the importance of effective communication among staff members in the OR was heightened.

Project Strengths

This QI project had several strengths. One of its major strengths was the simplicity of the design of the project. As mentioned previously, a fire risk assessment already existed in the nursing EHR documentation; however, it was cumbersome and involved multiple screens and checking several boxes on each screen within the documentation. In addition, the nurses were not verbalizing the assessment of the fire risk to other members of the surgical team. The simplistic design of the fire risk assessment checklist is functional, and promotes collaboration between members of the surgical team. The design of the checklist was intended to introduce and simplify the process of assessing fire risk in the OR, as well as promote communication among team members.

Another strength of the project was the periodic huddles with team members in the OR to follow up on the use of the checklist, educational needs of the staff, and promote a team approach to improving patient safety. In conversations with these team members, many were pleased with the simplified process, and voiced their opinions that the risk assessment tool was

concise and easily manageable during the typically busy starts of OR cases. In a letter received by the DNP student from one of the staff RNs, the nurse described how the QI project gave the staff a tool to assign a numerical value to the assessment, which gave the OR team a number they could recognize and understand. She went on to say that the fire risk component in the EHR is long and detailed, and the risk assessment tool and number assignment was concise and easily manageable, and has made it easy to accomplish the fire risk assessment, contributing to safer practice in the OR (D. Davis, personal communication, February 13, 2018).

Limitations

One of the limitations of this QI project was the high number of pro re nata (PRN) staff working in the project site OR. Because of this, many of the staff were not present for the initial educational presentation describing the project, its goals, and staff roles in the project. In addition, new staff were hired during the implementation and evaluation stages of the project, which required additional educational efforts to make sure all staff were aware of the project and how they would be participating.

Another limitation of the project could be the short time frame of the project and its evaluation period. As with any new task, people are often willing to try it in the beginning, but as time marches on, they become more unconcerned or cavalier about it, becoming less interested in performing the required task. Because the time frame of the project was fairly brief, the percentage of checklist completion and associated data may be falsely high, as the introduction of the project was a new concept, and staff were initially interested in the project. However, the DNP student has observed since the completion of the evaluation period that the staff continue to use the checklist, discussing it with each timeout and assigning a risk score to each procedure. Further evaluation for a longer period may give more accurate data.

Recommendations

Ultimately, the goal of this project was the successful implementation and use of a fire risk assessment checklist in the OR to increase patient safety. The checklist proved to be simple and concise, contributing to the increased likelihood that staff members will continue to use this tool to assess fire risk for each surgical patient in the OR.

Recommendations include continued evaluation of the use of the checklist, to ensure that the process has become embedded in the OR culture at the project facility. Using Lewin's Change Theory, it will be important to continue to demonstrate the benefits of the addition of the checklist, and decrease forces that may affect its use negatively. Clear communication and encouragement will be required to avoid losing sight of the ultimate goal of patient safety. To freeze the change into place, this behavior needs to become the new normal, and could be accomplished by establishing a policy or procedure for the surgical services department. Based on the results of this project, the DNP student will focus on disseminating the results and expanding this project to as many as 15 other facilities within the corporate system.

Chapter 6: Implications for Nursing Practice

Introduction

Throughout the development, implementation, and analysis of this QI project, the goal was to find a way to advance nursing practice and improve a process that would promote increased patient safety. This project is becoming a new routine for the staff at the selected site, and is being used consistently, on every patient that comes to the facility for surgical care.

Practice Implications

As a result of QI projects and other evidence-based learning, it is our responsibility as nurses to use the knowledge we gain in our daily practice. The practice implications of developing new processes, practice guidelines, and strategies is to use these tools to advance nursing practice and improve the care we provide to our patients. It is imperative that the delivery of evidenced-based, quality patient care remains central to the role of all nursing professionals.

The American Association of Colleges of Nursing (AACN) has determined that there are two types of doctorate degrees. One is research focused, and the other is practice-focused. In working towards the practice-focused Doctor of Nursing Practice (DNP) degree, the AACN has developed a list of eight essentials that outline the curricular elements and competencies that must be present in programs conferring the DNP degree (AACN, 2006). Following the essentials delineated by the AACN, DNP graduates will be prepared for a variety of nursing practice roles, from leadership, administration, policy, or advanced practice nursing. The eight DNP essentials and how they were met by this project are summarized in the following paragraphs.

Essential I: Scientific Underpinnings for Practice. The QI project used the introduction and implementation of a fire risk assessment checklist to improve patient safety in the OR. The existing literature was studied to determine background information on fire risks, causes, and prevention techniques. In addition, an existing, validated tool was obtained to aid in the development of the project and subsequent prevention of fires in the OR.

Essential II: Organizational and Systems Leadership for Quality Improvement and Systems Thinking. As this project was being developed, the DNP student identified an area of concern for patient safety. The DNP student subsequently developed the project to address this concern and advocate for patient safety at the selected facility. The DNP student presented an educational program to the staff members of the surgical services department as well as made written materials available for reference as the project implementation commenced.

Essential III: Clinical Scholarship and Analytical Methods for Evidence-Based Practice. As a result of determining there was a nursing process that could be improved to encourage patient safety, the DNP student conducted an extensive literature review to determine best practices for the prevention of fires in the OR. As a result of the literature review, a QI project was designed and implemented to promote fire prevention and improve patient safety. The project was evaluated to assess the effectiveness of the process and help develop new practice guidelines for the facility. At the conclusion of the project, the results will be disseminated to the nursing practice council for potential expansion to other facilities within the greater corporate network.

Essential IV: Information Systems/Technology and Patient Care Technology for the Improvement and Transformation of Health Care. This DNP essential focuses on the use of technological resources in practice. Throughout this project, many forms of technology were used in the development, approval process, implementation, and evaluation of the project. Research databases were accessed throughout the development and continued work on this project. Data collection and analysis was aided by the use of Excel spreadsheet technology. The EHR was utilized to determine what documentation existed in the OR record for surgical fire safety.

Essential V: Health Care Policy for Advocacy in Health Care. This QI project was about advocating for patient safety, from the perspective of the patients, nursing, and management in the selected facility. The stakeholders can be assured that the DNP student will continue to advocate for this process change and encourage its use not only at the designated facility but also across the greater corporate health care system.

Essential VI: Interprofessional Collaboration for Improving Patient and Population Health Outcomes. Throughout the development and implementation of this QI project, the DNP student collaborated with other professionals who could add suggestions to make the project better. Communication between the DNP student and the project chair, the project champion, and managers at the facility was ongoing to continually assess the project and make improvements. Additionally, communication between the aforementioned people will continue to occur as the results of the project are disseminated, and possible system-wide implementation occurs.

Essential VII: Clinical Prevention and Population Health for Improving the Nation's Health. The goal of this QI project was to improve a process that ultimately will improve patient safety and promote prevention of injury to surgical patients. By making a change in a health care delivery process, health care quality will be improved.

Essential VIII: Advanced Nursing Practice. Throughout the progression of this QI project, many activities constituting advanced nursing practice were demonstrated. The DNP student was the mentor and support person for the implementation segment of the project, providing background on the issue, instructions on the process, and encouragement of the use of the checklist in the OR. When there was any resistance from a staff member, the DNP student took the time to talk about the process, the benefits, and why it is important to make this change.

The DNP student designed, implemented, and evaluated a nursing process to improve patient safety and improve quality of health care. Implications for nursing practice are to continue to look for areas to make improvements and develop QI projects to address those areas.

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Appendix A: Literature Matrix

East Carolina University – DNP Program
Evidence Matrix Table

Student:	Course:	Faculty Lead:	Date:	Project:
Lisa Rodovich	DNP I	Dr. King/Dr. Tracey Bell	Summer 2017	Evaluation of Fire Risks to Improve Safety in the Operating Room
Article (APA Citation)	Level of Evidence (I to VII)	Data/Evidence Findings	Conclusion	Use of Evidence in EBP Project Plan
Hempel, S., Maggard-Gibbons, M., Nguyen, D.K., Dawes, A.J., Miake-Lye, I., Beroes, J.M., Shekelle, P.G. (2015). Wrong-site surgery, retained surgical items, and surgical fires: a systematic review of surgical never events. <i>Journal of the American Medical Association</i> 150(8), 796-805. http://dx.doi.org/10.1001/jamasurg.2015.0301	V	Two reviewers identified relevant publications in June 2014. Found 138 empirical studies that met inclusion criteria.	Current estimates for wrong-site surgery and retained surgical items are 1 in 100k and 1 in 10k procedures respectively, and the per-procedure prevalence of surgical fires is not known.	Description of the concept of never events. Main measures were incidence of wrong-site surgery, retained surgical items, and surgical fires.
Yoon, R.S., Alaia, M.J., Hutzler, L.H., Bosco, J.A. (2015). Using “near misses” analysis to prevent wrong-site surgery.	VI	A pre-post intervention study determined that education to decrease near misses for wrong-site surgery was effective.	A program designed to educate physicians on the importance of decreasing near misses is effective. The reduction in near misses observed in this study decreases	Important description of the concept of near misses and never events.

			the likelihood of a wrong-site surgery.	
Institute of Medicine (1999). To err is human: building a safer health system. Washington DC: National Academies Press	VII	At least 44k and as many as 98k people die in hospitals each year as a result of medical errors that could have been prevented.	To achieve better safety, must establish leadership, tools, and protocols to enhance knowledge, learn from errors through mandatory reporting, raise performance expectations, and implement safety systems in health care organizations to ensure safe practices.	Important tool for creating a safer health system. With adequate leadership, attention, and resources, improvements can be made.
Mehta, S.P., Bhananker, S.M., Posner, K.L., & Domino, K.B. (2013). Operating room fires: a closed claims analysis. <i>Anesthesiology</i> , 118, 1133-1139. http://dx.doi.org/10.1097/ALN.0b013e31828afa7b	V	Payments to patients were more often made in fire claims. Injuries occurred most often during head, neck, or upper chest procedures.	Continuing education and communication among OR personnel along with fire prevention protocols in high-fire-risk procedures may reduce the occurrence of OR fires.	Information about OR fire closed claims and information about how to reduce the risks of fires in the OR.
Hart, S.R., Yajnik, A., Ashford J., Springer, R., & Harvey, S. (2011). Operating room fire safety. <i>The Oschsner Journal</i> , 11(1), 37-42. Retrieved from https://www-ncbi-nlm-nih-gov.jproxy.lib.ecu.edu/pmc/articles/PMC3096161/pdf/i1524-5012-11-1-37.pdf	VII	Operating room fires are a rare but preventable danger in modern healthcare operating room.	OR fires occur more often than people recognize. Fire safety in the OR is every team member's responsibility. Prevention is the first step.	This article encourages that future work on fire safety should look into developing a national registry that surveys actual fire

				hazard time-out usage.
Dalal, P.K., Saha, R., & Agarwal, M. (2010). Psychiatric aspects of burn. <i>Indian Journal of Plastic Surgery</i> , 43(3), 136-142. Doi: 10.4103/0970-0358.70731	VII	Burn injuries and their subsequent treatment cause one of the most excruciating forms of pain imaginable.	A burn injury and its treatment can be one of the most painful experiences a person can encounter. Emotional needs of burn patients need to be addressed.	Examples of the repercussions of burn injuries.
Bucsi, R. (2006). Fire in the operating room. Retrieved from http://www.omic.com/fire-in-the-operating-room/	VII	A surgical fire during an ophthalmic procedure resulted in a lawsuit and subsequent payment of \$500,000 for damages.	Surgical fires are difficult to defend, even though they are rare. Proper precautions can decrease the risk.	Financial information about an OR fire related lawsuit.
Cowles, C.E., Wahr, J.A., & Nussmeier, M.A. (2016). Fire safety in the operating room. Retrieved from https://www.uptodate.com/contents/fire-safety-in-the-operatingroom?source=search_result&search=fire%20safety%20in%20the%20operating%20room&selectedTitle=1~150	VII	Fire in the OR is a relatively rare event, but when it does occur, the medical outcomes are often catastrophic for the injured patient, with severe legal and economic consequences for the surgical team and facility	Most OR fires are preventable with communication, appropriate education, and management of risks. Since these preventive measures have little cost and are nearly 100% effective, they are prioritized in patient safety initiatives.	Discussion of the causes of OR fires and preventive measures to reduce the risk.
Haugen, A. S., Muruges, S., Haaverstad, R., Eide, G. E., & Softeland, E. (2013). A survey of surgical team members' perceptions of near misses and attitudes towards time out protocols.	II	In the OR, 38% of respondents experienced uncertainty of patient identity, 81% surgical site or	The majority of surgical personnel in this study experienced near	This article can be applied to fire safety checklists in the operating room and

<p><i>BMC Surgery</i>, 13, 46. Doi: 10.1186/1471-2482-13-46</p>		<p>side, and 60% had prepared for the wrong procedure. 91% of the surgical team members supported implementing a time out protocol in their operating rooms.</p>	<p>misses with regard to correct patient identity, surgical site, or procedure. The study found that near-miss experiences are a wake-up call for systematic risk reducing efforts and the use of checklists in surgery.</p>	<p>validates their importance.</p>
<p>Erestam, S., Haglind, E., Bock, D., Andersson, A. E., & Angenete, E. (2017). Changes in safety climate and teamwork in the operating room after implementation of a revised WHO checklist: a prospective interventional study. <i>Patient Safety in Surgery</i>, 11(4), 1-10. http://dx.doi.org/10.1186/s13037-017-0120-6</p>	<p>IV</p>	<p>A single center prospective interventional study that discovered a need for improved teamwork and communication between professions. Adherence to the revised WHO checklist was insufficient, dominated by a lack of structure.</p>	<p>There was no significant change in teamwork climate by use of the WHO checklist, which may have been due to insufficient implementation. Lack of adherence to the WHO checklist was detected. Deficiencies were found in teamwork and communication.</p>	<p>A good example of a way to set up my project with pre-interventional observations, an educational program, and post-interventional observations on the use of the WHO checklist. In my project it will be regarding a fire risk assessment tool.</p>
<p>Zingiryan, A., Paruch, J. L., Osler, T. M., & Hyman, N. H. (2016). Implementation of the surgical safety checklist at a tertiary academic center: Impact on safety culture and patient outcomes. <i>The American Journal of Surgery</i>, 1-5. http://dx.doi.org/10.1016/j.amsurg.2016.10.027</p>	<p>IV</p>	<p>A survey to assess perspectives of surgical team members, and a database review compared the rates of 9 complications before and after implementation of the WHO surgery safety checklist (SSC). There was</p>	<p>Implementation of the SSC did not result in a significant decrease in perioperative morbidity or mortality. However, it did improve the</p>	<p>Proof that use of a safety checklist can improve communication, safety culture of the staff in the operating room, and prevent errors.</p>

		no significant decrease in any of the 9 complications 2 years after implementation; however, there was agreement that the SSC improved communication, safety, and prevented errors in the OR.	perception of safety culture by OR staff.	
Berntsen, K. J. (2004). Valuable lessons in patient safety: reporting near misses in healthcare. <i>Journal of Nursing Care Quality</i> , 19(3), 177-179. Retrieved from http://jproxy.lib.ecu.edu/login?url=http://search.ebscohost.com/login.aspx?direct=true&db=rzh&AN=106573050&site=ehost-live&scope=site	VII	The more near miss data collected and analyzed contributes to prevention because root causes for actual and potential errors are often the same.	Defining near misses will be the first step in creating data that can be widely shared. Hospital quality leaders can contribute to this improvement in patient safety by mandating near miss reporting within their hospital and participating in efforts to study and share data.	Definition of near miss and importance of reporting near misses in healthcare.
Mitchell, P. H. (2008). Defining patient safety and quality care. In R. G. Hughes (Ed.), <i>Patient safety and quality: an evidence-based handbook for nurses</i> (pp. 1-5). Retrieved from https://archive.ahrq.gov/professionals/clinicians-providers/resources/nursing/resources/nursesfdbk/nursesfdbk.pdf	VII	Concepts of patient safety and quality care are defined.	Nurses are key to improving quality through patient safety.	Reference for concept analysis for DNP project
Farquhar, M., Sharp, B. A., & Clancy, C. M. (2007). Patient safety in nursing practice.	VII	Patient safety is a central public concern, as evidenced	The ultimate goal must be the creation	Important in defining culture of safety, and

<p><i>Association of Operating Room Nurses. AORN Journal, 86(3),455-457.</i> http://dx.doi.org.jproxy.lib.ecu.edu/10.1016/j.aorn.2007.08.009</p>		<p>by the number of quality reporting and improvement initiatives that have proliferated across the country.</p>	<p>of a culture of safety, in which nurses are encouraged to report medical errors, near misses, or adverse events, and where errors can be discussed in an atmosphere of trust and mutual respect with no fear of retribution.</p>	<p>why it is important to develop.</p>
<p>Watanabe, Y., Kurashima, Y., Madani, A., Feldman, L. S., Ishida, M., Oshita, A., . . . Hirano, S. (2016). Surgeons have knowledge gaps in the safe use of energy devices: A multicenter cross-sectional study. <i>Surgical Endoscopy, 30(2)</i>, 588-592. Doi: http://dx.doi.org/10.1007/s00464-015-4243-5</p>	V	<p>Among participants, there were several deficiencies in knowledge fundamental to the safe use of electrosurgery (ES), including that 19% did not know how to manage an operating room fire.</p>	<p>Energy based surgical devices are used on a daily basis, and yet, they are poorly understood across varying levels of experience and geographic locations, increasing the risk of harm to patients.</p>	<p>Stresses the importance of education when using devices that may contribute to OR fires.</p>
<p>Schein, E. H. (1996). Kurt Lewin's change theory in the field and in the classroom: Notes toward a model of managed learning. <i>Systems Practice, 9(1)</i>, 27-47. Doi:10.1007/BF02173417</p>	VII	<p>Few people have had as profound an impact on the theory and practice of social and organizational psychology as Kurt Lewin.</p>	<p>There is nothing more practical than good theory.</p>	<p>Theoretical framework for the project</p>
<p>Burnes, B. (2004). Kurt Lewin and the planned approach to change: A re-appraisal. <i>Journal of Management Studies,</i></p>	VII	<p>Lewin's 3-step model is often cited as his key contribution to organizational change.</p>	<p>Lewin developed an integrated approach to analyzing, understanding, and</p>	<p>Theoretical framework for the project</p>

<p>41(6), 977-1002. Retrieved from http://www.onlinelibrary.wiley.com/doi/10.1111/j.1467-6486.2004.00463.x/epdf</p>			<p>bringing about change at the group, organizational, and societal levels.</p>	
<p>Watson, D. S. (2009). Sentinel events. <i>Association of Operating Room Nurses. AORN Journal</i>, 90(6), 926-929. http://dx.doi.org/10.1016/j.aorn.2009.11.043</p>	VII	<p>The OR is highly complex. If factors such as time pressures and conflicting and competing priorities for OR time, staffing, and instrumentation are not appropriately communicated, they may contribute to error with unexpected, untoward patient outcomes.</p>	<p>Although rare, sentinel events can occur at even the best of hospitals with the most skilled surgeons and with the most experienced perioperative teams. No one is immune to the potential risk for an untoward patient outcome that can result in significant injury or death.</p>	<p>Medical errors are the eighth leading cause of death, occurring at a rate of 195,000 patients annually in the US.</p>
<p>Clancy, C. M., Farquhar, M., & Sharp, B. A. (2005). Patient safety in nursing practice. <i>Journal of Nursing Care Quality</i>, 20(3), 193-197. Retrieved from http://jproxy.lib.ecu.edu/login?url=http://search.ebscohost.com/login.aspx?direct=true&db=rzh&AN=106499018&site=ehost-live&scope=site</p>	VII	<p>1 in 3 respondents reported that they or a family member had experienced a medical error at some point in their life. One fifth said it had caused serious health consequences such as death, long-term disability, or pain.</p>	<p>The Institute of Medicine (IOM) published a landmark report to create momentum for the patient safety movement of today.</p>	<p>Importance of healthcare safety and ways to provide safer care.</p>
<p>Choudhry, A. J., Haddad, N. N., Khasawneh, M. A., Cullinane, D. C., & Zielinski, M. D. (2016).</p>	III	<p>Data was collected using an online legal research data-set</p>	<p>High energy devices remain the most</p>	<p>Despite modern advances in surgical</p>

<p>Surgical fires and operative burns: Lessons learned from a 33-year review of medical litigation. <i>The American Journal of Surgery</i>, 213(3), 558-564. Doi:http://dx.doi.org.jproxy.lib.ecu.edu/10.1016/j.amjsurg.2016.12.006</p>		<p>on patient, procedure, and case characteristics over a 33-year period of review of medical litigation.</p>	<p>common cause of injury. Understanding and addressing pitfalls in operative care may mitigate errors and potentially lessen future liability.</p>	<p>practice, rare sentinel events such as surgical fires and operative burns continue to occur.</p>
<p>Neuhaus, C., Spies, A., Wilk, H., Weigand, M. A., & Lichtenstern, C. (2017). "Attention everyone, time out!": Safety attitudes and checklist practices in anesthesiology in Germany. A cross-sectional study. <i>Journal of Patient Safety</i>, doi:10.1097/PTS.0000000000000386</p>	<p>V</p>	<p>Only 59% of participants had knowledge of the theoretical framework behind the WHO campaign.</p>	<p>This study shows a diverse picture of the implementation, usage, and safety attitudes concerning the Safe Surgery Checklist as promoted by the WHO.</p>	<p>The focus of interdisciplinary training should be on human factors, communication, and collaboration rather than the mere implementation by decree.</p>

<p>Uppot, R. N., McCarthy, C. J., Haynes, A. B., Burk, K. S., Mills, T., Trifanov, D. S., . . . Yu, A. Y. A verbal electronic checklist for timeouts linked to the electronic health record. <i>Journal of the American College of Radiology</i>, doi: https://doi-org.jproxy.lib.ecu.edu/10.1016/j.jacr.2017.03.025</p>	<p>V</p>	<p>Surgical safety checklists have been shown to improve safety and communication, reduce malpractice claims, complications, and mortality. Compliance ranges from 70%-100%.</p>	<p>Despite supporting data and mandated accreditation from The Joint Commission, full compliance has been difficult to achieve.</p>	<p>Be mindful of pitfalls that will prevent a checklist from being used 100% of the time. Education is key so team members understand importance of checklist use.</p>
<p>Alidina, S., Hur, H. C., Berry, W. R., Molina, G., Guenther, G., Modest, A. M., & Singer, S. J. (2017). Narrative feedback from OR personnel about the safety of their surgical practice before and after a surgical safety checklist intervention. <i>International Journal for Quality in Health Care: Journal of the International Society for Quality in Health Care</i>, 1-9. Doi:10.1093/intqhc/mzx050</p>	<p>IV</p>	<p>Narrative feedback was utilized to understand surgical team perceptions about surgical safety checklists (SSCs) and their impact on safety of surgical practice.</p>	<p>Narrative feedback suggested that SSC implementation can facilitate patient safety by averting complications, but buy-in is a persistent challenge.</p>	<p>Presenting information of the impact of the SSC on lives saved, teamwork, and complications averted, adapting the SSC to local context, and demonstrating leadership support/champions could improve checklist adoption and efficacy.</p>
<p>Rinder, C. S. (2008). Fire safety in the operating room. <i>Current Opinions in Anaesthesiology</i>, 21(6), 790-795. Doi: 10.1097/ACO.0b013e328318693a</p>	<p>VII</p>	<p>Anesthesiologists are aware of the risk of airway surgery fires, but recently, head/neck surgery under monitored anesthesia care (MAC) has emerged as a high-risk setting for OR fires. Burn injuries represent 20% of MAC-related malpractice</p>	<p>OR fires are infrequent but catastrophic. Prevention depends on understanding the fire triad elements, knowing how equipment, supplies, and oxygen can</p>	<p>Tools for prevention of operating room fires.</p>

		claims, 95% of which involve head/neck surgery.	become one of the elements, and vigilance.	
Clarke, J. R., & Bruley, M. E. (2012). Surgical fires: trends associated with prevention efforts. <i>Pennsylvania Patient Safety Advisory</i> , 9(4), 130-135. Retrieved from https://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2012/Dec%3B9(4)/documents/130.pdf	V	A panel of patient safety analysts identified surgical fires reported between 2004-2011 and rates of occurrence were calculated. The rate varied, but seems to have gotten worse. 1/3 of the events indicated harm to the patient.	Surgical fires remain a significant enough risk to justify use of a Fire Risk Assessment Score, and the communication required to follow protocols for high-risk procedures.	Justification for the use of fire risk assessment tool.
McCarthy, P. M., & Gaucher, K. A. (2004). Fire in the OR – developing a fire safety plan. <i>Association of Operating Room Nurses. AORN Journal</i> , 79(3), 588-597. Retrieved from http://search.proquest.com/docview/200714917?accountid=10639	VII	Although a fire safety plan existed in this facility, the management felt it was too generic and did not adequately address the many complex issues that could develop during a fire in a multifaceted environment such as the OR.	When a fire plan is in place, a well-attended inservice program should be provided that includes OR, anesthesia, and other staff who may be involved in a fire emergency. Each members' role must be described in detail.	Excellent description of how to present a fire safety plan educational inservice.
Mathias, J. M. (2006). Scoring fire risk for surgical patients. <i>OR Manager</i> , 22(1), 19-20. Retrieved from http://search.proquest.com/docview/213098210?accountid=10639	VII	A surgical fire risk assessment score tool was developed by Christiana Care Health System (CCHS) to heighten awareness of fire risk in the OR.	This is an important patient safety tool in the prevention of fires in the OR.	Fire in the OR is a risk that requires prevention, vigilance, and quick action to prevent patient injury.

<p>Stewart, M. W., & Bartley, G. B. (2015). Fires in the operating room: prepare and prevent. <i>Journal of Ophthalmology</i>, 122(3), 445-447. http://dx.doi.org/10.1016/j.opthta.2014.08.049</p>	VII	<p>The mandated timeout before a surgical procedure is designed to reduce the risk of errors, including fires in the OR. OR fires have been publicly emphasized by the Joint Commission as important to prevent.</p>	<p>The entire OR staff should understand the risk level for each procedure, and steps to mitigate those risks. A fire safety timeout is crucial to this understanding.</p>	<p>Acknowledgement that OR fires are considered never events, and the importance of using a fire risk assessment checklist prior to each procedure.</p>
<p>Tichanow, S. (2016). Wring site surgery: a critical incident analysis of a near miss. <i>Journal of Perioperative Practice</i>, 26(1-2), 11-12. Retrieved from http://jproxy.lib.ecu.edu/login?url=http://search.ebscohost.com/login.aspx?direct=true&db=rzh&AN=112238274&site=ehost-live&scope=site</p>	V	<p>This is a reflective account of a near miss that happened in clinical practice during a busy operating room day.</p>	<p>This critical incident highlights issues that can arise from a breakdown of communication between team members, and how ineffective teamwork can jeopardize patient safety.</p>	<p>Importance of communication and teamwork among a multidisciplinary team.</p>
<p>Zahiri, H. R., Stromberg, J., Skupsky, H., Knepp, E. K., Folstein, M., Silverman, R., & Singh, D. (2011). Prevention of 3 “never events” in the operating room: fires, gossypiboma, and wrong-site surgery. <i>Surgical Innovation</i>, 18(1),55-60. Doi: 10.1177/155335061038996</p>	VI	<p>A literature review using the terms patient safety and operating room resulted in 2851 documents, of which 807 were directly related to patient safety concerns in the OR. 11% of these addressed fires.</p>	<p>Ultimately, fires, gossypiboma, and wrong-site surgery were selected as “never events” for discussion because of their potential for immediate and devastating outcomes.</p>	<p>Evidence that many lawsuits result annually from patient safety violations in the OR. Most cases are not negligence, but rather an accumulation of numerous minor errors made by several individuals that result in a major patient safety compromise.</p>

<p>Bruley, M. E. (2004). Surgical fires: perioperative communication is essential to prevent this rare but devastating complication. <i>Quality and Safety in Health Care</i>, 13, 467-471. Doi: 10.1136/qshc.2003.005819</p>	VII	<p>A fire on or within a surgical patient is a continuing risk in modern surgery. However, the sensitivity of surgical and anesthesia staff to this hazard has waned over the past 25 years with cessation of the use of flammable anesthetic agents.</p>	<p>Preventing surgical fires requires understanding the risks and effective perioperative communication between surgeons, anesthesia, and nursing.</p>	<p>Specific preventive measures exist but have yet to diffuse sufficiently across professional boundaries and are not yet ingrained in perioperative procedures.</p>
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Appendix B: Project Timeline

DNP Project Timeline – Lisa Rodovich

Date	Task
May 2017	Explore project topic
May 2017 – present	Review the literature for topic of interest
June 2017	Define project topic
June 2017	Establish project champion/content expert
June 2017	Permission has been received to use existing tools for project
June 2017	Receive project approval from DNP Program Director and DNP chair
June 2017	Submit DNP project timeline
June 2017	Write first draft of chapters 1-3
July 2017	Final paper approval by faculty lead
July 2017	Secure project team member approval form
July 2017	Secure project site approval letter
July 2017	Solidify the design of the project/intervention
July 2017	Design a data collection form for monitoring use of fire risk assessment tool
August 2017	Begin working on institutional IRB approval
August 2017	Submit project for institutional IRB approval
September 2017	Obtain IRB Approval
September 2017	Develop educational program for surgical services staff
November 2017	Completion of synthesis of the literature and literature matrix
November 2017	Submit final paper chapters 1, 2, & 3
December 2017	Give educational presentation to surgical services staff
January 2018	Begin implementing the fire risk assessment checklist in the OR
January – February 2018	Collect data on the use and correct use of the fire risk assessment checklist using data collection form
December 2017 – February 2018	Do chart reviews of EHR to measure pre and post intervention documentation rates
January – February 2018	Perform weekly chart and data collection reviews
March 2018	Begin data analysis
April 2018	Submit draft of chapters 4 & 5
June 2018	Continue working on chapters 4 & 5
July 2018	Final submission of DNP Project paper
July 2018	Create poster presentation of DNP Project
July 2018	Formal poster presentations on campus at ECU
July 2018	Present the results of the DNP Project at facility and at ECU
July 2018	Close IRB Approvals
July 2018	Submit final paper to ScholarShip repository

Appendix C: Fire Risk Assessment Tool

Fire Risk Assessment Tool

Each “yes” item receives 1 point:

Procedure site or incision above the xiphoid?	Yes	No
Open oxygen source? (face mask/nasal cannula)	Yes	No
Ignition source? (cautery, laser, fiberoptic light source)	Yes	No

Fire Risk Score _____

Score 0, 1, or 2: Initiate Routine Protocol

Score 3: Initiate High Risk Protocol

Routine Protocol:

1. Ensure that all flammable prepping solutions are completely dry and fumes have dissipated (a minimum of 3 minutes) before applying surgical drapes.
2. Do not allow prep solutions to pool on, around, or beneath the patient.
3. Close open bottles of flammable agents and remove bowls of volatile solution from sterile field as soon as possible after use.
4. Assess the flammability of all materials used in, on, or around the patient.
5. Utilize standard draping procedure.
6. Protect all heat sources when not in use (cautery pencil holster, laser in stand-by mode)
7. Activate heat source only when active tip is in line of sight.
8. Deactivate heat sources before tip leaves surgical site.
9. Check all electrical equipment before use.

High Risk Protocol:

1. All routine protocol measures.
2. Arrange drapes to minimize oxygen buildup underneath.
3. Keep oxygen concentrations below 30% if this can be safely accomplished.
4. Use an adherent incise drape, if possible, to help isolate head, face, neck, and upper chest incisions from oxygen-enriched atmospheres and from flammable vapors beneath the drapes.
5. Minimize the Electrical Surgical Unit (ESU) setting.
6. Use wet sponges as appropriate.
7. Have a basin of sterile saline and bulb syringe available for suppression purposes.

8. Have a syringe full of saline readily available to the anesthesia provider for procedures within the oral cavity.

For Head and Neck Procedures:

1. Stop supplemental oxygen at least 1 minute before and during use of ESU/laser/disposable cautery.
2. Scavenge deep within the oropharynx with a suction cannula to catch leaking oxygen and nitrous oxide.
3. Use air or inspired oxygen concentration of 30% or less for open delivery if applicable.
4. Use appropriate laser-resistant endotracheal tubes during upper airway or facial surgery.
5. Use wet gauze or sponges with un-cuffed endotracheal tubes to minimize leakage of O₂ into the oropharynx; keep wet.
6. If endotracheal tube cuff leaks are found during surgery in the oropharynx, wet sponges around the tube cuffs may provide extra protection to help retard fire potential. Do not use the ESU/laser for at least 1 minute after stopping cuff leak.

(Christiana Care Health System, n.d.)

Appendix D: Fire Checklist Evaluation Form**Fire Checklist Evaluation Form**

During the surgical timeout, was the fire risk assessment checklist completed?	Yes	No	
Were each of the three questions on the checklist addressed?	Yes	No	
Was a risk score assigned based on the answers to the questions?	Yes	No	
Was the risk score communicated to members of the surgical team?	Yes	No	
If an alcohol based prep solution was used, was the 3-minute dry time observed?	Yes	No	N/A
If case was considered high risk, were the additional protocols discussed? (minimize O ₂ concentration, decrease cautery setting, basin of sterile water available?)	Yes	No	N/A

Appendix F: Site Approval Letter



Brunswick Medical Center
240 Hospital Drive NE
Bolivia, NC 28422

June 22, 2017

To Whom It May Concern:

We at Novant Health Brunswick Medical Center have reviewed Lisa Rodovich's DNP Project: Evaluation of Fire Risks to Improve Safety in the Operating Room. Lisa has organizational support and approval to conduct her project within our institution. We understand that for Lisa to achieve completion of the DNP program, dissemination of the project will be required by the University which will include a public presentation related to the project and a manuscript submission will be encouraged.

Our organization has deemed this project as a quality improvement initiative and requiring institutional IRB review.

Thank you,

A handwritten signature in blue ink, which is mostly illegible but appears to be 'Lisa Rodovich'.

President

Novant Health Brunswick Medical Center

Appendix G: Permission to Use Fire Risk Assessment Tools

From: **Townsley, Judy** [mailto:JTownsley@Christianacare.org]
Subject: RE: [External] Surgical fire risk assessment
Date: June 13, 2017 at 5:11 AM
To: Lisa Rodovich [mailto:lrodovich72@gmail.com]



Absolutely--please you the tools and feel free to follow up with any questions that you might have. My nephew graduated from ECU last year in 2016. I was at the graduation. Have a great day and happy to be of assistance.

Judy

Judith A Townsley, MSN, RN, CPAN
Vice President, Perioperative Services
Christiana Care Health System
Office (302) 733-2639
Cell Phone (302) 893-7820
jtownsley@christianacare.org

Please contact Lisa Ressler @ 733-1350 to schedule appointments or for immediate assistance.

"We take pride in delivering excellent care to our patients; we believe that what we do everyday makes a difference - one patient at a time". -
PPFCC

-----Original Message-----

From: Lisa Rodovich [mailto:lrodovich72@gmail.com]
Sent: Monday, June 12, 2017 3:34 PM
To: Townsley, Judy
Subject: [External] Surgical fire risk assessment

Ms. Townsley,

My name is Lisa Rodovich. I am currently a DNP student at East Carolina University. The focus of my QI project is operating room fire safety, which I am just starting to develop. In performing a literature search regarding surgical fires and prevention, I came across the materials from your organization for the fire risk assessment.

I am writing to ask permission to use the fire risk assessment tools and materials you have developed in my work on this QI project. I may have some questions as begin working on this project, and would love to be able to contact you in the future.

I look forward to your response.

Warm regards,

Lisa Rodovich, MSN, CRNA

Appendix I: Educational PowerPoint Tool

9/11/17

Fire Safety Risk Assessment

Lisa Rodovich, MSN, CRNA



Fire in the Operating Room

- Fire in the OR is a relatively rare event – incidence is between 550 to 650 cases per year in the US
- Not all states have mandatory reporting
- Considered a low incidence/high impact event
- Outcomes are often catastrophic for the injured patient
- There are often severe legal and economic consequences for the surgical team and facility



Important Points to Remember

- Most OR fires are preventable through
 - Effective communication
 - Appropriate education
 - Management of risks
- Preventative measures have essentially no cost, and are nearly 100% effective
- Should be prioritized in patient safety initiatives



General Considerations

- As mentioned, the incidence of OR fires is somewhere between 550-650 events each year in the US
- That number is actually probably higher since half of the states do not have mandatory reporting.
- Most claims occur in an outpatient setting (76%), involve the upper body (85%), and most of the cases are anesthesiologically managed with MAC (61%).
- Patient injuries after an OR fire are often severe – painful and disfiguring burns to the face and neck or severe airway injury requiring tracheostomy and causing permanent lung damage.
- All members of the surgical team involved in an OR fire are typically implicated in some degree of negligence and culpability.
- Base on closed claims data, payments were made in 78% of claims after an OR fire.

Causes of OR Fires: The Fire Triangle

- If an **oxidizer** (oxygen, nitrous oxide), a **fuel** (alcohol-based prep solutions, surgical towels and drapes), and an **ignition source** (cautery, laser) are combined in a closed environment, then any spark may result in flames. This is known as the fire triangle.
- Each element of the fire triangle is typically managed by an individual member of the surgical team
 - Anesthesia – oxidizer
 - Surgeon – ignition source
 - Nurse – fuel
- Overall, awareness of fire risks is the shared responsibility of all team members



Risk-Based Approach to Fire Prevention

The key elements to fire prevention in the OR are:

- Risk assessment
- Communication between members of the surgical team
- Preventive measures based on level of risk

The Fire Risk Assessment Tool

- This tool is a formal fire prevention tool that has been published by the Anesthesia Patient Safety Foundation (APSF), and as an algorithm by the American Society of Anesthesiologists (ASA).
- It is easy to use, and is supported by closed malpractice claims data.
- This tool is a simple, 3-question checklist that is added to the regular surgical timeout performed prior to the start of surgery.
- For each question, 1 point is given for each of the following major risk factors:
 - Use of an open oxygen source (i.e. nasal cannula or face mask)
 - Presence of an ignition source (bovie or laser)
 - Any procedure at or above the level of the xiphoid process
- The points are totaled to produce a fire risk score of 0 to 3. The plan for surgical fire prevention is based on the level of risk. A score of 0-1 is low-risk, 2 is intermediate, and 3 is high-risk.

Fire Risk Assessment Checklist

Fire Risk Assessment Tool

Each "yes" item receives 1 point:

Procedure site or incision above the xiphoid?	Yes	No
Open oxygen source? (face mask/nasal cannula)	Yes	No
Ignition source? (cautery, laser, fiberoptic light source)	Yes	No

Fire Risk Score _____

Score 0, 1, or 2: Initiate Routine Protocol
Score 3: Initiate High Risk Protocol

Fire Safety Protocols - Routine

Routine Protocol:

- Ensure that all flammable prepping solutions are completely dry and fumes have dissipated (a minimum of 3 minutes) before applying surgical drapes.
- Do not allow prep solutions to pool on, around, or beneath the patient.
- Close open bottles of flammable agents and remove bowls of volatile solution from sterile field as soon as possible after use.
- Assess the flammability of all materials used in, on, or around the patient.
- Utilize standard draping procedure.
- Protect all heat sources when not in use (cautery pencil holster, laser in stand-by mode)
- Activate heat source only when active tip is in line of sight.
- Deactivate heat sources before tip leaves surgical site.
- Check all electrical equipment before use.



Fire Safety Protocol – High Risk

High Risk Protocol:

- All routine protocol measures.
- Arrange drapes to minimize oxygen buildup underneath.
- Keep oxygen concentrations below 30% if this can be safely accomplished.
- Use an adherent incise drape, if possible, to help isolate head, face, neck, and upper chest incisions from oxygen-enriched atmospheres and from flammable vapors beneath the drapes.
- Minimize the Electrical Surgical Unit (ESU) setting.
- Use wet sponges as appropriate.
- Have a basin of sterile saline and bulb syringe available for suppression purposes.
- Have a syringe full of saline readily available to the anesthesia provider for procedures within the oral cavity.



Protocol for Head/Neck Procedures

For Head and Neck Procedures:

- Stop supplemental oxygen at least 1 minute before and during use of ESU/laser/disposable cautery.
- Scavenge deep within the oropharynx with a suction cannula to catch leaking oxygen and nitrous oxide.
- Use air or inspired oxygen concentration of 30% or less for open delivery if applicable.
- Use appropriate laser-resistant endotracheal tubes during upper airway or facial surgery.
- Use wet gauze or sponges with un-cuffed endotracheal tubes to minimize leakage of O2 into the oropharynx keep wet.
- If endotracheal tube cuff leaks are found during surgery in the oropharynx, wet sponges around the tube cuffs may provide extra protection to help retard fire potential. Do not use the ESU/laser for at least 1 minute after stopping cuff leak.

Middle



Summary

- Fire safety is the shared responsibility of all members of the surgical team.
- Strategies to prevent OR fires are based on separation and control of the three elements of the fire triangle.
- Knowing the elements of the fire triangle and how to decrease or eliminate one or more components is essential information for surgical staff.
- Each member of the team is typically responsible for one element of the fire triangle, and must know how to manage fuels, oxidizers, and ignition sources.

Appendix J: Institutional IRB Approval Letter

Presbyterian Medical Center
200 Hawthorne Lane
Charlotte, NC 28204

DATE: September 19, 2017
TO: Lisa Rodovich, MSN, Surgery and Perioperative
FROM: Vickie Zimmer, Manager, Presbyterian Healthcare IRB
PROTOCOL TITLE: Evaluation of Fire Risks to Improve Safety in the Operating Room
PROTOCOL NUMBER: 17-813
Approval Date: September 19, 2017

The Presbyterian Healthcare IRB, operated by Novant Health, has reviewed the protocol entitled: Evaluation of Fire Risks to Improve Safety in the Operating Room. The IRB has determined that this project meets one or more criteria contained within 45 CFR 46.101(b) exempting the project from the requirements of continued review. You are free to conduct your study without further reporting to the IRB. In the event that you revise your study significantly, this revision must be submitted for review to ensure that the study continues to meet the federal guidelines for exemption from review.

Attachments

- Fire Risk Assessment Tool
- Fire Checklist Evaluation Form
- Permission for tool

This exempt determination will be documented in the minutes of the October 19, 2017 IRB meeting. A copy of the protocol is maintained by the IRB office. All minutes and proceedings pertinent to this protocol are maintained by the IRB office. The Novant Health IRBs are registered with the Office of Human Research Protections (OHRP) and in compliance with the requirements of federal regulations 45 CFR 46, 21 CFR 50, 21 CFR 56 and internal policies as revised to date. If you have any questions or need additional information, please contact the IRB office at (336)718-9670 or irb@novanthealth.org.

Sincerely,

Presbyterian Healthcare IRB Chair

Appendix K: East Carolina University IRB Approval Letter**EAST CAROLINA UNIVERSITY**

Office of Research Integrity and Compliance (ORIC)
 University & Medical Center Institutional Review Board (UMCIRB)
 Brody Medical Sciences Building, 4N-70 • 600 Moye Boulevard • Greenville, NC 27834
 Office 252-744-2914 • Fax 252-744-2284 • www.ecu.edu/irb

TO: Lisa Rodovich, ECU College of Nursing, DNP Program

FROM: Office for Research Integrity & Compliance (ORIC) *SR*

DATE: September 28, 2017

RE: Doctor of Nursing Practice (DNP) Project

TITLE: Evaluation of Fire Risks to Improve Safety in the Operating Room (OR)

This activity has undergone review on 9/28/17 by the ORIC. A Doctor of Nursing Practice candidate is planning a project at Novant Health Brunswick Medical Center to increase OR fire safety through the implementation of fire safety checklist prior to start of any surgical procedure. The Novant Health Presbyterian Healthcare IRB determined the project met one or more of the criteria at 45CFR46.101(b), exempting the project from the requirements of continued review. The ORIC agrees with this determination and will rely on the Novant Health Presbyterian Healthcare IRB for this research study.

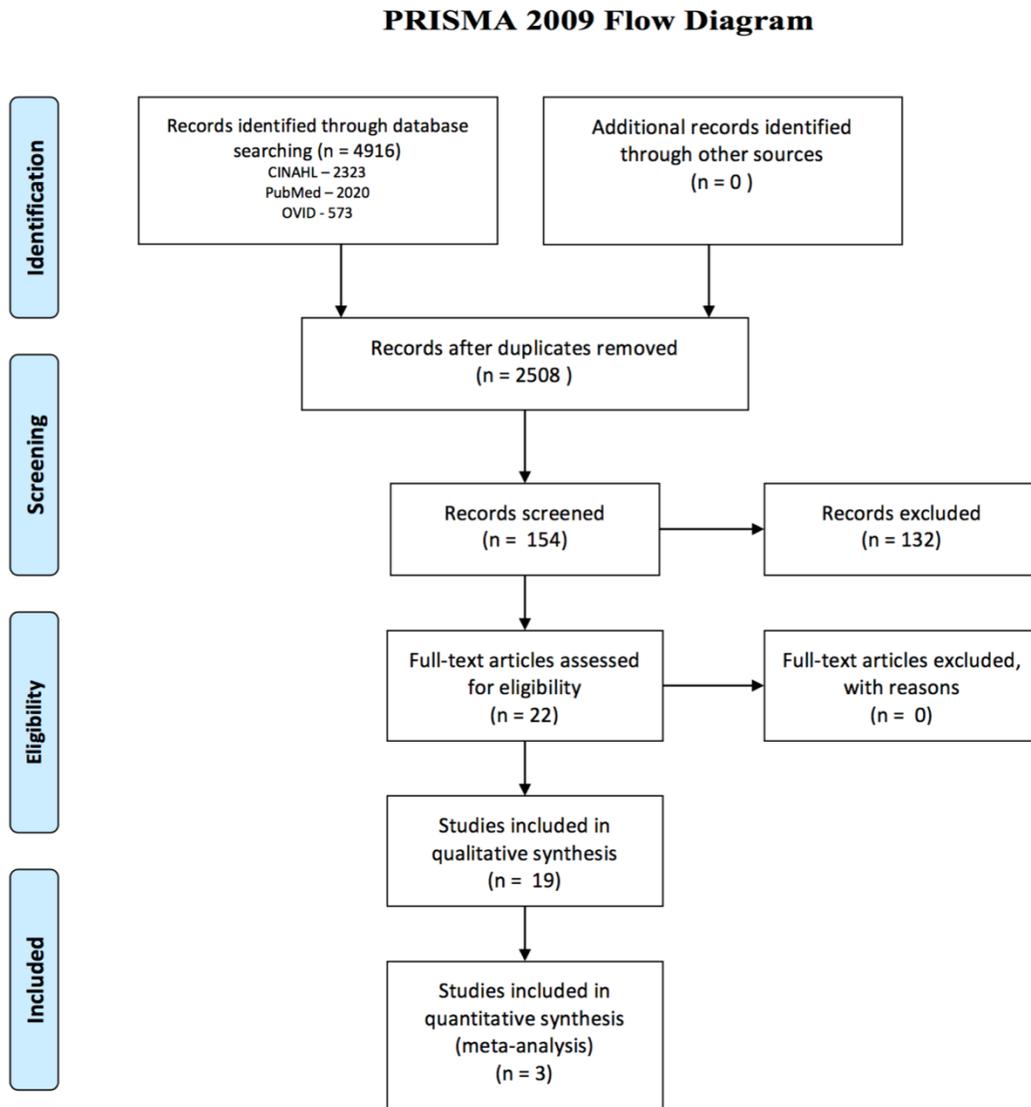
Contact the office if there are any changes to the activity that may require additional review.

Relevant Definitions for Human Subject Research:

- *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities
- *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains:
 - (1) Data through intervention or interaction with the individual, or
 - (2) Identifiable private information.

The UMCIRB applies 45 CFR 46, Subparts A-D, to all research reviewed by the UMCIRB regardless of the funding source. 21 CFR 50 and 21 CFR 56 are applied to all research studies under the Food and Drug Administration regulation. The UMCIRB follows applicable International Conference on Harmonisation Good Clinical Practice guidelines.

Appendix L: PRISMA Flow Diagram



(Moher D, Leberati, A., Tetzlaff, J., Altman, D. G., & The PRISMA Group, 2009).

Appendix M: Excel Data Table

Table 1
Excel data for use of the fire risk assessment checklist

Question	Yes	No	N/A
Was the fire risk assessment checklist completed?	267	13	0
Were each of the three questions on the checklist addressed?	230	50	0
Was a risk score assigned based on the answers to the questions?	250	30	0
Was the risk score communicated to members of the surgical team?	251	29	0
If an alcohol-based prep solution was used, was the minimum 3-minute dry time observed?	162	7	111
If the case was considered high risk, were additional protocols discussed?	14	13	253

Appendix N: Excel Data Table

Table 2
Percentages for the use of the fire risk assessment checklist

Question	Yes	No	N/A
Was the fire risk assessment checklist completed?	95%	5%	0
Were each of the three questions on the checklist addressed?	82%	18%	0
Was a risk score assigned based on the answers to the questions?	89%	11%	0
Was the risk score communicated to members of the surgical team?	90%	10%	0
If an alcohol-based prep solution was used, was the minimum 3-minute dry time observed?	57.9%	2.5%	39.6%
If the case was considered high risk, were additional protocols discussed?	5%	4.6%	90.4%

Y	Y	Y	Y	Y	NA	NA
Y	N	Y	Y	Y	Y	N
Y	N	Y	Y	Y	Y	N
N	N	N	N	N	Y	N
Y	Y	Y	Y	Y	Y	NA
Y	Y	Y	Y	Y	Y	NA
Y	Y	Y	Y	Y	Y	NA
Y	N	Y	Y	Y	Y	NA
Y	N	Y	Y	Y	Y	NA
Y	N	Y	Y	Y	Y	NA