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THE IDENTIFICATION AND CLASSIFICATION OF FLOW DISRUPTIONS IN THE OPERATING ROOM DURING LAPAROSCOPIC CHOLECYSTECTOMY AND OPEN HERNIA REPAIR PROCEDURES

by

SACHA N. DUFF

B.S., Embry-Riddle Aeronautical University, 2007

A Thesis Submitted to the College of Arts and Sciences in Partial Fulfillment of the Requirements for the Degree of Master of Science in Human Factors and Systems

> Embry-Riddle Aeronautical University Daytona Beach, Florida Summer 2013

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Sacha N. Duff

This Thesis was prepared under the direction of the candidate's Thesis Committee Chair, Dr. Albert J. Boquet, PhD., of the Department of Human and has been approved by the Thesis Committee. It was submitted to the College of Arts and Sciences in partial fulfillment of the requirements for the degree of Master of Science in Human Factors and Systems

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ABSTRACT

The operating room is one of the most complex work environments in healthcare; it is estimated that at least 7% of adverse events due to medical error occur in the operating room. Flow disruptions are events that cause a "break" in the primary surgical task, or the loss of any team member's situational awareness. An empirical link between flow disruptions and surgical errors in the OR has been established; therefore, identifying and classifying the specific flow disruptions present during different types of procedures should facilitate the development of evidence-based interventions. The goal of this study was to identify and classify flow disruptions during laparoscopic cholecystectomy (camera-assisted gallbladder removal) and open inguinal and umbilical hernia repair procedures. Results of this study revealed seven categories of disruption that emerged inductively from the data collected. These were: communication, coordination, external/extraneous source, training/supervisory, equipment/supplies, patient factors, and environment. Though the average duration and disruption rate were similar for both types of procedure, the type of disruptions present during each were unique. One example of this includes the higher incidence of equipment related flow disruptions during laparoscopic cholesystechtomies, which is the more equipment intensive procedure of the two observed.

iv

TABLE OF CONTENTS

	Page		
Review Committee Signature Pageii			
Acknowledgementsiii			
Abstract	Abstract iv		
List of Tables	viii		
List of Figures	ix		
Chapter I Introd	duction and Review of the Relevant Literature 1		
	Patient Safety and Adverse Events1		
	Technological Advances2		
	The Systems Perspective4		
	Human Factors5		
	Failures of Prevention		
	Evidence from Other Complex Industries6		
	Need for Valid Metrics7		
	Flow Disruptions		
	Classification and Taxonomy9		
	Study Goals10		
Chapter II Met	hodology12		
	Participants12		
	Apparatus and Materials12		
	Data Collection Tool12		

	Informed Consent	13
	Procedure	14
	Data Collection	14
	Observer Credentials	15
	Surgical Procedures	16
	Data Management	17
	Classification	18
	Variables	18
	Analysis	19
Chapter IV	Results	20
	Descriptive Statistics	20
	Reliability Testing	20
	Qualitative Data	22
Chapter V	Discussion, Conclusions, and Recommendations	
	Limitations	31
	Conclusions	32
References		
Appendices		
А	Informed Consent for Hospital Staff	
В	Informed Consent for Patients	
С	Final Categories, Sub-categories, and Error Codes	40
D	Pre- and Post- Procedure Survey for Surgeon	43
Е	Inside of the Data Collection Tool	44

F	Outside Cover of the Laparoscopic Data Collection Tool	45
G	Outside Cover of Generic Data Collection Tool	46
Н	Examples of Recorded Flow Disruptions	47
Ι	Example Flow Disruptions from Each Category	48
J	Percentage of Flow Disruptions by Category, Overall and by Procedure	49
K	Image of Hernia Repair Procedure	50
L	Percentage of Flow Disruptions by Category	51
М	Percentage of Flow Disruptions by Category and Procedure	52

LIST OF TABLES

		Page
Table	8	
1	Example Flow Disruptions from Each Category	20
2	Percentage of Flow Disruptions by Category, Overall and by Procedure	22

LIST OF FIGURES

Figure		
1	Image of Hernia Repair Procedure	.16
2	Image of Laparoscopic Chloecystectomy Procedure	.17
3	Percentage of Flow Disruptions by Category	.21
4	Percentage of Flow Disruptions by Category and Procedure	.22

CHAPTER I

INTRODUCTION AND REVIEW OF THE RELEVANT LITERATURE

The operating room (OR) is one of the most complex working environments in healthcare due to the acuity level of the patients, complex treatment protocols, high level of interaction with technology, and large amount of coordination necessary to manage the rapidly changing conditions (Christian, et al. 2005). Surgical teams must work together to effectively manage competing task responsibilities while also coping with the numerous distractions and interruptions that occur in the OR. Unfortunately, however, interruptions and distractions occur frequently and have been shown to negatively impact performance, teamwork, and surgical outcomes (Wiegmann, ElBardissi, Dearani, Daly, & Sundt, 2007; Beyea, 2007). Though estimates vary greatly, researchers estimate that around 45% to 50.3% of adverse events inmedicine relate to surgical procedures performed in the OR (O'Connor et al., 2010; Catchpole, Mishra, McCulloch, 2008).

Patient Safety and Adverse Events. Patient safety is a concern that has come to the forefront of the health care industry since it was reported that medical error contributes to over 100,000 deaths per year (Kohn, Corrigan & Donaldson, 2000). This statistic can be accounted for primarily by adverse events (AE). An adverse event is most commonly defined as "an injury caused by medical management (rather than disease process) that results in either prolonged hospital stay or disability at discharge" (de Vries, Ramrattan, Smorenburg, Guoma, & Boermeester, 2008; Michel, Quenon, Sarasqueta & Scemama, 2004; Thomas & Brennan, 2000).

A systematic review of the literature regarding in-hospital events found that the median overall incidence of AEs is 9.2%-15%, which means that more than one out of every ten patients admitted will experience an adverse event while under the hospital's care (de Vries et al., 2008; O'Connor, Papanikolaou, & Keog, 2010). To put this problem into perspective, AEs cause a greater number of deaths per year than auto accidents, aircraft accidents, suicides, falls, poisonings, and drowning combined (Barach & Small, 2000). Recent research suggests that at least 50% of past AEs were preventable (de Vries et al., 2008; Thomas & Brennan, 2000). A preventable AE is one that would not have occurred if the patient had received ordinary standards of care appropriate for the time (Michel, Quenon, Sarasqueta, & Scemama, 2004). Preventable AEs affecting hospitalized patients is the eighth leading cause of death in the United States (Thomas & Brennan, 2000). While patient safety is of utmost importance in the management of error in medical settings, one cannot ignore the financial burden placed upon the patient, the already cash-strapped medical industry, and related service providers. It is estimated that preventable adverse events cost the US between 17 and 29 billion dollars annually (de Vries et al., 2008). A review of 18 types of medical events concluded that medical errors may account for 2.4 million extra days in the hospital, and \$9.3 billion in excess charges annually (for all payers)(centers for Medicare and Medicaid services, press release) (Barach & Small, 2000).

Technological Advances. Advances in surgical technology and technique have made it possible for many procedures that previously required significant surgical invasion, to be performed with minimal invasion, on an outpatient basis. The assistance of a laparoscopic camera during surgery allows surgeons to operate very effectively inside the body through a few very small incisions. It is believed that using this technology allows shorter surgical time than the traditional method and allows for faster patient recovery periods. Improvements in performance

and patient safety have been observed since the introduction of laparoscopic technology (Manzey et al., 2009). Consequentially, an increase has been observed in the number of patients opting for surgical intervention than before this technique was widely available.

While there are benefits associated with these types of advances, there have also been unanticipated repercussions. For example, concerns have been raised about the ergonomic design of laparoscopic tools, and the postures required for viewing monitors displaying the laparoscopic camera feed. These concerns are increasing with the frequency and extended periods these tools are being used for. The implications of this type of surgical evolution illustrate how changes in one aspect of a system, such as introducing a new technology, can have unexpected effects of various, sometimes seemingly unrelated emergent properties or latent failures, that occur "downstream" from the actual change.

There are also cognitive concerns related to laparoscopic, or image-guided navigation (IGN) assisted procedures. These stem from the complexity of navigating within a three dimensional space represented by a two dimensional image, provided by the IGN system. The limited field of view provided by the camera and the lack of depth or spatial cues place high demands on the surgical team's perceptual and cognitive resources. Manzey et al. (2009) defines automation as "any function previously performed solely by a human and is now carried out partially or completely by a machine". According to this definition, IGN assisted surgery is a type of automation. Therefore, IGN is susceptible to the classic difficulties that accompany the benefits of automation. These include, increased cognitive demands, increased psychomotor demands, overreliance, and degradation of manual skill (Manzey et al, 2009; Catchpole et al., 2008). Studies also show that significant experience (>100 cases) is required before improvements in performance can be seen (Manzey et al., 2009). This suggests that significant

training and experience should accompany the introduction of IGN, though this is often not the case.

The Systems Perspective. James Reason introduced the "Swiss Cheese Model" of accident causation in 1991 as a means of organizing human error data. This model supports the view that errors are not caused by a single action, but rather, "holes", or vulnerabilities throughout the system, which allow actions to bypass usual safety measures that would normally compensate for them. Adverse events occur when several "latent" failures throughout the system, align with one another, allowing errors to penetrate several levels of intended defenses. This view supports a non-punitive approach to error that rejects personal repercussions in favor of utilizing information gleaned from the error to help improve the system. The "Swiss Cheese Model" has become the foremost conceptual "systems" model of human error since it's introduction 20 years ago (Reason, 1991).

A system is a construct or collection of different elements, that together, produce results not obtainable by the elements alone. The elements, or parts, can include people, hardware, software, facilities, policies, and documents; that is, all things required to produce systems-level properties, characteristics, functions, behaviors and performance. The value added by the system as a whole, beyond that contributed independently by the parts, is primarily created by the relationship among the parts; that is, how they are interconnected (A Consensus of the INCOSE Fellows", INCOSE, 2006). Humans are the most variable aspect of any system because they frequently deviate from normative work instructions and rules, and are bound to the confines of a fallible body and brain, prone to forgetfulness, inattention, poor motivation, carelessness, negligence, time pressure and recklessness, which can all increase the chance of performing an unsafe act (Friedman, Elinson, & Arenovich, 2005). These elements, either singularly or in combination can contribute to drifts in procedures, complacency, and work-arounds, that can form the basis for vulnerabilities in the system.

The systems approach to human error is based on three principles: (1) human error is unavoidable, as it is an inherent aspect of human work; (2) faulty systems allow human error to cause harm to the patient; (3) systems can be designed that prevent or detect human error before a patient is harmed (Etchells, O'Neill, & Bernstein, 2004). The question that human factors professionals are facing right now is; which measures are most closely associated with determining the potential for human error and identifying latent failures throughout the system? For measurement of the impact of any changes or interventions introduced to the healthcare system, a baseline measure of the current state must be recorded for comparison.

Human Factors. Human factors is the study of human physiological and psychological capabilities, limitations, and tendencies, and how they affect the interaction with their environment. Christien et al. (2005), defines human factors as "the study and (re)design of environments and processes (i.e. systems) to ensure safer, more effective, and more efficient use by humans". The extent to which the human and system "fit" together affects the success of the system. Human factors research aims to understand how the human fits within the system, and use that understanding to re-engineer the systems to better support the humans that operate within them. Human factors principles can be applied to the design of equipment, processes, procedures, team interactions, organizational directives, and any other system component that has the potential to influence human behavior within the system. Often, it is not the individual components of the system that are problems in their own right, rather it is the emergent properties that result from the interaction with other components in the system.

Failures of Prevention. It is better to catch failures up-stream, before they contribute to an incident. This is why it is important to record failures of prevention (Woods, 2002). If a preventative measure is not fulfilling its role, it may not be the ideal solution for that issue, or it could be causing unexpected emergent properties that could be negatively affecting the system. If the existing procedure does not prevent the target action, it may be more beneficial to look at the procedure as the source of the inadequacy rather than the actions of the people performing them. If the procedure itself is sound, determining why the procedure was not being followed will provide more insight to the underlying issue than simply assuming it wasn't followed was because the person didn't know it or was not willing to abide. A study by Wolf, Potter, Sledge, Boxerman, Grayson, & Evanoff (2006), found that when nurses followed the hospital policy for medication administration, they were twice as likely to be interrupted during the task, when compared to those who were noncompliant. The policy required repetitive trips to the medication supply room, which caused the nurses to be more visible, and therefore more frequently available for interruption. The results of this study illustrate one of the major downfalls of measuring quality by compliance to procedure. When a procedural "drift", or habitual non-compliance occurs, it is more beneficial to look at the reason that the procedure has been altered than to force or punish employees for abiding by it. It may be more efficient to accommodate the revision to the procedure, as it is likely that the drift occurred for a valid reason.

Evidence from Other Complex Industries. Several complex industries with highly effective safety programs including aviation, petroleum, and nuclear power have been widely receptive to the systems view of human error. Evidence from the successful safety records of these industries suggests that healthcare could benefit from adopting a similar perspective. "Pilot

error", has long been cited as the most common cause of accidents in aviation. At least 70% of the airline accidents and incidents over the past 20 years can be attributed to inadequacies in non-technical skills such as crew coordination, workload management, and decision-making (Hammond, 2004).

The Medical industry is similar to the aviation industry in the sense that they are both highly dynamic, time sensitive and performed in complex, technology rich environments. Many aspects of the system influence the state, decisions, and behavior of the humans that interact with it. Some topics that have been addressed in aviation are still plaguing the medical industry. These include excessive work hours, task overload, sleep deprivation, team communication and coordination, faulty equipment, poor interface design, budget constraints, and weak safety cultures. Introducing aviation analogs such as debriefs, simulation, recurrent training, checklists, and crew resource management (CRM) to the medical industry could greatly benefit hospitals and patients.

However, aviation models may not transfer seamlessly to the medical domain. The benefits of these programs and requirements in aviation have been years in the making. Aviation and medicine share some similarities, but the medical industry has many unique features not present in aviation. Therefore, as human factors and systems interventions are developed and brought to bear in the medical industry, tailored interventions based upon empirically derived data is of utmost importance (Helmreich, Musson, David, M., Sexton, J. B., Project).

Need for Valid Metrics. Valid metrics capable of capturing the effects of a broad range of systemic failures, across various procedures would be extremely beneficial as researchers proceed to explore areas other in the healthcare industry that offer the option for improvements. The benefits of using a consistent metric across procedures include the ability to present data in aggregate, so that results to be compared between departments or even across hospitals, states, or regions. This would also provide observers relatively consistent and easy to recognize, actions and events, which can be explored in aggregate to identify larger patterns or trends. The growing research interest directed at interruptions, distractions, and flow disruptions in health care suggest that these types of measures may be just such a metric.

Flow Disruptions. Interruptions and distractions occur frequently in the operating room, and have been shown to negatively impact performance, teamwork, and surgical outcomes (Wiegmann, ElBardissi, Dearani, Daly, & Sundt, 2007; Beyea, 2007). Surgical flow disruptions are events that result in a break in the flow of the primary surgical task, or the loss of any team member's situational awareness. Situational awareness in the operating room has been described as; the "ability to observe, understand, and predict events in the OR", and has shown to be strongly related to technical errors in surgery (Catchpole et al., 2008). The concept of "flow" does not have a single definition. In aviation, "flow" is [demonstrated through] the sequence of maneuvers, discussions, checklists, and read backs that mark the conduct of a safe flight" (Karl, 2009). In health care, it refers to the ease with which a task progresses. Some factors that contribute to flow are attention, understanding, proficiency, teamwork, preparation, communication, coordination, and culture. There is an empirical link between flow disruptions in the operating room and surgical errors (Wiegmann et al., 2007). From the systems perspective, flow disruptions can be a symptom of a latent failure somewhere within the system. Gaining a better understanding of the frequency and nature of flow disruptions will allow for the development of evidence-based interventions (Wiegmann et al., 2007).

Flow disruptions collected in a single case do not hold significant merit for indicating system failures because there are many variables such as team member fatigue or individual

patient factors that can influence the progression of any single case. Flow disruptions that indicate systemic failures will resurface within and across cases, revealing areas that warrant further investigation. Some benefits of flow disruptions as a metric include; the ability to capture systemic failures of any type, the ability to acquire baseline measures that can be used for comparison after any type of intervention, and the ability to use a consistent metric across procedures. The benefits of these features include being able to identify compensatory strategies, "best practices", set benchmark data across facilities, identify systemic failures that may be impacting multiple processes, and collect data that will inform the development of evidence based interventions that address system-specific issues.

Classification and Taxonomy. Classifying surgical flow disruptions using human factors taxonomies provides a means of organizing data so that trends and patterns can be identified. Defining the nature of generic problems in the OR can point to appropriate remedial action (Catchpole et al., 2008). A common taxonomy used by human factors practitioners is the Human Factors Analysis and Classification System (HFACS), which was originally developed for the aviation industry, but has since proved adaptable to many other complex industries (Wiegmann & Shappell, 2003). The HFACS taxonomy is based on Reason's "Swiss Cheese" model of accident causation (Wiegmann & Shappell, 2003; Reason, 1990). The taxonomy aims to fill in the "holes" of the cheese, or provide a method to determine what type of "latent failures" exist at each level of the organization. Once the latent failures are discovered, organizations can track and trend this data to monitor their frequency in each department and determine where interventions are needed most. "Near misses" are events during which an error occurred, but was recognized before it could contribute to an adverse event. Reporting these events can help to identify why latent failures before error occurs, and prevent them in the future.

A "latent failure" describes a bypassed or non-existent procedure, process, or equipment intended to act as a safety measure, but "failed" to fulfill it's intent. This could be a sub-optimal relationship between a procedure in one department of the hospital and information needed in another, or the implementation of a piece of equipment without adequate training for the staff. Identifying "latent failures" through reports of "near miss" incidents and classifying the human error components using the HFACS taxonomy will provide valuable data that can be translated into systemic interventions tailored to the given situation.

However, retrospective review of reported events impose several limitations to adequate identification of contributing factors related to the incident reported. "The most effective technique for learning how a system has failed is to collect data prospectively about individual, team and system performance" (Hamman, 2004). Prospective observation of patient care involves real-time data collection in a naturalistic environment. Prospective study methods are the best for identifying flow disruptions in highly dynamic and complex environments such as the OR because they allow detection of systemic vulnerabilities as well as beneficial strategies, which would not be possible from a method such as retrospective review of patient records (Hamman, 2004; Etchells et al., 2003).

Study Goals. The aim of this study was to prospectively observe, identify, and classify the type and frequency of flow disruptions present in the OR during two types of general surgery procedures. The results of this study will be the identification of the most common flow disruptions present during each type of procedure. Recent research has indicated that flow disruptions are correlated with surgical errors (Wiegmann et al., 2007). Identifying the disruptions that are most likely to have a negative impact on the performance of the surgical team will allow evidence based interventions to be designed into systems, to decrease their frequency, and mitigate their impact. Equally important is to determine which, or when, disruptions can be best tolerated by the team.

CHAPTER II METHODOLOGY

Participants

Study participants included the surgical staff of the main hospital and the "same day", or outpatient ORs in the affiliated southeastern regional hospital. Surgical teams usually consisted of the surgeon, one of three who voluntarily participated in the study; the "first assist" or "scrub" nurse, a registered nurse (RN) who assists the surgeon directly with the surgical task; the circulator nurse (CN), another RN who acts as the "manager" of the OR by assisting wherever necessary, keeping paperwork and computer records updated, and is the only team member who is not sterile and can leave the room on short notice without having to "scrub in"; and the anesthesiologist, who occasionally was assisted by, alternated with, or supervised a certified nurse anesthetist (CNA). The anesthesia team's job is to keep the patient immobile, out of pain, and breathing with the help of a machine. This requires administering several medications and closely monitoring the patient's vital signs. On rare occasions, a medical student or trainee was present during the procedure.

Apparatus and Materials

Data collection tool. The data collection tool used in this study was constructed after observing approximately 15 pilot procedures of various surgical nature including sarcoma removals, laparoscopic cholecystectomies and hernia repairs. Additional information was

obtained from an extensive literature review, thorough discussions with the participating surgeons, and trial runs, all of which helped to refine the tool into its final version. The tool was designed to be generic enough to collect flow disruption data across both types of procedures. The tool, a horizontally folded four-page paper booklet, provided blank space to record details of the events, the time the event occurred, and other features of the OR environment to help set the context. Further research will be necessary to validate the data collection tool as a reliable method for the uniform collection of the intended variables across procedures and surgical teams. The data collection tool can be seen in Appendices E-G. Two slightly different versions of the tool were used. One was specific to the laparoscopic cholecystectomy procedure and included a few additional items related to the laparoscope such as whether one monitor or two were present. The rest of these items can be seen on the back of the data collection tool (See Appendices F and G).

Informed consent. Slightly varied wording was used on the consent forms to denote the respective roles of the patient and employee. The staff was asked to consent to the observation and recording of "the surgical procedures you will <u>participate in</u> over the course of this study", and patients were asked about the procedure "you are about <u>to undergo</u>". Consent from the surgical team was obtained following an information session with the entire OR staff about the goals and implications of the study during a group information session, provided with hard copies of the slideshow presentation containing additional information about the study, a copy of the data collection form, the consent form, and a brief overview of other studies that have used video recording. The staff was then asked to sign the written informed consent. One of the three participating surgeons introduced the study to patients who met the study criteria during their pre-operative office visit, which usually occurred about a week before the procedure. They were

then presented with a written version of the study goals, risks, and procedure, and given the option to sign a written patient informed consent. After a patient provided their written consent to participate in the study, the research team was contacted with scheduling information using an unidentifiable patient number.

Procedure

This study was a naturalistic observation, during which, researchers were present in the OR to observe and collect data. Seagull and Guerlain's 2003 review of observational measures in healthcare found that all studies narrowed their focus to a single problem (procedure), used or developed a standard data collection tool, and involved the counting or categorizing of events to uncover underlying themes, distractions, barriers, or training opportunities (Seagull & Guerlain, 2003). This study provided the ability to compare flow disruption data across two general surgery procedures that share several similar properties but are performed with distinctly different surgical techniques.

Data Collection. Data was collected through the physical presence of a researcher using the earlier described data collection tool created specifically for this study. In addition, a discreet video recording device captured the procedure for the purpose of off-line verification. Flow disruption data was collected for the duration of the surgical procedure, which included everything that occurred between the first incision ("start time") and the final closure ("end time") as determined by the circulator nurse. Handwritten descriptions of each flow disruption were recorded during observations. In the case of successive, simultaneous, or related disruptions, each disruption was recorded and classified separately.

Surgical procedures took place in the "same day" surgical center (n=17) or in the main ORs (n=6) of the participating hospital. The researcher entered the operating room just before the patient and remained in a static location that allowed both good visibility of the entire room, and was least obtrusive to the surgical team. All of the surgical team members remained in the observer's direct field of view, except for the anesthesiologist, who was frequently obstructed by the surgical drape, and occasionally the circulator nurse who frequently performed tasks outside the scope of the camera lens. The observer could usually hear all team members' voices clearly.

Observer Credentials. The primary observer (PO) in this study was a senior graduate student with a B.S. in Human Factors Psychology, all graduate coursework completed, and substantial research experience studying human error in aviation. To prepare for this project, a thorough literature review was performed along with observation of approximately 15 surgical procedures to collect pilot data, which was used to develop the study design and data collection tool.

The PO trained two senior undergraduate research assistants (RA) by accompanying them to four procedures with at least one from each procedure type. During the first training procedure the RA was able to simply observe, become familiar with the OR, and watch and listen to the process of conducting the observation and data collection. During the second and third training observations the RA and PO both recoded data. The RA could see the PO's data sheet and they were able to quietly discuss any recording discrepancies or clarifications. During the fourth training procedure, the PO observed the RA while they performed the entire data collection procedure as if they were alone. Once training was complete, procedures were observed by whichever of the three qualified researchers was available to do so. All researchers were required to produce evidence that they were not currently infected with communicable diseases, and produce picture identification to gain entry to the surgery department.



Figure 1. Image of hernia repair procedure. From far left; Circulator nurse, surgeon, first assist or "scrub" nurse, and the surgical technician.

Surgical Procedures. The surgical procedures observed during this study were chosen specifically for their short duration, high frequency of occurrence, and the ability to provide a contrast between the open and laparoscopic surgical techniques. The participating surgeons were included in selecting procedures that qualified for inclusion in this study. The laparoscopic cholecystectomy procedure is a minimally invasive method of removing the gallbladder. This is achieved with the use of an instrument with a small camera on the end called a laparascope, which allows the surgeon to work inside the patient without having to make a significant

incision. During the open hernia repairs, which were either umbilical (near the bellybutton) or inguinal (near the groin), the surgeon had direct physical and visual access to the operative site through an incision in the lower abdominal area.

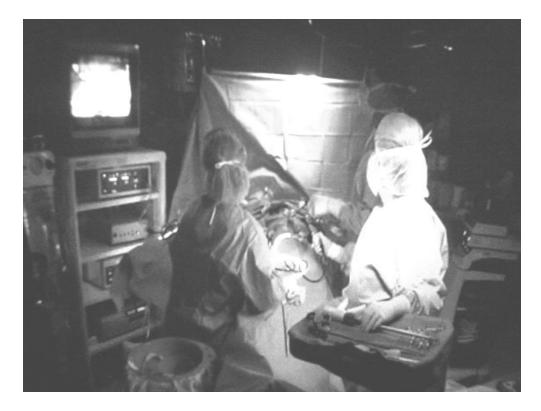


Figure 2. Image of laparoscopic cholesystectomy. From left; First assist or "scrub" nurse, surgical technician, surgeon (behind surgical technician).

Data Management. The aspect of this study that was most likely to raise concern was the video capture in the OR. To address this issue, the intent, purpose, storage and destruction protocol were outlined in the informed consent forms for all patient and staff participants who had the potential of being captured on video. Participants remained anonymous, personal information was not collected or retained in any way. Information collected from each surgery was referenced using an unrelated identification number. Videotapes were kept in a locked filing cabinet in a private office, and were only accessed by authorized researchers. The videos were reviewed promptly and subsequently destroyed.

Classification. Following an extensive literature review, a preliminary taxonomy was developed. After each case, the observer and principle investigator discussed the data collected, and made sure that the categories in the taxonomy could adequately represent all of the FDs observed, amending as necessary. The reason for this was to avoid losing the specificity of the data by using categories that were too broad. Organizing classified flow disruptions using a taxonomy provides a means of identifying trends in disruption patterns. When trends are recognized, it may be possible to trace them to sources of frequent disruption, which could indicate where latent system failures lie. The PO and one of the RAs who assisted with data collection classified flow disruptions into the categories of the taxonomy. A third human factors researcher, a third year PhD student with extensive experience collecting and classifying flow disruptions in the OR, resolved all discrepancies between the original two raters. Each discrepancy was identified and transcribed along with both possible classifications from the original raters. The third human factors researcher chose between one of the two potential categories in order to ensure 100% discrepancy resolution. Final classifications were entered into the database.

Variables. Flow disruptions are defined as events that result in a break in the flow of the primary surgical task, or the loss of any team member's situational awareness with regard to the procedure at hand. Time data was collected at many points throughout the procedure including the "start" time, "end" time as called by the circulator nurse, the time of each flow disruption, and the percentage of time the circulator nurse was on the computer. In addition to flow disruptions and time, several features of the surgical environment for the purpose of recording

the context and exploring other potential correlates to flow disruptions such as the frequency of the door opening and closing, the presence of music, and the number of procedures that the surgeon performed prior to the study procedure.

Analysis. Flow disruption data collected during 23 procedures, over a seven-month period were included in this analysis. Data were analyzed using a computer software program, Statistical Package for the Social Sciences (SPSS). Frequency counts were used to determine inter-rater reliability after the initial classification of flow disruptions, and to quantify the breakdown of flow disruption categories after the discrepancies were resolved. After flow disruptions were classified and entered into the database, descriptive statistics were obtained. The final categories of flow disruptions during both procedure types were analyzed in aggregate and in comparison to one another. A t-test was performed to determine whether the mean duration of each procedure was different at a significance level of a=.05. A second t-test determined whether the average number of flow disruptions for each procedure type was significantly different from the other, and a third compared rates between procedures. A Mann-Whitney U test was performed to determine if each category was significantly different between procedure type.

CHAPTER III

RESULTS

Of the 23 procedures analyzed, there were 14 laparoscopic cholecystectomies, and 9 open

hernia repair procedures. A total of 321 flow disruptions were recorded during 684 minutes of

procedure time, for an overall flow disruption rate of .44, or one flow disruption every 2.23

minutes. Examples of flow disruptions from each category are displayed in Table 1.

Table 1

Examples of flow disruptions recording during observation

Categories	Examples	
Communication	Anesthesiologist asks twice for scissors, receives no response, retrieves item himself	
Coordination	Circulator nurse leaves to retrieve equipment and returns with incorrect item.	
External/ Extraneous	Foreign staff comes in to relay information to the surgeon about a future patient	
Training/ Supervisory	Surgeon quizzing medical student about patient anatomy	
Equipment/ Supplies	Bovie ground wire became detached, function ceased and alarm engaged	
Environment	Music interrupted by loud static from cell phone interference	
Patient Factors	Patient hair preventing grounding pad from keeping contact	

The overall inter-rater reliability achieved after the first two researchers classified each disruption was 74.6%. The total number (and percentage) of flow disruptions in each of the seven categories are as follows; Communication, 109 (34.6%); Coordination, 89 (27.7%); External/Extraneous, 51 (15.9%); Training/Supervisory, 31 (10.1%); Equipment/Supplies, 29

(8.4%); Environment, 8 (2.3%); and Patient Factors, 5 (1.4%). The percentage of flow disruptions broken down by category is depicted in Figure 3.

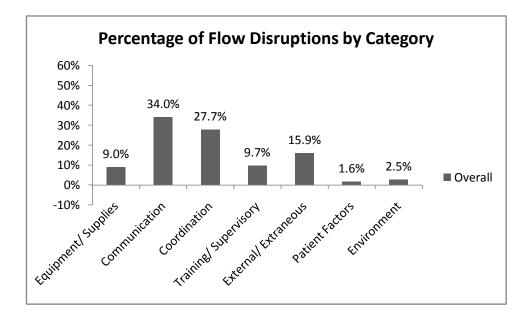


Figure 3. Total number of flow disruptions in each category.

When flow disruption data was analyzed for each type of procedure, it was discovered that the rate of disruption was similar for each. Laparoscopic cholecystectomies lasted an average of 29.25 (7.52) minutes and had an average of 13.29 flow disruptions per procedure, or one flow disruption every 2.20 minutes. Hernia repairs lasted 33.62 (5.92) minutes on average, with an average of 15 flow disruptions per procedure, for a rate of one flow disruption every 2.24 minutes. The categorical breakdowns of flow disruptions for each type of procedure are depicted in Figure 4. The number (and percentage) of flow disruptions by type and procedure are as follows; Laparoscopic Cholesystectomy: Coordination 61 (32.8%), Communication 42 (22.6%), External/Extraneous 28 (15.1%), Equipment/Supplies 25 (13.4%), Training/Supervisory 22 (11.8%), Environment 6 (3.2%), Patient Factors 3 (1.6%), and; Hernia Repair: Communication

67 (49.6%), Coordination 28 (20.7%), External/Extraneous 23 (17%), Training/Supervisory 9 (6.7%), Equipment/Supplies 4 (3.0)%, Environment 2 (1.5%), and Patient Factors 2 (1.5%) (See Table 2.).

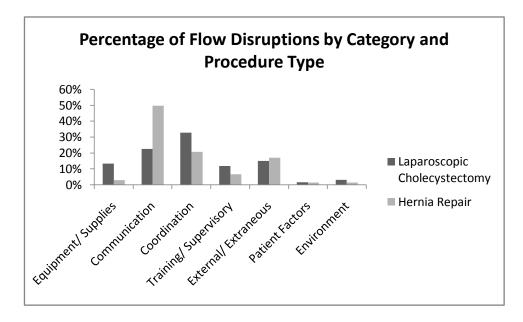


Figure 4. Percentage of flow disruptions by category and procedure type

Table 2

Percentage of flow disruptions overall and for each procedure by category

		Laparoscopic	Hernia
	Overall	Cholecystectomy	Repair
Equipment/ Supplies	9.0%	13.4%	3.0%
Communication	34.0%	22.6%	49.6%
Coordination	27.7%	32.8%	20.7%
Training/ Supervisory	9.7%	11.8%	6.7%
External/ Extraneous	15.9%	15.1%	17.0%
Patient Factors	1.6%	1.6%	1.5%
Environment	2.5%	3.2%	1.5%

Three t-tests were performed to determine if the average procedure time, number, and rate of flow disruptions per procedure differed between procedure types. The average duration of each procedure type are significantly different from each other (p=.001 a; $\alpha \le .05$). Hernia repair procedures lasted significantly longer than laparoscopic cholecystectomy procedures. The average number and rate of flow disruptions between procedures was not significantly different.

Results of the Mann-Whitney U test revealed that the coordination (p=.017), communication (p=.000), and equipment/supplies (p=.001) categories were significantly different between procedure type. The laparoscopic cholecystectomy procedures were significantly higher than hernia repairs in the categories of coordination and equipment/ supplies. Hernia repair procedures had significantly more flow disruptions related to communication than laparoscopic cholecystectomies.

CHAPTER IV

DISCUSSION, CONCLUSIONS, AND RECOMMENDATIONS

There has been increasing interest in and use of flow disruptions as a metric to identify sources of latent system failures in recent years. The first goal of this study was to identify the flow disruptions that occur in the operating room during laparoscopic cholecystectomies and open hernia repair procedures. Results of this study revealed a rate of one disruption every 2.2 minutes. This rate also held steady when calculated for the two types of procedures separately. The rate of disruptions determined by the results of this study are similar to those found by Chisholm, Collison, Nelson & Cordell (2000), who reported that emergency physicians (EP) performed 22.5 tasks per hour and were interrupted 17.2 times per hour, which is about three interruptions for every four tasks performed. A study by Healey, Sevdalis & Vincent, (2006) conducted during urological "same-day" surgical procedures; found a mean of 20.47 disruptions per case, with an interruption rate of 0.45 events/min, and average interruption duration of 13.05% of procedure time. Healey et al., (2006) recorded 13.56 disruptions per procedure, with an average rate of .29 events per minute. It is interesting to see the similarities between the findings of this study and the ones mentioned above. It seems that studies performed in the "same-day" surgical unit and emergency departments are more similar to each other in terms of interruption rate, than when compared to more intensive and time consuming procedures such as cardiac surgery. Studies have shown the disruption rates of these types of procedures to be as low as 8 per hour (Wiegmann et al., 2007).

The differences that stand out the most are in the communication, coordination, and equipment/supplies categories. The three largest categories of disruptions for each procedure type were communication, coordination, and external/extraneous. The laparoscopic

cholecystectomies, which are much more equipment intensive than the open hernia repair, had a much higher percentage of flow disruptions in the categories of equipment /supplies and coordination. External/extraneous and training/supervisory related disruptions were much more prevalent in the laparoscopic cholecystectomy than the hernia reduction. This may reflect the need for a greater depth of explanation and understanding before using laparoscopic technology. Using this technology may not be as straightforward and intuitive as direct manipulation of patient anatomy. Hernia repairs, which are performed using traditional surgical tools, had a much higher rate of communication related flow disruptions. Recall that the average rate of disruptions were almost identical between the two procedures. Though just as many flow disruptions occurred, the nature of disruptions were reflective of the environmental, equipment, and procedural differences between procedure types. It was an interesting finding that hernia repair procedures were significantly longer than laparoscopic cholesytectomy, even with far less equipment and coordination related disruptions. Future research could examine whether the additional visual feedback provided during laparoscopic procedures gives the team additional cues to guide the progression of the case.

Through the identification of the flow disruptions, a tailored taxonomy was created that was able to accommodate all of the disruptions identified. The taxonomy was developed, at first, from a review of the human factors literature, and was amended as data was obtained, to ensure that each disruption could be represented. In addition to the seven main categories used in the analysis for this study, subcategories and "nano-categories", or error codes, were also defined in the taxonomy. In order to compare and identify patterns across multiple studies and facilities, classification should be as unified as possible. The error codes provide valuable and detailed information for the development of specific interventions, but will also serve to assist future classification by providing examples of the type of disruptions assigned to each category. By providing this type of information, researchers will be able to unify the definitions of category, which could enable comparison and aggregation of results between studies, and the development of a flow disruption database.

The classification and analysis of flow disruptions allows the identification of issues that affect the immediate surgical environment. Using a human factors taxonomy to classify flow disruptions allows researchers to drill down to identify specific problem patterns within specific procedures, but can also provide a more general picture of the data that could be used to identify patterns across departments or between hospital systems. The nature and frequency of flow disruptions provide a general impression of how the larger influences like culture, scheduling, physical space, or budget constraints, may be creating unintended, unanticipated, and unnecessary problems "downstream" in the system, to the operating room. Of course, gaining an accurate understanding of these larger constructs would require gathering a significant amount of additional information. However, patterns identified in flow disruption data can indicate which aspects should be more closely scrutinized.

It could be assumed that since the surgical team members for each procedure are formed in different combinations from the same pool of potential members, and that they are in the same environment, that they would encounter the same types of disruptions. However, based on the results of this study, we see that is not the case. Despite the similarities in flow disruption rates for both procedures, the categorical breakdown revealed that the type of flow disruptions that occurred varied greatly from one procedure to the other. This suggests that variables other than simply individual differences and team performance influence the type of disruptions encountered. The flow disruption type that occurred most frequently overall was communication. This finding is consistent with similar studies in this area. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) identified communication as the leading root cause of wrong-site operations, and other sentinel events (Makary, et al., 2006). Fordyce et al.,'s (2003) prospective observational study in the emergency department (ED) revealed that 12% of reported errors were directly related to communication. Results of the Wiegmann et al. (2007) study of flow disruptions in the cardiac OR showed that communication had the strongest relationship to surgical errors, even when tested against all other disruption categories combined. Healey et al. (2006) determined that the most frequent disruption category was conversation, which also had the highest rating of interruption severity.

Communication is obviously a major problem in healthcare, as well as one of the most complex. In spoken communication, only 7% of meaning is derived from the actual words spoken, 38% is from paralinguistic qualities, such as tone and intonation, and 55% is revealed through facial expression (O'Connor et al., 2010). There are many features of the health care industry that hinder effective communication. Some are common to many complex industries such as environmental noise, physical distance, and time pressure to name a few. But some are unique to health care such as the complicated handoff path and transfer of patients and information, the frequent rotation of team members, and the use of surgical gowns and face masks, which hide body language and facial expression. The flow disruption subcategories under communication for this study are misunderstanding, communication unheard, case related communication, and extraneous conversation. To distinguish, extraneous communication under the communication category refers to conversation regarding non-case specific topics, whereas extraneous conversation under the external/extraneous category refers to a conversation initiated by or directed to someone outside of the surgical team. One intervention that has shown to have a positive impact on the rate of communication errors is the pre-operative brief (Hurlebert, 2009). Pre-flight briefings and debriefs have been standard operating procedure in commercial aviation for some time. "The pre-operative briefing sets expectations for how the case will proceed, informs the OR of equipment needed, and if any difficulties are expected (Hurlebert, 2009). Studies in the operating room have shown pre-operative briefings to open the lines of communication between team members and break down the traditionally steep professional hierarchy (Hurlebert, 2009).

Coordination related flow disruptions included personnel exchanges, improperly configured equipment, failure to adhere to surgeon or team preferences, and requesting or providing assistance to fellow team members. Some studies use the term "teamwork" to describe coordination and communication together (Makary, 2006). For this study, communication and coordination remained as separate categories due to the discord in the nature of disruptions that fell into these categories respectively. While communication disruptions usually involved the verbal transition of information between at least two team members, coordination related flow disruptions often involved the interaction with some piece of equipment as well as at least one other team member.

The equipment/supplies problems included malfunctions, improper use, unfamiliar equipment, and maintenance. Equipment/supply related disruptions were significantly more frequent during laparoscopic cholecystectomy procedures, these procedures require significantly more sophisticated technological equipment than the open hernia repair, which is performed using traditional surgical tools. While there is no doubt that laparoscopic surgery is an incredibly beneficial technology that has improved many procedures for both the medical community and patients alike, there are still a few features of laparoscopic surgery that require a high level of mindfulness to contend with. For one, the surgeon is required to work in a three dimensional space portrayed as a two-dimensional image, which is also magnified beyond its actual size, creating a discrepancy between the visual and kinetic placement of surgical tools. Also, the scrub nurse is usually responsible for manipulating the camera inside the patient, in synchrony with the surgeon, requiring her to maintain a high level of coordination, knowledge of the procedure, and high mental and physical demands. In all but one procedure observed, a single monitor was positioned opposite the surgeon, slightly higher than his direct line of sight. This means that the monitor was positioned directly next to the scrub nurse, causing her to have to twist her neck and head around to view the monitor. To maintain a better view of the image of the monitor the room must be darkened, making visual cues and body language difficult to see, and moving around large equipment and cords potentially dangerous.

Training/supervisory disruptions often included teaching a new skill, correcting an improper action, and posing questions to test the knowledge of the team, student, or trainee. Occasionally during this study a medical student observed and lightly participated in procedures. When the student was present, the surgeon would often verbalize his actions as he was performing the procedure, occasionally quizzing the student regarding patient anatomy, or other surgical knowledge. Since the participating hospital was not a teaching institution, the presence of the medical student was infrequent, sporadic, and relatively informal. Training/supervisory flow disruptions also included peer-to-peer training, and training to recognize surgeon-specific preferences. In a teaching hospital, training is a substantially higher priority that occurs much more frequently. Team stability and familiarity are believed to foster teamwork, which is integral to surgical success (Wiegmann, 2007). However, teams with consistent members may

be more affected by the addition of an unfamiliar member, when compared to teams that do not remain consistent. For future research, it would be interesting to determine how the presence of a new surgical, nursing, or surgical technician impacts case progression and perceived teamwork in both variable and static teams.

A similar percentage of extraneous disruptions were identified in both procedures. External/extraneous disruptions were generally imposed on the OR from outside and include extraneous people, phone calls, or intercom messages that did not relate directly to the procedure at hand. The consistency in the rate of external/extraneous flow disruptions suggests that these type of disruptions are not as influenced by the procedure type. Since these disruptions come from outside of the OR, it is understandable that the rate would remain consistent regardless of procedure type. Addressing disruptions from extraneous sources would most likely include developing procedures for determining if the disruption is warranted, to the entire surgical department. Future research could explore the relationship between external/extraneous flow disruptions and the safety climate of the surgery department.

Flow disruptions that occurred rarely in both procedures were related to environmental and patient factors. Environmental disruptions include problems with noise, temperature, and lighting. The most frequent source of environmental disruption in the OR was related to music, which is permitted to play at the surgeon's discretion. Patient factors were usually related to the patient's unique anatomy or condition being different from what the surgeon had expected. Most often, an excessive amount of unanticipated adhesions or scar tissue was encountered. Interruptions may not be entirely bad, one study showed that an "interruption lag", such as a phone ringing, can prompt a worker to mentally rehearse a task, which in turn can help them resume the task at the interrupted point more easily (Adamczyk & Bailey, 2004). It is just as important to understand which disruptions can be tolerated by the team in the operating room without causing a disruption, as it is to know which can't. This information can be used to develop new processes and procedures that substitute the most volatile disruptions with more harmless ones i.e. phone call vs. physically entering the room to deliver information or query a member of the surgical team. Each flow disruption is not necessarily a negative event, in fact, in a time sensitive, information intensive, complex system with the potential for catastrophic consequences, certain disruptions are beneficial and necessary. It is for this same reason that it is crucial to identify the disruptions that do have the potential to make a negative impact. The value of the interruption should be weighed against the potential impact it could have on patient safety before it is introduced into the operating room. It is difficult to balance an individual's capacity to handle interruptions, with their need for information (Adamczyk & Bailey, 2004). This can be especially true for the healthcare industry where patient confidentiality is a priority, and information can be time sensitive. For this study, there was no judgment made about the value of each disruption, nor was each disruption evaluated to determine the importance or the impact of the individual disruption. Future research could provide criteria for what makes a disruption "negative" or "positive", and how that information could be used in the design of interventions.

Limitations. There were several challenges that had to be faced at the beginning of this study. Prospective observation in the operating room has inherent resistance due to the sensitivity of patient privacy and perceived legal repercussions. To ensure that no patient personal health information was collected, we did not record audio transmissions. There is a chance that the observer may have misheard, misunderstood, or failed to hear some verbal transmissions. Since the surgical staff attends to several procedures a day, it was not possible to speak with them after the procedure to clarify or better understand their thought process behind some activities.

Patients were scheduled for surgery approximately 2-3 days per week, and only a fraction of those were willing to consent to observation. Consequently, the rate of data collection was sporadic and difficult to anticipate. In addition, the hospital moved to an entirely new facility before reaching the original target of 40 observations, 20 of each type of procedure. Though efforts were made to avoid such, on occasion a member of the surgical team would converse with the research assistants during the procedure. When this did occur, it was recorded as a flow disruption.

Conclusion

The goal of this study was to identify and classify flow disruptions that occurred during two common and frequently performed general surgery procedures. This yielded the quantity and rate of flow disruptions, as well as a breakdown of their "type", or nature. In addition, descriptions of the actual disruptions were recorded, allowing for a detailed analysis of recurring issues, which could serve to inform tailored interventions, or better understand the impact of specific disruptions. The comparison of two procedures, similar in duration and frequency, but contrasting in surgical technique and technological dependence, produced results that reflect these differences. Further research is needed to better understand how flow disruptions relate to surgical outcomes, and whether they are a reliable indicator of the potential for adverse events. However, the current results suggest that flow disruptions can be used as a metric to identify various sources of interruptions across procedure types, while still being sensitive enough to capture procedure-specific differences that exist between them. More validation is needed to determine whether flow disruptions provide specific enough information to develop interventions that can prevent or mitigate their damaging effects. The results of this study emphasize the need to analyze specific procedures individually in order to identify the disruptions unique to each.

As seen, the overall breakdown of disruptions across procedures can be misleading. Without investigating the data at a deeper level, blanket interventions could be put in place that may not be necessary or beneficial for all procedures.

REFERENCES

- Adamczyk, P.D., Bailey, B.P. (2004). If not now, when?: The effects of interruption at different moments within task execution. *Computer Human Interaction*, 6(1), 271-278.
- Barach, P., Small, S.D. (2000) Reporting and preventing medical mishaps: lessons from non-medical near miss reporting systems. *BMJ*, *320*, 759-763.
- Beyea, S.C. (2007). Distractions and interruptions in the OR: evidence for practice: perioperative clinicians must seek effective strategies that will reduce interruptions and distractions and thus make clinical care safer in the OR. *AORN Journal*, *86*(3), 465-467.
- Catchpole, K., Mishra, A., McCulloch, P. (2008) Teamwork and Error in the Operating Room: Analysis of Skills and Roles. *Annals of Surgery*, 247(4), 699-706.
- Chisholm, C.D., Collison, E.K., Nelson, D.R., Cordell, W.H. (2000). Emergency department workplace interruptions: Are emergency physicians "interrupt-driven" and "multitasking"? *Academic Emergency Medicine*, *7*(11), 1239.
- Christian, C.K., Gustafson, M.L., Roth, E.M., Sheridan, T.B., Gandhi, T.K., Dwyer, K., Zinner, M.J. & Dierks, M.M. (2005). A prospective study of patient safety in the operating room. *Surgery*, 139(2), 159-173.
- de Vries, E., Ramrattan, M.A., Smorenburg, S.M., Guoma, D.J., Boermeester, M.A. (2008). The incidence and nature of in-hospital adverse events: a systematic review. *Quality and Safety in Healthcare*, *17*, 216-223.
- Etchells, E., O'Neill, C., Bernstein, M. (2004). Patient Safety in Surgery: Error Detection and Prevention. *World Journal of Surgery*, 27(8) 36-941.
- Fordyce, J., Blank, F., Pekow, P., Smithline, H., Ritter, G., Gehlbach, S., Benjamin, E., & Henneman, P.L. (2003). Errors in a busy emergency department. *Annals of Emergency Medicine*, 42(3), 324.
- Friedman, S.M., Elinson, R., Arenovich, T., Hamman, W.R. (2005) A Study of Emergency Physician Work and Communication: A Human Factors Approach. Israeli Journal of Emergency Medicine, 5(3), 35-42.
- Hamman, W.R. (2004). The complexity of team training; what have we learned from aviation and its application to medicine. Quality and Safety in Healthcare, 13(1), 72-79.
- Healey, Sevdalis, N., Vincent, C. (2006). Measuring intra-operative interference from distraction and interruption observed in the operating theatre. *Ergonomics*, 49(16), 589-604.

- Helmriech, R.L., &and Davies, J.M. (1996). Human factors in the operating room: interpersonal determinants of safety, efficiency and morale. *Bailliere's Clinical Anaesthesiology*, *10*(2), 277-295.
- Hurlburt, S.N., Garrett, J. (2009). Improving operating room safety. Patient Safety in Surgery (3) 25, 1-6.
- Karl, R. (2009). Aviation. Journal of Gastrointestinal Surgery, 13, 6-8.
- Kohn, L.T., Corrigan, J.M., Donaldson, M.S. (2002). To err is human : building a safer health system. *Journal of Interprofessional Care*. 16(4).
- Makary, M.A., Sexton, B. J., Freischlag, J. A., Holzmueller, C. G., Millman, E.A., Rowen, L., & Pronovost, P.J. (2006). Operating room teamwork among physicians and nurses: Teamwork in the eye of the beholder. *Journal of the American College of Surgeons*, 202(5), 746-752.
- Manzey, D., Rottger, S., Bahner-Heyne, J.E., Schulze-Kissing, D., Dietz, A., Meixensberger, J., Strauss, G. (2009) Image-guided navigation: the surgeon's perspective on performance consequences and human factors issues *International Journal of Medical Robotics and Computer Assisted Surgery*. 5, 297–308.
- Michel, P., Quenon, J.L., Sarasqueta, M., Scemama, O. (2004). Comparison of three methods for estimating rates of adverse events and rates of preventable adverse events in acute care hospitals. *British Medical Journal*, *328*(7433),199-204.
- O'Connor, T., Papanikolaou, V., Keogh, I. (2010). Safe surgery, the human factors approach. *The Surgeon*, 8, 93-95.
- Pronovost, P.J. (2006). Operating room teamwork among physicians and nurses: Teamwork in the eye of the beholder. *Journal of the American College of Surgeons*. 202, 746-752.
- Reason, J.T., (1990). Human Error. Cambridge University Press, London, England.
- Seagull, F., Guerlain, S. (2003) Observation Measure of Team Process and Performance in Health Care. *Human Factors and Ergonomics Society Annual Meeting Proceedings*, Macroergonomics , pp. 1486-1487(2)
- Thomas, E.J, Brennan, T.A. (2000). Incidence and types of preventable adverse events in elderly patients: population based review of medical records. *British Medical Journal.* 320, 741-5.
- Wiegmann, D. A., ElBardissi, A.W., Dearani, J.A., Daly, R.C., Sundt, T.M. (2007).Disruptions in surgical flow and their relationship to surgical errors: An exploratory investigation. *Surgery*, 142(5), 658-665.

- Wiegmann, D. A., Shappell, S. (2003) A human error approach to aviation accident analysis: the human factors analysis and classification system. (Bodman, Cornwall, MPG Books Ltd.)
- Wolf, L.D., Potter, P., Sledge, J.A., Boxerman, S.B., Grayson, D., Evanoff, B. (2006).
 Describing nurses' work: combining quantitative and qualitative analysis
 The Journal of the Human Factors and Ergonomics Society. 48(1) 5-14
- Woods, D.D. (2002) Behind human error: human factors research to improve patient safety. *American Psychological Association*.

Appendices

А	Informed Consent for Hospital Staff	
В	Informed Consent for Patients	39
С	Final Categories, Sub-categories, and Error Codes	40
D	Pre- and Post- Procedure Survey for Surgeon	43
Е	Inside of the Data Collection Tool	44
F	Outside Cover of the Laparoscopic Data Collection Tool	45
G	Outside Cover of Generic Data Collection Tool	46
Н	Examples of Recorded Flow Disruptions	47
Ι	Example Flow Disruptions from Each Category	48
J	Percentage of Flow Disruptions by Category, Overall and by Procedure	49
Κ	Image of Hernia Repair Procedure	50
L	Percentage of Flow Disruptions by Category	51
М	Percentage of Flow Disruptions by Category and Procedure	52

APPENDIX A: Informed consent form for hospital staff

Information Form for Participation in a Research Study Embry-Riddle Aeronautical University

Your participation is requested in a research study being conducted by Dr. Chris Windham and members of the Human Factors and Systems department at Embry Riddle Aeronautical University.

This is a study aimed at identifying factors that enhance the efficiency of team performance in the operating room.

By signing this form, you are consenting to the observation of the laparoscopic cholesystectomy and hernia repair procedures you will take part in for the duration of this study. Throughout the procedures, data about team performance will be collected by a researcher. In addition to the physical presence of a researcher, the procedure will be videotaped at a wide angle to capture a view of the entire surgical team. The video data will be reviewed by an objective surgeon in order to score the technical aspects of the procedure.

Possible Benefits

Participation in this study broadens the scope of information available to human factors and medical professionals who share the goal of patient safety.

Risks and discomforts

There are no known risks associated with this study.

Protection of confidentiality

No personal staff member information will be retained. Video tapes of the surgery will be reviewed by researchers, surgeons, and other hospital personnel associated with the study only. Audio transmission will not be captured to ensure patient anonymity. Video tapes will be stored in a secured area and will only be referenced by an unrelated identification number. Video data will be reviewed promptly and subsequently destroyed. No names, identification numbers, or other sources of identity will collected during the course of this study.

Voluntary participation

Your participation in this research study is voluntary. You may choose not to participate and you may withdraw your consent to participate at any time. You will not be penalized in any way should you decide not to participate or to withdraw from this study.

Contact information

If you have any questions or concerns about this study or if any problems arise, please contact Dr. Bert Boquet or Sacha Duff at Embry-Riddle Aeronautical University at 386.226.6790. If you have any questions or concerns about your rights as a research participant, please contact the Embry-Riddle Aeronautical University Institutional Review Board (386-226-7037). A copy of the results of this study will be available upon request.

I have read this information form and have been given the opportunity to ask questions. I give my consent to participate in this study.

Participant's signature: _____ Date: _____

APPENDIX B: Informed consent form for patients

Information Form for Participation in a Research Study Embry Riddle Aeronautical University

You are invited to participate in a research study conducted by Dr. Chris Windham and members of the Human Factors and Systems department at Embry Riddle Aeronautical University.

This is a study aimed at identifying factors that enhance the efficiency of team performance in the operating room.

Your participation in this study will be consenting to the observation of the surgical procedure you are about to undergo. Throughout the procedure, data about team performance will be collected by a researcher. In addition to the physical presence of a researcher, the procedure will be videotaped at a wide angle to capture a view of the entire surgical team. Video data will be used to clarify data collected during the surgery, and will be reviewed by a surgeon in order to score the technical aspects of the procedure. The surgeon will be given two brief surveys that convey their perceived difficulty level of the procedure and the overall effectiveness level of the surgical team.

Possible Benefits

Participation in this study broadens the scope of information available to human factors and medical professionals who share the goal of patient safety.

Risks and discomforts

There are no known risks associated with this study.

Protection of confidentiality

No personal patient information will be retained. Video tapes of the surgery will be reviewed by researchers, surgeons, and other hospital personnel associated with the study only. Audio transmission will not be captured to ensure patient anonymity. Video tapes will only be referenced by an identification number. Video data will be reviewed promptly and subsequently destroyed.

Voluntary participation

Your participation in this research study is voluntary. You may choose not to participate and you may withdraw your consent to participate at any time. You will not be penalized in any way should you decide not to participate or to withdraw from this study.

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I have read this information form and have been given the opportunity to ask questions. I give my consent to participate in this study.

Participant's signature: _____ Date: _____

APPENDIX C: Final categories, sub-categories, and error codes

1. Equipment/ Supplies

A. Malfunction

- a) Machine not working properly
- b) Machine not responding to input
- c) Request/ require assistance
- d) Structure failure
- e) Wrong tools in kit
- **B.** Improper Usage
 - a) Tool used for unintended purpose
 - b) Machine improperly operated
- C. Unfamiliar
 - a) Team is unsure how to operate
 - b) Unaware of purpose
 - c) Capabilities not utilized/known
- **D.** Maintenance
 - a) Adjustment
 - b) Refill
 - c) Reconnection/ Restart
 - d) Preperation/ Cleaning (Camera, cautery tool, etc.)
- 2. Communication
 - A. Misunderstanding
 - a) Heard wrong transmission
 - b) Unaware of/ alternate meaning
 - c) Insufficient explanation
 - d) Used improper term
 - **B.** Unheard
 - a) Did not hear anything
 - b) Unsure of what was said
 - c) Message not received by intended recipient
 - d) No response/recognition
 - C. Extraneous Communication (not related to the case)
 - a) Personal
 - b) General-Medical/ hospital related
 - c) Aggressive communication
 - **D.** Case relavent communication
 - a) Completing/ Updating charts/records
 - b) Familiarization with team preferences
 - c) Query/ Explanation of action/ Observation
 - d) Suggestion
 - e) Request/ Command
 - f) Discuss/Request patient state/treatment

3. Coordination

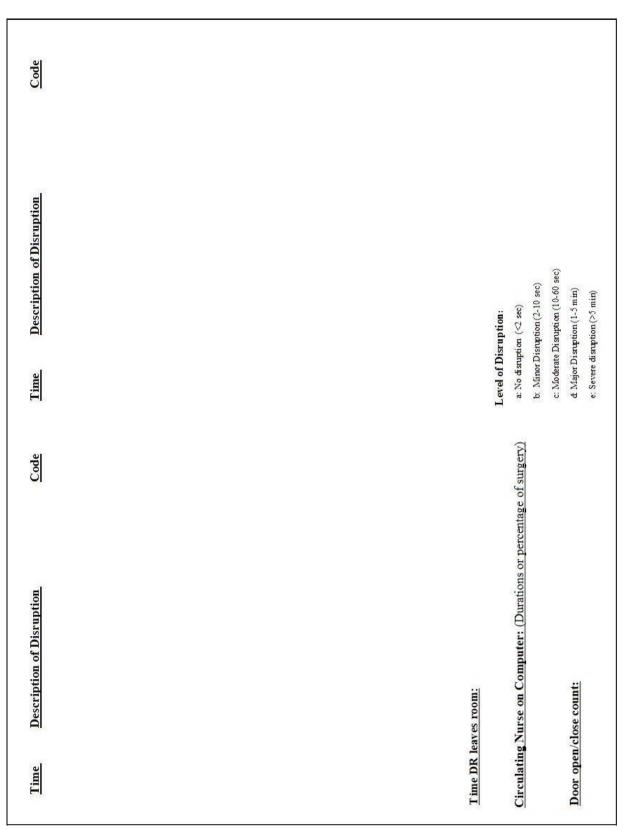
- A. Personnel Switch
 - a) Break
 - b) Shift change
 - c) Team member cleans up and leaves procedure
- **B.** Break in routine
 - a) Misplaced item
 - b) Dropped item

- c) Changing positions
- C. Preferences not adhered to
 - a) Preferred tool/supply not in room/available
- **D.** Equipment
 - a) Gas not on
 - b) Gas left on
 - c) Bovie pedal not set up
 - d) Not Present
 - e) Circulating nurse leaves to retrieve desired item
 - f) Incorrect assembly
 - g) Getting familiar/ testing
- E. Teamwork
 - a) Movement of table in undesired direction
 - b) Troubleshooting
 - c) Break in Cohesion
 - d) Performing multi-member task (e.g. Instrument count)
 - e) Team member leaves room temporarily
- F. Assistance Requested / Required
 - a) Setting/ Status change
 - b) Failure to assist
 - c) Responding to Request for Assistance
 - d) Responded incorrectly
 - e) Failure to request assistance
- 4. Training/Supervisory
 - A. Teaching new skill
 - a) Familiarization with instruments
 - b) Familiarization with anatomy
 - c) Familiarization with procedure/ process
 - **B.** Correcting improper action
 - a) Handing instruments to surgeon (wrong orientation, wrong tool)
 - b) Handing suture needle to surgeon
 - c) Guiding camera
 - d) Reminding of omitted action
 - C. Other Communication
 - a) Query to Dr.
 - b) Query to Anesthesiologist (AST)
 - c) Query to circulating nurse
 - d) Query/ Quizzing Trainee/ student
 - e) Instructing/ Verbalizing action for instruction
 - f) Advice/ Compliment
- 5. External/Extraneous
 - A. Extraneous person
 - a) Extraneous conversation
 - b) Query
 - c) Information about future patient
 - B. Phone call
 - a) Answered
 - b) Unanswered
 - c) Made to give/obtain information
 - d) Made extraneous call/ text
 - C. Query

- a) Case relevant
- D. Intercom
 - a) Notification of phone call
 - b) Query
 - c) DR responds
- 6. Patient Factors
 - A. Anatomy
 - **B.** Unstable Vital Signs
- 7. Environment
 - A. Music/Noise
 - a) Ipod malfunctioning
 - b) Distracted/sidetracked by music
 - c) Change volume/ song
 - **B.** Temperature
 - C. Lighting

APPENDIX D: Pre- and post-procedure survey for the acting surgeon

Ant	icip	ated Difficulty of Surgery	Ac	tual Difficulty of Surgery
	Eas	sy.		Easy
	Sor	newhat Easy		Somewhat Easy
	Ro	utine Difficulty		Routine Difficulty
	Sor	newhat Difficult		Somewhat Difficult
	Dif	ficult		Difficult
	Ve	ry Difficult		Very Difficult
<u>If d</u>	iffer	rent, why?		
<u>Tea</u>	mw	ork Rating		
<u>Tea</u>		ork Rating Highly Effective		
<u>Tea</u>		New Contract		
<u>Tea</u>		Highly Effective		
<u>Tea</u>		Highly Effective Effective Marginally Effective Marginally Ineffective		
<u>Tea</u>		Highly Effective Effective Marginally Effective Marginally Ineffective Ineffective		
<u>Tea</u>		Highly Effective Effective Marginally Effective Marginally Ineffective		
		Highly Effective Effective Marginally Effective Marginally Ineffective Ineffective		
		Highly Effective Effective Marginally Effective Marginally Ineffective Ineffective Very Ineffective		
		Highly Effective Effective Marginally Effective Marginally Ineffective Ineffective Very Ineffective		



APPENDIX E: Inside of the data collection tool

			ALL REAL REPORT OF A REAL PROPERTY OF A REAL PROPER
		Embry-Riddle Aerc	Embry-Riddle A eronautical University
 Camera and monitor (s) working properly 	y	Procedure: Laparoscopic Cholecystectomy	d
 Equipment Configured Correctly (plugs/ attachments) 	attachments)	Surgeon.	Dav of Week:
Music played during surgery			
 Computer functioning properly at start of surgery 	fsurgery		Scheduled 1 me:
Pre-surgical setup		# Surgery Performed Today:	
Grounding Pad in position		# Surgery Performed in this room:	
Patient completely draped before incision	п	In Room Time.	
Surgeon preferred instruments available			
Informative Communication		Intubation time:	
" Time out"/ Callout of patient and procedure performed	dure performed	Start time:	
Count Performed at beginning of surgery		"called" start time by nurse	
□ Count Performed at end of surgery		End time:	
Same person present for both counts?		"called" end time by muse	
White Board Used		Extubation time:	
Preparation for Lap Chole			
Pers	Personnel Present:	<u>Out of Room Time:</u>	
Conversion trav readily available D	1st Assist Nurse (1A)		
	Anesthesiologist (AST)		
	Nurse Anesthetist (NAST)	ASA:	
S	Surgical Tech (ST)		
V D	Additional Staff (AS)		
	Surgeon (DR)		
(Student/Ohserver (OB)		

APPENDIX F: Outside covers of laparoscopic cholecystectomy-specific data

<u>Equipment / T echnology</u>	Surgical Flow Disruption Data Collection Sheet	Data Collection Sheet
Yes No N/A	Embry-Riddle Ae	Embry-Riddle Aeronautical University
□ □ Camera and monitor(s) working properly	Procedure:	Date
□ □ Equipment Configured Correctly (plugs/ attachments)	Surgeon:	Dav of Week:
D D Music played during surgery		
Computer functioning properly at start of surgery		Scheduled 1 me:
Pre-surgical setup	# Surgery Performed Today:	
Yes No N/A	# Surgery Performed in this room:	
□ □ Grounding Pad in position		
D D Patient completely draped before incision	In Room Time:	
D D Surgeon preferred instruments available	Intubation time:	
Informative Communication		
Yes No N/A	Start time:	
□ □ □ Communication during intubation	"talled" start time bynurse	
□ □ Count Performed at beginning of surgery	End time:	
Callout of patient and procedure performed	"called" end time by nurse	
Additional Notes:	Extubation time:	
	Out of Room Time:	
	Sta	Start to End Time:
	Intubation – F	Intubation – Extubation Time:
	ASA:	
	Case ID #:	

APPENDIX G: Outside covers of the generic data collection tool

APPENDIX H: Image of Hernia Repair Procedure





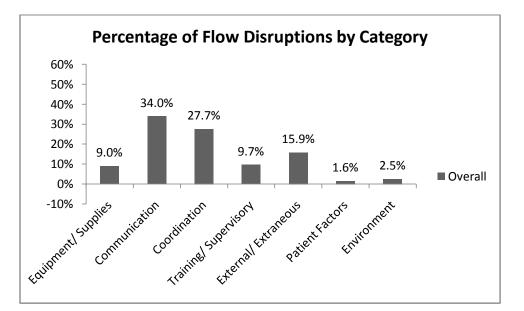
APPENDIX I: Image of Laparoscopic Cholesystectomy Procedure

APPENDIX J: Examples of Flow Disruptions Recorded

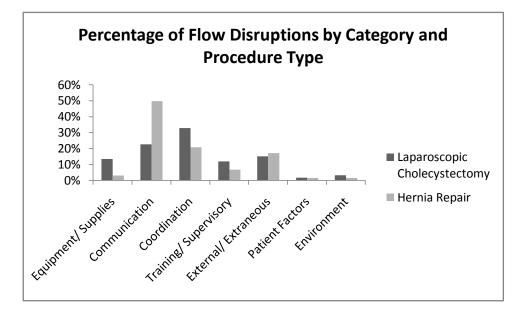
Categories	Examples
Communication	Anesthesiologist asks twice for scissors, receives no response, retrieves item himself
Coordination	Circulator nurse leaves to retrieve equipment for anesthesiologist, returns without it, anesthesiologist already had item
External/ Extraneous	Foreign staff comes in to relay information to the surgeon about a future patient
Training/ Supervisory	Surgeon quizzing medical student about patient anatomy
Equipment/ Supplies	Bovie ground wire became detached, function ceased and alarm engaged
Environment	Music interrupted by loud static from cell phone interference
Patient Factors	Patient hair preventing grounding pad from keeping contact

		Laparoscopic	Hernia
	Overall	Cholecystectomy	Repair
Equipment/ Supplies	9.0%	13.4%	3.0%
Communication	34.0%	22.6%	49.6%
Coordination	27.7%	32.8%	20.7%
Training/ Supervisory	9.7%	11.8%	6.7%
External/ Extraneous	15.9%	15.1%	17.0%
Patient Factors	1.6%	1.6%	1.5%
Environment	2.5%	3.2%	1.5%

APPENDIX K: Percentage of Flow Disruptions by Category and Procedure



APPENDIX L: Percentage of Flow Disruptions by Category



APPENDIX M: Percentage of Flow Disruptions by Category and Procedure Type