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Preventable adverse events in surgical patients: A meta-analysis and knowledge, attitude, and practice (KAP) assessme

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Preventable adverse events in surgical patients: A meta-analysis and knowledge, attitude, and practice (KAP) assessment

by

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A THESIS

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Abstract

All surgical procedures come with a risk of adverse events (AEs). To improve patient safety and prevent similar errors in the future, errors must be acknowledged and addressed.

In this study a meta-analysis of patient safety literature in surgery was conducted and a Knowledge, Attitudes, and Practice (KAP) assessment survey of Calgary academic surgeons was performed.

Results of the meta-analysis demonstrated a preventable adverse event (PAE) rate of 10.5 PAEs per 100 patients across all surgical specialties and a preventable death rate of 0.5 per 100 surgical patients. The KAP survey assessment demonstrated that 20% of surgeons could correctly identify the definition of both AE and error. Participants reported the factors contributing to an error to be multifactorial. The most frequently used methods to teach patient safety were Morbidity and Mortality rounds and individual feedback. Less than 25% of surgeons track their own AE rate.

These results have implications for surgical postgraduate education, as well as for surgical practice in Canada. Recommendations are made for the development of a formal patient safety curriculum for all surgical trainees, with the aim of decreasing the number of errors. In addition, it is essential that more high-quality studies that include reproducible methods and consistent definitions of AEs and errors be conducted.

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Dedication

I would like to dedicate this thesis to my two amazing children, Zachary and Hailey Phillips, who are always there with a hug and a snuggle, and my husband Craig Phillips, who is one of the most selfless people I know. I love you all more than words can say.

Table of Contents

List of Tables

List of Figures

List of Symbols, Abbreviations, and Nomenclature

Symbol	Definition
AE	Adverse Event
AH	Adrian Harvey
DB	Don Buie
EOP	Elizabeth Oddone-Paolucci
HFACS	Human Factors Analysis Classification System
HRO	High Reliability Organization
JLA	Janice Lynn Austin
KAP	Knowledge, Attitudes, and Practice
ML	Mark Lipson
MINORS	Methodological Index for Non-Randomized Studies
NSQIP	National Surgical Quality Improvement Program
PAE	Preventable Adverse Event
PD	Preventable Death
TD	Tyrone Donnon
TIPS	Teaching in Patient Safety
USD	United States Dollars

CHAPTER 1:
INTRODUCTION

1.1 Overview of Research Project

This thesis involved conducting a systematic review and meta-analysis of preventable adverse events (PAEs) and preventable deaths (PDs) in surgical patients, as well as performing a Knowledge, Attitudes, and Practice (KAP) assessment survey of surgeons working in academia in Calgary, Alberta. The goal was to create a foundation for the development of a curriculum to effectively teach residents about PAEs in surgery; specifically, how to handle PAEs and PDs that have occurred and how to minimize their occurrence in the future. The design and development of a full curriculum based on the results of the assessment survey is beyond the scope of this thesis. Therefore, this document includes a: 1) Review of the literature regarding PAEs in surgery and educational methods to teach medical learners around this subject; 2) Description of the development and results of a systematic review and meta-analysis of the prevalence of PAEs and PDs; 3) Description of the development and results of a KAP assessment survey of academic surgeons regarding education and PAEs; and 4) Discussion of the above work and recommendations regarding the next steps in improving PAE/PD education and future research. Contributions to this work are outlined in Appendix A.

1.2 Aim

The two primary aims of this project are to: 1) Determine the prevalence of PAEs and PDs across surgical specialties, in order to determine if this is indeed a problem that requires addressing, and 2) Identify the knowledge, attitudes, and practices of current surgeons with respect to AEs and how they are taught. Together, these will form the first step in delineating the

prevalence of the problem and assessing surgeons' awareness of the magnitude of the problem in surgical practice as well as their grasp of the definitions of PAEs and PDs.

1.3 Background

1.3.1 Adverse Events and Errors

Every surgical procedure comes with the risk of adverse events (AEs). An *AE* has been defined as an unintended injury causing some form of disability, increased length of stay, or death that was the result of the patient's medical care rather than their disease.(1-4) AEs can have serious and significant implications on a patient's life. The probability of an AE occurring can be affected by many factors such as patient comorbidities, the disease process, or errors in surgical management.(5) *Errors* are defined as an act of omission or commission in planning or execution of patient management that falls below the current standard and expected performance for practitioners or systems relative to their peers.(6-8) This definition is applied to individuals as only individuals can make errors. Systems on the other hand, including the environment, can create the error-producing conditions that lead an individual to make an error. *Error-producing conditions* are factors at the level of the environment and organization that promote errors in the workplace.(9) *Violations* are deviations from safe operating procedures, standards, or rules.(9) These can be deliberate, the act was intentional, but not necessarily a potential negative outcome, or erroneous, not being aware of the rule or that one is breaking a rule. AEs that are secondary to errors or violations represent those events that are potentially preventable, termed *preventable adverse events* (PAEs).(10) Surgeons are constantly working towards improving techniques, technology, and patient care to minimize the number of AEs experienced by patients. A reduction of the number of errors would reduce AEs, and therefore reduce patient morbidity and mortality, as well as decrease the cost of healthcare.(2,11-14) For example, the report created by

the Institute of Medicine (IOM) in the USA concluded that over 44 000 Americans die each year as a result of errors.(12) Levenson (2004) examined 16 types of patient safety incidents in Medicare patients in the USA and found that these cost the system over $8 billion USD annually.(13) Rigby and Litt (2000) also examined 12 different incidents thought largely to be preventable and found that in aggregate, these events cost Australian hospitals 2-3% of their total budget. Wound infections alone, for example, cost the Australian healthcare system over $60 000USD per 10 000 discharges.(14)

It is generally well accepted that to improve patient safety in surgery and lower costs for the healthcare system, errors must be acknowledged and addressed to learn and to prevent similar errors in the future.(2,12) Errors in the management of a patient can occur in the preoperative, intraoperative or post-operative setting. They are categorized as being either latent or active. *Latent conditions* are those that are related to a medical system's design and not directly attributable to an individual.(15,16) *Active errors*, on the other hand, are directly attributable to an individual's action or inaction.(15,16) Both active and latent errors have been incorporated into a number of different classification systems for errors, and several authors have grouped errors into various categories.(17-19) Elder et al. (2002) created a classification system by combining the categories from multiple authors. They grouped errors as either PAEs or process errors with several subheadings in each category. The PAE category answers the question "what went wrong," and the process error category addresses "why something went wrong."(17) This classification allows errors to be tabulated, but is criticized for having broad and nebulous categories that make it difficult to use and effect change.(20) In general, these classifications often focus more on who did what rather than why an event occurred.

An emerging alternative is the Human Factors Analysis Classification System (HFACS), as it is applied to healthcare.(20) This classification system involves four levels of error causation based on the work of James Reason: 1) Unsafe acts, 2) Preconditions for unsafe acts, 3) Supervision, and 4) Organizational influences.(20,21) There are several subcategories and multiple nanocodes (i.e., labels that represent specific human behaviours or system situations that contributed to the error) under each subcategory. An error is assigned to the one or more nanocodes that are applicable. Analysis of the errors can then occur with a focus on why an event happened rather than who did what, along with suggestions for a future corrective plan.

The HFACS has been used by many other high reliability organizations (HROs) such as the US Navy and Marine Corps aviation, US Department of Defense aviation, commercial and general aviation, as well as other high risk non-aviation industries such as mining, petroleum and gas, and rail.(20) HROs are industries that operate in hazardous conditions, but have fewer AEs than expected.(22) They are distinguished not by the absolute error rate, but the manner in which they effectively manage risky circumstances via organizational control of hazard and probability.(23) HFACS has only recently been modified for the healthcare system.(20) The benefit of the HFACS approach is that it addresses both active and latent errors and it incorporates Reason's "Swiss cheese" model. Reason's model (2000) recognises that humans are fallible, errors are due to multiple complex levels of failure, and the focus should be on why an error occurred rather than who did what.(20,21) The goal is to create an ultra-safe environment for the care of patients in which the practice of medicine can function. This may be achieved by applying HFACS analysis errors that are either active or latent to determine *why* they happen. This analysis would reveal actionable factors contributing to an error allowing the implementation of safe guards against similar future errors.

Errors have the potential to contribute to significant patient morbidity or even death.(12,24,25) Although not currently achieved, medicine, and surgery in particular, should strive for the same rigour as other HROs. In recognition of the concerns related to AEs, the Accreditation Council for Graduate Medical Education has incorporated patient safety into the residency program teaching requirements.(26) For the purposes of patient safety education, it is important to have an accurate estimate of the numbers and types of errors and AEs, in order to investigate: 1) how often errors affect patients negatively, and 2) what effect educational interventions have made on the reduction of errors that occur.

1.3.2 Patient Safety Education

Currently, medical education regarding patient safety, as it relates to errors, occurs in different formats or methods. One approach involves giving *individual feedback* or *team debriefing*, wherein only the person or group involved in the patient's care is made aware of the error and the resulting outcomes. This allows the individuals involved to modify their future behaviour and potentially teaches trainees to avoid the same error in the future. However, with this approach, only a limited number of individuals can benefit from this type of feedback and uninvolved individuals may go on to make the same mistake repeatedly.

A second method of providing patient safety education while addressing the issue of errors is through *Morbidity and Mortality (M & M) rounds*. This approach involves discussing adverse events in a large group, often consisting of medical students, residents, and surgeons. The purpose of this educational forum is to review AEs to identify possible errors so that everyone attending can benefit from the discussion and potentially modify their future behaviour and actions.(27) Ideally this is provided in a supportive environment without shaming or blaming, and involves examining the facts surrounding a case with the goal of "learning from our

mistakes." However, many surgeons still feel there is a significant amount of negative judgement from colleagues using this method. As a result, some do not report or may even try to hide their mistakes.(3,28) Consequently, complications are consistently under-reported at M and M rounds.(29)

A third educational method is a *class-based curriculum* for trainees. This involves using a variety of teaching methods (i.e., didactic sessions, group discussions, cases, role play, and/or simulations) to educate trainees on identifying and remediating potential errors.(3,30) The main advantages of this method is that it focuses on identified cases of errors or AEs without the need for individuals to be singled out and involves a collegial approach by working in groups. In addition, participants are emotionally unattached allowing for more objective analysis of cases. The main limitation involves the possible lack of commitment from trainees, as they may not see immediately how some cases are relevant to their patients or scope of practice. In addition, without emotional investment in the cases, there may be less motivation to change behaviours. Moreover, this approach does not promote or reinforce continued physician education on errors. Without ongoing reinforcement and reflection, there is concern that some of these initial lessons may be forgotten.

In developing a curriculum for trainees to learn about patient safety and addressing errors and AEs as a part of surgical education, all of the above approaches have merit, and all may be necessary for optimal knowledge acquisition. However, first it must be determined whether there is a knowledge deficit within the domain of patient safety and whether stakeholders perceive a need for a curriculum in patient safety and if so which teaching methods would best serve their learning needs.

1.3.3 Kern's Model of Curriculum Design

A curriculum is a planned learning experience. Curricula are variable in terms of number of sessions, nature of content, method of delivery, and instructors. Good curricula follow a framework that guides identification of the invested groups and their needs, curriculum content, teaching strategies and assessment, and ongoing program evaluation. One example of a framework used to guide the creation of curricula is the Kern Model. Kern's guide to developing a curriculum holds that there are six main steps; that include: 1) Problem identification and general needs assessment, 2) Needs assessment of targeted learners, 3) Goals and specific measurable objectives, 4) Educational strategies, 5) Implementation, and 6) Evaluation and feedback of the program.(31) Following an iterative process, as each step is completed, it incorporates what is learned from the previous steps and feeds back into the earlier completed steps. (31) In this study, a meta-analysis was employed as the method for identifying the problem, and a questionnaire was used as a needs assessment of educators. It was anticipated that once an estimate of PAEs could be established, and the current practices and opinions of the University of Calgary (U of C) affiliated surgeons determined, a future curriculum to reduce the number of PAEs could be developed. This thesis includes Kern's (2010) Step 1 (problem identification and general needs assessment) to the overarching goal of having a fully developed patient safety curriculum that includes the issues associated with errors and AEs in surgery that would incorporate a cycle of ongoing feedback and modifications to improve the curriculum over time. In addition, this thesis partially contributes to Step 2, which involves the needs assessment of both learners and the learning environment in the form of a needs assessment for the educators, however, to complete Step 2, a needs assessment of all other stakeholders, including the learners, would need to be completed as well. These steps in Kern's model that are

presented in the following chapters are intended to lay the foundation for future studies focused on carrying out the remaining steps in Kern's curriculum cycle.

1.3.4 Measurement of Adverse Events

Krizek (2000) has suggested that in spite of ongoing attempts, there has been a lack of improvement in quality of surgical care over time due to inadequate data about the incidence of AEs, a culture of blame, and difficulty in truth telling, among other reasons.(28) Therefore, the first step in reducing PAEs is to accurately quantify the prevalence of both PAEs and AEs of all types in surgical patients. An accurate assessment of the prevalence of PAEs will allow for the development of specific interventions (e.g., a focused curriculum for residents or staff) to target the most frequent errors or conditions leading to errors, as well as assist in the future measurement of the effectiveness of these interventions in reducing these errors.

Surgeons have been measuring and publishing the proportion of complications that are attributable to error since at least the 1980's.(32) A number of these studies now exist with a range of estimates of preventable AEs. While there is generally good consensus regarding what constitutes an adverse event, controversy exists regarding how to quantify the number of errors, and therefore, how to quantify preventable adverse events.(2,4,33) Troeng and Janzon (1990) proposed using death, prolonged length of stay, and referrals to other departments as markers for error in surgery.(5) The advantage of these measures is that they are concrete and easily measured and reproduced. However, these measures are not comprehensive, and a number of errors and potentially avoidable AEs would not be identified and addressed by using this system. Others have used prospective self-reporting systems in which healthcare workers declare any errors made.(6,10,19,34) Lastly, some have used retrospective chart reviews, where the determination of whether there was error is either inferred from the nature of the complication or

left to the discretion of the reviewer.(2,32,35-37) Currently, there is no perfect method of quantifying errors, as all methods may underestimate the number of errors made. Likely, some combination of methods is required to maximize the number of errors detected. Still, it is important to make the best estimate possible, keeping these caveats in mind when interpreting the data.

1.3.5 Meta-Analysis as a Measurement Method

Meta-analysis is a statistical method that can be used to obtain a quantifiable estimate of error occurrence. A meta-analysis synthesizes common quantitative measures across studies and provides a summary estimate of a measured outcome with specified confidence intervals.(38) Meta-analyses afford many advantages. For instance, both in medical education and other fields of research, meta-analyses can combine the data of several studies to give stronger conclusions than individual studies alone regarding the significance of an effect size estimation. It is especially useful when the primary research that exists on a certain topic has small sample sizes with opposing conclusions.(39) Moreover, it can be used when making decisions or resolving conflict about policy, protocol, or curricula changes by providing comprehensive evidence to stakeholders.(40) Meta-analyses can also be used to point out gaps in the existing research to direct additional studies. Lastly, by using a systematic review method that specifies the inclusion and exclusion criteria, it can be replicated by others or easily updated in the future as additional studies are conducted on the topic.

As with all tools, there are also noteworthy limitations of meta-analysis. Bias may be introduced into a meta-analysis by several means. Publication bias, for instance, refers to negative studies or those not reaching statistical significance that are not published or published in only obscure journals.(41) However, this is likely less applicable for studies reporting rates, as

there is no null hypothesis and therefore there cannot be a “negative” study. Potentially, this problem can be addressed by including abstracts and conference proceedings, doing a hand search of older journals, or contacting leading members of a given field to obtain all relevant data for the meta-analysis.(38) In addition, a fail-safe drawer analysis can be conducted to test the robustness of the meta-analysis results.(42,43)

The stated inclusion and exclusion criteria used to select studies may also introduce bias. This may be related to restrictions such as including only peer-reviewed journal articles in English which could systematically exclude studies from certain parts of the world. In order to address this concern, some have advocated for including papers written in all languages.(38) Alternatively, other restrictions that could introduce bias relate to the exclusion of specific subgroups (i.e. young or elderly patients, or patients receiving or not receiving a specific treatment) or constraining the inclusion criteria, which could produce estimates that are not widely applicable. However, by listing the inclusion and exclusion criteria a clinician can discern if the study results can be applied to his or her patients.

Subjectivity may also be introduced to a meta-analysis in the selection of Medical Subject Heading (MeSH) terms and inclusion criteria. However, as long as these are stated clearly in the methods section, readers can discern if the included publications are applicable to their specific groups or interventions of interest. Finally, the quality of a meta-analysis is dependent on the quality of the studies involved, poor quality or unreproducible studies as well as studies with a high risk of bias can decrease confidence in the combined estimate. One way to mitigate this limitation is to assess the quality of the included studies. Quality assessment of the studies refers mainly to the methodological rigor of the included studies. High quality studies, such as well-designed randomized control trials, reduce the risk of bias by accounting for or

eliminating sources of bias like selection or information bias, and other confounding variables. Instead, lower quality studies, such as case series, may introduce sources of bias. While many quality assessment tools exist for both randomized and non-randomized studies there is currently no universally accepted quality measurement rubric.(38,44,45)

High heterogeneity amongst studies may also be a limitation. Heterogeneity of the studies can be addressed using statistical measurements such as τ^2 and the I^2. The between study variance in the effect size, represented as τ^2, is also known as the absolute heterogeneity.(46) If τ^2 is greater than 1, then this suggests significant heterogeneity statistically. I^2 is a measure that gives the proportion of observed variance that is due to variance in true effect sizes. The value of I^2 is not dependant on the number of studies.(46) Therefore it is important to look at both measures when interpreting the heterogeneity of a study.

Knowing the benefits of meta-analysis and that many of these limitations can be addressed, meta-analysis has been widely used in medicine to try and achieve consensus. In the literature addressing surgical AEs, there are a number of meta-analyses and systematic reviews that have been conducted on various drugs or specific procedures.(47-49) By contrast, there have been only a handful of systematic reviews conducted on errors in hospitals, and fewer still focused on surgical patients. Devine et al. (2010) conducted a systematic review of wrong site surgery and found an incidence of wrong site spinal surgery varied and could be as high as 4.5 of 10 000 surgeries.(50) In de Vries et al.'s (2008) systematic review of adverse events in hospital care they found a median in-hospital adverse event rate of 9.2% with a median percentage of preventability of 43.5%.(51) This study, however, did not include studies with less than 1000 patients and was not specific to surgery. Although Anderson et al. (2013) performed a systematic review of adverse events in surgery,(33) they only included studies with a retrospective design

and data from general surgery. Excluding other study designs may have introduced bias and limited the generalizability of their results to the general surgery subspecialty. Moreover, Anderson et al.'s (2013) review included articles from both developed and developing countries, thereby potentially adding unnecessary heterogeneity. To date, we have not come across a meta-analysis published on PAEs in surgery.

1.3.6 Knowledge, Attitude, and Practice (KAP): An Assessment Method

After the number of PAEs have been quantified, interventions to reduce them should be developed. To do this, the current needs and opinions of the population targeted for intervention should be ascertained in order develop appropriate and effective interventions. There currently exists an abundance of data on methods used to teach patient safety and attitudes regarding systemic changes (e.g., work hour restrictions), aimed at reducing the number of errors made.(52,53) However, little or no data currently exist on the knowledge or attitudes of how patient safety is taught to clinicians. A KAP assessment survey is one potential method for measuring the perceptions and attitudes of surgeons towards how patient safety is taught.

A KAP assessment survey collects information on what is known, believed, and done by a population regarding a specific topic.(54,55) The data obtained from a KAP assessment survey can be used to help plan or make changes to a program or curriculum.(56) In this instance, it could allow for the collection of data to assess what surgeons *know* about errors, what their *attitudes* are towards teaching methods regarding patient safety, and *how* patient safety is taught to surgical learners in their respective section (i.e. *practice*). A KAP assessment survey is flexible as it allows for a variety of question types and for collection of data in the three domains of knowledge, attitudes, and practice.(54,55) There are several advantages to this study design. Use of a questionnaire would allow data collection from a larger sample size than interviews or

focus groups, thereby allowing for a more representative sample of the targeted cohort.(31,57) It would also allow for data collection from multiple sites and groups simultaneously in a shorter period of time. Therefore, creating an online questionnaire may facilitate its wider distribution, increase accessibility, and result in a higher response rate.

There are also some disadvantages to utilizing the survey approach. For instance, respondents would not have the opportunity to clarify questions regarding specific items.(31) To address this, questionnaires can be piloted with a small group of respondents to ensure items were clear and easy to comprehend. It would be expected that this would also improve face validity. A second disadvantage to employing a survey method, given the busy schedules of surgeons, is the risk of having a low response rate. If this occurred, the sample could be biased and non-representative, thereby limiting the generalizability of the results. Therefore, attempts could be made to secure participation by adopting strategies employed successfully by others. Some of these strategies include: 1) advertising the study via posters and announcements; 2) having a senior-level colleague (e.g., Department Head, Section Chief, Program Director) endorse the completion of the questionnaire; 3) emphasizing a clear deadline for study participation; and 4) sending reminder emails or following up with personal telephone calls.(58,59)

Following an iterative process, each step of the Kern model incorporates what is learned from the previous steps, and feedback into the earlier completed steps. For instance, in the current study, the meta-analysis was used to inform the KAP assessment survey. The meta-analysis also synthesized the current research examining the rate of PAEs in surgery. This method of analysis quantified the magnitude of the problem. Subsequently, an examination of the AE and error definitions used informed the *knowledge* section of the KAP survey assessment.

The subgroup analysis also identified particular areas that have increased AE or PAE rates, such as prospective studies, or decreased PD rates, such as General Surgery and Trauma as a subspecialty. Therefore, analysis of the results from the KAP assessment survey also addressed these areas, for example, keeping prospective AE and error data at the individual or divisional levels, in addition to the potential teaching methods provided in surgery. The KAP survey assessment serves as a needs assessment for the instructors who would be involved in teaching the curriculum and the meta-analysis served as a baseline measurement. Once a curriculum is implemented and follow up studies performed to evaluate patient safety, the results can be compared to the previously established rates in the meta-analysis, serving as one form of evaluation of the effectiveness of the curriculum.

1.4 Knowledge Gap and Significance

Currently in Calgary, patient safety is primarily taught to residents through the use of M and M rounds. However, as already presented, these are imperfect and can be inconsistent. Teaching within this context has not previously been evaluated at this institution, and outside of this context, it has not previously been measured. Both improving learning opportunities at M and M rounds as well as incorporating other educational tools comprise important steps to revising the existing curricula for residents and medical students. This work would provide a baseline for future comparisons following changes to the current patient safety curriculum in Calgary. To our knowledge, no other study has focused on developing a comprehensive and evidence-based approach to teaching patient safety to medical learners.

1.5 Goals and Objectives of this Research

The overarching goal of this thesis was to determine best practices in patient safety education in surgical specialties at the local level, in order to reduce the number of errors and ultimately

improve patient health outcomes. Specifically, the objectives of the proposed study were twofold: 1) to develop and implement a protocol for a systematic review and meta-analysis of PAEs and PDs in surgical patients; and 2) to measure the perceptions and practice of surgeons with respect to how patient safety is taught at the University of Calgary using a KAP assessment survey.

The specific research questions for the systematic review and meta-analysis were:

1. What is the prevalence of preventable AEs across surgical specialties?
2. What is the prevalence of preventable deaths across surgical specialties?
3. What is the prevalence of PAEs and PDs by time period, study design, subspecialty, and geographic region?

The specific research questions for the KAP assessment were:

4. What level of knowledge do surgeons have regarding adverse events and errors?
5. What are surgeons' attitudes regarding methods for teaching about PAEs?
6. What methods are used to teach about PAEs at the University of Calgary?

The following chapters will consider the above research questions in order. Chapter two will explore through meta-analysis the best estimate of the rate of AEs, deaths, PAEs and PDs and will address the first three research questions. Chapter three will explore the knowledge, attitudes and practice of staff surgeons through a KAP survey assessment and will address research questions four to six. Chapter 4 will integrate the results of these two studies and discuss the implications and future directions towards the development of a patient safety curriculum in surgery.

CHAPTER 2:
PREVENTABLE ADVERSE EVENTS IN SURGICAL PATIENTS: A META-ANALYSIS

2.1 Introduction

Patient safety has been studied for a number of years, however, only recently has quality improvement and patient safety been at the forefront of research. Since the publication of the *Harvard Medical Practice Study I* in 1991, there has been a significant increase in the number of studies examining adverse events (AEs) and specifically addressing the preventability of AEs.(2) The 1991 report was one of the first large scale studies measuring quality of care. In 2000, there was renewed interest in quality of care and patient safety after the publication of *To Err is Human: Building a Safer Health System*.(12) Conducted by the Institute of Medicine, *To Err is Human* not only demonstrated the high cost of error in terms of health consequences to the individual, but also the monetary cost to society as a whole.

Studies on quality of care are required as a form of self-feedback at the level of the surgeon, surgical division, national surgical community, and international surgical community. These studies can be used to inform decisions on policy, direct incentives to reduce the number or types of adverse events, and measure the effect of existing outcomes of AE reducing strategies. For example, these studies have been used to measure the reduction of wrong site surgery after the initiation of the surgical safety checklist. Thus, for these benefits, studies on quality of care should be viewed with the same importance as studies that measure the outcomes of new operative devices or medications relative to the existing approach.

One drawback to the current research on patient safety is that many studies are limited to a single centre or based on small patient numbers making it difficult to extrapolate to the general surgical population. The purpose of this study was to use meta-analytical techniques to determine

the overall preventable adverse event (PAE) and preventable death (PD) rates in surgical patients. Secondary variables were used to determine differences in measured rates by study design, geographic location of the study, type of institution, year of publication, and subspecialty.

2.2 Methods

2.2.1 Definitions Adopted in this Study

A *error* is defined as an act of omission or commission in planning or execution of patient management that falls below the current standard and expected performance for practitioners or systems relative to their peers.(6-8,34,60) *A violation* is defined as a deviation from safe operating procedures, standards, or rules.(9) For purposes of this chapter, these will be grouped together and referred to as errors as the two cannot be separated in the included studies. An *adverse event (AE)* is defined as an unintended injury that was the result of medical care (not the patient's underlying disease process) and the injury resulted in some form of disability, increased length of stay, or death.(2-4) The term AE is often used interchangeably with complication. A *preventable adverse event (PAE)* occurs if an error or violation was made by an individual, and that error or violation subsequently led to the AE. A *close call* is an error that could have led to patient harm, but did not reach the patient.(3) *All hospitalized patients* refers to a study sample taken from all sections including subspecialties of internal medicine, hospitalists, and/or psychiatry. *Surgical patients* refer to study samples made up of only surgical subspecialties and may include patients admitted to those services who did not undergo an operation.

2.2.2 Search Strategy

Using the PRISMA guidelines, a systematic review of the literature was performed in early June 2015 to identify all studies pertaining to AEs and errors. The PRISMA flow diagram

is shown in Figure 1. Articles were collected using the following databases: Medline, Embase, Pubmed, and the Cochrane Library of Randomized Control Trials. For Medline, Pubmed, and the Cochrane Library, the following pre-selected search strategy was used:

(1) human;

(2) incidence OR morbidity OR mortality OR hospital mortality OR death;

(3) diagnostic errors OR medical errors OR (prevent*.tw AND adverse event*.tw) OR (surg*.tw AND error*.tw);

(4) postoperative complications OR intraoperative complications OR iatrogenic disease;

(5) 1 AND 2 AND 3 AND 4; and

(6) Limit to English.

For Embase, the following search strategy was substituted due to variations in the MeSH terms used by Embase:

(1) human;

(2) incidence OR morbidity OR mortality OR surgical mortality OR death;

(3) diagnostic error OR medical error OR error OR surgical error OR (prevent*.tw AND adverse event*.tw) OR (surg*.tw AND error*.tw);

(4) postoperative complications OR peroperative complications OR iatrogenic disease OR complication OR perioperative complications.sh;

(5) 1 AND 2 AND 3 AND 4; and

(6) Limit to English.

In addition to these databases, the reference sections of included studies were searched manually for additional eligible studies. As a result of this manual search, two additional studies were identified. The search was concluded on June 30, 2016.

2.2.3 Inclusion and Exclusion Criteria

The titles and abstracts of studies identified in the initial search were screened according to a defined set of *a priori* inclusion/exclusion criteria. Once a first pass was conducted, the full text of 76 studies were assessed.

Studies were included in the systematic review and meta-analysis based on the following inclusion criteria:

1) The study was conducted in North America, Europe, or Australia;

2) The study involved accredited surgeons and could include residents;

3) The study included data on the prevalence of all AEs and/or mortality, and an estimate of the proportion due to all types of error;

4) There was data specific to one or more of the following surgical specialties: Colorectal Surgery, Endocrine Surgery, General Surgery, Hepatopancreaticobiliary Surgery, Minimally Invasive Surgery, Obstetrics and Gynecology, Orthopedics. Otolaryngology, Pediatric Surgery, Plastic Surgery, Thoracic Surgery, Trauma, Upper Gastrointestinal Surgery, Urology, or Vascular Surgery;

5) The study was peer reviewed and published as an abstract, conference proceeding, or article;

6) The study was published between January 1980 and June 2016; and

7) The study was published in English.

The following exclusion criteria were also defined *a priori*:

1) The study was of a single intervention or procedure;
2) The study recorded a single type of error (e.g. data only for wrong side surgeries); or
3) The study was unpublished, a dissertation, a non-indexed study, an editorial, or a review paper.

Where multiple studies were found to use the same data set, the more comprehensive study was selected for inclusion and the remainder were excluded. Additionally, the included study for abstraction was the one that contained the greatest number of variables pertaining to the meta-analysis. Where more than one existed, the first study published was used. A log was kept of all excluded studies, along with the reasons for exclusion.

2.2.4 Data Extraction

The first author (JLA) created a coding manual based on the study questions. Data were abstracted from the full texts of the studies obtained that met all the inclusion criteria. For each study, all data regarding authors, year of publication, country of study, study design (prospective/retrospective), patient population and characteristics (sex and age), specialties included in the study, primary outcome measure, AEs (type, number, and severity), and errors (type and number) were extracted using a standardized form, completed by two independent reviewers (JLA and ML). Where a scale of preventability was used, those AEs listed as "probably" preventable were also included as PAEs. A full list of variables abstracted in the review is provided in Appendix B. Reviewers were trained to abstract data from studies by practicing with several articles to calibrate (i.e. 10% of the total studies included), using the

standard form. The two reviewers met for approximately 1 hour to check interrater agreement and resolve discrepancies. Once coding was complete, a second meeting for 1 hour was held to again achieve consensus for all studies. Where possible, data for each surgical subspecialty was abstracted separately. All AEs listed as preventable or probably preventable were included as a PAE in the analysis. Disagreements were resolved by consensus of the two reviewers. There were no instances where consensus could not be reached.

Study quality was assessed by two reviewers (JLA and EOP) using the Methodological index for non-randomized studies (MINORS) instrument. The MINORS instrument is a previously validated tool for assessing the methodological quality of both comparative and non-comparative studies that are non-randomized.(45) All included studies were assessed and assigned a score out of 16. The two raters met after 10% of studies were coded to check interrater agreement. The remaining studies were coded and the two raters again met to discuss their ratings. Studies with widely discrepant ratings were reviewed.

2.2.5 Statistical Analysis

The proportion of PAEs and PDs, along with the standard error of the proportion, were calculated for each study. Meta-analysis was performed by analysis of variance with each observation weighted inversely to its variance. The effect measures were rates of the surgical or total population who had PAEs or PDs, as well as the proportion of AEs and deaths considered to be preventable. In addition, subgroup analyses were conducted by geographic location, study design, type of institution, and subspecialty to determine whether different groups were more or less affected by AEs or PAEs. Effect measures were reported as a rate per 100 units, forest plots were created and examined, and heterogeneity was measured using the I^2 statistic. Gwet AC1

values of inter-rater reliability and percent agreement were calculated for the quality rating of each item on the MINORS list as well as the overall quality score between raters.(61,62)

There are two frequently used models for performing meta-analysis: The DerSimonian-Laird method for random effects and the Mantel-Haenszel method for fixed effects.(63) Both measurements calculate a summary statistic of the outcome of an exposure with a confidence interval and can take the form of a risk ratio, rate difference, person-time data, or percentage.(63) The random effects model assumes the true effect from each study comes from a distribution, provides a more conservative estimate with wider confidence intervals, and is less likely to be significant.(41) The fixed-effect model assumes that there is one true effect that is the same for all studies included in the meta-analysis, typically has narrower confidence intervals, and is more appropriate for use in uniformly conducted studies.(41) Unlike the fixed effects model which answers the question "Did the treatment produce benefit on average in the studies at hand?", the random effects model answers the question "Will the treatment produce benefit 'on average'?"(64) Effect sizes were computed using both models, however due to high heterogeneity due to between study differences only the results from the random effects model are reported.

In the current study, the unit of analysis is AEs *per* patient. Admissions were taken as an approximation of the number of patients, recognizing that this may in fact decrease the effect size estimate (i.e., offer a more conservative estimate). However, sensitivity analyses were performed to ensure that the results were not significantly different. Specifically, this was done by calculating the effect estimate using only AEs *per patient* and then AEs *per admission*. These individual effects were compared to the overall analysis that included both AEs per patient and AEs per admission to ensure the measured effect size was not significantly different as a result of

combining the two sets of units. Including both sets of units ensured that minimal or no bias was introduced by excluding one type of study from contributing to the overall effect size estimate.

To assess interrater agreement of the MINORS tool the Cohen's Kappa statistic, Gwet's AC1, or other agreement calculations may be employed. However, this dataset is at significant risk of marginal homogeneity as the quality rating scale is limited to three items. Therefore, Gwet's AC1 statistic was used in lieu of Cohen's kappa. Although both measurements function to measure agreement, Gwet's AC1 statistic is less sensitive to marginal homogeneity and low prevalence.(62,65) Both the Gwet's AC1 statistic and percent agreement scores were calculated between reviewers and reported. All analyses were carried out using Stata IC version 12 (StataCorp.2011. College Station, TX: Stata Press).

2.3 Results

Using the terms outlined above, a search of the Medline, Embase, Pubmed, and Cochrane Library of Randomized Control Trials databases were searched, yielding a return of 2,001 articles. After duplicates were removed 1,364 articles remained. A review of these published paper titles and abstracts identified 84 articles for full text review. Of these, 29 articles met the full inclusion criteria. A manual search of the reference lists of these articles identified an additional two articles suitable for inclusion. These 31 studies formed the basis of our analysis. Figure 1 shows the flow of publications through the study and includes reasons for exclusion of all full text articles.

The characteristics of the 31 included studies are summarized in Table 1. The included studies were published between 1980 and 2016. Twenty (65%) studies were conducted in academic centres, 10 (32%) in a combination of academic and community centres, and 1 (3%) in a community centre. While 9 (29%) of these studies were published prior to the year 2000, 22

(71%) were published after year 2000. Fourteen (45%) of the studies employed prospective data collection, whereas the majority (17; 55%) were retrospective by design. Lastly, most of the studies were conducted in North America (15; 48%) and Europe (12, 39%), with 4 (13%) of the studies having been conducted in Australia or New Zealand.

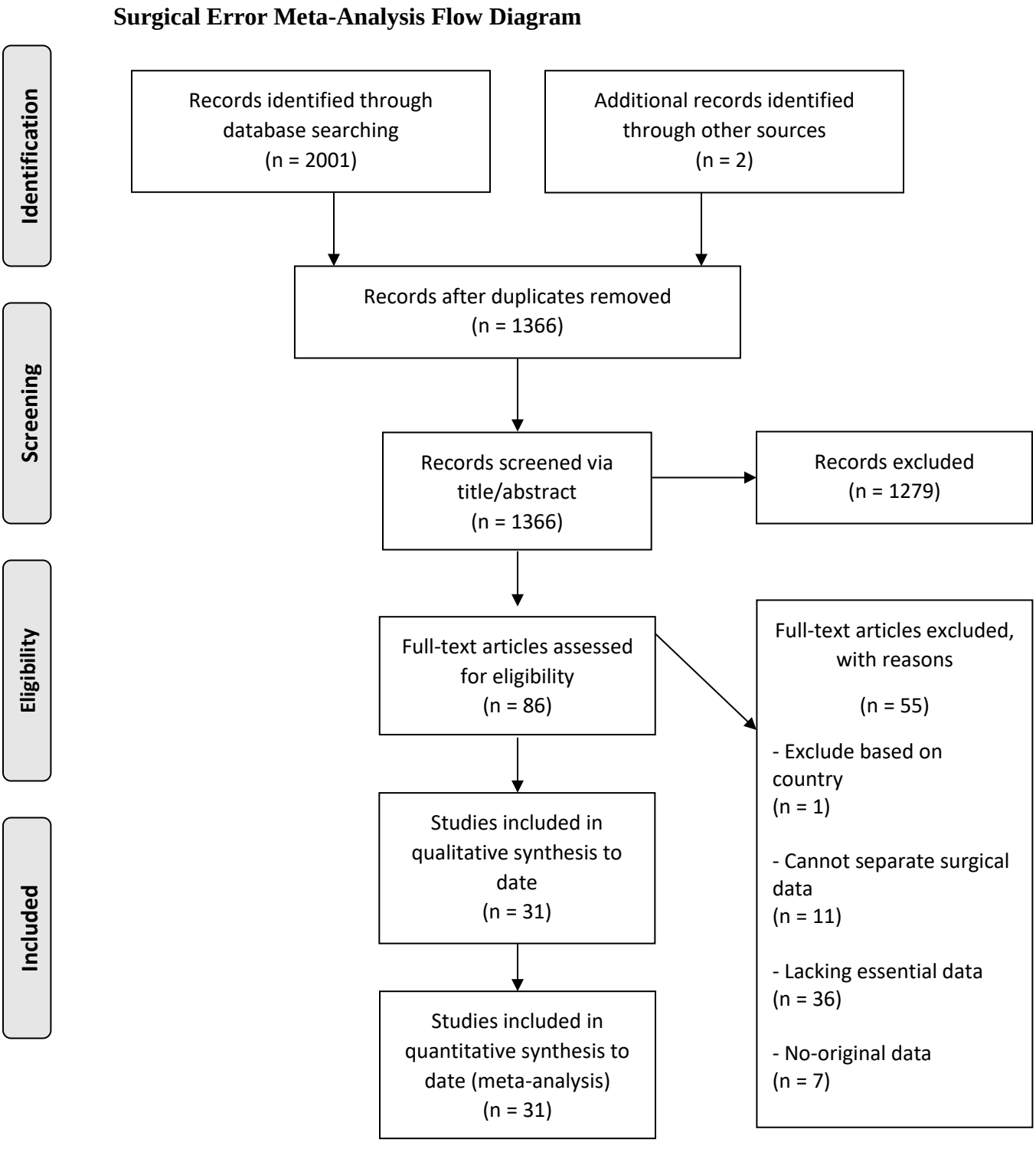

Figure 1: PRISMA Flow Diagram of studies in the systematic search and included in the meta-analysis.

Table 1: Description of the 31 included studies on preventable adverse events (PAEs) in surgical patients

Study (Origin)	Specialty (n)	Definitions	Data collection	AEs per 100 patients in total hospitalized* (Units)	PAEs per 100 patients in surgical (Units)	PDs per 100 deaths (PDs/Deaths)	Mean MINORS score (/16)
Aibar et al., 2015 (66) (Spain)	OBGYN (816)	AE = any unforeseen and unexpected accident recorded in the medical record that cause injury and/or disability and/or prolonged the hospital stay and/or led to death, which was the result of health care and not the patient's underlying condition. Error – none	Retro	N/A	2.2 (PAE/Pt)	N/A	7
Blanchard et al., 1980 (67) (Canada)	Mixed (3,520) Mixed (4,509) Mixed (5,473)	AE = none Error = none	Pro	N/A N/A N/A	N/A N/A N/A	32.8 24.1 32.0	8.5
Bosma et al., 2011 (6) (Netherlands)	Mixed (12,121)	AE = a condition or an event, unfavourable to the patients' health, causing irreversible damage or requiring a change in therapeutic policy. Error = an act of omission or commission in planning or execution that contributed or could contribute to an unintended result.	Pro	N/A	7.2 (PAE/Pt)	N/A	11

Study (Origin)	Specialty (n)	Definitions	Data collection	AEs per 100 patients in total hospitalized* (Units)	PAEs per 100 patients in surgical (Units)	PDs per 100 deaths (PDs/Deaths)	Mean MINORS score (/16)
Calland et al.,2002 (68) (USA)	Mixed (6,296)	AE = Unintended injury caused by medical treatment, and thus not primarily attributable to the patient's primary disease process. Error = episodes in care in which a planned sequence of mental or physical activities failed to achieve its intended outcome and this failure could not be attributed to chance occurrence.	Retro	N/A	N/A	12.6	9
Davis et al., 1991 (69) (USA)	General Surgery/ Trauma (12,910)	AE = none Error = (1) clinical decisions made contrary to information available to the physician at the time of the decision and subsequently proven to be wrong; (2) failure to monitor for a problem that subsequently contributed to the development of a complication or the patient's demise; (3) incorrect medication dosages, inappropriate drug selection, IV fluid management causing fluid imbalance, and iatrogenic electrolyte derangements requiring treatments; or (4) complications with chest tubes and iatrogenic pneumothoraces associated with central venous catheter placement.	Retro	N/A	N/A	7.6	10

Study (Origin)	Specialty (n)	Definitions	Data collection	AEs per 100 patients in total hospitalized* (Units)	PAEs per 100 patients in surgical (Units)	PDs per 100 deaths (PDs/Deaths)	Mean MINORS score (/16)
Davis et al., 2003 (7) (New Zealand)	Mixed (6,579)*	AE = an unintended injury, resulting in disability, and caused by healthcare management rather than the underlying disease process. Each of these criteria needed to be fulfilled. Preventable = as an error in healthcare management due to failure to follow accepted practice at an individual or system level.	Retro	7.4 (PAE/Adm)	N/A	N/A	8
Fabri et al., 2008 (19) (USA)	Mixed (9,830)	AE = none Error = slip (doing the correct thing, incorrectly) or mistake (doing the wrong thing, but correctly).	Pro	N/A	2.7 (PAE/Pt)	N/A	11
Farid et al., 2013 (70) (England)	Cardiac/ Thoracic/ Vascular (2,549)	AE = none Error = none	Pro	N/A	N/A	37.5	11.5
Forster et al., 2004 (71) (Canada)	Mixed (502)* Mixed (206) OBGYN (135)	AE = A score of 4 or greater on a 6 point scale indicated that the outcome was an adverse event (scale not provided). Preventable = on the basis of implicit judgement, [an adverse event] was felt to be due to an error in management.	Retro	5.8 (PAE/Adm) N/A N/A	N/A 2.9 (PAE/Adm) 0.7 (PAE/Adm)	N/A N/A N/A	9

Study (Origin)	Specialty (n)	Definitions	Data collection	AEs per 100 patients in total hospitalized* (Units)	PAEs per 100 patients in surgical (Units)	PDs per 100 deaths (PDs/Deaths)	Mean MINORS score (/16)
Frankel et al., 2007 (72) (USA)	General Surgery/ Trauma (4,655)	AE = none Preventable = injuries or disease would not have resulted in death or complication had optimal care been delivered.	Retro	N/A	N/A	13.9	9
Gawande et al., 1999 (1) (USA)	Mixed (14,700)*	AE = injury caused by medical management (rather than the disease process) that resulted in a prolonged hospital stay, disability at discharge, or death. Preventable = it was avoidable by available means unless those means were not considered the standard of care.	Retro	2.7 (PAE/Adm)	N/A	N/A	9.5
Hassan et al., 2003 (73) (United Kingdom)	Plastic Surgery (537)	AE = those caused by healthcare management rather than by the disease process itself. Preventable = 'an error in management due to failure to follow accepted practice at an individual or system level.'	Pro	N/A	N/A	N/A	11

Study (Origin)	Specialty (n)	Definitions	Data collection	AEs per 100 patients in total hospitalized* (Units)	PAEs per 100 patients in surgical (Units)	PDs per 100 deaths (PDs/Deaths)	Mean MINORS score (/16)
Healey et al., 2002 (74) (USA)	General Surgery/ Trauma (1,363) General Surgery/ Trauma (914) Cardiac/ Thoracic/ Vascular (978) Cardiac/Thoracic/ Vascular (1,403)	AE = none Preventable = when there were deficiencies in care as assessed by the surgeon's own peer group.	Pro	N/A N/A N/A N/A	13.6 (PAE/Pt) 13.9 (PAE/Pt) 24.5 (PAE/Pt) 11.4 (PAE/Pt)	28.0 19.0 44.1 25.0	11.5
Heslin et al., 2014 (75) (USA)	Mixed (11,899)	AE = Death, PSI, or HAC Error = none	Pro	N/A	2.4 (PAE/Pt)	28.9	9.5
Hoyt et al., 2003 (76) (USA)	General Surgery/ Trauma (13,382)	AE = none Error = none	Pro	N/A	33.4 (PAE/Pt)	2.1	8.5

Study (Origin)	Specialty (n)	Definitions	Data collection	AEs per 100 patients in total hospitalized* (Units)	PAEs per 100 patients in surgical (Units)	PDs per 100 deaths (PDs/Deaths)	Mean MINORS score (/16)
Inaba et al., 2013 (77) (USA)	General Surgery/ Trauma (4,030) General Surgery/ Trauma (4,121) General Surgery/ Trauma (2,486) General Surgery/ Trauma (2,332)	AE = none Error = none	Retro	N/A N/A N/A N/A	N/A N/A N/A N/A	2.3 3.1 0.9 N/A	9.5
Kable et al., 2002 (36) (Australia)	Mixed (14,179)* Mixed (5,432)	AE = an unintended injury or complication which results in disability, death, or prolongation of hospital stay, and is caused by health care management rather than the patient's disease. Preventable = an error in management due to failure to follow accepted practice at an individual or system level; accepted practice was taken to be the current level of expected performance for the average practitioner or system that manages the condition in question.	Retro	8.4 (Pt/Adm) N/A	N/A N/A	N/A N/A	8

Study (Origin)	Specialty (n)	Definitions	Data collection	AEs per 100 patients in total hospitalized* (Units)	PAEs per 100 patients in surgical (Units)	PDs per 100 deaths (PDs/Deaths)	Mean MINORS score (/16)
Kable et al., 2009 (78) (Australia)	Mixed (1,177)	AE = injury/complication (not a natural consequence of the patient's disease), disability/prolonged hospital stay, and an assessment that the disability was caused by health care management. Error = none	Retro	N/A	12.9 (PAE/Adm)	66.7	8
Lowe et al., 1983 (79) (USA)	General Surgery/ Trauma (659)	AE = none Error = none	Retro	N/A	N/A	25.2	8.5
McGuire et al., 1992 (80) (USA)	Mixed (44,603)	AE = none Error = none	Retro	N/A	3.1 (PAE/Adm)	7.5	10.5
Michel et al., 2007 (81) (France)	Mixed (8,734)* Mixed (4,808)	AE = an event that was unfavourable for the patient, and was consequent to medical management (treatment planning and treatment, diagnosis, prevention or rehabilitation) rather than being an inherent part of the pathological process. Preventable = they would not have occurred had the care provided complied with recommended or, in the absence of guidelines, commonly accepted practice at the time of occurrence of the event.	Pro	1.7 (PAE/Pt) N/A	N/A 1.0 (PAE/Pt)	N/A N/A	8

Study (Origin)	Specialty (n)	Definitions	Data collection	AEs per 100 patients in total hospitalized* (Units)	PAEs per 100 patients in surgical (Units)	PDs per 100 deaths (PDs/Deaths)	Mean MINORS score (/16)
Nilsson et al., (2016) (82) (Sweden)	Mixed (19,141)* Mixed (3,301)	AE = unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment, hospitalization, or that resulted in death. Error = none	Retro	3.4 (PAE/Adm) N/A	N/A 12.5 (PAE/Adm)	N/A 37.5	9
Proctor et al., 2003 (83) (Canada)	General Surgery/ Trauma (64)	AE = any unintended substantive harm to a patient resulting from medical treatment and not directly attributable to the patient's underlying disease. Error = incorrect medical care, whether action or inaction, that had the potential to cause substantive harm.	Pro	N/A	46.9 (PAE/Pt)	N/A	12
Rebasa et al., 2009 (10) (Spain)	Mixed (3,807)	AE = unexpected consequence or lesion caused to the patient as a result of treatment rather than the underlying illness. Preventable = event attributable to error. Error = produced by mistakes in the planning or execution of diagnosis and treatment.	Pro	N/A	8.7 (PAE/Pt)	32.4	12.5
Remmelt Veen et al., 1999 (25) (Netherlands)	Mixed (7,455)	AE = every unwanted development of the illness of the patient or of the treatment of the patient's illness that occurs in the clinic. Error = none	Pro	N/A	8.9 (PAE/Pt)	7.8	10

Study (Origin)	Specialty (n)	Definitions	Data collection	AEs per 100 patients in total hospitalized* (Units)	PAEs per 100 patients in surgical (Units)	PDs per 100 deaths (PDs/Deaths)	Mean MINORS score (/16)
Schepers et al., 2003 (84) (Netherlands)	Cardiac/ Thoracic/ Vascular (373)	AE = every unwanted development of the illness of the patient that occurs in the clinic. Error = none	Pro	N/A	29.0 (PAE/Pt)	N/A	11.5
Troeng et al., 1990 (5) (Sweden)	General Surgery/ Trauma (3,767)	AE = Death Error = (1) Error of omission in diagnosis: Failure or critical delay in making a determinant diagnosis; (2) Error of commission in diagnosis: Erroneous diagnosis leading to an important mishap or performing an unnecessary or contraindicated diagnostic procedure; (3) Error of omission in therapy: Failure or critical delay in performing an important surgical procedure; or (4) Therapeutic error of commission: Performing an unnecessary, inappropriate or contraindicated procedure or inadequate execution of an indicated procedure.	Retro	N/A	N/A	22.9	10.5

Study (Origin)	Specialty (n)	Definitions	Data collection	AEs per 100 patients in total hospitalized* (Units)	PAEs per 100 patients in surgical (Units)	PDs per 100 deaths (PDs/Deaths)	Mean MINORS score (/16)
Vincent et al., 2001 (85) (United Kingdom)	Mixed (1,014)* General Surgery/ Trauma (290) OBGYN (174) Orthopedic (277)	AE = refers to BMJ website (ne reference given). Error = none	Retro	9.3 (PAE/Adm) N/A N/A N/A	N/A 6.9 (PAE/Adm) 2.9 (PAE/Adm) 4.7 (PAE/Adm)	N/A N/A N/A N/A	10
Wanzel et al., 2000 (34) (Canada)	General Surgery/ Trauma (192)	AE = unintended, adverse outcome that occurred after medical management or a surgical procedure, was not caused by the underlying disease and resulted in impaired health. Error = unintended act of omission or commission, or an act of that did not achieve its intended immediate outcome.	Pro	N/A	13.5 (PAE/Pt)	N/A	12
Wilson et al., 1995 (86) (Australia)	Mixed (14,210)*	AE = 1) an unintended injury or complication which 2) results in disability, death, or prolongation of hospital stay, and is 3) caused by health care management rather than the patient's disease. Preventable = "an error in management due to failure to follow accepted practice at an individual or system level".	Retro	9.3 (Pt/Adm)	N/A	N/A	13

Study (Origin)	Specialty (n)	Definitions	Data collection	AEs per 100 patients in total hospitalized* (Units)	PAEs per 100 patients in surgical (Units)	PDs per 100 deaths (PDs/Deaths)	Mean MINORS score (/16)
Zegers et al., 2011 (8) (Netherlands)	Mixed (7,926)*	AE = 1) an unintended physical and/or mental injury, which 2) resulted in temporary or permanent disability, death or prolongation of hospital stay, and 3) was caused by health care management rather than the patient's disease. Preventable = care that fell below the current professional standards and expected performance for practitioners or systems.	Retro	3.6 (PAE/Adm)	N/A	N/A	10

* AEs related to surgical care, AE = Adverse Event, Pro = Prospective, Retro = Retrospective, Adm = Admission, N/A = No Data, PAE = Preventable adverse event, Pt = Patient

2.3.1 All Hospitalized Patients

Overall, 9 (29%) of the included studies reported on the rate of AEs in all hospitalized patients. Across those 9 studies measuring events in all hospitalized patients, this population suffered 5.7 AEs per 100 patients (95% CI: 3.9-7.5, I^2 99.4%) related to surgical care. Seven (23%) studies reported the rate of PAEs in all hospitalized patients. Among these seven studies, 2.0 PAEs per 100 patients (95% CI: 1.3-2.8, I^2 97.9%) occurred due to surgical care among all hospitalized patients.

2.3.2 Surgical Patients

The number of AEs in surgical patients was reported on by 17 (55%) studies. The combined rate of AEs in the random effects model was 24.6 AEs per 100 patients (95% CI: 14.9-34.3, I^2 100%). The subgroup analyses for AEs and PAEs are reported in Table 2. The rate of adverse events was higher in studies where the data was collected prospectively and in studies conducted in an academic setting; however, these differences did not reach statistical significance (i.e., $p>.05$).

Overall, 17 (55%) of the included studies measured the rate of PAEs among surgical patients. The rate of PAEs in the random effects model was 10.5 PAEs per 100 patients (95% CI: 8.2-12.8, I^2 99.7%). PAEs were identified more frequently in studies with prospective data collection and studies completed in academic centres, although again, these differences were not significantly different.

The proportion of AEs that are preventable was reported by studies in one of two ways: 1) by counting the number of PAEs per number of AEs (i.e. using AEs as the unit of count) in 20 (65%) studies with a combined effect of 44.7 PAEs per 100 AEs (95% CI: 38.5-50.9, I^2 98.9%);

or 2) by counting the number of patients with a PAE per number of patients with an AE (i.e. using the patient as the base unit of count) in 7 (23%) studies whose combined effect, using the base units of patients, was 48.7 patients with PAEs per 100 patients with AEs (95% CI: 33.1-64.2). Four (13%) studies reported these rates using both units and therefore contributed to both measurement approaches.

Table 2: Subgroup analysis of preventable adverse events (PAEs)

	Adverse Events			Preventable Adverse Events		
Subgroup	Number of studies	AEs per 100 patients (95% CI) in surgical population	I^2 (%)	Number of studies	PAEs per 100 patients (95% CI) in surgical population	I^2 (%)
Setting						
Academic	14	27.0 (15.7-38.2)	100	14	11.5 (8.8-14.2)	99.7
Mixed academic/community	3	9.0 (0.00-18.6)	99.6	3	5.2 (0.00-11.4)	99.5
Data Collection						
Retrospective	6	13.0 (7.2-18.8)	99.1	6	5.4 (2.7-8.1)	97.9
Prospective	11	32.1 (16.3-47.8)	100	11	14.4 (10.6-18.2)	99.8
Specialty						
Mixed services	10	18.6 (13.3-24.0)	99.9	10	6.1 (4.6-7.7)	99.3
Cardiac/Thoracic/Vascular	2	36.7 (25.4-48.0)	97.2	2	21.5 (10.4-32.6)	98.0
General Surgery/Trauma	4	48.1 (13.7-82.5)	99.9	5	20.7 (9.3-32.1)	99.4
OBGYN	3	3.9 (2.8-5.0)	N/A*	3	1.8 (0.7-2.9)	41.0
Orthopedic Surgery	1	14.4 (10.3-18.6)	-	1	4.7 (2.2-7.2)	-
Plastic Surgery	1	3.2 (1.7-4.6)	-	-	-	-
Time Frame						
Up to year 2000	3	30.2 (20.2-40.2)	99.8	3	8.0 (3.1-13.0)	99.4
After year 2000	14	23.6 (10.4-36.7)	100	14	11.2 (8.0-14.3)	99.7
Geographic Location						
Australia/New Zealand	1	37.5 (34.7-40.2)	-	1	12.9 (11.0-14.8)	-
Europe	9	18.7 (9.4-28.0)	99.9	8	8.0 (5.1-11.0)	99.3
North America	7	29.4 (13.1-45.6)	100	8	12.7 (8.9-16.5)	99.8

Note: Random effects model used

* Tau squared for this data set was < 0.00001 and therefore an I^2 cannot be calculated.

2.3.3 Preventable Deaths

Overall, in the 21 (68%) studies that reported on patient deaths, there were 3.9 deaths per 100 patients (95% CI: 3.0-4.7, I^2 99.7%). Sixteen (52%) studies measured the rate of PDs among surgical patients or admissions. The rate of PDs in the random effects model was 0.4 PDs per 100 patients (95% CI: 0.3-0.5, I^2 94.2). Sixteen (52%) articles included information on the proportion of all deaths that were preventable. The rate of deaths that were preventable was 17.5 PDs per 100 deaths (95% CI: 13.8-21.2, I^2 95.7%). In the subgroup analysis (Table 3), it was found that as a proportion of deaths, the number that were preventable was lower in General Surgery and Trauma patients relative to other specialties, and lower in retrospective relative to prospective studies. There were no differences between groups when examining the rate of PDs per deaths in the surgical population according to academic vs non-academic setting or year of publication. The difference between Australia and New Zealand and North America is likely due to the inclusion of only one study in the Australia and New Zealand group and does not reflect a true difference. There were no differences between groups when examining the rate of PDs per patient undergoing surgical care between any subgroups.

Table 3: Subgroup analysis of preventable deaths (PDs)

Subgroup	Number of studies	Preventable deaths per 100 deaths (95% CI)	I^2 (%)
Setting			
Academic	12	17.1 (13.0-21.3)	96.0
Mixed academic/community	3	20.7 (4.6-36.8)	92.4
Community	1	22.9 (15.7-30.1)	-
Study Design			
Retrospective	9	10.5 (6.9-14.1)	92.6
Prospective	7	25.2 (15.3-35.1)	97.1
Specialty			
Mixed services	8	24.3 (16.0-32.6)	95.2
Cardiothoracic/Vascular	2	33.8 (20.1-47.5)	40.9
General Surgery/Trauma	7	8.8 (5.6-12.1)	92.8
Year			
Up to year 2000	6	19.6 (13.0-26.2)	96.2
After year 2000	10	14.5 (10.5-18.6)	92.9
Geographic Location			
Australia/New Zealand	1	66.7 (28.9-100)	-
Europe	5	24.0 (11.4-36.6)	83.5
North America	10	16.1 (12.2-20.0)	96.5

2.3.4 Study Quality

Study quality was assessed by 2 different reviewers (JLA and EOP), using the MINORS tool (Appendix C). All studies were population based, non-comparative studies and therefore received a score out of a total of 16 potential points. The mean overall score for the included studies was 9 (SD 1.5). The Gwet's AC1 statistics are reported in Table 4 for each item. Overall, Gwet's AC1 scores were between 0.28 and 0.97, from fair to almost perfect.(87) The inter-rater reliability of the overall rating (AC1 = 0.56) was moderate.

Table 4: Gwet's AC1 statistic and percent agreement scores for items in the MINORS quality assessment tool

Item	Gwet's AC1	Percent Agreement
Overall Rating	0.56	58.1%
1) Clearly stated aim.	0.74	77.4%
2) Inclusion of consecutive patients	0.33	54.8%
3) Prospective collection of data	0.33	54.8%
4) Endpoints appropriate to the aim of the study	0.45	58.1%
5) Unbiased assessment of the study endpoint	0.28	48.4%
6) Follow-up period appropriate to the aim of the study	0.47	58.1%
7) Loss to follow up less than 5%	0.78	80.6%
8) Prospective calculation of the study size	0.97	96.8%

2.3.5 Definitions

As shown in Table 1, the definitions used in the studies were variable for both AEs and error or PAE. Twenty-one (67.8%) of the included studies provided a definition for AE and 18 (58.1%) of the included studies provided a definition of error or preventability. A*dverse event (AE)* was defined as an unintended injury that was the result of medical care (not the patient's underlying disease process) and the injury resulted in some form of disability or impaired health, or a variation of this in multiple studies.(2-4) Several studies also defined AE as specific events, for example a death. This was more common in studies where mortality was the primary endpoint.(5,75) One study used a 6 point scale, where a score of 4 or greater identified an adverse event.(71) The definition of error or preventability was much more variable. The most common definition was a variation of an act of omission or commission in planning or executing patient management that contributes or could contribute to an unintended outcome.(6,34,60) Fifteen (48.4%) studies determined the probability of an AE being preventable based on a 3 to 6 point scale of preventability ranging from "not preventable" to "preventable". (1,7,8,10,36,69,71,73-75,77,78,81,86,88)

2.4 Discussion

Although there are numerous studies focused on errors,(32,33,51) the current study is the first to provide a meta-analytic synthesis of the research that generates an overall estimate of PAEs and PDs in surgical patients. The meta-analysis findings reveal that overall, approximately 25 AEs occurred per 100 patients undergoing treatment on a surgical service, almost half of which were potentially preventable. When broken down by specialty, PAE and AE rates were higher on General Surgery and Trauma, as well as Cardiac/Vascular/Thoracic services. This is most likely due to patients with an increased number of comorbidities and higher acuity than the other listed specialties. It may also be due to reporting bias. However, regardless of the rate of AEs in each subspecialty, almost half of the AEs in each subspecialty were considered preventable.

Not surprisingly, most studies were conducted in academic centres or data was taken from a mix of academic and community centres. The majority of studies were also conducted after the year 2000. This may be in response to the controversial report “To Err is Human” that was released by the Institute of Medicine (IOM) in the year 2000.(12,89)

A systematic review of AEs in surgery previously published by Anderson et al. (2013) found an AE rate of 14.4% and a PAE rate of 5.2%.(33) However, only studies with a retrospective design and data from general surgery were included in this systematic review. Excluding other study designs may have introduced bias and limited the generalizability of their results to the general surgery subspecialty. This may also explain the lower AE and PAE rates in this compared to the present study. Moreover, the Anderson et al. (2013) review included articles from both developed and developing countries, thereby potentially adding unnecessary heterogeneity. In addition, this review did not address PDs.

The rates of PDs in the surgical population are small, less than 0.5 PDs per 100 patients. However, as a proportion of surgical deaths, 20% have been determined to be preventable. While these rates are low, the goal in surgery should be no PDs. These rates of PAEs and PDs reinforce the need to continuously improve surgical techniques and care. It is important to effectively teach residents and surgeons techniques on how to self-reflect and improve over time. In this meta-analysis, the proportion of deaths that were preventable were higher in prospective studies, which is likely more related to an improved ability to detect errors rather than a true difference. Moreover, the lower proportion of PDs in General Surgery and Trauma was likely related to a higher number of unsalvageable patients with acute presentations relative to other subspecialties.

The current study does have some limitations, all of which are inherent to conducting a meta-analysis. First, the included studies are all cohort designs, not randomized control trials, and therefore there is the absence of a comparison group thus they are subject to all of the recognized biases of non-randomized studies. Even so, given the questions posed in this study, a randomized control trial study design would not be practical or feasible. Another limitation is that there was high heterogeneity attributed to between study differences amongst the included studies. While this may be due to the varying study designs (i.e. prospective vs retrospective data collection and self reporting vs third party review for assignment of error), the differences in definitions of the AE and error constructs across studies also likely contributed.

Our study reinforces the need for consistent definitions of both AEs and errors so that accurate and reliable measurements of PAEs can be made. A definition generally accepted for adverse events was published by Gawande et al in 1999.(1) This definition requires three criteria be fulfilled: 1) the outcome must be unintended; 2) there must be some form of disability (not necessarily permanent or of great magnitude), increased length of stay, or death; and 3) the

outcome must be the result of the patient's medical care rather than their disease. Based on the results of our meta-analysis, we would recommend that future studies adopt this more comprehensive definition of AEs. This definition does not limit negative consequences to specific events and does not require the negative effects to be permanent. In addition, this definition clearly defines the negative impact as being from the patient's care differentiating it from a disease process. Lastly, this definition makes it clearly distinct from errors, which would lead to PAEs, a subclass of AEs.

By contrast, the definition of error has been less well established in the literature. There are a number of different definitions that have been presented, unfortunately with a lack of consensus. Moreover, definitions of error often focus on actions or inactions or on performing at a standard relative to one's peers. Few definitions seem to focus on both. As a result of the present analysis, we propose the use of the following definition: "an act of omission or commission in the planning or execution of patient management that falls below the current standard and expected performance for practitioners or systems relative to their peers." This should be distinct from violations defined as a deviation from safe operating procedures, standards, or rules.(9)

It is noteworthy, that a patient's medical co-morbidities cannot be the sole contributing factor of an AE; rather, an event can only be classified as an AE if it would otherwise not have occurred had the patient not undergone the medical treatment. While a comorbidity or disease process can increase the odds of an AE occurring and affecting a person's risk of AE, it cannot be the sole contributor. Any event that would have occurred independent of medical treatment can be seen only as disease progression. More difficult, is how to discern whether or not the error contributed to an AE, making that AE a PAE. In order to make such determinations going forward, special consideration needs to be directed to quality of care research. As this portion

seems to be judgement dependent, often it can be impossible to determine with absolute certainty whether an AE is actually a PAE. It therefore may be best to consider AEs on a scale of preventability, such as that used by Hassan et al. (2003) or Healey et al. (2002).(73,74) If adopted, the scale should be accompanied by a set of guidelines that are specific so as to guide reviewers and ensure both scoring consistency and universal applicability across specialties and procedures. Perhaps in the future it may even be more informative to conduct studies of a few specific AEs, where a detailed and specific guideline can exist to judge preventability.

The high rate of patients experiencing PAEs and PDs also has implications for medical education. These data demonstrate an area of surgery where education can have a high impact. It follows that by incorporating patient safety into surgical curricula for learners at all levels of training the number of PAEs and PDs will potentially decrease over time. Currently programs that track patient AEs exist and they can feedback rates to individuals and divisions, and if they are exceptionally high relative to other institutions, the division can introduce changes to try and reduce the specified AE.(90-92) The limitation of these programs is that they do not specifically address errors. Specific AEs require analysis to identify errors (i.e. to identify PAEs, a subset of AEs), which when eliminated will decrease the rate of that AE. These changes can be introduced across several institutions impacting a significantly higher number of patients. Therefore, to have a positive impact on PAE or PD rates, it is imperative to teach medical personnel to identify and learn from errors in order to prevent future ones.

In conclusion, based on the current meta-analysis, approximately 25 AEs occur per 100 surgical patients, of which almost half were thought to be preventable. Moreover, there were 4 deaths per 100 patients undergoing surgical care, wherein approximately 20% were thought to be preventable. To advance knowledge in this area, it is important that universal definitions of AE

and error be applied, and that reliable measures of preventability be established. In doing so, high quality studies that reliably measure preventable AEs and deaths need to be conducted, which in turn can be used to inform future practice and educational activities to reduce the number of preventable events occurring in surgical patients.

2.5 Acknowledgements

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CHAPTER 3:

PREVENTABLE ADVERSE EVENTS IN SURGICAL PATIENTS: A KNOWLEDGE, ATTITUDE, AND PRACTICE (KAP) ASSESSMENT

3.1 Introduction

Every surgical procedure comes with the risk of adverse events (AEs). These AEs can have serious and significant implications on a patient's life and can be costly to society as a whole.(12) Therefore, it is important to prioritize patient safety education when preparing trainees for a medical career. However, a survey by Alper et al. (2006) found that only 25% of institutional members reported having explicit patient safety curricula at their respective school.(93)

There are a number of methods currently available to teach patient safety including feedback, debriefing, Morbidity and Mortality (M and M) rounds, and formal curricula. Feedback involves discussing performance directly with the individual or group performing the care. Debriefing involves groups of healthcare professionals discussing and asking questions about the task performed. In a more formal setting, M and M rounds involve specifically discussing any errors or AEs that have occurred while a patient is under the care of the medical team. It involves both individuals who were and were not involved in the patient's care. Lastly, a formal curriculum seeks to use a variety of planned teaching methods to convey knowledge about patient safety that can be applied to a future patient's care. Of these varied methods, M and M rounds, in particular, are widely used across specialties in medicine. As a patient safety reporting system, these rounds are known to significantly under report the rate of AEs in patient populations.(29) However, they do have the potential to allow for an open discussion of complications and potential errors, as well as improve patient care by helping prevent future complications.

Still, a number of barriers exist that must be overcome in order for surgeons to make changes in their practice. In a model described by Reimer et al. (2005), the success of implementing system or treatment level programs is dependent on the clinicians who work within these systems.(94) This model includes macro-level and micro-level processes to adopting change. Macro-level changes include: 1) becoming aware and gaining an understanding of a new treatment, 2) exploring the options for the personal use of the treatment, 3) experimenting with the treatment in one's practice, and 4) seeking feedback or confirmation that the change was worthwhile. Alternatively, micro-level processes consist of motivation and ability. While motivation can be external or internal to the individual, ability requires that a person apply his or her knowledge and skills. The cognitive-affective process described by Reimer et al. (2005) focuses on motivation to change.(94) First, there must be a perceived discrepancy between the goal state and the current state. The individual must: 1) be committed to the goal, 2) recognize when the goal has not been reached, 3) be motivated to move towards the goal, and 4) accept personal responsibility if he or she is not moving toward the goal. Overall, this theory suggests that buy-in by both trainees and educators is one of the most important factors that determines the successful education of trainees.

A Knowledge Attitude and Practice (KAP) assessment survey collects information on what is known, believed, and done by a population regarding a specific topic.(54,55) The data obtained from a KAP assessment survey can be used to help plan or make changes to a program or curriculum with input from stakeholders, thus increasing buy-in.(56) In this instance, a KAP assessment survey can serve as a needs assessment of one of the major stakeholders, the educators who would deliver the patient safety education for medical trainees. Hence, the purpose of this study was to determine from Calgary surgeons their baseline knowledge of

patient safety, attitudes towards error and patient safety education, and how as educators, patient safety education fits into their daily practice.

3.2 Methods

3.2.1 Population and Setting

The present cross-sectional survey was conducted in Western Canada, within Alberta Health Services and the University of Calgary, between December 7, 2016 and March 30, 2017. In Calgary, there are two surgical departments; one is the Department of Obstetrics and Gynecology and the other is the Department of Surgery. Specifically, the Department of Surgery includes several divisions: Cardiac Surgery, General Surgery (Colorectal, Endocrine, Hepatobiliary, Pediatric, Surgical Oncology, Thoracic, Trauma, Upper GI/Bariatric, and Vascular), Neurosurgery, Orthopedic Surgery, Otolaryngology, Plastic Surgery, and Urology. Short term locums (<6 months) were excluded from this study, as were Ophthalmology and Podiatry. Short term locums were excluded as they may not have had enough experience to be able to comment on teaching methods at the University of Calgary. Ophthalmology was excluded as they were also excluded from the meta-analysis. The patient safety data for this subspecialty is more developed than for other subspecialties. Lastly, although included under the Department of Surgery, podiatrists were excluded as they are not medical doctors. The surgeons work in one or more of the five teaching hospitals across Calgary: Foothills Medical Centre (FMC), Peter Lougheed Centre (PLC), Rockyview General Hospital (RGH), South Health Campus (SHC), and the Alberta Children's Hospital (ACH). Table 5 illustrates the breakdown of surgeons by specialty.

Table 5: Distribution of Calgary academic surgeons by specialty

Specialty	**Number of Surgeons**	
	n	**%**
Cardiac Surgery	11	3.6
General Surgery	45	14.7
Neurosurgery	14	4.6
Obstetrics and Gynecology	68	22.1
Orthopedic Surgery	67	21.8
Otolaryngology	23	7.5
Pediatric Surgery*	21	6.8
Plastic Surgery	27	8.8
Thoracic Surgery	6	1.9
Transplant	3	1.0
Urology	15	4.9
Vascular Surgery	7	2.3
Total	**307**	**100%**

* All subspecialties

3.2.2 Questionnaire Development

There is currently no existing KAP assessment survey addressing how patient safety is taught or attitudes towards these methods. Therefore, the questionnaire was developed through an extensive review of the literature, as well as iterative discussions with various expert members in surgery and medical education. A preliminary 15 item questionnaire was developed to investigate the level of *knowledge* of surgeons regarding patient safety, their *attitudes* regarding patient safety teaching methods, and the actual methods they employ in their teaching of patient safety to learners (*practice*) at the University of Calgary. In order to more accurately reflect the focus, the KAP questionnaire was later named the TIPS (Teaching in Patient Safety) Questionnaire, and is presented in Appendix D.

With the aim of collecting both quantitative and qualitative data, questions on the TIPS questionnaire were either created de novo or adapted from a variety of studies addressing variably similar goals.(27,93,95-98) A combination of open ended, yes or no, multiple choice,

and Likert scale questions were used. The questionnaire was confined to 15 items, in order to limit the time commitment required by participating surgeons. The questionnaire was designed to measure faculty knowledge of the definitions of errors and AEs, as well as reporting practices within Alberta Health Services. In addition, the instrument measured attitudes and practices regarding how the subject of surgical and error is taught in residency. Of specific interest, was surgeon opinion on M and M rounds, which are used widely across surgical specialties. The questionnaire was reviewed by a panel of five experts (EOP, TD, DB, JLA, and AH) in the *Departments of Surgery* and *Community Health Sciences* to improve face and content validity, as well as for relevance and clarity. In order to ensure the sample pool was not reduced by this phase, the questionnaire was pilot tested on a group of eight fellows and chief surgical residents to ensure clarity, accessibility, and relevance of the items. Due to the time constraints of surgeons, focus groups or individual interviews were not considered feasible.

The TIPS questionnaire was comprised of various question types. For instance, knowledge questions were either presented as true or false questions, or in a multiple-choice format, with the option to disagree with all the provided options accompanied by an open free text box for respondents to include customized responses. Overall knowledge was determined by aggregating the number of correct answers among all participants. Attitude statements were scored on Likert scales of "almost never" to "almost always" for *frequencies*, "strongly disagree" to "strongly agree" for *level of agreement*, and "not effective" to "very effective" for *degree of effectiveness*. Overall attitude was determined by aggregating the ratings of all study participants. There was one open-ended question in the attitudes section, which was grouped according to repeating themes. The practice section aimed to determine the surgeon's own practices and thus, was comprised of lists with multiple selections allowing for yes/no responses. Overall practice

patterns were determined by the percentage of participants selecting each option or selecting yes in the yes/no questions.

3.2.3 Data Collection

In order to collect information regarding the methods used in their respective programs to teach residents about patient safety, the TIPS questionnaire was electronically distributed to all 307 surgeons, who had an academic staff appointment or long-term locum (≥ 6 months) at the University of Calgary. With endorsement from the Head of the Department of Surgery and the Department of Obstetrics and Gynecology, Section Chiefs were identified and contacted to obtain email addresses for participant recruitments (refer to Appendix E).

The potential respondents were emailed with a cover letter (Appendix F) and a link to the survey along with the consent form (Appendix G). Participants who proceeded to the first question in the survey were understood to have provided consent. The TIPS questionnaires was administered online using Survey Monkey. After the initial questionnaire was sent, two reminder emails were sent at 2 and 4 weeks after the initial questionnaire invite. Two weeks after the final recruitment email reminder was sent (i.e. 6 weeks), the questionnaire was closed. This study was reviewed and approved by the Research Ethics Board of the University of Calgary (#REB15-1588).

3.2.4 Statistical Analysis

In accordance with the American Association of Public Opinion Research, a survey was considered complete if at least 80% of the questions were answered.(99) Analysis was based only on complete responses. Quantitative responses were summarized using descriptive statistics: means and standard deviations for continuous data or proportions with confidence

intervals for categorical data. As questionnaires were administered at only one point in time, data analysis was limited to descriptive statistics. Quantitative data was analyzed using StataIC, Version 12 (College Station, TX: StataCorp., 2011). Qualitative data were coded based on content and according to repeating themes.

3.3 Results

Overall 128 (41.7%) surgeons responded and 119 (38.8%) completed the survey. Since partial responses were not included, a total of 119 surgeons formed the basis of our analysis. A complete summary of survey responses is provided in Appendix H. The majority of respondents were male (n = 89, 74.8%) and the median length of practice was 16 years (Range: 0.5-44). While 47 (40%) surgeons were situated at Foothills Medical Centre, the remaining surgeons were equally distributed among the other four hospitals in Calgary, and 2 (1.9%) were primarily situated at an institution outside of the hospitals. The greatest number of respondents were from General Surgery (n = 32, 26.9%), Obstetrics and Gynecology (n = 28, 23.5%), and Orthopedic Surgery (n = 20, 16.8%). The remaining sections each contributed to less than 10% of the respondents.

3.3.1 Knowledge

Participants' knowledge about adverse events is presented in Supplemental Table 2, Appendix H. While the definition of an adverse event was identified correctly by 93 (78.2%) respondents, the definition of a error was identified correctly by 26 (21.8%) of the respondents. Twenty-three (19.3%) respondents answered both the adverse event and error questions correctly. The Performance Improvement Department of Alberta Health Services was correctly identified as the official body where patient safety concerns can be presented by 69 (58.0%)

respondents. Thirty-seven (31.1%) respondents correctly identified that at Alberta Health Services, reporting of adverse events is not mandatory.

3.3.2 Attitudes

Participants' attitudes about adverse events is presented in Supplemental Table 3, Appendix H. This section was used to determine which factors contributing to errors were felt to contribute most and least to errors. When asked to score the frequency of involvement of various factors contributing to errors, the highest rated items, starting from the highest ranked item, were *poor communication* (M = 3.3, SD = 1.0), *poor coordination* (M = 3.0, SD = 1.0), and *misinterpretation of the situation by the care provider* (2.8±0.9). These items are at the level of the individual or environment and were rated as "half of the time" or "sometimes". The lowest rated items were all at the individual level and included: *permanent mental or physical limitations of the care provider* (M = 1.3, SD = 0.6), *temporary illness or injury of the care provider* (M = 1.5, SD = 0.6), and *care provider working when not fit for work* (M = 1.5, SD = 0.7). None of the items reached a mean rating of "often" or "almost always". Moreover, there was no difference in ratings between those who had the correct versus incorrect definition of AE and error.

The mean score out of "5" for importance of formal education regarding patient safety was 4.0 (SD = 0.8). However, only 58 (49.2%) respondents agreed or strongly agreed that the residents graduating from their program were adequately trained to prevent adverse events.

3.3.3 Morbidity and Mortality (M and M) Rounds

Sixty-three (52.9%) respondents agreed or strongly agreed that M and M rounds were effective for preventing future errors, 37 (31.1%) disagreed or strongly disagreed, and 19

(16.0%) were neutral. The mean score out of "5" was 3.3 (SD = 1.1). Ninety-three (78.2%) respondents reported changing their practice after attending an M and M round.

Respondents' opinions regarding what makes M and M rounds effective or ineffective were grouped into repeating themes. These were again collapsed into central themes and are presented in Table 6. Data saturation occurred at 39 questionnaires, after which no new themes emerged. The most frequently emerging theme was that of judgement or bias. Comments were made that a safe space was required for M and M rounds to be successful, and many felt bias still existed at their rounds. The next most frequently reported comment was that M and M rounds presented a valuable opportunity to learn from other's mistakes and experiences.

Table 6: Central themes for effective/ineffective Morbidity and Mortality (M and M) rounds

Central Theme	Theme
Design	• Structure of presentation • Resources • Addressing multifactorial nature of errors
Content	• Less serious/common problems • More serious/uncommon problems • System problems • No adverse event (interesting cases)
Focus	• Focus on prevention • Focus on causes/errors
Tone	• Judgement/Bias
Participation	• Attendance/Participation of Staff/Residents • Depth of Discussion • Evidence Based Discussion • Providing Several Perspectives
Outcomes	• Learning from others • Self-reflection • No long-term changes • No tracking of implemented changes

3.3.4 Practice

Participants' practices with respect to AEs are presented in Supplemental Table 4, Appendix H. The most frequently used methods to teach residents about patient safety and avoidance of error were reported to be *Morbidity and Mortality Rounds* (n = 103, 86.6%), followed by *Individual Feedback* (n = 93, 78.2%). The ratings for preparedness of residents and methods used to teach patient safety by section are presented in Table 7. There is no statistical difference in preparedness of residents or the methods used to teach patient safety by section. *Morbidity and Mortality Rounds* (n = 93, 78.2%) and *Individual Feedback* (n = 83, 69.7%) were also the leading answers for reasons a respondent had changed their own practice. Eight (6.7%) respondents reported that they had never changed their practice as a result of any of the listed methods for addressing patient safety. Sixty (50.4%) respondents reported having led a debrief session after an error had occurred. Debriefing sessions seemed to most commonly involve the individual who made the error and any other residents on service.

Twenty-eight (23.7%) surgeons reported keeping a written or electronic record of their own adverse events. Sixty-five (55.6%) respondents reported having a section reporting system for either adverse events alone or along with errors.

Table 7: Residency training preparedness by Section

Section	Cardiovasc/ Thoracic	General Surgery	OBGYN	Ortho	Other	P value
Residents adequately train, Mean (SD)	3.0 (0.8)	3.25 (0.8)	3.5 (0.8)	3.0 (0.7)	3.4 (0.8)	0.16
Methods Used, n (%)						
Individual Feedback	7 (70)	23 (72)	22 (79)	15 (75)	26 (90)	0.48
Team Debriefing	7 (70)	14 (44)	21 (75)	11 (55)	16 (55)	0.15
Morbidity and Mortality Rounds	10 (100)	27 (84)	22 (79)	17 (85)	27 (93)	0.36
Half day presentation	4 (40)	14 (44)	18 (64)	13 (65)	19 (66)	0.24
Formal curriculum	3 (30)	4 (12)	7 (25)	9 (45)	10 (34)	0.11

3.3.5 Interactions

When considering the effect of length of time in practice, there was no effect on the perception of importance of safety education, however, there was a significant difference in the perception of the value of M and M rounds ($p = 0.02$). In a post hoc analysis using the Tukey's Honestly Significant Difference test, a significant difference was found between those in practice for more than 20 years versus those in practice between 11 and 20 years ($p = 0.01$). The remaining pairwise comparisons were not significant. Additionally, there was no difference in the frequency of leading a debriefing or keeping records of adverse events by years in practice (Table 8).

Table 8: Effect of years in practice on attitudes and practice

Group	0-10 years	11-20 years	>20 years	P value
Importance of Safety Education, Mean (SD)	4.0 (0.8)	3.9 (0.8)	4.0 (0.8)	0.61
Morbidity and Mortality Rounds Effective, Mean (SD)	3.3 (1.1)	2.9 (1.2)*	3.6 (0.9)*	**0.02**
Led a debriefing, n (%)	25 (54)	17 (50)	18 (46)	0.75
Record of Own Errors, n (%)	11 (24)	9 (26)	8 (21)	0.86

* = significantly different in post hoc analyses

When considering whether a method is used to teach residents regarding patient safety versus perceptions of its effectiveness, those who reported using the methods generally rated the respective method higher. The difference in the ratings were only significant for team debriefings ($p = 0.04$) and M and M rounds ($p = 0.03$). Similarly, whether a respondent had changed their practice in response to a teaching method versus how that method was scored as an effective technique was also assessed (Table 9). There was a significant difference for individual feedback ($p = 0.02$), team debriefing ($p < 0.01$), and M and M rounds ($p < 0.01$).

Table 9: Attitude vs practice – rating of method effectiveness by change in surgeon practice

Change in Practice	Mean Effectiveness Score (SD)	P value
Individual Feedback		**0.02**
No	3.6 (1.1)	
Yes	4.1 (0.9)	
Team Debriefing		**<0.01**
No	3.6 (0.9)	
Yes	4.3 (0.7)	
Morbidity and Mortality Rounds		**<0.01**
No	2.7 (1.0)	
Yes	3.4 (1.1)	
Half Day Presentation		0.20
No	3.4 (1.0)	
Yes	3.6 (0.9)	
Formal curriculum I taught		0.81
No	3.3 (1.1)	
Yes	3.4 (0.7)	
Formal curriculum I attended		0.27
No	3.2 (1.2)	
Yes	3.5 (0.9)	

3.4 Discussion

The findings of the present study provide insight into the knowledge, attitude, and behaviors related to AEs among surgeons in Calgary. We observed that almost 80% (n = 93) of surgeons

correctly identified the definition of an adverse event. Those who did not correctly identify the definition typically included patients' underlying disease as a cause of adverse events. However, only approximately 20% (n = 26) of surgeons correctly identified error. Those who did not correctly identify the definition felt that an unintended or adverse outcome was part of the definition. While there is no consensus on the definition of an error, most would agree that the definition is independent of outcomes. In fact, an error that did not lead to an adverse event is termed a *close call*, while an error that did lead to an adverse event is termed a *preventable adverse event* (PAE).(3)

Research has shown that the reasons an individual makes a error is multifactorial.(32,100,101) There are many reasons an error may occur and several of these reasons may contribute to an error being made. This idea was also reflected in the ratings of factors contributing to error as reflected by the Calgary surgeon participants. The factors contributing to error were balanced across all contributing factors and at all levels: individual, environment, supervision, and organizational. There was no dominant contributing factor that was felt to contribute to all cases. Only communication and coordination were thought to contribute to errors more than half of the time. It is well established in literature that typically multiple errors are required in order for an PAE to occur and therefore many errors may never be reported or even go unnoticed.(4,21,102)

It is not surprising that the most commonly used methods of teaching patient safety are individual feedback and M and M rounds. Interestingly, these are the same methods reported by surgeons as serving as the impetus for change within their own practices. Individual feedback, in particular, is quick and does not require wide scale organization. M and M rounds have also become common in surgical departments. The problem with this method is that M and M rounds

are typically not standardized and there is no guarantee that the feedback given or corrections made are evidenced based. However, more surprising is that in spite of multiple studies demonstrating their efficacy, formal curricula are the least used in training programs and rated lower in terms of influencing changes in surgical practice. Also, not surprising, surgeons typically rated a particular method higher if they used it in their residency training program or if they had changed their own practice in response to that method. This shows consistency in surgeon attitudes and practice. However, the reason for this consistency may be that surgeons feel these are truly the best methods. Alternatively, it may be that these are the methods surgeons have been exposed to during their own training and have had little or no experience with other methods, such as team debriefing. Therefore, out of comfort level or habit, surgeons are utilizing and rating highly only those methods with which they have experience. It would not be expected that a surgeon would change his or her practice in response to a method (s)he has possibly never experienced; likewise, it would be difficult to know if that method would be effective.

Three quarters of surgeons reported that they did not keep track of their own adverse events and almost half reported that they either did not have a section reporting system or were unsure if one existed. In order to self-reflect and improve, an accurate record regarding previous performance is required as physicians have been shown to have a limited ability to self-assess.(103) Therefore, it should be standard practice to keep track of such changes. For these reasons, a number of large scale reporting systems, such as the National Surgical Quality Improvement Program (NSQIP) exist, thereby ensuring hospitals know their rates of adverse events and can make comparisons to other hospitals.

In conclusion, while most surgeons in this study were aware of what constitutes an adverse event, fewer were able to identify the correct components of error. Furthermore, surgeons

recognize that errors are multifactorial and that no single factor contributed to all errors. They also tend to use and make changes in their practice in response to teaching methods they find more effective. It is evident that in order to improve quality of care, surgeons should track their errors, either using a section reporting system or via personal tracking. Without such tracking, accurate assessments cannot be made regarding areas for improvement.

3.5 Acknowledgements

We would like to thank all our participants for their time in responding to the survey. We would also like to thank Dr. Adrian Harvey for his input into the TIPS questionnaire.

CHAPTER 4:
CONCLUSION

4.1 Summary of main study findings

Patient safety education is an important part of medical training. Adopting a framework like the Kern's model can assist in the development of a curriculum for trainees that aims to teach trainees to learn from and prevent future errors or AE. In the two parts of the current research, the main objective was to lay the ground work to create such a curriculum by delineating the extent of the problem of PAEs in the surgical field and establishing the baseline approach of surgeons in Calgary to addressing PAEs.

Aligned with Kern's curriculum development model, the first part of the study involved conducting a meta-analysis and focused on problem identification and general needs assessment – how prevalent are errors in surgery? The results reported in Chapter 2 of this work demonstrated that 25 AEs occurred per 100 patients under surgical care and that almost half of AEs experienced by surgical patients are potentially preventable. This significant negative impact to surgical patients creates the impetus for us to better identify errors and study their contributing factors so we can implement more effective preventative strategies to reduce them. A significant change in these rates through education would decrease the risk of patients being negatively impacted by AEs during their surgical care. The meta-analysis also revealed that of the 4 patients who died per 100 patients under surgical care, almost 20% were considered preventable deaths. While one cannot eliminate errors completely, this estimate is likely higher than it could be with proper implementation of educational and preventative interventions. When making comparisons, the rate of AEs in medicine is significantly higher than in HROS, for examples plane crashes in aviation or loss of life in mining accidents, but the proportion of these

PAEs or preventable incidents appear to be lower in medicine than other HROs, for example, it is estimated that 60-80% of plane accidents are at least in part attributable to human error.(104) While medicine should try and achieve HRO status through the implementation of interventions targeting errors, it will likely never achieve the low rates of AEs that exist in other HRO industries. The reason is the higher number of non-PAEs, i.e. AEs that cannot be prevented. Medicine is an inherently riskier undertaking than other industries as there are a number of factors that cannot be controlled, for example patient comorbities or acute, unstable presenting conditions. Instead, our recommendation would be to implement HFACS analysis then make a new measurement to determine whether the rate of PAEs could be decreased.

Conducting the meta-analysis also highlighted the difficulty in measuring a construct that has not yet achieved definitional consensus which is a significant limitation in the identification and reporting of AEs and errors. Interestingly, 35% of the studies did not provide a definition for AE and 42% did not provide a definition for error. As a result of reviewing existing and diverse definitions, the following definitions are proposed for adoption: An *adverse event (AE)* should be defined as an unintended injury that was the result of medical care (not the patient's underlying disease process) and the injury resulted in some form of disability, increased length of stay, or death. This term is used interchangeably with complication. An *error* is an act of omission or commission in planning or execution of patient management that falls below the current standard and expected performance for practitioners or systems relative to their peers.(6-8) A *violation* is a deviation from the safe operating procedures, standards, or rules.(9)

In the second part of this study, results of the meta-analysis were used to develop the KAP survey assessment. The definitions developed in the meta-analysis for AE and error were included in the knowledge section of the KAP survey assessment. The KAP assessment survey

demonstrated that approximately 80% of surgeons could correctly identify the definition of an AE and the most common reason for an incorrect answer was inclusion of the patient's medical condition as a cause of an AE. The definition of error was identified correctly by 20% of surgeons, where many felt that an adverse event or unintended outcome needed to have occurred for there to have been an error. Just as there was greater variability in the definitions of error than AE in the meta-analysis, there is a less clear understanding of what constitutes an error by surgeons. Moreover, approximately 50% of surgeons correctly identified the reporting practices at their institution. This may be that these practices are not well advertised and therefore surgeons do not know of their existence, or that surgeons may not have learned about these practices due to a perceived lack of time and a feeling that reporting does not effect change. Alternatively, surgeons may have avoided these practices due to fear of the legal implications of reporting errors and therefore have not fully engaged in this practice. In terms of surgeon attitudes, they identified that PAEs were multifactorial with no dominant contributing factor. This is consistent with the literature and suggests both insight and a change in culture, as previously errors were thought to be the sole responsibility of the individual rather than the error provoking conditions of systems.(105-107) When asked about patient safety, surgeons agreed that a formal curriculum is important, but only half felt that M and M rounds were an effective ways of teaching patient safety. If perceived as ineffective, this may lead to under-reporting. This would support the notion that studies based on self-reporting would also under-report AEs and PAEs. However, this measure of effectiveness reflects the opinions of surgeons in Calgary, it may be that surgeons in other provinces or countries would rate their local M and M rounds as either more or even less effective which would have implications for local reporting practices. Lastly, in spite of only half of surgeons believing M and Ms to be effective, both M and Ms and

Individual feedback were the most frequently used method to teach patient safety in surgical programs as well as the most frequently cited reasons a surgeon had changed their own practice. These strategies may be perceived as the most effective because, in the case of M and M rounds, they are in a public forum where there is accountability or peer pressure to change erroneous behaviours or, in the case of individual feedback, are delivered by a senior surgeon or mentor who is well respected. It may also be that because these are the methods most used, they are also the methods surgeons experienced most frequently during their own training and practice, and therefore, these methods have provided the greatest number of opportunities for change relative to other teaching methods. In other words, this is what they are most comfortable with. This does not imply that these are objectively the most effective tools overall or the best methods to proceed with in the future, rather only that they are currently rated as most effective and most frequently used by surgeons. Lastly, less than 25% of surgeons reported keeping a record of their own adverse events. This implies that the majority of surgeons have a lack of awareness of their own AE rates. Just over half report a section tool for tracking adverse events, however, this data is conflicting with multiple surgeons from the same section reporting that their section is or is not tracking AEs. While this represents a needs assessment of the teachers and not the learners, it can be used in conjunction with a future needs assessment of learners to inform the development of a set of goals and objectives as well as select educational strategies for a curriculum in patient safety.

4.2 Study Limitations

4.2.1 Meta-analysis

One of the main limitations of the study is the high heterogeneity that exists in the effect estimates. This may be due to differences in study design or differences in the definition of AE

and error used in each study. A second limitation is that in all studies, error was determined either through self-report or review of the medical chart by an external party. In both cases the number of AEs and errors may be underestimated. Therefore, the overall effect size is likely an underestimation the actual number of AEs and errors that actually occur in surgical patients. However, these are currently the best methods available and by combining the currently available literature, the closest approximation of the true rate of AEs and PAEs can be achieved. In addition, provided the same methods are employed in future studies, conclusions about improvements or deterioration in patient safety over time can still be reliable.

4.2.2 KAP Assessment Survey

There are also some limitations specific to developing and conducting needs assessment surveys. While the response rate was good for a population made up of surgeons (i.e., overall response rate of over 40%), this was still less than average response rate of surveys published in medical journals and goal of 60%.(108,109) In order to maximize the survey response, endorsement from department chiefs was obtained, personalized emails were sent to surgeons, and two reminders were sent to individuals who had not responded. As with all surveys, the non-responders may represent a specific subgroup of surgeons and their systematic exclusion may result in selection bias. Therefore, to help determine if bias was introduced by the nature of responders versus non-responders, a summary of responders and non-responders was created stratifying by section and sex. This summary revealed that our participants represented all sections and both sexes with a slightly higher proportion of General Surgeons responding than other sections. Non-responders likewise represented all sections and both sexes with similar proportions from each. Another limitation with the second part of our study reflects a concern of all surveys; by nature of the survey format, responses are collected without the ability to seek

further clarification. Although alternative methods of data collection, such as interviews, would have enabled further probing of participants, the large number of surgeons across multiple sites in our study rendered this option unfeasible.

While a needs assessment of all stakeholders involved in a curriculum is desirable, this survey addresses one, the surgeons. Therefore, the results apply only to the educators (i.e. surgeons) and no information was ascertained from other stakeholders of medical training programs such as medical students, residents, or administrators. Still, prior to introducing a new curriculum, it was deemed an essential first step to assess surgeons' knowledge, attitudes, and practice related to patient safety in order to subsequently initiate surgeon buy-in.

4.3 Recommendations and Future Directions

4.3.1 Immediate Recommendations

In the immediate period, while further needs assessments and a curriculum are in development, many of the currently run M and M rounds currently used to address patient safety would benefit from modification. First and foremost, the tone of many of these conferences needs to change. Surgeons need to make these rounds a safe space to openly discuss cases without blame, this would require a change in the *focus* of surgeons from blame to prevention strategies, i.e. less focus on *who* and more focus on *why*. This continues to be a concern for surgeons participating in Calgary as *bias* was most frequently cited as a reason for ineffective M and M rounds.

A second, immediate recommendation for change involves modifying the format of M and M rounds. These would address the cited concerns regarding *design*, *content*, and *participation* from the qualitative analysis of M and M rounds in Chapter 3. 1) The process of case selection should be modified. Only those who have died or experienced an adverse event should be

presented. While complex patients and interesting or rare cases do have learning value, the appropriate forum for these cases is at teaching sessions around those disease topics so that knowledge of the disease process or procedure can be gained, not at M and Ms where the purpose is to learn how to decrease the rate of AEs. In addition, time for M and Ms is typically limited and presenting cases that do not contain an M and M only serves to further decrease the time allotted to addressing patient safety. 2) The format for presentation should be modified. Discussion should be focused on *why* an event happened rather than *who* or *what*. This would be an area where the application of HFACS analysis would be helpful as potentially actionable factors contributing to errors could be identified and would allow for discussion of various changes that could be made to avoid similar adverse events in the future. In particular, there should be discussion about whether there is opportunity to insert systemic changes or checks to help with prevention on a larger scale. 3) Where possible, best current evidence should be included when discussing possible interventions or when reviewing the medical care itself in a particular case. In creating guidelines for clinicians to follow in medicine, the level of evidence is considered and reported. Our recommendation would be to take this same approach at M and M rounds. Currently, recommendations for future changes or what others would do in a similar situation are made by peers or mentors at M and M rounds, which comprises only level III evidence according to the hierarchy published by the Canadian Task Force on the Periodic Health Examination.(110) This may require each M and M be considered on two separate days, first to review the case and identify the *why*, then again to discuss the literature supporting various changes.

Finally, there should be a follow up process to determine whether the changes being made are affecting patient safety. To address concerns in the qualitative analysis regarding *outcomes* of

M and M rounds, a comprehensive reporting system is required which would include the rates of significant events such as death and the most frequent AEs (such as wound infections and urinary tract infections) presented on an annual or semi-annual basis with comparisons to previous terms. This would help determine if the implemented changes have been followed and whether they have affected the rate of PAEs.

In terms of future practices, it is recommended that that an adverse event tracking system be implemented at the level of the division or department with accepted reproducible definitions of AEs and errors, as well as third-party tracking and reporting of adverse events. This would maximize the accuracy and reproducibility of measurements of AEs and errors. If this is not feasible or available at one's hospital, then surgeons should make an effort to track their own AEs. However, to make this approach successful, a section mandate on recording or the implementation of incentives may be necessary to motivate surgeons to begin recording AEs. As previously discussed, recording AEs forms the backbone of creating a curriculum to address patient safety, but also provides a mechanism for feedback after a curriculum has been introduced. An increase or decrease in the number of PAEs and AEs would provide one measure of the effectiveness of such a curriculum. In addition, formal records of AEs would allow individual surgeons to evaluate new techniques or processes they have incorporated into their own practice or aid in self-reflection to maximize the quality of their own patient care. In this manner, changes to one's practice can be focused and intentional. Recording can also identify deficits in a surgeon's practice thus providing the motivation to change. As discussed above, recording at the divisional or departmental level would be optimal. The advantage of this would be that some AEs, such as wound infections, thromboembolic complications, or urinary tract infections, may be more related to system wide processes. Measuring these AE rates, then

implementing system wide changes or new protocols may provide benefits for patients treated by multiple surgeons.

4.3.2 Curriculum Development

The current research serves as both identification of the problem and a needs assessment for surgeons in the development of a patient safety educational program for medical learners. Moving forward, the next steps would be to conduct a similar needs assessment of medical learners and other stakeholders. For medical learners, a KAP assessment survey could be used to ascertain their baseline level of knowledge in addition to their perceptions of factors contributing to errors and attitudes towards various teaching methods. It would be valuable to gather information on what methods have been successful for knowledge transfer for other medical topics. Once this has been completed, specific objectives and goals can be created based on all needs assessments and a curriculum can be designed applying the various educational strategies. This does not necessarily have to be an exclusively formal curriculum and should continue to use informal teaching techniques such as team debriefings and individual feedback. This educational plan can then be implemented and should be evaluated to allow for continuous improvement over time. This cycle should be ongoing in order to constantly improve and refresh the curriculum based on all stakeholder input.

The patient safety curriculum may be best served by having two separate components; a formal curriculum for medical trainees regarding patient safety, and a patient centered curriculum in which patients can learn to advocate for themselves or their hospitalized loved ones. By educating trainees, the effects can be far reaching, as each trainee will treat a number of patients and will interact with other surgeons who may also pick up on the skills those trainees employ. Patient centered education gives autonomy and a sense of empowerment to patients.

While this study has addressed only curriculum development for trainees, simultaneous curriculum development can be undertaken to focus on patient centered education.

One focus that should be included in a patient safety curriculum is teamwork. Teams exist throughout medicine. Poor teamwork is responsible for a significant number of AEs, specifically accounting for up to 60% of AEs in some series.(111,112) This was reinforced by the results of the KAP survey, as the top three rated factors contributing to errors were found to be poor communication, poor coordination, and misinterpretation of the situation by a healthcare provider. These are all important elements of teamwork. Potentially addressing these areas in a focused curriculum could maximize the impact of an educational intervention on PAEs.

Regardless of whom the curriculum is aimed at educating, a curriculum for surgeons (i.e. educators) on how to optimize the various teaching methods used in patient safety is advisable. The main benefit is that most surgeons in academic centres and mid sized hospitals are expected to contribute to the education of their up-coming trainees; however, many have never had any instruction on how to be an effective educator. One area of difficulty for surgeons in general is giving constructive feedback. This is problematic since this is one of the most often used methods to teach patient safety in residency programs in Calgary. It is imperative that, at a minimum, steps must be taken to improve this skill set for all educators.

4.3.3 Future Research

Ongoing research in this area is imperative to know what the burden of medicals errors is overtime, as well as to measure the effect of any interventions on the rate of errors, PAEs, and PDs. However, to effectively and precisely make these two measurements, the consistency and quality of patient safety research needs to be improved. First, as discussed, a universal language must be used. Definitions for AE and error have been proposed and if universally applied could

decrease the variation in measurement between studies. Error is also not always apparent and often difficult to definitively show. Often whether a error has occurred will come down to a judgement, and therefore it may be more appropriate to grade error on a scale of probability. While no validated scale of preventability currently exists, a scale consistently used across studies could decrease variation between studies. Perhaps even more effective would be a preventability risk assessment tool that may using a scoring rubric or nomogram and could include factors such as the type of AE and review of documentation. If such a tool were to be developed, it would also require validation. The principles of a useful and well-developed tool would be that it is: 1) simple to use, 2) clinically relevant, 3) employs precise definitions, 4) reproducible, and 5) validated. The tool should lead to gradation of preventability demonstrating a continuum that is easily understood and applied. Lastly, while not always feasible, studies should try to minimize bias. This requires that studies employ prospective methods in order to collect data on all patients and minimize the risk of not identifying an error. Data should also be collected by a third party, an individual who is not emotionally invested in the case and can make unbiased judgements, rather than relying on self-reporting. These measures can improve the quality of studies that exist, as well as increase the precision of the measurement of PAEs and PDs.

4.4 Patient and learner implications

The goal throughout a physician's career is to provide the highest quality of care possible. In addition to educating medical experts, one of the pillars of this goal is the thoughtful creation and implementation of a patient safety education program resulting in improved care, with fewer unnecessary deaths and adverse outcomes.

For trainees, a patient safety curriculum would help to decrease the number of errors by teaching medical trainees to identify and reflect on adverse events and errors, allowing them to make appropriate changes in practice to prevent them in the future. While the immediate effect would be a reduction in errors and PAEs, in the long term, trainees would ideally have the tools to advocate for and implement systemic safe guards to protect patients from errors in their future practice. Over time, this would bring the profession of medicine closer to the goal of creating an ultra-safe industry similar to aviation and mining.

This work has laid the ground work for such a curriculum by describing and quantifying the problem of PAEs and PDs, and developing the baseline knowledge of surgeons who would deliver such a curriculum. It has also delineated surgeon teaching preferences and current practices regarding patient safety.

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APPENDIX A:

CONTRIBUTION OF AUTHORS

Student: Dr. Janice L Austin (JLA)

Supervisor: Dr. Elizabeth-Oddone Paolucci (EOP)

Supervisory Committee Members: Dr. Don Buie (DB)

Dr. Tyrone Donnon (TD)

Additional Contributors: Dr. Mark Lipson (ML)

Dr. Adrian Harvey (AH)

JLA performed the majority of developing the project including background research and literature review. Further project conceptualization involved contributions from JLA, DB, TD, and EOP.

The meta-analysis protocol was primarily developed by JLA with assistance from TD and EOP. Data collection was performed by JLA, ML, and EOP. Analysis was performed by JLA with input from DB, TD, and EOP.

The TIPS questionnaire was primarily developed by JLA with input from DB, TD, AH, and EOP. Survey distribution was undertaken by JLA. Data analysis was performed by JLA with input from DB, TD, and EOP.

The thesis manuscript was written by JLA with supervisory input and guidance from EOP, DB, and TD.

APPENDIX B:

DATA ABSTRACTION LIST

Data Abstraction List

- Study Number
- Authors
- Number of investigators
- Year of publication
- Journal
- Country of Study
- Academic or Community Centre or Mixed
- Definition of Error
- Definition of Complication
- Length of Study Period
- Year of Study
- Study Design
- Units (# procedures vs # pts)
- Total number of hospitalized patients (nt)
- Total number of surgical patients (ns)
- Percent Male
- Percent Female
- Mean age (SD)
- Mean Length of stay (SD)
- Procedures/Services
- Primary outcome measured
- Units for Error (# error vs # pts with an error)
- Total Errors/preventable complications
- Number of errors by type of error
- Near Misses/Close Calls
- Equipment Failures
- Units for Adverse Events (# adverse events vs # patients with adverse event)
- Adverse events/Complications
- Number of complications by type
- Classification system for complications
- Number of complications according to classification system
- Total Number of deaths
- Number of deaths secondary to error
- Notes

APPENDIX C:

QUALITY ASSESSMENT TOOL - MINORS

Methodological Items for Non-Randomized Studies (MINORS) Quality Assessment Tool

1. **A clearly stated aim:** the question addressed should be precise and relevant in the light of available literature
2. **Inclusion of consecutive patients**: all patients potentially fit for inclusion (satisfying the criteria for inclusion) have been
included in the study during the study period (no exclusion or details about the reasons for exclusion)
3. **Prospective collection of data**: data were collected according to a protocol established before the beginning of the study
4. **Endpoints appropriate to the aim of the study**: unambiguous explanation of the criteria used to evaluate the main outcome
which should be in accordance with the question addressed by the study. Also, the endpoints should be assessed on an
intention-to-treat basis.
5. **Unbiased assessment of the study endpoint**: blind evaluation of objective endpoints and double-blind evaluation of subjective
endpoints. Otherwise the reasons for not blinding should be stated
6. **Follow-up period appropriate to the aim of the study**: the follow-up should be sufficiently long to allow the assessment of
the main endpoint and possible adverse events
7. **Loss to follow up less than 5%**: all patients should be included in the follow up. Otherwise, the proportion lost to follow up
should not exceed the proportion experiencing the major endpoint
8. **Prospective calculation of the study size**: information of the size of detectable difference of interest with a calculation of
95% confidence interval, according to the expected incidence of the outcome event, and information about the level for
statistical significance and estimates of power when comparing the outcomes
Additional criteria in the case of comparative study
9. **An adequate control group**: having a gold standard diagnostic test or therapeutic intervention recognized as the optimal
intervention according to the available published data
10. **Contemporary groups**: control and studied group should be managed during the same time period (no historical comparison)
11. **Baseline equivalence of groups**: the groups should be similar regarding the criteria other than the studied endpoints. Absence
of confounding factors that could bias the interpretation of the results
12. **Adequate statistical analyses**: whether the statistics were in accordance with the type of study with calculation of confidence
intervals or relative risk

Additional Notes:

All items are scored on a scale of 0-2, 0 implies the item was not done/addressed, 1 that it was partially completed/addressed, and 2 that it was done/addressed completely.

Only first 8 items apply to studies in the current meta-analysis, items 9-12 are applied when studies have a comparator group.

APPENDIX D:

TEACHING IN PATIENT SAFETY (TIPS) QUESTIONNAIRE

TIPS (Teaching In Patient Safety) Questionnaire

Page 1

Implied Consent Form (See Appendix G)

Page 2

Instructions:

This survey is intended to assess your knowledge, attitudes, and practices regarding medical errors and prevention of medical errors. The following 20 items will take no longer than 10 minutes of your time. Please do your best to provide a response for every question. Thank you for taking the time to participate in our study!

Page 3

Section:

- Cardiac Surgery
- General Surgery
- Neurosurgery
- Obstetrics and Gynecology
- Orthopedic Surgery
- Otolaryngology
- Pediatric Surgery
- Plastic Surgery
- Thoracic Surgery
- Urology
- Vascular Surgery

Sex: Male Female

Primary Site: ACH FMC PLC RGH SHC

Years in practice: ____

Page 4

1) The best definition for an adverse event is an unintended injury that was of…
    a. the patient's underlying disease process and the injury resulted in some form of disability or impaired health
    b. medical care and the injury resulted in some form of disability or impaired health
    c. medical care and the injury resulted in permanent disability
    d. the patient's underlying disease process and the injury resulted in permanent disability
2) The best definition for medical error is an act of omission or commission in planning or execution of patient management that…
    a. caused an adverse event.
    b. falls below the standard expected of physicians.
    c. could contribute to an unintended outcome.
    d. results in an undesirable but potential outcome.

Page 5

3) In Alberta Health Services, patient safety concerns are reported to…
    a. Patient Safety Department of Alberta Health Services
    b. Conjoint Health Research Ethics Board
    c. Unit Manager
    d. Performance Improvement Department of Alberta Health Services
4) Reporting of errors is mandatory at Alberta Health Services. True False

Page 6

5) For the following reasons a care provider makes an error, please indicate the frequency with which you think they occur:

Individual actions	Never	Almost Never	Occasionally/ Sometimes	Almost Every Time	Every Time
Lack of medical knowledge or skill or information by care provider	1	2	3	4	5
Making a mistake in a common or familiar task by care provider	1	2	3	4	5
Misperception of the situation by care provider	1	2	3	4	5
Excess fatigue, stress, etc… of care provider	1	2	3	4	5
Temporary illness or injury of the care provider	1	2	3	4	5
Permanent mental or physical limitations of the care provider	1	2	3	4	5
Habitual or tolerated violations of protocol by care provider	1	2	3	4	5
Violations of rules or protocol outside of the norm by care provider	1	2	3	4	5
Failure of care provider to anticipate patient needs or to create a clear plan	1	2	3	4	5
Care provider working when not fit for work	1	2	3	4	5
Other:____	1	2	3	4	5

Page 7

Work Environment	Never	Almost Never	Occasionally/ Sometimes	Almost Every Time	Every Time
Physical environment (e.g. lighting, noise, room layout, etc...)	1	2	3	4	5
Technological environment (e.g. design and function of equipment)	1	2	3	4	5
Poor communication or flow of information between care providers	1	2	3	4	5
Poor coordination between team members	1	2	3	4	5
Other:	1	2	3	4	5

Page 8

Supervision	Never	Almost Never	Occasionally/ Sometimes	Almost Every Time	Every Time
Inadequate supervision of care provider	1	2	3	4	5
Care giver not aware of or unable to execute a work plan	1	2	3	4	5
Failure of supervisors to correct known problems in work environment	1	2	3	4	5
Supervisor asks care provider to perform tasks outside of their qualifications	1	2	3	4	5
Other:	1	2	3	4	5

Page 9

Organizational Influences	Never	Almost Never	Occasionally/ Sometimes	Almost Every Time	Every Time
Ill-defined policies, unofficial rules, or confusion of rules exists	1	2	3	4	5
Failure of formal processes, (e.g. scheduling), procedures (e.g. documentation) or oversight (e.g. risk management) within the organization	1	2	3	4	5
Poor allocation or maintenance of organization's resources	1	2	3	4	5
Other:	1	2	3	4	5

Additional comments about the reasons a care provider makes an error: (free text)

Page 10

For the following questions, please indicate your level of agreement.

	Strongly Agree	Disagree	Neutral	Agree	Strongly Disagree
6) Formal education in patient safety is important.	1	2	3	4	5
7) Residents in our program are adequately trained to prevent adverse events during their residency.	1	2	3	4	5
8) Morbidity and Mortality rounds, as they exist in my section, are effective for learning to prevent future errors.	1	2	3	4	5

9) Why are Morbidity and Mortality rounds effective/ineffective? (free text)

Additional comments about what you think about education in patient safety specific to how patient safety is taught: (free text)

Page 11

10) What other methods do you think would be effective to teach residents and staff about preventing medical errors?

	Not at all Effective	Slightly Effective	Somewhat Effective	Moderately Effective	Extremely Effective
Individual feedback	1	2	3	4	5
Team debriefing	1	2	3	4	5
Topic presented at one or more half days	1	2	3	4	5
Formal curriculum for residents	1	2	3	4	5
Other: _____	1	2	3	4	5

Additional comments about effectiveness of resident teaching in preventing medical errors: (free text)

Page 12

11) What methods are used to teach patient safety in your section? (Select all that apply):

Individual feedback	Yes	No
Team debriefing	Yes	No
Morbidity and Mortality rounds	Yes	No
Topic presented at one or more half days	Yes	No
Formal curriculum for residents	Yes	No
Other: _____	Yes	No

Additional comments about methods used to teach patient safety in your section: (free text)

Page 13

12) Since starting my position in Calgary, I have changed the way I practice medicine based on:

Individual feedback given to me	Yes	No
A team debriefing I have been a part of	Yes	No
Morbidity and Mortality rounds I have attended	Yes	No
A topic I saw presented at one or more half days	Yes	No
A formal curriculum I taught for residents	Yes	No
A formal curriculum I have attended as a staff	Yes	No
Other: _____	Yes	No

None of the above

Additional comments about how or why you have changed your practice based on previous medical errors: (free text)

Page 14

13) Have you ever led a debriefing after an error has occurred? Yes No

a. If so, who was involved? (Select All that Apply)

Resident who made error only
All residents on service
Medical students on service
Other staff members
Allied health members of team

Additional comments about debriefing after medical errors: (free text)

Page 15

14) Do you keep a written or computerized record of your own adverse events? Yes No

Additional comments about if or how you record adverse events: (free text)

Page 16

15) Does your section have a reporting system for adverse events and errors?

Yes – for errors only

Yes – for adverse events only

Yes – for both

No

Unsure

Additional comments about the use of a reporting system at your facility: (free text)

Page 17

16) Do you have any additional comments? (free text)

Page 18

Thank you. Your responses have been saved. A summary of the results will be available in 1 month upon request. Please email jaustin@ucalgary.ca if interested.

Answers to Knowledge section and Scoring Rubric

1) an unintended injury that was the result of medical care (not to the patient's underlying disease process) and the injury resulted in some form of disability or impaired health

   Answer: B

2) an act of omission or commission in patient management that could lead to an adverse event or that does not have the intended outcome

   Answer: C

3) Patient Safety Department of Alberta Health Services

   Answer: A

4) Mandatory reporting of Errors at Alberta Health Services

   Answer: No

APPENDIX E:

LETTER TO SECTION CHIEFS

UNIVERSITY OF CALGARY

Teaching Patient Safety (TIPS) Questionnaire

Dear Section Chief,

My name is Janice Austin, I am a graduate student in the Department of Community Health Sciences at the University of Calgary working with my supervisor, Dr. Elizabeth Oddone-Paolucci. As part of my master's thesis requirement, we are conducting a study on preventable adverse events in surgery. We are interested in the opinions of staff surgeons regarding the prevalence of preventable adverse events and the methods used to address them in your residency program.

We invite you to participate and are grateful for your support of this project. We are requesting that you share with us a list of the names of staff surgeons within your section, along with their contact email addresses. We would like to distribute a questionnaire to them, which is voluntary and should take no more than 10 minutes to complete. The first page of the questionnaire will explain the study, issues of privacy, and seek to obtain participant informed consent.

Should you have any questions or concerns, please do not hesitate to contact us at jaustin@ucalgary.ca. or eoddone@ucalgary.ca

We thank you in advance for your support!

Janice Austin R5, General Surgery
Master's Student in Medical Education, CHS
University of Calgary

Elizabeth Oddone Paolucci, PhD
Departments of Surgery & Community Health Sciences
Graduate Student Supervisor
University of Calgary

APPENDIX F:

QUESTIONNAIRE COVER LETTER

UNIVERSITY OF CALGARY

Teaching Patient Safety (TIPS) Questionnaire

Dear Participant,

My name is Janice Austin, I am a graduate student in the Department of Community Health Sciences at the University of Calgary working with my supervisor, Dr. Elizabeth Oddone-Paolucci. As part of my master's thesis requirement, we are conducting a study on preventable adverse events in surgery. We are interested in the opinions of staff surgeons regarding the prevalence of preventable adverse events and the methods used to address them in your residency program.

Please note that all of your responses will be kept strictly confidential and are anonymous. All information will be presented in a summarized and aggregated form only. This questionnaire is voluntary and should take no more than 10 minutes to complete. The first page will explain the consenting procedure; by continuing on to the second page, you will be providing us with your consent.

This study has been approved by the University of Calgary Conjoint Health Research Ethics Board. Should you have any questions or concerns, please do not hesitate to contact us at jaustin@ucalgary.ca. or eoddone@ucalgary.ca.

Your input is very important. We would like to thank you in advance for your participation!

Janice Austin R5, General Surgery
Master's Student in Medical Education, CHS
University of Calgary

Elizabeth Oddone Paolucci, PhD
Departments of Surgery & Community Health Sciences
Graduate Student Supervisor
University of Calgary

APPENDIX G:

QUESTIONNAIRE IMPLIED CONSENT FORM

UNIVERSITY OF CALGARY

SURVEY INFORMATION/ IMPLIED CONSENT

TITLE: Knowledge, Attitude, and Practice (KAP) of surgeons on education regarding Patient Safety.

INVESTIGATORS: Elizabeth Oddone-Paolucci PhD, Don Buie MD, Tyrone Donnon PhD, and Janice Austin MD

SPONSOR: University of Calgary

This information sheet is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, please ask. Take the time to read this carefully and to understand any accompanying information.

BACKGROUND

Every surgical procedure comes with the risk of adverse events (AEs). These AEs can have serious and significant implications on a patient's life. AEs can be the result of many factors such as patient comorbidities, the disease process, or errors in surgical management (Troeng and Janzen, 1990). Adverse events that are secondary to errors represent those events that are potentially preventable termed preventable adverse events (PAEs). Surgeons are constantly working towards improving techniques, technology, and patient care to minimize the number of adverse events had by patients. A reduction of the number of errors can also potentially significantly reduce patient morbidity and mortality, as well as decrease the cost of healthcare (Brennan, 1991). There currently exists an abundance of data on methods used to teach patient safety and attitudes regarding systemic changes (e.g., work hour restrictions), aimed at reducing the number of medical errors made (Fletcher, 2008). However, there currently exists little or no data on the knowledge or attitudes of how patient safety is taught. In order to make ongoing improvements, it is important to first study the current knowledge, attitudes, and practices regarding education in patient safety.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to assess the knowledge, attitudes, and practices of surgeons affiliated with the University of Calgary regarding patient safety and the methods used to teach patient safety to residents at the University of Calgary.

WHAT WOULD I HAVE TO DO?

Your participation will involve responding to 15 survey questions online. It should take approximately 10 minutes of your time. This is a one-time survey only. No other participation is requested. Please note that all of the data will be compiled into an aggregated format and published anonymously such that information from any one person will be kept strictly confidential.

WHAT ARE THE RISKS?

There are no anticipated risks to participating in this study than those ordinarily experienced in daily life.

WILL I BENEFIT IF I TAKE PART?

There are no physical benefits to you. However, once your results are compiled, the direct benefit to you will be a summary report. Moreover, any improvements made via the outcome of this questionnaire can benefit your future patients by reducing the risk that they experience an error in their care.

DO I HAVE TO PARTICIPATE?

Participation in this study is completely voluntary. You can refuse to allow your information to be included in the study and you may withdraw your consent and information from the study up to 6 months after the date you initially agreed to participate, without retribution.

WILL I BE PAID FOR PARTICIPATING, OR DO I HAVE TO PAY FOR ANYTHING?

There is no compensation for participation and there are no costs to you.

WILL MY RECORDS BE KEPT PRIVATE?

All of your responses will be kept confidential and anonymous by the primary investigator. Therefore, each participant will be assigned a study identification number. Information will be presented as summarized data only such that any one individual cannot be identified. Completed questionnaires will be kept in a locked drawer at the University of Calgary for 10 years after the completion of the research. Only the graduate student and the principal investigator will have access to the data. Summarized information may be submitted for publication in scientific journals, however, no identifying features of any individual will be included in these publications.

Data is being collected using Survey Monkey:

> *"This online survey company is hosted by Survey Monkey, a web-survey company, located in the USA and as such is subject to U.S. laws. In particular, the US Patriot Act which allows authorities access to the records of internet service providers. This survey or questionnaire does not ask for personal identifiers or any information that may be used to identify you. The web-survey company servers record incoming IP addresses of the computer that you use to access the survey but no connection is made between your data and your computer's IP address. If you choose to participate in the survey, you understand that your responses to the survey questions will be stored and accessed in the USA. The security and privacy policy for the web-survey company can be found at the following link: https://www.surveymonkey.com/mp/take-a-tour/?ut_source=header#safe-secure*

Study Title: Preventable adverse events in surgical patients: a meta-analysis and Knowledge, Attitude, and Practice (KAP) assessment

PI: Dr. Elizabeth Oddone Paolucci

IF I SUFFER A RESEARCH-RELATED INJURY, WILL I BE COMPENSATED?

In the event that you suffer injury as a result of participating in this research, the University of Calgary, the Cumming School of Medicine (formerly known as the Faculty of Medicine) or the researchers will provide no compensation to you. You still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

AGREEMENT TO PARTICIPATE

Your decision to complete and return this survey will be interpreted as an indication of your agreement to participate and indicates you have understood to your satisfaction the information regarding participation in the research project. In no way does this waive your legal rights nor release the investigators or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time. You should feel free to ask for clarification or new information throughout the study.

If you have further questions concerning matters related to this research, please contact:

Dr. Elizabeth Oddone-Paolucci (403) 944-3151

or

Dr. Janice Austin (403) 805-4101

If you have any questions concerning your rights as a possible participant in this research, please contact the Chair of the Conjoint Health Research Ethics Board, Research Services, University of Calgary, 403-220-7990.

The University of Calgary Conjoint Health Research Ethics Board has approved this research study.

APPENDIX H:

SURVEY RESPONSES

Supplemental Table 1: Baseline Characteristics

Characteristic	n	%
Sex		
Male	89	74.8
Female	28	23.5
Prefer no answer	2	1.7
Section		
Cardiovascular/Thoracic Surgery	10	8.4
General Surgery	32	26.9
Obstetrics and Gynecology	28	23.5
Orthopedic Surgery	20	16.8
Other	29	24.4
Primary Site		
Alberta Children's Hospital	12	10.1
Foothills Medical Centre	47	39.5
Non-hospital Facility	2	1.9
Peter Lougheed Centre	21	17.6
Rockyview General Hospital	19	16.0
South Health Campus	18	15.1
Years in Practice		
0-10	46	38.7
11-20	34	28.6
>20	39	32.8

Supplemental Table 2: Survey Responses – Knowledge Section

Question	n	%
Definition Adverse Event		
Incorrect	26	21.8
Correct	93	78.2
Definition Error		
Incorrect	93	78.2
Correct	26	21.8
Reporting		
The Conjoint Health Research Ethics Board		
The Patient Safety Department of Alberta Health Services	1	0.8
The Performance Improvement Department of Alberta Health Services	69	58.0
	1	0.8
The Unit Manager	48	40.3
Mandatory Reporting?		
FALSE	37	31.1
TRUE	82	68.9

Italicized response is the correct response

Supplemental Table 3: Survey Responses – Attitudes Section

Question	Mean	SD
Causes of Errors - Individual Level		
Lack of medical knowledge, skill, or information by care provider	2.4	0.9
Mistake by care provider while performing a common or familiar task	2.5	1.0
Misperception of the situation by care provider	2.8	0.9
Care provider experiencing excess fatigue, stress, etc.	2.3	0.9
Temporary illness or injury of the care provider	1.5	0.6
Permanent mental or physical limitations of the care provider	1.3	0.6
Habitual or tolerated violations of protocol by care provider	2.1	1.0
Violations of rules or protocol outside of the norm by care provider	1.9	0.9
Failure of care provider to anticipate patient needs or to create a clear plan	2.5	0.9
Care provider working when not fit for work	1.5	0.7
Causes of Errors - Environmental Level		
Physical environment (e.g. lighting, noise, room layout, etc.)	2.0	0.8
Technological environment (e.g. design and function of equipment)	2.2	0.7
Poor communication (e.g. hand over or sign out)	3.3	1.0
Poor coordination between team members (e.g. scheduling appointments, work up, etc.)	3.0	1.0
Causes of Errors - Supervision Level		
Inadequate supervision of care provider	2.2	0.8
Care provider not aware of or unable to execute a work plan	2.0	0.8
Failure of supervisors to correct known problems in work environment	2.2	0.8
Supervisor asks care provider to perform tasks outside of their qualifications	1.9	0.8
Causes of Error - Organizational Level		
Ill-defined policies, unofficial rules, or confusion of rules exists	2.1	0.8
Failure of formal processes, (e.g. scheduling), procedures (e.g. documentation) or oversight (e.g. risk management) within the organization	2.1	0.8
Poor allocation or maintenance of organization's resources	2.3	0.9
Statements about education		
Formal education in patient safety is important.	4.0	0.8
Residents in our program are adequately trained to prevent adverse events during their residency.	3.3	0.8
Morbidity and Mortality rounds, as they exist in my section, are effective for learning to prevent future errors.	3.3	1.1
Effective Teaching Methods		
Individual feedback	3.9	0.9
Team debriefing	4.0	0.9
Topic presented at one or more half days	3.5	0.9
Formal curriculum for residents	3.3	1.1

Supplemental Table 4: Survey Responses – Practice Section

Question	N	%
Methods Used in Residency		
Individual Feedback	93	78.2
Team Debriefing	69	58.0
Morbidity and Mortality Rounds	103	86.6
Topic presented at one or more half days	68	57.1
Formal curriculum for residents	33	27.7
Change in Practice		
Individual Feedback	83	69.7
Team Debriefing	57	47.9
Morbidity and Mortality Rounds	93	78.2
Topic presented at one or more half days	40	33.6
Formal curriculum I taught for residents	21	17.6
Formal curriculum I have attended as staff	54	45.4
Led a Debriefing		
No	59	49.6
Yes	60	50.4
Involved in debriefing		
Individual who made the error	53	89.8
Residents on service	41	69.5
Medical students on service	18	30.5
Other staff members	45	76.3
Allied health members involved in that patient's care	47	79.7
Record of own adverse events		
No	90	76.3
Yes	28	23.7
Section reporting system		
No	18	15.4
Yes - for errors only	0	0.0
Yes – for adverse events only	25	21.4
Yes – for both	40	34.2
Unsure	34	29.1