THE USE OF SURGICAL SAFETY CHECKLISTS DURING TIME-OUTS IN RURAL AND URBAN OPERATING ROOMS

A Dissertation
Presented to
The Faculty of the Graduate School
At the University of Missouri

In Partial Fulfillment
Of the Requirements for the Degree
Doctor of Philosophy

By
VANESSA LYONS, MSN, RN, CNOR

Dr. Lori Popejoy, Dissertation Supervisor

December 2015
The undersigned, appointed by the dean of the Graduate School, have examined the Dissertation entitled

THE USE OF SURGICAL SAFETY CHECKLISTS DURING TIME-OUTS IN RURAL AND URBAN OPERATING ROOMS

Presented by Vanessa Lyons, MSN, RN, CNOR
A candidate for the degree of
Doctor of Philosophy
And hereby certify that, in their opinion, it is worthy of acceptance.

__________________________________________________________________________
Dr. Lori Popejoy

__________________________________________________________________________
Dr. Bonnie Wakefield

__________________________________________________________________________
Dr. Amy Vogelsmeier

__________________________________________________________________________
Dr. Gregory Alexander

__________________________________________________________________________
Dr. Mihail Popescu
DEDICATION

This work is dedicated to my family. To my best friend and husband, Evan, this would not have been possible without your support. You have been there to encourage me when I did not think I could finish. You were supportive when I was not home as much as I wanted to be and picked up the slack I left behind. You worked just as hard as I have on this project and your name should be on this work. To my children, Mariah, Thomas, and Laya, you were my motivation to complete this project. The best way for me to teach you the importance of education is to model it in life. Do not ever give up your dreams because they are too hard. I do not know anyone who regretted their education but I know plenty who regretted not continuing their education. I must also mention my extended family: my mother, Janice Curtis; my in-laws, Tom and Deborah Balash; and my siblings, Spencer Ervin and Ron and Susan Ervin. Every one of you supported me when I needed it the most. Thank you for your love and encouragement.
ACKNOWLEDGEMENTS

I need to express my gratitude to many people for making this project possible. First, I need to acknowledge my employer, Murray-Calloway County Hospital, and the Perioperative Services Department. My directors, Norma Butler and Jill Asher, have been the most supportive and accommodating employers for which anyone could hope. Norma, you could not have imagined the Pandora’s Box you opened when you gifted me my first membership to AORN. You lit a fire in me and fanned the flame for a passion for perioperative nursing. Jill, you provided me everything I needed to finish this project. You have been one of my biggest cheerleaders when I needed it the most. I could not have done this without both of you. To my coworkers in surgery, you have been with me through this entire journey. You are an amazing group of people and I am honored to have the opportunity to work with you.

I also need to thank my Sunday School class, Tenderhearts, and my teacher, Martha Parker. Everyone is this group has cried with me, prayed for me, and walked with me during this entire process. Words cannot express my gratitude for everything you have done to encourage and inspire me.

I would also like to thank the Sinclair School of Nursing for the support provided during this experience. I could not have completed this project without the faculty, staff and resources that were available to me during this program.

Finally, I must thank the members of my doctoral committee for their guidance, leadership, support, and encouragement. Dr. Lori Popejoy, you have been an amazing
mentor, advisor, and friend. You always knew when I needed a pat on the back or a kick in the behind and never hesitated to give either one. Because of this, I will be eternally grateful. Thank you for the opportunity to work with you, not only on this project, but all of the other projects. I would also like to thank Drs. Greg Alexander, Amy Vogelsmeier, and Bonnie Wakefield. You provided your time and expertise to help me succeed and it has been an extraordinary experience. I am honored to have had the opportunity to work with each of you. Dr. Mihail Popescu, thank you for serving on my committee and the opportunity to work with you on the ontology project. It was a challenging but enriching experience that provided immeasurable knowledge.

I am humbled by the support from so many amazing, talented, intelligent, and caring individuals to help me reach my goals. Words can never express my appreciation for everything you have done for me. Thank you for supporting me and sharing your expertise with me during this process. I could have never done this without all of you.
# TABLE OF CONTENTS

Acknowledgements .................................................................................................................. ii

List of Illustrations .................................................................................................................. vii

List of Tables .......................................................................................................................... viii

Abstract .................................................................................................................................. ix

Chapter One: Introduction ....................................................................................................... 1

  Perioperative Patient Safety .................................................................................................. 1
  Time-outs and Checklists ..................................................................................................... 3
  Compliance with Surgical Safety Checklists ...................................................................... 4
  Rural Population and Healthcare ....................................................................................... 6
  Time-outs and Rural Operating Rooms .............................................................................. 7
  Aims and Research Questions ............................................................................................ 8

Chapter Two: A Meta-Analysis of Surgical Safety Checklists ............................................. 25

  Abstract .............................................................................................................................. 25
  Introduction ......................................................................................................................... 25
  Method ................................................................................................................................. 27
  Sample Inclusion and Exclusion Criteria ......................................................................... 28
  Data Management Procedures ......................................................................................... 29
  Data Coding and Analysis ................................................................................................. 30
  Results ................................................................................................................................. 31
## LIST OF ILLUSTRATIONS

<table>
<thead>
<tr>
<th>Figure</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Surgical Safety Checklist Search Results</td>
<td>47</td>
</tr>
<tr>
<td>2. Donabedian's Structure, Process, Outcome Model in the Perioperative Setting</td>
<td>53</td>
</tr>
<tr>
<td>3. States Represented in Study</td>
<td>68</td>
</tr>
</tbody>
</table>
## LIST OF TABLES

<table>
<thead>
<tr>
<th>Table</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. WHO Surgical Safety Checklist</td>
<td>48</td>
</tr>
<tr>
<td>2. Surgical Safety Checklist Studies Included in Sample</td>
<td>49</td>
</tr>
<tr>
<td>3. Results of Surgical Safety Checklist Meta-Analysis</td>
<td>51</td>
</tr>
<tr>
<td>4. Sample Demographics</td>
<td>85</td>
</tr>
<tr>
<td>5. Time-Out Process Results</td>
<td>86</td>
</tr>
<tr>
<td>6. Checklist Content</td>
<td>87</td>
</tr>
<tr>
<td>7. Recommendations for Successful Surgical Safety Checklist Use</td>
<td>108</td>
</tr>
</tbody>
</table>
ABSTRACT

The purpose of this study was to examine the time-out process and checklist use immediately prior to incision in rural operating rooms. Operating rooms continue to be one of the most common locations for adverse events such as wrong site surgery and retained foreign items, despite interventions aimed at reducing the occurrence of these adverse events. Surgical safety checklists were introduced by the World Health Organization as a tool to improve perioperative patient safety. Operating room safety impacts both urban and rural operating rooms, and little research has been completed examining surgical safety practices in rural operating rooms. Research indicates that urban and rural hospitals are influenced by different factors such as financial influences and patient mix but how these factors affect patient care is unknown. This study used Donabedian’s framework of structure, process, and outcome to examine the current time-out process and checklist use in rural and urban operating rooms with a comparison of current practice and the standards of care from The Joint Commission and recommended practices from the Association of PeriOperative Registered Nurses (AORN). Adherence to recommended practices were measured through a survey of intraoperative nurses. Seventy-seven rural and forty-seven urban nurses completed the survey. Time-outs were completed by almost all subjects (98.7% rural [n = 76], 100% urban [n = 47]) but compliance was lower for verbal confirmation from team members (66% rural [n = 50], 75% urban [n = 35]) and for the cessation of all other activities (55.8% rural [n = 43], 57.4% urban [n = 27]). Rural (83%, n = 63) and urban (85%, n = 40)
respondents report using a checklist during the time-out. Checklist items most often included in the time-out include the patient’s name, consent, site marking, and antibiotic administration. Checklist content were less likely to include team names, anticipated case duration, and surgeon’s anticipated critical or non-routine steps. Urban nurses were significantly more likely (58% [n = 22] vs. 25% [n = 15], p < .05) to verify sterilization indicators. Barriers identified by urban subjects were checklist fatigue, anesthesia and surgeon resistance. Barriers reported by rural subjects were a lack of upper management support, lack of education, lack of monitoring, and practice variances between surgeons and organizations. This research shows that while checklist use has been adopted in many organizations, its use is lacking consistency across both settings and there is a need to understand variation in practice in order to develop effective strategies to improve utilization.
CHAPTER ONE: INTRODUCTION

Every month, 15,000 Medicare beneficiaries are estimated to die from preventable medical errors (Office of the Inspector General, 2010). This extraordinarily high rate of error persists despite an increased emphasis on patient safety (Landrigan et al., 2010). In addition to the cost of lives, the financial cost of medical errors for Medicare beneficiaries between 2007 and 2009 was $7.3 billion with surgical errors alone costing $1.5 billion annually (Agency for Healthcare Research and Quality, 2008; Reed & May, 2011). The full cost of medical errors for all patients would make this total considerably higher.

Perioperative Patient Safety

Preventable adverse events cause nearly 210,000 deaths annually, making it the third leading cause of death in the US (James, 2013). The surgical setting is one of the most common locations for medical errors (Gawande, Zinner, Studdert, & Brennan, 2003; Rogers et al., 2006). In the United States, 45 million inpatient surgical procedures are performed annually (Centers for Disease Control and Prevention (CDC), 2011). It is projected that the average American will undergo over nine surgical procedures in their lifetime, six of which will occur in the operating room (Lee, Regenbogen, & Gawande, 2008). One-half to two-thirds of all errors are attributed to surgical care with one in ten surgical patients dying from a preventable postoperative complication (Gawande et al., 2003; Leape et al., 1991; Reed & May, 2011; Rogers et al., 2006). While not all postoperative deaths are preventable, patients who experience an adverse event are 12
times more likely to die postoperatively than those who did not experience an adverse event (Fecho, Lunney, Boysen, Rock, & Norfleet, 2008; Reed & May, 2011). Nearly 20% of surgical patients do not receive appropriate antibiotic prophylaxis (Agency for Healthcare Research and Quality, 2011). Over 5% of all surgical patients experience a catheter-related urinary tract infection (Agency for Healthcare Research and Quality, 2011). The rate of postoperative sepsis, directly related to the inappropriate use of preoperative antibiotics, has not changed since 2008 (Agency for Healthcare Research and Quality, 2015).

The surgical environment contributes to adverse events. First, the patient is frequently under an anesthetic rendering them incapable of participating in their own care during a surgical procedure, which increases the surgical team’s responsibility to protect the patient from harm. Second, the surgical setting is prone to the development of unsafe practices because it is a high stress environment focused on productivity (Espin, Lingard, Baker, & Regehr, 2006). Finally, multiple and simultaneous demands on team members’ time and attention reduce the focus on a single task, which further contributes to likelihood of making errors (Espin et al., 2006). Additionally, these unique features of surgical environments encourages team members to develop unsafe “work arounds” in an attempt to manage multiple workload demands, administrative tasks, and/or physician expectations. Finally, successful surgical procedures require a coordinated effort between nurses, surgical technologists, anesthesia, surgeons, sterile supply, radiology, pathology, and laboratory. With so many different team members involved in patient care, communication failures are common (Lingard et al., 2004).
**Time-outs and Checklists**

Communication breakdown is identified as the most common contributor to errors and adverse events (Lingard et al., 2004; Makary et al., 2006; Stahel et al., 2010). Preoperative briefings are one way to improve communication among team members. In 2004, The Joint Commission introduced the Universal Protocol to prevent wrong site surgery (The Joint Commission, 2015). One requirement of this protocol is a preoperative briefing known as the time-out; an intentional pause in surgery immediately prior to the start of the procedure for all team members to verify the name of the patient and the correct procedure. In 2009, WHO studied the use of a surgical safety checklist to guide preoperative briefings, including the time-out and found that its use reduced morbidity and mortality by one third (Haynes, A B. et al., 2009). As of 2012, 1,790 facilities worldwide have implemented the WHO’s Surgical Safety Checklist (World Health Organization, 2012). The following year, AORN released the Comprehensive Surgical Safety Checklist which combines the content of the WHO Surgical Safety Checklist with the Joint Commission’s Universal Protocol in one checklist (AORN, 2013; The Joint Commission, 2015).

Preoperative briefings, as found in the checklists have been shown to improve compliance with safety measures such as preoperative antibiotic prophylaxis administration (Askarian, Kouchak, & Palenik, 2011; de Vries, Dijkstra, Smorenburg, Meijer, & Boermeester, 2010; Paull et al., 2010). Furthermore, briefings improve teamwork (Böhmer et al., 2012; Haynes, A B et al., 2011; Helmiö et al., 2011; Kearns et al., 2011; Lyons & Popejoy, 2013; Makary et al., 2007; Paige, John T., Aaron, Deborah L.,
Yang, Tong, Howell, D. Shannon, & Chauvin, Sheila W., 2009; Wolf, Way, & Stewart, 2010), employee satisfaction (Böhmer et al., 2012), and communication (Awad et al., 2005; Helmiö et al., 2011; Kearns et al., 2011; Lingard et al., 2008; Lyons & Popejoy, 2013; Makary et al., 2007). Briefings also reduced postoperative complications (Askarian et al., 2011; de Vries, Prins, Crolla, den Outer, van Andel, van Helden, Schlack, van Putten, Gouma, Dijkgraaf, Smorenburg, & Boermeester, 2010; Haynes, A B. et al., 2009; Lyons & Popejoy, 2013; Panesar et al., 2011; Young-Xu et al., 2011), mortality (de Vries, Prins, Crolla, den Outer, van Andel, van Helden, Schlack, van Putten, Gouma, Dijkgraaf, Smorenburg, & Boermeester, 2010; Haynes, A B. et al., 2009; Lyons & Popejoy, 2013), wrong site surgery (Makary et al., 2007), nonroutine events (Einav et al., 2010), near-misses (Panesar et al., 2011), and operating room delays (Wolf et al., 2010). Semel et al. (2010) found that facilities performing 4,000 non-cardiac surgeries a year saved over $100,000 annually by implementing the checklist. Surgical safety checklists are now a quality measure for ambulatory surgery because they have been demonstrated to be effective for preoperative briefings (Centers for Medicare & Medicaid Services, 2012).

**Compliance with Surgical Safety Checklists**

Despite research indicating the positive effects of the use of surgical safety checklists, facilities have had difficulty implementing this tool. Some studies report that the checklist was seen as inconvenient, and its use required adjusting ingrained behavior patterns (Aveling, McCulloch, & Dixon-Woods, 2013; Gardezi et al., 2009; Lingard et al., 2005). Barriers to use include anxiety with unfamiliar processes, hierarchy of staff, logistics and timing, duplication, relevance of checklist, absence of
consequences when the checklist was not completed, misuse of the checklist, and a lack of integration into existing hospital information systems (Aveling et al., 2013; Braaf, Manias, & Riley, 2013; de Vries, Hollmann, Smorenburg, Gouma, & Boermeester, 2009; Fourcade, Blache, Grenier, Bourgain, & Minvielle, 2012; Gagliardi, Straus, Shojania, & Urbach, 2014; Haugen, HÅ,yland, Thomassen, & Aase, 2015; Low, Walker, Heitmiller, & Kurth, 2012; Lyons & Popejoy, n.d.; Mahajan, 2011a; Makary et al., 2006; Papaconstantinou, Jo, Reznik, Smythe, & Wehbe-Janek, 2013; Russ et al., 2015; Vats et al., 2010; Wæhle, Haugen, Søfteland, & Hjälmhult, 2012). Even when checklists were implemented, the use was frequently inconsistent in timing and location (Gagliardi et al., 2014; Lingard et al., 2005; Low et al., 2012). Studies on compliance with surgical safety checklists show use rates ranging from 12% to 100% (Berrisford, Wilson, Davidge, & Sanders, 2012; Borchard, Schwappach, Barbir, & Bezzola, 2012b; de Vries et al., 2012; de Vries et al., 2009; France, Leming-Lee, Jackson, Feistritzer, & Higgins, 2008; Kasatpibal et al., 2012; Kearns et al., 2011; Mainthia et al., 2012; Nugent et al., 2013; Vogts, Hannam, Merry, & Mitchell, 2011). No research has found 100% compliance in the overall completion of all of the components of a structured surgical safety checklist despite some facilities reporting 100% compliance with documentation of compliance (McDowell & McComb, 2014; Morgan et al., 2013a). This raises the concern that compliance with surgical safety checklists may be even lower than reported in the existing literature.
**Rural Population and Healthcare**

Most research about perioperative patient safety occurs in urban facilities despite the fact that one in five Americans lives in rural areas (U.S. Census Bureau, 2013b). The rural population is more likely to be poor, older, and have multiple comorbid medical conditions (Institute of Medicine, 2005). Despite the health needs of this population, rural areas frequently experience a shortage of health care workers with only 9% of physicians practicing in rural areas (van Dis, 2002). Almost 2,000 hospitals service this population, and about 75% of these hospitals have 50 or fewer beds (American Hospital Association, 2013; van Dis, 2002). The increased number of comorbid conditions greatly increases the complexity of care required by rural patients (Vartak, Ward, & Vaughn, 2010) by increasing the risk of postoperative complications and morbidity (Roche, Wenn, Sahota, & Moran, 2005).

Rural hospitals also face unique challenges to overcoming quality of care issues. Rural hospitals have a larger percentage of nurses educated at the diploma or associate’s degree level (Newhouse, 2005). Nurses with diploma or associate’s degree levels of education are less likely to have received training and education about quality improvement or to evaluate research studies at a basic level, both are skills needed to implement evidence-based practice (Burns, Dudjak, & Greenhouse, 2009; Hutchinson & Johnston, 2004; Olade, 2003,2004; Schoonover, 2009). In addition, educational opportunities to develop these skills are less available for health care professionals in rural locations (Jukkala, Henly, & Lindeke, 2008; Newhouse, 2005). Nurses in rural hospitals are expert generalists and may provide care to a variety of patients from
pediatrics to geriatrics, and across the lifespan from birth to death (Bushy & Bushy, 2001).

Rural hospitals are challenged to remain financially viable. Finances play an important role in rural hospital quality of care. With the current financial crisis in healthcare, budget constraints of rural hospitals may limit the implementation of technological advances that can improve quality and safety, such as electronic medical records, barcode medication administration technologies, and automated dispensing cabinets (Calico, Dillard, Moscovice, & Wakefield, 2003; Newhouse, 2005).

Finally, rural hospitals may have difficulty measuring quality of care. The low patient volumes experienced by rural hospitals make the accurate measurement of quality indicators such as prophylactic preoperative antibiotic administration difficult (Lutfiyya, Sikka, Mehta, & Lipsky, 2009; Moscovice & Rosenblatt, 2000; Newhouse, 2005). The difficulties of quality indicator measurements are reflected by the exclusion of some rural hospitals in quality indicator reporting (Leapfrog Group, 2007). Critical access hospitals, which are generally located in rural areas, are not required to submit quality reporting for Medicare’s pay-for-performance programs as well as penalties for substandard care.

**Time-outs and Rural Operating Rooms**

There is a dearth of research regarding the time-out process in rural operating rooms. One study examined the effects of the implementation of a checklist for the time-out on teamwork in a rural operating room (Paige, John T. et al., 2009). This study found that the use of a time-out protocol such as a checklist improved time-outs and
teamwork in the rural setting; however, there is little research on how rural facilities use these tools (Paige, John T. et al., 2009). A second study that included the rural setting also found that the use of a surgical safety checklist improved patient outcomes; however, this study only included one rural hospital and aggregated the findings with the results from seven urban facilities (Haynes, A B. et al., 2009). Almost all research on time-outs occurred in large, teaching facilities. Many of the interventions designed to improve the time-out process have been developed and tested in large, urban facilities and may or may not be applicable to the rural setting. Compliance with time-out recommendations may also be an issue as one study in an urban setting found that verifications of surgical site markings, patient positioning, radiographic imaging, and verification of the availability of the appropriate equipment and implants occurred in less than 30% of surgical cases (France et al., 2008).

**Aims and Research Questions**

This descriptive survey study of rural and urban operating room team members describes the use of surgical safety checklists during time-outs. Specifically, this study identified the time-out process, the extent to which surgical safety checklists were used immediately prior to incision, variations from standards of care and recommended practices, and barriers to using a surgical safety checklist during the time-out. The specific aims of this study were:

**Specific Aim 1:** To describe the current state of time-out preoperative briefings in rural and urban operating rooms.
**Research Question 1.1:** How do rural and urban operating room staff members currently conduct time-out preoperative briefings?

**Research Question 1.2:** How do time-out preoperative briefings in rural operating rooms differ from the time-out preoperative briefings in urban operating rooms?

**Specific Aim 2:** To identify compliance in the time-out process and checklist use from The Joint Commission’s Universal Protocol and AORN’s Comprehensive Surgical Safety Checklist in rural and urban operating rooms.

**Research Question 2.1:** Does the time-out preoperative briefing process differ from The Joint Commission’s Universal Protocol and AORN’s Comprehensive Surgical Safety Checklist in rural and urban operating rooms?

**Research Question 2.2:** How does the compliance to The Joint Commission’s Universal Protocol and AORN’s Comprehensive Surgical Safety Checklist in rural operating rooms differ from the compliance in urban operating rooms?

**Specific Aim 3:** To identify factors that influence compliance in the time-out preoperative briefing in rural and urban operating rooms.

**Research Question 3.1:** What prevents the completion of all recommended time-out preoperative briefing and checklist components in rural and urban operating rooms?

This study explores the time-out process and the use of surgical safety checklists in rural and urban operating rooms. Chapter 2 is a meta-analysis of the effects of surgical safety checklists was conducted and that identified the safety benefits of
surgical safety checklists. Chapter 3 discusses the methods used in this study. Chapter 4 presents the results of the study as a manuscript submitted for publication. Chapter 5 is a manuscript discussing the barriers to implementation and recommendations for practice. Chapter 6 concludes with a review of this study. This study provides a knowledge base for the successful implementation and improved use of surgical safety checklists.
References


http://archive.ahrq.gov/research/sep08/0908RA1.htm


CHAPTER TWO: A META-ANALYSIS OF SURGICAL SAFETY CHECKLISTS


**Abstract**

The purpose of this study is to examine the effectiveness of surgical safety checklists on teamwork, communication, morbidity, mortality, and compliance with safety measures through meta-analysis. Four meta-analyses were conducted on 19 studies that met the inclusion criteria. The effect size of checklists on teamwork and communication was 1.180 (p=0.003); morbidity and mortality 0.123 (p=0.003) and 0.088 (p=0.001) respectively; and compliance with safety measures was 0.268 (p<0.001). The results indicate that surgical safety checklists improve teamwork and communication, reduce morbidity and mortality, and improve compliance with safety measures. This meta-analysis is limited in its generalizability based upon the limited number of studies and the inclusion of only published research. Future research is needed to examine possible moderating variables for the effects of surgical safety checklists.

**Introduction**

In the United States, 51.4 million ambulatory surgery visits and 48 million inpatient surgeries are performed annually (Centers for Disease Control and Prevention
(CDC), 2011; Cullen, Hall, & Golosinskiy, 2009). This results in the average person undergoing 3.4 inpatient operations and 2.6 outpatient operations in their lifetime (Lee et al., 2008). The operating room is one of the most common locations for medical errors and adverse events with one half to two thirds of all errors being attributed to surgical care. (Gawande et al., 2003; Leape et al., 1991; Rogers et al., 2006). With over 275,000 surgical procedures performed daily, an emphasis on perioperative safety is a necessity. The most commonly cited cause of surgical error is breakdown in communication (Lingard et al., 2004; Makary et al., 2006). One documented method to improve communication and reduce errors and adverse events is the surgical safety checklist, introduced by the World Health Organization (WHO) (Haynes, A B. et al., 2009).

Checklists are designed to improve patient outcomes by providing a visual tool for standardized communication (Haynes, A B. et al., 2009). The WHO conducted the first study of surgical safety checklists and found that the use of the checklist reduced morbidity and mortality by over 30% (Haynes, A B. et al., 2009). Since the release of this landmark study, hospitals have adapted and implemented checklists to improve patient outcomes. Moreover, the Centers for Medicare & Medicaid Services (CMS) recommended the use of surgical safety checklists as a quality measure in 2016.

Despite the increased use of surgical safety checklists, research regarding the effects of surgical safety checklists has been varied. Researchers have examined the effects of surgical safety checklists on antibiotic prophylaxis administration (Askarian et al., 2011; de Vries, Dijkstra, et al., 2010; Paull et al., 2010), perception of teamwork
(Böhmer et al., 2012; Haynes, A B et al., 2011; Helmiö et al., 2011; Kearns et al., 2011; Makary et al., 2007; Paige, J. T., Aaron, D. L., Yang, T., Howell, D. S., & Chauvin, S. W., 2009; Wolf et al., 2010), postoperative complications (Askarian et al., 2011; de Vries, Prins, Crolla, den Outer, van Andel, van Helden, Schlack, van Putten, Gouma, Dijkgraaf, Smorenburg, & Boermeester, 2010; Haynes, A B. et al., 2009; Young-Xu et al., 2011), in-hospital mortality (de Vries, Prins, Crolla, den Outer, van Andel, van Helden, Schlack, van Putten, Gouma, Dijkgraaf, Smorenburg, & Boermeester, 2010; Haynes, A B. et al., 2009), employee satisfaction (Böhmer et al., 2012), wrong site surgery (Makary et al., 2007), communication (Awad et al., 2005; Helmiö et al., 2011; Kearns et al., 2011; Makary et al., 2007), and operating room delays (Wolf et al., 2010). Most studies identified significant improvements in the surgical process and patient outcomes but the size of the improvement varied greatly across the studies. No comprehensive review or meta-analysis has been conducted to provide a measurement of the effect of these checklists on teamwork, communication, patient outcomes, and compliance with recommended safety measures. To overcome this gap in the state of the science about surgical safety checklists, the researchers conducted a meta-analysis that quantitatively synthesizes the current literature. This paper reports the meta-analysis results on the effect of surgical safety checklists on teamwork, communication, morbidity, mortality, and compliance with operating room safety measures.

**Method**

Meta-analysis is a method to quantitatively combine research findings from multiple studies that allow researchers to measure the effects of interventions on
outcomes from multiple studies thus increasing the power and precision of study findings (Cooper, Hedges, & Valentine, 2009). The following research questions guided this meta-analysis: (1) What is the effect of surgical safety checklists on teamwork and communication? (2) What is the effect of surgical safety checklists on patient morbidity and mortality? (3) What is the effect of surgical safety checklists on compliance with recommended surgical safety measures?

Sample Inclusion and Exclusion Criteria

In meta-analysis, it is essential to employ diverse search strategies to avoid introduction of bias from narrow searches (Cooper, Hedges, & Valentine, 2009). For this meta-analysis, the researcher conducted a database search of CINAHL, Proquest, and Medline databases using the search terms “checklist,” “operating room,” “surgery,” “perioperative,” “surgical,” “teamwork.” and “communication tools.” This search included an author search for the Checklist Manifesto author Atul Gawande (2010) and Alex Haynes, the principal investigator of the WHO study (2009). The researcher also conducted a search for studies that were previously cited in the research studies. Finally, a Google Scholar search identified any additional research studies, conference, and presentations that may have been missed using other search strategies.

Research studies were included if they were in English, conducted in inpatient or ambulatory operating room settings, used a surgical safety checklist conducted immediately prior to incision by the operating team, used communication and teamwork measures that had documented reliability and validity, or reported complications related to surgery as identified by the American College of Surgeons’
National Surgical Quality Improvement Program (Khuri et al., 1995). The complications included from the aforementioned program are acute renal failure, bleeding requiring the transfusion of 4 or more units of red cells within the first 72 hours after surgery, cardiac arrest requiring cardiopulmonary resuscitation, coma of 24 hours’ duration or more, deep-vein thrombosis, myocardial infarction, unplanned intubation, ventilator use for 48 hours or more, pneumonia, pulmonary embolism, stroke, major disruption of wound, infection of surgical site, sepsis, septic shock, the systemic inflammatory response syndrome, unplanned return to the operating room, vascular graft failure, or death. Mortality was defined as patient death in or out of the hospital from any cause within 30 days after surgery (Grover et al., 1994). Recommended surgical safety measures were defined as the 19 evidenced-based practices indicated on the WHO’s Surgical Safety Checklist as outlined on Table 1 (World Health Organization, 2008). Finally, studies were included that utilized a two group post intervention comparison or a one group pre-posttest design and reported sufficient statistical results to be able to calculate an effect size.

Data Management Procedures

As research studies were located, abstracts were examined for inclusion in the meta-analysis. Eligibility for the meta-analysis was based upon the previously identified inclusion and exclusion criteria. EndNote, a bibliographic management software program, was used to organize publications. Full text documents were collected and saved as PDF documents attached to the reference in EndNote. Using the abstract, studies were categorized into one of three categories: not eligible, possibly eligible, and
eligible. All search strategies and results were saved and documented for record keeping. Full text documents of abstracts categorized as possibly eligible were retrieved, read, and judged as eligible or not eligible. A hard copy of each research study was printed out and organized in a file cabinet drawer dedicated to the meta-analysis project. The final studies in the eligible category were coded in the codebook for inclusion in the meta-analysis.

Data Coding and Analysis

Coded variables included: (a) characteristics of the study setting (teaching status, number of operating rooms, number of licensed beds); (b) surgical checklist details (components, training, time of use, type of surgery); and (c) outcomes (time until final measurement, teamwork measures, communication measures, morbidity measures). In addition, data needed to complete effect size estimations (sample size, means, standard deviation, standard error, direction of effect) were also coded for each study. Each study was coded by one researcher on two separate occasions. The coding was then compared and no differences were found.

The standardized mean difference of post-intervention scores ($d$) was used to estimate effect sizes (Cooper, 2010). Conceptually, a standardized mean difference is the mean of the treatment group minus the mean of the control group, divided by the pooled standard deviation. The effect size is a unitless measure which can be averaged across primary studies using different measures of constructs. A random-effects model was used for data analysis because of the heterogeneity across studies in order to include both within study and between study variance (Cooper et al., 2009). The
random-effects model assumes that the true effect size varies across different studies based upon different confounding variables (Cooper et al., 2009). Heterogeneity was expected because of site, intervention, and measurement variables. Statistical heterogeneity was calculated using the $Q$ and $I^2$ statistics for between study variation and observed variation due to real differences in effect size. Calculations were completed using an Excel spreadsheet designed with the required formulas for statistical analysis. A significance level of $p<0.05$ was used for this study.

**Results**

Figure 1 illustrates the flow diagram of the literature search. A total of 55 articles were identified from the search. There were 36 articles excluded because data needed for the meta-analysis were not included. These missing data included statistical results needed for effect size calculations (28 studies), eligible outcome variables (5 studies), or not using a checklist as the intervention (3 studies). The remaining 19 studies were fully eligible for inclusion in the meta-analysis and are listed in Table 2. The research sample varied based on the goals of the study. Some studies examined patients while others examined surgical procedures. These samples differed because patients may undergo multiple surgical procedures; thus procedures may include a single patient multiple times. Finally, studies that examined teamwork and communication sampled employees or staff members.

There were a number of differences in the studies. The sample included national and international studies with three studies including multiple countries. The majority of studies were from the United States ($n = 9$); the rest were Great Britain ($n = 1$),
Netherlands (n = 2); Liberia (n = 1), Iran (n = 1), Germany (n = 1), and Finland (n = 1). Three studies conducted by the WHO had multiple countries in the sample (Canada, India, Jordan, New Zealand, the Philippines, Tanzania, England, and the United States). Ten studies used a single group, pre-posttest design (Awad et al., 2005; Böhmer et al., 2012; Haynes, A B et al., 2011; Helmiö et al., 2011; Kearns et al., 2011; Makary et al., 2007; Paige, J. T. et al., 2009; Paige et al., 2008; Paull et al., 2010; Wolf et al., 2010), five studies used a two-group, pre-posttest design (Askarian et al., 2011; de Vries, Prins, Crolla, den Outer, van Andel, van Helden, Schlack, van Putten, Gouma, Dijkgraaf, Smorenburg, & Boermeester, 2010; Haynes, A B. et al., 2009; Weiser et al., 2010; Yuan et al., 2012), three studies used a retrospective analysis design (de Vries, Dijkstra, et al., 2010; Neily et al., 2010; Young-Xu et al., 2011), and one study used a randomized control trial (Calland et al., 2011). Sample size varied from 20 to over 3,000 and the units of analysis were hospitals, surgical team members, patients, and surgical procedures. Some studies examined specific types of complications such as pneumonia, while others focused on all postoperative complications. Samples were calculated as a single unit regardless of the type of sampling unit used in the study with regard to statistical analysis. Teamwork and communication was measured with the most variety due to the availability of different tools to measure teamwork and communication. Heterogeneity was interpreted by $I^2$ and classified as low (25%), moderate (50%), or high (75%).

The results of the four meta-analyses on the outcome measures are displayed in Table 3. A positive effect size indicates an improvement in outcomes. For the effect of
checklists on teamwork and communication, ten studies were included in the analysis. The summary effect size of these studies was 1.180 (SE = 0.392, 95% CI = 0.411 - 1.999, $p = 0.003$). Teamwork and communication also demonstrated high heterogeneity ($Q = 638.500$, $p = 0.035$, $I^2 = 98.6\%$). Seven primary studies were included in the meta-analysis for morbidity. The summary effect size for morbidity was 0.123 (SE = 0.041, 95% CI = 0.043 – 0.204, $p = 0.003$). Morbidity analysis also showed a high level of heterogeneity ($Q = 13.474$, $p = 0.035$, $I^2 = 77.7\%$). Mortality analysis consisted of four studies with a summary effect size of 0.088 (SE = 0.026, 95% CI = 0.038 - 0.139, $p = 0.001$) indicating reduced mortality. The results of the analysis of mortality identified a moderate amount of heterogeneity ($Q = 6.013$, $p = 0.035$, $I^2 = 50.1\%$). Finally, the compliance meta-analysis for effect size included four studies. The summary effect size was 0.268 (SE = 0.052, 95% CI = 0.166 - 0.370, $p = 0.000$) and the analysis found low heterogeneity ($Q = 3.193$, $p = 0.035$, $I^2 = 6\%$).

**Discussion**

This study sought to measure the effect of surgical safety checklists on teamwork and communication, morbidity, mortality, and compliance with safety measures. The positive effect found in this study indicated improvement in outcome variables following the checklist intervention. The meta-analysis identified the use of a surgical safety checklist reduced morbidity and mortality, improved teamwork, communication, and compliance with safety measures in operating rooms. These results should be interpreted with some caution because the heterogeneity found in the analyses indicates large variability in the studies which could inflate the effect size.
The strongest effect of checklists was on teamwork and communication. As previously noted, surgical error is commonly attributed to breakdown in communication (Lingard et al., 2004; Makary et al., 2006) and surgical safety checklists were originally designed to improve communication between surgical team members (Awad et al., 2005; Carney, West, Neily, Mills, & Bagian, 2010; Haynes, A B. et al., 2009). These results confirm that surgical safety checklists are effective in improving communication and potentially reducing surgical error and adverse events since a significant number of these are caused by a breakdown in communication (Gawande et al., 2003; Rogers et al., 2006; The Joint Commission, 2013).

Surgical mortality is estimated to be 21 out of every 1,000 surgical procedures (Fecho et al., 2008). In addition, with almost 100 million surgical procedures performed annually in the US, roughly 1,000,000 patients will die within 30 days of surgery (Centers for Disease Control and Prevention (CDC), 2011). While the effect size for morbidity and mortality was small, given the number of surgical procedures performed each year even a small improvement in these outcomes would save lives and reduce the burden of complications.

This meta-analysis also found a significant improvement in compliance with safety measures with the use of surgical safety checklists. As with communication this result was expected because a checklist provides a visual reminder of recommended safety measures, reducing the reliance on memory and improving compliance (Abdel-Rehim, Morritt, & Perks, 2011; Rydenfält et al., 2013). For example, a surgical safety checklist provides a reminder to surgical team members to ask the patient about
surgical site, or administer a prophylactic antibiotic within 60 minutes of incision. These reminders increase compliance with safety recommendation resulting in reduced incidence of surgical site infections.

Teamwork, communication, morbidity, and mortality were significantly heterogeneous. This finding was not surprising and occurred because of the varied units of analysis of the studies e.g. when measuring morbidity, samples were surgical procedures, patients, or hospitals. Mortality had a moderate variability but was limited in sample type to hospitals or patients. This can explain why there is less variability for mortality. Patients can experience multiple complications from one procedure or patients may undergo multiple procedures. Mortality is a single event relating back to only one patient and one procedure. Since the number and types of outcomes vary more for morbidity than mortality, it is logical to see a larger variance on morbidity than on mortality. In contrast, compliance with safety measures showed low heterogeneity. The samples in all of the included studies were adults undergoing surgical procedures. The consistency of the units of analysis can explain the low heterogeneity.

Future research on the effect of surgical safety checklists would be strengthened by the conduction of a moderator analysis. The publications range in dates from 2005 through 2012 showing the relative newness of checklists as an intervention and more research is needed in order to complete a reliable moderator analysis. Possible moderators identified in this study include length of time between implementation and evaluation, size of facility, type of surgical procedure, content of the checklist, and type of facility. While possible moderators were identified during the conduction of this
meta-analysis, a moderator analysis was not conducted due to the small number of available studies for inclusion. Conducting a moderator analysis would provide evidence about which characteristics maximize the benefits of the use of a checklist. As more primary studies accrue, adequate studies will be available to conduct moderator analysis.

There are limitations to this meta-analysis. First, only published research was included. There is a tendency in scholarly publications to publish research that results in significant findings (De Oliveira, Chang, Kendall, Fitzgerald, & McCarthy, 2012; Dwan et al., 2008). Studies that fail to find significant results are either not submitted or not published. This tendency could result in non-significant findings being excluded due to a possible publication bias. Next, there were 28 studies with statistically significant findings that were not included due to a lack of reported data necessary to calculate an effect size. The inclusion of these studies may have significantly increased the effect size of surgical safety checklists. Another limitation was the lack of a second coder to validate the coding of the studies. Finally, the studies used different sampling units: nine studies used surgical team members, six studies used patients, three studies used surgical procedures, and two studies used facilities. This difference could have an impact on the effect as patients may undergo multiple surgical procedures or experience multiple complications making a comparison of patients to procedures, or complications difficult, however, the random-effects model compensates for these differences in units of analysis. The studies were screened to ensure that multiple results from the same study were not included in the analyses.
Limitations of the primary studies themselves could also affect the findings of this meta-analysis. An increase in awareness of communication resulting from training on the use of the checklist could have improved communication even without the use of the checklist thus increasing the measured effect of the checklist for communication. The measures used in primary studies frequently required the use of subjective opinions of team members and may have presented a bias into the subjective findings as participants may respond with socially acceptable answers or with responses that the participants feel the researcher is expecting. Compliance with safety measures could have been influenced by potential observer bias as practitioners may have changed their practice when being monitored or observed increasing the measured effect of surgical safety checklists. Finally, the studies included the use of surgical safety checklists that were designed and personalized by each facility to meet their needs. While the checklists included much of the same content (patient identity, procedure, preoperative antibiotic administration, venous thrombosis prevention, etc.), there may have been other characteristics in the checklist or how it was implemented that affected the findings and reduced the generalizability.

This is the first study to our knowledge that quantitatively synthesized the effect of surgical safety checklists on teamwork, communication, morbidity, mortality, and compliance with safety measures. Findings from this meta-analysis indicated that the use of surgical safety checklists resulted in significant positive effects on teamwork and communication, morbidity, and mortality but not on compliance with safety measures. Future research is needed to identify moderating variables that can positively influence
the effect of surgical safety checklists on patient outcomes. The use of the surgical safety checklist as a safety measure is growing exponentially and more research about how to maximize the benefits of this tool is needed.


http://missouri.summon.serialssolutions.com/link/0/eLvHCXMwY2CwRisPETiSgOgDW5oa4FyglLSAW9myhDiJtriLOHLvSKAN0CCyNL3TSLVJPERFNl42RgHz7N3NgM2Di3NEoTjNIQcU2HYGkmUVqWkqqcaqapiaF5sjfQjbBCTjFINjUytTY2NjTk27td_fCOM64GO39dLHlafnNCACSXOPY


ZqAEgnLKEJh7ybKIOfmGuLsoQupKuLI0cxxBsBq2Bzc2B_nC9R9LxxW7pnda_vLLe
Pk96vAgCFiySH
Figure 1: Surgical Safety Checklist Search Results (Moher, Liberati, Tetzlaff, & Altman, 2009)

- **Identification**: Records after duplicates removed (n = 96)
- **Screening**: Records screened (n = 96) → Records excluded (n = 41)
  - Full-text articles assessed for eligibility (n = 55) → Full-text articles excluded, with reasons (n = 36)
  - Studies included in quantitative synthesis (meta-analysis) (n = 19)
### Elements of the WHO Surgical Safety Checklist

<table>
<thead>
<tr>
<th><strong>Before induction of anesthesia:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• The patient verifies his or her identity, surgical site, and procedure and the consent is completed</td>
</tr>
<tr>
<td>• The surgical site is marked, if applicable</td>
</tr>
<tr>
<td>• The pulse oximeter is on the patient and functioning</td>
</tr>
<tr>
<td>• Any allergies are communicated to all team members</td>
</tr>
<tr>
<td>• The patient’s airway and risk of aspiration is addressed and all applicable supplies and assistance are available</td>
</tr>
<tr>
<td>• If there is a risk of at least 500 ml blood loss, IV access and fluids are available</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Before skin incision:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• All team members are introduced by name and role</td>
</tr>
<tr>
<td>• The patient’s identity, surgical site, and procedure are confirmed</td>
</tr>
<tr>
<td>• Anticipated critical events are reviewed</td>
</tr>
<tr>
<td>• Surgeon reviews critical and unexpected steps, operative duration, and anticipated blood loss</td>
</tr>
<tr>
<td>• Anesthesia provider reviews concerns</td>
</tr>
<tr>
<td>• Nursing staff reviews confirmation of sterility, equipment availability, and other concerns</td>
</tr>
<tr>
<td>• Prophylactic antibiotics are administered no longer than 60 minutes before incision if indicated</td>
</tr>
<tr>
<td>• All essential imaging is available</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Before the patient leaves the operating room:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Nursing staff reviews the following:</td>
</tr>
<tr>
<td>• Name of procedure is recorded correctly</td>
</tr>
<tr>
<td>• All needle, sponge, and instrument counts are completed and correct, if applicable</td>
</tr>
<tr>
<td>• Any specimens are labeled correctly, including the patient’s name</td>
</tr>
<tr>
<td>• Any equipment issues are addressed</td>
</tr>
<tr>
<td>• The surgeon, nurse, and anesthesia provider reviews any key concerns for the recovery and care of the patient</td>
</tr>
<tr>
<td>Author and Year of Publication</td>
</tr>
<tr>
<td>-------------------------------</td>
</tr>
<tr>
<td>Yuan et al., 2012</td>
</tr>
<tr>
<td>Askarian, Kouchak, &amp; Palenik, 2011</td>
</tr>
<tr>
<td>Haynes et al., 2011</td>
</tr>
<tr>
<td>Weiser et al., 2010</td>
</tr>
<tr>
<td>De Vries et al., 2010</td>
</tr>
<tr>
<td>Böhmer et al., 2012</td>
</tr>
<tr>
<td>Kearns et al., 2011</td>
</tr>
<tr>
<td>De Vries, Dijkstra, Smorenburg, Meijer, &amp; Boermeester, 2010</td>
</tr>
<tr>
<td>Study</td>
</tr>
<tr>
<td>-------------------------------</td>
</tr>
<tr>
<td>Calland et al., 2009</td>
</tr>
<tr>
<td>Haynes et al., 2009</td>
</tr>
<tr>
<td>Wolf, Way, &amp; Steward, 2010</td>
</tr>
<tr>
<td>Paull et al., 2010</td>
</tr>
<tr>
<td>Makary et al., 2007</td>
</tr>
<tr>
<td>Young-Xu et al., 2011</td>
</tr>
<tr>
<td>Neily et al., 2010</td>
</tr>
<tr>
<td>Awad et al., 2005</td>
</tr>
<tr>
<td>Helmiö et al., 2011</td>
</tr>
<tr>
<td>Paige et al., 2008</td>
</tr>
<tr>
<td>Paige, Aaron, Yang, Howell, &amp; Chauvin, 2009</td>
</tr>
<tr>
<td>Outcome measure</td>
</tr>
<tr>
<td>-----------------------------------------</td>
</tr>
<tr>
<td>Teamwork and Communication</td>
</tr>
<tr>
<td>Morbidity</td>
</tr>
<tr>
<td>Mortality</td>
</tr>
<tr>
<td>Compliance with safety measures</td>
</tr>
</tbody>
</table>
CHAPTER THREE: METHODS

The purpose of the study was to identify the current time-out process and checklist use by perioperative teams and to compare this process with The Joint Commission’s Universal Protocol and AORN’s Comprehensive Surgical Safety Checklist in rural and urban operating rooms. An assessment of the time-out process identified variations from these standards and recommended practice. These variances were examined through a survey of perioperative staff members regarding the conduction of time-outs.

Conceptual Model

This study used Donabedian’s framework of structure, process, and outcome. This framework is linear and consists of three dimensions: structure, process, and outcomes (Figure 2). Each dimension is positively or negatively affected by the previous dimension. Structure refers to the healthcare setting (Donabedian, 1988). Many factors impact the dimension of structure, including physical resources (human and material) and organizational factors (management design, social and safety cultures). The process relates to the actual provision of care. In the perioperative setting, this refers to the preparation, performance, and resolution of the surgical procedure. Finally, outcomes occur as a result of the structure and process dimensions. Donabedian noted that in healthcare, the goal is to improve positive outcomes and reduce negative outcomes (Donabedian, 1988). There is very little research regarding rural perioperative patient
safety. This study identified characteristics of perioperative structure that contribute to the time-out process.

Figure 2: Donabedian’s Structure, Process, Outcome Model in the Perioperative Setting

**Study Design**

This study used a cross-sectional survey design. Cross-sectional surveys are frequently used to assess patient safety climates in a variety of settings, including the operating room (Bleckley, Boyden, Hobbs, Walsh, & Allard, 2006; Bognár et al., 2008; Haynes, A B et al., 2011; Sexton et al., 2006; Wolf et al., 2010). A cross-sectional survey was used to obtain a description of the current state of time-outs and to generate future research questions.

**Study Setting and Population**

This study used a comprehensive cross-sectional survey design of perioperative nurses in rural and urban operating rooms who are involved with direct patient care. Rural determination was based upon the U.S. Office of Management and Budget definition of metropolitan and micropolitan areas (U.S. Census Bureau, 2013b). Urban
areas are defined as a city with a population of more than 50,000 or a total metropolitan statistical area population of at least 100,000. Any area that does not meet this definition of urban will be classified as a rural location.

**Procedure**

The P.I. recruited participants through AORN member groups and word of mouth. Contact was made through social media sites such as AORN's social networking site, ORNurseLink, Facebook, and email. The P.I. shared a standardized message, about the P.I.’s background, purpose of the study, and process for accessing the electronic survey. Additionally, a link to the survey was included in the message. Participants were also encouraged to give the survey link with other perioperative nurses.

**Measurement instrument**

A survey developed by the P.I. was used as the measurement tool for this study. This survey was developed based upon the process outlined in The Joint Commission’s Universal Protocol (The Joint Commission, 2015) and content from AORN’s Comprehensive Surgical Safety Checklist (Brown-Brumfield & DeLeon, 2010). Demographic data included accreditation status of facility, number of operating rooms, years of experience at the current hospital, years of perioperative experience, job title, hours of direct patient care, professional certification status, education level, and zip code of facility. The survey asked about compliance with the required process as directed by The Joint Commission and the content of the time-out as recommended by AORN.
A pilot study of the survey was conducted using a think aloud protocol with 18 perioperative nurses with perioperative experiences ranging from 1 year to 25 years. In this pilot study, each nurse was provided a copy of the survey and asked to verbally answer each question to the researcher. If the subject had any difficulty understanding the question or did not feel the responses adequately answered the question, the subject was asked about what part of the question was unclear and for suggestions on how to improve the question. Based upon the feedback from the subjects, the survey was edited for clarity.

An electronic survey platform, Qualtrics, was used to administer the survey. Qualtrics is an online survey tool which allows researchers to develop surveys, collect responses, and analyze data (Qualtrics Inc., 2015). The survey asked nurses if each of the surgical checklist components were addressed always, usually, sometimes, rarely or never. In addition, the process of the time-out was evaluated according to the Joint Commission’s Universal Protocol. Process questions included identification of participating team members in the time-out process, the cessation of all other activities during the completion of the time-out, and verbal confirmation from all team members. For each item that is identified as completed “sometimes”, “rarely”, or “never”, staff members were asked why they are not completed routinely. The primary investigator tested the functionality of the electronic survey in both Windows and iOS operating systems using Internet Explorer, Mozilla Firefox, Safari, and Google Chrome browsers.
Data Analysis

Data was downloaded from Qualtrics in a spreadsheet format for analysis. IBM SPSS Statistics for Windows, Version 22 was used for statistical analysis (IBM Corp., 2013b). Chi-square and Mann-Whitney U tests were conducted to adjust for non-normally distributed data with a significance level of p < .05. Normality was determined using Shapiro-Wilks test.

A content analysis was performed on the open-ended responses to identify any reoccurring concepts in responses using Dedoose software (Dedoose, 2015). Dedoose is an internet-based application for coding qualitative and mixed methods research. Open-ended responses were copied to separate word documents based upon location classification and question. Each document was uploaded individually into Dedoose for coding based upon question.

Human Subjects Involvement and Characteristics

This study is a cross-sectional survey of perioperative nurses to identify and compare the time-out process in rural and urban operating rooms. Participants were not excluded on the basis of age, gender, or race. No special classes of populations such as fetuses, neonates, children, prisoners, incarcerated individuals, or other vulnerable populations were included in this study because the participants had to be active providers of healthcare.
Sources of Materials

Data collection occurred through surveys of perioperative nurses. No individually identifiable information was collected except in the instance of subjects voluntarily providing a name and contact information for possible follow-up interviews. Any individually identifiable information was stored electronically through a secure online storage system.

Potential Risks

Potential risks included possible personal and professional distress caused by an increased examination of patient safety practices however this risk was minimal and did not exceed that which the subjects would encounter in normal daily activities.

Recruitment and Informed Consent

Recruitment of participants occurred through social media communication, email, and word of mouth. The study link was shared on AORN’s online community, ORNurseLink, Facebook, and emailed to perioperative nurses. Individual participants were encouraged to share the survey with other perioperative nurses and AORN chapters were encouraged to share the survey with their membership. This study was approved by the Health Sciences Institutional Review Board at the University of Missouri. A waiver of documentation of consent was approved due to the minimal risk associated with participation. All participants were provided with information regarding the purpose of the study, the risks and benefits of the study, and the voluntary nature of participation in the study. Additionally, the contact information for the P.I. and faculty
advisor also was provided. Participants were informed that completing the survey would serve as their consent to participate.

**Protections against Risks**

Protection against personal and professional distress was provided through reinforcement of the voluntary nature of the responses and participation can be terminated at any time during the survey. Contact information for the P.I. and the I.R.B. were provided to all participants.

**Potential Benefits of the Proposed Research to Human Subjects and Others**

Potential benefits to research participants were minimal but may include a sense of personal and professional satisfaction related to participation in patient safety research. Benefits to perioperative healthcare workers include the development of a broader knowledge regarding the time-out process. The resulting knowledge will assist in the development of patient safety initiatives tailored to meet the needs perioperative nurses in order to improve perioperative patient safety. The minimal risk of participation for participants was outweighed by the potential benefits that the obtained knowledge would provide for patient safety.

**Importance of the Knowledge to be Gained**

The financial and human costs of medical errors are significant. Through examination of preoperative communication, patient safety can be improved in all care settings. Unfortunately, despite rural hospitals constituting over 30% of all hospitals,
research into preoperative briefings such as the time-out has been limited to large, urban facilities (American Hospital Association, 2013). To address the unique needs of the rural hospital, more research into the process of time-outs of these facilities is needed. The study will provide a starting point for patient safety initiatives tailored to fit the differing needs of rural and urban operating rooms.

**Summary**

Strengths of this research include the objective nature of the Comprehensive Surgical Safety Checklist. Concerns regarding methodology primarily include the possibility of a participant bias in responses to the survey. Participant biases occur when participants tend to respond in a way that is consistent with what the participant feels the researcher is desiring. However, this bias should not affect the comparison between groups.

The information obtained through this study will begin to provide a clearer picture of the time-out process in rural and urban operating rooms. Baseline information is needed to begin to develop interventions to improve communication and improve postoperative outcomes.
References


CHAPTER FOUR: RESULTS


Abstract

Surgical safety checklists were introduced to improve patient safety. Urban and rural hospitals are influenced by differing factors but how these factors affect patient care is unknown. This study examined time-out and checklist processes in rural and urban operating rooms and shows that while checklist use has been adopted in many organizations, use is inconsistent across both settings. An understanding of these variations in needed in order to improve utilization.

Introduction

Despite an increased emphasis on patient safety, 400,000 deaths occur annually in United States hospitals due to preventable harm (James, 2013). Adverse events occur in one-third of hospital admissions with operating rooms being one of the most frequently cited location for medical errors (Classen et al., 2011; James, 2013). In an effort to curb preventable errors in the operating room, the Joint Commission introduced time-outs in its Universal Protocol in 2004 (The Joint Commission, 2015). Then in 2009, the World Health Organization expanded this process by introducing surgical safety checklists (Haynes, A B. et al., 2009); however, compliance with this intervention is reported to be as low as 12% (Borchard, Schwappach, Barbir, & Bezzola, 2012a; Haynes, A B. et al., 2009). Furthermore, the majority of research on time-outs
and surgical safety checklists has been conducted in urban settings resulting little being known about the use of recommended safety processes in the rural setting. The purpose of this study was to describe and compare the differences in time-out processes and surgical safety checklist use between rural and urban operating rooms, and to identify barriers to use of surgical safety checklists.

Background

Surgical safety checklist

Communication breakdown is identified as the most common contributor to errors and adverse events (Stahel et al., 2010). Preoperative briefings are one way to improve communication among team members, and expand upon the traditional time-out by including additional safety measures such as discussion of patient allergies and antibiotic administration. In 2009, The World Health Organization (WHO) studied the use of a surgical safety checklist to guide preoperative briefings and found its use reduced morbidity and mortality by one-third (Haynes, A B. et al., 2009). In 2010, AORN released the Comprehensive Surgical Safety Checklist which combined the content of the WHO Surgical Safety Checklist with The Joint Commission’s Universal Protocol (AORN, 2013; The Joint Commission, 2015). Preoperative briefings have been shown to improve compliance with safety measures such as preoperative antibiotic prophylaxis administration (Askarian et al., 2011; de Vries, Dijkstra, et al., 2010; Paull et al., 2010), teamwork (Böhmer et al., 2012; Haynes, A B et al., 2011; Helmiö et al., 2011; Kearns et al., 2011; Lyons & Popejoy, 2013; Wolf et al., 2010), employee satisfaction (Böhmer et al., 2012), and communication (Helmiö et al., 2011; Kearns et al., 2011; Lyons &
Popejoy, 2013). Briefings also reduced postoperative complications (Askarian et al., 2011; de Vries, Prins, Crolla, den Outer, van Andel, van Helden, Schlack, van Putten, Gouma, Dijkgraaf, Smorenburg, & Boermeester, 2010; Lyons & Popejoy, 2013; Panesar et al., 2011; Young-Xu et al., 2011), mortality (de Vries, Prins, Crolla, den Outer, van Andel, van Helden, Schlack, van Putten, Gouma, Dijkgraaf, Smorenburg, & Boermeester, 2010; Lyons & Popejoy, 2013), wrong site surgery, non-routine events (Einav et al., 2010), near-misses (Panesar et al., 2011), and operating room delays (Wolf et al., 2010).

Despite the benefits, facilities have had difficulty implementing surgical safety checklists. Studies report the checklist was seen as inconvenient and its use required adjusting ingrained behavior patterns (Braaf et al., 2013; Haugen et al., 2015; Papaconstantinou et al., 2013). Barriers to use include unfamiliarity with the checklist process, hierarchy between surgeons and nurses, logistics and timing, duplication, perceived irrelevance of checklist, absence of consequences for not completing the checklist, misuse of the checklist, and a lack of integration into existing hospital information systems (Aveling et al., 2013; Borchard et al., 2012b; Fourcade et al., 2012; Gagliardi et al., 2014; Low et al., 2012; Mahajan, 2011b; Morgan et al., 2013b; Russ et al., 2015; Rydenfalt, Ek, & Larsson, 2014; Sendlhofer et al., 2015; Treadwell, Lucas, & Tsou, 2014; Vats et al., 2010; Vogts et al., 2011). Studies on compliance with surgical safety checklists show a wide range of use from 28% to 99% (Berrisford et al., 2012; de Vries et al., 2012; Kasatpibal et al., 2012; Kearns et al., 2011; Mainthia et al., 2012; Nugent et al., 2013; Vogts et al., 2011) justifying the concerns regarding compliance.

Rural and urban settings
Most research about perioperative patient safety occurs in urban facilities despite the fact that one in five Americans lives in rural areas (U.S. Census Bureau, 2013b). The rural setting presents unique challenges to healthcare quality. The rural population is more likely to be poor, older, have multiple comorbid medical conditions, and have limited access to healthcare (DeNavas-Walt & Proctor, 2015; Meit et al., 2014).

There is scant research regarding preoperative briefings in rural operating rooms and no studies comparing rural and urban settings. Many of the interventions designed to improve preoperative briefings have been developed and tested in large urban facilities, and may or may not be applicable to the rural setting.

Methods

Study design and Sample

This was a descriptive, cross-sectional electronic survey study of operating room personnel. Study participants were recruited through a convenience snowball sampling approach through AORN’s online community, social media, email, and through word of mouth. Participants were encouraged to recruit perioperative staff members to complete the survey. Rural and urban determination was based upon the U.S. Office of Management and Budget classification (U.S. Census Bureau, 2013a). Urban was defined as any city with a population of more than 50,000 or a metropolitan area of more than 100,000. Any area that did not meet the classification for urban was considered rural. Respondents were asked to provide the zip code for their workplace for classification purposes only. Approval for this study was obtained through the University of Missouri Institutional Review Board.
**Instrument**

Data were collected using an investigator-developed survey based upon The Joint Commission’s Universal Protocol and AORN’s Comprehensive Surgical Safety Checklist. Content validity was established using a focus group of 18 perioperative staff members. The participants completed the survey and provided feedback about how to improve question readability. The final survey included 6 individual demographic questions, 3 organizational demographic questions, and 27 time-out and checklist questions. There were 13 multiple choice, 18 6-point Likert scale questions, and 5 open-ended questions. Participants were first asked about the frequency and initiation of time-outs and team member participation. Participants were next asked about the use and format of surgical safety checklists during time-outs. Finally, participants were asked to identify the frequency of verbalization (not included, never, rarely, sometimes, usually, or almost always) of each component of AORN’s Comprehensive Surgical Safety Checklist. The survey concluded with open-ended questions regarding additional components of the time-out, barriers to the verbalization of each component, and any additional comments regarding time-outs and surgical safety checklists. A copy of the instrument is available through the primary investigator.

**Data collection and analysis**

Qualtrics, an electronic internet survey platform, was used for data collection (Qualtrics Inc., 2015). After the survey was built in Qualtrics by the primary investigator, functionality was tested by completing the survey through multiple platforms and operating systems. The survey was tested in both Windows and iOS operating systems.
and in a variety of browsers such as Internet Explorer, Mozilla Firefox, Safari, and Google Chrome. After functionality had been confirmed, the primary investigator emailed the survey link to perioperative nurses and posted on AORN’s online community, ORNurseLink, and social media. Individual participants were encouraged to share the survey with other perioperative nurses and AORN chapters were invited to share the survey with their membership.

The data was downloaded from the survey platform in a spreadsheet format for analysis. All statistical analyses were completed using IBM SPSS Statistics for Windows, Version 22 (IBM Corp., 2013a). Statistical analysis included chi square and Mann-Whitney U test to adjust for non-normally distributed data with a significance level of \( p < .05 \). Normality was determined using Shapiro-Wilks test.

For the open-ended responses, a content analysis was completed using Dedoose software (Dedoose., 2015). Dedoose is a web-based application for coding of qualitative and mixed-methods research. Responses were downloaded into a spreadsheet and grouped according to location. Responses were then copied to separate word processing documents according to the question answered and location. Each document was then uploaded into Dedoose and thematically coded by question for similar comments, concerns, or problems. The responses were coded by the primary investigator for common themes.

**Results**

There were a total of 134 respondents, (77 rural, 47 urban). Of these, 10 surveys were excluded because respondents did not provide a zip code for rural or urban
classification or respond beyond the demographic questions (n = 6 and 4, respectively). Respondents represented 30 states (Figure 3). The majority of respondents had worked in the perioperative setting greater than 10 years (76.6% rural [n=59], 78.3% urban [n=36]) and had an undergraduate nursing degree (71.4% rural [n=55], 74.5% urban [n=35]). Over half of the respondents had CNOR certification (55.8% rural [n=43], 73.9% urban [n=34]). The difference in certification rates between the groups was approaching significance (p =.055) with urban nurses being more likely to be certified than rural nurses. Most respondents worked in not-for-profit organizations (77.9% rural [n=60], 87.2% urban [n=41]). Significantly more urban respondents worked in Joint Commission-accredited organizations than rural respondents (85.7% rural [n=66], 97.9% urban [n=46], p=.03) (Table 4).

Figure 3. States Represented in Study
**Time-out process**

Time-outs were reported to occur *almost always* by a majority of the participants (98.7% rural [n=76], 100% urban [n=47]). Verbal confirmation of the time-out was reported *almost always* by 66% of rural respondents (n=50), compared to 75% of urban respondents (n=35), but the result was not significant (p = .79). Just over half of respondents from both groups (55.8% rural [n=43], 57.4% urban [n=27]) reported all activity *almost always* stops during the time-out process. Nearly, 90% urban (n=42) and 99% of rural respondents (n=73) viewed the initiation of the time-out as the responsibility of the circulator, and 52% of rural and 51% of urban respondents (n=40 and n=24, respectively) also viewed it as a surgeon’s responsibility. Almost all team members participated in the time-out more than half of the time but the surgeon was significantly more likely (p = .01) to have participated in the time-out in urban operating rooms than in rural operating rooms, while other team members were significantly more likely to have participated in rural operating rooms (p = .02) (Table 5).

**Checklist use**

Over 82% of rural (n=63) and 85% of urban (n=40) respondents used some form of a surgical safety checklist during time-outs. Nearly equal numbers of both groups used a hospital-designed checklist (45% rural [n=33], 50% urban [n=23]). One-third (n=15) of urban respondents used a paper format, while 43% (n=31) of the rural respondents reported using paper. The most common checklist items in both rural and urban operating rooms were the patient’s name, the procedure name, consent, site marking, and antibiotic administration. The least common checklist items for rural
operating rooms were team member names and anticipated case duration. For the urban operating rooms, the least common items were surgeon’s anticipated critical or non-routine steps and anticipated case duration. Urban operating rooms were significantly more likely to include the verification of sterilization indicators than rural operating rooms (p=.04). Respondents reported communicating items not included in AORN’s Comprehensive Surgical Safety Checklist. The most frequent additions were patient allergies, fire risk, beta-blocker administration, DVT prophylaxis, patient’s date of birth, and pregnancy test results (Table 6).

Self-identified barriers

Open-ended responses were voluntary and were provided by only 17% of all respondents. Common self-identified barriers included using checklists as needed, checklist fatigue, the process for use, surgeon resistance, and perceived lack of benefits. Rural participants were more likely to cite a lack of upper management support, education, a need for monitoring compliance, and practice variances between surgeons and organizations as barriers to the use of checklists. Urban respondents were more likely to cite checklist fatigue, anesthesia and surgeon provider resistance as barriers to checklist use.

Rural and urban respondents reported using checklists when needed but not as a routine practice for all cases. For example, one rural respondent stated “If there are equipment concerns or any problems anticipated someone would communicate that to the team probably before the time-out”. One urban respondent stated “If it is a short
case the [doctor] will mention it so we can send for the next patient. The site is not verified unless it is [bilateral].”

Checklist fatigue was a concern among rural and urban respondents. One urban respondent noted “It becomes routine, and it's questionable if staff are truly participating or just going along with what someone else said”. Another urban respondent states “We always do a time-out and sometimes I feel that it has started to be ‘routine’ or done by rote. Sometimes I wonder if some people are paying attention”. Finally, one rural respondent states “It seems like we keep adding checklists. The surgical and anesthesia members start to block some of it out because it seems to be redundant”.

The process was cited as a barrier to implementation by respondents in both settings. Respondents reported verifying content included in the Comprehensive Surgical Safety Checklist prior to the time-out. For example, an urban respondent stated “Sterilization confirmation is a continuous expectation, just as maintaining sterile technique, therefore we do not mention this in a time-out.” and a rural respondent stated “Equipment concerns are usually done prior to time-out. Team members are introduced before time-out”. The most frequently mentioned items completed at times other than the time-out included team members names and sterilization indicators for both urban and rural respondents.

Surgeons were also identified as a barrier in both settings. The surgeon is focused on time and urban and rural respondents reported this pressure can impact the time-out process. One rural respondent stated “Some surgeons do not want a lengthy
time-out, so if too many details are added, they complain”. An urban respondent shared “The surgeon or anesthesia says it isn't necessary to tell the anticipated time of procedure, they don't mention anticipated blood loss, and they are in a hurry to start so the scrub tech doesn't say anything about sterilization indicators”. “He [the surgeon] wants the [time-out] to be quick” was the response of another rural respondent.

Finally, the lack of value was mentioned by respondents. One respondent shared “Also in the surgeries we perform, we lose very little blood other than total joints and [cesarean sections] where the blood loss is predictable so not worth adding in a [time-out]”. Another comment was “We know how long most surgeries last so don't need to ask”. Finally, another respondent stated “I don't think it's necessary to say team members’ names or expected case duration”. These comments were more frequent in the rural setting than the urban setting (14 rural, 7 urban). Respondents from urban settings also had concerns about the benefits of the checklists. As one urban respondent stated “I find that stating names and introduction of staff that have been working together for years the source of jokes and ridicule”.

Discussion

Consistent with prior research, this study found the most common barrier to implementation was the process of using the checklist (Braaf et al., 2013; Haugen et al., 2015; Treadwell et al., 2014). Participants in rural and urban settings both commented some of the information included in the Comprehensive Surgical Safety Checklist was verified at times other than the time-out. This is supported by the survey results indicating low compliance with these components.
Urban and rural respondents frequently commented they modify the content of the checklist depending on the unique characteristics of the patient or the procedure. The use of checklist content on an “as needed” basis requires operating room staff to remember to include the content when needed, which defeats the primary purpose of checklists which is to reduce the reliance on memory (Gawande, 2010).

Respondents in both settings disclosed some negative perceptions of checklists. Comments indicated some respondents did not value the inclusion of some content in the time-out, which is consistent with previous research (Braaf et al., 2013; Haugen et al., 2015; Sendlhofer et al., 2015). Additionally, checklist fatigue was mentioned by some respondents. There were some concerns the increasing frequency and number of checklists could discourage meaningful participation by team members. Respondents commented that the use of multiple checklists makes the process redundant and resulted in staff members becoming complacent in the practice.

Staff and physician resistance, altering checklists to fit individual circumstances, and missing data elements in the checklist are worthy of more study. The checklist has been in use for six years and it is time to reconsider what is working and what is not. Process reviews should be conducted to identify opportunities for modifying the checklist for to fit into workflow and reduce redundancy without jeopardizing patient safety. Additionally, checklist education should extend beyond the use to include the reasons behind the content included in the checklist. The education must be interdisciplinary to allow opportunities to address the concerns from all team members.
and to promote teamwork. Separate education for individual disciplines discourages interdisciplinary collaboration.

**Limitations**

This was a small study limited by sample size. The results of a larger scale study on the process and content may show additional significant differences not present in this small study. Additionally, this study did not take into consideration multiple respondents from the same organization. Finally, the snowball sampling method, the recruitment of participants through AORN, and the recruitment through social media may have resulted in a sample that is not representative of all perioperative staff members. The use of social networking and an electronic survey could also impact the findings as the rural population may have limited internet availability (Stenberg et al., 2009). Prior to the study, the PI conducted a poll of rural operating room nurses in one state to determine whether an electronic or paper survey would be preferred by respondents. The majority of nurses polled preferred paper surveys. The use of ORNurseLink limited the sample to only members of AORN which may not reflect the characteristics of the perioperative nursing population. Additionally, not all AORN members are active on ORNurseLink. Facebook was also used to recruit through sharing of the link and posting on AORN chapter pages. This was difficult because to post on these groups, the person posting must be a member of the group. Facebook also limits the number of times a post can be posted to prevent spamming which can limit recruitment.
Conclusion

This study identified considerable variances from recommended practice when it comes to the time-out process and the use of surgical safety checklists in both rural and urban settings. While few differences between rural and urban settings were identified, a larger scale study would provide a clearer picture of how checklists are used in each setting. The documented benefits of checklists support the need to identify factors affecting adherence in order to increase compliance and improve patient safety, and to consider if changes to the checklist are needed.


doi:10.1097/SLA.0000000000000793


Table 4. Sample Demographics

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Rural</th>
<th>Urban</th>
</tr>
</thead>
<tbody>
<tr>
<td>Years with current employer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;6 months</td>
<td>6(7.8)</td>
<td>4(8.5)</td>
</tr>
<tr>
<td>6 months-2 years</td>
<td>5(6.5)</td>
<td>6(12.8)</td>
</tr>
<tr>
<td>3 years-5 years</td>
<td>11(14.3)</td>
<td>10(21.3)</td>
</tr>
<tr>
<td>6 years-10 years</td>
<td>18(23.4)</td>
<td>8(17)</td>
</tr>
<tr>
<td>11 years or more</td>
<td>37(48.1)</td>
<td>19(40.4)</td>
</tr>
<tr>
<td>Years of operating room experience</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;6 months</td>
<td>1(1.3)</td>
<td>0(0)</td>
</tr>
<tr>
<td>6 months-2 years</td>
<td>1(1.3)</td>
<td>1(2.2)</td>
</tr>
<tr>
<td>3 years-5 years</td>
<td>4(5.2)</td>
<td>2(4.3)</td>
</tr>
<tr>
<td>6 years-10 years</td>
<td>12(15.6)</td>
<td>7(15.2)</td>
</tr>
<tr>
<td>11 years or more</td>
<td>59(76.6)</td>
<td>36(78.3)</td>
</tr>
<tr>
<td>No degree</td>
<td>1(1.3)</td>
<td>0(0)</td>
</tr>
<tr>
<td>Undergraduate degree</td>
<td>55(71.4)</td>
<td>35(74.5)</td>
</tr>
<tr>
<td>Graduate degree</td>
<td>21(27.3)</td>
<td>12(25.5)</td>
</tr>
<tr>
<td>Certified</td>
<td>43(55.8)</td>
<td>34(73.9)</td>
</tr>
<tr>
<td>For-profit</td>
<td>14(18.2)</td>
<td>5(10.6)</td>
</tr>
<tr>
<td>Not-for-profit</td>
<td>60(77.9)</td>
<td>41(87.2)</td>
</tr>
<tr>
<td>Employed by Joint Commission Accredited organization</td>
<td>66(85.7)</td>
<td>46(97.9)*</td>
</tr>
<tr>
<td>Time-out process</td>
<td>n(%) - Rural</td>
<td>n(%) - Urban</td>
</tr>
<tr>
<td>-------------------------------------------------------</td>
<td>--------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Time-out performed prior to any surgical procedure</td>
<td>Almost always</td>
<td>76(98.7)</td>
</tr>
<tr>
<td></td>
<td>Usually</td>
<td>1(1.3)</td>
</tr>
<tr>
<td></td>
<td>Almost always</td>
<td>50(65.8)</td>
</tr>
<tr>
<td>Verbal confirmation during the time-out</td>
<td>Usually</td>
<td>19(25)</td>
</tr>
<tr>
<td></td>
<td>Sometimes</td>
<td>5(6.6)</td>
</tr>
<tr>
<td></td>
<td>Rarely</td>
<td>2(2.6)</td>
</tr>
<tr>
<td>All activity stops during time-out</td>
<td>Almost always</td>
<td>43(55.8)</td>
</tr>
<tr>
<td></td>
<td>Usually</td>
<td>26(33.8)</td>
</tr>
<tr>
<td></td>
<td>Sometimes</td>
<td>6(7.8)</td>
</tr>
<tr>
<td></td>
<td>Rarely</td>
<td>2(2.6)</td>
</tr>
<tr>
<td>Responsible for time-out initiation</td>
<td>Circulator</td>
<td>73(94.8)</td>
</tr>
<tr>
<td></td>
<td>Surgical</td>
<td>7(9.1)</td>
</tr>
<tr>
<td></td>
<td>technologist</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Anesthesia</td>
<td>14(8.2)</td>
</tr>
<tr>
<td></td>
<td>Surgeon</td>
<td>40(51.9)</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>1(1.3)</td>
</tr>
<tr>
<td>Verbally participates in time-out</td>
<td>Circulator</td>
<td>77(100)</td>
</tr>
<tr>
<td></td>
<td>Surgical</td>
<td>57(74)</td>
</tr>
<tr>
<td></td>
<td>technologist</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Anesthesia</td>
<td>68(88.3)</td>
</tr>
<tr>
<td></td>
<td>Surgeon*</td>
<td>68(88.3)</td>
</tr>
<tr>
<td></td>
<td>Other*</td>
<td>18(23.4)</td>
</tr>
<tr>
<td>Checklist used</td>
<td>Uses checklist</td>
<td>63(82.9)</td>
</tr>
<tr>
<td>Which checklist is used</td>
<td>WHO</td>
<td>10(13.7)</td>
</tr>
<tr>
<td></td>
<td>AORN</td>
<td>9(12.3)</td>
</tr>
<tr>
<td></td>
<td>Hospital-designed</td>
<td>33(45.2)</td>
</tr>
<tr>
<td></td>
<td>Do not know</td>
<td>7(9.6)</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>1(1.4)</td>
</tr>
<tr>
<td></td>
<td>Do not use</td>
<td>13(17.8)</td>
</tr>
<tr>
<td>Checklist format</td>
<td>Paper</td>
<td>31(42.5)</td>
</tr>
<tr>
<td></td>
<td>Electronic</td>
<td>13(17.8)</td>
</tr>
<tr>
<td></td>
<td>White board</td>
<td>10(13.7)</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>6(8.2)</td>
</tr>
<tr>
<td></td>
<td>Do not use</td>
<td>13(17.8)</td>
</tr>
</tbody>
</table>
### Table 6. Checklist Content

<table>
<thead>
<tr>
<th>Checklist</th>
<th>Not included/Never</th>
<th>Rarely/Sometimes</th>
<th>Usually/April</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rural</td>
<td>Urban</td>
<td>Rural</td>
</tr>
<tr>
<td>Team member names</td>
<td>32(53.3)</td>
<td>18(46.1)</td>
<td>14(23.4)</td>
</tr>
<tr>
<td>Patient’s name</td>
<td>1(1.7)</td>
<td>1(2.6)</td>
<td>0(0)</td>
</tr>
<tr>
<td>Procedure name</td>
<td>0(0)</td>
<td>1(2.6)</td>
<td>0(0)</td>
</tr>
<tr>
<td>Incision site</td>
<td>12(20)</td>
<td>9(23.1)</td>
<td>6(10)</td>
</tr>
<tr>
<td>Consent verified</td>
<td>9(15)</td>
<td>2(5.2)</td>
<td>3(5)</td>
</tr>
<tr>
<td>Site marked and visible</td>
<td>4(6.6)</td>
<td>1(2.7)</td>
<td>3(5)</td>
</tr>
<tr>
<td>Relevant images available</td>
<td>10(16.7)</td>
<td>2(5.2)</td>
<td>8(13.3)</td>
</tr>
<tr>
<td>Equipment concerns</td>
<td>15(25)</td>
<td>2(5.3)</td>
<td>11(18.3)</td>
</tr>
<tr>
<td>Surgeon’s anticipated critical or nonroutine steps</td>
<td>19(32.2)</td>
<td>9(23.7)</td>
<td>18(30.5)</td>
</tr>
<tr>
<td>Anticipated case duration</td>
<td>29(48.3)</td>
<td>18(47.3)</td>
<td>18(30)</td>
</tr>
<tr>
<td>Anticipated blood loss</td>
<td>27(45)</td>
<td>10(26.3)</td>
<td>18(30)</td>
</tr>
<tr>
<td>Antibiotic prophylaxis</td>
<td>2(3.3)</td>
<td>1(2.6)</td>
<td>2(3.4)</td>
</tr>
<tr>
<td>Anesthesia concerns</td>
<td>10(16.7)</td>
<td>6(15.4)</td>
<td>16(26.7)</td>
</tr>
<tr>
<td>Sterilization indicators confirmed*</td>
<td>32(53.3)</td>
<td>14(36.9)</td>
<td>13(21.7)</td>
</tr>
<tr>
<td>Scrub and circulating nurse concerns</td>
<td>15(25)</td>
<td>8(20.5)</td>
<td>16(26.6)</td>
</tr>
</tbody>
</table>

* = p < .05
CHAPTER FIVE: DISCUSSION


Abstract

The operating room is one of the most common locations for preventable errors. The communication failures are the most common cause of these errors. To improve quality of care in the operating room, the World Health Organization introduced surgical safety checklists to improve communication and reduce preventable errors. Surgical safety checklists have been shown to improve morbidity, mortality, communication, and teamwork, however, research shows that the positive effects of the surgical safety checklist is dependent on the quality of use. Research shows that compliance with checklist use is low across different operating room settings causing a concern that the full benefits of the checklist are not being realized. Barriers to implementation include staff resistance, timing, redundancy, and the social structure of the operating room. Recommendations for implementation and continued quality management include active leadership, extensive discussion and training, checklist design, and quality improvement activities. This article discusses these barriers and recommendations to improve compliance and perioperative quality of care.
Introduction

Patients undergo an estimated 234 million surgical procedures worldwide (Weiser et al., 2008). Surgical adverse events, such as wrong site surgery, retained foreign items, and surgical site infections, are the most frequently reported adverse events in healthcare and over 60% of these events are potentially preventable (De Vries, Ramrattan, Smorenburg, Gouma, & Boermeester, 2008; Mendes, Martins, Rozenfeld, & Travassos, 2009). The most commonly reported contributing factor to these adverse events is communication breakdown (Lingard et al., 2004). In the operating room, communication failures can lead to inefficient use of resources, lower staff satisfaction, and adverse events (Lingard et al., 2004). To improve patient safety, surgical safety checklists were developed to address communication failures in the operating room but the implementation has not been without resistance (Borchard et al., 2012b).

We conducted a survey study to better understand staff compliance with the time-out process and surgical safety checklists (Lyons & Popejoy, n.d.). This study shows that compliance with the recommended practices of these checklists is low across different settings. Our findings indicate that, while checklists are used in many organizations, the use is inconsistent and shows a lack of understanding of the purpose of the checklist. In the six years since the introduction of a surgical safety checklist, its use is broad but does not yet permeate deeply enough to change ingrained behaviors, beliefs, and attitudes of staff and surgeons. Therefore the purpose of this article is to describe barriers to successful implementation of surgical safety checklists and to provide recommendations to improve compliance and quality of use.
To prevent adverse events in surgery, the World Health Organization followed the lead of the aviation industry and developed a checklist to emphasize verification of important safety measures in the operating room (Gawande, 2010). Pilot testing of the surgical safety checklist, which included safety measures such as procedure name, antibiotic administration, and anti-embolism measures, showed a 30% reduction in morbidity and mortality in a wide variety of operating room settings (Haynes, Alex B. et al., 2009). The checklist includes 19 items to be verified at 3 separate times: Prior to entering the operating room, prior to incision, and at the end of the procedure. These processes are designed to be a guide for team communication to reduce reliance on memory (Gawande, 2010).

The positive effects of checklist use are well documented. Lyons and Popejoy conducted a meta-analysis and found use of surgical checklists can reduce mortality and morbidity (Bergs et al., 2014; de Vries, Prins, Crolla, den Outer, van Andel, van Helden, Schlack, van Putten, Gouma, Dijkgraaf, Smorenburg, Boermeester, et al., 2010; Haynes, Alex B. et al., 2009; Lyons & Popejoy, 2014; van Klei et al., 2012; Weiser et al., 2010). Other research indicates that compliance with safety interventions included in the checklist, such as antibiotic prophylaxis and thromboembolism prevention, increased after checklists were introduced (Truran, Critchley, & Gilliam, 2011; W-Dahl, Robertsson, Stefánsdóttir, Gustafson, & Lidgren, 2011). Checklists have also been reported to improve teamwork and communication in the operating room (Lyons & Popejoy, 2014). Finally, checklist use has the potential to improve safety attitudes and culture (Haynes,
Alex B. et al., 2011). In a study of 257 operating room clinicians, more than 90% say they would want the checklist used if they were a patient (Haynes, Alex B. et al., 2011).

The effects of surgical safety checklists; however, are dependent on correct use of the checklist (van Klei et al., 2012). Compliance with surgical safety checklists may not be sufficient to consistently ensure these improved patient outcomes (Lyons & Popejoy, n.d.). Borchard and colleagues conducted a systematic review and found checklist use ranged from 12% to 100% (2012b). Mindless recitation of checklist requirements are also a concern because suboptimal checklist use can result in no improvements in patient outcomes and may actually contribute to patient harm (Bergs et al., 2014; Bosk, Dixon-Woods, Goeschel, & Pronovost, 2009; Braaf et al., 2013; Cullati et al., 2013; Fourcade et al., 2012; Gagliardi et al., 2014; Hannam et al., 2013; Haugen et al., 2015; Levy et al., 2012; Morgan et al., 2015; Morgan et al., 2013b; Russ et al., 2015; Rydenfalt et al., 2014; Saturno, Soria-Aledo, Da Silva Gama, Lorca-Parra, & Grau-Polan, 2014; Sendlhofer et al., 2015; Sheena et al., 2012; Sparks, Wehbe-Janek, Johnson, Smythe, & Papaconstantinou, 2013; van Klei et al., 2012; Vogts et al., 2011; Walker, Reshamwalla, & Wilson, 2012). Staff members may begin to view the checklist as a check-box activity and verification of measures become rote instead of intentionally directed; thereby, allowing errors to occur (Lyons & Popejoy, n.d.). We have classified the barriers to successful implementation into two groups: human factors and environmental characteristics.

**Barriers to Successful Implementation**

**Human factors**
There are a number of barriers to implementation. The number one barrier to surgical checklist use is staff resistance (Lyons & Popejoy, n.d.; Russ et al., 2015). Staff resistance to change is multifactorial. There may be a lack of education about why the checklist was developed which contributes to staff resistance in using the checklists (Lyons & Popejoy, n.d.). The simplicity of the checklist can lead to the incorrect assumption that its introduction does not require much training. As a result of a lack of training, surgical team members are unaware of the reasons behind checklist use and are not trained in how to use it, which results in unfamiliarity, inconsistent execution, and variable quality of use (Aveling et al., 2013; Fourcade et al., 2012; Low et al., 2012; Lyons & Popejoy, n.d.; Vats et al., 2010). Additionally, checklist implementation planning may not allow for front line staff input, reducing the sense of ownership by the staff (Gagliardi et al., 2014). Without staff buy-in, team members may use the checklist as a checkbox task and not a communication guide (Papaconstantinou et al., 2013).

**Environmental characteristics**

The checklist process may become a barrier to use (Lyons & Popejoy, n.d.). The timing of some of the checklist components is a potential problem. Some of the safety checks, such as verification of sterilization indicators, are completed prior to the time-out because delaying this verification until the time out may be too late to prevent patient harm (Lyons & Popejoy, n.d.; Russ et al., 2015). Additionally, there is redundancy built into the checklists, such as with verifying allergies, which are checked by both nurses and anesthesia. This redundancy, intended as a mechanism to identify potential errors at multiple points before they occur (Institute of Medicine, 2004), can be
misunderstood by staff as extra-work. The operating room setting places a strong emphasis on efficiency and anything that may be perceived as unnecessary, such as redundant safety measures in the checklist, may result in shortcuts and workarounds (Braaf et al., 2013; Haugen et al., 2015).

The checklist is greatly impacted by the social structure of the operating room (Lyons & Popejoy, n.d.; Wæhle et al., 2012). The operating room has historically been a hierarchical environment in which the surgeon is perceived to be the captain of the ship; therefore, surgeon resistance to checklists results in staff members also dismissing the process. The perceptions of teamwork and communication, key elements of checklist use, vary across disciplines supporting the need for improvements in these areas before successful implementation can be achieved (Makary et al., 2006).

**Keys to Successful Implementation**

Successful checklist use requires a focus beyond the checklist and demands that the safety culture of the organization be examined (Haugen et al., 2015; Vats et al., 2010). Implementation of processes such as surgical safety checklists is complex and requires multidisciplinary participation at every level of the organization. Even with the support of administration, the implementation of a surgical safety checklist cannot be effective without attempting to change the culture in the operating room (Porter, Narimasu, Mulroy, & Koehler, 2014). Some keys to successful implementation include active leadership, checklist design, extensive discussion and training, and ongoing feedback (Table 7) (Gagliardi et al., 2014; Haugen et al., 2015; Low et al., 2012; Russ et al., 2015).
**Active leadership**

Team facilitators need to be in place not only for implementation but also for continued support. Facilitators must be able to manage resistance in a proactive and positive manner (Russ et al., 2015). Additionally, clinicians such as anesthesia providers and surgeons should be recruited as facilitators to reduce this hierarchy in the operating room. The checklist is designed to improve multidisciplinary communication which should start in the planning phase. The use of facilitators should continue beyond the implementation into ongoing quality management.

**Extensive discussion and training**

Interdisciplinary training and education about teamwork, not just checklist implementation, is key to successful implementation (Haugen, Murugesh, Haaverstad, Eide, & Softeland, 2013). Successful implementations must involve team trainings, not just individual training (Haugen et al., 2015). The aviation industry utilizes human factors and team building trainings in conjunction with safety trainings with the understanding that the tools to improve safety cannot be adequately implemented without the necessary skills to utilize them (Vats et al., 2010). It has been reported that team members do not believe the checklist is a team responsibility and instead view it as the responsibility of a nurse or surgeon. Checklist implementation offers opportunities to encourage development of mutual respect and collaboration across disciplines that are required for successful checklist use. Interdisciplinary training allows for team members to practice communication and address concerns in an encouraging environment and provide opportunities for role-playing difficult situations (Paige et al., 2007). Content of
the education should include the background of checklist development, evidence supporting its use, and the benefits to patient safety and the local organization (Russ et al., 2015). Educational sessions should also provide examples of its correct use and simulate difficult situations to prepare staff members on how to manage resistance (Russ et al., 2015). This allows staff members to discuss concerns and provide scenarios based upon their experiences at the bedside and promotes real world simulations.

**Checklist design**

Checklists must be customized to the local organization. Customization to the facility and/or procedure type allows for opportunity for employee feedback thus promoting ownership of the process (Russ et al., 2015). It is imperative that end users are involved from the beginning. Without this involvement, team members may not use the checklist in a meaningful way (Gagliardi et al., 2014). Modifications of the checklist should focus on the needs of the patients and consideration of the surgical team usability including integration with current processes and practices (Russ et al., 2015). A workflow analysis should guide the modifications by focusing on current safety processes compared to the ideal safety processes. Removal of non-applicable verifications and unnecessary repetitions should also be a priority. End-users should be included in this process in order to identify hidden processes and workarounds and to promote buy-in.

The physical design of the checklist can also promote or detract from compliance. To be used effectively as a communication tool, the checklist should be visible to all team members (Russ et al., 2015). Having a paper checklist is not conducive
to team participation and cannot be integrated into electronical records effectively. Electronic checklists are one solution to displaying checklists. Changing from a paper checklist to a displayed electronic checklist can improve compliance with the safety measures by 30% (Mainthia et al., 2012). Electronic checklists can facilitate team participation by encouraging dynamic interactions among team members (Norton, 2012). Staff members reported forgetting to use the checklist. The visibility of an electronic checklist can guide and remind users, thus reducing reliance on rote memory and improving compliance with individual safety measures (Borchard et al., 2012b; Norton, 2012). It can improve workflow by assisting with documentation through automated data capture; however, some research suggests that there may be increased variation between observed compliance and documented compliance with electronic checklists, possibly due to staff using the tool as a check box activity instead of a communication tool (Norton, 2012; Saturno et al., 2014).

**Quality improvement**

It is absolutely necessary to obtain feedback about use. Staff members need to know results of audits and its effect on patient outcomes (Gagliardi et al., 2014; Low et al., 2012; Russ et al., 2015). There is research to suggest that staff members believe that the checklist offers no benefits because they hold the mistaken belief that the events the checklist is designed to prevent would never occur at their local organization (Aveling et al., 2013). Champions and organizational leadership should conduct audits and report on improvements at the local organization. Additionally, examples of how the checklist prevents possible errors in the organization should be shared to
demonstrate the value in the checklist to the specific setting. Some organizations are reluctant to share this information openly with staff but this information is needed to demonstrate the need and value of checklists.

It is essential that compliance be measured by observation as opposed to record audits. Significant discrepancies between documentation and observed behaviors indicate that documentation of compliance may not provide an accurate picture of behaviors (Gagliardi et al., 2014; Mahmood et al., 2015; Saturno et al., 2014). Strict reliance on documentation audits may result in a false sense of security in the degree of implementation penetration and accuracy, of checklist use due to an inflated completion rate. Audits should include observation, preferably without the participants’ awareness in order to prevent a possible Hawthorne effect. A “secret shopper” approach is one effective method to complete the observation. In this method, team members are secretly auditing the process without the knowledge of the other team members. Results are shared with the staff and the identity of the auditor is kept confidential. A second option for observational audits is peer reviews by representatives from each discipline.

Finally, a process needs to be in place to provide consequences for noncompliance (Gagliardi et al., 2014; Russ et al., 2015). Initially, a review should be conducted to identify any barriers to the checklist process. After barriers are addressed, remediation should be provided if indicated. If compliance continues to be an issue, a policy outlining consequences should guide any disciplinary process. Decisions regarding consequences must be planned and clearly communicated prior to implementation.
Without clear consequences for noncompliance, successful implementation may never be achieved.

**Conclusion**

Surgical safety checklists offer a great start for improving patient safety but the checklist itself is not a magical tool. Successful checklist implementation must include addressing teamwork and safety culture. Without addressing underlying issues of hierarchy, staff resistance, and process concerns, checklist will never be fully integrated into the operating room. The use of a checklist alone does not guarantee improved patient outcomes but including it in comprehensive team trainings will lay the foundation for successful implementation and long term maintenance.


Norton, E. (2012). In focus: Electronic surgical safety checklists: Can they improve surgical outcomes? *AORN Journal, 96*(2), C10. Retrieved from [link](http://missouri.summon.serialssolutions.com/2.0.0/link/0/eLvHCXMw3V3fS8MwEA6CIKlorl5xbzoi0xG-isORQaYOBQFnccI8TRMYajfWVVvS_965pm26wf8DXNKtpd-HUJf3ujhCHXfW6K5wgIuVJr-cLpSNXSKZFDEcvR8QidhxXx8uZleqKqrbtPxh-jNJBmRdSt5EtcpPmC0NyqdAo0wRjyY9PMHlREbkQXMFFjJpczL6V7T7LM5gbKueWFICDI9fnyxZ8CpsnohTjN8Vi9aUCqijN4damgDBFyzLzrmdIlqFVOa2rPlimAN2huW0tSldNYr20wtnN8D85YHucXmN38K57K7EYI3fc32EjBP0Vd5t3jE6ZulbN5nja2-8ke2S39dDow-103)


Porter, A. J., Narimasu, J. Y., Mulroy, M. F., & Koehler, R. P. (2014). Sustainable, effective implementation of a surgical preprocedural checklist: An "attestation" format for all operating team members. *Joint Commission Journal on Quality and Patient Safety, 40*(1), 3-9. Retrieved from http://missouri.summon.serialssolutions.com/2.0.0/link/0/eLVHCXMwjV1LS8QwEA7KijAx-7PiDs2da2SduPM4mIly ufUnSBlttd7HuLϾPO9PsrlUQPPVQAiUzmW--dOYbQlgsRsmQvOAK5K2xVdqkuXQCWFHGVJwaYbXmQqQfykob2e2uhN_oMmyqOmzK1675ogPFbclFRz3wbTKAHDlD735Gpu6jMBOim4OLY3GCDHaeVX9XK3pgs4O9H8u2BymTw02bny8qkZdVCFuOd-llr8q6J9f4n688IgerDJpee5c4Jlu2OSGft9-NUjFUF3FAnKNilva4fRwPRuaOKtsx3LhzSBSpeAr4VKM1BwbrmrQKvuoKqoWPUP5


# Table 7. Recommendations for Successful Surgical Safety Checklist Use

<table>
<thead>
<tr>
<th>Active leadership</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Utilize team facilitators</td>
</tr>
<tr>
<td>• Manage resistance</td>
</tr>
<tr>
<td>• Interdisciplinary rep.</td>
</tr>
<tr>
<td>• Ongoing leadership</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Extensive discussion and training</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Thorough analysis of current workflow</td>
</tr>
<tr>
<td>• Develop use cases</td>
</tr>
<tr>
<td>• Extensive training</td>
</tr>
<tr>
<td>• Interdisciplinary education</td>
</tr>
<tr>
<td>• Checklist training</td>
</tr>
<tr>
<td>• Role play difficult situations</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Checklist design</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Customized to local org.</td>
</tr>
<tr>
<td>• Feedback from end users</td>
</tr>
<tr>
<td>• Workflow compatibility</td>
</tr>
<tr>
<td>• Visible to all team members</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quality improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Ongoing feedback</td>
</tr>
<tr>
<td>• Transparency near misses</td>
</tr>
<tr>
<td>• Compliance measured</td>
</tr>
<tr>
<td>• Consequences for noncompliance</td>
</tr>
</tbody>
</table>
CHAPTER SIX: CONCLUSION

It has been over 15 years since the release of *To Err is Human: Building a Safer Health Care System* which brought patient safety to the center stage of health care (Kohn, Corrigan, & Donaldson, 2000). Despite the call to arms from this pivotal study, patient safety in the US healthcare system continues to be a problem. Operating rooms are a unique environment within the healthcare system; the majority of operating room errors result from a lack of communication and patient safety initiatives must focus on improving intraoperative communication (Lingard et al., 2004). The operating room setting consists of characteristics that make effective communication difficult. Multiple team members are performing various tasks at the same time. There is great emphasis on efficiency with speed being a priority. The patient, an essential partner in patient safety, is frequently under anesthesia and is unable to advocate for themselves. The perceived hierarchy of the social environment discourages other team members from speaking up about patient safety concerns. With these influences, it is not surprising that adverse events occur so frequently in the operating room.

The airline industry successfully implemented checklists to improve safety and made flying one of the safest ways to travel (Gawande, 2010). In 2009, the World Health Organization followed in the airline industry’s footsteps and tested the use of a standardized checklist in the operating room (Haynes, Alex B. et al., 2009). The results showed that this tool improved communication and resulted in a 30% improvement in mortality and morbidity. Based upon these results, hospitals all over the world began
implementing checklists (World Health Organization, 2012). AORN took the contents of the WHO checklist and combined it with requirements of The Joint Commission’s Universal Protocol to create the Comprehensive Surgical Safety Checklist (Association of periOperative Registered Nurses (AORN), 2013). The purpose of the checklist was to provide verification of essential patient safety measures while improving communication by encouraging all team members to be active participants in the process while reducing the reliance on memory (Gawande, 2010).

Research now shows that the effects of the checklist is dependent on the successful implementation and use by surgical team members (van Klei et al., 2012). Compliance with checklist measures appears to be lacking as staff members may use the checklist as a check box activity instead of a communication tool (Levy et al., 2012; Sparks et al., 2013). With the effect of compliance on patient outcomes, it is important to understand how the checklist is used and the reasons behind low compliance.

This study sought to describe the time-out process and the use of surgical safety checklists in rural and urban settings through a survey of perioperative staff-members (Lyons & Popejoy, n.d.). While almost all respondents reported conducting time-outs, just over half report performing the time-out according to the standards of The Joint Commission. The most common issues in the time-out process were a lack of verbal confirmation from all team members and a lack of cessation of all activities not directly related to the time-out. Regarding compliance, the results are consistent with previous research. The most common components verified during the time-out in both groups were the patient’s name, procedure, site marking, and antibiotic prophylaxis. The
components included the least in the time out were team members’ names, anticipated case duration, and anticipated blood loss. Compliance rates for each component ranged from 22% to 100%. The patient’s name was the only component reported to be included by 100% of rural respondents. No component was reported to be included by 100% of urban respondents. Urban respondents were significantly more likely to verify sterilization indicators and have verbal participation from the surgeon. Rural respondents were significantly more likely to have other team members verbally participate in the time-out beyond the surgeon, anesthesia provider, surgical technologist, and circulator.

Respondents were also asked about barriers to the use of checklists in the operating room (Lyons & Popejoy, n.d.). Common barriers identified by rural respondents focused on the lack of leadership support, education, and compliance monitoring. Additionally, rural respondents discussed the difficulty in consistently using checklists when performance expectations vary across settings and surgeons. Urban respondents identified resistance from anesthesia providers or surgeons and checklist fatigue as common barriers. Clearly, the implementation and use of checklists needs to be improved.

Based upon the findings of this study and previous research, several proposals for improvement were presented. First, the use of checklists require active leadership. This leadership committee must be multidisciplinary and be utilized beyond the initial implementation for managing ongoing resistance and continuous quality improvement. Next, the training on checklist use must be included in a larger teamwork and
communication training program. Simply providing education on the checklist alone is not enough to change the underlying safety culture of the organization. The training should also include simulations of various difficult scenarios to allow team members to role-play. The checklist itself should be designed for usability by modifying the checklist to meet the needs of the individual organization. Additionally, the checklist must be visible to all team members simultaneously in order to promote a team approach to the use of the checklist. Finally, compliance must be monitored through observation and feedback specific to the local setting on outcomes should be provided to team members. Based upon compliance reporting, a system of consequences must be in place for low compliance.

Although the sample for this study is small, it is unique in that this study measured compliance through self-reporting of behavior. The anonymous design of the survey allowed respondents to answer the questions honestly without fear of repercussions. Previous research has used chart review and observation to measure compliance. Chart review has been shown to be exaggerated when compared to observational results (Gagliardi et al., 2014; Low et al., 2012; Mahmood et al., 2015). On the other hand, observational measures of compliance presents the risk of a possible Hawthorne effect where participants may improve compliance due to the presence of the observer.

This study is not without its limitations. First, this study had a small sample size. Possible differences in practices in the two settings may not have been identified due to this small sample. Additionally, the survey methodology allows for participant bias
where participants may respond with answers they view as desirable by the researcher. Future research should consist of a larger scale survey to provide a more accurate picture of possible differences between the settings. The findings from this study can be used to develop safety initiatives and interventions tailored to meet the needs of the different settings.
References


Appendix A. Meta-analysis codebook

Report Characteristics

Author name

Location of report (journal article, webpage, pdf document, etc.)

Year

Study setting

Teaching status

Teaching - 1
Non-teaching – 2
Not identified – 0

Location

Northeast - 1
Southeast - 2
Midwest - 3
Northwest - 4
Southeast - 5
Not identified - 0

Size

Bed size

Less than 100 – 1
100-199 – 2
200 – 299 – 3
300 or higher – 4
Not identified - 0
Number of operating rooms

- Less than 5 – 1
- 5-9 – 2
- 10-14 – 3
- 15-19 – 4
- 20 or higher – 5
- Not identified - 0

Independent variable

Components of checklist

- Time Out - 1
- Preoperative antibiotic administration - 2
- DVT prevention - 3
- Blood components available - 4
- Concerns of other team members – 5
- Not identified - 0

Any additional training beyond the checklist training

- Communication training - 1
- Teamwork training – 2
- None identified - 0

Checklist initiated by whom

- Nurse - 1
- Surgeon - 2
- Anesthesia – 3
- Not identified – 0
Time of initiation of checklist in each procedure

Prior to arrival in the OR – 1
After arrival and before incision – 2
At the end of the procedure – 3
Not identified - 0

Type of surgical procedure

General - 1
Orthopedic - 2
Cardiac - 3
Pediatric – 4
Other - 5
Not identified - 0

Dependent variable

Length of time until final outcome measure

Less than 3 months – 1
3-5 months – 2
6-8 months – 3
9-11 months – 4
1 year or more – 5
Not identified - 0

Communication measures

Errors/Breakdowns in communication - 1
Perceptions of teamwork - 2
Staff satisfaction - 3
Perceptions of safety – 4
Not measured - 0

Postoperative outcome measures

Death - 1
Adverse events - 2
Errors - 3
Infection rates - 4
Cardiac events - 5
Length of hospitalization -6
Not measured - 0

Effect Size

Sample size
Means
Standard deviation
Standard error
Direction of effect
Appendix B. Institutional Review Board approval notification

May 20, 2014

This project was reviewed and approved by the University of Missouri–Columbia Health Sciences Institutional Review Board (HSIRB) according to the terms and conditions described below:

Project Number: 1211872
Project Title: The Use of Surgical Safety Checklists during Time-Outs in Rural Operating Rooms
Principle Investigator: Lyons, Vanessa E
Primary Contact: Lyons, Vanessa E
Approval Date: May 20, 2014
Expiration Date: May 20, 2015
Approval Category: Exempt #5 CFR 46.101(b) 2
Level of Review: Exempt

All documents reviewed and approved can be found in digital documents and are highlighted green.

You are expected to comply with the requirements outlined in the MU HSIRB Policies (http://research.missouri.edu/hsirb/policies.htm). This includes reporting any unanticipated problems involving risk to research participants or others.

Changes in the conduct of the study, including consent process or materials, require submission of an amendment form which must be approved by the HSIRB prior to implementation of the changes. Changes in the source of study funding must also be reported.

According to federal regulations, this project requires IRB continuing review. As such, prior to the expiration date above, you must submit either an Exempt Annual Update (EAU) or the Completion/Withdrawal Form. If you have questions or require additional information, please contact us at (573) 882-3181 or irb@missouri.edu

Sincerely,

Betty Wilson
Compliance Officer, HS IRB
Appendix C. Time-out and checklist survey

Rural Hospital Time-Out Checklist Survey

You are being asked to participate in a research study about the use of surgical safety checklists during time-outs in rural hospitals. This study is part of my dissertation study to complete the requirements for my PhD at the University of Missouri, Sinclair School of Nursing. The purpose of this research is to determine how rural operating rooms use surgical safety checklists during time-outs. You are being asked to complete this short survey about how surgical safety checklists are used at your organization. This survey should take you approximately 5 minutes to complete. At the completion of the survey, you will be asked if you are willing to answer any possible follow-up questions from the researcher. If you are willing to answer future questions, please provide your contact information. Your participation in this survey study is voluntary. Your answers will be kept confidential and will not be shared with anyone outside of this study. For the purpose of this survey, a time-out is a momentary pause taken by the surgical team immediately before skin incision or the start of an incisionless procedure in order to confirm that several essential safety checks are undertaken. The time out involves everyone on the surgical team. A checklist is a standard visual list of tasks that must be completed before the operation can proceed. For any questions or concerns please contact, Vanessa Lyons, MSN, RN, CNOR PhD Candidate University of Missouri Vanessalyons@mail.missouri.edu (270)978-2536  Lori Popejoy, PhD, APRN, GCNS-BC Associate Professor PopejoyL@missouri.edu (573)884-9538
Q1 What is your job title?
- Circulator (1)
- Surgical Technologist (2)
- RNFA (3)
- Anesthesia provider (4)
- Charge nurse/ Board runner (5)
- Operating Room Educator (6)
- Director/ Assistant Director (7)
- Other (please describe) (8) ____________________

Q2 How many years have you worked in the operating room at your current employer?
- less than 6 months (1)
- 6 months - 2 years (2)
- 3 years - 5 years (3)
- 6 years - 10 years (4)
- 11 years or more (5)

Q4 How many years have you worked in the operating room overall?
- less than 6 months (1)
- 6 months - 2 years (2)
- 3 years - 5 years (3)
- 6 years - 10 years (4)
- 11 years or more (5)

Q5 What is your highest level of education?
- High school or equivalent (1)
- Vocational or technical program (2)
- Associate's degree (3)
- Diploma nurse (4)
- Bachelor's degree (5)
- Master's degree (6)
- Doctorate (7)

Q6 Are you certified (CNOR, CRNFA, CST)?
- Yes (1)
- No (2)

Q7 About how many hours a week do you perform direct patient care?
- less than 10 (1)
- 10 - 19 hours (2)
- 20 - 29 hours (3)
- 30 or more hours (4)
Q8 Is your hospital for-profit or not-for-profit?
   - For-profit (1)
   - Not-for-profit (2)
   - Do not know (3)

Q9 Is your hospital Joint Commission accredited?
   - Yes (1)
   - No (2)

Q10 What is your zip code? This is for rural classification purposes only.

Q11 Do you complete a time-out prior to starting any surgical procedure?
   - Almost always (76% - 100% of the time) (1)
   - Usually (51% - 75% of the time) (2)
   - Sometimes (26% - 50% of the time) (3)
   - Rarely (1% - 25% of the time) (4)
   - Never (5)

Answer If Do you complete a time-out prior to starting any surgical procedure? Never Is Not Selected

Q12 During the time-out, do all team members verbally confirm agreement with the time-out?
   - Almost always (76% - 100% of the time) (1)
   - Usually (51% - 75% of the time) (2)
   - Sometimes (26% - 50% of the time) (3)
   - Rarely (1% - 25% of the time) (4)
   - Never (5)

Answer If Do you complete a time-out prior to starting any surgical procedure? Never Is Not Selected

Q13 During the time-out, do all team members stop any activity not directly related to the time-out?
   - Almost always (76% - 100% of the time) (1)
   - Usually (51% - 75% of the time) (2)
   - Sometimes (26% - 50% of the time) (3)
   - Rarely (1% - 25% of the time) (4)
   - Never (5)
Answer If Do you complete a time-out prior to starting any surgical procedure? Never Is Not Selected

Q14 Who is responsible for starting the time-out (check all that apply)?
- Circulator (1)
- Surgical technologist (2)
- Anesthesia provider (3)
- Surgeon (4)
- Other (please specify) (5) ____________________

Answer If Do you complete a time-out prior to starting any surgical procedure? Never Is Not Selected

Q15 Which team members verbally participate in the time-out (check all that apply)?
- Circulator (1)
- Surgical technologist (2)
- Anesthesia provider (3)
- Surgeon (4)
- Other (please specify) (5) ____________________

Answer If Do you complete a time-out prior to starting any surgical procedure? Never Is Not Selected

Q16 For which surgical procedures is a time-out typically not conducted?

Q17 Do you use a checklist during the time-out?
- Yes (1)
- No (2)
- Do not complete a time-out (3)

Answer If Do you use a checklist during the time-out? Yes Is Selected

Q18 Which checklist do you use?
- World Health Organization (WHO) (1)
- AORN Comprehensive Surgical Safety Checklist (2)
- Hospital-designed checklist (3)
- Other (please specify) (4) ____________________
- Do not know (5)

Answer If Do you use a checklist during the time-out? Yes Is Selected

Q19 What is the format of your checklist?
- Paper (1)
- Electronic (2)
- White board/ Dry erase board (3)
- Other (please describe) (4) ____________________
Answer: If Do you use a checklist during the time-out? Yes Is Selected
Q20 How often are the following items verbalized during the time-out process?
<table>
<thead>
<tr>
<th></th>
<th>Not included in the checklist (1)</th>
<th>Never (2)</th>
<th>Rarely (1% - 25% of the time) (3)</th>
<th>Sometimes (26% - 50% of the time) (4)</th>
<th>Usually (51% - 75% of the time) (5)</th>
<th>Almost always (76% - 100% of the time) (6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Team member names (1)</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Patient's name (2)</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Name of the procedure (3)</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Incision site (4)</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Consent verified (5)</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Site marked and visible (6)</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Relevant images properly displayed (7)</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Equipment concerns (8)</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Surgeon's anticipated critical or non routine steps (9)</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Anticipated case duration (10)</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Anticipated blood loss (11)</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Antibiotic prophylaxis within one hour before incision (12)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------------------------------------------------------</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Anesthesia concerns (13)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sterilization indicators confirmed (14)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scrub and circulating nurse concerns (15)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Answer** If Do you use a checklist during the time-out? Yes Is Selected

Q21 Please list any additional parts of the checklist used by you or your team that has not been mentioned.

**Answer** If Do you use a checklist during the time-out? Yes Is Selected

Q22 We are interested in understanding challenges to the use of surgical safety checklists. If you did not answer "almost always" to any of the items regarding the specific content of the time-out process, what prevents you from verbalizing these items more often?
Q23 Is there anything else you would like to tell us about the use of checklists during time-outs at your hospital? Please include any questions, concerns, observations, or experiences. If there is any information that we have not covered in this survey, please feel free to mention it here.

Answer If Do you use a checklist during the time-out? Yes Is Selected
Q24 Would you be willing to share your checklist?
☐ Yes (1)
☐ No (2)

Q25 Are you willing to be contacted for further questions? If so, please complete the following information:
   Name (1)
   Phone (2)
   Email (3)

Q26 Preferred contact method:
☐ Phone (1)
☐ Email (2)


http://www.aorn.org/Clinical_Practice/Toolkits/Correct_Site_Surgery_Tool_Kit/
Comprehensive_checklist.aspx

postoperative morbidity and mortality rates, Shiraz, Faghihy hospital, a 1-year
doi:10.1097/QMH.0b013e318231357c

Association of periOperative Registered Nurses (AORN). (2013). Comprehensive
checklist. Retrieved from
http://www.aorn.org/Clinical_Practice/Toolkits/Correct_Site_Surgery_Tool_Kit/
Comprehensive_checklist.aspx.

experiences of the surgical safety checklist in hospitals in high-income and low-
income countries. BMJ Open, 3(8), e003039. doi:10.1136/bmjopen-2013-003039

Berger, D. H. (2005). Bridging the communication gap in the operating room with

Organization surgical safety checklist on postoperative complications. British


doi:10.1097/SLA.0b013e3182682f27


study of social interactions in the operating rooms of a tertiary hospital. BMJ Quality and Safety, 22(8), 639-646. doi:10.1136/bmjqs-2012-001634


bias and outcome reporting bias. *PloS One*, 3(8), e3081. doi:10.1371/journal.pone.0003081


checklists: A qualitative study. *PLOS One*, 9(9), e108585.

doi:10.1371/journal.pone.0108585


nurses, and anesthesiologists to reduce failures in communication. *Archives of Surgery, 143*(1), 12-17. doi:10.1001/archsurg.2007.21


Mainthia, R., Lockney, T., Zotov, A., France, D. J., Bennett, M., St. Jacques, P. J., . . .


Makary, M. A., Mukherjee, A., Sexton, J. B., Syin, D., Goodrich, E., Hartmann, E., . . .


Norton, E. (2012). In focus: Electronic surgical safety checklists: Can they improve surgical outcomes? *AORN Journal, 96*(2), C10. Retrieved from http://missouri.summon.serialssolutions.com/2.0.0/link/0/eLvHCXMW3V3fS8MwEA6CIKlKor15xbzoi0xG-isOROaYOBQFnc8lTRMYajfWVVs_965pm26wf8DXNKTpd-HUJf3ujhCHxFw6K5wgluVJr-clpSNXSKZFDevR8QidhxXx8uZleqKqrbtPxhrjNJBmRdSt5EtcpPmC0NyqdAo0wRjyY9PMHLREbkQXMFFjJpczl6V7T7LM5gbKueWFICDl9fnY-
Z8CpnsohTjn8Vj9aUCqij4damgDBFyzLzrmDlqFVOa2rPlimAN2huW0tSIdNYr20wt
_nN8D85YHuXmN38K57K7EYi3fc32EjBP0Vd5t3jE6ZulbN5nja2-8ke2S39dDow-
O6TDZUckMk4oQW2fWqRpRVU1CBLLbJ9CrhSxJWWuNrOFa63h-
TsfiQZPnTNRMK5yf8R1h_AjsiOwECEJCScFWMgXGZBCeLgyur3YgH1zqIluBNcAqg
WQdtr4yHAtrTFvZC7nlfzno--E9h9pO1SWvda4_XP-
qQbWvOE7KpYSmrU7lFnlE_g6Z_6L4saA


[http://missouri.summon.serialssolutions.com/2.0.0/link/0/eLvHCXMwjV1LS8QwEA7KijAx-7PiDs2da2SdPUm4iJy_ufUnSBlttd7HuL_CPO9PsrlUQPPVQAiiUzmW--](http://missouri.summon.serialssolutions.com/2.0.0/link/0/eLvHCXMwjV1LS8QwEA7KijAx-7PiDs2da2SdPUm4iJy_ufUnSBlttd7HuL_CPO9PsrlUQPPVQAiiUzmW--)


doi:10.1093/bja/aes175


doi:10.1097/SLA.0b013e3181d970e3


doi:10.1016/S0140-6736(08)60878-8


and surgical morbidity. *Archives of Surgery, 146*(12), 1368-1373.


http://missouri.summon.serialssolutions.com/link/0/eLvHCXMwQ7QySSwPTEGD

ZqAEgnLKEUj7ybKIOfmGuLsoQupKuLI0cxxBsbq2Bzc2B_nC9R9LxxW7pnda_vLLe

Pk96vAgCFiysH
VITA

Vanessa Ervin Lyons was born in 1977 to Robert and Janice Ervin. She has four brothers and one sister and grew up in Paducah, Kentucky. She attended Reidland High School where she was active in band, color guard, and choir and graduated with honors. She attended Murray State University where she majored in math and psychology for four years before changing her major to nursing and transferring to Madisonville Community College. During her first semester of nursing, the terrorist attacks of 9/11 required the army to relocate her husband to Germany and she transferred to Paducah Community College to finish her degree closer to family. She earned an Associate’s Degree in Arts, an Associate’s Degree in Science, and an Associate’s Degree in Applied Science in Nursing from Paducah Community College in 2003. In 2009, she completed her Masters in Nursing with specialization in education from Walden University. Shortly afterward, she was accepted as a PhD student at the University of Missouri where she also completed a graduate certificate in informatics in 2013. She currently works as the Staff Development and Technology Coordinator at Murray-Calloway County Hospital in Murray, Kentucky. She also is an instructor for Grand Canyon University in Phoenix, Arizona. She is very active in the Association of periOperative Registered Nurses, serving on the National Committee on Education, Scholarship Committee, Continuing Education Committee, and is currently the education chair for the Informatics Specialty Assembly. She is married to Evan and has three children, Mariah, Thomas, and Laya. She is an active volunteer with the high school band, speech, and archery teams.