NURSES' UNDERSTANDING OF TUBING MISCONNECTIONS BETWEEN ENTERAL AND INTRAVENOUS SYSTEMS: A MULTIPLE CASE, EXPLANATORY, GROUNDED THEORY STUDY

A DISSERTATION

SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS

FOR THE DEGREE OF DOCTOR OF PHILOSOPHY

IN THE GRADUATE SCHOOL OF THE

TEXAS WOMAN'S UNIVERSITY

COLLEGE OF NURSING

BY

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AUGUST 2011

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July 6, 2011

To the Dean of the Graduate School,

I am submitting herewith, a dissertation written by Debora Simmons entitled "Nurses' Understanding of Tubing Misconnections Between Enteral and Intravenous Systems: A Multiple Case, Explanatory, Grounded Theory Study." I have examined this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy with a major in Nursing Science.

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DEDICATION

For Nurses who go to work every day, give unselfishly, and pray they don't make a mistake.

This work is especially for Flower, Glenda, Jerick, Robin, Addison, Chloe and Johannah.

ACKNOWLEDGMENTS

No one succeeds alone. My favorite saying is persistence is omnipotent but I was also blessed to have many people help me. Thank you is simply not enough express my gratitude but I will try.

Thank you to the other one of "those two nurses from Texas", my best friend and my brave partner in crime solving, Krisanne Graves. Thank you to Marybeth Thomas and Kathy Thomas at the Texas Board of Nursing for support past what is in their job description and devotion to both the profession of nursing and the patient. Thank you, Hedy and Mike Cohen, Jane Ezell, Gwen Sherwood, Peggi Guenter, Bryanne Patail and Rod Hicks for support, clarity and mentorship. Thank you to Hisham Sherif for always being there. Not in the least, thank you to those who told me I could never do this because sometimes it was just what I needed.

My gratitude always to Dr. Sandra Cesario for her soft shoulder and creative open mind; Dr. Jan Foster who is the best Clinical Nurse Specialist I know and my role model ; and Dr. Elizabeth Young who challenged me to think in so many different ways. Dr. Zhang, Dr. Patel, and James Reason for making me think about how I was thinking. Thank you to kind hearted Dr. Betty Duscon who guided me through yet another existential crisis. Forever my gratitude and respect to Dr. Lene Symes who was very kind to me through many troubles and taught me so much more than she was obligated to teach.

ABSTRACT

DEBORA SIMMONS

NURSES' UNDERSTANDING OF TUBING MISCONNECTIONS BETWEEN ENTERAL AND INTRAVENOUS SYSTEMS: A MULTIPLE CASE, EXPLANATORY, GROUNDED THEORY STUDY

AUGUST 2011

The simple act of connecting two tubes seems minor in the complex healthcare system of today. However, the seemingly mundane can quickly turn tragic in healthcare. Misconnecting an enteral system (meant to deliver nutrition to the gastrointestinal system) to an intravenous system (meant to deliver fluids and medications intravenously) has often resulted in death of the patient. In this study, exploring nurses' understanding of misconnecting an enteral system to an intravenous system, served as a way to better understand healthcare safety and nurses' understanding of tubing misconnections. The findings reflect nurse's awareness of their work environment, the equipment they work with, and safety and factors that contribute to errors. Insight into nurses understanding of tubing misconnections may provide guidance for preventing tubing misconnections and other errors in patient care.

Grounded theory methodology was used to answer the question "what do nurses understand about tubing misconnections between enteral and intravenous systems?" Direct care nurses with experience in connecting enteral and intravenous tubing

participated in a highly interactive interview. Two groups contributed to and validated the findings, institutional level quality and safety professionals and safety experts.

The study findings suggest that applying both systems analysis of errors and focusing on cognitive load will lead to effective actions for preventing healthcare errors. The singular data elements of the findings point to usual routine occurrences within the daily practice of nursing that can go unremarked and be trivialized when observed independently. However the aggregate data supports a view of a hazardous stressful workplace where accumulative cognitive load, policy, culture, environment, and a deceptively simple device can result in patient death.

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CHAPTER I

INTRODUCTION

"My 24-year-old daughter was 35 weeks pregnant when she was hospitalized for vomiting and dehydration. A bag of ready-to-hang enteral feeding was brought to the floor, and the nurse, assuming it was total parenteral nutrition, pulled regular intravenous tubing from floor stock, spiked the bag, and started the infusion of tube feeding through the patient's peripherally inserted central catheter line. My daughter's fetus died—and then my daughter, after several hours of excruciating pain.

Multiple mistakes were made by multiple persons, but I believe if the enteral feeding bag had not been accessible to regular IV tubing, this tragedy would never have happened. I am writing you in hopes you can give me some direction on who I can contact in order to encourage the industries to standardize design changes in their enteral feedings bags so that they are inaccessible to regular IV tubing."

(Glenda Davis RN, Personal communication, 2010)

Focus of Inquiry

Since 1972, there have been published reports of unintentional failures to connect the correct tubing between systems used for patient therapy (Berwick; 2001; Beyea, Simmons & Hicks, 2006; Cohen, 2007; Eakle, Gallauresi, & Morrison, 2005; Institute for Safe Medication Practices, 2004a; Reason, 2004; Simmons & Graves, 2008b; Wallace, Payne, & Mack, 1972). Misconnecting an enteral system (meant to deliver nutrition to the gastrointestinal system) to an intravenous system (meant to deliver fluids and medications intravenously) has often resulted in death of the patient. The presence of universally compatible luer connectors throughout these patient care systems creates a persistent opportunity for any tubing system with luer connectors to be accidently misconnected to virtually any other tubing system with a luer connector.

Case studies of misconnections recount a connection of a feeding tube inadvertently connected to intravenous tubing and often the misconnection results in patient death (Casewell & Philpott-Howard, 1983, Hicks & Becker, 2006). In 2006, Hicks and Becker reported over 300 tubing misconnections causing patient harm found in the Med Marx® database. It is widely accepted that reported errors are often far smaller in numbers when compared the actual occurrences and that reported cases of tubing misconnections are not truly representative of the larger number occurring (Guenter, Hicks, et al., 2008; Guenter, Simmons & Hicks, 2008; The Joint Commission, 2006; Kohn, Corrigan, Donaldson, 2000). Therefore, the risk of inadvertently misconnecting an enteral feeding tube to an intravenous line is a relentlessly present and potentially fatal menace to patient safety that has been recognized but not remedied for a significant period of time.

Common luer connectors were considered a hazard to safety by expert organizations as early as 1986, when the ECRI Institute published the Medical Device Safety Report describing the connection of enteral feeding tubing to a tracheostomy cuff (ECRI, 1986). Consistently, ECRI publications have acknowledged that the existing universal inter-compatibility of the connectors in tubing systems in healthcare present a safety hazard (ECRI, 2006). The Institute for Safe Medication Practices (ISMP) has published multiple warnings and alerts including a case report of a neonate accidently infused with breast milk (ISMP, 2001; 2004a; 2004b; 2006). The Joint Commission (JC, formerly the Joint Commission on Accreditation of Healthcare Organizations or JCAHO) has also recognized the danger of tubing misconnections and issued Sentinel Event Alert #36 in April of 2006 (JC, 2006). Internationally, tubing misconnections have been recognized as a patient safety hazard by the World Health Organization (WHO) (World Health Organization Collaborating Centre for Patient Safety Solutions, 2007). The Food and Drug Administration (FDA) has alerted the public to the hazards of luer connectors in several publications and web casts (FDA, 2003; 2004). The United States Pharmacopeia (USP), the standards setting organization for pharmaceutical products, has issued error avoidance recommendations that ask for a redesign of connectors as well (Simmons, Phillips, Grissinger & Becker, 2008).

It is clear that universal connectors in healthcare create a hazard to patient safety. But it is unclear why universal connectors are still being used, if healthcare providers understand the risk, logic suggests that if healthcare providers understand the risk of misconnection, they would take action to make changes. The warnings about universal connectors have come from substantive sources, who have recommended changes in the design, yet a change has not been made. Therefore, it is fundamentally important to explore how nurses understand accidental tubing misconnections between enteral and intravenous systems in order to inform a safer method for caring with patients.

Problem of Study/Statement of Purpose

This study sought to explore: ***What do nurses understand about tubing misconnections between enteral and intravenous systems?*** The research provides a grounded theory generated model framing healthcare providers understanding of the risk for a misconnection, and of what happens when a misconnection occurs. Answering this question provides a basis for further interventions and research in creating safer devices for healthcare. Since grounded theory is an inductive process, it provides insight into the thought paradigms of the nurses.

Rationale for the Study

Efforts to understand and prevent a tubing misconnection have labored under the barriers common to other patient safety research areas. Classical research and epidemiology methods used to research healthcare errors have not been successfully applied to healthcare safety (Kohn et al. 2000; Wiengart et al., 2000). Healthcare safety experts maintain that underreporting and non-detection of errors in healthcare, both on a national and institutional level, remain barriers to recognizing threats to patients' safety, learning how to avoid errors, and to quantifying the actual number of errors (Kohn et al.,2000; Wiengart et al., 2000) Medical error rates have been established on a population level by only two studies, the Harvard Practice Study and the Australian study (Brennan et al., 1991; Brennan, Sox, & Burstin, 1996; Leape, 2002; Wilson et al., 1995).

Analysis of patient safety data, however, is crucial to inform the industry regarding hazards to safe care and to create proactive approaches to patient safety. The landmark publication by the Institute of Medicine (IOM), *To Err is Human* (Kohn et al., 2000), cited poor familiarity with safe practices in the industry and called for an increase in safe practices. An integral aspect of the new paradigm presented in the IOM reports is an examination of the role of human performance and systems factors relating to adverse medical errors. Focusing on both human performance and systems factors is expected to allow for a better understanding of why errors occur, development of more robust interventions, and a resulting increase in safety for both patient and practitioner. A definitive lack of evidence has remained a key barrier to progress (Kohn et al., 2000).

Evidence of tubing misconnections between enteral and intravenous systems is not absent in published literature, however definitive explanations of the incidents are not established. A literature review of 116 published accounts of accidental misconnections was analyzed for this study (Simmons, Symes, Guenter & Graves, 2011). The cases described misconnections across care settings, and with adults and children. Patient death was reported in 21 cases. Hypersensitivity reactions, hypercoagulopathy, renal failure, multi organ failure, severe and permanent neurological damage, and respiratory arrest were also reported. Glaringly absent in these reviewed cases is an explanation or exploration of the nurses interaction with the tubing systems and explanation of how a misconnection could occur.

Practical wisdom implies nurses have the knowledge and skill to make a connection to the correct system because it is an ordinary and repetitive nursing task. Enteral feeding and intravenous infusion are common pieces of undergraduate nursing education and nurse licensing examinations. Competency examination on the institutional level often also includes intravenous and enteral therapy, and in most settings where these are present, there are also policy and procedures outlining correct use. From these examples, it is clear that nurses know not to connect these physiologic incompatible tubing systems. Nevertheless misconnections happen all too often, frequently with deadly consequences. Therefore, in order to develop effective strategies to prevent the misconnections it is essential to understand misconnections in the context of the nurses understanding of the process and risk.

Nurses involved in events where patients are harmed are often reported to the regulatory boards for disciplinary action. The focus on the individual nurse's accountability has long been the purview of regulatory boards such as boards of nursing. However, emerging evidence from patient safety research supports the theory that multiple factors may contribute to errors in healthcare and nursing. Regulatory boards have been asked to explore new methodology to more thoroughly evaluate reported nursing practice errors and differentiate them from willful harm to patients (Page, 2004). Creating knowledge regarding the influence of factors outside the control of the nurse is essential to contributing to the new paradigm for nursing regulation and has broad implications for regulation.

Nurses have been described as "inseparably linked" to the safety of patients (Page, 2004, p. 23). Sheer presence alone in the majority of settings where healthcare is delivered is one reason nurses are key to the safety of patients- simply stated wherever healthcare is delivered, one of the three million nurses in the United States is present to coordinate and manage the daily needs of patients. Creating a work environment where nurses can practice safely is key to safer care and essential to the lives of patients. Tubing misconnections are one aspect of the nurse's work that should be explored in order to create a safe healthcare environment.

The knowledge gained in this study also contributes to the regulation of medical devices in general, and luer connectors specifically. Currently, there is no mandatory regulation of enteral feeding tube connectors although numerous reports have cited the luer connector present on the connectors presents a safety threat (Association for the Advancement of Medical Instrumentation [AAMI], 1996; 2004; FDA, 2003; 2004;). The standing recommendations are voluntary in nature, and to date, the FDA is still approving luer compatible feeding tubes for use in neonatal areas (FDA, 2010). The use of universal connectors for numerous healthcare devices creates the same hazard each time a patient has one or more tubing systems present that are physiologically incompatible.

Researcher's Relationship to the Topic and the Study

Early in 2002, the Healthcare Alliance Safety Partnership (HASP) received a report from a participating hospital that an error had occurred. As a member of HASP, I participated in the resulting interview with the nurse, which was heart wrenching. Every person in the room was tearful at the end of the interview. A 15 year veteran expert nurse had accidently connected a breast milk enteral feeding to an intravenous line. The remorse and guilt the nurse experienced coupled with her not understanding how she could have made this error after performing the task perfectly for many years – was enough to compel her to stop practicing nursing. The question of how an experienced expert nurse could ever make such an error was haunting.

The following investigation was even more alarming and inciting – years of published cases in the literature and a 1996 voluntary standard that would have changed the connectors to non compatible if it had been followed. Why this standard - passed as recognition of a threat to safety and the need for a change, was not enforced by the FDA was even more perplexing. Why have nurses not demanded a safer alternative? What do nurses understand about this threat to care in their everyday nursing tasks? The answer to these questions and the compelling need to change has not been determined.

This study relies upon the following assumptions:

1. Nurses are equipped with knowledge about risk factors for tubing misconnections. Having a model of that knowledge will provide a basis for taking effective action to prevent tubing misconnections.
2. Visualization of the process of tubing misconnections is possible through the participant's process mapping of a connection in this study and participants will be able to locate failure points as they process map.
3. Triangulation of the data through three levels of participants will validate depth and breadth of data.
4. Using the research methods of grounded theory (Blumer, 1969) with an understanding of how sense making is achieved (Weick, 1995), supports the development of a model for understanding and preventing tubing misconnections.
5. Because grounded theory fits within the naturalistic paradigm assumptions that apply to the naturalistic paradigm also apply to grounded theory. These assumptions include:

a. Reality is a mental construct which is multiple and subjective and is constructed by individuals (Polit & Beck, 2007).

Philosophical Underpinnings

Blumer and Weick

"Symbolic interactionism", as described by Blumer (1969) and expounded by Weick (1995) to "sensemaking", provides a structure to understand the nature of the person's thoughts around things and their interpretation of those things. Symbolic interactionism is the sociologic perspective that considers an understanding of social interaction, human thinking, definition of the situation, the present and the active nature of the human being as being necessary to understand human actions (Charon, 2010). In this philosophical orientation, the approach centers to the study of human group life and human conduct (Blumer, 1969). Blumer described symbolic interactionism as having three basic premises in this perspective:

1. "Human beings act toward things on the basis of the meanings they ascribe to those things."
2. "The meaning of such things is derived from, or arises out of, the social interaction that one has with others and the society."
3. "These meanings are handled in, and modified through, an interpretative process used by the person in dealing with the things he/she encounters." (Blumer, 1969, p. 2)

As tubing misconnections occur within a social construct of the healthcare setting, it is important to understand the meaning placed on the object (tubing connectors) and the interpretative process used in dealing with connections. Blumer posits that during each and every interaction with an object meaning is recreated- so the process of connecting and reconnecting tubing is dynamic in its interpretive nature (Blumer, 1969, p. 5). If people do indeed act in certain situations because of their definition of such a situation at that moment, it is relevant to the research question to explore the meaning of tubing misconnections to nurses in the context of making the connection.

The landmark publication by the Institute of Medicine, *To Err is Human*, called for a knowledge base "for patient safety however a lack of knowledge has remained a major barrier to learning from safety events (Kohn et al., 2000). Subsequent reports from the IOM (Aspden, Corrigan, Wolcott, & Erickson, 2004; Corrigan, Donaldson, & Kohn, 2001; Page, 2004) have repeated the call for increasing the knowledge base for safety through "systems" analysis of error events so healthcare institutions can become learning organizations. Learning organizations must make "sense" of their environments and learn from safety events. The process of "sensemaking," as described by Weick is to build an understanding that can inform and direct actions that eliminate risk and hazards to safety (Battles, Dixon, Borotkanics, Rabin-Fastmen, & Kaplan, 2006; Weick, 1995). True sensemaking, according to Battles et al., requires a constant process of learning from errors, identifying hazards and continually making "sense" of these at a micro and macro level. Sensemaking for organizations with high reliability safety needs such as healthcare requires both a continuous retrospective and prospective approach to learning in order to lead to informed designs for safety (Battles et al., 2006).

Weick's descriptions of sensemaking in organizations extend to the micro level of individuals in the healthcare organization. On an individual level sensemaking is useful to understand events and make order and explanation from ambiguous events (Battles et al., 2006). Within an individual's attempt to sensemake lie important cognitive processes illuminating the reasons for behaviors which add to the knowledge regarding unsafe behaviors, thoughts and feelings (Battles et al., 2006; Rudolph, Simon, Dufresne, & Reamer, 2006). Learning from the individual's framework of sensemaking has been attempted in healthcare through quality methods for single events such as root cause analysis (Battles et al., 2006).

Summary

"Medical errors can be defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim" (Aspden et al., 2004, p.36)

The basis for safety in any industry is the prediction of behaviors and the control of variations in process and outcomes. While this has an elusive quality in application to healthcare, the prediction and eventual control of harmful variation is dependent upon understanding the behaviors of humans, which is grounded within their understanding and interaction with the world and society around them. It is accepted that errors in care originate in faulty systems, faulty process and conditions rampant throughout the healthcare industry (Kohn et al., 2000).

Tubing misconnections are unexplained. The nurse has the knowledge, the demonstrable skill, and the ultimate goal to protect the patient. Yet, nurses who have connected tubing successfully have also connected two physiologically incompatible systems with disastrous effects. Even given this disastrous consequence, the FDA approved a luer compatible neonatal feeding tube June 30, 2010 (FDA, 2010). Grounded theory, symbolic interactionism, and sensemaking share common aims of revealing the unexplained meaning to things, actions or behaviors. Tubing misconnections are implausible events that have a meaning, an action, and a behavior that urgently needs explanation.

CHAPTER II

TUBING MISCONNECTIONS: NORMALIZATION OF DEVIANCE

A Paper Published in

Nutrition in Clinical Practice

Debora Simmons, Lene Symes, Peggi Guenter, and Krisanne Graves

ABSTRACT

Background: Accidental connection of an enteral system to an intravenous (IV) system frequently results in the death of the patient. Misconnections are commonly attributed to the presence of universal connectors found in the majority of patient care tubing systems. Universal connectors allow for tubing misconnections between physiologically incompatible systems. *Methods:* The purpose of this review of case studies of tubing misconnections and of current expert recommendations for safe tubing connections was to answer the following questions: In tubing connections that have the potential for misconnections between enteral and IV tubing, what are the threats to safety? What are patient outcomes following misconnections between enteral and IV tubing? What are the current recommendations for preventing misconnections between enteral and IV tubing? Following an extensive literature search and guided by 2 models of threats and errors, the authors analyzed case studies and expert opinions to identify technical, organizational, and human errors; patient-related threats; patient outcomes; and recommendations. *Results:* A total of 116 case studies were found in 34 publications. Each involved misconnections of tubes carrying feedings, intended for enteral routes, to IV lines. Overwhelmingly, the recommendations were for redesign to eliminate universal connectors and prevent misconnections. Other recommendations were made, but the analysis indicates they would not prevent all misconnections. *Conclusions:* This review of the published case studies and current expert recommendations supports a redesign of connectors to ensure incompatibility between enteral and IV systems. Despite the cumulative evidence, little progress has been made to safeguard patients from tubing misconnections. (*Nutr Clin Pract*. 2011;26:286-293)

Keywords: enteral nutrition; nutrition therapy; feeding methods; equipment safety; nutritional support

INTRODUCTION

Since 1972, several reports on unintentional failures to connect the correct tubing between intravenous (IV), epidural, intracranial, intrathecal, gas, and other tubing systems used for patient therapy have been published.[1-8] Inadvertently connecting an enteral system (meant to deliver nutrition to the gastrointestinal (GI) system) to an IV system (meant to deliver fluids and medications intravenously) has often resulted in patient death by embolus or sepsis. The common element in misconnection of these tubing systems is the presence of a universally compatible luer connector. Luer connectors are used widely throughout healthcare in systems that deliver fluids and gases and in drains and inflation cuffs. The presence of luer connectors throughout these patient care systems creates a persistent opportunity for any tubing system with luer connectors to be accidently misconnected to virtually any other tubing system with a luer connector. Because the luer connector is used across the continuum of healthcare settings, the potential for a misconnection is ever-present.

The luer tubing connector is commonly called the luer lock, luer slip, luer tip, or small-bore connector. For the purpose of this article, the connector will be called the luer connector. This article explores the published evidence of misconnections between enteral and IV systems. Posited causative factors, patient outcomes, and recommendations for prevention gleaned from a review of published case studies and current expert recommendations are reviewed.

HEALTHCARE INDUSTRY ACTIONS

The healthcare device manufacturing industry classifies luer connectors as small-bore connectors, which are defined by industry standards for production of medical devices, as published by the Association for the Advancement of Medical Instrumentation (AAMI).[9] In 1996, the Infusion Device Committee of AAMI passed American National Standard ANSI/AAMI ID54:1996, prohibiting the use of luer connectors on feeding sets (which by definition included feeding tubes). This specially convened expert group at AAMI had concluded that the universal connecting properties of luer connectors found on feeding sets and adaptors carried a high risk of patient harm. In 2004, the standard was revisited by the AAMI in response to a query by the United States Pharmacopoeia, and the standard was officially recognized as being "in force."[10] AAMI continues to participate in the International Standards Organization efforts to coordinate a change to safer connectors across healthcare tubing systems, including epidural, respiratory, and enteral tubing, but this laborious process will yield a voluntary standard in 2013 at the earliest. To date, there is no enforcement of the AAMI standard for luer connectors in feeding sets with manufacturers in the United States, and tubes are connected and reconnected an untold number of times during the day.[10]

Common luer connectors were considered a hazard to safety by expert organizations as early as 1986 when the ECRI Institute published the Medical Device Safety Reports describing the connection of enteral feeding tubing to a tracheostomy cuff.[11] ECRI followed in 2006 with another alert regarding safe use recommendations for feeding tubes.[12] Consistently, ECRI publications have acknowledged that the existing universal intercompatibility of the connectors in tubing systems in healthcare presents a safety hazard. The Institute for Safe Medication Practices (ISMP) has published multiple warnings and alerts, including a case report of a neonate accidently infused with breast milk.[6,13-15]

The Joint Commission (JC, formerly the Joint Commission on Accreditation of Healthcare Organizations) has also recognized the danger of tubing misconnections and, in April 2006, issued Sentinel Event Alert #36. The Sentinel Event Alert cited 9 cases reported to the Sentinel Event Database and noted that this type of error is often underreported.[16] Internationally, tubing misconnections have been recognized as a patient safety hazard by the World Health Organization (WHO). Preventing tubing misconnections is a part of the WHO's "9 solutions" for patient safety published in 2007.[17] Although the JC jointly published the WHO patient safety solutions, the JC has failed to make the resolution of tubing misconnections a national patient safety goal in the United States.

The U.S. Food and Drug Administration (FDA) has alerted the public to the hazards of luer connectors in several publications and webcasts.[18,19] In January 2007, the FDA met with concerned stakeholders and developed a consensus paper asking for a redesign of connectors.[20] The United States Pharmacopeia, the standard-setting organization for pharmaceutical products, has issued error avoidance recommendations that ask for a redesign of connectors as well.[21] Although the AAMI standard was passed in 1996 and 2004, the FDA continues to publish alerts and cautions regarding luer connectors.

FREQUENCY OF TUBING MISCONNECTIONS

Understanding and preventing tubing misconnections has been affected by the same barriers as other patient safety issues. Classic research and epidemiological methods used to research healthcare issues have not been successfully applied to healthcare safety.[22,23] Healthcare safety experts maintain that underreporting and nondetection of errors in healthcare, on both a national and an institutional level, are barriers to recognizing threats to patient safety, learning how to avoid errors, and quantifying errors.[22,23] Medical error rates have been established on a population level by only 2 studies, the Harvard Practice Study and the Australian study.[24-27] Acquiring safety data is problematic on many levels, requiring substantial efforts in retrospective data collection, aggressive case finding, complicated data mining from technology sources, or costly observational studies to uncover representational data.[23] Medical malpractice claims data are not fully representative of error rates.[27] Epidemiological data are not available across care settings, and the findings of the published studies that focus on 1 specialty or procedure are not generalizable.[24]

The healthcare industry continues to rely on reporting systems to acquire safety data but barriers to reporting, such as cultural norms, preclude real progress. Cultural disincentives to reporting errors are often attributed to long-standing punitive healthcare traditions and include threats of legal and regulatory action coupled with disciplinary action at the institutional level.[22,28,29] Poor character judgments rendered among professional peer groups and colleagues can also negatively influence reporting behaviors.[22,25] In addition, errors may simply not be detected. James Reason,[29,30] the author of *Human Error*, describes the poor detection of errors as a barrier to learning from errors and therefore a significant barrier to preventing recurrence.

Analysis of patient safety data is crucial to inform the industry regarding hazards to safe care and to creating proactive approaches to patient safety. The landmark publication by the Institute of Medicine (IOM), *To Err Is Human*,[22] cited poor familiarity with safe practices in the industry and called for an increase in safe practices. Lack of evidence has remained a key barrier to progress. Further reports from the IOM have repeated the call for increasing the knowledge base for safety through "systems" analysis of error events. The IOM repeatedly has asked healthcare institutions to become learning organizations with increased organizational agility to respond to safety threats. Before healthcare providers can agilely respond to safety threats, they must understand how to analyze and learn from adverse events and to disseminate the resulting knowledge about safe practices.

CASE STUDY APPROACH

In consideration of these barriers to learning about tubing misconnections and other errors, a case study approach was used for this literature search. A case study approach is pertinent for 3 reasons. The first is that case study reports may be the only information published and available about specific healthcare errors. Second, case study reports offer narrative description of events that may not be found in traditional databases. These narrative reports can offer essential information regarding safety threats, patient outcomes, and interventions that are crucial to the success of any safety program aimed at error reduction.[31,32] The third consideration for a case study approach is the absence of traditional research in the area of human performance and healthcare safety. Because safety research in human performance and error often relies heavily on retrospective analyses, case studies may prove the sole informative source.[24] This analysis of case study reports provided sole source information to answer the following questions: When completing tubing connections with the potential for enteral to IV tubing misconnections, what are the threats to safety? What are patient outcomes following misconnections between enteral and IV tubing? What are the current recommendations for preventing misconnections between enteral and IV tubing?

Understanding any healthcare error is difficult without understanding the systems approach. The model of threats and errors authored by Helmreich[33] is an example of a theoretical model adapted to healthcare to explain threats to safety. In this model, threats are factors that increase the likelihood of an error occurring.[34] Consistent with Helmreich, van der Schaaf[35] presented an expanded model, explaining that threats and dangers to safety are a composite consisting of technical, organizational, human, and patient-related factors. Using these models, the case studies were gleaned for threats to safety.

SEARCH STRATEGY AND LIMITS

The terms used for the search was "misconnections of tubes carrying feedings, intended for enteral routes, to intravenous lines." The search was limited to publications in the English language. Methods of inquiry included internet searches using major search engines, such as Alta Vista, MSN, Google, Google Scholar, Yahoo, and AOL, as well as searches conducted within major research publication databases such as PubMed and CINAHL. A web-published bibliography was included for review.[36] Keywords were used alone and in combination for this targeted search, and included *luer, luer slip tip, luer lock, small bore connector, enteral feeding, syringe set, intravenous connector, tubing error, feeding tube error, inadvertent connection and misconnection or misconnections*, and *misconnection of incompatible tubing* or *systems*. This case study search included results from 1972 through 2010. The cases are listed in Table 1.

Table 1. Data on Enteral Tube Misconnections from Case Studies

Case reports
(N =116 in 34 reports)
 	
Patients
Adult (N=60)
Child/infant (N=30)
Not Specified (NS) (N=26)
	Patient Outcome from 116 cases
	
	Death (N=21)
	
	Survival:
	• Hypersensitivity and Hypercoagulopathy reaction (N=1)
	• Septicemia/sepsis (N=16):
	  o 2 with neurologic damage
	  o 2 with respiratory arrest
	  o 33 with hypoxia
	  o 1 with seizure & hypoglycemia
	  o 5 with intracranial hemorrhage
	• Renal impairment (N=8)
	• Respiratory arrest/distress (not listed above) (N=2)
	• Neurologic damage (not listed above) (N=2), 1 with blindness & deafness
	• No harm, or outcome not given (N=12)

Threats identified from 32 reports
• Similar appearance of enteral feeds and intravenous infusion (N=6)
• Compatible (luer) tubing connectors (N=15)
• Enteral pumps and intravenous pumps:
  o on same IV pole
  o identical in appearance, or used interchangeably
  o tubes running from pumps which look the same (N=5)
• Inadequate lighting (N=2)
• Lines:
  o confused
  o use of tubes or catheters for unintended purposes
  o placing functionally dissimilar tubes in close proximity to one another (N=5)
• Using luer lock syringes instead of oral syringes and unlabeled syringes (N=1)
	Recommendations from 32 reports
	• Write the order in full (N=1)
	• Redesign connectors to prevent misconnection (eliminate cross system compatible connectors) (N=22)
	• Visual cues:
	  o label or color to indicate system and contents
	  o place catheters and tubing for differing systems on different sides of patient's body (N=7)
	• Use oral syringes for feedings (N=2)
	• Modify human factors through:
	  o training
	  o changes in policies and protocols
	  o routinely trace lines back to source
	  o increased vigilance
	  o increased supervision
	  o double checks (N=6)
	• Other equipment modifications:
	  o use an IV incompatible NG tube

• Human factors: ○ knowledge deficit ○ confusion ○ fatigue ○ mistake, (N=11) Modified tubing connector (N=1)	and administration set. ○ use different pumps for different purposes, when possible (N=1)

RESULTS

Notably, the oldest case identified in this search was a case report of an inadvertent connection of an enteral infusion into the IV system reported in 1972 in *The Lancet*. Wallace et al.[8] reported that a "milk drip" of pasteurized cow's milk intended as therapy for a patient with exacerbation of a duodenal ulcer was accidently connected to an IV line. The authors suggested that the error occurred because the written order by the physician did not specify an intragastric route and did not fully name the intragastric infusion. Although luer connectors are not specifically named in this early account, it is suggested that the enteral tubing was compatible with IV connections. The patient in this case survived a hypersensitivity reaction and developed a hypercoagulopathy after the event.

In 1979, in a letter to the editor of the *Journal of Parenteral and Enteral Nutrition*, O'Donovan[37] reported that an advertisement in the described a proximal connector of the enteric feeding tube as being able to connect to the standard IV sets. O'Donovan reported that he was aware of cases occurring in Australia where the accidental connection of enteral feeding to IV tubing lines resulted in patient deaths. The reasons for these inadvertent connections were identified as being the similar appearance of parenteral nutrition (with lipids) and enteral nutrition (EN).

A total of 116 case studies involving feeding intended for enteral routes misconnected to IV lines were reviewed (see details in Table 1). Full descriptions of the events the patients, and their outcomes were not available in each case. Of the representative cases, adults were reported in 60 cases and children or infants in 30 cases. Twenty-six cases did not specify an age for the patient. One case reported the death of a pregnant mother and her unborn child.20 Patient death was reported in 21 cases. Frequent causes of death were sepsis and embolus related to the feeding. Hypersensitivity reactions, hypercoagulopathy, renal failure, multiorgan failure, severe and permanent neurological damage, and respiratory arrest were also reported.

Threats to Safety from Case Studies

The majority of case studies were focused on the description of the patient's treatment, condition, and outcome, with very brief descriptions of the actual event. Despite the brevity of descriptions, threats to safety are identified within these case studies. The cases reviewed were written by clinicians who were most likely not familiar with safety science, and certainly those describing cases prior to the IOM reports had little or no awareness of systems analysis. It is important to note that current thought recognizes that attribution of an error solely to the individual's actions is neither an informed opinion nor helpful in creating safer healthcare practices.[2-4, 7, 22, 23, 25, 28, 34, 38, 39]

Organizational factors that can increase threats to safety include the practice of purchasing ubiquitous connectors and deploying them in patient care areas and the use of confusing policies and procedures.[40] Insufficient supervision of nursing staff is cited within one case.[41] Poor lighting design was also suggested as a contributor to confusing similar tubing.[42,43] The locations presented in the case studies suggest that there are multiple care settings in which tubing misconnections occur, the majority of which occur in acute care. Cases are described occurring in intensive care, medical surgical units, rehabilitation facilities, emergency rooms, nursing homes, nurseries, and neonatal units.

Human factors (attributes of human performance) are also described within cases as being threats to safety. Several cases suggest that a lack of vigilance on the nurse's part was a casual factor.[41,42,44] However, expert opinion in most industries accepts that relying upon vigilance is a flawed defense against danger and errors.[30,45-47] Confusion of lines attributable to the similar appearance of IV lipids and enteral feeding is named in 8 case reports.[7,8,37,42,44,48-50] Knowledge deficits and a lack of experience are also described in several cases.[51,52]

In the majority of the cases, the misconnection is described as being accidental in nature.[43,47-62,76,77] In one case the written order for the feeding is described as "hard to understand" and therefore a contributing factor.[8] Staff fatigue is cited in one case described in the JC Sentinel Event Alert.[16] One case describes an adult patient who accidently misconnected his own tubing for enteral feeding to an IV line during the night, when he woke and found it had come apart.[53]

Technical factors presented in these cases point to one common factor. The luer connectors found on enteral lines are universal in their capacity to fit to IV catheters. In 25 of the published case reports reviewed, authors noted that the connector is interchangeable and therefore problematic, and they recommended a redesign of the connectors.[6, 7, 15, 16, 20, 37, 41, 42, 48-51, 53-65] The use of luer syringes for medication preparation and delivery, instead of oral syringes, led to multiple medications, intended for the enteral feeding tube, being injected into the IV system.[20]

REDUCING THE RISK OF TUBING MISCONNECTIONS

Reducing the risk of a misconnection requires compound interventions.[29,65] Typically, these interventions are aimed at the technical and human level in order to decrease risk.[65] Numerous connections can be attached to one patient, and there is an increased opportunity for errors with multiple connections and reconnections, which occur frequently in routine care.[50,57] Reducing the risk of tubing misconnections requires a constant assessment of the risks in the environment and a reassessment each time compatible tubing is introduced. The following interventions are suggested within the case studies and within expert papers.

Visual cues such as labeling and color-coding were suggested in several articles, however, color-coding has been considered a disadvantage as a sole defense against an error.[12, 16, 39, 42, 57, 58, 66-68] Color should serve only as an indication to the nurse that this connection should be carefully made and should never be used as sole cue when making a connection. Significant threats can be introduced when practitioners begin to rely on color-coding rather than on ensuring line type.[65] Color blindness and lighting problems that result in altered hue identification are well-known hazards to relying on color.[21,50] Labeling is also recommended at the proximal and distal tubing ends.[16,20,21,50,67,68,69] Other visualization measures suggested include tracing lines to identify the correct tubing, routing tubing in different directions, and having independent practitioners who double-check and recheck lines at any transition point (i.e., hand-offs and shift changes).[4,12,16,21,65]

Expert groups have recommended changes in organizations' supply practices that will decrease risk by taking the possibility of a misconnection of enteral and IV lines away from the patient. The recommended changes include purchasing only tubing that is incompatible with IV tubing.[4,9,10,16,50,65,68,69] In contrast, substituting a functionally similar medical device for a device with safety features increases risk of error. An example is using luer tip syringes when administering enteral feeding or medication instead of purchasing and using orange oral syringes [21,60,65,69,71] Therefore, purchasing and using tubing with incompatibility to other lines is suggested as a way to remove the risk to the patient. This can be very confusing and can introduce other hazards inadvertently into the clinical environment, because multiple products are available on the market that have "incompatible" connectors. Unless the full risk is understood and a comprehensive coordinated strategy in place, purchasing and using tubing with multiple incompatible connectors is a complex, time-intensive chore not accommodated by most organizations purchasing plans.

Increasing awareness of risk by conducting risk assessments, acceptance testing, training, and orientation is suggested as an interim intervention for reducing the risk of a tubing misconnection.[12,16] Increasing awareness among providers has been attempted.[16,21,67,70] The American Society for Parenteral and Enteral Nutrition—Nestlé Be ALERT Campaign in 2009 was an initiative to raise awareness among staff nurses about safe practices for EN, including prevention of misconnections.[67] Increased vigilance is named in one report as a way to reduce risk, although present knowledge in safety recognizes that 100% human vigilance is an unobtainable state.[22,44] Finally, it has been suggested that clinicians teach patients and caregivers not to reconnect a line that has become disconnected.[16,20,21,67,71]

Simply stated, there is no substitute for a change in the design of connectors to force incompatibility of enteral to IV systems. Clearly, there is a pervasive understanding among safety experts that a redesign to incompatibility is the only fail-safe measure to reduce the possibility of an accidental tubing misconnection. Redesigning the connector to force incompatibility has been suggested as the most tangible intervention. A redesign to incompatibility is called for by consensus statements and expert groups and is recommended in the majority of case reports.[4, 6, 7, 9, 10, 12, 15, 16, 20, 37, 41-43, 48-51, 53-65, 68-72]

CONCLUSIONS

The use of universal connectors such as luer connectors in healthcare is a fundamental failure to protect patients. A system that carries a high risk of injury if connected unintentionally to another system should, by intent and pragmatic logic, have design features that prevent the possibility of inadvertent connection. It is clear that connectors in healthcare create a hazard to patient safety as evidenced by multiple alerts, patient deaths, and publications by safety experts and regulatory bodies. In *The Challenger Launch Decision: Risky Technology, Culture, and Deviance at NASA*, sociologist Diane Vaughan[74] describes NASA as having an organizational culture that evolved to accept danger signals as normal and did not react to clear signs that the Challenger was doomed to fail. The term Vaughn uses to describe this phenomenon is "normalization of deviance," which not only describes NASA's culture but has been applied to healthcare as well.[75] Vaughn poses the idea that the decision to launch the Challenger in 1986, although not intended to kill the entire crew, was a decision made in the face of clear signals of danger. Vaughn states, "This was a story about routine decisions in a workplace" that have disastrous, though unintentional, consequences.[74(p403)] The normalization of signals of danger created the tragedy of the Challenger.

The signals of disaster regarding tubing misconnections begin from a distance in time and diversity of locations that can encourage a sense of detachment on a personal level. The decisions made at the provider level, the institution level, and within the regulatory bodies have been routine decisions never intended to kill patients. The decisions are made in a healthcare workplace focused on production, where danger becomes normal and signals of impending tragedy are ignored. However, without a doubt, each patient's death is a red flag to those using universal connectors—eventually, through daily repetition and relentless presence, a tubing misconnection death is possible. The healthcare industry, despite its acknowledgement of dangerous elements of the connectors and attempts to change the voluntary standard for these connectors, continues to produce, distribute, and use universal connectors.

In 2009, a story was published reporting a neonate who had been emergently delivered from a mother dying of the H1N1 viral infection and was killed in an inadvertent connection of enteral feeding to an IV line.[52] The nurse in the case was reported to have pending charges of manslaughter. In May 2010, the accidental injection of barium sulfate through a central venous catheter in a 17-month-old was reported in the

American Journal of Health Systems Pharmacists.[64] On July 15, 2010, the ISMP reported that a 19-month-old died after receiving an oral medication through a central line.[78] On a broader perspective, these are clear signals of danger for all of us who use universal connectors; on a human level, these events simply should not have happened.

ACKNOWLEDGEMENTS

This article is dedicated to Flower, Glenda, Jerick, Robin, Addison, Chloe, and Johannah.

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CHAPTER III

METHODS

Procedure for Collection and Treatment of Data

This study used grounded theory methodology to answer the question: What do nurses understand about tubing misconnections between enteral and intravenous systems? The research goal is congruent with the goals of grounded theory. Glaser explains grounded theory as "…. to generate a theory that accounts for a pattern of behaviors that is relevant and problematic for those involved" (1978, p. 93). Grounded theory methods also offer a systematic method to explore how nurses make sense of their experiences and analytically explore their understanding (Charmaz, 2006, p.11). Grounded theory is a relevant as an investigative technique for this subject because there are no previous studies of nurses understanding of tubing misconnections and there is a need for deeper understanding of the process.

The strength of the study design relied upon triangulation and constant comparative methods (Patton, 1990). Triangulation of data and of methods was used at each level of the study. The triangulated methods of data collection were process mapping done with the researcher, semi-structured interviews, and real time validation of process maps by participants (Patton, 1990; Speziale & Carpenter, 2003). The study used triangulation of data sources among three levels of interviews; direct care nurses, followed by quality and safety professionals, and ultimately a view from experts. This was particularly valuable to the study's goal to "make sense" of the present state of understanding of tubing misconnections.

Setting

Interviews with participants took place at a location selected by the participant and acceptable to the researcher. The direct care nurses and experts in quality and safety were interviewed in local locations at times convenient to them. Both the researcher and participants were seated at a table holding the process maps, analysis documents, drawing markers, sticky notes, and the interview guides. As the model emerged and more data were collected the researcher also used a laptop computer to display the excel spreadsheet of the data for participants. The locations were selected to ensure that the interviews were confidential.

Participants

This was a purposeful sample of participants outside any relationship of employment or academic affiliation to the researcher. Had the interview data left unanswered concepts, the researcher would have employed purposeful snowballing to recruit more participants. As building grounded theory requires iterative steps, the researcher explored initial categories and increase data in "thin" categories with appropriate theoretical sampling. Saturation occurred when there were no new emerging categories and existing categories are repeated (Glaser & Strauss, 1967).

The sample size for the study was 16 direct care nurses for the first layer of data. Inclusion criteria for direct care nurses included current nursing practice and adult status.

There was no requirement for specialty licensure, education, or credentialing. Recruitment was by telephone or in person using a recruitment script (Appendix A).

The next layer of data was a purposeful sample of five quality and safety professionals in healthcare known to the researcher. As there is no requirement for specific background in these type job categories, there was no requirement that these professionals have a nursing background. There is no requirement for specialty licensure, education or credentialing. They were recruited by telephone or in person using a recruitment script (Appendix A).

Finally, there were three safety experts familiar with tubing misconnections for the final review. Safety experts reviewed emerging findings from the data provided by the direct care nurses and quality and safety professionals. The emerging model, aggregate mapped data, and detailed categories under each theme were reviewed. They commented upon the findings, contrasting it with their own understanding, based in experience in reviewing safety data, and pointed out any incongruencies. There was no requirement these professionals have a nursing background, specialty licensure, education, or credentialing. They were recruited by telephone or in person using a recruitment script (Appendix A).

Participants in this study were from a purposeful sample specifically chosen to speak about practice based upon their experience with tubing connections (Lincoln & Guba, 1985; Munhall, 2007). This method was used in order to narrow the distribution of the sample. The purposeful sample and constant comparative methods served to deliberately focus the research to the subject area and provide dense and rigorous data collection (Munhall, 2007). Saturation occurred when no new data emerged from the ongoing interviews (Speziale & Carpenter, 2003). Once saturation was reached at each level, then recruitment of participants at that level ceased. Had new data emerged at the next level the researcher would have returned to recruit new subjects at the previous expertise level.

Protection of Human Subjects

It has been well established that the culture of healthcare presents significant barriers to error reporting, and error investigation and analysis, by nature of the punitive repercussions associated with making an error and the dampening effect this has had to healthcare providers contributing knowledge to safety (Aspden et al., 2004; Jeffe et al., 2004; Kohn et al., 2000). This study was designed to be specifically sensitive to the participants' comfort in discussing how and where an error could cause severe patient harm. Methods to support comfort included:

1. Individual interactive interviews, without audio recording, offer a measure of confidentiality to enrich discussion in an atmosphere of confidentiality (Opdenakker, 2006; Patton, 1990; Schwartz & Jacobs, 1978).
2. Providing the participant with the option to sign the informed consent. In the event the participant decided not to sign, the researcher signed with her own name and dated the consent. A copy of the written consent was provided to each participant.
3. Ensuring there is no record of the participant's name other than the optional signed consent.

4. Although the demographic data sheets contained no identifying information they were kept with the signed (by participant or by researcher, as the participant elected) consent forms in a locked cabinet in the researcher's home behind a locked office door. The demographic data sheet, which had no identifying data, was completed by the participant, then placed in an envelope and immediately sealed until the end of the study. The demographic data sheet was not coded. The demographic data were used to describe the interview participants in aggregate and then destroyed. No one other than the researcher had access to the locked office.
5. All data were coded without names or other identifiers to link to the participants, and data were kept in a locked cabinet in the researcher's home.
6. Electronic data had no identifying information, and were kept on the researcher's personal, password protected, computer in password protected files. The process maps and field notes (hand written by the investigator or entered into an electronic document by the investigator) formed the audit log. The process maps and field notes had no identifying information and were used by the primary investigator of this study or, with her agreement, by other researchers or interested individuals to establish the rigor/trustworthiness of the study and also for secondary data analysis or qualitative metaanalysis. The researcher may also use the process maps and field notes, in the future, to educate others about the use of interactive interviews to develop process maps and collect rich data for qualitative studies.

7. The audio-taped field notes in the researcher's personal password protected cell phone were only reviewed or created in a private place and were erased within one week of the interview. No one other than the researcher had access to the cell phone.

In addition, special consideration was made for participants who were nurses licensed under the rules and regulations of the Texas Board of Nursing (TBON). The following statement on the consent and study recruitment documents addressed the special requirements for nurses under those legislative rules:

Special Consideration for Nurses Licensed in Texas

The Texas Nursing Board and the law require mandatory reporting by a licensed nurse if they have knowledge of any errors known to harm the public or any practitioner who has risk of harm to the public; therefore you should not discuss with the researcher any identified examples of cases of patient harm or potentially harmful practitioners. The law identifies as the appropriate entities that fulfills a mandatory report; BON or Peer Review Committee. Should you need to report such a case or should you need information about the nurse practice act and/or your responsibilities as a nurse, please contact the Texas Board of Nursing at http://www.bne.state.tx.us/ or Texas Board of Nursing,333 Guadalupe #3-460,Austin, Texas 78701.Office: (512) 305-7400 Fax: (512) 305-7401

Participants were asked if they would like the results of the study. If a participant requested final results of the study, the researcher gave them a blank envelope to record the address where they wish to receive the results. The results were mailed using that envelope and the address was not recorded. The envelopes were also kept in a locked cabinet behind locked doors in the researcher's home.

Data Collection and Analysis

This dissertation research wholly used the constant comparative, descriptive approach of grounded theory. The initial sources of data were: a literature review of published cases of enteral to intravenous tubing misconnections (completed), process maps of tubing connections created by participants; and three levels of validated data from semi-structured interviews with participants. The three levels of data from semi-structured interviews represent three levels of the healthcare system, the frontline nurse, the quality and safety professionals that review aggregate data as a part of their jobs, and experts in safety and tubing misconnections.

Research Design Phase

The first or research design phase consisted of three steps. Step one of the research design phase was completed with the review of published cases of misconnections between intravenous and enteral lines in published literature. Step two of the research design phase was completed with development of three fictitious example cases for use in interviews, and step three was completed with the IRB approved pilot study which tested and refined the methodology in December of 2009.

Data Collection and Analysis Phase

First level of data collection. The second phase is the data collection and analysis phase began after IRB approval in March 2011. The first level of data collection was with direct care nurses. The data collection method resulted in highly interactive interviews, which provided rich data. Exploratory and generative questions were used as diagramming of the process of tubing connections and misconnections evolved to illustrate nurses understanding of tubing misconnections. The map generated during each individual interview was constantly checked for accuracy with the participant throughout the interview as both researcher and participant drew and wrote upon the map and made notes. The resulting process map and notes of the conceptual understanding of both a successful and unsuccessful tubing connection were generated between the researcher and participant following these steps:

1. A large piece of blank paper was placed between the researcher and the participant who faced each other across a comfortable table while they are both seated.
2. A large selection of colored markers, Post-It notes ®, crayons, pens, and pencils were placed on the table and the participant was invited to use as many or few as they wished to mark, write, and draw on the paper.
3. Each interview followed a semi-structured interview guide and used the visual aid of a process map created by the participant and researcher during the interview to locate problematic areas or areas of interest. A process map example was discussed and described at the beginning of the interview (Appendix B).
4. The participants were asked to create a process map, or if they wished, to simply list the steps of a successful tubing connection. They were encouraged

to draw as many or few steps as they wished. They were told to take as much time as they needed and were encouraged to ask questions at any time.

5. The researcher verified the intent and accuracy of the drawing and marks on the process map during the interview session and continually encouraged the participants that there is no wrong way to illustrate a process.
6. The researcher informed the participants that they could take breaks or pauses at any time if the interview became tiresome.
7. After the participants drew a successful connection the researcher read aloud the descriptions of three example fictitious example cases of tubing misconnections (Appendix C). Each example case was presented slowly, with time provided for the participant to think and reflect upon the process map. Participants were then asked where in the process of connecting the tubing the misconnection may have occurred. The participants added to the process map, noting the points where they believed failure occurred and how it occurred as the researcher took notes and verified the accuracy of the notes.
8. During each step of the session, the researcher verified that her notes reflected an accurate understanding of the participants meaning, and compared and contrasted different thoughts, themes, and comments with the participant.
9. After creating the total map, participants were asked to review the map for accuracy, change any areas they wished to change, and discuss any unclear areas with the researcher.

At the conclusion of every interview the researcher logged the data collected from the map and the interview into an audit log, excluding any identifying data about the participant. As noted above, in a private place as soon as possible after the interview, the researcher dictated field notes from her own reflections on the interview session into her own personal password protected cell phone. That recording was used for personal review within one week of the session in a private place, and then erased completely. At no time was the participant's identity logged into the recording.

Initially, the researcher identified as many categories as possible and then compressed the data into converging categories. As concepts emerged the researcher logged developing concepts, categories, and properties (open coding) (Glaser & Strauss, 1967). Each new interview was compared to the previous analysis and categories. This generated several iterative categories that either continued to gain data or were re-coded to fit emerging categories. Any outlying data were noted and explored more fully in the next interview.

As the analysis and interviews continued connections very naturally began to develop between categories and subcategories (axial coding) and very distinct relationships began to emerge - capturing relationships and conditions (Glaser & Strauss, 1967). Selective coding followed as core variables were revealed. Memos and journal entries were incorporated into the coding methods as the study progressed. Each stage of development was captured and archived sequentially without identifying information about the participants.

Second level of data collection. In semi-structured interviews, the quality and safety professionals reviewed the method of interview used with direct care nurses. Then, the model of aggregate mapped data as well as detailed categories under each theme, were reviewed. They were asked to comment upon the findings, contrasting them with their own experience in reviewing safety data and pointing out any incongruencies. Each interview concluded by asking the participant if they felt the information accurately described the understanding of nurses about tubing misconnections.

Third level of data collection. The final level of interviews for review is the expert level. Experts in safety reviewed method of interview used for the level one direct care nurses also reviewed level two data from quality and safety professionals. The model of aggregate mapped data as well as detailed categories under each theme was reviewed. They were asked to comment upon findings, contrasting them with their own experiences reviewing safety data, and pointing out any incongruencies.

The final step of the study was comparing the experts' review and amalgamated maps. This step of the study included a comparison of the emergent theoretical constructs developed from the previous data sources. The researcher also compared the data against known and accepted frameworks.

This method of interview offered a unique opportunity to establish descriptive and interpretive validity in real time with the participant. When audio recordings are used to capture the interview, the transcription takes place at a later time. The transcription of tapes may invalidate descriptive validity because there is no chance to verify accuracy. In addition, there may be decay of information recall over time and there is no assurance that the researcher can avoid interpretation bias without the participant present (Sandelowski, & Barroso, 2007).

Had the interview data left thin or unanswered concepts, the researcher planned to employ a snowball strategy to recruit more participants. However, there was no need for additional participants. Saturation occurs when there are no new emerging categories and existing categories are repeated (Glaser & Strauss, 1967). When saturation was reached data collection ended.

Specific Methods for Process Maps

Critical to any effort is the shared knowledge and understanding of the task. Process mapping is a tool that delineates the interaction of the individual in a system and creates an understanding of the task or a shared concept (Barach & Johnson, 2006; Scholtes, 1996). Process maps or flow charts are powerful techniques in identifying critical points of breakdown (Battles, 2007; Deming, 1982). Process maps can be at different levels of granularity. Often a process begins being mapped at a high level and achieves detail as further information is integrated into the map until it reaches a saturation point. It is not unusual to place conflicting information along a process map when different people are giving input – this is understandable when one considers individual differences and views.

In order to build the shared concept of a successful tubing connection, the study participants were asked to draw or list the steps in the process. The steps were placed in a process map as they recalled the steps necessary to connect tubing using a luer connector.

Process mapping was used in this study to visually represent the data from interviews and aggregate results to a shared conceptual level.

Participants were also given the option of simply listing the steps instead of placing them on a process map if they chose to do so. Some participants took this option, others created detailed and colored maps with drawings of tubing, connectors, and made categories themselves as they worked through example cases. At the second level of quality and safety professionals, it was identified that participants were not comfortable drawing or listing the successful steps in a connection. One stated "it's been years since I touched one." The researcher continued through the interview then in the same manner without the map.

Process maps developed in this study were archived in two ways. First, for each individual, the map was kept separately in order to archive the individual's contribution. Second, the knowledge from the interviews was included in one aggregate process map. A chronologic development of the aggregate maps was captured after each refinement. Consistent with the constant comparative method; the process maps formed the basis for comparison (Lincoln & Guba, 1985).

Arraying aggregate data chronologically on process maps served as an initial theoretical framework. Categories emerged as data were ordered. Closure of the direct care nurse interviews occurred when theoretical saturation was established. At level two of the data collection, when improvements to the aggregate map, categories, and sub categories become redundant and interviews provide little additional information, the study moved to the final phase of data analysis and validation with the expert participants.

Use of Theory and Models

The philosophical foundations for data analysis were Blumers' Symbolic Interactionism and Weick's Sensemaking. When emerging findings made clear the relevance of Robert Helmreich's Threat and Error model (Helmreich & Musson, 2000, slide 10), James Reason's Swiss Cheese Model (Reason, 1990), and finally safety expert Perrow's (1999) Normal Accident Theory (NAT), these models were applied to developing the final model. Helmreich's model of threats and errors in healthcare basically defines the stages of an errors evolution from latent (systemic) threats to active threats (at the moment actions) and the error management behaviors required to mitigate those threats. James Reason also applied a systems approach to understanding errors, by describing error management behaviors, and holes within the defensive systems built to catch errors, as lining up like the holes in Swiss cheese.

Both Helmreich and Reason used a systems approach in which each contributing factor, no matter how trivial, is a part of the system and a part of the error. This approach leads to a deeper understanding of the complexity within the healthcare environment. Normal Accident Theory (NAT) applies to complex and "tightly coupled" systems such as nuclear power (Perrow 1999). Not unlike Helmreich and Reasons' work, NAT posits that in highly reliable systems accidents will occur – because the subcomponents are flawed and failure is inevitable. This makes accidents "normal" and only by designing subsystems for redundancy can they be avoided.

Understanding NAT and placing it within the models posed by Reason and Helmreich allowed careful consideration of each nurse's description of contributing factors to a tubing misconnection. While each factor individually is not substantial – a systems view paints a larger portrait of a highly complex environment. Each component part must be carefully considered as an additional weight on the systems defense mechanisms against errors and may be the tipping point for an error to occur.

Scientific Rigor

Established rigor in the qualitative research is dependent upon trustworthiness (Lincoln & Guba, 1985). This study establishes trustworthiness through the four domains described in Speziale and Carpenter (2003), these are credibility, transferability, dependability, and conformability.

Credibility was conferred through the use of structured interview process which allowed the researcher to have prolonged contact with participants. Participants confirmed and validated their own data in real time with the researcher, reflecting on the process maps and the researcher's notes. To allow others to assess transferability the researcher created "thick" descriptions of the research assumptions, process, and participants. Those who consider applying the research to their setting can use the information to determine the applicability of the findings. Dependability was established by the triangulation of data collection methods, process maps of tubing connections and semi-structured interviews and data sources from multiple sources, including direct care nurses (micro), quality and safety professionals (mid-level), and experts (macro).

Confirmability was established by maintaining a complete audit trail of each interview's data and process map. The researcher used Excel® workbooks as a manner of archiving –sometimes daily- as comparison, journal entries and interviews evolved. Each workbook was dated and timed and then archived; the next addition was created with a new date and time and archived – in this manner the researcher captured the evolution of the study. As well as the chronologic archival of the aggregate maps, interviews, memos, and journaling, the evolution of concepts and themes was captured. Thus the process of checking and rechecking, as well as the development of the study, was maintained in a detailed audit trail (Lincoln & Guba, 1985, Speziale & Carpenter, 2003).

CHAPTER IV

TRIVIAL EVENTS IN A NON-TRIVIAL SYSTEM:

NURSES AND TUBING MISCONNECTIONS

A Paper Submitted for Publication in the

Joint Commission Journal on Quality and Patient Safety

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ABSTRACT

Background: Connecting two tubes seems minor in the current complex healthcare system. However, the seemingly minor and the trivial can quickly turn tragic. Misconnecting an enteral system (meant to deliver nutrition to the gastrointestinal system) to an intravenous system (meant to deliver fluids and medications intravenously) may result in patient death. In this study, exploring nurses' understanding of misconnecting these systems served as a way to better understand healthcare safety. Methods: Grounded theory methodology was used to answer the question "what do nurses understand about tubing misconnections between enteral and intravenous systems?" Direct care nurses with experience in connecting enteral and intravenous tubing participated in a highly interactive interview. Two groups contributed to and validated the findings, institutional level quality and safety professionals and safety experts.

Findings: Nurses understand that environmental, cognitive, and technical factors may contribute to a tubing misconnection. Quality and safety professionals who reviewed the findings suggested these problems are not new but reflect the poor progress in creating a work environment conducive to safety in healthcare.

Discussion: The findings support applying systems analysis of errors and cognitive load principles to determining effective actions for preventing errors.

BACKGROUND

Trivial events in non-trivial systems should not go unremarked (Perrow, 1984)

The act of connecting two tubing systems seems trivial in an intricate healthcare system. However, misconnecting an enteral system (delivers nutrition to the gastrointestinal system) to an intravenous system (delivers fluids and medications intravenously) has resulted in death. Nurses who have connected tubing successfully have also connected two physiologically incompatible systems with disastrous effects. Published case studies. New York Times articles and alerts by safety and regulatory agencies provide evidence for alarm about tubing misconnections.[1-6] Yet, this hazard remains unexplained. The purpose of this study was to describe nurses' understandings of tubing misconnections. The findings apply to safe patient care in many situations.

METHODS

This study followed grounded theory methodology. Data were collected from a purposeful sample composed of three levels of participants: first, direct care nurses (n=15), second, institutional based quality professionals (n=5), and third, safety experts with experience reviewing aggregate reports above the institutional level (n=3, Table 1). Data collection had 3-parts, guided by a highly interactive, semi-structured interview process. Using a constant comparative method, data were analyzed sequentially, first individually and then in relation to emerging findings.

Nurse participants were shown how to draw a process map. In the first part of the interview nurses were asked to map, or list, the actions required in making a tubing connection. The researcher made notes of the participants' comments directly onto the same page or another page of paper. Throughout the interview the participant verified the accuracy of the researcher's notes.

In the second part of the interview three summary case studies of tubing misconnections were presented (Table 2). Participants identified, by marking on the process map or list they had developed, where errors may have occurred. In the third part of the interview participants reviewed the process map or list they had created for accuracy, changing any areas they wished to change, and discussed any unclear areas with the researcher. Each interview concluded with the researcher asking if the participant felt the information accurately described their understanding.

Following findings from the first level, the quality and safety professionals participated in semi-structured interviews.. The quality professionals were asked to comment upon the preliminary findings. Following completion of data collection from second level participants, the experts, who have experience reviewing aggregate safety reports above the institutional level, reviewed 3 sets of preliminary findings, those based in data from the nurse participants, those based in data from the quality and safety professionals, and the aggregate findings, including the aggregate map. The researcher concluded each interview by asking if they felt the information described nurses' understanding of tubing misconnections.

Safety models were consulted in light if the findings. It was important to apply the systems science of safety, thus Helmreich's Threat and Error model[7] and James Reason's Swiss Cheese model[8] were chosen. These models were developed to illustrate the relationship between threats and classify the processes.[8, 9] Final data analysis relied heavily on the cognitive taxonomy of errors by Zhang et al.[10] This taxonomy provided a method to systematically categorize errors along cognitive dimensions.

The theoretical framework used to develop this study relied upon Sensemaking[11] and Symbolic Interactionism.[12] Symbolic Interactionism expounded to Sensemaking, provides a structure to understand the nature of a person's thoughts and their interpretations. Participants engaged in Sensemaking as they considered the example cases through their own interpretation.[13]

FINDINGS

The study findings, Nurses Understanding of Tubing Misconnections between Enteral and Intravenous Systems, make clear that in a non-trivial healthcare system; seemingly trivial events may lead to deadly errors. The seemingly trivial events or actions involved in tubing connections include interactions between the work environments, technical properties, and cognitive constructs (Figure 1). Each major category, work environments, technical properties, and cognitive constructs, has several subcategories of more detailed descriptors.

Work Environment-- Chaos, Lighting, Policy and Procedures:

Although the nurses interviewed worked in various healthcare settings they shared common understandings regarding the influence of the work environment on the ability to perform. The stress of a chaotic work environment, poor lighting, and policies and supplies related to cost rather than to safety were identified as contributors to misconnections.

- *Chaos:* Nurses vividly described the work environment as chaotic. The multitude of tasks was described as ever changing with nothing ever being "routine". The result of the many tasks was described as never "feeling done". About the tubing misconnection cases, one nurse commented: "I am almost not surprised these happen- it is too hard to do the work some days- this is hard, hard, work."
- *Lighting:* One exemplary case scenario described a misconnection in a dimly lit room in a neonatal unit. Nurses described dim lighting as normal in areas such as the Newborn and Infant Critical Care Unit (NICCU). Nurses described working in the dark for fear of waking patients. One nurse commented: "how do they draw blood in the dark? But they do!"
- *Policies, Supplies, and Cost*: Nurses described hospital purchasing practices and stocking as possible contributions to connection errors, explaining that when a patient needed something the nurses "made do" and would use whatever equipment on hand to make sure a treatment was given. Backordering of supplies, which left non-optimal equipment as the only alternative, was named as a possible contributing event because it introduced other unfamiliar products. Nurses stated

that changes in purchasing practices might prevent errors by decreasing the variability and by making purchasing decisions for safer products.

Technical Properties -- Labels, Location of the Tube, Physical Attributes:

Nurses commented that technical aspects of equipment impact their ability to distinguish tubing systems and tubing purposes. Some nurses described the technical properties of the tubing, syringe, and connector as identifiers and, in contrast, others noted that the same properties could be confusing. They described labels and the location of tubing and connectors as potentially confusing factors.

- *Labels:* Nurses depicted labeling as one way that tubing was quickly identified, but also noted that labels could have fallen off, not been applied, or been labeled poorly. One said: "you never knew who would label the line or if they would not label it, so it was not good to rely on the label".
- *Location:* The physical location of the tubing and connectors can be confusing when they are tangled in "a spaghetti bed". Tubing attached to small patients was described as more difficult to manage because tubing was closer together. Nurses noted tubing tangles easily because patients move and tubes get tangled in bed. One suggestion was to put tubing for one system on one side of the bed and for another on the other side of the bed, or separate the location of the tubing around the bed.
- *Physical properties of the equipment:* Nurses reported that equipment both helped and hindered the identification of the different systems. Some nurses reported that equipment for adults made it easier to identify different systems because the

pumps look different. In contrast, another nurse commented that the pumps all look similar. Another nurse stated "100 in-services on 100 products – how can you remember?"

Several nurses commented that the cap being off an intravenous line, such as a central line, or color might contribute to a misconnection because intravenous lines look similar to feeding tubes. One identified that each line had a universally fitting connector. One nurse stated "all of them have colored tips, you have to know each one, and clamps are different so you have to know the clamps". One nurse reported that a certain color of tubing was the cue to knowing it was the end that was to go to the patient. But another commented "never know what color new things will be so you can't rely on it".

Cognitive Constructs -- Human Ability, Factors Outside the Control of the Nurse, Characteristics of the Nurse, Patient and Family:

Nurses readily commented on their perception of other nurses' thought processes or abilities and their beliefs about their own ability to perform tasks. These findings fell into three broad categories of human ability, factors outside the control of the nurse, and characteristics of the nurse, patient, and family.

- *Knowledge of the nurse:* Nurses described ignorance, poor education, and inexperience as being a contributor to misconnections. Others suggested nurses who made tubing misconnections had initially "learned wrong", "practiced wrong", or had not had a preceptor. In contrast others did not think misconnections were due to a knowledge problem: "anyone could have connected it wrong" and "this isn't not knowing"- they know better". One nurse said "it is common sense until you are in the thick of it – but an average nurse would not have caught this".

- *The ability to control attention:* Nurses expressed contrasting beliefs about the ability to control thinking and attention. Nurses described connecting tubing as: "I don't think about it I just do it". But others commented that a misconnection could be attributed to a not thinking or having a "bad habit of not thinking". One nurse described being "present in the moment: "you have to think about what you are doing" while another stated "your mind can be just not in the here and now - you are thinking of what needs to be done next".
- *Forgetting, interruptions, and distractions:* Nurses described that simply forgetting to do something is a possible contributor to misconnections happening. Forgetting might happen when they are distracted, interrupted, or thinking about another task. Nurses said they "forget things all the time" when they are tired and busy. They described it as "you take every care and then turn your head and miss one step "and "you just can't stay alert". One nurse commented that "multitasking is not what it is supposed to be – you can make mistakes".

Interruptions and distractions were described as a part of each normal day. Nurses stated that possibly the interruption of a connection of tubing could have happened because of emergencies, questions, and family's needs, and other urgent needs could have caused the misconnection when the nurse returned to the task. One nurse said "I try to never leave a task until it's done- but that's hard to do".

- *Physical and emotional influences:* The emotional state and physical state of the nurse was described in many interviews as possibly being a contributor to an error. This was described as *"crazy busy* stressed" on a daily basis as "every day things change". The stress brought to the job from outside the workplace was described: "you never know the emotional state of someone you work with – maybe something is happening at home."

  Fatigue was depicted as a major contributor to errors. One said: it got worse "during the red zone- mid shift when you are so very tired, have not eaten, and are so busy". Fatigue was described as resulting in decreasing alertness to details. Working 16-hour shifts, double shifts, or four 12-hour shifts in sequence, as well as having extra patient loads and not taking breaks "because no one will take care of my patients", could all contribute to fatigue. One nurse said: "on night shift- maybe they took care of a child all day and could not get any sleep" and another said: "even seasoned nurses are human – you have to get rest to do this job".

- *Shiftchange pressure:* Shift change demands were described as a contributor to the stress nurses felt to get "done" with work. Nurses described being not able to stay over after the shift because they were not allowed to work overtime. Some nurses reported receiving reduced performance points on their evaluations if they clocked out late. The alternative was to get a signed waiver from the charge nurse to stay over and finish "but they are so busy at shift change they don't want to and so some nurses just clock out and keep working – you have to take care of your patients. Experts in safety commented "this is an artificially induced pressure with an unintended consequence- it creates rush and pressure between shifts."

- *Characteristics of the nurse:* Nurses discussed the personal characteristics of nurses as possible reasons misconnections occurred. Some attributed bad work habits, ignorance, and laziness to the nurses who made the misconnections described in the case studies. One commented: "some people are just not cut out for nursing". In contrast, some nurses said that even an experienced nurse could miss a step. There comments included: there is just "too much going on to judge a nurse in these cases" and "you can't say if you were not there".
- *Characteristics of the patient and family:* Nurses said the patient, in some cases, would be able to assist the nurse by pointing out a problem before a misconnection occurred. Some said families might provide assistance in performing a connection successfully, while others said families being present were a distraction. Although one commented "great we can't figure out this problem- you can't make the patient responsible for that".
- *Improbability, probability, and fate:* Many nurses were shocked there was even one occurrence of a tubing misconnection. Their reaction was an astonished look and remarks like: "bizarre", "is this for real?", and "I don't even know how this can even happen". One nurse said "how can you not see it when you just unhooked the old one? In contrast, other nurses were very aware of tubing misconnections and said: "I have known of this happening". One nurse attributed a misconnection to "fate".

Review by Safety and Quality Professionals and Experts in Safety

Five quality and safety professionals reviewed the emerging findings from the nurse interviews and reflected on the emerging categories. Findings from their review are noteworthy within the context of understanding healthcare at the micro (nurse at bedside) and the macro (mid level quality and safety personnel) level. Three experts in safety, chosen by virtue of their experience reviewing data at the meta-analysis level, provided the final review of the findings. Consistently, the comments of these reviewers confirmed the model as representing a cross section of the present state of nursing understanding of tubing misconnections and, on a broader level, what is known about safety. One expert commented "It is interesting that they share so much of this –and that you caught both ends of the spectrum- they see these things and yet they don't get the impact to their work environment on their practice".

Safety professionals and experts noted that some of the nurses were not aware of the possibility of a tubing misconnection. In great disappointment that efforts to increase awareness of safety had not had more effect one said: "I am not surprised; they don't get this anywhere not in school, not in orientation, and not from quality and safety- there are not enough of us." Quality professionals and the experts commented on the unsafe conditions prevailing in healthcare despite years of efforts. One remarked "There is nothing new here - we have been having this conversation 11 plus years –and it remains the same old rut".

One expert suggested that grief was apparent in nurses' responses: "you see it all- denial it can happen, shock, acceptance, and anger". Another suggested the character judgments against nurses in the misconnection cases may represent a way for nurses to shield themselves from the thought that they might one day make an error. In short – if they believe nurses who make errors to be bad, uneducated people then it can't possibly happen to them because they are good and well educated. One expert commented: "The nurses express the continuum of people who are traumatized in a hostile work environment: some are aggressive toward each other, some are in denial, and some are a passive victim".

The emotional responses of nurses at each level of interviews support the observations by the expert. Many nurses overtly demonstrated that they were emotionally shaken as they considered the sample cases of tubing misconnections. Several nurses were silent for many minutes just shaking their heads and saying "so sad" and "no, no, no". Perhaps the most emotional response was from a staff nurse who had tears in her eyes and said at the end of the interview: "Did all those people die?"

DISCUSSION

The nurse has been described as "inextricably tied to the safety of patients;"[14, p. 23] however the environmental factors' weight in contributing to an adverse event has not been quantified. There are research results that emphasize the importance of minimizing distraction, increasing nursing influence on the practice environment, and creating a safety culture.[12-16] The findings of this study make clear the difficulty there is in applying that knowledge to nursing practice and workplace environments.

Perfect human performance is not realistic in life or in healthcare. There has been little research consideration paid to errors in tasks performed, in what James Reason terms, "automatic mode."[8] James Reason describes automatic mode as the level of functioning where tasks that are familiar are performed effortlessly and skillfully. Performing a tubing connection is a routine, familiar, and common task in nursing, often performed many times on one shift and certainly thousands of times throughout a bedside nursing career. Healthcare has yet to address the possibility that a routine task, performed successfully thousands of times by an individual, can inadvertently, be performed disastrously by the same person.

Cognitive load or the ability to perform in the presence of competing and taxing processes increases with each interruption, task, or complication in work. Nurse researchers, Ebright and Potter both found that increased cognitive load interrupts the nurse's ability to critically think.[17] Potter found evidence of cognitive shifts occurring in response to patients' needs and environmental demands. Both researchers found numerous work patterns that added to the complexity of nurses' work and interruptions. The research findings of Potter and Ebright, as well as of this study, point to a number of seemingly simple tasks that individually are manageable but cumulatively are catastrophic. In such environmental complexity it is not surprising nurses describe themselves as "crazy busy "and "never done".

While nurses commented upon the experience or education of nurses, it is unclear, empirically, whether years of experience or type of education influences the ability of nurses to avoid errors. One nurse summed it up by saying "You don't know what people know and don't know about this or tubes". Expert reviewers found this consistent with nurse responses in the events they review. One commented: "The expert nurses think they can't make a mistake and the new nurses don't know they can".

Obviously, cognitive processes in simple tasks such as tubing connections are not simple but complex. Memorizing a color to identify tubing, checking a fluids consistency to identify a function or looking to location (whether location of the tube on the patient or which side of the bed the pump is on) may be hazardous practices. These practices are likely short cuts to increase the speed of the work and may be generated by unrealistic workloads. Educational programs, nursing instructors, preceptors, and others who influence the development of skills may actually encourage these types of mental short cuts by describing them as they teach the skills. Identifying these mental models and replacing them with an understanding of safety may lead to safer practice.

In accidents there is typically a complexity in interactions that can either be technological and/or organizational.[18] If we acknowledge the complexity of the task and workload there are obvious lessons to be learned. For example, medical devices can be redesigned. Design must meet the expectations of imperfect performance under pressure. Redesigning tubing connectors to prevent tubing misconnections is one major step for safety in tubing, but there remain multiple opportunities to make other missteps with other processes that have not been addressed.

There are opportunities for translating basic safety principles into pragmatic solutions here that are almost embarrassing to report. Adequate task lightning is a reasonable expectation. Staffing levels should be adequate to allow time for breaks and basic nutrition and it is painful to consider that these may be denied to nurses.

The findings of this study also focus a high beam on the lengths nurses go to in order to take care of patients, even to the point of working around organizationally imposed barriers to patient care. Each of these imposed work environmental factors have unintended consequences. The practices of "clocking out and keep working" or "making do" with the supplies at hand send clear signals that inadequate staffing levels, end of shift practices, and lack of supplies may result in unsafe patient care. Given the difficulties at shift change there are opportunities to improve both the process of handoffs and decrease the tension between shifts imposed by artificially enforced "rules", such as a 30-minute time limit for shift change.

Limitations to this study include that, although the direct care nurses and quality professionals all worked in different settings, they all worked in or near the same large southern city. This is offset somewhat because the findings were confirmed by safety experts who worked in various areas of the United States and evaluated safety data from many areas of the county. Participants were recruited without regard to education, years of practice, or certification. Future studies that focus on whether nurses vary in their understanding of safety issues by education level, experience, or certification, and by the interaction of these characteristics with workplace culture would add to our findings.

The expectations of perfect performance stand against the discordant reality of healthcare and reflect what Perrow explains as a "normal accident". Normal accidents typically involve interactions that are never unexpected, but are inexplicable for some critical period of time.[18] Tubing misconnections can easily be described as normal accidents because they are routine tasks, unexpected and incomprehensible in their consequence. Whether or not the act of making a tubing connection is *acknowledged* as potentially significant or as trivial is pivotal in moving towards safer healthcare. Essentially our choice is to create a work environment where nurse can assure safe passage for a patient through the high risk healthcare industry – or leave trivial hazards in their path that create non-trivial tragedy.

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Table 1: Participant Characteristics

Data Level	Gender	Age (Years)	Years nursing	Ethnicity	Education	Practice setting
Level one: Direct care nurses	15 females and one male	22 to 66	2 to 45 years	2 Asian American 13 Caucasian 1 Hispanic	6 BSN 3 ADN 5 Masters 1 Diploma	Academic and community care settings
Level Two: Quality and safety profession als	5 female	43 to 63	18 to 41 years	Small sample size prevents revealing ethnicity	MSN	Academic and community care settings
Level Three: Safety Experts	3 total	Small sample size precludes detail			PhD and other advanced degrees	Reviews aggregate safety data above the institutional level

Table 2: Case Studies

Case #1

First statement	A nurse connects the feeding tube to the intravenous line.
Second statement	The patient is an adult with a feeding tube and a peripheral intravenous line
Third statement	The patient is in an intensive care unit and under sedation.

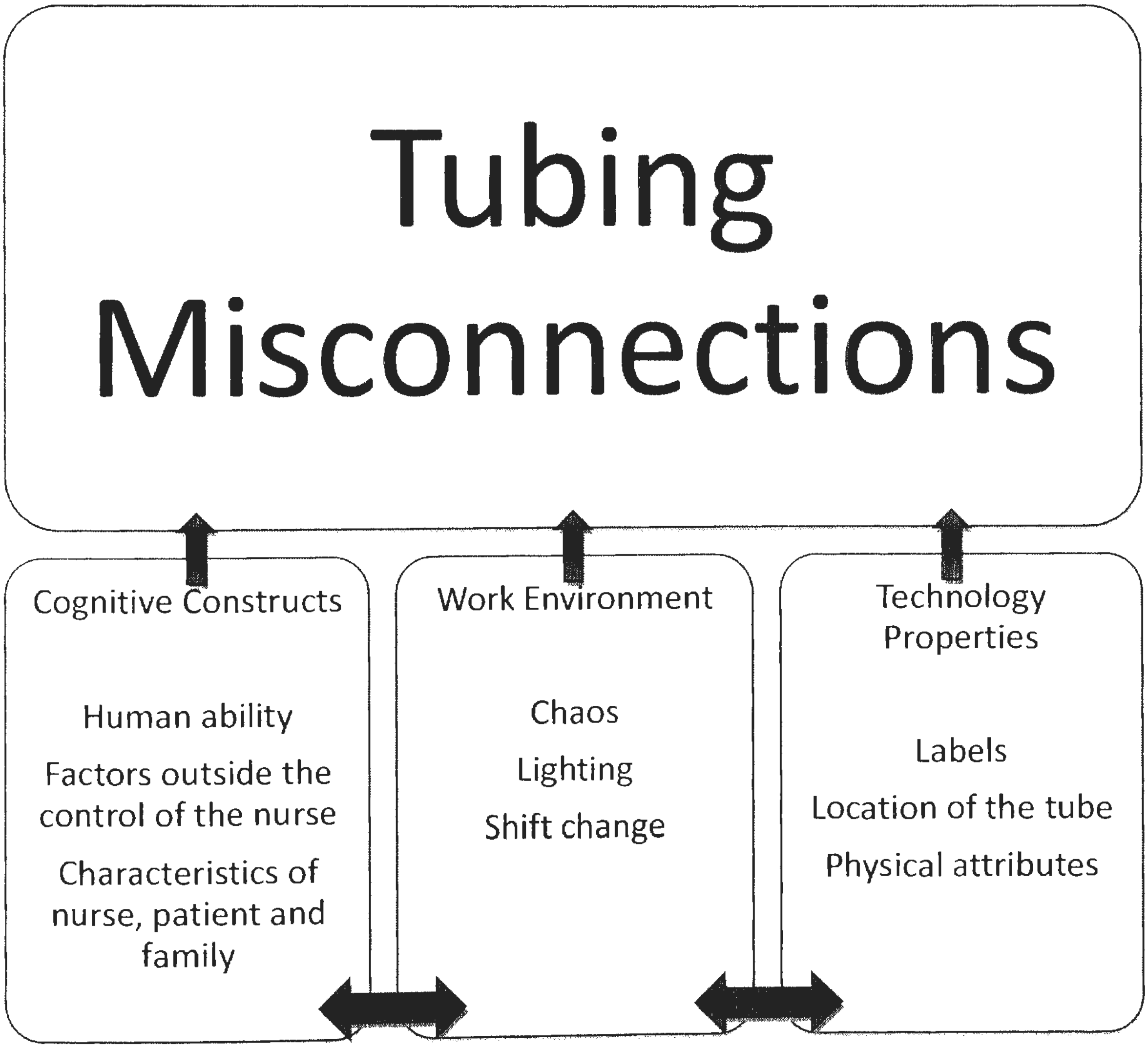
Case#2

First statement	In a medical surgical unit a nurse answers a call bell in a patient's room and finds the feeding tube connected to a central line catheter.
Second statement	The patient has a central line and a feeding tube. The family is present and it is shift change.
Third statement	The patient is an adult and is not cognitively impaired.

Case #3

First statement	In a neonatal unit where feedings take place every 4 hours, the nurse responds to the alarm that a feeding is finished and finds the feeding tube has been attached to the PICC line.
Second statement	The neonate is getting feeding 20 cc of expressed breast milk every 4 hours and also getting an intravenous infusion of antibiotics every 8 hours.
Third statement	The same syringe pump is used for tube feeding and for infusions; the syringes are also identical but are labeled. The room is darker for low stimulation.

Figure 1: Nurses understanding of tubing misconnections between enteral and intravenous systems



CHAPTER V

SUMMARY

The act of connecting two tubing systems seems simplistic in an intricate healthcare system. However, competent educated well-intentioned nurses who have connected tubing successfully for many years have also accidently connected two physiologically incompatible systems. The purpose of this study was to describe nurses' understandings of tubing misconnections. This study followed grounded theory methodology. Data were collected from a purposeful sample composed of three levels of participants: first, direct care nurses (n=16), second, institutional based quality professionals (n=5), and third, safety experts with experience reviewing aggregate reports above the institutional level (n=3). Data collection had three parts, guided by a highly interactive, semi-structured interview process.

Using a constant comparative method, data were analyzed sequentially, first individually and then in relation to emerging findings. The study findings make clear that in a non-trivial healthcare system; seemingly trivial events may lead to deadly errors. The findings also may be applicable to patient care in many situations. This chapter reviews the findings against theory and safety models and recommends a future path for education, research and theory development.

Discussion of the Findings

Blumer and Weick: Symbolic Interactionism and Sensemaking

"Symbolic Interactionism", as described by Blumer (1969) and expounded by Weick (1995) to "sensemaking", provided a theoretical structure to understand the nature of the nurse's thoughts and interpretation. In order to make sense of the environment, nurses interpreted their surrounding and interactions according to individual paradigms, observations about the environment, and their emotional feelings about tubing misconnections. The findings delineated the social interactions (i.e. shift change), human thinking (i.e. being attentive), definition of the situation (i.e. never done and chaos), and understandings of the nurse in order to illustrate the unexplained phenomena of tubing misconnections.

Weick's description of sensemaking is useful to understand events and make order and explanation from ambiguous events. This framework readily applies to healthcare safety data, which can be vague, perplexing, and defies the usual quantitative methods (Battles et al, 2006). Nurses readily engaged in highly interactive "sensemaking" with the researcher as they considered what would happen in the three summary cases presented during the interviews. There were nurses who struggled with the concept that a misconnection could occur and nurses who readily applied their knowledge of their environment to the possible causes. Both groups made sense of the unexplained events with incomprehensible consequences by rendering the three case studies understandable in the context of their everyday work environment.

Reason's Swiss Cheese Model and Helmreich's Threat and Error Model

Helmreich (Helmreich & Musson, 2000) and Reason (1990) propose a systems structure relevant to this research and sobering for its resolution. James Reason and Robert Helmreich both adhered to a systems view of errors and therefore provided important comparisons as findings emerged. James Reason proposed a Swiss Cheese Model to visually suggest holes in the layers of defenses healthcare uses to prevent accidental harm. Reason suggested that the holes in the Swiss cheese – which are holes in defenses against errors, must be changed in order to prevent error. Seen clearly in this study were the holes in defensive layers that allow hazards to advance to the patient whether they are of the environment (distractions, confusing colors) or of the individual (not being in the moment, fatigued).

Robert Helmreich further suggested, with the Threat and Error Model that only recognizing a threat will generate error reduction behaviors. Helmreich states his model is recursive with each error reaching a resolution, precipitating further errors or continuing to repeat unless the cycle is broken with error management behavior. Findings of this study suggest there is no one clearly defined defense against tubing misconnections. Further, in some interviews it became apparent there was a complete absence of error management behaviors because nurses did not believe there was a risk or believed that the connection was such a simple thing to do that there was no chance for error.

Perrow and Normal Accident Theory: Trivial Events in Non-trivial Systems Should not go Unremarked (Perrow, 1999)

Charles Perrow makes the point that even seemingly trivial events in a non-trivial system should be considered in evaluating errors or potential errors because they may have non-trivial consequences. Perrow describes Normal Accident Theory (NAT) as applying to complex and "tightly coupled" systems such as nuclear power and healthcare (Perrow 1999). NAT posits that highly reliable systems will always have accidents – because the subcomponents (including humans) are flawed and failure is inevitable. Contradictions to this thought emerged readily in the current study. Tubing misconnections were not thought of as a normal accident in the complex system of healthcare – more they were thought bizarre, mind boggling, and perhaps false, as in one nurse commented "did you make these up?" Further, other nurses found great fault with nurses who had made a tubing misconnections, often calling personal abilities, personality, and education into question.

Understanding systems safety failures requires recognizing contributing factors. This study extends systems safety models and illustrates the micro level realm of nursing on the frontline. As with the systems model of safety proposed by Reason, Helmreich, and Perrow, nurses in this study were able to suggest many different environmental factors that might contribute to errors as well as some individual factors such as fatigue and emotional distress. Although the study touched only on the error of a tubing misconnection, clearly the findings can be expanded to the entire scope of nursing care to pose questions about many other unexplained errors.

Healthcare safety information exists within silos in institutions. Each level and department maintains its own safety information and frequently it is not disseminated, thereby remaining unactionable. This common theme was identified implicitly and explicitly in the interviews of this study and echoes the Institute of Medicine report "To Err is Human" created a decade before this study commenced. The hazards articulated so passionately in the interviews with direct care nurses; sadly validated as the state of healthcare in the quality interviews; and understood by safety experts – are not communicated through the levels of the hospital in a meaningful manner. If the purchasing department heard these nurses and understood their impact; if the nurse executive heard the tension between shifts; and the nurse at the bedside informed meaningful change: it is a logical conclusion that safer care would result. This study however suggests we remain in a broken system, charging forward without hope of fundamental changes needed for safer care – many of which are literally within arm's reach.

Implications for Nursing Education

There is obvious evidence that safety concepts were absent on the "micro" systems level despite the last ten years of patient safety emphasis in healthcare. This not quite blissful state of naivety will not serve nursing well as healthcare continues to increase in complexity, increase in demands for performance, and face dwindling resources. Safety experts, such as Perrow, Reason, and Helmreich, clearly see the obvious outcome - errors will continue to occur without interventions to change the system. Application of safety principles that are well known in other high risk industries offer pragmatic answers, but these must be understood and valued by nursing faculty before they can pass the principles to new nurses.

Implications for Nursing Research

Nurses in this study attached mnemonic mental cues such as "a cone is a feeding tube connector", "purple goes to the patient", or "if you have an alcohol wipe in your hand it's an intravenous line", to inanimate components of the work environment. It may be detrimental to teach mnemonics as way of remembering complex relationships. Significant threats may be introduced when nurses begin to rely on simple mnemonics, color-coding, or visual cues such as shapes in identifying equipment (ECRI & the Institute for Safe Medication Practices, 2010). However, nurses still rely upon such simplifying concepts when teaching or practicing using such memory tools as the "Five Rights of Medication Administration". There is doubt that administering medications can be this as simple as only 5 steps so how can a simple mnemonic provide a measure of safety (Aspden, 2004, Cohen, 2007)?

Implications for Nursing Practice

The findings from this study make clear the effects of cognitive overload on safety. Nursing, as one participant explained, is "hard, hard work" with a complex mental work component that cannot be ignored. Although thresholds for reaching cognitive overload have not been explored, the mental work of nursing cannot be set aside when designing safer systems. Undoubtedly the ability to sustain attentive mental effort is a moving target influenced by the individual's physical and emotional capabilities. These findings suggest that the mental work of nurses is not supported in the work environment.

Nursing Theory Development

Grounded theory sustained the development of these findings from the beginning to the conclusion of this dissertations work. Strauss and Corbin state:

> ...data collection, analysis, and theory should stand in *reciprocal* relationship with each other. One does not begin with a theory, and then prove it. Rather, one begins with an area of study and what is relevant to that area is allowed to emerge. (Strauss & Corbin, 1990, p. 23)

This was the experience of this study- as data were collected and analyzed a model emerged of nurses understanding of tubing misconnections between enteral and intravenous systems. The model however leaves many unanswered questions regarding safer work environments for nurses. Each major node of the model leaves ample room for exploration of environmental, cognitive, and technical aspects of nurses' interpretation of their work. This study contributes to theory regarding safe nursing practice by indicating problematic issues/concerns. For example, the findings that nurses' cognitive constructs about human ability, factors outside the control of the nurse, and characteristics of the nurse, patient, and family contribute to error would benefit from further testing and development.

Conclusions

The specific conclusions of this study are:

Cognitive Constructs

1. Nurses have a wide variation in their knowledge regarding the occurrence of tubing misconnections, ranging from disbelief that a misconnection can occur to awareness that it can happen when the nurse experiences a brief distraction.
2. Limits on human ability, factors that nurse cannot control, and characteristics of the nurse, patient, and family may contribute to tubing misconnections.

Work Environment

1. In the work environment, organizational practices do not support the mental work of nurses.
2. Healthcare has not applied common knowledge, easily understood and reachable safety concepts such as avoidance of stress and fatigue, lighting, cultural support of safe practices, awareness of risk, and understanding of the limits of human performance to the work environment.

Technical Properties

1. While some nurses rely on labels, location of tubes, and physical attributes of the tubes and related materials to cue them to make tubing connections others report that relying on such cues may lead to misconnections.

Overarching Conclusions

1. Most nurses do not conceptualize making a tubing connection as a linear process.
2. Nursing has not assimilated basic safety principles for application in practice.
3. Factors related to the cognitive constructs of nurses, the work environment, and technology properties are widespread and create an environment that may be deadly for patients.

Recommendations for Further Research

Based on the findings of this study, research is recommended in the following areas:

Cognitive Constructs

1. Nursing education research is desperately needed to explore the most effective manner to increase the generic safety knowledge within the nursing workforce.
2. Research is needed to better understand how human (nursing) ability and function in the face of uncontrollable factors can be developed to be most effective in providing safe and effective patient care.

Work Environment

1. Further research is needed to understand how the work environment and organizational practices can be most effectively modified to support the work of nurses.

Technical Properties

1. Nursing practice is in urgent need of research aimed at understanding the nurses' attachment of meaning to common medical devices and tasks. As well, the pragmatic application of this meaning in performing critical tasks must be understood in order to create a safer environment for nursing practice.
2. An evidence base is needed for the design of healthcare devices that will support nurses' cognitive work. The tasks that are performed in "automatic mode" in nurses' work must be further understood in order to inform the design of technical aspects medical devices to make them less susceptible to error.

Research Related to Overarching Conclusions

1. Further research that leads to a more developed theory of the environmental, cognitive, and technical aspects, as well as the interactive complexity, of the socio-technical work environment of nurses is needed in order to explain the influence of these factors on safe nursing practice.

Concluding Summary

The act of connecting two tubing systems seems simplistic in an intricate healthcare system. In this chapter the findings of this study were reviewed and compared against known theory and safety models. The study's major findings created a model representing nurses understanding of tubing misconnections, and perhaps this understanding of errors and risk is applicable to nurses' work in a larger sense. Intrinsic and extrinsic factors were identified and a path for future work discussed.

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APPENDIX A

Recruitment Script

Recruitment Script:

"______________________, I am beginning the study for my dissertation work at Texas Woman's University. As a part of this work I need approximately a 90 minute long interview with direct care providers and with people who work in quality and safety. The purpose of the study is to explore what healthcare providers understand about tubing misconnections. The interview will consist of:

1. Writing down all the steps you can think of in a successful tubing connection
2. Reviewing a summary of anonymous cases of tubing misconnections from a national database.
3. Looking over the steps in your successful connection of tubing and discussing where you think the misconnection could have occurred.

The interview should take about 60 minutes and you can take breaks or stop the interview at any time you wish without a penalty of any kind.

There is no remuneration for this interview except my gratitude, a Starbucks coupon, and the hope that the information will help to improve patient care.

Do you want to consider participating? If so – what is a convenient time and place for you? "

APPENDIX B

Interview Introduction and Guide

Interview Introduction and Guide

I am interested in learning more about how health care professionals understand tubing misconnections that occur when a luer lock or luer tip is used. My focus is only on the luer lock, and the ability for an intravenous infusion to connect to a feeding tubing.

You are being asked to participate in this study because you are an experienced health care provider. It doesn't matter if you know firsthand of a misconnection event. First I will ask you to describe a time when you successfully made a tubing connection using a luer lock and to write the steps down. The paper you write on will be coded – your name will not be on it. After we have reviewed those steps I will show you three descriptions of connection errors and ask you to consider what led to the error and what might have prevented it, referring to what you described about the steps in a successful tubing connection.

I appreciate your answers and will write down comments as we go. At the end you will be able to correct what I have written and add or subtract as you like.

Special consideration for nurses licensed in Texas:

The Texas Nursing Board and the law requires mandatory reporting by a licensed nurse if they have knowledge of any errors known to harm the public or any practitioner who has risk of harm to the public; therefore you should not discuss with the researcher any identified examples of cases of patient harm or potentially harmful practitioners. The law identifies as the appropriate entities that fulfills a mandatory report: BON or Peer Review Committee. Should you need to report such a case or should you need information about the nurse practice act and/or *your responsibilities as a nurse, please contact the Texas Board of Nursing at*

http://www.bne.state.tx.us/ or

Texas Board of Nursing

333 Guadalupe #3-460

Austin, Texas 78701

Office: (512) 305-7400

Fax: (512) 305-7401

Remember you can stop the interview or take a break anytime you wish. Are you ready to proceed?

Misconnections of tubing are defined as incompatible systems that are connected inadvertently, which might cause life threatening events in the clinical arena- this includes acute and long term care as well as home health. We are interested in only tubing misconnections between enteral and intravenous lines. We are going to use process maps to be a picture of what happens.

1. Describe a time when you successfully made a tubing connection using a luer lock.
    a. Write out the steps to making a successful tubing connection.
    b. To do that we can make a process map and here is an example (process map guide page)

Now that you have made clear what makes a successful tubing connection using a luer lock I am going to talk with you about some case studies of tubing misconnections.

2. What do you think happened or didn't happen that resulted in the misconnection?

    a. Do you think anything else contributed to the misconnection?

    b. What do you think could have prevented the misconnection?

Up to now we have been talking about specific tubing connections and misconnections and may have missed information that is relevant to other connections using luer locks.

3. What else is important when thinking about causing or preventing tubing misconnections?

    Probes: *What do you mean when you say……? Tell me more about……*

    What is an example of…? What else can you say about ……?

APPENDIX C

Case Studies

Case Studies

Case #1

First statement	A nurse connects the feeding tube to the intravenous line.
Second statement	The patient is an adult with a feeding tube and a peripheral intravenous line
Third statement	The patient is in an intensive care unit and under sedation.

Case#2

First statement	In a medical surgical unit a nurse answers a call bell in a patient's room and finds the feeding tube connected to a central line catheter.
Second statement	The patient has a central line and a feeding tube. The family is present and it is shift change.
Third statement	The patient is an adult and is not cognitively impaired.

Case #3

First statement	In a neonatal unit where feedings take place every 4 hours, the nurse responds to the alarm that a feeding is finished and finds the feeding tube has been attached to the PICC line.
Second statement	The neonate is getting feeding 20 cc of expressed breast milk every 4 hours and also getting an intravenous infusion of antibiotics every 8 hours.
Third statement	The same syringe pump is used for tube feeding and for infusions; the syringes are also identical but are labeled. The room is darker for low stimulation.

APPENDIX D

Institutional Review Board Approval Letters

TWU
EXAS WOMAN'S UNIVERSITY
DENTON DALLAS HOUSTON

Office of Research
6700 Fannin Street
Houston, TX 77030-2343
713-794-2480 Fax 713-794-2488

September 22, 2009

Ms. Debora Simmons
College of Nursing - Lene Symes Advisor
6700 Fannin
Houston, TX 77030

Dear Ms. Simmons:

Re: What do members of the healthcare industry understand about tubing misconnections? A qualitative, multiple-case, explanatory study using a grounded theory approach

Your application to the IRB has been reviewed and approved.

This approval lasts for one (1) year. The study may not continue after the approval period without additional IRB review and approval for continuation. It is your responsibility to assure that this study is not conducted beyond the expiration date.

Any changes in the study or informed consent procedure must receive review and approval prior to implementation unless the change is necessary for the safety of subjects. In addition, you must inform the IRB of adverse events encountered during the study or of any new and significant information that may impact a research participant's safety or willingness to continue in your study.

Remember to provide copies of the signed informed consent to the Office of Research, IHS 10110 when the study has been completed. Include a letter providing the name(s) of the researcher(s), the faculty advisor, and the title of the study. Graduation may be blocked unless consents are returned.

Sincerely,

Dr. John Radcliffe, Chair
Institutional Review Board - Houston

TWU
TEXAS WOMAN'S UNIVERSITY
DENTON DALLAS HOUSTON

Office of Research
6700 Fannin Street
Houston, TX 77030-2343
713-794-2480 Fax 713-794-2488

January 12, 2011

Ms. Debora Simmons
College of Nursing - Lene Symes Faculty Advisor
6700 Fannin Street
Houston, TX 77030

Dear Ms. Simmons:

Re: "Nurses' Understanding about Tubing Misconnections between Enteral and Intravenous Systems: A multiple-case, explanatory grounded theory study" (Protocol #: 16298)

Your application to the IRB has been reviewed and approved.

This approval lasts for one (1) year. The study may not continue after the approval period without additional IRB review and approval for continuation. It is your responsibility to assure that this study is not conducted beyond the expiration date.

Any modifications to this study must be submitted for review to the IRB using the Modification Request Form. Additionally, the IRB must be notified immediately of any unanticipated incidents. If you have any questions, please contact the TWU IRB.

The signed consent forms, as applicable, and final report must be filed with the Institutional Review Board in the Office of Research, IHS 10110, at the completion of the study.

Sincerely,

Carolyn Kelley
Carolyn Kelley, PT, DSc, NCS
Institutional Review Board - Houston