

A Human Factors Investigation of Intraoperative Handoffs during Cardiac Surgery

by

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Dedication

I dedicate my dissertation to the gentlelady from Georgia, my mother, Bertha Boswell-Blocker—you are an incredible wondrous woman.

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There were many individuals that have played an integral role in my doctoral degree pursuit and dissertation completion, and I would be remiss if I did not take this opportunity to highlight and acknowledge those that have sewn so much into the fabric of my current being. Your invariable support was warranted and beneficial to me successfully completing this rigorous doctoral program at the University of Wisconsin-Madison and for you I am thankful.

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Abstract

Very little is known about intraoperative handoffs and their relationship to the occurrence of non-routine events (NREs) that impact patient care during surgery. The purpose of the present study, therefore, was to address this issue by studying intraoperative handoffs and their potential association to NREs during cardiac surgery. The specific aims of this study are 1) to identify the characteristics of intraoperative handoffs among surgical staff, 2) to identify the characteristics of non-routine events during surgery, and 3) to describe how the characteristics of intraoperative handoffs relate to the occurrence of non-routine events. These aims were achieved through prospective observations. A multidisciplinary team conducted prospective observations of 36 cardiac surgeries across two hospitals for a total of 166 hours of observation. Observers recorded handoffs and NREs from beginning to end of the surgical procedures using a Tablet-PC Data Collection Tool. Both quantitative and qualitative analyses were performed to identify relationships between handoffs and NREs. A total of 90 handoffs were observed across the 36 surgical cases ($M = 4.09$ per case, $SD = 3.337$; range: 1-13). Handoffs occurred most often during the surgical repair phase and most frequently involved a nurse or surgical technician. Handoffs that occurred during the initiation of by-pass and surgical repair phases of the procedure were rated as most disruptive to other members of the surgical team. NREs totaled 2036 across the 36 surgical cases ($M = 56.56$ per case, $SD = 29.262$; range: 14-122). The majority of NREs involved environmental distractions (52.55%), technological problems (13.51%) and teamwork failures (10.76%). The vast majority of NREs did not have a major impact on the surgical flow of the case. However, a qualitative analysis identified 55 NREs as contributing to safety-compromising consequences across 19 cases as a result of an intraoperative handoff. Of those NREs, the most frequent categories were again environmental

distractions (50.91%), followed by technological problems (20%) and teamwork failures (16.36%). There were four themes (or patterns) that emerged relating intraoperative handoffs to NREs. The first theme was that “improper technology –instrument preparation induced by intraoperative handoffs can lead to machine malfunctions or tool unavailability”; the second theme was that “inadequate handoff communications can lead to teamwork issues that negatively impact the case”; the third theme was that “environmental distractions induced by intraoperative handoffs can lead to a delay in the surgical procedure”; and finally the fourth theme identified was that “exchange of personnel with various technical skill sets and/or experience can either negatively or positively affect the case”. This study is the first to show that intraoperative handoffs can be disruptive to surgical flow and can produce NREs that may threaten patient safety during cardiac surgery. This study also found that there are fewer instances where handoffs prove beneficial rather than detrimental. In broadening our understanding of intraoperative handoffs during cardiac surgery, this study’s results will assist us with developing methodologies for implementing effective interventions. Findings may also have implications for improving intraoperative handoffs during other types of surgeries, as well as other dynamic healthcare environments where handoffs have the potential to disrupt team functioning and patient care.

Chapter 1: Introduction and Literature Review

1.1 Overview and Research Objective

The overall objective of this empirical study is to evaluate intraoperative patient handoffs and their relationship to the occurrence of non-routine events. Transition of care has been widely recognized as a source of major vulnerability for patient safety (Arora et al., 2009; Behara et al., 2005; Burce & Suserud, 2005; Cohen & Hilligoss, 2010; Jenkin et al., 2007; Ong & Coiera, 2011; Owen et al., 2009; Thakore & Morrison, 2001; Walker, 1995; Yong et al., 2008). The U.S. health care system often fails to meet the needs of patients during transitions because care is rushed and responsibility is fragmented, with little communication across multiple care providers' settings (Arora et al., 2008; Borowitz et al., 2008; Bost et al., 2010; Cohen & Hilligoss, 2010; Lingard et al., 2004; Nagpal et al., 2010; Nestel et al., 2006; Ong & Coiera, 2011; Owen et al., 2009; Wears et al., 2003). To the contrary, however, some studies suggest that patient handoffs can occasionally have a positive impact on care by reducing provider fatigue or by providing a "fresh set of eyes" that allow patient problems to be viewed from a new or unique perspective (Arora et al., 2005; Cohen & Hilligoss, 2010; Cooper et al., 1982; Nagpal et al., 2010; Smith et al., 2008).

Much of the published literature on perioperative transitions of care or handoffs has focused primarily on preoperative and postoperative transitions (Arora et al., 2009; Bost et al., 2010; Cohen & Hilligoss, 2010; Dracup et al., 2009; Horwitz et al., 2006; Klaber et al., 2009; Owens et al., 2009; Smith et al., 2008; Suserud and Bruce, 2003). Very little is known about intraoperative handoffs or their relationship to the occurrence of non-routine events during surgery. Therefore, the purpose of the present study is to prospectively examine the

characteristics of intraoperative handoffs and their potential relationship (both negative and positive) to the occurrence of non-routine events during cardiac surgery.

For this study, intraoperative handoffs are defined as the exchange of surgical staff members in which one person transfers control over, or responsibility for, the performance of specific tasks associated with the surgical care of a patient and then subsequently departs the operating room (OR) for any given period of time (Christian et al., 2006; Cohen & Hilligoss, 2010). This study may use the terms: “observed breaks”, “sign-outs”, “transfers” and “reliefs” interchangeably to describe handoffs (Cohen & Hilligoss, 2010). Occasionally, the person who originally transferred his or her control or handed off his or her responsibilities may return to resume his or her role, with the initial relief individual subsequently departing the OR. These instances will be referred to as “return handoffs.”

Another key term used in this study is “non-routine events” (NREs). There are other terms such as flow disruptions (Wiegmann et al., 2007) and distraction and interruption (Healey, et al., 2006) that are often used to describe NREs. Since there is no consistent or agreed-upon definition in the literature for NRE, for this research, the term is defined, based upon a definition adapted from the nuclear power industry, as “any event that is perceived by care providers or skilled observers to be distracting, undesirable, unusual, or atypical” (Schraagen, 2011; Weinger & Slagle, 2002). This is a broad definition and includes everything ranging from unexpected or distracting phone calls to serious incidents endangering the patient’s well-being. This broad definition of NREs contains a considerably greater set of events than adverse events, medical errors, or near-misses. For purposes of this study, NREs that did pose a potential threat were called contributing NREs because they “increased the vulnerability of systems and had the potential to lead to an adverse event” (Christian et al., 2006). Based on previous studies (Blocker

et al., 2010; Hendrickson et al., 2010; Wiegmann et al., 2007), non-routine events will be categorized using an adapted Systems Engineering Initiative for Patient Safety (SEIPS) framework (Carayon et al., 2006). These categories are (a) individual technical factors (skills or technique issues); (b) environmental factors (case-irrelevant conversations, pagers/phones, noises/alarms/music); (c) technological factors (equipment malfunction/not ready, instruments/devices not at table); (d) training/procedural issues (training or instruction regarding unfamiliar patient issues, or performing new or difficult procedures); (e) teamwork failures (miscommunication/coordination) and (f) other (not previously specified).

1.1.1 Brief Review of Handoff Literature

In recent years, handoff research has increasingly become an area of focus for many health care and human factors researchers (Cohen & Hilligoss, 2010). Handoffs are a source of potential harm to the safety of patients since the process of transferring information and equipment increases the likelihood for error (Wilson, 2007). Human factors research has found that a lack of protocols, formal guidance and procedural training are associated with inconsistencies in the handoff process and can cause coordination problems and threaten patient safety (Cohen & Hilligoss, 2010; Dean et al., 2002; Stanton et al., 2005). Much of the current literature emphasizes communication breakdowns as the foremost problem that hinders the effectiveness of handoffs (Cohen & Hilligoss, 2010). Breakdowns in communication during handoffs can lead to confusion about the patient's condition and appropriate care, inconsistent patient monitoring, medication errors, delays in diagnosis and lack of follow through on referral (Arora et al., 2005; Arora et al., 2008; Cohen & Hilligoss, 2010; Dracup et al., 2009; Dunn et al., 2008; Horwitz et al., 2006; Jenkin et al., 2007; Klaber et al., 2009; Suserud & Bruce, 2003; Thakore & Morrison, 2001). Recent literature promulgates the notion that communication

breakdown during handoffs is due to a lack of active listening skills, problems with quality and quantity of information exchanged, and quandaries resulting from ineffective processes and practices corresponding to busy and complex milieus (Bruce & Suserud, 2005; Jenkin et al., 2007; Owen et al., 2009; Thakore & Morrison, 2001; Walker, 1995; Yong et al., 2008). Several studies have found that handoffs that contribute to communication and teamwork breakdowns have resulted in patient injury (Arora et al, 2005; Borowitz et al., 2007; Greenberg, 2007; Mistry et al., 2008). Therefore, vulnerabilities or threats to patient safety result from the reality that errors or omissions in the information promulgated during the handoff often become a “fact” for the next person or team using the information (Philibert & Leach, 2005). Hence, comprehensive handoff studies are essential to understanding their intrinsic ability to impact health care processes.

1.2 Previous Research on Intraoperative Handoffs

As stated previously, much of the published literature on perioperative transitions of care or handoffs has focused primarily on preoperative and postoperative transitions. Very little is known about intraoperative handoffs. However, to discover any knowledge that does currently exist, a literature review was conducted to identify previous studies on intraoperative handoffs. The inclusion criteria were 1) the article’s domain was healthcare; 2) one of the main focuses of the article was intraoperative handoffs or the concept of transferring the care of patient between surgical personnel during surgical procedures; 3) the article was published in a peer-reviewed journal; 4) the article presented empirical data; and 5) the article was published prior to 1 August 2011. Articles were excluded if they only contained conceptual or theoretical discussions of intraoperative handoffs.

The online databases PubMed and Web of Science (Web of Knowledge) were searched. The Web of Science online database simultaneously searched the Science Citation Index Expanded (SCI-EXPANDED), Social Sciences Citation Index (SSCI) and Arts and Humanities Citation Index (A&HCI) using the following search phrases: 1) healthcare* AND handoffs*; 2) healthcare* AND transitions*; 3) healthcare* AND intraoperative*; 4) intraoperative* AND handoffs*; and 5) intraoperative* AND exchanges*. As a result, these searches identified a combined total of 892 articles that examined handoffs in healthcare settings. However, only three of these articles specifically focused on intraoperative handoffs. A search of their references did not yield any additional articles that met the inclusion criteria. Additionally, a search of several handoff review papers did not yield any additional articles meeting the inclusion criteria.

In addition to the search outlined above, a cited reference search in Web of Knowledge was performed on the three articles. The following search phrases were used to search within results from the cited reference search: 1) intraoperative* AND handoffs* and 2) intraoperative* AND exchanges*. These searches within the cited reference search results did not yield any additional papers.

The results of the literature review revealed only three empirical articles on intraoperative handoffs. Given this small number, each of these articles will be reviewed in detail in order to glean as much information as possible about the topic. A discussion of the remaining gaps in our knowledge regarding intraoperative handoffs will then be provided.

The earliest of the three studies identified was by Cooper and colleagues (1982) titled “Critical incidents associated with intraoperative exchanges of anesthesia personnel”; it was the first paper to examine handoffs. This study was conducted by anesthesia researchers at Harvard

Medical School and Massachusetts General Hospital. Data for this study were gathered over a 5-year period, 1975—1980, from four hospitals in the Boston Metropolitan Area.

Cooper et al. (1982) used the critical incident technique for gathering data about intraoperative exchange of anesthesia personnel. According to the authors, during long surgical operations, anesthesiologists typically substitute for one another, especially for short breaks. As described in the article, the critical incident method is an established technique for the collection of information about human performance (Cooper et al., 1982). Validation has been established in certain applications; however, the method is based on self-reporting, in which the potential for bias always exists (Cooper et al., 1982). Reports of anesthesia-related human errors and equipment failures were gathered from 40 anesthesiologists, 30 residents, and 13 nurse anesthetists from four hospitals. Two of the hospitals had extensive teaching programs and the other two hospitals, were staffed primarily by nurse anesthetists.

In this study, each of the participants was interviewed and was asked to describe directly observed incidents which involved a preventable human error or equipment failure during anesthesia care. The participants were not required to provide any specific examples of error or equipment failures during anesthesia care. In addition to data collected from the aforementioned interviews, a second type of interview was conducted. These interviews involved what Cooper and colleagues called “trained observers.” These trained observers included 18 anesthesiologists, 21 residents and 9 nurse anesthetists. The participants in this part of the investigation were asked specific types of questions from a prepared list about various incidents such as disconnections in the breathing circuit or drug administration errors. They were also asked two additional questions about relief-related incidents. The participants were asked to report incidents as soon as possible after they occurred by telephone to their original interviewer. All interviews and telephone

reports were electronically recorded. The information from the data collected was then coded and analyzed. Cooper et al. (1982) classified reports as critical incidents, defined as “human errors or equipment failures that could have led or did lead to an undesirable outcome ranging from increased length of hospital stay to death” (p. 457). All of the incidents were examined and classified into one of the four outcome categories: (1) favorable, (2) unfavorable, (3) neutral and (4) other. Three of the investigators reviewed all relief-associated critical incidents and independently assigned the aforementioned labels to them. Within each category, other characteristics of incidents were extracted and summarized in search of causal relationships.

Cooper and colleagues (1982) collected a total of 1,089 reports of preventable errors and failures associated with anesthesia management, of these, 96 involved a relief anesthetist. These 96 reports were reviewed for the purpose of identifying common characteristics and patterns of cause and discovery of errors (Cooper et al., 1982). Results of this study revealed 28 incidents during which the relief anesthetist discovered an error or the source of an error. The relief anesthetist discovered errors such as disconnections of the breathing circuit, a partially open pop-off-valve, or an empty vaporizer leading to tachycardia. In 10 incidents, the process of relief (handoff) was identified as having contributed to the commission of an error. The conclusion of the study is that relief or handoffs can have both a negative and positive impact on patient safety and that the positive impact goes beyond the presumed beneficial effect or compensation for the reduced vigilance of the primary anesthetist.

The Cooper et al. (1982) study alerted the health community to the benefits and vulnerabilities of intraoperative handoffs. However, the results of this study were based on critical incident reports and therefore participants were retrospectively providing information about incidents that occurred during prior intraoperative exchanges. As the authors indicated, the

critical incident technique relies solely on events that participants remember (Cooper et al., 1982). Therefore, since critical incidents in this study relied on memory, incidents may have lacked accuracy, and some incidents may not have been reported. As the authors mention, the method has a built-in bias toward incidents that have recently occurred because recent incidents are usually easier for participants to recall (Cooper et al., 1982). While this study provides a foundation for intraoperative handoff research, it is apparent that this study's methodology does not capture the direct characteristics of intraoperative handoffs. Therefore, a subsequent study that involves naturalistic observations is warranted.

In addition, there are many factors that influence intraoperative handoffs or exchanges; however, Cooper and colleagues (1982) focused solely on preventable human errors and equipment failures. A systematic approach to intraoperative handoffs could have yielded more significant insights into anesthesia personnel exchanges than presented in this study. Perhaps, with a systems approach, the researcher could have provided insights on the impacts that anesthesia personnel exchanges have on the entire surgical team, as well as the impact of the timing of the handoff (when in the surgical procedure the personnel exchanges occur), and how often they occur (their frequency).

The scope of Cooper and colleagues' (1982) study was also limited to anesthesia intraoperative exchanges. Therefore, since this study is the only in-depth study on intraoperative handoffs, the literature at the time lacked sufficient empirical data about intraoperative handoffs between other surgical staff members (i.e., nurses, surgical technicians, perfusionists, and surgeon/residents).

The second article on intraoperative handoffs that was identified was a study by Greenberg and colleagues (2007) titled, "Patterns of communication breakdowns resulting in

injury to surgical patients.” This study was conducted in collaboration with researchers at Brigham and Women’s Hospital, the Harvard School of Public Health’s Department of Health Policy and Management, and Massachusetts General Hospital’s Department of Surgery. Data for this study were collected as part of a larger study, the Malpractice Insurers’ Medical Error Prevention Study (MIMEPS). The MIMEPS, according Greenberg and colleagues (2007), analyzed surgical errors in closed claims at four malpractice insurance companies that together cover approximately 21,000 physicians at 46 acute care hospitals and 390 outpatient facilities.

The goal of this research study was to develop and prioritize initiatives to prevent communication breakdowns resulting in injury to surgical patients (Greenberg et al., 2007). Greenberg and colleagues (2007) reviewed 444 surgical malpractice claims from 4 liability insurers to identify cases that involved communication breakdowns resulting in harm to patients. These 444 surgical claims were gathered from a random sampling process of closed malpractice claims. Each of the 444 surgical claims was reviewed by senior surgical residents, surgical fellows, and board-certified surgeons who all were trained by the study’s researchers (Greenberg et al., 2007). A total of 60 cases of miscommunication were identified. Two additional surgeon reviewers conducted a secondary review of all information gathered on the 60 cases to identify common characteristics and contributing factors to communication breakdowns (Greenberg et al., 2007). The data were analyzed descriptively, and frequency counts for the variables and categories of interest were calculated. The variables and classification categories were based on findings from previous field studies and included: synchronous communication, asynchronous communication, status asymmetry, handoff, a transfer in care, and an emergent case.

The results of this study revealed that within these 60 cases, 81 communication breakdowns occurred. Most of the communication breakdowns occurred in the preoperative

phase (38%). There were a slightly smaller percentage of communication breakdowns that occurred in the intraoperative (30%), and postoperative phases (32%) (Greenberg et al., 2007).

Greenberg and colleagues (2007) found that “ninety-two percent of the breakdowns were verbal and the majority occurred between a single transmitter and a single receiver” (p. 535).

“Attending surgeons were the most common transmitters (24 of 83, or 29%) and receivers (55 of 98, or 56%) in the overall communication breakdowns” (p. 536). Status asymmetry (74%) and ambiguity about responsibilities (73%) were frequently issues associated with communication breakdowns. Greenberg and colleagues (2007) defined status asymmetry “as the situation in which one agent has substantially more power or greater rank than another” (p. 535).

Communication breakdowns occurred with handoffs (43%) and with transfers (39%) in the patient’s location (Greenberg et al., 2007). For this study, Greenberg and colleagues defined handoffs as a complete transfer of care from one provider to another and the first provider physically leaves the scene. The authors defined transfers as the physical movement of patients from one location of care to another. Greenberg and colleagues (2007) noted that “the most common communication breakdowns involved residents failing to notify the attending surgeon of critical events and a failure of attending-to-attending handoffs.”

This study’s authors argued that the proposed interventions could prevent 45% to 73% of communication breakdowns in this series of cases. One intervention proposed was the trigger list, which was only applicable to preoperative and postoperative settings and not intraoperative care. The trigger list included items that would prompt house staff to immediately communicate with the surgical attending. These items were related to changes in location of patient, serious events, and staff concerns. The next intervention was the standard use of read-backs, which

could improve communication. Finally, the study recommended structured protocols for handoffs and transfers in care.

As noted, this study revealed that 30% of perioperative surgical communication breakdowns occur during intraoperative care periods. However, this study did not directly link those communication breakdowns to intraoperative handoffs. The study further revealed that 43% of communication breakdowns occurred with handoffs, but, again, it did not detail the percentages that were related directly to intraoperative handoffs.

While the results presented by Greenberg and colleagues (2007) provide some insight into how to improve patient safety, there are several limitations to the study. First, the authors used retrospective data analysis methods and they only examined one aspect of the system that could have led to patient harm (i.e., communication). Their study also focused only on the potential negative effects of intraoperative handoffs. Furthermore, there are inherent biases that affect both the reporting and investigation of malpractice claims, which also can limit their value for improving patient safety (Weinger et al., 2003). The main reason is that malpractice claims represent only a small proportion of events that occur in hospitals that lead to adverse events. Therefore, retrospectively analyzing this small, potentially biased, sample could lead one to draw misleading conclusions (Weinger et al., 2003). Retrospective analysis of these malpractice claims can be tainted by hindsight and attribution biases (Barach & Small, 2000; Weinger et al., 2003; Woods & Cook, 1999). In addition, these malpractice claims could be influenced by the context and the perspective of event participants and analysts (Barach & Small, 2000; Rasmussen et al., 1994; Tversky & Kahneman, 1974; Weinger et al., 2003; Woods & Cook, 1999). Finally, the results from retrospective analysis can be influenced by the knowledge of the malpractice claims outcome. Weinger and colleagues (2003) argued that such limitations could

hinder researchers in their quest to improve safety. As a result, there remains a need for prospective studies of both the positive and negative impact of intraoperative handoffs on patient care from a holistic or system perspective.

The final article that was identified comes closest to addressing this need. This was a study by Christian and colleagues (2006) titled; “A prospective study of patient safety in the operating room.” The aim of this study was to understand the operating room as a system and to identify systems features that influence patient safety (Christian et al., 2006). The study provided a prospective approach to exposing critical system features in the operating room, unlike the studies of Greenberg and colleagues (2007) and Cooper and colleagues (1982). The study was conducted by an interdisciplinary group of researchers from Brigham and Women’s Hospital’s Department of Surgery and Division of General Medicine, Roth Cognitive Engineering, the Massachusetts Institute of Technology, the Risk Management Foundation, and the Beth Israel Deaconess Medical Center’s Department of Health Care Quality.

The team, comprised of human factors experts and surgeons, conducted a prospective observation of 10 complex general surgeries involving pelvic dissections and hepatobiliary cases in an academic hospital. One human factors expert and one surgeon observed each case. Observations started in the preoperative holding area and the case would be observed up until post-anesthesia care. Minute-to-minute observations were recorded freehand into each observer’s field notes, and then later were coded and analyzed both quantitatively and qualitatively (Christian et al., 2006). In their field notes, the observers recorded observations including such occurrences as entrances and exits of individuals, operative events, key communications, additions of instruments to the surgical field, and counts of instruments, as well as intraoperative handoffs (Christian et al., 2006). At the completion of the 10 observations, 2

separate analyses were performed. The qualitative analysis focused on safety-influencing system features, where each case was analyzed individually to identify system features that influenced team performance or case progression and patient safety (Christian et al., 2006). A quantitative analysis of the safety-influencing system features identified from this qualitative analysis was then performed.

The results from this study revealed that problems in communication and information flow, workload, and competing tasks were found to have measureable negative impact on team performance and patient safety in all 10 cases (Christian et al., 2006). While the study's focus was not exclusively on intraoperative handoffs, it revealed that intraoperative handoffs were particularly vulnerable to information loss. There was an average of 5 handoffs per case, and 22% of the observed instances of information loss were related temporally to an intraoperative handoff (Christian et al., 2006). In addition, this study found that auxiliary activities such as handoffs, exits and counts, were synchronized poorly with predictable high workload or high-risk phases of the case (Christian et al., 2006).

While this study does not focus specifically on intraoperative handoffs, it does provide some insights into the frequency and timing of intraoperative handoffs and their impact on information loss using a prospective data collection method. However, the study lacks an extensive characterization of intraoperative handoffs such as the duration of the handoff process, the interval between handoffs and return handoffs (if there is a return handoff), or the distractive nature of the handoff itself to the rest of the surgical team. The study also focuses primarily on one aspect of the system (i.e., information exchange) while ignoring other elements of a work system model. Finally, the study by Christian and colleagues (2006) focuses on only the potentially negative impact that intraoperative handoffs might have on patient care. However, as

illustrated by Cooper and colleagues (1982), intraoperative handoffs can also have a beneficial impact of helping to detect errors, at least within the context of anesthesia. Consequently, a more thorough understanding of handoffs that occur during complex surgery cases is needed to inform the design and implementation of interventions that either reduce the occurrence of NREs or ensure their capture and remediation.

In summary, only three studies have examined the impact of intraoperative handoffs on patient care. Generally, these studies have found that intraoperative handoffs can pose a threat to patient safety by increasing the likelihood of an error, but in some instances can be beneficial by facilitating error detection and correction. However, these studies are extremely limited because, as previously mentioned, two are based primarily on self-report or retrospective analysis (i.e., Greenberg et al., 2007 and Cooper et al., 1982), and they do not capture the impact of intraoperative handoffs on the procedure as a whole or elsewhere throughout the system. The third study by Christian and colleagues (2006) uses a prospective data collection method based on a system approach. However, it does not solely focus on intraoperative handoffs and, therefore, lacks an extensive characterization of the phenomenon. Only one of the three articles (Cooper et al., 1982) focuses on the positive as well as the negative impact that intraoperative handoffs can have on patient care. Finally, all three studies are limited in their analysis of association of intraoperative handoffs and NREs in general. The purpose of the present study, therefore, is to address these limitations by applying a system approach to prospectively examine the characteristics of intraoperative handoffs and their potential relationship (both negative and positive) to the occurrence of non-routine events during complex surgical procedures.

1.3 Previous Research on Non-Routine Events (NREs) during Surgery

Given the goal of the present study is to examine the relationship between intraoperative handoffs and NREs, a literature review was conducted to determine what is already known about NREs independent of handoffs. This review of literature was conducted using the same databases as described above, but it used the following search phrases: 1) healthcare* AND non-routine events*; 2) surgery* AND non-routine events*; 3) healthcare* AND surgical flow disruptions*; 4) handoffs* AND non-routine events*; 5) Human factors* AND non-routine events*; 6) Human factors* AND surgical flow disruptions*; 7) non-routine events*; 8) surgical flow disruptions*; and 9) safety* AND non-routine events*.

The inclusion criteria were 1) the article's domain was healthcare, 2) one of the main focuses of the article was non-routine events and their occurrence during surgical procedures, 3) the article was published in a peer-reviewed journal, 4) the article presented empirical data, and 5) the article was published prior to 1 August 2011. Articles were excluded if they only contained conceptual or theoretical discussions of non-routine events. Results of this literature search yielded a combined total of 75 articles. Given the large number of papers identified, this section will summarize the key findings from articles that are particularly relevant to the present study in that they are prospective in nature and they focus on studying NREs from a system approach.

Weinger and Slagle (2002) introduced the novel concept of “non-routine events” (NREs) and their relevance to human factors research and patient safety. The concept of non-routine events was proposed as “a mechanism to more efficiently capture dysfunctional clinical system attributes or potentially dangerous conditions” (Weinger & Slagle, 2002, p. S69). Weinger and Slagle (2002) state that NREs represent disruptions in everyday clinical activities or processes that are otherwise conducted seamlessly. “NREs encompass a substantially larger class of events

than adverse events, medical errors, or near misses” (Weinger & Slagle, 2002, p. S69).

Therefore, based on Weinger and Slagle’s (2002) assertions, the concept of NRE can include surgical flow disruptions or deviations from the desired or planned care processes. This section will also highlight studies that used the term “surgical flow disruptions” to describe the same concept that Weinger has expressed in his definition of non-routine events.

Weinger and Slagle (2002) conducted a pilot study to detect near real-time non-routine events that occurred in a post-anesthesia care unit (PACU). The data collection process was basically a retrospective study, where the researchers obtained initial reports of intraoperative NREs immediately after they occurred. A trained observer, using a standardized data collection form, conducted a 5-minute interview of anesthesia personnel after they signed their patients over to the PACU nurse (Weinger & Slagle, 2002). The data collection form was used to determine whether a NRE occurred in the just-completed cases (Weinger & Slagle, 2002). The analysis of 51 cases from this studied identified several types of NREs, including equipment failure or usability problems, team coordination or communication, deficient drug therapy, patient disease/clinical issues and surgical issues, controlled ventilation performed via mask, patient positioning, and logistical or system issues (Weinger & Slagle, 2002). Weinger and Slagle (2002) argued that the results from this study show that “providers will reliably report NRE immediately after case completion and the incidence of NRE is high” (p. S62). From this study, the types of NREs were extracted and can be used in future studies to assist in easily identifying NREs.

Schraagen and colleagues (2010) conducted a study on how to assess the role of intraoperative non-routine events (NREs) and team performance on pediatric cardiac surgery outcomes. However, the central focus of this research was on improving methods for studying

teamwork. Schraagen et al. (2010) extensively trained human factors observers to record the NREs and teamwork issues from the time a patient arrived in the operating room (OR) until the patient handoff in the intensive care unit for each case. For this study, non-routine events were subdivided into “task-related NREs” and “non-task related NREs” (Schraagen et al., 2010, p. 2). Schraagen and colleagues (2010) defined task-related NREs as events related to the task of team members when performing a technical skill. The authors defined non-task related NREs as all the other NREs, unrelated to the task to perform as technical skill (Schraagen et al., 2010). After the surgical procedure, NREs were corroborated by the team members, using a questionnaire and through interviews with team members using an open-ended validated tool (Schraagen et al., 2010). The observers’ performance was later assessed, via video, by a senior medical expert and a human factors expert (Schraagen et al., 2010).

Evaluation of data recorded during 19 pediatric cardiac surgeries indicated 76% agreement of event type and 91% agreement across teamwork categories. Schraagen and colleagues (2010) recommended that researchers planning to observe teamwork and identify NREs in the operating room should consider training observers using video recordings of real operations and then should rate teamwork in real time and not retrospectively.

In another study, to develop a method to assess teamwork skills and to provide evidence for improvements in training and performance, Schraagen and colleagues (2011) conducted a study on pediatric cardiac surgery procedures. This study aimed to examine the notion that small intraoperative non-routine events (NREs) can escalate to more serious situations, and that effective teamwork can prevent the development of serious situations (Schraagen et al., 2011). Trained human factor observers coded NREs and teamwork elements from the time of patient arrival in the operating room to patient handover to the intensive care unit (Schraagen et al.,

2011). “Real-time teamwork observations were coupled with microsystem preparedness measures, operative duration, assessed difficulty of the operation and patient outcome measures” (Schraagen et al., 2011, p. 1). “Behavior was rated based on whether it hindered or enhanced teamwork” (Schraagen et al., 2011, p. 1). The NREs were categorized into the following categories: (a) disturbances during the execution of the procedure; (b) remarkable individual behavior, unrelated to the procedure; (c) external events; and (d) events caused by unpredictable patient factors. However, Schraagen and colleagues’ (2011) study did not categorize equipment problems or face mask violations (mask not worn properly) as NREs due to the high frequency of the events.

Past research has shown that good teamwork is associated with fewer NREs (Schraagen et al., 2011). The results from this study found a “significant correlation between surgical decision making during cardiopulmonary bypass and the number of NREs, $r=0.66$, $p<0.01$ ” (Schraagen et al., 2011, p. 3). “These findings suggest that, as NREs during the cardiopulmonary bypass phase increased, the surgeons scored higher on decision making” (Schraagen et al., 2011, p. 3). In conclusion, Schraagen and colleagues (2011) found that complex surgical operations take longer and lead to more NREs, particularly during the bypass and repair phases.

Many studies examining non-routine events use a work system approach to define and categorize events. For example, Wiegmann et al. (2007), Hendrickson et al. (2010), and Duff et al. (2010) utilized a work system type framework such as the SEIPS model to define and categorize recorded events. The SEIPS model is an integration of the Work System Model and Donabedian’s Structure-Process-Outcome Framework (Carayon et al., 2006). Carayon et al (2006) posit that the SEIPS model can be employed to evaluate systemic adherence to patient

safety and to design or redesign the system to ensure a safe environment for patients and staff. As astutely stated by Carayon et al. (2006), “the structure of an organization (the work system) affects how safely care is provided (the process); and the means of caring for and managing the patient (the process) affects how safe the patient is (outcome)” (p. 151). As indicated in Figure 1 below, the work system is comprised of five interrelated elements: the tools and technology, the organization, the person, the tasks, and the environment. The interworking of these five elements impact the care process, which, in turn, affects the outcome of the patients and employees.

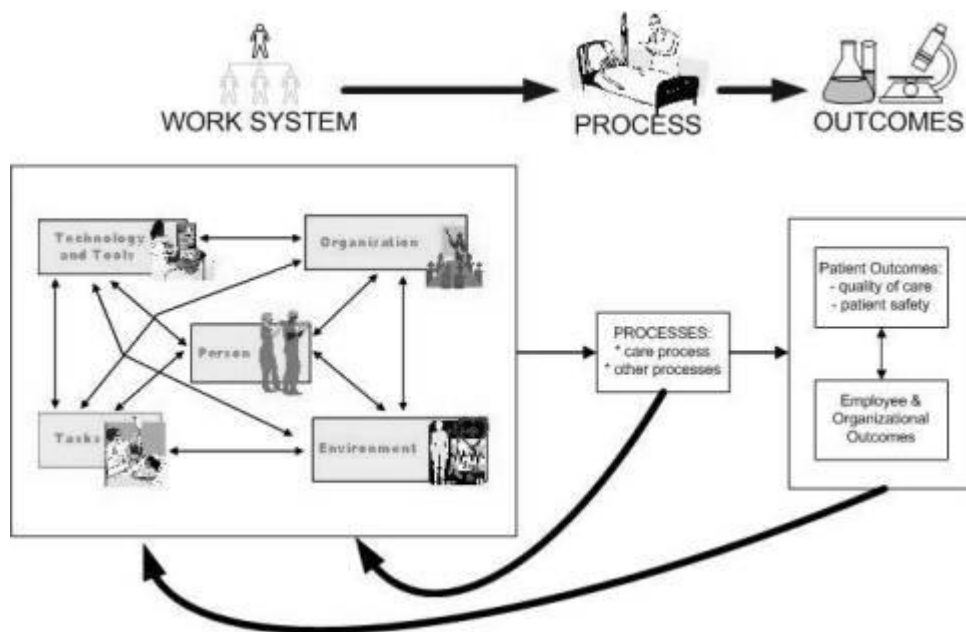


FIGURE 1: THE SYSTEMS ENGINEERING INITIATIVE FOR PATIENT SAFETY (SEIPS) MODEL (CARAYON ET AL., 2006)

Several studies using a work system approach have linked non-routine events to errors or vulnerability in patient safety. For example, Wiegmann et al. (2007) conducted an investigation of events that disrupted the surgical flow and found that surgical errors increased significantly with an increase in flow disruptions. Using a work system approach, this study categorized events, described as flow disruptions, into several categories, including teamwork, extraneous interruptions, equipment and technology, resource-based issues, and supervisory/training-related

issues. The study was conducted over a 3-week period, during which trained observers recorded surgical flow disruptions and surgical errors for 31 cardiac surgery operations. At the completion of the observations, an interdisciplinary team of experts analyzed the data collected. The study indicated that disruptions in surgical flow categorized as teamwork/communication accounted for the greatest percentage (52%) of the events that occurred followed, by external/extraneous disruptions (17%) and equipment/technology disruptions (11%). After the completion of a multiple regression analysis, a significant relationship was found between surgical errors and teamwork-related disruptions. The authors argued that operative errors that occur during cardiac surgery are associated with surgical flow disruptions and these disruptions consist of a variety of system factors (Wiegmann et al., 2007).

Lingard et al. (2004) conducted a study on communication failures in the operating room and their effects on patient safety. The study was conducted over a 3-month period, during which observers observed 48 surgical procedures. Field notes from this study were analyzed to identify the failures in communication (Lingard et al., 2004). The findings suggest that communication failures in the operating room revealed a collective set of problems, including occasion failures, content failures, audience failures, and purpose failures. Lingard and colleagues (2004) defined occasion failures as “problems in the situation or context of the communication event” and content failures as “insufficiency or inaccuracy apparent in the information being transferred” (p. 332). Audience failures were defined as “gaps in the composition of the group engaged in the communication,” while purpose failures were defined as “communication events in which purpose is unclear, not achieved, or inappropriate” (Lingard et al., 2004, p. 332). Those communication failures occurred in approximately 36.4% of team exchanges. In addition, “a third of these failures resulted in visual effects on the system process with included inefficiency,

team tension, resource waste, workaround, delay, patient inconvenience, and procedural error, all of which compromised the safety of patients” (Lingard et al., 2004, p. 332).

In addition to the aforementioned studies that have shown that NREs can have safety compromising consequences, there have been several studies (Carthey et al., 2001; Carthey et al., 2003; de Leval et al., 2000) that suggest that as minor events increase, the ability of the surgical team to cope with major events decreases. Therefore, minor NREs may also compromise the safety of patients. However, while there have been many prospective studies of NREs during surgery, none of these studies have directly examined the relationship between intraoperative handoff and the occurrence of these events. The present study therefore provides a unique perspective and approach to studying handoffs and their association (both negative and positive) with NREs. Moreover, this study argues that not all NREs are created equal and therefore identified NREs that contributed to safety-compromising consequences and mitigated the possible occurrence of a safety-compromising consequence. The potential for intraoperative handoffs to negatively or positively impact NREs will be discussed in the following sections.

1.4 Why Intraoperative Handoffs Might Increase the Occurrence of NREs.

In respect to intraoperative handoffs, the theory of Transactive Memory (Wegner et al., 1985) helps one understand why handoffs during cardiac surgery may lead to undesired outcomes. This section will explain in greater depth the effects that intraoperative handoffs may have on transactive memory. Transactive memory is discussed here as a rationale for why intraoperative handoffs may increase the occurrence of NREs. It is not presented here as a method for empirically collecting prospective data but rather as an interpretive framework for understanding the phenomenon.

Intraoperative handoffs are unique in that they have the potential to impact (for better or worse) the dynamics of the entire surgical team, rather than just an individual healthcare professional. Perhaps, within the dynamic team environment of the OR, protocols and techniques for patient handoffs could be designed to ensure that they support the transactive memory of the surgical staff. Transactive memory is defined in terms of two components: (1) an organized store of knowledge that is contained entirely in the individual memory systems of group members, and (2) a set of knowledge-relevant transactive processes that occur among group members (Wegner et al., 1985). Transactive memory theory asserts that a person's departure from a team will disrupt the group memory and "shake-up" the entire system (Wegner et al., 1985). Intraoperative handoffs involve surgical staff members departing from and returning to working surgical teams. This poses a potential threat to the safety of patients during cardiac surgical procedures, since teamwork is integral to surgical success.

The theory of transactive memory was developed by Wegner and colleagues (1985) and evolved out of the idea that individual members of a group can serve as external memory aids to each other. Each member in the group or team is able to benefit from the knowledge of the other and from each other's expertise if they develop a shared understanding of "who knows what" in the group or unit (Wegner et al., 1985). The transactive memory system is built on the distinction between internal and external memory encoding (Wegner et al., 1985). Internal memory encoding is described as knowledge that individual members store within. External memory encoding is described as knowledge stored outwardly and can be used as an "aid" or a central storage area for an extensive amount of information. Although individuals encode new knowledge internally, they often, however, encode or use knowledge encoded externally

(Wegner et al., 1985). In these instances, “the individual internally encodes the label (subject) of the knowledge as well as its location but not the knowledge itself” (Wegner et al., 1985, p. 258).

Wegner et al. (1985) stated that the transactive memory system is “a set of individual memory systems in combination with the communication that takes place between individuals” (p. 256). According to Wegner and colleagues (1985), there are two components of transactive memory. The first component of the transactive memory is the structural or knowledge component—the individual memory systems where information on individual areas of expertise as well as knowledge on “who knows what” are stored. The second component is the communication processes among group members. According to Wegner and colleagues (1985), these components distinguish the transactive memory system from a concept of group mind because transactive memory system processes are observable and communication is taken into account (Wegner et al., 1985). The concept of group mind was used to capture similarity within a group such as similar attitudes, worldviews and shared languages (Wegner et al., 1985).

The transactive memory system of a group develops over time and is not forced on a group. When members of a group work together for a long time, they learn more about each other and expertise judgments become more accurate. The transactive memory system is developed when group members possess different expertise, recognize the expertise of the others, and can generously communicate to combine their expertise when necessary (Wegner, 1995). There are two advantages of a developed transactive memory system. The first advantage is that transactive memory allows group members to reduce individual information burden by dividing cognitive labor. The second advantage is that people in the groups are experts in different areas; therefore, it is possible for members to provide answers to questions that are far beyond their individual expertise (Wegner, 1995).

In recent years, the transactive memory theory has attracted extensive research attention in the study of group memory systems (Ren et al., 2006; Wegner, 1995; Wegner et al., 1991; Wegner et al., 1985). The theory offers suggestions about how groups extend and maintain mechanisms for communication and information sharing among members. In addition, the transactive memory theory offers suggestions on how groups develop and assess individual member expertise in relevant knowledge domains (Wegner et al., 1995; Wegner, 1985). The transactive memory theory has informed research in various areas including group interaction (Hollingshead, 1998) and team processes (Fulk, Monge, & Hollingshead, 2005).

Research indicates that transactive memory can serve as a facilitator of group performance, where groups whose members are aware of the knowledge and expertise of other group members perform better than groups whose members do not possess such knowledge (Lewis, 2003; Lewis, 2004; Lewis et al., 2005; Moreland & Argote, 2003). Research further indicates that groups with well-developed transactive memory systems outperform those groups in which transactive memory systems are disrupted (Lewis, 2004; Lewis et al., 2005; Michinov & Michinov, 2009; Moreland, 1999). A group's transactive memory system can be disrupted through regrouping. Research that has studied the reassignment of group members to new teams has shown performance and transactive memory to be negatively affected (Lewis et al., 2005; Moreland, 1999). Lewis and colleagues (2005) argued that team performance and transactive memory are negatively affected because the extra demands caused by developing a new transactive memory system interfere with learning and performance.

Therefore, it is evident how the occurrence of intraoperative handoffs could lead to undesired outcomes. When intraoperative handoffs occur during a surgical procedure, it can disrupt the surgical team's transactive memory system (Lewis et al., 2005; Moreland, 1999). At

first glance, intraoperative handoffs may not appear to pose a threat to the safety of patients; however, when an initial staff member leaves the operating room as a result of a handoff, that initial staff member takes with him or her a fraction of the group's memory. As implied previously, each member of the surgical team serves as a memory aid for other members of the team. Therefore, when a new (or relief) staff member replaces the initial staff member as a result of an intraoperative handoff, the initial staff departure disrupts the group memory, and other members of the team have to form a new transactive memory with the new staff member. Although knowledge between the two staff members involved in the handoff may have been effectively shared, the physical appearance of the initial staff member served as a visual external memory aid to others in the team. Consequently, when the original team member departs, whatever knowledge that person represented for the other individual team members also vanishes. Therefore, this could lead to problems in the entire system and team performance (Lewis et al., 2005).

It is evident that intraoperative handoffs occurring during surgical procedures have the potential of having a much more complex impact than just the adequate transfer of verbal knowledge (Christian et al., 2006). The results of the study by Christian and colleagues (2006), discussed previously, which showed that intraoperative handoffs can result in information loss that poses a threat to patient safety could be attributed to a breakdown in transactive memory. Specifically, Christian and colleagues (2006) found that the information loss due to intraoperative handoffs had significant consequences for case progression, which included delays in cases, increased workload, and uncertainty for other team members. Therefore, the mere departure of a team member could affect the group memory and consequently impact the entire surgical team.

1.4.1 The Relationship between the Team Shared Mental Models and Transactive Memory

In this section, it is important to discuss the relationship between another commonly used concept of team performance, namely “team shared mental models” and transactive memory. The concept of team shared mental models (Cannon-Bowers et al., 1993; Guzzo et al., 1996; Kraiger & Wenzel, 1997; Lim and Klien, 2006; Mathieu et al., 2000; McIntyre and Salas, 1995; Mohammed et al., 2001; Rouse and Morris, 1986; Stout & Salas, 1993; Stout et al., 1996; Van den Bossche et al., 2010) has been used to explain the performance of teams in many fields including aviation, military, and engineering (e.g. Carley, 1997; Heffner, Mathieu, & Cannon-Bowers, 1995; Stout, Cannon-Bowers, Salas, & Milanovich, 1999). The concept of team shared mental models suggests that when an individual team member organizes his or her knowledge, tasks, equipment, roles, goals, and abilities in a similar fashion as it relates to the team, mental models are shared (Lim & Klien, 2006; Mohammed et al., 2001; Van den Bossche et al., 2010). This will lead to improved coordination, communication, and other behaviors among the team members (Cannon-Bowers et al., 1993). However, Cannon-Bowers and Salas (1991) stated that “it does little good for team members to share detailed mental models if the information contained in the models are inaccurate” (p. 1418). Cannon-Bowers and Salas (1991) further disclosed that “if the models that team members share are accurate, but are extremely global, team members will not possess the specific knowledge they need to function together effectively” (p.1418). Therefore, sharing of specific and accurate mental models is essential for improved team behaviors.

On the surface, team shared mental models and transactive memory may seem like completely contradictory concepts. However, Mohammed and Dumville (2001) argued that research on both concepts can benefit from each other. Team mental models emphasize

homogeneity of any part of the whole spectrum of knowledge and not only the task-related parts (Mohammed & Dumville, 2001). Conversely, the transactive memory system concept emphasizes heterogeneity in relation to task-related expertise possessed by team members (Mohammed & Dumville, 2001). Heterogeneity and homogeneity of knowledge are both vital for team performance. Heterogeneity and homogeneity, are present in the structural component of the transactive memory system. “Differentiation of individual expertise describes heterogeneity of task-related knowledge while awareness of ‘who knows what’ represents homogeneity of team-related knowledge” (Cannon-Bowers et al., 1993, p. 226). Research on team mental models may assist in measuring structural components of transactive memory systems, especially their homogeneous constituents (Austin, 2003; Lewis, 2003).

Correspondingly, team mental model research can benefit from studies on transactive memory systems by examining methods for measuring heterogeneity (Mohammed & Dumville, 2001). In any case, both perspectives provide a theoretical explanation as to why intraoperative handoffs might increase the occurrence of NREs.

1.5 Why Intraoperative Handoffs might decrease or prevent the occurrence of NREs.

In addition to being a recognized point of vulnerability (Barden et al., 2002), handoffs have the potential to decrease the occurrence of non-routine events. During a handoff, the person who is accepting responsibility has a “fresh perspective and a rested mind” or “fresh set of eyes,” which has been shown to increase the detection of fixation errors (DeKeyser & Woods, 1990; Guerlain et al., 1999; Jones et al., 2005). The person accepting responsibility is able to capture problems that the person transferring the responsibility may have missed due to being mentally and physically fatigued. In these instances, over-worked health care professionals may

be suffering from decision-making fatigue and therefore are not capable of capturing any problems that could lead to the occurrence of non-routine events (Jones et al., 2005).

Several studies have indicated that a problem can be discovered simply as a result of renewed attention to a patient following a handoff (Jones et al., 2005). One can argue that the discovery of these problems during the handoff process can decrease or prevent the occurrence of subsequent non-routine events. Cooper et al.'s (1982) study of anesthesia intraoperative handoffs found that 28 out of the 96 preventable errors studied included "favorable incidents" in which the relief anesthetist discovered an error or the cause of an error generated by the doctor going on break. A study conducted by Wears et al. (2003) revealed an instance in which a person accepting responsibility for a patient questioned the patient's diagnosis given by the person transferring the responsibility. After subsequent discussion, the diagnosis of the person accepting responsibility was shown to be correct. In this instance, the person accepting the responsibility suggested aortic dissection as an alternative diagnosis to the acute stroke that the initial physician diagnosed.

Patterson and Woods' (2001) study of handoffs during the Center STS-76 Space Shuttle mission demonstrates how handoffs can be structured to capture problems that can prevent the possible occurrence of subsequent non-routine events. During 16 observed shift change handoffs between NASA mechanical systems personnel, eight out of 75 questions were asked to detect errors. The remaining questions were to initiate an update or a new topic, to obtain more details, and to confirm understanding (Patterson & Woods, 2001). Although Patterson and Woods' (2001) study is not from the healthcare domain, it does illustrate how the intraoperative handoff process can be modeled to detect minor errors to prevent the occurrence of non-routine events.

While handoffs can negatively affect a surgical team's transactive memory and possibly increase the occurrence of NREs, a disrupted transactive memory system can prove beneficial to a group and could possibly explain the beneficial effects of handoffs described above. Specifically, a group that is created with prior familiarity can result in a poorly developed transactive memory system (Lewis, 2004). In this case, removing a member from the group (disrupting the group's transactive memory system) and introducing a new member will force the group to form a new transactive memory (i.e., redistributing expertise). In the process of forming a new transactive memory, the person accepting responsibility may detect problems or errors while trying to understand each member's role and expertise within the group. Therefore, the newly formed transactive memory system could possibly increase the team's performance and perhaps decrease the occurrence of NREs following a handoff.

Intraoperative handoffs can create mutual understanding and simultaneously repair breaks in understanding or coordination within the team. Handoffs can ensure that information that may become relevant at some later stage of care is preserved for use. Consequently, in some instances, handoffs might decrease or prevent the occurrence of NREs.

1.6 Current Handoff Recommendations

There is a paucity of research on the impact that the transfer of responsibilities (handoffs) in the operating room (OR) might have on surgical care and/or whether there are unique aspects of intraoperative patient handoffs that might prevent the Joint Commission's recommendations for conducting handoffs from being sufficient or even applicable. The Joint Commission (2006) has required organizations to implement a standardized approach to "handoff" communication, including an opportunity to ask and respond to questions. The rationale for the standardization

requirement is to ensure that the information communicated during a handoff is accurate and therefore more capable of meeting the patient safety goals (Cohen & Hilligoss, 2010; The Joint Commission, 2008). The Joint Commission (2008) disclosed that the primary objective of a “handoff” is to provide accurate information about a patient’s care, treatment, services, current condition, and any recent or anticipated changes (Arora et al., 2005; Arora et al., 2008; Bost et al., 2010; Dunn et al., 2008; Klaber et al., 2009; Leora et al., 2006; Patterson, 2008; Sharit et al., 2005; Solet et al., 2005; Talbot and Bleetman, 2007). However, a standardized approach to handoffs may not yield the results that the Joint Commission specifies in its rationale, especially in the case of intraoperative handoffs, where little is known about how intraoperative handoffs impact patient care. Enforcing a standardized approach to handoffs may not be appropriate considering that there are various types of handoffs within the healthcare domain that may require slightly different approaches (Cohen & Hilligoss, 2010).

In adhering to the Joint Commission’s requirements, it has been recommended that healthcare organizations use the SBAR (Situation—Background—Assessment—Recommendation) technique or several other standard handoff techniques to assist with handoffs (AORN, 2008; Arora et al., 2006; Dracup et al., 2008; Haig et al., 2006; Mistry et al., 2008; Patterson et al., 2004; Philibert, 2009). In addition to those recommended techniques, information technology has been integrated to assist in improving the handoff interactions (Jacques et al., 2006; Patterson et al., 2008; Soto et al., 2006; Webster et al., 2006; Wong et al., 2007). These suggested handoff techniques were created to provide frameworks for communication between members of the healthcare team. A few of the suggested techniques provide formal documentation for recording the content of handoffs for future use. Again, given that little is known about intraoperative handoffs during the surgical care process, it is unclear

whether the Joint Commission's guidelines and recommendations for standardizing handoffs will be sufficient to support intraoperative handoffs during complex surgical procedures (Brandwijk et al., 2003; Perry et al., 2008). One possible problematic issue with the Joint Commission's guidelines is that it advocates for standardization of handoffs in general, and this may not be the appropriate method for solving intraoperative handoff issues. As previously indicated, intraoperative handoffs can disrupt the transactive memory system, and one must understand the implications for the surgical care process. Clearly, more research is needed.

1.7 Purpose of the Present Study

While many studies have been conducted to examine non-routine events during surgery, few studies have been conducted to determine the role that intraoperative handoffs play in this process. Those studies that do exist have varied in their research approaches, have not always used prospective methods, and have not used a systems approach to examine both the negative and positive impact that intraoperative handoffs can have on NREs. The fact that so little is known about the characteristics of intraoperative handoffs makes it difficult to design a method for improving the process. Therefore, the purpose of this study is to prospectively evaluate and understand the intraoperative patient handoff process during cardiac surgical care.

Cardiac surgery was chosen because this type of surgery is usually long (4 to 5 hours) and, therefore, more likely to involve intraoperative handoffs and have multiple personnel engaged in those handoffs and an increased number of NREs as indicated in previous studies (Blocker et al., 2010; Duff et al., 2010; Hendrickson et al., 2010; Scharaagen et al., 2011; Wiegmann et al., 2007; Wiegmann et al., 2010).

The following are the specific aims of this study:

1. Specific Aim #1: *To identify the characteristics of intraoperative handoffs during cardiac surgeries.*
2. Specific Aim #2: *To identify the characteristics of non-routine events during cardiac surgeries.*
3. Specific Aim #3: *To describe how the characteristics of the intraoperative handoffs relate to non-routine events and safety compromising consequences.*

To address the first aim, the researcher performed prospective observations of cardiac surgical cases to answer several fundamental questions regarding intraoperative handoffs. These include:

- a) How often do intraoperative handoffs occur per case?
- b) When do intraoperative handoffs occur (what stage of the operation)?
- c) How long do intraoperative handoffs last?
- d) Who is involved in the intraoperative handoff?
- e) What is the interval between initial and return handoffs when the team member who left comes back to the OR?
- f) What is the immediate impact (disruptiveness) of the handoff process on other members of the surgical team?

To address the second aim, prospective observations were utilized to identify the occurrence of non-routine events using a tablet PC data collection tool designed around the SEIPS model. The SEIPS model was chosen as the framework for this study because it has been shown to be effective in other areas of healthcare, that the model allows one to view a phenomenon, such as an intraoperative handoff, from a systematic approach (Alvarado et al., 2004; Carayon et al., 2004; Carayon et al., 2005; Carayon et al., 2006a; Carayon et al., 2006b; Hundt, 2003; Hundt, 2004; Sainfort et al., 2001). The SEIPS model compels one to understand

that intraoperative handoffs are impacted by multiple elements within the system and not just from an individual (communication) perspective (Arora et al., 2005; Carayon et al., 2006a).

Specifically, the data collection tool facilitated the identification of multiple types of non-routine events associated with (a) technical factors (technical skills issue); (b) environmental factors (case-irrelevant conversations, pagers/phones, noises/alarms/music); (c) technological factors (equipment malfunction/not ready, instruments/devices not at table); (d) training/procedural issues (unexpected patient issues, training difficulty performing procedure); (e) teamwork failures (miscommunication/coordination) and (f) other (not previously specified).

With this approach, one can analyze non-routine events on a broader scale to see how each system element lends itself to failure and how each system element is impacted by handoffs.

The data were used to answer several fundamental questions regarding non-routine events. These include:

- a) How often do non-routine events occur per case?
- b) When do non-routine events occur (what stage of operation)?
- c) From a systems (SEIPS) perspective, what are the types of NREs that occur and which occur most often?
- d) What is the impact (disruptiveness) of non-routine events on the surgical team or patient?

To address the third aim regarding the relationship between intraoperative handoffs and the occurrence of NREs, particularly NREs that have safety compromising consequences, qualitative analyses were performed. While the specifics regarding these analytic methods will be described in more detail in the following sections, some questions to be addressed include:

- a) Do intraoperative handoffs tend to lead to any specific type of NRE that contributes to safety-compromising consequences?
- b) Are there instances where intraoperative handoffs have a positive impact on NREs (facilitated detection or management of an NRE)?

1.8 Significance of the Study

This research is of significance to the domain of human factors, healthcare, and handoffs as it extends the knowledge base that currently exists in these areas of study. Intraoperative handoffs are an area of transitions that have not been extensively studied like preoperative and postoperative handoffs (Cohen & Hilligoss, 2010). This study posits that intraoperative handoffs could pose vulnerability and benefit to patients' safety similar to preoperative and postoperative handoffs. While intraoperative handoffs were among the first to be published in the literature (Cooper et al., 1982), much of the current handoff literature focuses instead on preoperative and postoperative handoffs. The implications of the findings of this study will offer new knowledge about the process of intraoperative handoffs during cardiac surgery. Consequently, results from this study will assist us with developing methodologies for effectively studying intraoperative handoffs in order to implement compatible interventions. It is anticipated that the results will eventually have implications for improving intraoperative handoffs during other types of surgeries as well as other dynamic healthcare team environments where handoffs occur that could disrupt team functioning and patient care.

Chapter 2: Methodology

As previously indicated, this study on intraoperative handoffs is part of a larger study to improve cardiac surgical care. The research methodology includes observations using the validated Tablet-PC based OR Data Collection Tool (Blocker et al., 2010). The observations identified non-routine events and intraoperative handoffs in terms of their frequency, timing (phase of the operation), duration, impact or disruptiveness on the surgical team, and other descriptions of the event by the observers. This section discusses the methodologies used in this study. This section will discuss the researcher's philosophical stance, research quality assurance, the study setting and participants, the data collection tool, the observations procedure and data analysis strategy.

2.1 Philosophical Stance

The philosophical worldview proposed in this study is pragmatism. Pragmatism derives from the work of Charles Sanders Peirce, William James, and John Dewey (Creswell, 2009). Pragmatists connect the choice of approach directly to the purpose of and the nature of the research questions posed (Creswell, 2003; Creswell, 2007). Research is often multi-purpose, and a "what works" tactic allows the researcher to address questions that do not sit comfortably within a wholly quantitative or qualitative approach to design and methodology (Creswell, 2003, Creswell, 2007). Therefore, "pragmatism opens the door to multiple methods, different assumptions, as well as different forms of data collection and analysis" (Creswell, 2009, p. 11). For the present study on intraoperative handoffs and their relationship to other non-routine events, an inductive approach to data collection and analysis was implemented. Given that the

present research study is a new approach studying intraoperative handoffs, an inductive, exploratory approach to this research is reasonable.

2.2 Research Quality Assurance

To ensure the quality of the data, the member checking strategy was used. Member checking is the process of presenting findings, interpretations, and conclusions to the participants for their views on the credibility of the findings (Creswell, 2007). Member checking is used to ensure research rigor by assessing the internal validity of the research project. The researcher presented findings, interpretations, and conclusions to members at each participating medical center: the University of Wisconsin Hospital and Clinic and Marshfield Clinic and St. Joseph's Hospital. The member checking process included a registered nurse and a surgeon from both medical centers. Each of the clinicians received a condensed summary of the research findings and was asked to provide the researcher with feedback. The feedback provided by the clinicians was positive, and therefore the researcher concluded that the research findings are representative of each respective medical center and that the data were being interpreted correctly (Creswell, 2007; Devers, 1999). In addition to member checking from the previously mentioned clinicians, a surgeon who was unaffiliated with this study and who has background in human factors and experience in identifying NREs viewed the cases identified in the qualitative analysis for clinical relevance.

In addition to member checking, analyst triangulation and triangulation of sources was used to ensure that this empirical study would represent the highest quality possible (Denzin, 1987; Patton, 1999). In regard to analyst triangulation, multiple observers were used to collect the data. Considering that both a public and private hospital participated in the study, triangulation of sources (Patton, 1999) will determine the consistency between the two different

data sources. Table 1 displays additional strategies that were used to ensure that this empirical study was credible and valid.

TABLE 1: THE STRATEGIES TO ENSURE QUALITY RESEARCH

Criteria (Devers, 1999)	Strategies for proposed study
Credibility/Internal Validity	<ul style="list-style-type: none"> • Dissertator is knowledgeable on the topic on handoffs and NREs in hospitals (Blocker et al., 2010) • Dissertator kept a research journal to report his thoughts, assumptions, biases, and actions (Carmines & Zeller, 1979; Devers, 1999; Malterud, 2001; Mays & Pope, 2000; Sandelowski, 1986)
Transferability/External Validity	<ul style="list-style-type: none"> • Two different surgical departments (different hospital) have been selected (Malterud, 2001; Mays & Pope, 2000) • Detailed descriptions of the hospitals have been recorded (Creswell & Miller, 2000; Devers, 1999)
Dependability/Reliability	<ul style="list-style-type: none"> • Data Collection Tool inter-rater reliability at 87% (Blocker et al., 2010) • Debriefing of team members after each case (Carmines & Zeller, 1979; Creswell, 2003) • Team members added notes to express thoughts and actions during observation (Carmines & Zeller, 1979; Creswell, 2003) • Dissertator kept a journal to report his thoughts, assumptions, biases, and actions (Devers, 1999; Malterud, 2001; Mays & Pope, 2000)
Confirmability/Objectivity	<ul style="list-style-type: none"> • Data skeptically reviewed by Advisor, Dr. Wiegmann and other committee members (Devers, 1999) • Dissertator kept a research journal to report his thoughts, assumptions, biases, and actions (Devers, 1999; Malterud, 2001; Mays & Pope, 2000)

2.3 Study Setting and Participants

Participants in the study were members of a cardiac surgical team that performed normal activities in the OR during observation periods at a large academic medical hospital (the University of Wisconsin Hospital and Clinic) and a private hospital (St. Joseph's Hospital associated with Marshfield Clinic). The cardiac surgical team typically includes the surgeon, resident, surgical tech (or scrub technician), anesthesiologist(s), perfusionist(s), registered nurse

(RNs), and staff members in training. In this paper, the sterile surgical team, which is considered a subset of the cardiac surgical team, included the surgeon, resident, surgical assistant/ technician (or scrub technician) and a second surgeon. The non-sterile surgical team, a second subset of the cardiac surgical team, included the anesthesiologist(s), perfusionist(s), registered nurses (RNs) and other staff members in training. There were typically 10—14 people in the room who contributed to the cardiac surgical procedure. The University of Wisconsin Hospital and Clinic is a 493-bed facility in Madison, Wisconsin. There are more than 1, 200 University of Wisconsin Hospital and Clinic physicians and 85 outpatient clinics. The University of Wisconsin Hospital and Clinic offers six intensive care units (trauma and life support, pediatric, cardiac, cardiothoracic, burn, and neurosurgery) with 83 beds. The Marshfield Clinic's St. Joseph's Hospital is a 504-bed, tertiary care institution in Marshfield, Wisconsin; it is one of the largest private, multispecialty group practices in the United States. There are more than 775 physicians in 80 medical specialties and subspecialties located in 52 locations throughout Wisconsin.

Prior to the observations, the principal investigator (PI) and research team met with the surgeons and staff at each hospital to discuss the research objective in detail and also build rapport with the healthcare professionals. At the meeting, a presentation was given about the research, the data collection tool was explained, and an information sheet (see Appendix B) was provided to each surgical staff. The team also discussed practical needs and logistics, such as cardiac surgery schedule and times, room numbers, hospital identification cards, and wearing scrubs. Gaining the acceptance of the physicians and staff was essential to the success of the present study (Neuman, 2000).

The research staff observed for the duration of a cardiac surgical case on multiple occasions over a 6-month period. At each hospital, surgical personnel often rotated among different teams; therefore, many of the staff members were observed on multiple occasions.

Convenience sampling was used to select the hospitals and the cardiac surgical cases to observe (Malterud, 2001). The researchers simply determined which case to observe based on the researchers' availability to do observations and whether or not the patients agreed to allow the observers to observe their cardiac surgical procedure.

No personal information regarding patient or surgical team was collected. Therefore, the Institutional Review Board (IRB) agreed to waive the requirement of written informed consent by both patients and surgical staff (see Appendix B). However, patients and surgical teams were informed that the observer would be monitoring the case for the purpose of understanding surgical team interactions and were given the ability to opt out of the study. If the patients or surgical staff opted out of the study, that particular case was not observed. There was only one instance in which a surgical staff member (anesthesiologist) opted out of the study and the observation team had to abandon the case. In regard to the patients, the surgical staff at each hospital only provided us with scheduled cases where patients had agreed to participate.

2.4 Data Collection Tool

As stated previously, a tablet-PC data collection tool (see Appendix A) was designed based on the paper prototype described elsewhere (Henrickson et al., 2010). Specifically, the tool helps to capture the onset/offset of events that impact surgical flow, the nature/type of event, a description of the event, and the magnitude of the disruption and/or impact of the event on surgical performance. The tool also includes an "Event History" tab where observers can edit entries as needed and a "Case Detail" tab where observers can input the type of surgical

procedure being performed and any delays in start time of the procedure. There was also a data entry field that allowed for observers to indicate when intraoperative handoffs occurred.

Using the PC-based tool, observed events were time-stamped and categorized by observers in real time according to a framework derived from the SEIPS model: (a) type of event (Table 2); (b) the potential and/or actual impact of the event on a scale from 1 to 6 (Table 3); (c) the surgical team member affected by the event; (d) the description of the event; (e) the location of the observer; (f) the phase in the procedure; and (g) whether the event was purposeful in relation to the OR, purposeful in relation to the patient, or not purposeful at all. The type of event was further categorized according to (1) technical factors (technical skills issue); (2) environmental factors (case-irrelevant conversations, pagers/phones, noises/alarms/music); (3) technology instruments (equipment malfunction/not ready, instruments/devices not at table); (4) training procedures (unexpected patient issues, training difficulty performing procedure); (5) teamwork (miscommunication/coordination); (6) handoff (observed break); and (7) other (not specified). The observers were allowed to input notes in the data collection tool during the observation to record issues that occurred during the surgical procedure. These issues were discussed during debriefing. The issues included technical problems with the data collection tool, additional case details that could not be captured elsewhere on the tool, event classification difficulty, and event timing issues.

The categorization of the NREs and the impact levels were derived from previous research (Elbardissi et al., 2007; Hendrickson et al., 2010; Weigmann et al., 2007). The categorization of the NREs (or surgical flow disruptions) and the impact levels and definitions were based on a preliminary observation conducted during 12 cardiovascular surgery cases (Elbardissi et al., 2007; Weigmann et al., 2007). The data collection tool form was used in the

operating room during two surgical procedures and the two observers constantly reevaluated the form for usability, adequacy and clarity in capturing NREs (or surgical flow disruptions) (Hendrickson et al., 2010). The two raters involved in this study reevaluated the tool during calibration session in order to properly define the categories and improve the tool's reliability. There were a total of 11 calibration sessions through the tool design process. There was a calibration session after each surgery which resulted in "specific tool definitions and behavioral makers being added to the definitions; however, no major categories were changed from the original version of the tool" (Hendrickson et al., 2010, p. 354). This iterative design process took one month to complete.

TABLE 2: EVENT CATEGORIZATION (BLOCKER ET AL., 2010; HENDRICKSON ET AL., 2010)

Type of Events	Definition	Specific event categorization
Technical factors	Any skill-based or decision (thinking) error, including poorly executed tasks, misinterpretation of relevant information, and omitted steps	<ul style="list-style-type: none"> • Technical skills issues
Environmental factors	Any disruption affecting the auditory or visual status of the operating room and not directly relevant to the treatment of the patient	<ul style="list-style-type: none"> • Case-irrelevant conversations • Pagers/phone • Noises/alarms/music
Technology-Instruments	Any equipment problem hindering the smooth progression of the surgical procedure	<ul style="list-style-type: none"> • Equipment malfunction/Not ready • Instruments/devices not at table
Training-Procedures	Patient-specific issues resulting in disruptions; training is included due to unfamiliarity of how to perform a task on a particular patient	<ul style="list-style-type: none"> • Unexpected patient issues • Training difficulty performing procedure
Teamwork	Any breach or lapse in team cooperativeness, cohesion, and/or familiarity negatively affecting surgical flow	<ul style="list-style-type: none"> • Miscommunication/coordination
Handoff	Any intraoperative handoff where a staff member left the room.	<ul style="list-style-type: none"> • Observed break • Shift-changes
Other	Any disruption not falling into one of the above categories	<ul style="list-style-type: none"> • Not specified (e.g. visitor)

TABLE 3: EVENT IMPACT CLASSIFICATION (BLOCKER ET AL., 2010; HENDRICKSON ET AL., 2010)

Potential/Actual Impact of Event	Definition
No impact/minor disruption (no response)	No acknowledgement of the event occurring despite the disruption
Momentary disruption (acknowledge disruption, no pause in task)	A surgical team member is aware of the disruption, but there is no pause in the flow of the operation.
Momentary distraction (task cessation or change <10 seconds)	Pauses in surgical flow of the operation for <10 seconds as a result of the surgical flow disruption
Primary task interrupted (task cessation or change > 10 seconds)	Pauses in surgical flow of the operation for >10 seconds as a result of the surgical flow disruption
Surgical flow disrupted (secondary task engaged)	A surgical staff member(s) must pause the task and engage in a secondary activity that impedes the progress of the original task and disruption the surgical flow.
Repeated tasks	The surgical task must be repeated, halting the rest of the procedure until this task is completely successfully

Multiple observers were used to code selected cases to establish reliability in the data collection process; 87% agreement between a pair of observers was reached (see Appendix A; Blocker et al., 2010). The observational team in the University of Wisconsin Hospital and Clinic was composed of a medical student who received training in Human Factors and two Human Factors graduate students who received training in observing medical/surgical teams. The training involved watching previously recorded cardiac surgery procedures and using the data collection tool to identify NREs. The observers would then compare event classification and impact level coding for consistency. Finally, the observers would discuss any inconsistency during the training process.

2.4.1 Additional Data Collected (Organizational Policies)

In an effort to represent all of the elements of the SEIPS model, the researcher asked each hospital to provide information regarding its policies and procedures related to handoffs, breaks or sign-outs during cardiac surgical procedures. Each hospital's Division of Cardiothoracic Surgery provided policies and procedures, if they existed, regarding health personnel handoffs, breaks, or sign-outs during surgical procedures. Only one of the hospitals provided a two-page policy and procedure document regarding breaks. Essentially, there are no specific details in the policy that outlined or mandated when a team member in the operating room was required to

take a break. There were also no details on handoffs in the policy and procedure document. The policy and procedure merely stated that there would be RNs and surgical technicians assigned to work a relief shift to provide lunch and break reliefs as well as provide coverage after 3PM.

2.5 Observations Procedure

The research team was generally notified about the following week's surgical schedule the Friday before the first scheduled surgery. On the morning of the surgery, the observation team (two observers) would arrive at the operating room at least 15 minutes prior to the case start time. The team would introduce themselves to the surgical staff and distribute additional information sheet regarding the study if needed. They then found a location in the OR that did not interfere with the surgical staff work flow. The research team did not actively engage in conversations with the surgical staff during the operation to minimize the possibility of a surgical staff member being distracted. This also ensured that the team carefully captured events that occurred during the procedure.

At each hospital there was a calibration phase and a validation phase. The calibration phase was the stage where the researcher would conduct observations for testing, design improvement, and coding checking. The validation phase was the stage where the researchers conducted observations for research analysis. The researchers conducted observations both in the same location (standing side-by-side) within the OR and apart (in different locations within the OR). The purpose of this was to resolve the consistency of event recording depending on placement in the room. Debriefing after each case ensured the consistency of coding. This helped ensure the credibility of the researcher and the dependability of the research (Devers, 1999; Mays & Pope, 2000; Sandelowski, 1986). As previously stated, an 87% agreement between a pair of observers was reached (Blocker et al., 2010).

Upon completion of the study period, the researchers were able to observe 26 cases at the University of Wisconsin Hospital and Clinic and 10 cases at Marshfield Clinic and St. Joseph's Hospital. The observations at the University of Wisconsin Hospital and Clinic were conducted in 2009. The observations at Marshfield Clinic and St. Joseph's Hospital were conducted in 2010. The observation period spanned 6 months, and the cardiac surgical cases lasted roughly five hours each (Blocker et al., 2010; Henrickson et al., 2010). Observations were conducted in multiple operating rooms within the two hospitals and across multiple surgical teams. The type of cardiac surgical procedures observed varied, but included procedures such as Coronary Artery Bypass Graft (CABG), Mitral Valve Repair (MVR), and Aortic Valve Replacement (AVR).

2.6 Overview of Data Analysis Strategy

As previously mentioned, both qualitative and quantitative methods were employed. Specifically, descriptive statistics were primarily used to analyze the characteristics of intraoperative handoffs (Research Question #1: *What are the characteristics of intraoperative handoffs during cardiac surgeries?*) and the characteristics of non-routine events (Research Question #2: *What are the characteristics of non-routine events that occur during cardiac surgery?*). However, to answer Research Question #3 (*How do the characteristics of the intraoperative handoffs relate to other non-routine events?*), a qualitative method was utilized. The qualitative data analysis, cross-case analysis, was conducted to analyze a smaller set of handoffs as they relate to (positive or negative) non-routine events. The following sections provide a more detailed description of the cross-case analysis. Please note that in discussing the data from this study; the use of the word 'case' refers to the entire 'surgical case'. Surgical case is defined as the observation period—the time the patient enter the room until the time the patient left the room.

2.6.1 Qualitative Data Analysis: Cross-Case Analysis

There are many qualitative research across several disciplines (Baartman et al., 2011; Rodriguez et al., 2010) that employ the cross-case analysis methodology with “the aim of increasing generalizability, and reassuring oneself that the events and processes in one well-described setting are not wholly idiosyncratic” (Miles & Huberman, 1984, p. 151). The researcher’s ability to review several cases will afford him or her with the ability to “establish the range of generality of a finding or explanation, and, at the same time, pin down the conditions under which that finding will occur” (Miles & Huberman, 1984, p. 151). Therefore, the use of cross-case analysis in the present study is warranted, as this analysis provides greater insights into intraoperative handoffs and how they relate to NREs.

There are several methods for cross-case analysis. However, since the present study is rather exploratory in nature, an unordered meta-matrix method is employed. Meta-matrices are master charts assembling descriptive (relevant) data from each of the cases in a standard format (Miles & Huberman, 1984). Essentially, the meta-matrix method combines all the single-case summarizing charts into one massive chart that allows for the data to be easily partitioned and/or clustered. Therefore, an unordered meta-matrix is essentially a massive chart that displays descriptive data about each case without ordering the cases by strength or multitude of the occurrence of some key variable. The unordered meta-matrix affords one the ability to see “what’s there” (Miles & Huberman, 1984).

Succinctly, Miles and Huberman’s (1984) method of cross-case analysis involves meaningfully reducing or reconfiguring the data (data reduction), then organizing the data into different displays such as diagrams or matrices (data display) from which conclusions can be

drawn and verified (conclusion and verification) (Baartman et al., 2011). The results from a cross-case analysis could vary from a unified description across cases (meaning that reinforcement was found across cases) to an emergent of new categories, themes or concepts (Merriam, 1998, p. 195).

There are five steps involved in the Miles and Huberman's (1984) cross-case analysis-unordered meta-matrix method. The steps are described below:

1. The researcher creates the reporting format for each case. This involves comprehensively answering the sub-research questions for each case.
2. The researcher creates a case-level summarizing display and enters the data from the finding in the previous step (1). This requires the researcher to create a matrix or chart template that will be used to input data for each case individually. This template is developed based on the sub-questions.
3. The researcher builds the unordered meta-matrix and enters the data from step (2). In this step, the researcher, in iterations, condenses case-level summaries into brief descriptions.

Miles and Huberman (1984) stated that the next two steps will “depend more on what the data have to say and on the kinds of relationships the analyst is most interested in” (p.155). There are two extensions, “one involving within-category sorting (partitioning) and the other cross-category clustering” (p. 155).

4. Within-category sorting requires the researcher to investigate or scan a single category to identify concerns or patterns across the cases within that category. These findings can be displayed in a summary table.

5. Across-category clustering requires the researcher to investigate or scan multiple categories to identify concerns or patterns across the cases. These findings can be displayed in a summary table.

In the present research, the human factors experts followed the five steps above. The goal was to identify relationships (positive or negative) between intraoperative handoffs and non-routine events that happened several minutes or hours apart during an operation or during a different surgical phase of the procedure. The first step of the cross-case analysis involved the experts answering the following sub-questions individually for each case: (1) What intraoperative handoffs (if any) led to a safety-compromising consequence or conversely prevented a safety compromising consequence from causing harm?; (2) What are these safety-compromising consequences?; (3) What (if any) were the NREs that contributed to the safety-compromising consequences as a result of the intraoperative handoff?; (4) What impact did the intraoperative handoff have on the case as a result?; and (5) What phase of the operation did the intraoperative handoff and safety-compromising consequence occur? Safety-compromising consequences were defined as “an action or inaction that significantly increased the vulnerability of the system and had the potential to lead to an adverse event” (Christian et al., 2006, p. 163). The contributing NREs were defined as “circumstances surrounding the events were examined to identify system factors that appeared to contribute to the event and system factors that appeared to mitigate the impact of the event” (Christian et al., 2006, p.163). In answering the sub-questions, the human factors experts were able to identify and code instances where an intraoperative handoff led to safety-compromising consequences later in the case or intraoperative handoffs that *could have* led to consequences in the current case under different

circumstances (i.e., “close-calls” or “near-misses”) (Christian et al., 2006; Mitchell et al., 2011). The assumption is that an intraoperative handoff could have occurred sometime before not necessary right before the NREs that contributed to safety-compromising consequences. It is plausible that an intraoperative handoff could logically be linked to the consequence, given the circumstances surrounding the intraoperative handoff and consequences. Therefore, in each case, the circumstances surrounding the intraoperative handoff and consequence were examined, and NREs that were a result of the intraoperative handoff and appeared to contribute to the consequence were coded (Christian et al., 2006). The safety-compromising events were confirmed by consulting medical staff—specifically a surgeon.

In the next step, as outlined by Miles and Huberman (1984), each human factors expert placed in the Excel spreadsheet cells answers to the five questions listed above. In this regard, Miles and Huberman (1984) state that researchers should use charts, and the human factors experts used Excel spreadsheets in lieu of developing charts. There were five category titles for each column within the spreadsheet: “handoff/case number,” “safety-compromising consequence,” “contributing factors (NREs),” “impact,” and “handoff phase/consequence phase.” After each human factors expert independently entered his or her data into the Excel spreadsheets, they collaboratively reviewed the cases and examined the instances that they independently identified and coded to make amendments and corrections. If there were any differences between the two experts, they discussed and resolved them by consensus (Carmines & Zeller, 1979; Christian et al., 2006; Devers, 1999; Malterud, 2001; Mays & Pope, 2000; Sandelowski, 1986).

The next step involved creating the unordered meta-matrix and entering the data from each individual case into a massive spread. Since the Excel spreadsheet was used in this study,

creating the meta-matrix did not involve much work. In this step, the researcher alone, and in iterations, condensed each case-level summary into brief descriptions. However, the more in-depth summaries were saved in a separate document to be used, if necessary, in explaining or providing examples about the cases (Miles & Huberman, 1984).

In the final steps (steps 4 and 5), the researcher conducted within-category sorting and across-category clustering analysis. This involved the researcher taking a “quick scan—‘sprint analysis’ down rows and across columns to see what jumps out” (Baartman et al., 2011; Miles & Huberman, 1984; Miles & Huberman, 1994). The researcher verified or revised that first impression through a more careful review, which included going back to the original data sets (i.e., raw data and individual case summaries) (Miles & Huberman, 1984). When emerging conclusions begin to formulate in the researcher’s mind, the researcher made notes explaining the conclusion. However, the researcher would always check those conclusions against written field notes and raw data (Miles & Huberman, 1984). The results chapter will provide details about the four conclusion or themes that emerged from this analysis. However, there were three additional themes that emerged from this research that will not be addressed in this study, but will be discussed in future research. Those themes include: (1) “intraoperative handoff can lead to personnel that are unfamiliar with how to mitigate NREs related to patient factors”; (2) “training-procedures induced by an intraoperative handoff can lead to a delay in the surgical case”; and (3) “multiple intraoperative handoffs with multiple personnel during a surgical case can negatively impact case”.

In addition to analyzing the 22 cases that contained an intraoperative handoff, the two human factors experts independently analyzed the 14 cases that did not contain an intraoperative handoff to identify and code safety-compromising consequences. In each case, the circumstances

surrounding the consequence were also examined to identify NREs that appeared to contribute to the consequence (Christian et al., 2006). In the final step of the coding, the human factors experts collaboratively reviewed the cases and examined the instances they had independently identified, to make amendments and corrections. If there were any differences between the two experts, they discussed and resolved them by consensus (Carmines & Zeller, 1979; Christian et al., 2006; Devers, 1999; Malterud, 2001; Mays & Pope, 2000; Sandelowski, 1986). However, a cross-case analysis was not conducted on these 14 cases, as the Research Question #3 is focused on understanding cases that involve an intraoperative handoff.

2.6.2 Data Coding and Interrater Reliability

After the observations, two human factors experts (as mentioned above) examined the data, and additional codes were created (see Appendix C). The human factors experts entered impact codes into the database previously created by the data collection tool (Blocker et al., 2010). More specifically, a 3-point impact score, ranging from [-1] to [1], was assigned to each observation to reflect whether the intraoperative handoff had a positive [1], negative [-1], or no impact [0] on the natural progression of the case. All safety-compromising consequences were identified and coded based on whether they had the potential to lead to an adverse event and/or caused a halt in the natural progression of the case (potential/actual impact level identified by the observers are described in Table 3). If NREs were deemed by the experts to be causally linked to an intraoperative handoff and its consequence, a “linked-to” data field enabled recording of this relationship (Christian et al., 2006; Miles and Huberman, 1984; Saldana, 2009). The human factors experts determined whether the NREs were linked by examining the circumstance surrounding the intraoperative handoff and the consequence to identify whether the NRE appeared to contribute to the consequence and appeared to occur as a result of the intraoperative

handoff. In addition, the human factors expert determined whether the NREs were linked by examining the circumstance surrounding the intraoperative handoffs and potential consequence to identify if the NRE appeared to mitigate the impact (Christian et al., 2006, p.163). In addition, all of the events (NREs and Intraoperative Handoffs) in the database were labeled with a contributing factors code so that the data could be easily searched. If a handoff contributed to the consequence, it was assigned the code [hcc], and if NREs contributed to the consequence, they were assigned the code [ecc]. However, if the handoff did not contribute to the consequence, it was assigned the code [hncc], and if NREs did not contribute to the consequence, they were assigned the code [encc]. If the handoff prevented a consequence, it was assigned the code [hpc], and if NREs prevented a consequence, they were assigned the code [epc].

In the previous section, the researcher mentioned that the human factors experts coded each case independently and then collaboratively reviewed the cases. Prior to coding all the cases, the human factors experts coded two cases to calibrate their method. The coder agreement on safety-compromising consequences and intraoperative handoffs related to those safety-compromising consequences was perfect; both human factors experts identified the same intraoperative handoffs that were related to safety-compromising consequences (Miles & Huberman, 1984). However, agreement on NREs that contributed to safety-compromising consequences as a result of an intraoperative handoff in the cases was roughly 87%. After the two human factors experts collaboratively reviewed the cases, any differences were discussed and a consensus was reached. Notes were recorded in the database to indicate the rationale for either removing or keeping a code.

Chapter 3: Research Results

This chapter presents the results from this study. As previously mentioned, there are three distinct research questions, and this section will present the result for each question separately. There were also several sub-questions associated with each major research question and these will be addressed in this section as well.

3.1 Research Question #1: What are the characteristics of intraoperative handoffs during cardiac surgery?

There were a total of 90 handoffs identified across 36 surgical cases observed in this study ($M = 2.5$ per case, $SD = 3.28$; range: 0-13). Further review of these handoff events revealed that for some handoffs, the person who was initially relieved by a new staff member actually returned and resumed his/her role (producing another handoff). For other handoffs, however, the person who was initially relieved never returned. Therefore, each handoff was categorized into one of three distinct fields: (1) Initial Handoffs—the person will return, (2) Return Handoff, and (3) Initial Handoff—the person never returned. A breakdown of each type of handoff is presented in Figure 2.

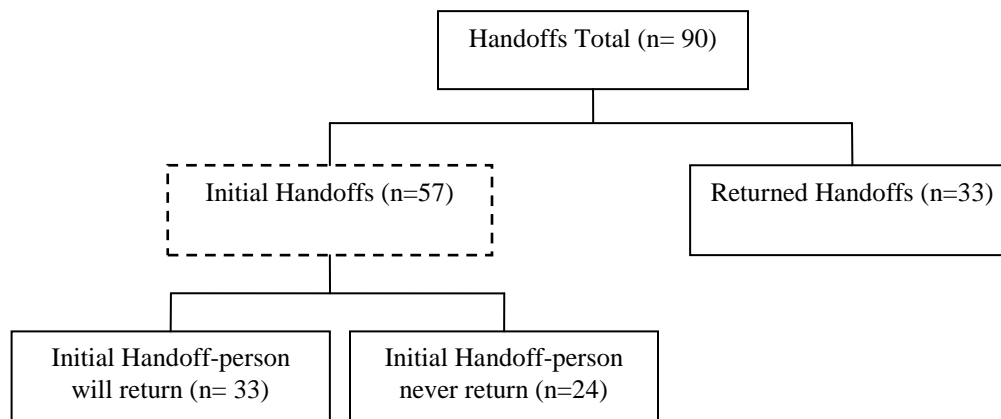


FIGURE 2: NUMBER OF INTRAOPERATIVE HANDOFFS TYPES

Initial Handoffs were handoffs identified, after reading the event descriptions, as the beginning of a handoff cycle. In categorizing the handoffs, the event descriptions would clearly indicate whether the original health personnel had been relieved by relief personnel (i.e., “*Main nurse leaving again and provides updates to relief nurse; explain how to use computer and reviewed the paper work quickly.*”), or whether the relief health personnel had been relieved by the original health personnel (i.e., “*Main Nurse returns and starts to help, no hand-off updates or brief*”). A handoff cycle is indicated based on the analysts matching the initial handoff with the return handoff. “Return handoffs” are therefore those handoffs identified as the ending of a handoff cycle where the original (or initial) surgical staff member returns to the OR to resume his or her responsibility for the patient. “Initial handoffs—person never returned” are those initial handoffs where there was no recorded instance in the data set indicating that the staff member had ever returned to the OR. Multiple analysts were used to code the initial handoffs, return handoffs, and initial handoffs—person never returned (Denzin, 1987; Patton, 1999). The analysts reviewed the entire data set for indications of whether a surgical staff member had returned or not. These reviews included reading through the descriptions of all recorded events (not just those marked as “handoffs” or “other (not specified)”).

Results revealed that of the 90 total intraoperative handoffs, 57 of these were initial handoffs. Of the 57 initial handoffs, roughly 58% involved the initially relieved individual returning to the OR (33 returned handoffs). A total of 24 of the initial handoffs (42%) were handoffs in which the relieved individual never returned. Specifically, the breakdown of handoffs types are: Initial handoff—person returns (n=33), Return handoff (n=33), Initial handoff—person never returns (n=24).

A. How often do surgical team members handoff per case?

There were 36 cases observed, 22 of these included a recorded handoff. As previously indicated, these cases involved various cardiac surgical procedures including procedures such as Coronary Artery Bypass Grafts (CABGs), Mitral Valve Repairs (MVRs), and Aortic Valve Replacements (AVRs). Figure 3 displays the average durations for each phase of the surgical cases, however, the cases lasted roughly 5 hours; and on average, there were 2.5 intraoperative handoffs per case and these handoffs (initial and return) usually occurred during the surgical phases of the operation.

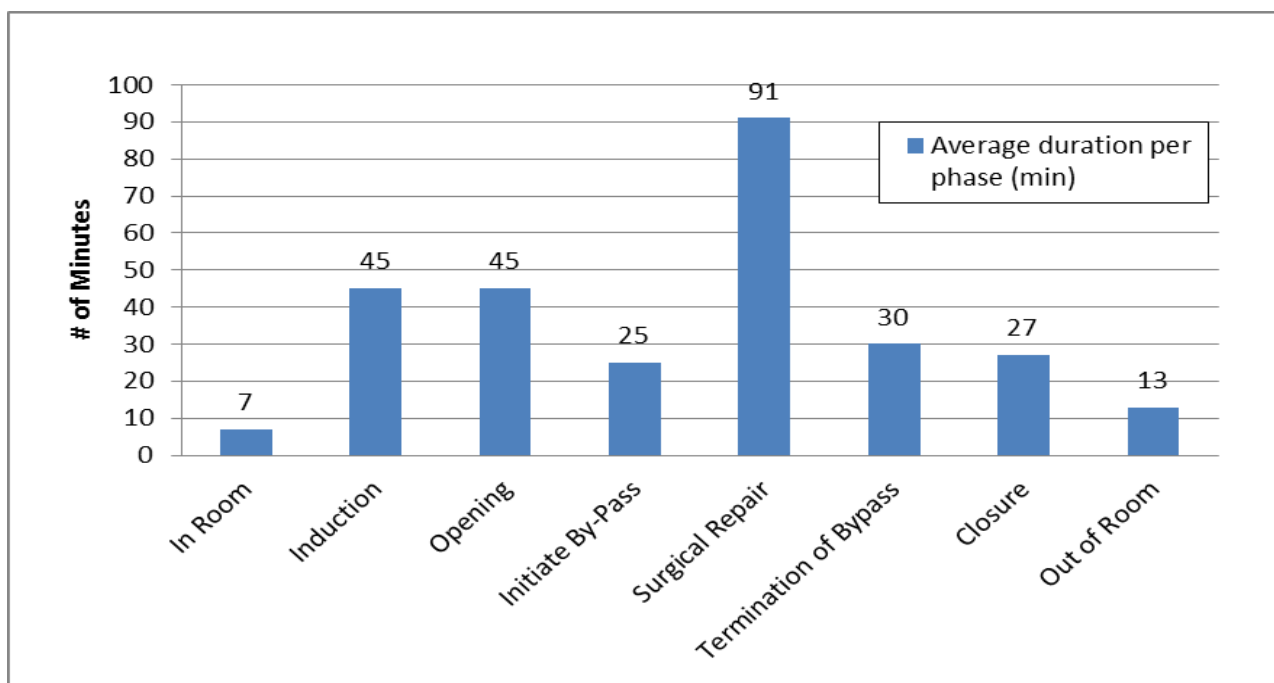


FIGURE 3: AVERAGE DURATION PER PHASE (MINUTES)

B. When do intraoperative handoffs occur?

Figure 4 below indicates the phases of the surgical case in which intraoperative handoffs occurred. Handoffs occurred most often during surgical repair (53.33%), initiation of by-pass

(20.00%), opening (15.56%), closure phase (5.56%), and termination of by-pass (4.44%).

However, Figure 6 shows a high rate of flow disruptions per minute in initiation of by-pass (.72 per min), surgical repair (.52 per min) and opening (.31 per min) phases. Figure 5 indicates the phases where the initial and return handoffs occurred more frequently. The initiation of by-pass and surgical repair phases are when most of the initial handoffs occurred. Of the initial handoffs, 47.37% occurred during the surgical repair phase, and 22.81% occurred during the initiation of by-pass phase. In respect to the return handoffs, 63.64% of the return handoffs occurred in the surgical repair phase, and 15.15% of the return handoffs occurred during the initiation of by-pass phase.

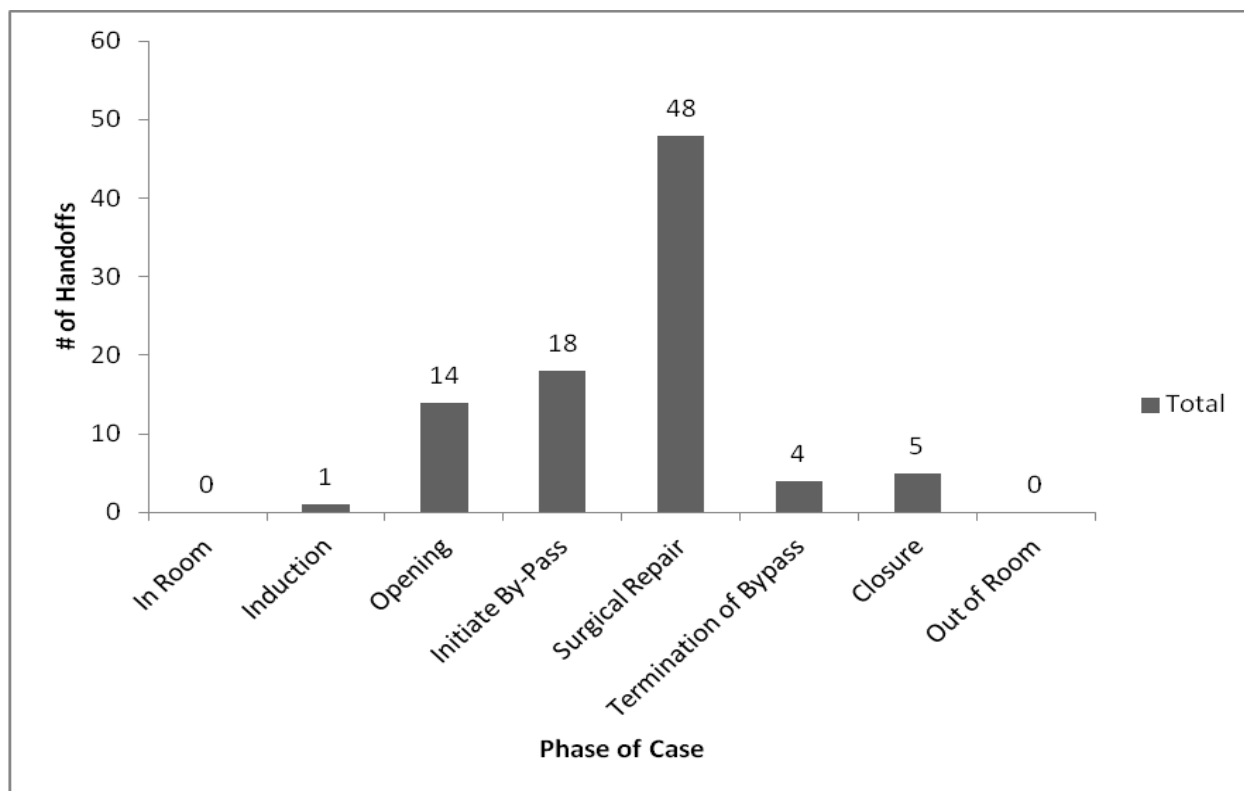


FIGURE 4: HANDOFF FREQUENCY BY PHASE OF CASE

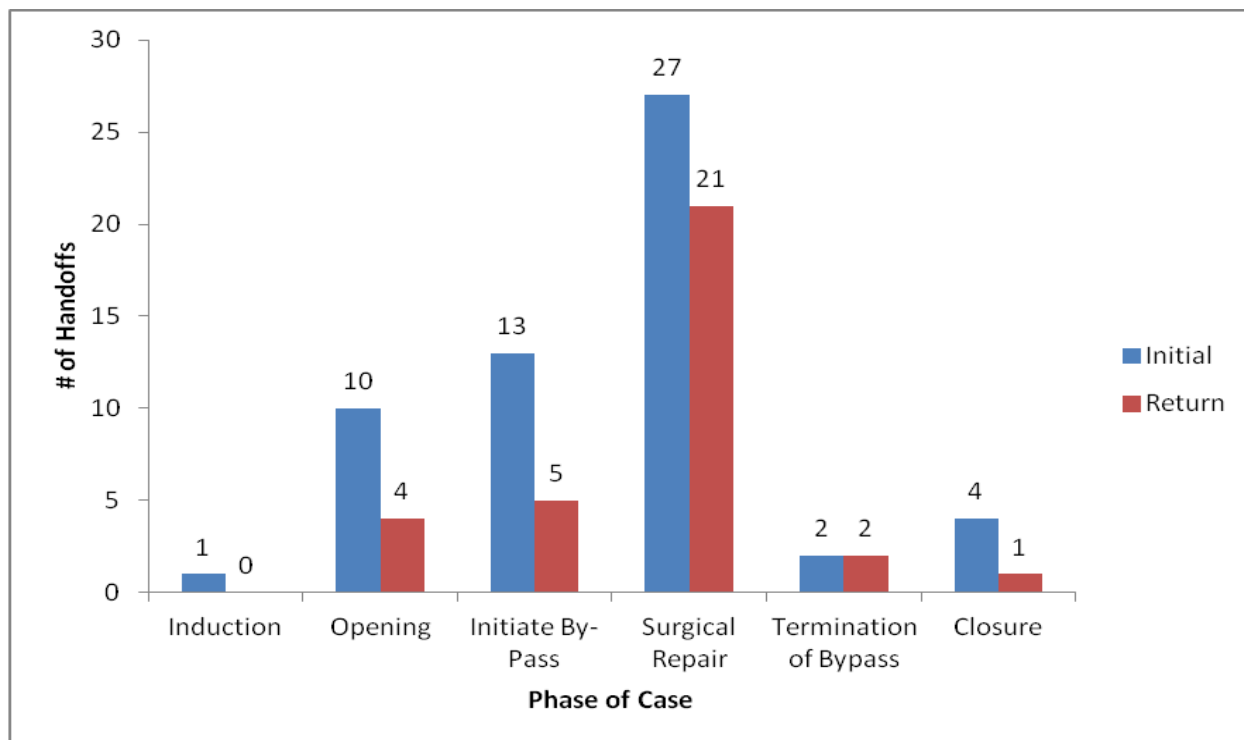


FIGURE 5: INITIAL AND RETURN HANDOFF BY PHASE OF CASE

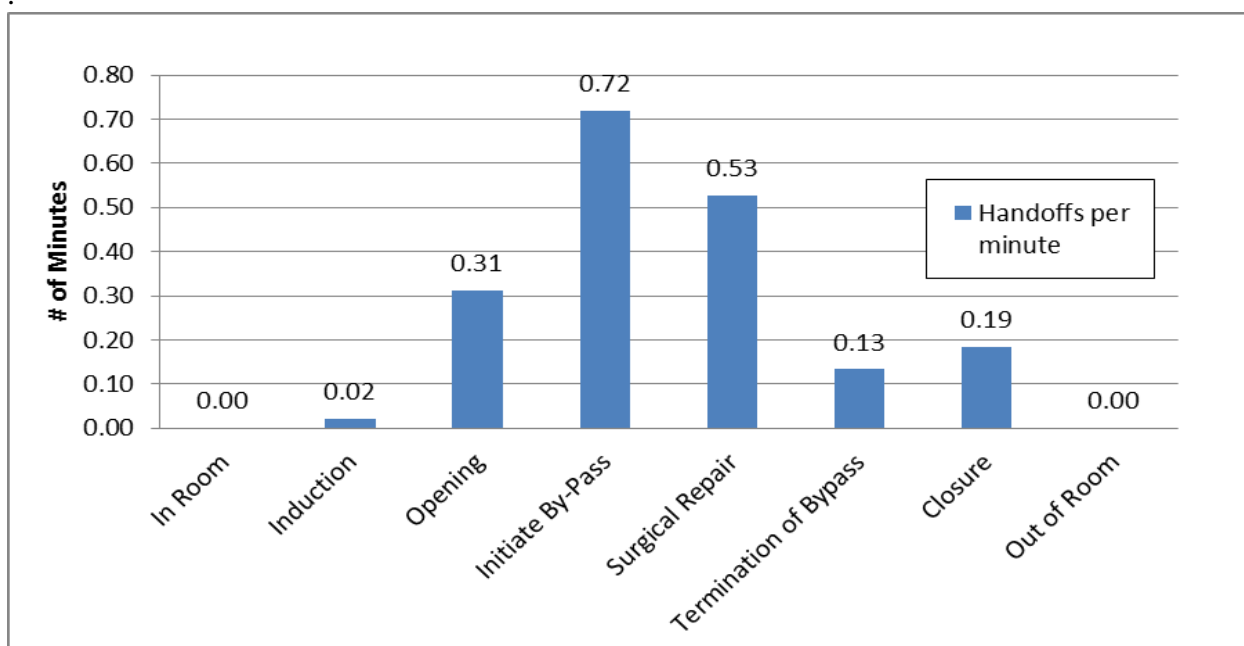


FIGURE 6: HANDOFF RATE PER MINUTE (BY PHASE)

C. How long do intraoperative handoffs last?

The handoff duration was calculated by subtracting the handoff end time from the start time.

Mean intraoperative handoff duration was 1 minutes 42 seconds (SD = 00:01:38 min/sec). The

observer was able to capture the start time and end time of the handoff process between two surgical staff (i.e., the original RN and the relieving RN interaction). The intraoperative handoff durations ranged from a quick 3 seconds to 9 minutes, 30 seconds.

D. Who was involved in the intraoperative handoff?

The nurse (61.11%), surgical tech (26.67%), perfusionist (6.67%), surgeon/resident (4.44%) and anesthesiologist (1.11%) were the staff members more frequently involved in intraoperative handoffs. Table 4 displays the phases of the operation that the surgical staff members were more frequently involved in an intraoperative handoff. Table 4 shows that during the surgical repair phase, the nurse (n = 24) and the surgical tech (n = 17) were more frequently involved in a handoff. In addition, the nurse (n = 16) was more frequently involved in a handoff during the initiation of by-pass phase than any other clinician.

TABLE 4: SURGICAL STAFF INVOLVEMENT BY PHASE

In Room					
Induction					1
Opening	1	4			9
Initiate By-Pass	1		1		16
Surgical Repair	2	17		5	24
Termination of Bypass		2		1	1
Closure		1			4
Out of Room					
	Surgeon/Resident	Surgical Tech	Anesthesiologist	Perfusionist	RN

E. What was the interval between those that left and came back?

There are a total of 33 intraoperative handoff cycles. As previously defined, a handoff cycle is indicated based on the analysts matching the initial handoff with the return handoff. The mean interval between initial handoffs and return handoffs was 35 minutes, 3 seconds (SD = 00:23:32 min/sec). However, the interval between the initial handoffs and return handoffs ranged from 1

minute, 9 seconds to 2 hours, 28 minutes, 20 seconds. Therefore, a handoff interval could be relatively brief or could last almost half the case length.

F. What is the impact of handoff process on the surgical team?

The impact of intraoperative handoffs on the surgical team was measured using the event impact classifications in Table 3. During the surgical procedures the observers rated the immediate impact of the handoff on the surgical team (disruptiveness of the handoff process). The impact intraoperative handoffs had on the surgical team range from no impact (33.33%) to primary task interrupted (14.44%). The impact levels are defined in Table 3. A significant amount of intraoperative handoffs were momentary disruptions (20.00%) and momentary distractions (32.22%), indicating that team members acknowledged the disruption, but there was no pause in flow of the operation; if there were a pause in the flow, it lasted less than 10 seconds. Comparing the intraoperative handoff impact level on the surgical team based on sterile members versus non-sterile surgical members, the data reveal a difference (Figure 7). Non-sterile members (19%) had a higher percentage of intraoperative handoffs where the primary task was interrupted than sterile surgical members (3.57%). In contrast, sterile members were more likely to be only momentarily disrupted by handoff than non-sterile members.

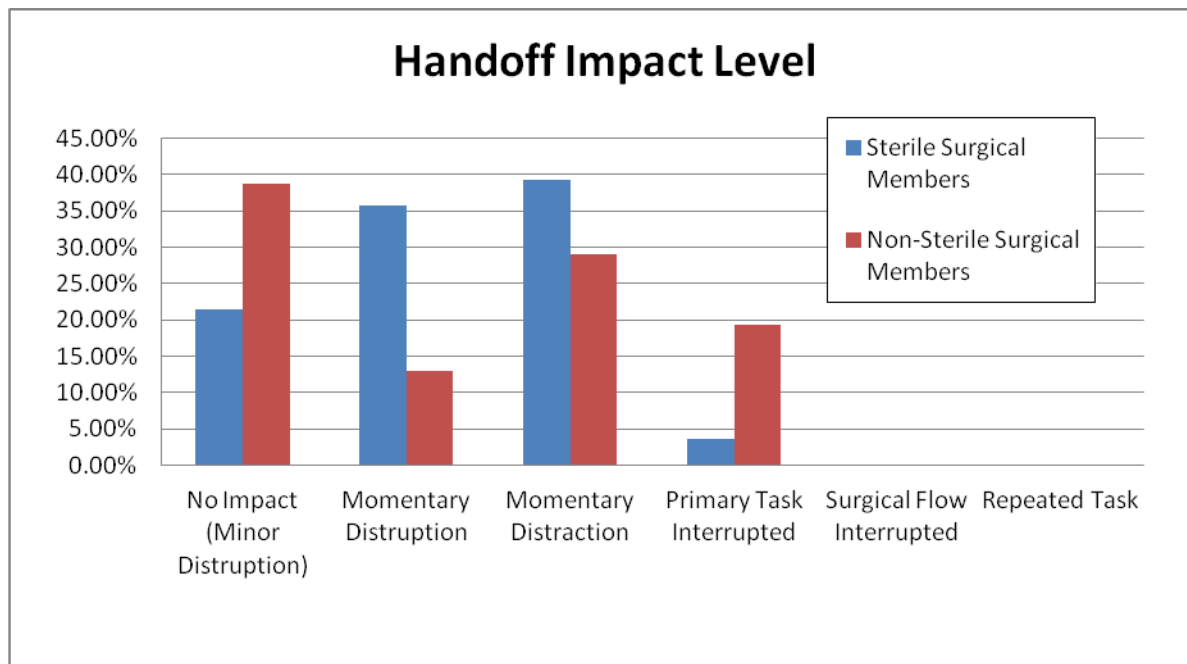


FIGURE 7: INTRAOPERATIVE HANDOFF IMPACT LEVEL (STERILE MEMBERS VS. NON-STERILE MEMBERS)

3.2 Research Question #2: What are the characteristics of non-routine events (NREs) that occur during cardiac surgery?

A. How often do non-routine events occur per case?

Across all observed cardiac surgical cases, on average there were 56.55 non-routine events per case (SD = 29.262; range: 14 –122). The majority of the non-routine events were environment related (52.55%) followed by technology related non-routine events (13.51%). Teamwork breakdowns (10.76%), training interruptions (8.50%), and technical/skill factors (4.32%) were the least prevalent across the cases (Figure 8). However, the other or non-specified related non-routine events accounted for 10.36%. Given that the majority of the non-routine events were environment and technology related, the researcher analyzed those categories to see what the specific non-routine events were. The specific environment related non-routine events were pagers and phones (32.81%); case-irrelevant conversation (15.08%); and noises, alarms, and music (4.67%) (Figure 9). The specific technology related non-routine events were “equipment

malfunction/not ready” (7.66%) and “instruments/devices not at table” (5.84%) (Figure 10).

Table 5 below illustrates NREs captured by the observers.

TABLE 5: NRES CAPTURED BY THE OBSERVERS

Environmental Related Non-Routine Events (NREs)		
	Specific NRE	Example
	Pagers and phones	“Surgeon pager went off circulating nurse goes and grabs it for him”
	Case-irrelevant conversation	Surgeon says to team "kids went to college; won their basketball game"
	Noises, alarms and music	“Extremely loud alarm by perfusionist area. He pressed a button to shut it off.”
Technology-Instruments Non-Routine Events (NREs)		
	Equipment malfunction/not ready	“Nurse had to get new equipment because the current one stopped working”
	Instruments/devices not at table	RN calls out to request supplies

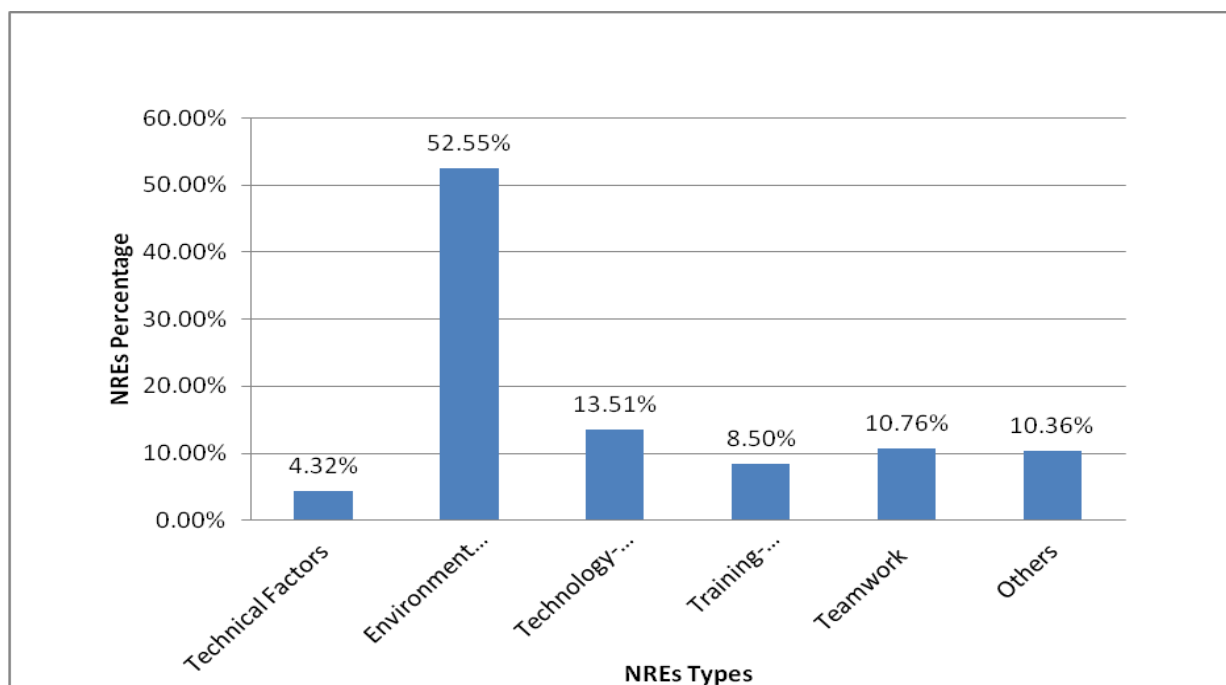


FIGURE 8: NON-ROUTINE EVENTS (NRES) TYPES

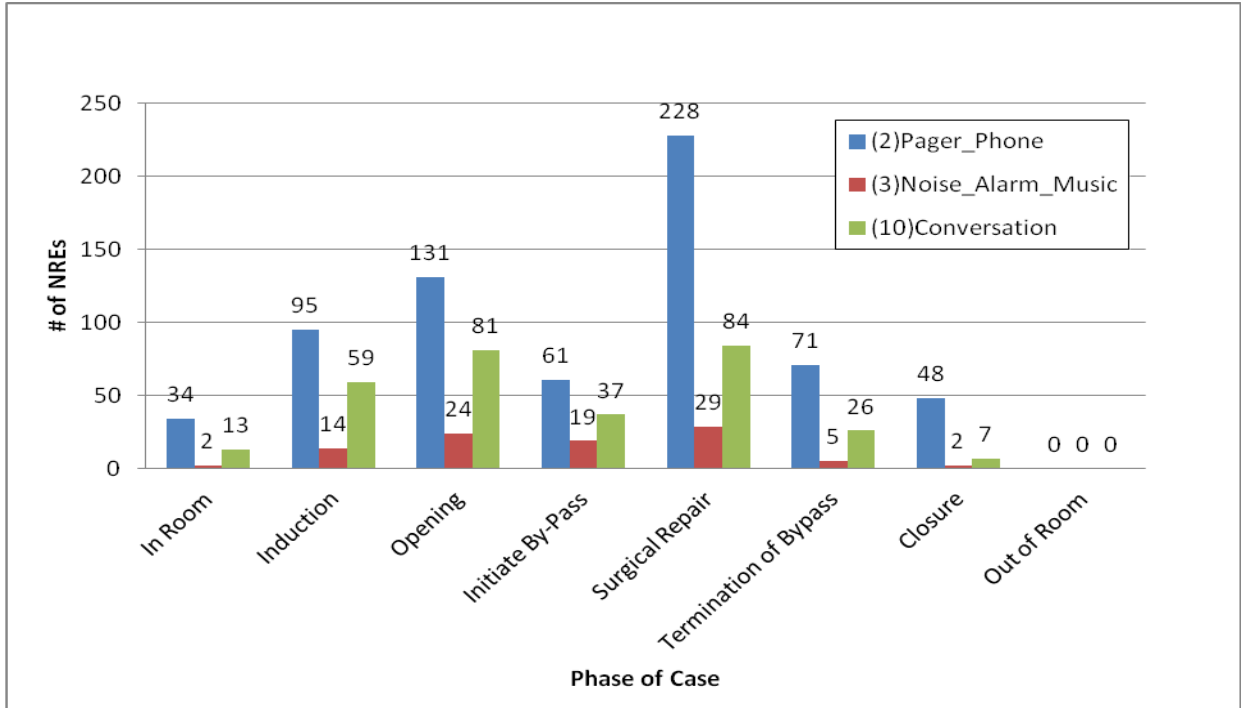


FIGURE 9: NON-ROUTINE EVENTS SPECIFIC ENVIRONMENTAL EVENTS BY PHASE

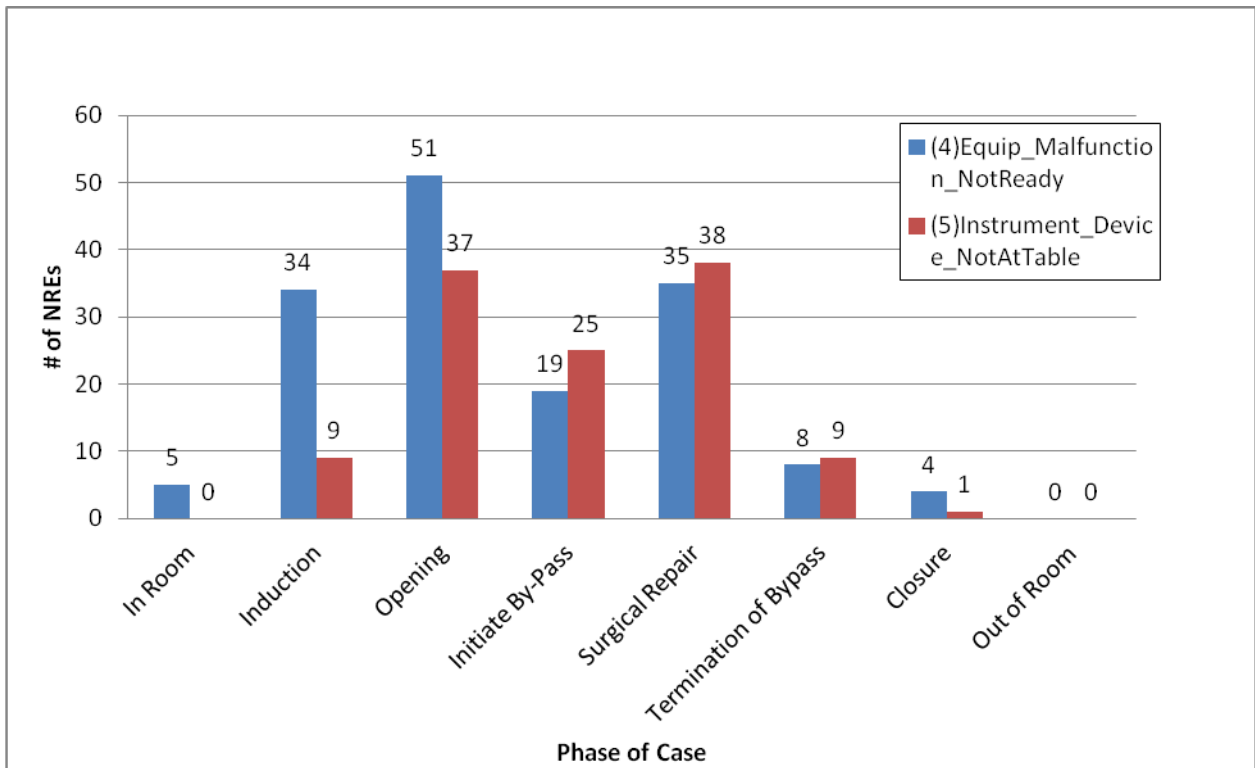


FIGURE 10: NON-ROUTINE EVENTS SPECIFIC TECHNOLOGY EVENTS BY PHASE

B. When do non-routine events occur?

Figure 11 indicates the phases of the surgical case when non-routine events occurred. Non-routine events occurred during all the surgical phases: induction (15.62%), opening (23.77%), initiation of by-pass (12.67%), surgical repair (30.35%), termination of by-pass (9.23%), and closure phase (3.88%). As indicated in Figure 11, the opening and surgical repair phases were the times when most non-routine events occurred. There was a small percentage (4.47%) of non-routine events that occurred when the patient was “in the room” before induction. Given that the majority of NREs identified in the previous sub-research question were environment and technology related, Figure 9 and Figure 10 highlight the phase in which the specific NREs occurred. In regard to the specific environment related NREs, most occurred during the surgical repair phase. The specific technology related NREs occurred mostly during the opening phase and the surgical repair phase.

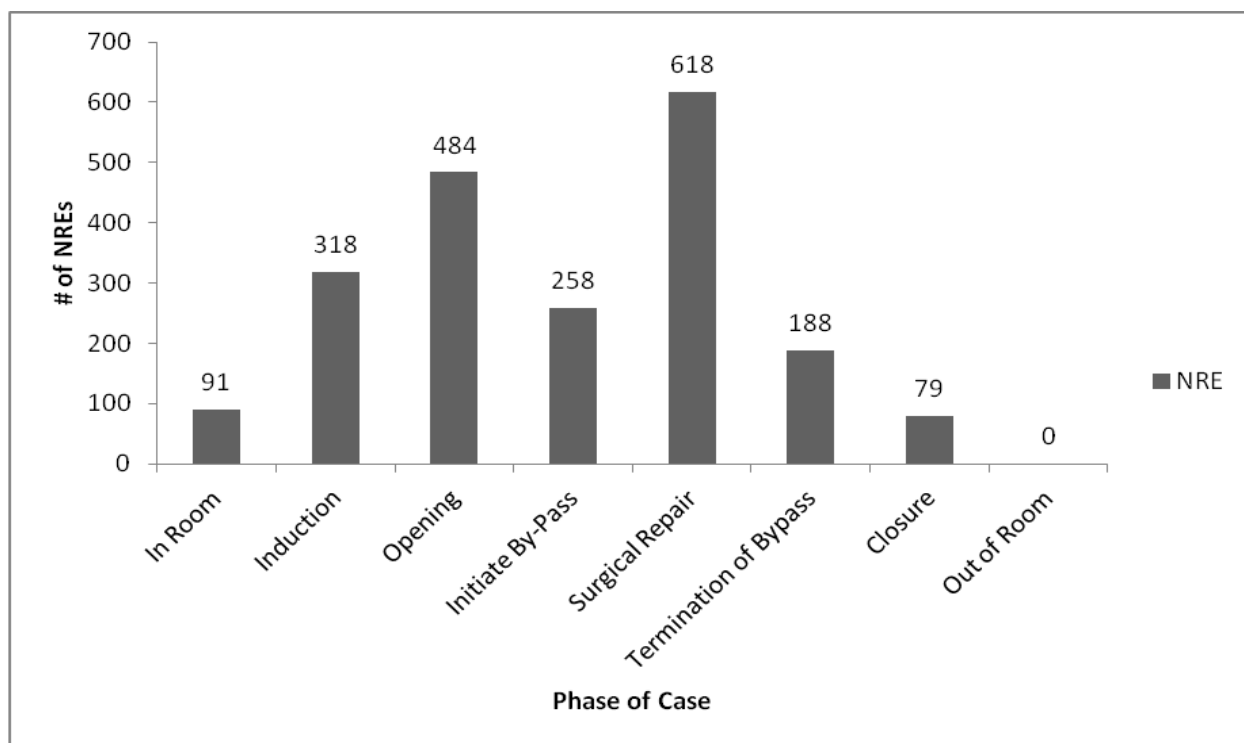


FIGURE 11: NON-ROUTINE EVENTS BY PHASE

C. How long do non-routine events last?

The mean non-routine event duration was 3 minutes, 2 seconds (SD = 00:07:57 min/sec). A non-routine event duration can be as brief as 1 second to as long as 2 hours, 55 minutes, 5 seconds (range 00:00:01—02:55:05). A brief non-routine event was usually environment related (i.e., pagers/phone), and in this instance the non-routine event that lasted the longest was teamwork related (specifically, a miscommunication/coordination event).

D. Who was involved in the non-routine events?

The results (Figure 12) revealed that a large portion (29.81%) of non-routine events involved the nurse. The surgeon/resident (14.05%), anesthesiologist (11.15%), perfusionist (13.46%), and the entire sterile surgical team (14.73%) were also involved in non-routine events, but at a much lower rate than nurses. The surgical tech (6.24%) and the second surgeon/resident (6.93%) were involved in a minimal amount of non-routine events.

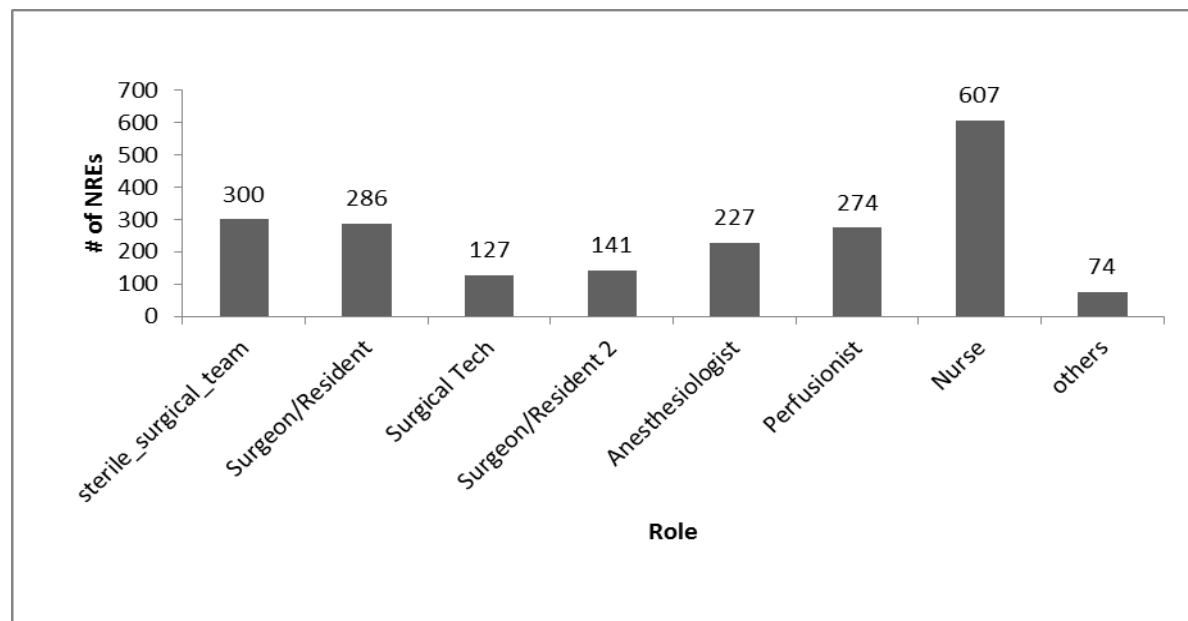


FIGURE 12: NON-ROUTINE EVENTS PERSONS INVOLVED

E. What is the impact of non-routine events on the surgical team?

The impact of non-routine events on the cardiac surgical team range from no impact (22.99%) to tasks being repeated (1.77%) (Figure 13). The majority of non-routine events were considered momentary distractions (27.75%), meaning that there was a pause in the flow of the operation that lasted more than 10 seconds. There was also a significant amount of non-routine events that were momentary disruptions (26.08%). There were a small, but significant percentage of non-routine events that caused the primary task to be interrupted (17.53%) and surgical flow to be interrupted (3.88%). NREs where the surgical flow was interrupted were usually when the equipment would malfunction. For example, observers noted instances where the CO₂ equipment was not working and the balloon malfunctioned. Comparing the NREs' impact level on the surgical team based on sterile members versus the non-sterile surgical members, the data reveal a significant difference. The impact level of NREs on the sterile members was momentary disruption (33.72%) and momentary distraction (27.17%) and on the non-sterile members was momentary disruption (21%) and momentary distraction (28%). Non-sterile members (20%) had a higher percentage of intraoperative handoffs where the primary task was interrupted than did sterile surgical members (14.40%). However, for NRE impact level identified as "surgical flow interrupted," sterile surgical members (8.43%) had a higher percentage than did non-sterile members (1%) (Figure 14).

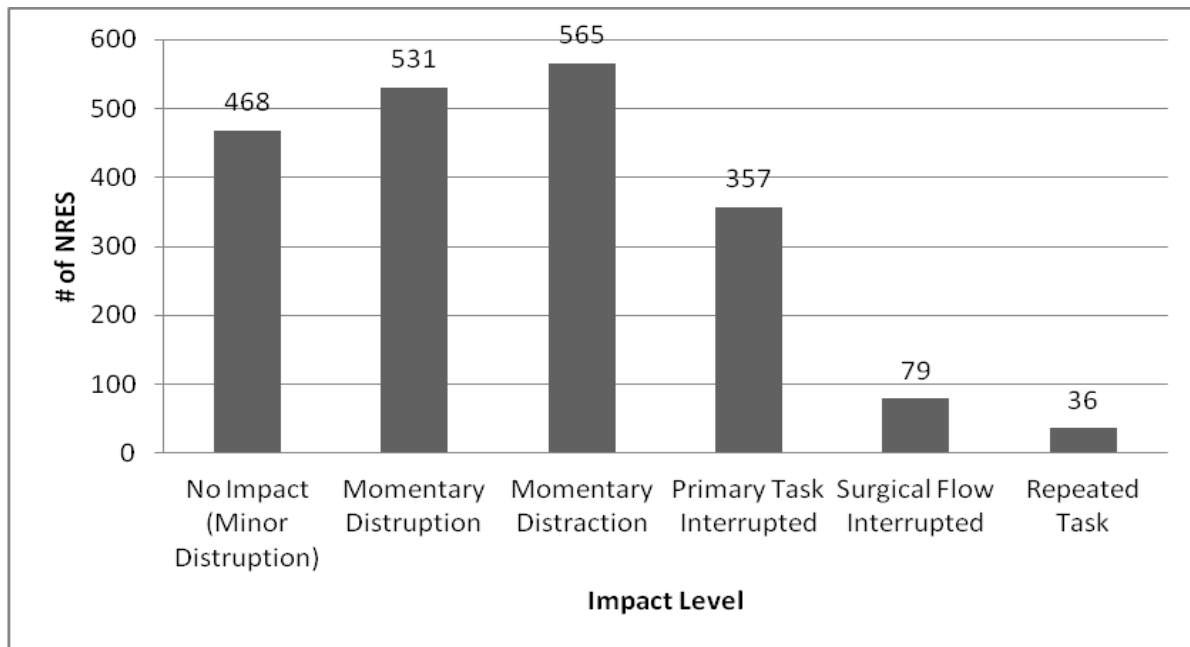


FIGURE 13: NON-ROUTINE EVENTS IMPACT LEVEL

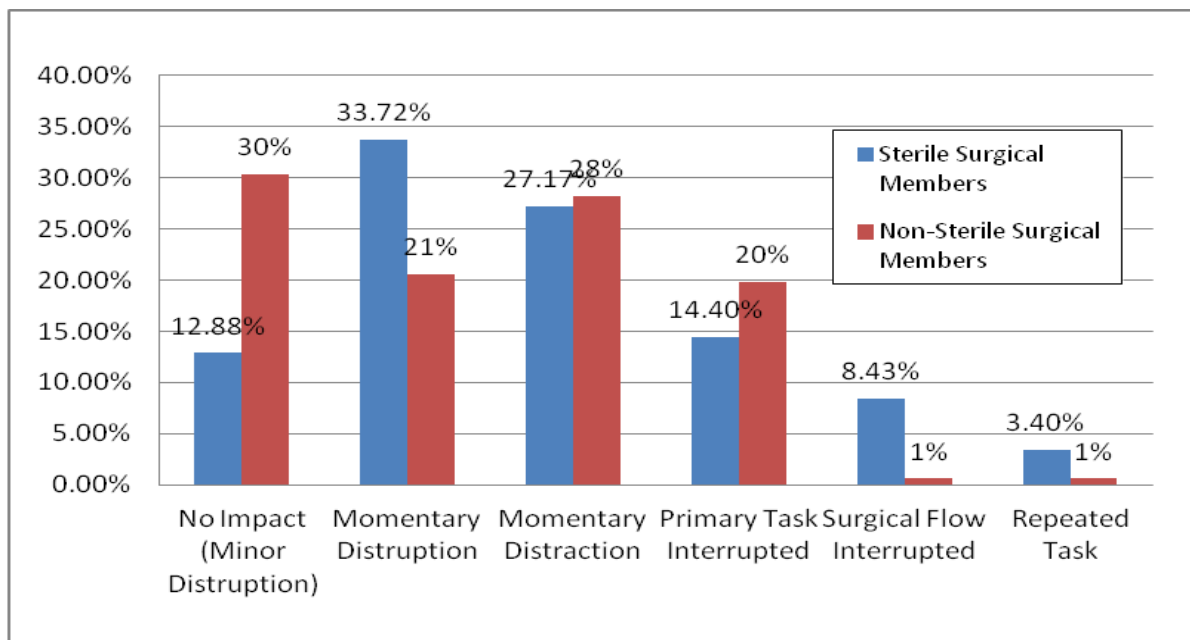


FIGURE 14: NON-ROUTINE EVENTS IMPACT LEVEL (STERILE VS. NON-STERILE)

3.3 Research Question #3: How do the characteristics of the intraoperative handoffs relate to non-routine events?

In discussing the results of this research question, safety-compromising consequences became the level of analysis. Therefore, after the two human factors experts analyzed each of the 36 cases individually and collectively reached a consensus, they identified 19 cases that involved a safety-compromising consequence. However, of the 19 cases involving a safety-compromising consequence, 12 were identified as having manifested later in the cases as a result of an intraoperative handoff coupled with NREs, and 7 were identified as not being linked to an intraoperative handoff. Of the 12 safety-compromising consequences linked to the coupling of intraoperative handoffs and NREs, 10 were labeled as having a negative impact and 1 was labeled as having a positive impact. There was 1 case that had two intraoperative handoffs where one handoff was considered to have a negative impact and the other was considered to have a positive impact. Therefore, there were a total of 13 safety –compromising instances that occurred across the 12 cases linked to intraoperative handoffs coupled with NREs. Of the 7 safety-compromising consequences not linked to an intraoperative handoff, 5 occurred in cases that did not contain an intraoperative handoff, and 2 occurred in cases that had intraoperative handoffs but the handoff was considered to not be associated with the safety-compromising consequence (Figure 15).

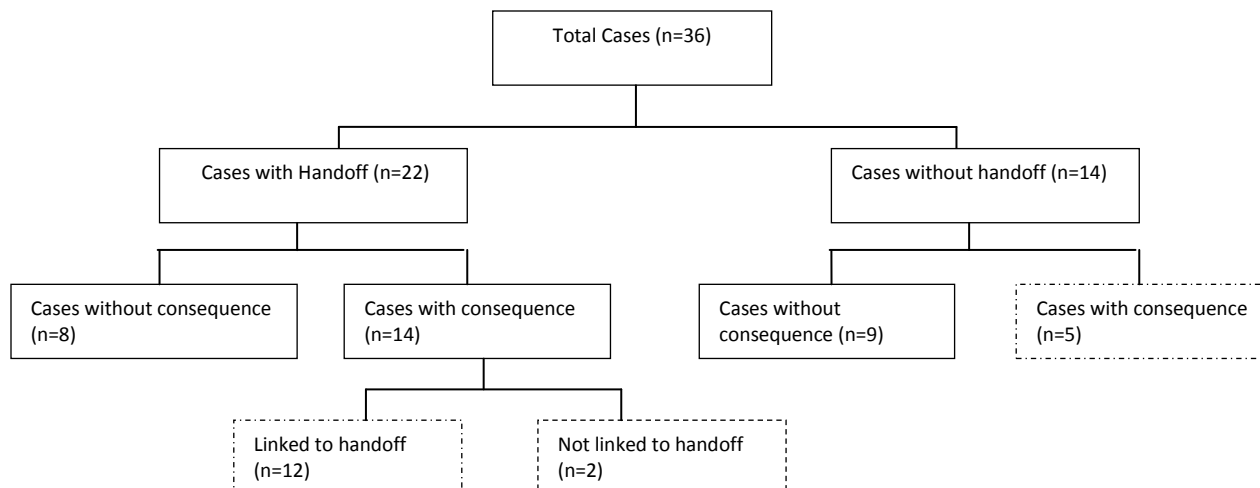


FIGURE 15: NUMBER OF CASES INVOLVING SAFETY-COMPROMISING CONSEQUENCES

The 12 cases involving safety –compromising instances that were linked to intraoperative handoffs coupled with NREs were analyzed using Miles and Huberman’s (1984) method of cross-case analysis. As described in the methodology chapter, a meta-matrix was developed (Table 6) assembling descriptive data from each of the 12 cases into a standard format for analysis.

A within-category sorting analysis using the meta-matrix revealed that across the 12 cases, “equipment malfunction/not ready” and “instruments/devices not at table” were the contributing NREs that were most prevalent (Table 7). A within-category sorting analysis specifically examining the “safety-compromising consequence” category of the meta-matrix revealed that the majority of the safety-compromising consequences were related to inadequate communication and surgical tools not being immediately available (Table 8). The researchers finally conducted a within-category sorting analysis on the “handoff phase/consequence phase” category and found that intraoperative handoffs occurred most frequently in the opening phase and the consequences occurred most frequently in the surgical repair phase (Table 9).

TABLE 6: UNORDERED META-MATRIX: INTRAOPERATIVE HANDOFFS, NRES AND SAFETY-COMPROMISING EVENTS

Case #	Impact (+ or -)	Handoff Phase/ Consequence Phase	Safety-Compromising Consequence*	Contributing Factors* (NREs)										Themes*		
				A	B	C	D	E	F	G	H	I	J			
Case [1]	-Negative	Opening (handoff)/Surgical Repair (consequence)	Inadequate Machine Preparation		X	X			X	X						1,3
Case [3]	-Negative	Opening(handoff)/Surgical Repair (consequence)	Inadequate Communication/ Surgical tools not immediately available.						X					X		1,2
Case [5]	+Positive	Initiation of Bypass (handoff)/Initiation of Bypass (consequence)	Error Detected/wrong machine setting.	O												4
Case [7]	-Negative	Opening(handoff)/Opening(consequence)	Inadequate Communication/ Surgical tools not immediately available.			X				X						1,2,3
Case [10]	-Negative	Surgical Repair (handoff)/Surgical Repair (consequence)	Inadequate Communication/ Surgical tools not immediately available.	X		X				X						1,2,3
Case [11]	-Negative	Opening (handoff)/Initiation of Bypass (consequence)	Inadequate Machine Preparation and communication				X	X					X			1,2,3
	-Positive	Closure(handoff)/ Closure(consequence)	Error Detected/ wrong surgical tool prepared.	O												4
Case [15]	-Negative	Termination of Bypass (handoff)/Closure (consequence)	Inadequate technical skills/ Machine malfunctioned.		X	X		X								1,3
Case [18]	-Negative	Opening (handoff)/Initiation of Bypass (consequence)	Inadequate Communication/ Surgical tools not immediately available.			X		X	X							1,2,3
Case [19]	-Negative	Opening(handoff)/Surgical Repair (consequence)	Inadequate Communication/ Surgical tools not immediately available.			X			X							1,2,3
Case [20]	-Negative	Surgical Repair (handoff)/Surgical Repair (consequence)	Inexperienced assistant Inadequate Communication/ Inadequate Machine Preparation			X			X				X			1,2,4
Case[23]	-Negative	Surgical Repair (handoff)/Termination of Bypass (consequence)	Inexperienced assistant/ Delay due to training and surgical revision.	X					X				X			4
Case [24]	-Negative	Initiation of Bypass (handoff)/ Surgical Repair (consequence)	Surgical tools needed, Inadequate Communication						X		X					1,2

+ (positive) or - (negative) indicates the handoff's impact on the consequence

[O] Indicates that the contributing factor was positive to the case.

[X] Indicates that the contributing factor was negative to the case.

*Contributing Factors: A, Technical skills issue; B, Case-irrelevant conversations; C, Pagers/Phone; D, Noises/Alarms/music; E, Equipment Malfunction/Not ready; F, Instruments/Devices not at table; G, Unexpected Patient Issues; H, Training Difficulty performing procedure; I, Miscommunication/coordination; J, not specified.

Themes: 1= Improper technology –instrument preparation induced by intraoperative handoffs can lead to machine malfunctions or tool unavailability; 2= Inadequate handoff communications can lead to teamwork issues that negatively impact the case; 3= Environmental distractions induced by intraoperative handoffs can lead to a delay in the surgical procedure; 4= Exchange of personnel with various technical skill sets and/or experience can either negatively or positively affect the case.

As indicated in Table 9, there were 8 intraoperative handoffs that occurred during one phase (i.e. opening) and the consequence occurred in another phase (i.e. surgical repair). In the other 5 instances, intraoperative handoffs and the consequence occurred in the same phase.

TABLE 7: WITHIN-CATEGORY SUMMARY TABLE: CONTRIBUTING NRES

Contributing Factors (NREs)	Cases at which item appeared
(A) Technical Skills	5, 10, 11, 23
(B) Case-irrelevant conversations	1, 15
(C) Pagers/Phone	1, 7, 10, 15, 18, 19, 20
(D) Noise/Alarms/Music	11
(E) Equipment Malfunction/Not ready	1,3,11, 15, 18
(F) Instruments/Devices not ready	1, 7, 10,18, 19, 20,23,24
(H) Training Difficulty performing procedure	24
(I) Miscommunication/coordination	3, 11, 19, 23

TABLE 8: WITHIN-CATEGORY SUMMARY TABLE: SAFETY-COMPROMISING CONSEQUENCE

Safety-Compromising Consequences	Cases at which item appeared
Inadequate Machine Preparation	1, (11), (20),
Inadequate Communication/Surgical tools not immediately available.	3,7, 10, 18, 19, (24), (11), (20)
Error Detected/wrong machine setting/tool prepared	5, (11)
Inadequate technical skills/machine malfunctioned	15

TABLE 9: WITHIN-CATEGORY SUMMARY TABLE: HANDOFF PHASE/CONSEQUENCE PHASE

OPENING	INITIATION OF BY-PASS	SURGICAL REPAIR	TERMINATION OF BY-PASS	CLOSURE
	(N=3)			
	(N=1)			
(N=1)		(N=2)		
	(N=2)			(N=1)
			(N=1)	(N=1)
		(N=1)		

N = the number of intraoperative handoffs that occurred during one phase (i.e. opening) and the consequence occurred in another phase (i.e. surgical repair).

In the across-category clustering (Table 10), the researcher looked across the meta-matrix categories to group the NREs that occurred as a result of the intraoperative handoffs. The results from the analysis revealed that NREs linked to intraoperative handoffs that contributed negatively to consequences later in the case were tools/technology, environment, and teamwork related. However, the results show that technical skill issues linked to intraoperative handoffs were both negative and positive.

TABLE 10: CLUSTERED SUMMARY TABLE: CONTRIBUTING FACTORS/CONSEQUENCES

NRE Clusters	Safety-compromising Consequence
Technology-instrument Issues [Negative] 1,3, 7, 10,11,15,18,19, 20, 23, 24,	Inadequate Machine Preparation and/or Surgical tools not immediately available
Teamwork Issues [Negative] 3, 11, 20, 23, 15	Inadequate communication
Environmental Issues [Negative] 1, 7, 10, 11, 15, 18, 19, 20	Phone/pager and irrelevant conversation distraction
Technical Skills Issues [Negative] 10, 23	Inexperienced assistant and inadequate technical skills
Technical Skills [Positive] 5, 11	Error Detected: wrong surgical tool or equipment

After reviewing the analysis presented in this section on the 12 cases involving an intraoperative handoff, four themes (or patterns) emerged relating intraoperative handoffs to NREs and safety-compromising situations (Miles & Huberman, 1984; Saldana, 2009). The first theme is that “improper technology –instrument preparation induced by intraoperative handoffs can lead to machine malfunctions or tool unavailability”; the second theme is that “inadequate handoff communications can lead to teamwork issues that negatively impact the case”, the third theme is that “environmental distractions induced by intraoperative handoffs can lead to a delay in the surgical procedure”; and the fourth theme identified is “exchange of personnel with various

technical skill sets and/or experience can either negatively or positively affect the case”.

Multiple themes were prominent in a single case given the fact that multiple NREs could lead to a safety-compromising consequences in a single case. These themes simply suggest that intraoperative handoffs can lead to NREs related to technology-instrument, teamwork, environmental, and technical skills issues that can impact the case. Each of the four themes that emerged from this analysis will be discussed in the following sections.

3.3.1.1 Theme one: Improper technology –instrument preparation induced by intraoperative handoffs can lead to machine malfunctions or tool unavailability.

The theme “improper technology –instrument preparation induced by intraoperative handoffs can lead to machine malfunctions or tool unavailability” appeared in 10 of the 12 cases. This theme involved the occurrence of an intraoperative handoff that was directly linked to an “instrument/device not at table” or “equipment malfunction/not ready” which led to a safety-compromising consequence. For example, in Case #1, the surgeon requested that he would need a specific machine for the coronary artery bypass graft (CABG) surgical procedure. This machine was not in the room at the time and the surgeon, being proactive, requested the machine so that it would be in the room when he needed it. However, about 15 minutes later, the surgeon asked the circulating nurse, “Where is that machine? Here?” and the nurse replied, “No,” but the machine arrived in the room shortly after. The circulating nurse became involved in an ongoing irrelevant conversation with the resident immediately after the machine arrived and continued another irrelevant conversation with another staff member. After completing the irrelevant conversation with a staff member, an intraoperative handoff occurred between the circulating nurse and the relief nurse. The circulating nurse did not provide any updates to the relief nurse prior to departing the room. The circulating nurse went on a short break and returned with no

updates from the relief nurse. Roughly two hours later, a second intraoperative handoff occurred where the circulating nurse left the operating room and actually provided an update to the relief nurse before departing. Roughly 30 minutes after the second intraoperative handoff, the surgeons say, irritably, to the relief nurse that the machine is not recording and it is not connected.

In this case (case #1), it is clear that the machine was not operable when the surgeon needed it. In this case, both human factors experts agreed that the first intraoperative handoff in this case led to the machine not being connected. The observers also agreed that case-irrelevant conversations (a non-routine event) coupled with an intraoperative handoff led to the nurse not connecting the machine needed for the CABGx2. In addition, the nurse did not communicate the need to connect the machine to the relief nurse during the intraoperative handoff. The non-routine events most likely disrupted the nurse's workflow and the intraoperative handoff accentuated it. While the researcher highlights case #1, this theme appeared in 9 other cases (case #3, case#7, case #10, case #11, case #15, case #18, case #19, case #20, and case #24).

3.3.1.2 Theme two: Inadequate handoff communications can lead to teamwork issues that negatively impact the case.

The theme "inadequate handoff communications can lead to teamwork issues that negatively impact the case" appeared in 8 of the 12 cases. This theme involved the occurrence of intraoperative handoffs that were directly linked to a "miscommunication and/or coordination breakdown" which led to a safety-compromising consequence. For example, in Case #11, the circulating nurse told the surgeon that engineering would change the room temperature and that the computer monitor would be cleared as he requested. The surgeon wanted the computer monitor "cleared" because the Pandora Internet Radio dialogue box was on the screen. Immediately after the circulating nurse provided the surgeon with the previously mentioned

update an intraoperative handoff occurred. During the intraoperative handoff, the initial circulating nurse departed, and the relief circulating nurse took responsibility for the patient care. The circulating nurse informed the relief nurse that the computer monitor needed to be cleared. The relief circulating nurse immediately cleared the computer monitor and told the surgeon the computer screen was cleared (i.e., the music was turned off). Roughly two minutes later, the surgeon became upset that the angiogram was not left on the monitor because he needed to view it right away. He angrily said to the relief circulating nurse to put the angiogram back on the screen. The procedure was slightly delayed while the relief circulating nurse placed the angiogram back on the screen.

In the case described above (case #11), it is clear that the surgeon did not communicate to the initial circulating nurse that he only wanted the Pandora Internet Radio dialogue box cleared from the screen. Therefore, the initial circulating nurse, during the handoff process, instructed the relief nurse to clear the screen. This was a safety-compromising consequence, because not having access to the angiogram on the monitor placed the patient at risk. It is evident here that the intraoperative handoff and “miscommunication/coordination” led to patient safety being compromised. While the researcher highlights case # 11, this theme appeared in 7 other cases (case#7, case #10, case #18, case #19, case #20, and case #24).

3.3.1.3 Theme three: Environmental distractions induced by intraoperative handoffs can lead to a delay in the surgical procedure.

The theme “Environmental distractions induced by intraoperative handoffs can lead to a delay in the surgical procedure.” appeared in 6 of the 12 cases. This theme involved the intraoperative handoffs that were directly linked to “case-irrelevant conversations,” “pagers/phone,” and “noises/alarms/music” issues that led to a safety-compromising

consequence. For example, in case #18, an intraoperative handoff occurred in which the initial circulating nurse departed and the relief circulating nurse took responsibility for patient care. The initial circulating nurse informed the relief circulating nurse that the surgeon needed an instrument, therefore roughly 6 minutes later, the relief nurse made several calls in an effort to get the tool. Roughly two minutes after the relief nurse made the calls; the relief nurse receives a call not related to obtaining the tool. Immediately following this call, the relief nurse receives a second call not related to obtaining the tool. The relief nurse then became engaged in an irrelevant conversation and briefly left the operating room and missed three calls. An intraoperative handoff occurred shortly after the calls ended, and the initial circulating nurse returned and the relief nurse departed; a very brief update transpired. The initial circulating nurse engaged in an irrelevant conversation with a visitor. Then the surgeon irritably asked, “What happened to the tool, I need it now.” There was a short delay (roughly five minutes) in the procedure while the circulating nurse went to personally obtain the tool.

In this case (case #18), it is clear that after the intraoperative handoffs occurred, the phone and irrelevant conversations contributed to the circulating nurse’s not being able to focus on obtaining the tool for the surgeon at the appropriate time. This led to a safety-compromising consequence, because not having access to the tool when needed led to a delay in the procedure and lengthened the time the patient’s incision was open, increase the risk of infection. While the researcher only presented case # 18, this theme appeared in 5 other cases (case #1, case #7, case #10, case #11, case #15, and case #19).

3.3.1.4 Theme four: Exchange of personnel with various technical skill sets and/or experience can positively affect the case.

The theme “exchange of personnel with various technical skill sets and/or experience can positively affect the case” appeared in 4 of the 12 cases. In the 4 cases where this theme emerged, two of the impacts were negative and two were positive. In this section, the researcher will highlight a positive instance. For example, in Case #3, the surgical assistant dropped thread packets and therefore the circulating nurse had to replace the threads. While the nurse was picking up the thread packets from the floor, the surgeon asked for a tool. Immediately after the surgeon requested the tool, an intraoperative handoff occurred, and the circulating nurse explained to the relief nurse the situation. The circulating nurse departed, and the relief nurse went to retrieve the tool that the surgeon had requested. Roughly four minutes later, the relief nurse made a phone call and stated that she noticed that the dial (a name of a specific dial was not identified in the observational data) should have been set to 30 instead of 20 and that she would change it.

In this instance, both observers agreed that the intraoperative handoff was positively executed. The observers agreed that the circulating nurse communicated to the relief nurse the need to get the tool that the surgeon requested. Therefore, the relief nurse left the room to get the tool the surgeon requested. In addition, the observers agreed that the intraoperative handoff provided a “fresh set of eyes” that allowed the relief nurse to use her technical skills to identify the dial error. While it is not clear whether this could have caused a life-threatening consequence, the observers agreed that this probably prevented an event from occurring later in the case. The researcher highlights case #3; however, this theme appeared in 3 other cases (case #3, case #11, case #20 and case #23). In case #20 and case #23, the clinicians “technical skills” negatively impacted the case.

3.3.1.4.1 Theme four: Exchange of personnel with various technical skill sets and/or experience can negatively affect the case.

As previously mentioned, the theme “exchange of personnel with various technical skill sets and/or experience can negatively affect the case” had impacts that were both negative and positive. In this section, the researcher will highlight the negative instance. For example, in Case #20, during the surgical repair phase the surgeon stated that he needed to redo a procedure roughly three minutes before an intraoperative handoff occurred. The initial surgical assistant (tech) departed and the relief surgical tech took responsibility for the patient. There was no update. The surgeon’s received a call on his cell phone and the circulating nurse answered the call and relayed the message to him (message was not relevant to the case). Shortly after the phone call, the surgeon demanded that the surgical assistant give him an instrument. The surgical assistant gave the surgeon the wrong tool and the surgeon became even more flustered.

In this instance, both observers agreed that the intraoperative handoff led to an unskilled or unaware surgical assistant taking control for the patient. Perhaps the relief surgical assistant was not as skilled as the initial surgical assistant or the initial surgical assistant may not have informed the relief surgical assistant during the handoff process that the surgeon was planning to redo a procedure and needed a particular set of tools. However, this placed the patient at risk and could have resulted in a surgical error. The researcher highlights case #20; however, this theme appeared in case #23.

Chapter 4: Research Discussion

This chapter highlights the discussion of the research results. There will be three discussion sub-sections, one for each research question. The chapter will begin by discussing the characteristics of intraoperative handoffs, followed by a discussion highlighting the characteristics of non-routine events. Finally, a discussion of how intraoperative handoffs relate to non-routine events, framework implications and recommendations will be presented.

4.1 The characteristics of intraoperative handoffs during cardiac surgeries

The 90 intraoperative handoffs observed by the researchers transpired during various stages within cardiac surgical processes. As previously indicated in the literature, handoffs can place patients at risk but can also sometimes be beneficial (Cooper et al., 1982). In investigating intraoperative handoffs, the researcher found that there are three types of handoffs that occur during cardiac surgeries. Those handoffs were categorized as (1) Initial Handoff—the person will return, (2) Return Handoff, and (3) Initial Handoff—the person never returned. These findings, at the very least, suggest that the type of intraoperative handoffs could be assessed and explored in order to understand the level of vulnerability or benefit that each affords to the safety of patients. Understanding the characteristics of the intraoperative handoffs and their complexity is important in order to develop and implement effective quality and safety improvements.

Further examination of the intraoperative handoffs revealed that 58% of the initial handoffs involved the initially relieved individual returning to the OR and 42% of the initial handoffs involved the initially relieved individual never returning. This finding suggests that the responsibility for patient care can be relinquished to multiple OR personnel, rather than being shared by two. For instance, if an initial circulating nurse is relieved by a second nurse and the initial circulating nurse never returns to the OR, the second nurse will probably have to call a

third nurse to be relieved for a break—if one is needed. This could possibly pose a threat to the safety of the patient. However, Arora and colleagues (2005) found that handoffs communication failures, involving just two clinicians, led to subsequent uncertainty when making decisions regarding patient care. Therefore, one could argue that handoffs between multiple clinicians could lead to even greater levels of uncertainty when making decisions regarding patient care. Thus, the researcher argues that a reduction in the number of handoff occurrences can decrease the likelihood for errors or breakdowns in care.

On average, the cardiac surgical procedures lasted an estimated 5 hours; there were roughly 4 intraoperative handoffs per case. Handoffs also occurred most frequently during the surgical repair phase of the operation (53.33%) and another significant amount occurred during the initiation of the by-pass (20%) phase. Further analysis of the data revealed that a vast majority of the initial handoffs (47.37%) and return handoffs (63.64%) occurred during the surgical repair phase. These findings suggest that perhaps the surgical repair phase and the initiation of by-pass phase of the operation could possibly be the most appropriate (or worst) time to conduct handoffs, depending on the workload of the team. However, Wadhera and colleagues' (2010) study demonstrated that there is no discrete time period of high risk and high mental workload from the standpoint of the entire team, and that in cardiac surgery each team member may have a different high risk and high mental workload, depending on the phase of the operation. Therefore, this suggests that there is no “perfect time” to conduct intraoperative handoffs from an entire team standpoint.

More evaluation of the data revealed that nurses and surgical techs were more frequently involved in intraoperative handoffs during the surgical repair phase (Table 4). In addition, the data revealed that nurses were more frequently involved in intraoperative handoffs during both

the opening and initiation of the by-pass phase (Table 4). Wadhera and colleagues (2010) found that the opening phase is a high risk and high workload phase for nurses and that the surgical repair phase is a low workload phase for nurses. They also found that the surgical repair phase was a high risk and high workload phase for surgical assistants/techs. Therefore, the data from the present study show that the majority of the nurse intraoperative handoffs occurred during the surgical repair phase, a time when the nurse workload was relatively low. However, the present study also showed that the majority of the surgical tech intraoperative handoffs occurred during the time when their workload was high. Hence, the researcher posits that understanding the best circumstance for intraoperative handoffs for each team member can assist in developing suitable interventions—as it may not be beneficial for the surgical tech to conduct intraoperative handoffs during a high workload phases of the procedure.

The findings from this study highlighted the fact that the interval between initial handoffs and return intraoperative handoffs on average is 35 minutes. The researcher argues that knowing the time period that the relief staff will be responsible for the patient care process can help in the development and implementation of interventions. Knowing the average interval between initial handoffs and return handoffs, one can begin to evaluate, understand, and postulate the possible key patient information that needs to be communicated to relief personnel during a handoff. Providing key information will ensure that the relief person succeeds in making decisions regarding patient care and properly respond to other surgical team members (Arora et al., 2005; Arora et al., 2008; Dracup et al., 2009; Dunn et al., 2008; Klaber et al., 2009).

While a meager majority of intraoperative handoffs had little or no effect on the workflow of other surgical team members, occasionally handoffs did lead to a complete pause in the surgical procedure. This finding provides evidence to support the notion that intraoperative

handoffs impact the surgical team's functioning and may place the patient at risk due to distraction-induced errors. The researcher argues that recognizing the level of impact that an intraoperative handoff has on team functioning can be essential to implementing an intraoperative handoff intervention that is seamlessly integrated into the workflow of the team.

4.2 The characteristics of non-routine events during cardiac surgeries

There were over 2,000 NREs identified by the observers across the 36 cases and, on average, there were roughly 56 NREs occurred per case. The most frequent NREs were environmental and technology issues with teamwork factors, training interruptions, and technical/skills issues also contributing substantially. A further examination of environmental related NREs showed that these events were more frequently categorized as pagers and phones; case-irrelevant conversation; and noises, alarms, and music. While many may argue that the environmental related NREs are minor, these findings reflect those from other studies in a wide variety of health care settings (e.g., Catchpole et al., 2007; Duff et al., 2010; Wiegmann et al., 2007) that have demonstrated that even seemingly minor events can be detrimental to safe and appropriate patient care. A further examination of the technology related NREs highlighted that those events were frequently categorized as "equipment malfunction or not ready" and "instruments and devices not at table". These technology related NREs are much more detrimental to the safety of patients and can quickly lead to catastrophic outcomes. The Agency for Healthcare Research and Quality (2003) found technology failures to be one of the most common root causes of medical error, and stated that in many instances equipment and devices such as infusion pumps or monitors can fail and lead to significant harm to patients. Findings from this study suggested that environmental and technological NREs can further complicate and distract team members from seamlessly completing the surgical procedure.

NREs occurred throughout the surgical care process; however, they most frequently occurred during the surgical repair phase (30.35%) and the opening phase (23.77%). It is evident that environmental and technological related NREs occurred at a higher percentage than did other NREs, and a further examination of these two types of NREs revealed a more frequent occurrence during the opening and surgical repair phase (Henrickson et al., 2010). Wadhera and colleagues (2010) found that the opening, initiation of by-pass, surgical repair and termination of by-pass phases were the principal periods of high risk and high mental workload for the surgeon, surgical tech, and perfusionist. Therefore, the occurrence of any NREs during the phases can be problematic for the surgeon, surgical tech and perfusionist. More specifically, the occurrence of technological related NREs during opening and surgical repair, therefore, may pose a great risk to patient safety.

In examining the characteristic of NREs during cardiac surgical care, the results revealed that NREs' duration can be brief or can last over two-hours. However, on average, the duration of NREs was 3 minutes. Nurses were usually most involved in NREs; however, the entire sterile surgical team, surgeon/resident and the perfusionist were generally involved in NREs as well. Nurses were found to be more frequently involved in NREs in other studies (e.g. Hendrickson et al., 2010); however, the entire sterile surgical team or surgeon involvement in NREs can possibly contribute to more severe patient safety issues than a nurse involvement as the sterile team is more directly involved in physically carrying out the procedure. Previous research indicates that NREs can distract the entire sterile surgical team and lead to errors (Wiegmann, 2007). The researcher suggests that understanding the aspects of NREs during the surgical process is vital to creating methodologies for studying and interventions for managing them.

Similar to handoffs, most NREs had little impact on workflow and only occasionally led to a complete halt in the surgical care process. The results indicated that the majority of the NREs were considered momentary distractions with only a small percentage actually causing the surgical flow to be interrupted. However, a series of minor events that have little immediate effects on the surgical care process could possibly prolong the case and lead to unwarranted outcomes. Carthey and colleagues (2001) highlighted a case study that showed how a series of minor events, both internal and external distracters, set an incident sequence in motion that could have resulted in the occurrence of an adverse event. Therefore, the findings suggest that while most NREs in the present study, at first glance, have a minor effect on the workflow of the surgical team, those minor effects could possibly lead to problems later in the procedure, as will be discussed in the following section. Understanding the effects of NREs on surgical care and their complexity is valuable to the development of safety improvements.

4.3 Intraoperative handoffs relationship to non-routine events

As discussed previously, most handoffs impact the workflow of the surgical team. However, these impact assessments were based on the immediate disruptive nature of the handoff process itself. They did not assess the potential impact that the handoff might have had on other NREs that occurred later in the case. Therefore, in an effort to develop a more in-depth understanding of the relationship between intraoperative handoffs and NREs, each of the 36 cases was analyzed individually, and 19 cases were identified as having a safety-compromising consequence. Of the 19 cases, 12 cases were identified as having a safety-compromising consequence as a result of an intraoperative handoffs linked to NREs. The results revealed that intraoperative handoff occurred most frequently in the opening phase and the consequences manifested most frequently in the surgical repair phase. As previously mentioned, Wadhera and

colleagues (2010) found the opening and surgical repair phases to be a period of high risk and high mental workload for the members of the sterile team. Therefore, these two phases poses a threat to the safety of the patient if a member of the sterile team is involved in the intraoperative handoff and its consequence.

From the 12 cases involving intraoperative handoffs coupled with NREs, four themes revealed that intraoperative handoffs led to contributing NREs related to technology-instruments, teamwork, environment and technical skills. These contributing NREs are identical and consistent with the finding across all 36 cases, where the majority of the 2036 NREs were related to the environment, technology-instruments and teamwork. Additionally, these findings are consistent with Weigner and Slagle (2002) who similarly identified NREs related to usability problems or equipment failures, team coordination or communication, and surgical issues. In the present study, multiple themes were prominent in a single case, which suggest that an intraoperative handoff impacts the entire system, just as the SEIPS model has demonstrated in various healthcare settings (Alvarado et al., 2004; Carayon et al., 2004; Carayon et al., 2005; Hundt, 2003). Evidence suggests that intraoperative handoffs have an impact on the entire system that leads to various system related NREs, as illustrated in the present study. Suggesting that intraoperative handoffs lead to one particular type of NRE would not be adequate given that studies (Cohen & Hilligoss, 2010) have shown that handoffs can affects all aspects of the system and, therefore, unpredictable NREs may occur as a result. However, the study provides evidence to support the notion that intraoperative handoffs will, more likely, lead to NREs related to technology or instrument issues. In the across case analysis, this notion appeared frequently across 12 studies involving an intraoperative handoff linked to NREs that lead to safety-compromising consequences. The findings suggest that when an intraoperative handoff occurs

the equipment malfunctions or is not ready because the initial staff member did not properly prepare the equipment for use or did not inform the relief staff member to complete the equipment preparations. Therefore, the relief staff member is not aware and, as a result, NREs related to technology or instruments lead to safety-compromising consequences such as a halt in the case due to the machine is not function properly or tool not available.

As discovered in the previous studies (e.g. Cooper et al., 1982), intraoperative handoffs can be positive for long surgical procedures. In the present study, there were two instances reveal where an intraoperative handoff mitigated the occurrence of a safety-compromising consequence. In both instance, the intraoperative handoff provided a “fresh set of eyes” that allowed for an error to be detected. This suggests that intraoperative handoffs are needed, but handoffs should be structured to capture problems to prevent the occurrence of NREs and safety-compromising consequences (Patterson and Woods, 2001) and to adequately relinquish the care of the patient to the relief staff.

4.4 Theoretical Framework Implications

The results of this study support the SEIPS model as a viable framework that can help explain the effects that intraoperative handoffs have on the cardiac surgery care system. The SEIPS model offered a holistic framework for evaluating and addressing patient safety problems in the intraoperative handoff process. More specifically, the model facilitated an understanding of the relationship between intraoperative handoffs and NREs during cardiac surgery.

Using SEIPS as the underpinning theoretical framework for studying intraoperative handoffs and NREs, the researcher was able to capture the impacts that intraoperative handoffs had on other parts of the cardiac surgery care system. For instance, in many of the cases when an individual (i.e. surgeon, resident, surgical/scrub tech, anesthesiologist, perfusionist, or RN)

engaged in an intraoperative handoff, one could see the effects it had on the system and analyze which other team members were affected, what was the impact, whether any policies or procedures (organizational factors) contributed to the occurrence of the intraoperative handoffs, and whether the environment enhanced or hindered the success of the intraoperative handoff.

The results from the study reveal the interrelationships of elements from the SEIPS model. The results suggest that when an intraoperative handoff occurs, individuals (teamwork and technical skills), technology-instrument, environment and tasks can be affected. The cases shown in Table 6 provide examples of how elements from the SEIPS model are influenced by one another and, therefore, interwork.

The transactive memory system, as previously described, was used to help explain why intraoperative handoffs might increase the occurrence of NREs. After reviewing the findings from this study, one can argue that when the transactive memory system is disrupted due to intraoperative handoffs, the entire system is disrupted. A disrupted transactive memory forces the team to regroup in order to understand “who knows what” or who are the experts—thus building a new transactive memory system. In the process of building a new transactive memory after an intraoperative handoff, the researcher argues, NREs increase. Therefore, when an intraoperative handoff occurs, the findings from this study suggest that there is a stronger likelihood that the surgical case will be negatively impacted (Lewis et al., 2005; Moreland, 1999) and the occurrence of NREs will increase, which could lead to safety-compromising consequences.

For instance, Case #1 (discussed in Section 3.3.1.1) demonstrates the impacts that a disrupted transactive memory can have on the natural progression of a surgical case and how a disrupted transactive memory can lead to safety-compromising consequence. In this particular

case, the surgeon was being proactive by requesting a machine so that it will be in the room when he needed it. The original circulating nurse that was in the room when the machine arrived failed to connect the machine, which resulted in a delay in the case and the surgeon becoming irritable. An investigation of this case suggests that transactive memory was disrupted during the multiple intraoperative handoffs that resulted in information loss and hinder the nurse's ability to effectively coordinate the task at hand. Wegner et al. (1985) argues that a behavioral hallmark of teams with good transactive memory is evidence of smooth coordinated task processes (Wegner et al., 1985). In this particular case, the task was not coordinated properly by the original circulating nurse and the relief nurse was not aware of the fact that the machine was not connected. Therefore, the relief nurse did not connect the machine during the period he or she was responsible for the patient care. Wegner et al. (1985) suggested that one component of coordination is an understanding of where to locate specialized knowledge. Since the relief nurse was just introduced to the team as a result of the intraoperative handoff and was not briefed on the fact that the machine need to be connected by the original circulating nurse, then he or she would not have known where to get information ("specialized knowledge") about whether or not this task needed to be completed. While this example may appear minor, it indicates that relief personnel can be unaware of where to locate specialized knowledge ("who knows what") following an intraoperative handoffs and, thus, poses a threat to patient safety. Minimizing the number of intraoperative handoffs during a surgical case can possibly reduce the treat to patient safety. For instance, if the original circulating nurse transactive memory was not disrupted as a result of the intraoperative handoff, his or her external memory aids could have possible reminded him or her to connect the machine before the surgeon became annoyed and surgical procedure delayed.

While much of the discussing have centered on how intraoperative handoffs negatively impacts or disrupts the transactive memory of the team, there are results from this study that suggest that a disrupted transactive memory can be beneficial to the team. For instance, Case #3 (discussed in Section 3.3.1.4), revealed that following an intraoperative handoff a relief nurse noticed that dial on a machine should have been on 30 instead of 20 and stated that she would correct it. In this instance, disrupting the team's transactive memory revealed an error that could have caused a life-threatening consequence. This analysis suggest that forcing the team to rebuild or build new transactive memories as a result of an intraoperative handoffs can provide a "fresh set of eyes" to the surgical procedure and mitigate the occurrence of adverse events. Lewis (2004) study suggests that individuals that have worked together in a team before can develop a poor transactive memory. Poor transactive memory could be developed because individuals in the team are not adequately examining the expertise that each member possess and, therefore, could be extending creditability to those members' expertise based on pass and/or related experiences with members. When a poor transactive memory is developed, the results of this analysis suggest that things can go undetected. Therefore, the findings from this study can be indicating that eliminating handoffs during surgical procedures could be more damaging then beneficial, but minimizing the occurrence of handoffs disrupting the team's transactive memory can decrease patients being susceptible to errors.

4.5 Intraoperative Handoff Improvement Recommendations

As previously mentioned, attempts at improving handoff have been explored in various healthcare domains. Standardizing the handoffs process has been the method that many have tried to use to rectify issues with handoffs (AORN, 2008; Arora et al., 2006; Haig et al., 2006;

Patterson et al., 2004). The integration of information technology for handoffs has also been used to try to solve problems with handoffs (Jacques et al., 2006; Patterson et al., 2008; Soto et al., 2006). However, using the aforementioned recommendations for improving intraoperative handoffs may not be that beneficial.

Findings from this study revealed that intraoperative handoffs are important to the overall functioning of the OR, and that the handoffs can be both beneficial and detrimental to the safety of the patient (Cooper et al., 1982). Therefore, to improve intraoperative handoffs, there are recommendations based on the present research findings. The researcher suggests that the key to improving intraoperative handoffs and reducing the occurrence of NREs as a result of a handoff is to require the relief clinician to work at least 5 to 10 minutes with the initial clinician to gain a feel for what the situation is before the case nurse departs (Ulmer et al., 2008). In addition, the researcher suggests that intraoperative handoffs should be coordinated with periods of low workload to reduce the impact that they could have on the surgical team procedures and to mitigate the occurrence of NREs that lead to safety-compromising consequences (Christian et al., 2006). A final recommendation is for the relief clinician to validate that he or she feels comfortable with the amount of knowledge he or she has obtained from the initial clinician, just as many of the standardized handoffs methods have attempted to address—similar to those employed by the aviation industry (Dracup et al., 2008).

In addition to the three recommended interventions, technology developed specifically for intraoperative handoffs could prove beneficial. In many of the cases presented in this study, the original personnel often seem unaware that an intraoperative handoffs was about to occur and, therefore, did not have time to fully prepare to give control or responsibility of the patient to the relief personnel. Implementing a handheld device/smartphone that monitors the patient condition

and allows the health personnel to quickly input notes, reminders and tasks using text messaging language/shorthand and/or voice can help with the intraoperative handoff process. The original personnel can simply use the smartphone to quickly guide the handoff process. However, if the original personnel did not mention all the pertinent information verbally, the relief personnel will have access to the smartphone and can quickly review the notes, reminders, tasks and voice messages. Implementing such a handheld device will help ensure that relevant information is transferred and is not lost during the transition because someone failed to mention it. In addition to implementing a smartphone, another technology based intervention would be to redesign computer software that is currently being used in the operating room environment to facilitate intraoperative handoffs. Redesigning the currently used computer software can simply mean developing an electronic intraoperative handoff aid as part of the electronic patient chart. The electronic intraoperative handoff software should allow for a quick review of the patient status, notes, reminders and task to be completed. To aid in the software adaptation among the OR personnel, utilizing human-computer etiquette (Hayes & Miller, 2010) can help facilitate smooth and effective interactions between the OR personnel and computer software, thus, possibly making the OR personnel more inclined to wanting to adapt the software during intraoperative handoffs. Human-computer etiquette is essentially concerned with the development of computer responses that are “polite” and sensitive to the context and reaction of people since computers are part of the OR team (Hayes & Miller, 2010). Implementing one of the suggested technological recommendations laterally with the first three improvement recommendation mentioned in this section can possibly provide to be beneficial in improving intraoperative handoffs and decreasing the threat to patient safety.

The results from this study are of significance to the domain of human factors, healthcare, and handoffs because it provides new knowledge to the current literature where intraoperative handoffs have not been studied extensively. The results reveal that intraoperative handoffs indeed pose a threat to the safety of patients. However, the results also reveal that intraoperative handoffs can be beneficial to the patients like Cooper et al. (1982) study revealed. Consequently, this study's results will assist us with developing methodologies for effectively studying intraoperative handoffs in order to implement compatible inventions such as the improvement recommendation mentioned in this section. The researcher argues that the results can be used to improve intraoperative handoffs during other types of surgeries as well as other dynamic healthcare team environments where handoffs occur that could disrupt team functioning and patient care.

Chapter 5: Research Conclusion

This research aimed to understand intraoperative handoffs and the occurrence of NREs in cardiac surgical care. Given that this was the first study to examine intraoperative handoffs and their relationship to NREs, it was very exploratory in nature. In order to fully examine the phenomenon, the researcher employed both quantitative and qualitative analyses to identify relationships between handoffs and NREs.

The study found a total of 90 intraoperative handoffs and 2,036 NREs were observed across the 36 surgical cases. Cases that involved at least one intraoperative handoff tended to have more NREs than cases that did not involve a handoff. Handoffs occurred most often during the surgical repair phase and most frequently involved a nurse or surgical technician. Previous studies found that the surgical repair phase was a high risk and high workload period for surgical technicians and a low risk and low workload period for nurses (Wadhera et al., 2010). The majority of NREs involved environmental distractions, technological problems and teamwork failures. A qualitative analysis in which each of the 36 cases was analyzed individually identified 12 cases where handoffs were associated with NREs that specifically lead to safety-compromising consequences. From these 12 cases involving intraoperative handoffs coupled with NREs, four themes revealed that intraoperative handoffs led to NREs related to technology-instruments, teamwork, the environment, and technical skills. There were two cases where an intraoperative handoff coupled with NREs appeared to mitigate the occurrence of more NREs and safety-compromising consequences.

Therefore this study provided support for other researchers who have argued that intraoperative handoffs and NREs are both negative and positive to surgical cases. The study also proved the SEIPS model to be a viable framework for studying a phenomenon like

intraoperative handoffs and NREs. In addition, the transactive memory system, used as an interpretative framework, provided an understanding for why intraoperative handoffs have an impact on the functioning of the surgical team. The findings from this study allowed the researcher to formulate recommendation for improving intraoperative handoffs in order to assist in managing the number of NREs that occur as a result of the handoffs.

Much more research needs to be conducted in order to understand the complexities of intraoperative handoffs and the occurrence of NREs. Given the fact that this study is the first to explore intraoperative handoffs and their relationship to NREs, there are many directions for future research. Next steps for this research is to (1) refined the data collection method and include more clinicians; (2) explore from a clinician standpoint the best time to handoff and the key information to include in the handoff process; and (3) explore why intraoperative handoffs can (or more likely) lead to NREs related to technology-instrument, environmental and teamwork issues.

5.1 Research limitations

As with all research, this study is subject to several limitations. The first limitation is the use of the convenience sampling method for gathering participants employed in this study. It can be argued that a sample of this nature may be biased and not representative of the general population. However, convenience sampling provides an opportunity for quickly discovering a complex phenomenon such as intraoperative handoffs. Another limitation may include the argument posed by critics of the SEIPS model, who suggest that this framework provides “no specific guidance as to the critical elements” (Carayon et al., 2006, p. i56). This could also be considered a major strength because the model is adaptable and, therefore, can be used across several contexts or situations, and it encourages maintaining a consideration for a “big picture”

or holistic view (Carayon et al., 2006). In addition, the SEIPS model allows the researcher to define his or her own critical elements. However, the SEIPS model is useful for the present study because it helps to explain how intraoperative handoffs can be systematically impactful and influenced by the system. In addition, the data collection tool used in this study was developed using the structure provided by the SEIPS model (Blocker et al., 2010). The observational data collection methods used for this study presented limitations due to the inability to discern all verbal content relayed between the parties during the handoff. The environment did not allow for the observers to be close enough to all health professionals to capture all handoff communications. However, this method resulted in the collection of valuable data that contribute significantly to the existing knowledge on intraoperative handoffs. Some researchers would argue that the inconsistency in the research teams poses a bias in the data collection process. However, this diversity adds further validity to the electronic measurement tool developed during previous work by this study's researcher and colleagues (Blocker et al., 2010). The final limitation addressed is the use of the two human factors observational observers to qualitatively analyze each case and the use of one researcher to conduct the final steps in the cross-case analysis. Critics will argue that the findings of the qualitative analysis in particular are limited and biased based on the human factors observers' background. One would argue that one with a different background can arrive at different conclusions. However, the researcher received input from OR staff to confirm that the qualitative analysis was clinically relevant. In the future, the researcher plans to involve members from the OR staff, if possible, in analyzing and identifying safety-compromising consequences during the initial step of the cross-case analysis. There are many qualitative approaches that the researcher could have employed, but cross-case analysis

enables the researcher to make sense of puzzling or unique finding and pin down the conditions under which findings will occur.

References

- Alvarado, C.J., Carayon, P., & Hundt, A.S. (2004). Patient safety climate (PSC) in outpatient surgery centers. Paper presented at the Human Factors and Ergonomics Society Conference, New Orleans, LA.
- AORN. (2010). Perioperative patient “hand-off” tool kit. AORN. Retrieved September 18, 2010 from <http://www.aorn.org/PracticeResources/ToolKits/PatientHandoffToolki/>.
- Arora, V., & Johnson, J. (2006). A model for building a standardized hand-off protocol. *Joint Commission Journal on Quality and Patient Safety*, 32(11), 646-55.
- Arora, V., Johnson, J., Lovinger, D., Humphrey, H.J., & Meltzer, D.O. (2005). Communication failures in patient sign-out and suggestions for improvement: a critical incident analysis. *Quality of Safety in Health Care*, 14(6), 401-407.
- Arora, V.M., Manjarrez, E., Dressler, D.D., Basaviah, P., Halasyamani, L., & Kripalani, S. (2009). Hospitalist handoffs: a systematic review and task force recommendations. *Journal of Hospital Medicine*, 4(7), 433-440.
- Arora, V.M., Johnson, J.K., Meltzer, D.O., & Humphrey, H.J. (2008). A theoretical framework and competency-based approach to improving handoffs. *Quality & Safety in Health Care*, 17, 11-14.
- Austin, J.R. (2003). Transactive memory in organizational groups: the effects of content, consensus, specialization, and accuracy on group performance. *Journal of Applied Psychology*, 88 (5), 866-878
- Baartman, L., Prins, F., Kirschner, P., van der Vleuten, C. (2011). Self-evaluation of assessment programs: A cross-case analysis. *Evaluation and Program Planning*, 34, 206-216
- Bakeman, R., & Quera, V. (1995). Analyzing interaction: Sequential analysis with SDIS & GSEQ. New York, NY: Cambridge University Press.
- Barach, P., and Small, S.D. (2000). Reporting and preventing medical mishaps: lessons from non-medical reporting systems. *British Medical Journal*, 320,759–63.
- Barden, C.B., Specht, M.C., McCarter, M.D., Daly, J.M., Fahey, T. J. (2002). Effects of limited work hours on surgical training. *Journal of the American College of Surgeons*, 195, 531–538.
- Behara, R., Wears, R.L., Perry, S.J., Eisenberg, E., Murphy, A.G., Vanderhoef, M., Shapiro, M., Beach, C., Croskerry, P., Cosby, K. (2005). A conceptual framework for studying the safety of transitions in emergency care. In: Henriksen, K. (Ed.), *Advances in Patient Safety. Agency for Healthcare Research and Quality* (pp. 309-321). Rockville, MD: Department of Defense
- Blocker, R.C., Eggman, A., Zemple, R., Wu, C.E., & Wiegmann, D.A. (2010). Developing an observational tool for reliably identifying work system factors in the operating room that impact cardiac surgical care. *Human Factors and Ergonomics Society Annual Meeting Proceedings, Health Care*, 5, 879-883.
- Borowitz, S., Waggoner-Fountain, L., Bass, E., & Sledd, R. (2008). Adequacy of information transferred at resident sign-out (in-hospital handover of care): a prospective survey. *Quality of Safety in Health Care*, 17(6), 6-10.
- Bost, N., Crilly, J., Wallis, M., Patterson, E., & Chaboyer, W., (2010). Clinical handover of patients arriving by ambulance to the emergency department-a literature review. *International Emergency Nursing*, 18(4), 210-220.
- Brandwijk M, Nemeth C., O’Connor. M., Kahana, L., & Cook, R.I. (2003). Distributing

- cognition: ICU handoffs conform to Grice's Maxims. Proceedings of the National Conference of Critical Care, San Antonio, TX.
- Bruce, K., & Suserud, B.O. (2005). The handover process and triage of ambulance-borne patients: the experiences of emergency nurses. *Nursing in Critical Care* 10 (4), 201–209.
- Cannon-Bowers, J. A., Salas, E., & Converse, S. A. (1993). Shared mental models in expert team decision making. In N. J. Castellan, Jr. (Ed.), *Current issues in individual and group decision making* (pp. 221-246). Hillsdale, NJ: Erlbaum.
- Cannon-Bowers, J.A. & Salas, E. (1991). Team member shared mental models: A theory and some methodological issues. *Proceeding of the Human Factors and Ergonomics Society Annual Meeting*, 35, 19, 1417-21.
- Carayon, P., Alvarado, C. J., Hundt, A. S., Springman, S., & Ayoub, P. (2006a). Patient safety in outpatient surgery: The viewpoint of the healthcare providers. *Ergonomics*, 49(5-6), 470-485.
- Carayon, P., Hundt, A. S., Karsh, B.-T., Gurses, A. P., Alvarado, C. J., Smith, M., et al. (2006b). Work system design for patient safety: The SEIPS model. *Quality & Safety in Health Care*, 15(Supplement I), i50-i58.
- Carayon, P., Hundt, A., Alvarado, C., Springman, S., Borgsdorf, A., & Jenkins, L. (2005). Implementing a systems engineering intervention for improving safety in outpatient Surgeries. *Advances in Patient Safety*, 3.
- Carayon, P., Wetterneck, T.B., Hundt, A.S., Ozkaynac, M., Ram, P., DeSilvey, J., Hicks, B., Roberts, T.L., Enloe, M., Sheth, R. and Sobande, S. (2004). Assessing nurse interaction with medication administration technologies: The development of observation methodologies. Paper presented at the WWCS Conference, Kuala Lumpur, Malaysia.
- Carley, K.M. (1997). Extracting team mental models through textual analysis. *Journal of Organizational Behavior*, 18, (S1), 533-558
- Carmines, E. & Zeller, R. (1979). *Reliability and validity assessment*. Thousand Oaks, CA: Sage Publications, Inc.
- Carthey, J., de Leval, M.R., and Reason, J.T. (2000). The human factor in cardiac surgery: errors and near misses in a high technology medical domain. *The Annals of Thoracic Surgery*, 72, 300-305.
- Carthey, J., de Leval, M.R., Wright, D.J., Farwell, V.T., and Reason, J.T. (2003). Behavioural markers of surgical excellence. *Safety Science*, 41, 409-425.
- Christian, C.K., Gustafson, M.L., Roth, E.M., Sheridan, T.B., Gandhi, T.K., Dwyer, K., Zinner, M.J., Dierks, M.M. (2006). A prospective study of patient safety in the operating room. *Surgery*, 139, 159-73.
- Cohen, M. D., & Hilligoss, P. B. (2010). The published literature on handoffs in hospitals: deficiencies identified in an extensive review. *Quality and Safety in Health Care*, 19, 493-497.
- Cooper, J. B., Long, C.D., Newbower, R.S., & Philip, J.H. (1982). Critical incidents associated with intraoperative exchanges of anesthesia personnel. *Anesthesiology*, 56(6), 456-461.
- Creswell. J.W. (2003) *Research design: qualitative, quantitative and mixed methods approaches* (2nd ed.). London: Sage.
- Creswell. J.W. (2009) *Research design: Qualitative, quantitative and mixed methods approaches* (3rd ed.). London: Sage.
- Creswell, J. W. (2007). *Qualitative inquiry & research design: Choosing among five approaches* (2nd ed.). Thousand Oaks: Sage Publications, Inc.

- Creswell, J. W., & Miller, D. L. (2000). Determining validity in qualitative inquiry. *Theory into Practice*, 39(3), 124-130.
- de Leval, M.R., Carthey, J., Wright, D.J., Farwell, V.T., and Reason, J.T. (2000). Human factors and cardiac surgery: a multicenter study. *Journal of Thoracic Cardiovascular Surgery*, 119, 661-672.
- Dracup, K. & Morris, P. (2008). Passing the torch: the challenge of handoffs. *American Journal of Critical Care*, 17(2), 95-97.
- De Keyser, V., and Woods, D.D. (1990). Fixation errors: failures to revise situation assessment in dynamic and risky systems. In: Colombo AG, Saiz de Bustamante A (eds). *Systems Reliability Assessment*, 231–251.
- Devers, K. J. (1999). How will we know "good" qualitative research when we see it? Beginning the dialogue in health services research. *Health Services Research*, 34(5 Part II), 1153-1188.
- Denzin, N.K. (1978). *Sociological Methods*. New York: McGraw-Hill.
- Duff, S.N., Windham, T.C., Wiegmann, D.A., Kring, J., Schaus, J.D., Malony, R., & Boquet, A. (2010). Identification and classification of flow disruptions in the operating room during two types of general surgery procedures. *Human Factors and Ergonomics Society Annual Meeting Proceedings*, 54, 884-888.
- Dunn & Murphy. (2008). The patient handoff: Medicine's formula one moment. *Chest Journal*, 134, 9-12.
- Emerson, E., Reeves, D., Thompson, S., Henderson, D., Roberston, J., and Howard, D. (1996). Time-based lag sequential analysis and the functional assessment of challenging behavior. *Journal of Intellectual Disability Research*, 40(3), 260-274.
- Elbardissi, A.W., Wiegmann, D.A., Dearani, J.A., Daly, R.C., Sundt, T.M. (2007). Application of the human factors analysis and classification system methodology to the cardiovascular surgery operating room. *The Annals of Thoracic Surgery*, 83, 1412-1419.
- Fulk, J., Monge, P. & Hollingshead, A. (2005). Knowledge resource sharing in dispersed multinational teams: Three theoretical lenses. In D. Shapiro, M.A. Von Glinow & J. Cheng (Eds.), *Managing multinational teams: Global perspectives* (pp. 155-188). Amsterdam: Elsevier.
- Gottman, J. M. and Roy, A. K. (1990). *Sequential analysis: a guide for behavioral researchers*, Cambridge: Cambridge University Press
- Greenberg, C., Regenbogen, S., Studdert, D., Lipsitz, S., Roger, S., Zinner, M., Gawande, A. (2007). Patterns of communication breakdowns resulting in injury to surgical patients. *Journal of American College of Surgeons*, 204, 533-540.
- Guerlain, S., Smith, P.J., Obradovich, J.H., Rudmann, S., Strohm, P., Smith, J.W., Svirebely, J., and Sachs, L. (1999). Interactive critiquing as a form of decision support: an empirical evaluation. *Human Factors*, 41, 72–89.
- Guzzo, R. A., & Dickson, M. W. (1996). Teams in organizations: Recent research on performance and effectiveness. *Annual Review of Psychology*, 47, 307-338.
- Haig, K.M., Sutton, S., & Whittington, J. (2006). SBAR: a shared mental model for improving communication between clinicians. *Joint Commission Journal on Quality and Patient Safety*, 32(3), 167-75.
- Hawks, I. K. (1987). Facilitativeness in small groups: a process-oriented study using lag sequential analysis. *Psychological reports*, 61, 955-962.

- Hayes, C., & Miller, C.A. (2010). Human-computer etiquette. USA:Taylor and Francis.
- Healey, A.N., Sevdalis, N., Vincent, C.A. (2006). Measuring intra-operative interference from distraction and interruption observed in the operating theatre. *Ergonomics*, 49(5-6), 580-604.
- Heffner, T. S., Mathieu, J. E., & Goodwin, G. F. (1995). An empirical investigation of mental models in team performance. In J. E. Mathieu (Eds.), *Mental models and team effectiveness: Three empirical tests*. Symposium conducted at the Annual Meeting of the Society for Industrial and Organizational Psychology, Orlando, FL.
- Henrickson, S.E., Laviana, A.A., Wadhera, R.K., Wiegmann, D.A., & Sundt III, T.M. (2010). Development and evaluation of an observational tool for assessing surgical flow disruptions and their impact on surgical performance. *World Journal of Surgery*, 34(2), 353-361.
- Hollingshead, A. B. (1998a). Distributed knowledge and Transactive processes in groups. In M. A. Neale, E. A. Mannix, and D. H. Gruenfeld (Eds.), *Research on managing groups and teams* (Vol.1). Greenwich, CT: JAI Press
- Horwitz, L., Meredith, T., Schuur, J., Shah, N., Kulkarni, r., & Jenq, G. (2009). Dropping the baton: A qualitative analysis of failures during the transition from emergency department to inpatient care. *Annals of Emergency Medicine*, 53(6), 701-710.
- Horwitz, L.I., Parwani, V., Shah, N., Schuur, J., Meredith, T., Jenq, G., & Kulkarni, R. (2009). Evaluation of an asynchronous physician voicemail sign-out for emergency department admissions. *Annals of Emergency Medicine*, 53(3), 368-378.
- Hundt, A.S., Carayon, P., Springman, S.R., Smith, M., Florek, K., Sheth, R. and Dorshort, M. (2004). Outpatient surgery and patient safety – the voice of the patient. *Advances in Patient Safety: From Research to Implementation*, 4.
- Hundt, A., Carayon, P., Ayoub, P. and Alvarado, C. (2003). Collecting workers' perceptions of performance obstacles in outpatient surgery. Annual Conference of the Human Factors and Ergonomics Society Conference, Denver, Colorado.
- Jacques, P.S., France, D.J., Pilla, M., Lai, E., & Higgins, M.S. (2006). Evaluation of a hands-free wireless communication device in the perioperative environment. *Telemed Journal and E-Health*, 12,(1), 42-49.
- Jenkin, A., Abelson-Mitchell, N., & Cooper, S. (2007). Patient hand-over: time for a change? *Accident and Emergency Nursing*, 15, 141-147.
- Jones, D., Bates, S., Warrillow, S., Opdam, H., Goldsmith, D., Gutteridge, G., and Bellomo, R. (2005). Circadian pattern of activation of the medical emergency team in a teaching hospital. *Critical Care*, 9,4,R303-306.
- Joint Commission (2006). *National patient safety goals: 2006 critical access hospital and hospital national patient safety goals*.
- Joint Commission (2008). *2008 national patient safety goals handbook*, 1-19.
- Karsh, K.G., Repp, A.C. & Ludewig, D. (1989) PCS: portable computer systems for observational research. Communitech International, DeKalm, IL.
- Klaber and Macdougall (2009). Maximizing learning opportunities in handover. *Archives of Disease in Childhood, Education & Practice Edition*, 94, 118-122.
- Kraiger, K., & Wenzel, L. H. (1997). A framework for understanding and measuring shared mental models of team performance and team effectiveness. In E. Salas, M. T. Brarmick, & C. Prince (Eds.), *Team performance assessment and measurement: Theory, methods, and applications* (pp. 63-84). HiUsdale, NJ: Erlbaum.

- Leora, I., Horwitz, L., Harlan, M., et al. (2006). Transfers of patient care between house staff on internal medicine wards: a national survey. *Archives of Internal Medicine*, 166, 1173-1177.
- Lewis, K. 2003. Measuring transactive memory systems in the field: Scale development and validation. *Journal of Applied Psychology*, 88: 587-604.
- Lewis, K. 2004. Knowledge and performance in knowledge-worker teams: A longitudinal study of transactive memory systems. *Management Science*, 50: 1519-1533.
- Lewis, K., D. Lange, L. Gallis. 2005. Transactive memory systems, learning, and learning transfer. *Organization Science*, 16(6) 581–598
- Lim, B., & Klein, K. J. (2006). Team mental models and team performance: A field study of the effects of team mental model similarity and accuracy. *Journal of Organizational Behavior*, 27, 403-418.
- Lingard L, Espin S, Whyte S, Regehr, G., Baker, G.R., Reznick, R., Bohnen, J., Orser, B., Doran, D., & Grober, E. (2004). Communication failures in the operating room: an observational classification of recurrent types and effects. *Quality and Safety in Health Care*, 13,330-334.
- Malterud, K. (2001). Qualitative research: Standards, challenges and guidelines. *The Lancet*, 358, 483-488.
- Mathieu, J.E., Heffner, T.S., Goodwin, G.F., Salas, E., & Cannon-Bowers, J. A. (2000). The influence of shared mental models on team process and performance. *Journal of Applied Psychology*, 85(2), 273-283.
- Mays, N., & Pope, C. (2000). Qualitative research in health care - Assessing quality in qualitative research. *British Medical Journal*, 320(7226), 50-52.
- McGill, P., Hewson, S. & Emerson E. (1994). CTS: A software package for the collection of observational data on psion organisers. Tizard Centre, University of Kent, Canterbury.
- Mcintyre, R. M., & Salas, E. (1995), Measuring and managing for team performance: Emerging principles from complex environments. In R.Guzzo & E. Salas (Eds.), *Team effectiveness and decision making in organizations* (pp. 149-203). San Francisco: Jossey-Bass.
- Mistry, K. P., Jagers, J., Lodge, A. J., Alton, M., Mericle, J. M., Frush, K. S., & Meliones, J.N. (2008). Using Six Sigma methodology to improve handoff communication in high-risk patients. Retrieved September 16, 2010 from http://www.ahrq.gov/downloads/pub/advances2/vol3/Advances-Mistry_114.pdf
- Michinov, N., & Michinoy, E. (2009). Investigating the relationship between transactive memory and performance in collaborative learning. *Learning and Instruction*, 19, 43-54
- Miles, M., & Huberman, M. (1984). *Qualitative data analysis: A sourcebook of new methods*. Beverly Hills, CA: SAGE Publications.
- Miles, M., & Huberman, M. (1994). *Qualitative data analysis: An expanded sourcebook*. Beverly Hills, CA: SAGE Publications.
- Merriam, S. (1998). *Qualitative research and case study applications in education*. Revised and expanded from “case study research in education.” San Francisco, CA: Jossey-Bass Publishers.
- Mitchell, R., Chung, A., Williamson, A.N., & Molesworth, B. (2011). Human factors and healthcare-related deaths: review of coronial findings using a human factors classification framework. *Ergonomics Australis Journal-HFESA Conference Edition*, 11, 18.
- Mohammed, S., & Dumville, B., (2001). Team mental models in a team knowledge framework:

- expanding theory and measurement across disciplinary boundaries. *Journal of Organizational Behavior*, 22, 89-106.
- Montague, E., Xu, J., Chen, P., Asan, O., Barrett, B.P., & Chewing, B. (2011). Modeling eye gaze patterns in clinician-patient interaction with lag sequential analysis. *The Journal of the Human Factors and Ergonomics Society*, 53,3, 502-516.
- Moreland, R. L., L. Argote. 2003. Transactive memory in dynamic organizations. In R. Peterson, & E. Mannix (Eds.), *Understanding the Dynamic Organization*. Lawrence Erlbaum Associates, Mahwah, NJ, 135–162
- Moreland, R. L. (1999). Transactive memory: Learning who knows what in work groups and organizations. In L. Thompson, D. Messick, & J. Levine (Eds.), *Shared cognition in organizations: The management of knowledge* (pp. 3–31). Mahwah, NJ: Erlbaum
- Mortensen, C.D. (1972). *Communication: The study of human communication*. New York: McGraw-Hall Book Co.
- Nagpal, K., Vats, A., Lamb, B., Ashrafian, H., Sevdalis, N., Vincent, C., & Moorthy, K. (2010). Information transfer and communication in surgery: a systematic review. *Annals of Surgery*, 252(2), 225-239.
- Nestel, D. & Kidd, J. (2006). Nurses' perceptions and experiences of communication in the operating theatre: a focus group interview. *British Medical Journal Nursing*, 5(1).
- Neuman, W.L. (2000). *Social research methods: Quantitative and qualitative approaches* (4th ed.). Needham Heights, AM: Allyn & Bacon.
- Owen, C., Hemmings, L., & Brown, T., (2009). Lost in translation: maximizing handover effectiveness between paramedics and receiving staff in the emergency department. *Emergency Medicine Australasia*, 21, 102-107.
- Olson, G. M., Herbsleb, J. D. and Rueter, H. H. (1994). Characterizing the sequential structure of interactive behaviors through statistical and grammatical techniques. *Human-Computer Interaction*, 9, 427-472.
- Ong, M. & Coiera, E. (2011). A systematic review of failures in handoff communication during intrahospital transfers. *Joint Commission Journal on Quality and Patient Safety*, 37, 6, 274-8AP.
- Patterson, E.S. (2008). Structuring flexibility: the potential good, bad and ugly in standardization of handovers. *Quality & Safety in Health Care*, 15, 4-5.
- Patterson, E.S. & Wood, D.D. (2001). Shift changes, updates, and the on-call architecture in space shuttle mission control. *Computer Supported Cooperative Work Archive*, 10, 317-346.
- Patterson, E.S., Roth, E.M., Woods, D.D., Chow, R., & Gomes, J.O. (2004). Handoff strategies in settings with high consequences for failure: lessons for health care operations. *International Journal for Quality in Health Care*, 16(2), 125-132.
- Patton, M.Q. (1999). Enhancing the quality and credibility of qualitative analysis. *Health Services Research*, 34(5), 1189-1208.
- Perry, S.J., Wears, R.L., Patterson, E.S. (2008). High-Hanging fruit: improving transitions in health care. *Advances in Patient Safety: New Directions and Alternative Approaches*. 3, Agency for Healthcare Research and Quality, Rockville, MD. Retrieved March 14, 2011 from <http://www.ahrq.gov/qual/advances2/>
- Philibert, I. (2009). Use of strategies from high-reliability organizations to the patient hand-off by resident physicians: practical implications. *Quality & Safety in Health Care*, 18, 261-266.
- Philibert, I. & Leach, D.C. (2005). Re-framing continuity of care for this century. *Quality &*

- Safety in Health Care, 14*, 394-396.
- Putnam, L. L. (1981). Procedural messages and small group work climates: A lag sequential Analysis. In Burgoon M (Eds), *Communication Yearbook 5*, Transaction Books, 331-350
- Rasmussen, J., Pejtersen, A.M., and Goodstein, L.P. (1994). *Cognitive systems engineering*. New York: Wiley.
- Ren, Y., Carley, K.M., Argote, L. (2006). The contingent effect of transactive memory: When is it more beneficial to know what others know? *Management Science, 52(5)*, 671-682.
- Rodriguez, M., Chambers, T., Gonzalez, M., Scheurich, J. (2010). A cross-case analysis of three social justice-oriented education programs. *Journal of Research on Leadership Education, 5*, 138-153.
- Rouse, W., Morris, N. (1986). On looking into the black box: Prospects and limits in the search for mental models. *Psychological Bulletin, 100*, 359-396.
- Sackett, G. P. (1987). Analysis of sequential social interaction data: some issues, recent developments, and a causal inference model. In Osofsky, J. D. (Eds), *Handbook of Infant Development*, New York: Wiley, 855-878
- Sainfort, F., Booske, B.C. and Karsh, B. (2001). Job and Organizational Determinants of Employee Perceptions of Nursing Home Quality. Proceedings of the 13th Annual Society for Health Systems Conference (pp. 143-152). Norcross, GA: Institute of Industrial Engineers.
- Saldana, J. (2009). *The coding manual for qualitative researchers*. London, UK: Sage Publications.
- Sandelowski, M. (1986). The problem of rigor in qualitative research. *Advances in Nursing Science, 8(3)*, 27.
- Schraagen, J.M., Schouten, T., Smit, M., Hass, F., Beek, D., Ven, J., Barach, P. (2010). Assessing and improving teamwork in cardiac surgery. *Quality and Safety in Health Care, 19*, 1-6.
- Schraagen, J.M., Schouten, T., Smit, M., Hass, F., Beek, D., Ven, J., Barach, P. (2011). A prospective study of paediatric cardiac surgical Microsystems: Assessing the relationships between non-routine events, teamwork and patient outcomes. *British Medical Journal Quality & Safety, 20(7)*, 599-603.
- Sharit, J., McCane, L., Thevenin, D.M., & Barach, P. (2005). Examining issues in communicating patient care information across shifts in a critical care setting. *Proceedings of the Human Factors Ergonomics Society 49th Meeting*, 1062-1066.
- Smith, A., Pope, C., Goodwin, D., Mort, M. (2008). Interprofessional handover and patient safety in anaesthesia: observational study of handovers in the recovery room. *British Journal of Anaesthesia, 101* (3), 332-337.
- Solet, D.J., Norvell, J.M., Rutan, G.H., & Frankel, R.M. (2005). Lost in translation: challenges and opportunities in physician-to-physician communication during patient handoffs. *Academic Medicine, 80(12)*, 1094-1099.
- Soto, R.G., Chu, L.F., Goldman, J.M., Rampil, I.J., Ruskin, K.J. (2006). Communication in critical care environments: mobile telephones improve patient care. *Anesthesia & Analgesia, 102*, 535-541.
- Stout, R. J., Cannon-Bowers, J. A., & Salas, E. (1996). The role of shared mental models in developing team situational awareness: Implications for training. *Training Research Journal, 2*, 85-116.
- Stout, R.M. & Salas, E. (1993). The role of planning in coordinated decision making:

- Implications for training. In Proceedings of the Human Factors and Ergonomics Society 37th Annual Meeting (pp. 1238-1242). Santa Monica, CA: Human Factors and Ergonomics Society.
- Stout, R.J., Cannon-Bowers, J.A., Salas, E., & Milanovich, D.M. (1999). Planning, shared mental models, and coordinated performance: An empirical link is established. *Human Factors*, 41(1), 61-71.
- Suserud, B., Bruce, K.. (2003). Ambulance nursing-part three. *Emergency Nurse*, 11, 16-21.
- Talbot, R. & Bleetman, A., (2007). Retention of information by emergency department staff at ambulance handover: do standardized approaches work? *Emergency Medicine Journal*, 24, 539-542.
- Thakore, S. & Morrison, W., (2001). A survey of the perceived quality of patient handover by ambulance staff in the resuscitation room. *Emergency Medicine Journal*, 18, 293-296.
- Tversky, A., and Kahneman, D. (1974). Judgment under uncertainty: heuristics and biases. *Science*, 185, 1124–31.
- Ulmer, C., Wolman, D.M., & Johns, M.M.E. (2008). Resident duty hours: Enhancing sleep, supervision, and safety (pp.480). Washington, DC: National Academies Press.
- Van den Bossche, P., Gijssels, W., Segers, M., Woltjer, K., Kirschner, P. (2010). Team learning: building shared mental models. *Instructional Science*.
- Wadhwa, R., Hendrickson, S., Burkhart, H., Greason, K., Neal, J., Levenick, K., Wiegmann, D., & Sundt III, T. (2010). Is the “sterile cockpit” concept applicable to cardiovascular surgery critical intervals or critical events? The impact of protocol-driven communication during cardiopulmonary bypass. *Journal of Thoracic and Cardiovascular Surgery*, 139, 321-319.
- Walker, D. (1995). The handover process. *Australian Journal of Emergency Care*, 2, 11–12.
- Wears, R.L., Perry, S.J., Shapiro, M., Beach, C., Croskerry, P., and Behara, R. (2003). Shift changes among emergency physicians: Best of times worst of times. Proceedings of the Human Factors and Ergonomics Society 47th Annual Meeting, 1420-1423.
- Weber, Robert P. (1990). *Basic content analysis*. (2nd ed.) Newbury Park, CA: Sage Publications. A standard introductory overview.
- Webster, J.L., Cao, C.G. (2006). Lowering communication barriers in operating room technology. *Human Factors*, 48, 747–758.
- Weinger, M.E. & Slagle, J. (2002). Human factors research in anesthesia patient safety: Techniques to elucidate factors affecting clinical task performance and decision making. *Journal of the American Medical Informatics Association*, 9(6), S58-S63.
- Weinger, M.B., Slagle, J., Jain, S., & Ordonez, N. (2003). Retrospective data collection and analytical techniques for patient safety studies. *Journal of Biomedical Informatics*, 36, 106-119.
- Wegner, D. M., Giuliano, T., & Hertel, P. (1985). Cognitive interdependence in close relationships. In W. J. Ickes (Eds.), *Compatible and incompatible relationships* (pp. 253-276). New York: Springer-Verlag.
- Wegner, D. M. (1995). A computer network model of human transactive memory. *Social Cognition*, 13, 319–339.
- Wegner, D. M. (1986). Transactive memory: A contemporary analysis of the group mind. In B.Mullen & G. R. Goethals (Eds.), *Theories of group behavior* (pp. 185–205). New York: Springer-Verlag
- Wegner, D. M., Erber, R., & Raymond, P. (1991). Transactive memory in close relationships. *Journal of Personality and Social Psychology*, 61, 923-929.

- Wiegmann, D., Eggman, A., ElBardissi, A., Henrickson-Parker, S., & Sundt III, T. (2010). Improving cardiac surgical care: A work systems approach. *Applied Ergonomics*, 41(5), 701-712
- Wiegmann, D.A., ElBardissi, A.W., Dearani, J.A., Daly, R.C., & Sundt, T.M. (2007). Disruptions in surgical flow and their relationships to surgical errors: An exploratory investigation. *Surgery*, 142, 658-665.
- Woods, D.D. & Cook, R.I. (1999). Perspectives on human error: hindsight biases and local rationality. In F.T. Durso, R.S. Nickerson, R.W. Schvaneveldt, S.T. Dumais, D.S. Lindsay, M.T.H. Chi (Eds). *Handbook of applied cognition*. New York: Wiley
- Wong, M.C., Turner, P., & Yee, K.C. (2007). Socio-cultural issues and patient safety: a case study into the development of an electronic support tool for clinical handover. *Information Technology in Healthcare*, 130, 279-289.
- Yong, G., Dent, A., & Weiland, T. (2008). Handover from paramedics: observations and emergency department clinician perceptions. *Emergency Medicine Australasia*, 2, 149-155

Appendices

Appendix A: Developing an Observational Tool... (Blocker et al., 2010)

PROCEEDINGS of the HUMAN FACTORS and ERGONOMICS SOCIETY 54th ANNUAL MEETING - 2010

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DEVELOPING AN OBSERVATIONAL TOOL FOR RELIABLY IDENTIFYING WORK SYSTEM FACTORS IN THE OPERATING ROOM THAT IMPACT CARDIAC SURGICAL CARE

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The objective of this study is to develop a reliable Tablet-PC based observational tool for identifying work systems factors that impact cardiac surgical care. Using the tool we observed 26 open heart surgeries over a five-month period. In thirteen of the 26 observations, both observers stood in the same location and in the other thirteen cases the observers stood in different locations within the operation room (OR). The surgical cases typically last five hours and were conducted in multiple operating rooms within the hospital and with mixed surgical teams. There was an average of 8.49 flow disruptions per hour related to work system factors with an average of 42.45 disruptions per case. Results revealed that inter-rater reliability in identifying work system factors that disrupted surgical flow was roughly 87% when observers were standing in the same location. However, when standing in different locations, the reliability decreased to an average of 75%.

INTRODUCTION

Over the past 50 years, there have been significant improvements in the number of patients who survive and fully recover from open heart surgery (Likosky et al., 2008). However, considerable variability in surgical outcomes still exists across institutions, and surgical errors that significantly impact patient safety continues to be reported in both the professional literature and the public media. Many of those surgical errors are due to work system factors, contrary to the historical notion that surgical errors are due entirely to the skills of the individual surgeon.

A work systems perspective asserts that an individual surgeon's skill alone is not sufficient to determine surgical outcomes, because the process of delivering surgical care involves several interdependent variables that may or may not be under the control of the surgical team. The Systems Engineering Initiative for Patient Safety (SEIPS) model (Carayon et al., 2003) indicates that in addition to surgical skill (individual factors) and the condition of the patient (task factors), errors and patient outcomes are also impacted by factors that disrupt the surgical flow in the operating room (OR). These include distractions in the working environment, technology/tool design and organizational processes (ElBardissi et al., 2007; Carthey et al., 2001; Wiegmann et al., 2003).

In order to continuously improve the success rate and reliability of cardiac surgery, we must move from the historical notion that surgical errors are caused by individual surgeons and focus our attention on identifying and rectifying sources of system variability

that negatively impact the delivery of safe and effective surgical care. Anecdotal and sentinel event reports lack detail concerning the specific nature of systemic problems; however, these reports account for the majority of data collected on patient safety in the operating room. Consequently, there is a need for the development of reliable tools for proactively identifying work system factors. Without such tools, empirical evaluations of process improvement initiatives on patient safety will certainly be difficult to ascertain.

The purpose of this study is to develop and validate a computer-based measurement tool for reliably identifying work system factors in the OR that impact cardiac surgical care.

Background and Instrumentation

In the preliminary study (Wiegmann et al., 2007), data was collected using a blank sheet of paper, observers were not provided with a structured form, and classification of events occurred after the fact rather than in real time, which is often much more efficient. To address these issues, several paper and pencil data collection tools have been developed within the context of surgery (Healy et al., 2004; Sevdalis et al., 2008). We, too, have previously validated a paper-based prototype for a new Tablet-PC data collection tool (Hendrickson et al., 2010). The paper-based prototype was developed from the foundations of several previous publications and allowed us to further define specific categories of surgical flow and the real-time classification of these events during open heart surgery.

With all the benefits of paper-based data collection tools, there are still several issues that

computerized tools might help to overcome. For example, computer-based tools can be used to automate several functions (such as time stamping events) which could allow for more events to be documented (e.g., events can be missed when one is writing for a long time on a paper form). Data can also be more easily merged into databases for analysis, avoiding potential transcriptions and data-entry errors associated with paper-based tools. As a result of the unique qualities of PC-based tools, however, reliability data from observations performed using paper-based prototypes cannot automatically be assumed to be the same for the PC-based tool.

In this paper, we describe a Tablet-PC tool for collecting work system factors that impact surgical flow during cardiac surgery. The goal was to evaluate the inter-rater reliability of observers using the tool when standing in similar locations in the OR. However, because our previous research also found that the types of events observed during surgery depend upon the location of the observer in the OR, we further tested inter-rater reliability when observers were standing in different locations within the surgical suite.

METHODS

Participants

Participants in the study were surgical staff who performed normal activities in the OR during observation periods at a large academic medical hospital. The staff was observed for the duration of a surgical case on multiple occasions over a five month period. Team mixing was a common practice in this hospital; therefore, many of the staff members were observed on multiple occasions.

No personal information regarding patient or surgical team personnel was collected. The Institutional Review Board (IRB) waived the requirement of informed consent. However, surgical teams were informed that the observer would be monitoring the case for the purpose of understanding surgical team interactions.

Data Collection Tool

A Tablet-PC data collection tool was designed based on the paper prototype described previously (Henrickson et al., 2010). Specifically, the tool helps to capture the onset/offset of events that impacted surgical flow, the nature/type of event, a description of the event, and the magnitude of the disruption and/or impact of the event on surgical performance (see Figure 1). The tool also includes an event history tab (see Figure 2) where

observers can edit entries as needed and a case detail tab (see Figure 3) where observers can input the type of surgical procedure being performed and any delays in start time of the procedure. Our study posits that this tool provides more elaborate and reliable data than using basic unstructured observations alone.



Figure 1: Tablet-PC Data Collect Tool Case Event Tab

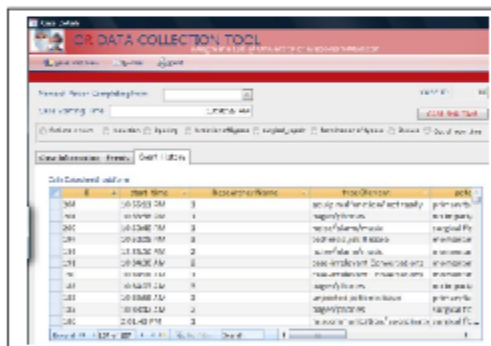


Figure 2: Tablet-PC Data Collect Tool Event History Tab

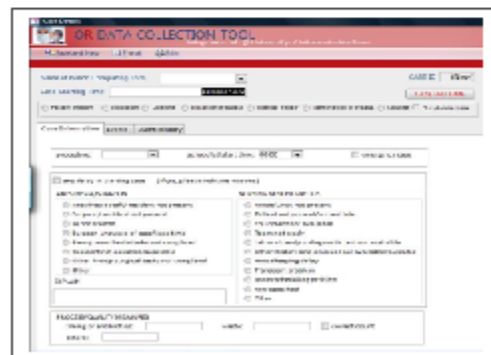


Figure 3: Tablet-PC Data Collect Tool Case Information Tab

Using the PC-based tool, observed events are time-stamped and categorized by observers in real time according to: (1) type of event; (2) the potential and/or actual impact of the event on a scale from 1 to 6; (3) the surgical team member affected by the event; (4) the description of the event; (5) the location of the observer; (6) the stage in the procedure; and (7) whether the event was purposeful in relation to the OR, purposeful in relation to the patient, or not purposeful at all. The type of event was further categorized according to: (1) technical factors (technical skills issue); (2) environmental factors (case-irrelevant conversations, pagers/phones, noises/alarms/music); (3) technology instruments (equipment malfunction/not ready, instruments/devices not at table); (4) training procedures (unexpected patient issues, training difficulty performing procedure); (5) teamwork (miscommunication/coordination); and (6) other (not specified, handoff, observed break).

Data Collection Process

We used multiple observers to code selected cases to establish reliability in our data collection process, with the goal of reaching 80% agreement between a pair of observers. The observational team was composed of a medical student who had received training in human factors and two human factors graduate students who received training in observing medical/surgical teams. Twenty-six observations were conducted over a five-month period. In thirteen of the observations, two observers observed from the same location, and in the other thirteen cases the observers observed from different locations within the OR. Each surgical case lasted roughly five hours. Observations were conducted in multiple operating rooms within a single hospital but across multiple surgical teams. The classification of cardiac surgical procedures observed varied but included procedures such as Coronary Artery Bypass Graft (CABG), Mitral Valve Repair (MVR), and Aortic Valve Replacement (AVR).

RESULTS

Frequency of Flow Disruptions

After analyzing the data collected during the 26 observations, we found a total of 898 flow disruptions in 127.31 hours over a five month period. On average, there were a total of 8.49 flow disruptions per hour and an average of 42.45 flow disruptions per case.

Inter-rater Reliability

Results revealed that inter-rater reliability in identifying work system factors that disrupted surgical flow was roughly 87% when observers were standing in the same location. However, reliability increased slightly to 89% for events that observers rated as highly salient events. Highly salient events are defined as those events coded with an impact of (1) momentary distraction (task cessation or change < 10 seconds), (2) primary task impact interrupted (task cessation or change > 10 seconds), (3) surgical flow disrupted (secondary task engaged) or (4) repeat tasks (see figure 1). However, when standing in different locations, the reliability decreased to an average of 75%.

Event Types

Most of the surgical flow disruptions observed were due to environmental factors—primarily pagers/phones and case-irrelevant conversations. Teamwork was another factor that was identified most often by the observers. The teamwork factors identified were primarily miscommunications among the surgical staff members. The third most commonly identified factor by the observers was equipment malfunctions due to the fact that instrument/devices were not at the table. Overall, the observers identified the potential and/or actual impact of the flow disruptions as momentary in nature. Observers also indicated a significant number of the flow disruptions as having no observable impact. The observers indicated that, on average, the perfusionist and circulating nurse were often impacted by flow disruptions, and the majority of the flow disruptions were purposeful (patient related). Observations mainly took place at either the foot of the patient's bed or in the perfusionist's area.

DISCUSSION

The findings in this study further validate the reliability and validity of the paper-based instrument from which the Tablet PC-based tool was developed: it yields similar results (Hendrickson et al., 2010). In the first thirteen observations, both observers stood in the same location and recorded every event that they deemed a surgical flow disruption from the beginning of the cardiac surgery (the time the patient entered the room) to the end of the cardiac surgery (the time the patient left the room). The observers did not discuss the events that were recorded during the observations, since that would have created a bias. The results from the study revealed that even while both observers were standing in the same location, the observer's expertise had an effect on the

number of events recorded by each observer; however, the observers' inter-rater reliability of 87% exceeded the goal of 80% agreement. In the second thirteen cases, the observers stood in different locations within the OR. As reported in previous studies, the location of the observer had a strong impact on the number of events recorded, thus affecting the inter-rater reliability (Hendrickson et al., 2010; Lingard et al., 2004). In this study, the majority of the observations took place at either the foot of the patient's bed or the perfusionist's area. More events were recorded in the perfusionist's area than at the patient's foot. This was true across observers. It was difficult for the observer at the foot of the patient's bed to capture all events because many of the events were not verbalized and could not be seen/noticed from the patient's foot. We argue that the actual set-up of the OR will make it almost impossible for each observer to capture the same events all the time, as each location provides a view of events that an observer standing in a second location will not be able to record. However, the two observers standing at different locations were still able to maintain an average of 75% inter-rater reliability.

There are a couple of limitations to the use of the Tablet-PC tool. The first limitation is the battery life. If the observer did not adjust the Tablet-PC power plan to conserve power, after six hours the battery would die. The second limitation is the Windows update automatic restart feature; the computer updates would automatically restart the computer in the middle of observations. This occurred a few times during observations and left one of the observers unable to record for about three minutes. The observer's previous data was automatically saved each time. To ensure that the battery did not die during observations, we carried the AC power supply/battery charger adapters with us and the circulating nurse helped us identify sockets within the OR where we could easily plug our Tablet PCs. In regards to the Windows update automatic restart feature, we checked the computer for updates prior to entering the OR and if any updates were needed we would allow the computer to update and restart prior to entering the OR. After implementing these workarounds, we did not experience too many problems regarding the use of the Tablet-PC tool.

While not the primary objective of this study, the results from this study also further validate the assumption that surgical teams are immersed in latent factors that can lead to adverse events (de Leval et al., 2000). While all events were obviously not identified, due to the observers' location and limited surgical knowledge, the events that were identified may lead to adverse events in the OR. The results indicate, on average, that each observer identified 8.49 flow disruptions per hour. Therefore, approximately every 7

minutes and 6 seconds there is a flow disruption that occurs during the surgical procedural, placing both patients and the surgical staff at risk of unforeseeable outcomes.

This study provides a significant contribution to the field, as it validates the results of previous smaller studies (Wiegmann et al., 2007; Hendrickson et al., 2010) that teamwork (miscommunication/coordination) and environmental factors (case-irrelevant conversations, pagers/phones, noise/alarms/music) are the leading work system factors that may lead to adverse events in the OR. Therefore, teamwork and environmental factors need to be addressed so that data-driven interventions may be implemented and tested with the goal of reducing surgical disruptions. Clearly, however, a tool for reliably assessing the impact of interventions on improving patient safety is needed to validate such programs.

FUTURE RESEARCH

This study was conducted at a single academic hospital that has potentially unique characteristics such as team composition, available technology, and organizational structure. We, therefore, plan to conduct another study to examine the reliability of our tool and the nature of surgical flow disruptions during cardiac surgery in a non-academic hospital setting. Results will provide further insight into the applicability of our tool and the generalizability of our findings.

ACKNOWLEDGEMENT

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REFERENCES

- Carayon P, & Smith M.J. (2000). Work organization and ergonomics. *Applied Ergonomics*, 31(6), 649-662.
- Carayon, P., Alvarado, C.J., Brennan, P., Gurses, A., Hundt, A., Karsh, B., Smith, M. (2003). Work system and patient safety. In H. Luczak & K.J. Zink (Eds), *Human factors in organizational design and management-VII* (pp. 583-589). Santa Monica, CA: IEA Press.
- Carthey, J., de Leval, M.R., Reason, J.T. (2001). The human factor in cardiac surgery: Errors and near misses in high technology medical

- domain. *Annals of Thoracic Surgery*, 72, 300-305.
- de Leval, M.R., Carthey, J., Wright, D.J., Farewell, V.T., & Reason, J.T. (2000). Human factors and cardiac surgery: A multicenter study. *Journal of Thoracic and Cardiovascular Surgery*, 119(4), 661-672.
- ElBardissi, A., Wiegmann, D., Dearani, J., & Sundt, T. (2007). Application of the Human Factors Analysis Classification System (HFACS) methodology to the cardiovascular surgery operating room. *Annals of Thoracic Surgery*, 83, 1412-1419.
- Flin, R., Martin, L., Goeters, K., Hormann, J., Amalberti, R., Valot, C., & Nuijhsen, H. (2003). Development of theNOTECHS (non-technical skills) system for rating pilots' CRM skills. *Human Factors and Aerospace Safety*, 3, 95-117.
- Healy, A.N., Undre, S., & Vincent, C.A. (2004). Developing observational measures of performance in surgical teams. *Quality and Safety in Health Care*, 13 (Suppl 1), i33-i40.
- Helmreich, R.L., Roushee, H.C. (1993). Why crew resource management? Empirical and theoretical bases of human factorstraining in aviation. In: Wiener E, Kanaki B, Helmreich R (eds), (pp.3-45). *Cockpit Resource Management*. San Diego, CA: Academic Press.
- Henrickson, S.E., Laviana, A.A., Wadhera, R.K., Wiegmann, D.A., & Sundt III, T.M. (2010). Development and evaluation of an observational tool for assessing surgical flow disruptions and their impact on surgical performance. *World Journal of Surgery*, 34(2), 353-361.
- Likosky, D., Dacey, L., Baribeau, Y., Leavitt, B., Clough, R., Cochran, R., Quinn, R., Sisto, D., Charlesworth, D., Malenka, D., MacKenzie, T., Olmstead, E., Ross, C., & O'Connor, G. (2008). Long-term survival of the very elderly undergoing coronary artery bypass grafting. *Annals of Thoracic Surgery*, 85(4), 1233-1237.
- Lingard, L., Espin, S., Whyte, S., Regehr, G., Baker, G.R., Reznick, R., Bohenen, J., Orser, B., Doran, D., Grober, E. (2004). Communication failures in the operating room: An observational classification of recurrent types and effects. *Quality and Safety in Health Care*, 13, 330-334.
- Malec, J.F., Torsher, L.C., Dunn, W.D., Wiegmann, D.A., Arnold, J.J., & Brown, D.A. (2007). The high performance teamwork (HPT) scale: Reliability and validity for evaluating key crew resource management skills. *Simulation in Healthcare*, 2(1), 4-10.
- Sevdalis, N., Davis, R., Koutantji, M., Undre, S., Darzi, A., & Vincent, C. (2008). Reliability of a revised NOTECHS scale for use in surgical teams. *American Journal of Surgery*, 196, 184-190.
- Wiegmann, D.A., Shappell, S.A. (2003). *Human error approach to aviation accident analysis: the human factors analysis and classification system*. Burlington, VT: Ashgate Press.
- Wiegmann, D.A., ElBardissi, A.W., Dearani, J.A., Daly, R.C., & Sundt, T.M. (2007). Disruptions in surgical flow and their relationships to surgical errors: An exploratory investigation. *Surgery*, 142, 658-665.
- Yule, S., Flin, R., Paterson-Brown, S., & Maran, N. (2006). Non-technical skills for surgeons in the operating room: a review of the literature. *Surgery*, 139, 140-149.
- Yule, S., Flin, R., Maran, N., Rowley, D., Youngson, G., Paterson-Brown, S. (2008). Surgeons' non-technical skills in the operating room: Reliability testing of the NOTSS behavior rating system. *World Journal of Surgery*, 32, 548-556.

Appendix B: Institutional Review Board Proposal and Approval

I. Institutional Review Board (IRB) Proposal

Improving Cardiac Surgical Care: A Work Systems Approach

UW Madison Health Sciences Minimal Risk IRB Formal Protocol

Douglas A Wiegmann, UW Madison – ISyE Department

Protocol Version Date: 04/24/2009

Coordinating Center: University of Wisconsin - Madison

Funding Sponsor: ICTR Grant

<i>Study Team</i>	<i>Credentials</i>	<i>Department</i>	<i>Role Description</i>
Niloo Edwards	MD	Surgery, UW-Madison	Co-Investigator, analyze data
Hope Maki	MD	Marshfield Clinic	Co-Investigator, analyze data
Renaldo Blocker	MS	ISyE	Doctoral Research Assistant, obtain subject consent, observe surgeries
Elise (Chi-Tao) Wu	BS	ISyE	Graduate Research Assistant, obtain subject consent, observe surgeries
Ashley Eggman	BS	ISyE	Graduate Research Assistant, obtain subject consent, observe surgeries

Study Objectives

Over the past 50 years, significant improvements in the number of patients who survive and fully recover from open heart surgery have occurred. The average complication rate for most heart surgeries is now less than 5%. Nevertheless, considerable variability in surgical outcomes still exists across institutions and individual surgeons, and surgical errors that significantly impact patient safety continue to be reported in both the professional literature and the public media. Historically, surgical errors have been viewed as being determined solely by the technical skill of the surgeon. However, focusing only on individual skill assumes that surgeons and other members of the surgical team will perform highly and uniformly, regardless of the variable working conditions within the operating room (OR) environment. Alternatively, a work systems approach recognizes that surgical skill alone is not sufficient to determine outcomes because the process of delivering surgical care involves several interdependent variables, many of which vary across hospitals, operating rooms or surgical cases and most of which are not normally under the control of the surgical team. Staffing, workload, noise, equipment reliability, team familiarity, and the general conditions of the operating environment may all affect anesthesia, nursing and surgical performance. The implication of this argument is that to further improve the success rate and reliability of cardiac surgery, we must focus on identifying and rectifying sources of system variability that negatively impact the delivery of safe and effective surgical care. Indeed, this is the approach to safety that has been adopted and successfully applied in other high-risk domains such as the aviation and nuclear power industries. Our **long-term goal**, therefore, is to further improve cardiac surgical care by enhancing or re-engineering the surgical care process. The **immediate goal** of this pilot project is to develop a methodology for reliably identifying work system factors in the operating room that negatively impact surgical performance, so that future data-driven interventions for reducing errors and improving surgical care can be developed and evaluated.

Study Aims

Specific Aim #1 – *Develop and validate a measurement tool for reliably identifying work system factors in the OR that impact cardiac surgical care.* Our preliminary study applying the SEIPS model to the cardiac surgery OR indicates that important work system factors include teamwork failures, technological malfunctions, external interruptions, and resource availability. Still, several other system factors may exist and a method for reliably measuring these variables needs to be developed.

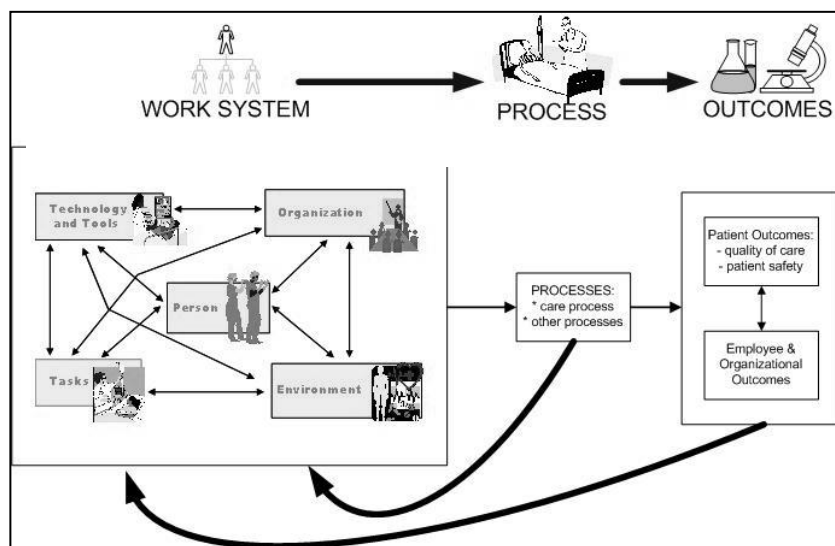
Specific Aim #2 – *Identify the types of surgical errors and patient care variables that are negatively impacted by work system factors in the OR.* Our goal is to identify the impact that work system factors in the OR have on the occurrence of intraoperative risk factors (processes of care and patient variables during surgery) that have been linked to either postoperative outcomes or to increases in the cost of care. Given negative postoperative events are somewhat infrequent, it would be infeasible as part of this pilot project to observe enough cases to use postoperative events as the primary outcome variable. Nevertheless, establishing a relationship between intraoperative work system factors and “surrogate outcomes” would make a unique contribution to the field and would provide the basis for a larger scale project that would include postoperative variables.

Significance

Despite dramatic improvements in patient outcomes following cardiac surgery over the past 50 years, surgical errors with serious consequences continue to occur [2]. Historically, surgical outcomes have been attributed solely to the technical skills of the surgeon. For example, within most surgical specialties, the primacy of technical skills is the underlying assumption driving rankings of surgical performance across institutions or among one's surgical colleagues. In general, once patient outcomes (usually mortality) have been adjusted for patient risk factors, the remaining variance is presumed to be explained by individual surgical skill" [3, p. 476]. Hence, when things go wrong or surgical errors are made, it is logical *from this perspective* to question the particular surgeon's skill or aptitude.

In contrast to this viewpoint, a systems safety approach suggests that human error is often caused by a combination of work system factors rather than simply the incompetency of the individual surgeon. Specifically, the **Systems Engineering Initiative to Patient Safety (SEIPS) model** [1] indicates that in addition to surgical skill (person factors) and the condition of the patient (task factors), errors and patient outcomes are also impacted by such factors as the working environment, technology/tool design and organizational variables, including teamwork, training, staffing, policies, procedures, and resources [4,5,6]. According to this perspective, errors are the natural consequences (not causes) of the systemic breakdown among these factors impacting performance. Therefore, patient safety programs are likely to be most effective when they intervene at specific failure points within the system rather than focusing solely on the competency of the individual who committed the error.

Although the work systems approach is relatively new to many surgical specialties, there is an increasing awareness of the impact that systemic factors can have on shaping surgical performance. Unfortunately, this



growing acceptance of the systems perspective has not translated into a similar development of effective patient safety programs within the operating room [7]. This situation is due, at least in part, to the fact that many patient safety programs have been developed without a full understanding of the underlying systemic problems that actually cause surgical errors. To date, the majority of data concerning systemic factors that impact patient safety in the OR has come primarily from anecdotal and sentinel event reports that often lack details concerning the specific nature of the systemic problems. As noted by de Leval et al., [8], there is a critical need for studies that use methods of prospective data collection to determine empirically the real-time dynamics of system factors and surgical flow disruptions that impact surgical performance. Only then can evidence-based patient safety programs be developed and subsequently evaluated.

The goal of this project is to prospectively study work systems factors to determine their nature and relationship to surgical errors and patient safety within the context of cardiac surgery. The specific aims of this study are twofold: (1) Develop and validate a measurement tool for reliably identifying work system factors in the OR that impact cardiac surgical care, and (2) identify the

types of surgical errors and patient care variables that are negatively impacted by work system factors. This project, when combined with other preliminary data, is expected to provide the necessary tools and resources for obtaining peer-reviewed funding for conducting a large scale multi-institutional study and the subsequent development of an evidence-based intervention that will improve cardiac surgical care.

Research Design and Methods

The purpose of the proposed project is to build upon our preliminary work by broadening our research tools and methods and our set of relevant outcome measures. Specifically, we plan to (1) develop a electronic (Tablet PC) data collection instrument to facilitate the collection of observational data and the time-stamping of events; (2) use video recordings of selected cases to further refine and validate our observational methods and data collection processes; (3) utilize multiple observers to establish the reliability of our observational methodology; (4) expand our observations to a larger set of surgical cases across three hospitals, and (5) identify and collect additional patient outcome and process variables that may be impacted by work system factors in the OR. As stated previously, this project is expected to provide the necessary tools and resources for obtaining peer-reviewed funding for conducting a large scale multi-institutional study and the subsequent development of an evidence-based intervention that will help improve surgical care.

Study Population: Participants in our study are surgical staff who will be performing normal activities in the operating room during observation periods. Most cardiac surgery cases last around five hours. The staff will be observed for the length of one case. Some staff members may be observed on multiple occasions due to team mixing over a three month period.

Data collection tool: In our preliminary study, data was collected using a black sheet of paper. No structured form was provided to the observer nor were observations time-stamped. Currently, no tool exists for documenting dynamic work system factors, surgical team behaviors, or outcome variables in real time. Measurement instruments that do exist focus on subjective rating of the work process or team performance [13]. Therefore, as part of this project, we will develop a Tablet PC data collection tool that will help standardize observations across observers and automatically time stamp entries. Similar Tablet PC data collection instruments have been developed as part of other SEIPS projects. Figure 3 provides a sketch of a possible interface. It will be designed to capture the onset/offset of the event, the type of event, a description of the event and the disruptive nature of the event on surgical performance. An event history will also be provided so that observers can edit entries as needed. As in our previous studies within other healthcare settings, we expect that our tool will provide more elaborate and reliable data than basic unstructured observations.

Video Recordings: No video recordings will occur at either UW or Marshfield Clinic. Digital recording devices have been installed in one OR at Mayo Clinic. These devices include 5 cameras, a microphone, and associated software tools that can help facilitate the prospective analysis of system factors in the OR that impact surgical care. In this project, we will use selected recordings of surgical cases to (1) train observers, (2) pilot our data collection tool, and (3) establish reliability among observers. Given the devices are only installed in one OR, they will not be used as the primary data source. However in the future, cameras may be installed in other ORs as part of a larger study. Approval for these video recordings is under a separate IRB protocol at Mayo Clinic.

Multiple Observers: In this study, we will use multiple observers to code selected cases in order to establish reliability of our data collection process. These observers will be medical students or residents who have received training in human factors, or human factors scientists who have prior experience observing medical/surgical teams. All observers will be provided the Tablet PC data collection tool and trained in utilizing the tool by watching video recordings of cases, or via direct observations of surgeries. The reliability of the observations will be calculated by using percent agreement among observers with regards to the frequency of work system factors during an operation that disrupt the surgical flow and technical errors committed by the surgical team. Consistent with conventional standards, 80% agreement will be considered an acceptable level of reliability.

Case Selection: To ensure the robustness of our observation methodology, we plan to observe 60 operations, with an equal number of cases (n=20) being observed at each hospital (UW-Madison, Marshfield Clinic and Mayo Clinic). Given the average duration of open heart surgery is roughly 5 hrs, 60 cases will result in approximately 300 hrs of observation. Our preliminary data suggests that work system factors disrupt the flow of operations at a rate of roughly 8/hr, which would result in approximately 2,400 events across 60 cases. Based on our previous research, this number of events is sufficient to inform the development of a PC-based data collection tool and to establish inter-rater reliability. To further establish robustness and reliability of our methodology, we also plan to observe a variety of different types of common cardiac surgical procedures including Coronary Artery Bypass Grafting (CABG; n = 15), valve repair/replacement (n = 15), aortic root replacement (n = 15), or other procedures (e.g., combined procedures or emergency procedures, n = 15) with an equal number of these various types of cases being observed at each hospital.

**Table 1. Intraoperative
“Outcome” Variables**

Process and Efficiency of Care Events

- Timing of Activities (actual vs. planned/expected)
 - Delayed Incision time
 - Delay in administering drugs (antibiotics, heparin, inotropes, cardioplegia, etc.)
 - Time to perform anastomosis (duration)
 - X-clamp time (duration)
 - Closing time
- Technical/Surgical Events
 - Cannulation Problems
 - Accidental injury/perforation of artery
 - Use of wrong instrument/suture
 - Positioning, tension, or instrument handling errors
- Resource Management

Outcome Measures: Given postoperative mortality and morbidity occur in roughly 5% of patients, few critical post-operative events are expected to occur across 60 cases. Consequently, we will be focusing primarily on intraoperative risk factors (processes of care and patient specific variables) as surrogates to patient outcomes. As listed in Table 1, many of these variables occur frequently and are routinely recorded during surgical cases. They have also been linked to either postoperative outcomes (e.g., x-clamp time associated with length of stay in ICU; cerebral desaturation associated with postoperative stroke) or to increases in the cost of care [14, 15]. A power analysis based on our preliminary data indicates that to detect a moderate relationship ($r^2=0.20$; OR = 2.0) between work system factors and surrogate outcomes at a significance level of 0.05, a sample size of 60 surgical cases will have sufficient power (power = 0.95) when using multiple regression for analyzing continuous variables and adequate power when using a logistic regression (power = .75) to analyze discrete outcome events.

<ul style="list-style-type: none"> ○ Discrepant sponge/instrument count ○ Material Waste ○ Equipment Availability <p><u>Patient Specific Events (actual vs. desired)</u></p> <ul style="list-style-type: none"> ● Hemodynamics (e.g, periods of hypotension) ● Cerebral Desaturation (rSO₂ levels) ● Lowest core body temperature achieved ● Hematocrit Values

Study Coordination

The lead study site will be University of Wisconsin – Madison. The PI will be responsible for notifying the co-investigator from Marshfield Clinic of any IRB approved changes that occur throughout the study period. Only the PI and student members of the study team from UW – Madison will collect data at UW – Madison and Marshfield Clinic. No members from Marshfield Clinic will collect observational data. Data collection will occur at UW-Madison and Marshfield Clinic and data will be securely stored in UW-Madison research offices. All members of the study team may participate in data analysis at the UW-Madison site.

Recruitment of Subjects

For all sites, the consent process for participants, surgical staff, will occur at a regular staff meeting when the PI hands out an information sheet, explains the purpose of the OR observational study, and explains that the observation will last the duration of the surgical case. The PI will also explain the research has minimal risk to the participants, no identifiable information will be collected or reported to a supervisor, and their participation is entirely voluntary. The participants may consider participation up to the start of the surgical case and may opt out of any surgical case.

Data and Safety Monitoring Plan

Since the proposed study is minimal risk, precautions will be taken to monitor and handle any breaches of confidentiality. The precautions taken in data monitoring is that no PHI information will be collected and any data collected will be de-identified. There is also no procedure in place for participants or persons not working on this study to withdraw information from the database. All data will be stored, analyzed, and secured according to established research practices. Specifically, physical data and an electronic database will be secured in locked research offices and on secure password protected servers maintained by Facilities Planning Management staff at the University.

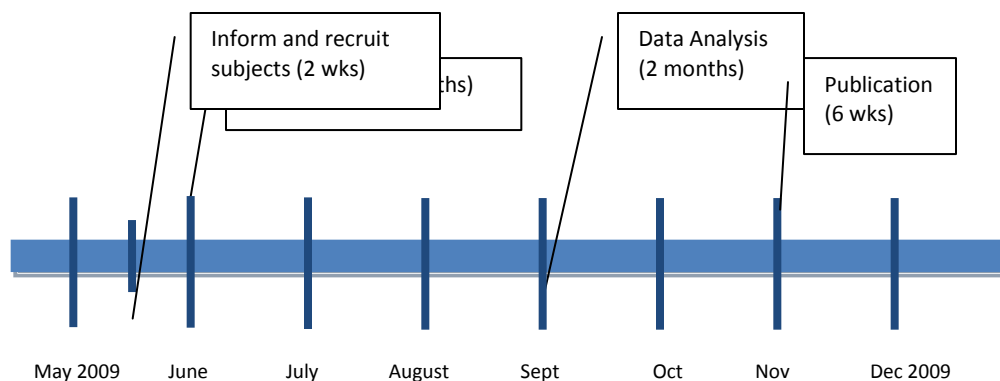
Statistical Considerations

Similar to our preliminary study, both qualitative and quantitative methods will be used. Qualitative analyses will include detail descriptions of the nature of key events, using observer notes and quotes of surgical personnel. Quantitative methods will include inferential and non-inferential statistics, such as correlational and regression analyses to determine the relationship among events. If more elaborate statistical analyses are required (e.g., path analyses) a professional statistician will be consulted.

Data and Record Keeping

The data will be collected directly from observations of the surgical team members in the operating room. The observer records descriptions of each event/error on a blank note pad or tablet PC. These field notes will then be transcribed into an electronic database and reviewed by an interdisciplinary research team, consisting of the original observer, a senior cardiovascular surgeon, and human factors scientist. Only investigators listed in the application will have access to the secure database. Any future use of data will be for cardiac surgery research only. The data will be stored up to five years following publication of results. Electronic data will be erased and paper documents will be shredded when the data is destroyed.

Timeline



Bibliography and References Cited

1. Carayon P, Smith M.J. *Work organization and ergonomics*. Applied Ergonomics, 2000; 31(6): 649-662.
2. Kohn LT, Corrigan JM, Donaldson MS. *To err is human*. Washington, DC: National Academy Press; 1999.
3. Vincent C, Morrthy K, Sarker SK, Chang A, Darzi AW. *Systems approaches to surgical quality and safety from concept to measurement*. Ann of Surg 2004; 239(4): 475-482.
4. ElBardissi A, Wiegmann D, Dearani J, Sundt T. *Application of the Human Factors Analysis Classification System (HFACS) Methodology to the Cardiovascular Surgery Operating Room*. In press, Annals of Thorac Surg 2007; 83: 1412-1419

5. Carthey J, de Leval MR, Reason, JT. *The human factor in cardiac surgery: Errors and near misses in high technology medical domain*. Ann Thorac Surg 2001; 72: 300-305).
6. Wiegmann DA, Shappell SA. *Human error approach to aviation accident analysis: the human factors analysis and classification system*, Ashgate Press; 2003.
7. Carthey, J, de Leval MR, Wright, DJ, Farewell, VT, Reason, JT. *Behavioural markers of surgical excellence*. Safety Science 2003; 41:409-425.
8. de Leval MR, Carthey, J, Wright, DJ, Farewell, VT, Reason, JT. *Human factors and cardiac surgery: A multicenter study*. J. Thorac Cardiovasc Surg, 2000; 119(4): 661-672.
9. Healy AN, Undre S, Vincent CA. *Developing observational measures of performance in surgical teams*. Qual Safe Health Care 2004; 13 (Suppl 1):i33-i40.
10. Lingard L, Espin S, Whyte S, Regehr G, Baker GR, Reznick R, Bohenen J, Orser B, Doran D, Grober E. *Communication failures in the operating room: An observational classification of recurrent types and effects*. Qual Saf Health Care 2004; 13:330-334.
11. Wiegmann, D.A., ElBardissi, A.W., Dearani, J.A., Daly, R.C., & Sundt, T.M. *Disruptions in surgical flow and their relationships to surgical errors: An exploratory investigation*. Surgery 2007; 142: 658-665.
12. Reason J. *Human error: Models and management*. BMJ 2000; 320: 768-770.
13. Malec JF., Torsher LC., Dunn WD., Wiegmann DA., Arnold, J.J., Brown, DA. *The high performance teamwork (HPT) scale: Reliability and validity for evaluating key crew resource management skills*. Simulation in Healthcare 2007; 2(1): 4-10.
14. DioDato CP, Likosky DS, DeFoe GR, Groom RC, Shann KG, Krumholz CF, Warren CS, Pieroni JW, Benak A, McCusker K, Olmstead EM, Ross CS, O'Connor GT. *Cardiopulmonary bypass recommendations in adults: the northern New England experience*. J Extra Corpor Technol. 2008; Mar;40(1):16-20.
15. Michalopoulos A, Tzelepis G., Pavlides G. Kriaras J. Dafni U. Geroulanos S. *Determinants of duration of ICU stay after coronary artery bypass graft surgery*. British J. of Anaesth, 1996; 77(2): 208-212.

II. Patient Information Sheet

Version 1 04/25/09

Information Sheet for Patient

Title of Study: "Improving Cardiac Surgical Care: A Work Systems Approach"

Study Investigator: Douglas Wiegmann, PhD

Introduction: We are conducting a study to improve efficiency in the operating room. As a result, there may be researchers from the University of Wisconsin present in the operating room during your surgery to observe the process and interactions among the surgical team.

What is the purpose of the study? The purpose of this study is to develop a method for identifying work system factors in the operating room that impact surgical performance. Our long-term goal is to further improve cardiac surgical care by enhancing or re-engineering the surgical care process.

What does the study involve? The study involves the observation of surgical staff performing their normal duties during surgery. These observations will be conducted by researchers from the University of Wisconsin-Madison.

How long will the observations last? Observations will last up to the entire duration of the surgery in the operating room. Researchers will only conduct observations within the operating room.

Will any personal information be collected? No personal information regarding your surgery will be collected.

Are there any risks or benefits to me? This study poses no additional risk or benefit to you.

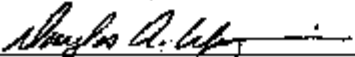
Do I need to sign any paperwork? There is no paperwork to sign but if you prefer that these observations not be performed during your surgery please inform your surgeon.

If you have any questions about this research, please contact:

Douglas Wiegmann, phone 608-890-1932 or email: dawiegmann@wisc.edu

If you have questions about clinical research or patient rights, please call the UW Patient Relations Representative at (608) 263-8009.

Thank you,

 _____ Douglas A. Wiegmann, PhD Professor, Industrial and Systems Engineering University of Wisconsin - Madison

III. Research Subject Information Sheet

Version 2 12-08-08



Information Sheet for Research Subject

Title of Study: "Improving Cardiac Surgical Care: A Work Systems Approach"

Study Investigators: Douglas Wiegmann, PhD

Invitation: You are invited to participate, because you work on a cardiac surgery team, in a research study about the general work activities of various professions in an operating room. Your hospital supports this study and your participation is entirely voluntary.

What is the purpose of the study? The purpose of this study is to develop a methodology for reliably identifying work system factors in the operating room that impact surgical performance. Our long-term goal, therefore, is to further improve cardiac surgical care by enhancing or re-engineering the surgical care process.

What are the procedures for this study? As a member of the cardiac care team you are invited to participate in this study by allowing us to observe you perform your job over the duration of a surgical case. We only want to document general tasks associated with your professional role and learn more about your work environment. During observations, we will not interfere or talk to you while you are completing patient care tasks and we will not collect any patient information from the patient's medical record. This information will not be used to evaluate your performance and therefore we will not record your name, gender, or age.

What will my participation involve? If you decide to participate, your involvement will include allowing the researchers to observe you perform your typical duties within the operating room.

How long will I participate? Each subject's participation will last up to the duration of the surgical case or up to the time the subject leaves the operating room.

Will I be paid? You will not be paid.

If I decide to start the study, can I change my mind? You may change your mind at any time and discontinue your participation in the study. If you decide not to participate or change your mind about participating, you will not be penalized or lose any benefits you would have otherwise been entitled to.

Are there any risks? There is minimal risk associated with these observations. However, because these observations occur in your place of work, there is a chance your anonymity may not be maintained and that data collected could be traced back to you. We are taking precautions to protect against this by only collecting information about general work tasks and

Version 2 12-08-08

NOT collecting any specific data about you. Generic job titles such as "nurse" or "surgeon" will be used instead. There is a minimal possibility of a breach of confidentiality occurring.

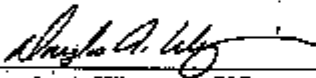
Are there any benefits? There are no direct benefits to participants.

If you have any questions about this research, please contact:

Douglas Wiegmann, phone 608-890-1932, or email: dawiegmann@wisc.edu

If you have questions about the rights of research subjects, please call the UW Patient Relations Representative at (608) 263-8009.

Thank you for your assistance with this project,



Douglas A. Wiegmann, PhD
Professor, Industrial and Systems Engineering
University of Wisconsin - Madison

Appendix C: Coding Scheme and Definitions

C.1 CODING SCHEME/PROCESS [The codes added during qualitative analysis process]

Directions: Read the events recorded in each case in sequential order. Independently code each recorded event using the following coding system. Each event in the database should be coded.

Handoff=intraoperative handoff

Event=non-routine event

STEP 1: *Identify safety –comprising consequences/instances and code as SCE. Place your code in excel column “ES”*

1=instance identified as a safety comprising consequence (sce)

STEP 2: For each consequence code events that contributed to the consequences. In addition, code any event that prevented a serious consequence. Place your code in excel column “ET”

Contributing Factors Coding:

1=handoff contributed to consequence (hcc)

2=event contributed to consequence (ecc)

3=handoff did not contribute to consequence (hncc)

4=event did not contribute to consequence (encc)

Compensatory Factors Coding (positive handoffs/NREs)

5=handoff prevent serious consequence (hpc)

6=event prevented serious consequence (epc)

STEP 3: In excel column “EV” code the handoff impact on the case

Impact Score

-1=handoff had a negative impact in the case

0=handoff had no impacts in the case

1=handoff had a positive impact in the case

STEP 4: Provide linkage code for handoff-event-consequence group (see example below).

Event Linkage

0= enter zero for no linkage

1= first “handoff-event-consequence” combination

2=second “handoff-event-consequence” combination

3=third “handoff-event-consequence” combination

4, 5, 6, and etc.

Case#	Recorded Event	Event Linkage
1	handoff	1
1	event	1
1	event	0
1	event	1
1	consequence	1
2	handoff	2
2	event	2
2	event	2
2	consequence	2

STEP 5: Meet to compare and discuss any differences and resolve by consensus.