EPIDEMIOLOGY OF PATIENT SAFETY EVENTS IN AN ACADEMIC TEACHING HOSPITAL

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Table of Contents

Abstract

Background:

Adverse events are poor health outcomes caused by medical care rather than the underlying disease process. Voluntary reporting is a key component to adverse event reduction; however, incident reporting systems contain many limitations. The Patient Safety Learning System (PSLS) is an electronic incident reporting system with several unique features that were designed to address the weaknesses of previous systems, including a process for physician assessment of reported events to determine their significance. The primary objectives for this study were to determine the positive predictive value of the PSLS for identifying adverse events. Secondary objectives were to identify event, patient, and system-level factors associated with true events, and to assess event rates over time.

Methods:

I performed a retrospective cohort study using electronic health care data collected data from the Ottawa Hospital, between April 1 2010 and September 30, 2011. We Included all reported patient safety events if they occurred in adults aged 18 and older, admitted to an inpatient ward at the Civic, General, or Heart Institute campus. Events that occurred on Psychiatry, Rehabilitation services, were excluded due to data restrictions. A Clinical Reviewer manually reviewed each event to distinguish true events from non-events. For each hospital program, we used a generalized linear mixed model (GLIMMIX) to predict true events, using the role of the reporter as a random effect.

Results:

Over the study period, there were 2,569 events reported by hospital staff and physicians. Of these, 660 were rated as adverse events and 1,909 were rated as near misses. This yielded an overall positive predictive value of the PSLS system of 63% (95% CI 62-65%). The variance between reporters was not significant for Critical Care, Heart Institute, Nephrology, Obstetrics and Gynecology, Surgery and Periops, therefore I used a

traditional logistic regression model with a common intercept. Number of months the PSLS was available was the only significant covariate found in all programs; the direction of the relationship was the same across all programs, and showed a decrease in true events reported over time. Other common covariates included: time from admission to event, severity of illness, and admission type. All models achieved a good calibration, yet discrimination was poor (c <0.70) in all models except Heart Institute**.** Discrimination ranged from 65% in Critical Care to 77% in the Heart Institute. Overall, the rate of patient safety events reported for inpatients was 6.39 per 1000 patient days. After an initial learning period, from April 2010-January 2011, in which rates were low, reporting rates *increased and* stabilized; remaining constant from month to month. The rate of true patient safety event reporting fluctuated greatly from April 2010-January 2011, after which they began to steadily decline. Trends in reporting were similar across hospital campus, reporter, and program. The majority of patient safety events were reported by nurses (44%), and laboratory staff (42%). The remaining 14% of events were reported by the classification 'Other,' which included all other hospital staff, such as technicians, physicians, and administrative staff. Only 7 physicians reported events to the PSLS during my study period, therefore, they were categorized under 'Other'.

Conclusions:

Despite the many unique advantages of the PSLS, the proportion of true events reported has remained low. The overall utility of statistical models to predict patient safety events is limited. The traditional patient and system-level covariates, which are used to predict risk of adverse outcomes with high accuracy, did not help us discriminate between true patient safety events from non events. It is possible that many different individual and institutional barriers are influencing reporting and perhaps reviewing behavior, which in turn leads to non-clinical variability in what gets reported and classified as a patient safety event.

Acknowledgements

I would like to thank my parents for their constant support and encouragement. This degree is only one of the many things that would have never been possible without you.

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1.0 Introduction

The publication of To Err is Human (IoM, 2000) marked the start of patient safety as a prominent issue in health care; it was the first study that attempted to estimated the rate of adverse events on a national level. This IoM report suggested that human error is responsible for between 44,000 and 98,000 accidental deaths annually in the United States alone. This number exceeds the number of deaths due to motor vehicle accidents, breast cancer, or HIV (IoM, 2000).

Subsequent studies revealed that adverse events (AEs) [identified as any undesirable outcome that is caused by health care rather than the underlying disease progression] are a common problem worldwide. Two different US studies found that adverse events occurred in between 2.5% (Thomas, 2000) and 3.7% (Brennan, 1991) of all hospitalizations; rates of 10.8% (Vincent, 2001) and 16.6% (Wilson, 1995) were found in British and Australian studies respectively. In Canada, adverse events occur in between 7.5% and 12% of all hospitalizations (Baker, 2004) with 1 in 6 such events resulting in the patient's death (Baker, 2004).

AEs also result in a significant economic burden. A Canadian study found that adverse events increased hospital stay by 6, 4, and 8 days in teaching hospitals, large community hospitals, and small hospitals, respectively (Baker, 2004). Based on average daily costs, AEs will incur an extra $10,000 per event. Extrapolating these statistics to a typical acute care hospital that admits 20,000 patients annually, 2,000 patients will experience an AE, resulting in an additional $20,000,000 in direct incremental charges, 1,600 additional bed days, and 300 deaths. These statistics have prompted many countries to invest more resources into patient safety.

In 2002, the Canadian government budgeted $50 million over 5 years for the creation of the Canadian Patient Safety Institute (CPSI). The CPSI is an organization dedicated to the implementation of patient safety initiatives in healthcare facilities. However, despite efforts to improve patient safety, the safety culture in healthcare still lags behind other high risk organizations (Eibling, 2014). Furthermore, recent studies suggest that there has been no significant decrease in the incidence of AEs since the 1990's (Landrigan, 2010). In

contrast, industries such as aviation and nuclear facilities have developed sophisticated incident prevention programs that focus on complete and accurate measurement of adverse events (Wilf-Miron, 2003). These programs have been very successful in reducing human error (Doucette, 2006) and many researchers believe that the same principles can be applied to healthcare (Weiner, 1989; Sexton, 2000; Wilf-Miron, 2003; Majahan, 2010).

Measurement plays a key role in patient safety because it can be used to identify trends and factors associated with adverse events. It has the potential to provide health care providers with the opportunity to learn from common errors and allows management staff to correct any underlying issues within the healthcare system. This will ultimately prevent the recurrence of similar events and reduce patient harm.

The remainder of this introduction will discuss the definition of adverse events and medical errors, describe the current methods used for measuring adverse events, and review the literature on descriptive event statistics from previous incident reporting systems. Next, I will introduce the Patient Safety Learning System (PSLS) and how it might improve voluntary reporting of AEs.

1.1 Definitions

Health care safety is typically measured by evaluating adverse events, preventable adverse events and near misses. These can collectively be termed patient safety events. Bates et al proposed the conceptual model presented in Figure 1 to illustrate the relationship between adverse events, preventable adverse events, adverse outcomes, near misses and medical errors. Table 1 includes a glossary of patient safety terms that I will use throughout my thesis, with a definition and brief explanation of how these were classified by the clinical reviewer. (For a more detailed explanation, see Appendices B and C). A medical error is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Medical error is a process-related term rather than an outcome-related term, thus the majority do not lead to an adverse event or adverse outcome (IOM, 2000; IOM 2001). This is depicted in figure 1, where medical

errors are represented by the blue box, and the regions that overlap with near misses and adverse outcomes represent the proportion of medical errors that result in a near miss or adverse outcome. An **adverse event** (AE) is any undesirable outcome that is caused by health care rather than the underlying disease progression (Baker, 2004). It is represented by the green circle in figure 1; all adverse events are a subset of adverse outcomes (the orange circle). A **preventable AE** is an adverse event caused by medical error or by a remedial health system flaw (Forster, 2004); it is represented by the proportion of the green circle that overlaps with medical errors in figure 1. Although preventable AEs represent a relatively small portion of medical errors and adverse outcomes, their clinical impact is significant. Among the 2.5 million annual hospital admissions in Canada, about 185,000 are associated with an AE and close to 70,000 of these are potentially preventable (Baker et al, 2004). A **near miss** is defined as an event that did not lead to an undesirable outcome but could have (Phimister, 2000); it is represented by the yellow circle in figure 1. Note that most near misses are due to medical error, as indicated by that large region that overlaps with medical errors, but a smaller subset are not.

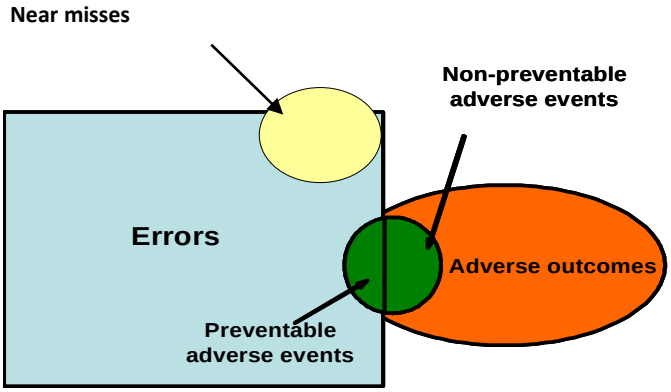


Figure 1 adverse events, preventable adverse events, near misses, and errors

Table 1 Glossary of common patient safety terms	
Medical error (blue square)	Failure to complete an action as intended, or the use of a wrong action to achieve an aim. The majority do not represent true patient safety events.
Adverse outcome (orange circle)	An event where the patient experienced harm, injury, or bad outcome.
Patient safety event	All adverse events (green circle) and near misses (yellow circle).
Adverse event (green circle).	An adverse outcome that the clinical reviewer determined was likely, most likely, or definitely due to medical management. Adverse events can be further subdivided into preventable or non-preventable adverse events.
Preventable adverse event	An adverse event that the clinical reviewer determined was was likely, most likely, or definitely preventable.
Non-preventable adverse event	An adverse event that the clinical reviewer determined was likely, most likely, or definitely not preventable.
Near miss (Yellow circle)	An event that did not lead to an adverse outcome, but that the clinical reviewer determined was likely, most likely, or definitely had the potential to cause harm.
Non-event	This consists of adverse outcomes that the clinical reviewer determined were likely, most likely, or definitely due to the patient's underlying condition, or an event that did non lead to an adverse outcome, and the clinical reviewer determined that there was likely, most likely, or definitely no potential for harm.
Event type	This refers to the Bates' classification of an event as either: an adverse event (preventable or non-preventable), near miss, or non-event.
Event class	This refers to the Datix Common Classification System (CCS), level 1 classification of events, which classifies events into 14 major categories: Accident (no falls), behaviour, clinical administration, clinical process/procedure, documentation, equipment/product/medical device, fall, healthcare associated infection, laboratory, maternity care, medication/IV fluid, biological (includes vaccine), nutrition, transfusion medicine, vascular access lines, other.

1.2 Current methods for detecting adverse events

Voluntary reporting, using either paper-based or electronic media, is by far the most common – and simplest - method used for AE detection in North American hospitals (Manajan, 2010). It is also the only method mandated by accreditation organizations such as Accreditation Canada and the US Joint Commission for Accreditation of Healthcare Organizations. In voluntary reporting, healthcare providers voluntarily report incidents that they believe harmed a patient or unnecessarily placed them at risk of being harmed. Voluntary

reporting systems usually consist of forms in which the reporter must categorize the event using pre-defined event classifications. Despite its widespread use, voluntary reporting has been demonstrated to have several limitations:

1) **Underreporting:** Many AE's are not reported, therefore, they cannot be properly measured or corrected (Harper, 2005; Zhan, 2008; Montesi 2009). Furthermore, physicians consistently under-report adverse events more than any other healthcare worker, and their lack of input can skew the representativeness of event data (Kingston 2004; Wild, 2005; Schectman,2006; Evans, 2006; Hirose, 2007; Braithwaite 2008; Nuckols, 2009; Gong, 2011; Bodina, 2014). I will explore the factors leading to physician under-reporting and their implications in the discussion.
2) **Over-reporting of non-events:** A significant proportion of events reported by healthcare providers are not actually true events. These mainly include duplicate events or employee incidents. Furthermore, most voluntary reporting systems do not have the ability to distinguish these from true adverse events (without manual review of these reported events).
3) **Inconsistent coding of events:** There is a lack of standardized procedures and education on how to code or classify in-hospital AEs (Gong 2008; Montesi, 2009; Gong, 2011). This also renders the quality of data poor and prevents the hospital from producing meaningful and comparable statistics.
4) **Lack of denominator information:** The majority of incident reports contain no information on the population affected (i.e. demographic characteristics), or specific services and wards within the hospital where the event occurred (Ahluwalia, 2005; Zhan, 2008; Travagli, 2009). Therefore, AE rates cannot be calculated for specific services or patient populations.
5) **Lack of contextual information:** In most reporting systems, providers are limited to drop down menus and single-word answers, which do not always capture all pertinent information and make it more difficult to assess the validity of the event and its type (Johnson, 2003; Gong, 2011, Tarig, 2012).

There are alternative methods to measure safety other than voluntary reporting. These include electronic health record surveillance, clinical surveillance, and two-staged chart review. A formal description of these methods is beyond the scope of this project, however, a common component of these methods that distinguishes them from voluntary reporting is their use of a peer reviewer, which is a care provider who reviews the event to determine its validity, its importance, and its cause. In theory, the inclusion of a peer reviewer improves the completeness and reliability of adverse event detection. However, these methods are expensive to implement and maintain, and require sophisticated technology. Therefore, these methods are not often implemented by hospitals.

1.3 Descriptive statistics reported to previous incident reporting systems

I searched PubMed, Medline, and Scopus for descriptive event data reported in previous incident reporting systems. I identified a total of 92 studies that recorded descriptive event data for incident reporting systems in a clinical setting. I collected data on the patient population, method of data collection, time period of data collection, role of healthcare providers using the system, the type of adverse events recorded (AE vs ADE), the method of classification of events, descriptive statistics on the types of events reported, reporting frequency by role of the reporter, and incidents rate of reporting per 1,000 patient days. Of these studies, I identified 39 that were conducted in a hospital setting, on an adult population, and reported descriptive statistics for adverse events and/or adverse drug events (as opposed to clinical or medical errors).

A complete list of the 92 studies I reviewed can be found in Appendix G; the results from my included studies can be found in tables 2-5 below.

Table 2 Types of patient safety events reported in previous studies

	Total studies	Preventability		Near Miss	
Row Labels	**N**	**N**	**Majority**	**N**	**Majority**
AE	**27**	**4**	**3**	**10**	**4**
All hospital	11	2	2	5	2
Anesthesiology	3	1		1	
Anesthesiology, ICU	1			1	1
Critical care	5	1	1	1	1
Kidney transplantation center	1			1	
Surgery	3			1	
Transfusion	2				
Anesthesiology	1				
ADE	**7**				
All hospital	4				
Psychiatry	3				
Lab	**3**			**1**	**1**
Laboratory	3			1	1
Near miss	**2**	**1**	**1**		
Anesthesiology, ICU	1				
Orthopedics	1	1	1		
Total	**39**	**5**	**4**	**11**	**5**

Table 2 above describes the type of events reported from each of the 39 included studies. The column labelled Total studies represents all 39 studies that meet my inclusion criteria. The N column indicates the number of studies that recorded that particular event type, while the Majority column indicates how many studies recorded that event type as the majority of events reported (> 50% of events reported)

15 studies included data on all hospital services, while 24 were ward specific; the most common were ICU, anesthesia, and surgery. 27 studies reported on all AEs (11 from all hospital, 16 from ward specific studies), 7 studies reported ADEs only (4 from all hospital, and 3 from ward specific studies), 2 studies reported near misses only (all from ward specific studies), and 3 studies reported laboratory events only (all from ward specific studies). There were significant differences in the method of event classification between studies. None of the studies used the Bates model of event classification used in my study, which categorizes events as: AEs, which is further subdivided into preventable AE and non-preventable

AE, near miss (or potential AE), and non-AE. 5 studies commented on preventablity of an event, 11 studies reported AEs and near misses, but did not include preventability, and 2 studies included near misses only. Out of the 5 studies that commented on preventability, 4 studies found that the majority of events were preventable. Out of the 11 studies that reported near misses, 5 studies recorded near misses as the majority event type.

Table 3 Most common severity rating in previous studies, by event type and patient population

	No Harm	Low	Low/No Harm	Significant/ Serious
AE	**9**	**3**	**1**	**4**
All hospital	3	1	1	2
Anesthesiology	1			
Anesthesiology, ICU	1			
Critical care	2	2		1
Kidney transplantation center				
Surgery	2			
Transfusion				1
ADE	**2**	**1**	**2**	**2**
All hospital	1	1	1	1
Psychiatry	1		1	1
Lab	**1**			
Laboratory	1			
Near miss				
Anesthesiology, ICU				
Orthopedics				
Total	**12**	**4**	**3**	**6**

Table 3 summarizes the most common severity ratings from previous studies; for each study, I recorded the severity rating that comprised >50% of the events recorded. Overall, 25 studies reported on the severity of patient safety events. In 12 studies, the majority of events caused no harm to the patient, in 4 studies the majority of events caused low harm, in 3 studies, the majority of events caused low or no harm (these studies only recorded the number of deaths or severe injuries, since it was very low, I concluded that the majority of events caused either no harm or low harm), and in 6 studies, the majority of events caused serious harm.

Table 4 Top 3 event classes reported in previous studies, by patient population and event type

Event Class	Total	ADE	AE	Near Miss
All Hospital				
Falls	5		5	
Medication	4		4	
Equipment/Device	3	1	2	
Laboratory	2		2	
Administration stage	1	1		
Blood	1		1	
Clinical processes	1		1	
Clinical services	1		1	
Delayed hemolytic transfusion reactions	1		1	
Failure to act on or recognize deterioration	1		1	
Febrile non-hemolytic transfusion reaction	1		1	
Inappropriate nursing procedure	1		1	
Operative incidents	1		1	
Other process problems	1		1	
Pharmacy dispensing stage	1	1		
Prescribing stage	1	1		
Pressure Ulcers	1		1	
Product incidents	1		1	
Swelling or bleeding or IV puncture site	1		1	
Therapy	1		1	
Healthcare associated infection	1		1	
Anesthesiology				
Equipment/Device	2		2	
Airway	1		1	
Cardiovascular	1		1	
Drug administration	1		1	
include in comparison with other methods	1		1	
Infusion delivery	1		1	
Respiratory	1		1	
Critical care				
Circulatory and organ failure/sepsis	1		1	
Delayed hemolytic transfusion reactions	1		1	
Equipment/Device	1		1	
Febrile non-hemolytic transfusion reaction	1		1	
Management/planning education problems	1		1	
Medication	1		1	
Other	1		1	
Product incidents	1		1	
Treatment/diagnosis delay	1		1	
Kidney transplantation center				
Documentation	1		1	
Equipment/Device	1		1	

Event Class	Total	ADE	AE	Near Miss
Patient accidents	1		1	
Psychiatry				
Other	1	1		
Wrong Drug administered	1	1		
Wrong time	1	1		
Surgery				
Equipment/Device	1		1	
Nursing related	1		1	
Staff shortage	1		1	
Surgery/theatre related	1		1	
Healthcare associated infection	1		1	
Communication	1		1	
Transfusion				
Blood bank error alone	1		1	
Compound error	1		1	
Non-blood bank error alone	1		1	

Table 4 describes the class of events reported, by event type and patient population. For each study, I recorded the 3 most common event classes. The method of classification varied significantly between studies, so there were many unique event descriptions, however, some common themes still emerged. Overall, equipment/device related events were mentioned in 12 studies, medication-related events were mentioned in 9 studies, and falls were mentioned in 6 studies. Falls were the most common event in studies that included all hospital services, while Equipment/device related events were the most common among ward-specific studies.

Table 5 Provider responsible for the majority of event reporting in previous studies, by event type and patient population

Row Labels	Nurse	Nurse and midwife	Non-physician	Pain team	Physician
AE	**7**	**1**	**2**	**1**	**2**
All hospital	3	1	1		1
Anesthesiology			1	1	
Anesthesiology, ICU					
Critical care	2				1
Kidney transplantation center	1				
Surgery	1				
Transfusion					
ADE	**1**				
All hospital	1				
Psychiatry					
Lab					
Laboratory					
Near miss					
Anesthesiology, ICU					
Orthopedics					
Total	**8**	**1**	**2**	**1**	**2**

A total of 14 studies recorded statistics on reporting frequency by role of healthcare provider. I summarized the results in table 5 above; for each study, I recorded the provider who was responsible for recording the majority of events (> 50%). Out of the 14 studies, only 2 studies listed physicians as the primary reporter of events, 8 studies listed nurses while 1 study listed nurses and midwives as the primary reporter. In the remaining studies, 2 listed healthcare providers in non-physician roles as the main reporter, and 1 study listed a pain team (a specializes team in ICU consisting of physicians and nurses) as their primary reporter.

8 studies recorded an incidence rate of reporting, and 5 expressed it per 1,000 pt days. The rates differed dramatically between 0.79/1,000 patient days to 17/1,000 patient days.

In addition, my search also identified 7 studies (Beckmann 2003, Benson2000, Levtizion-Koarch 2010, McElroy 2014, Olsen 2007, Weignart 2000, Weingnart 2010) that compared the types of events reported through incident reporting to event types reported through other methods. A summary of the results from

each individual study can be found in table 3 of Appendix G. The methods used as a comparison included: manual chart review, automated detection, patient complaints, malpractice claims, walk rounds, debriefing responses, pharmacy surveillance, house officer reports, and hospital safety reports (some studies compared multiple methods). Despite the variety in different comparators, each study had the same overall result: there is very little overlap in events reported in more than one system.

1.4 The Patient Safety Learning System

With these considerations in mind, the Ottawa Hospital (TOH) designed and implemented the Patient Safety Learning System (PSLS). Information about the development and implementation timeline of the PSLS is presented in Appendix A. The PSLS is a unique system that integrates voluntary event reporting using electronic forms combined with physician peer-review without the added expenses associated with complex surveillance methods. The review process is a regular component of the PSLS; it was not study specific.

The PSLS consists of 5 stages (Figure 2): Voluntary Reporting, Clinical Review, Core Review, the Clinical Manager Review, and the Data Warehouse. Figure 2 illustrates the work flow of these stages.

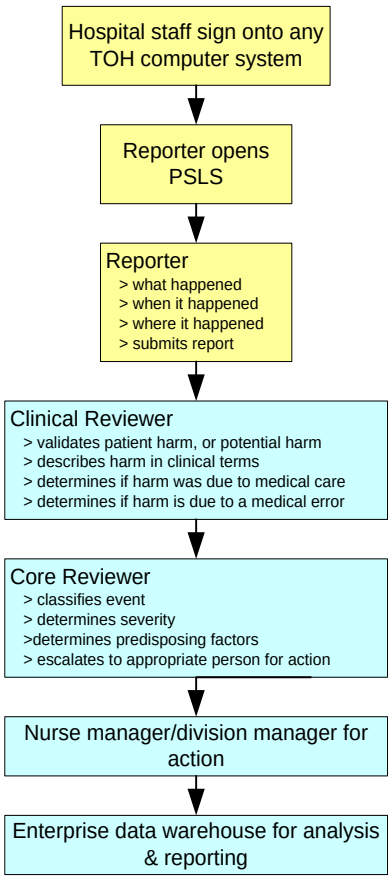


Figure 2 PSLS voluntary reporting workflow

1.4.1 The voluntary reporting stage

All TOH physicians and employees can report events using the PSLS; reporting is completed on a voluntary basis. They are taught to monitor for any incident in which the patient might experience an undesireable outcome or be put at unnecessary risk of having an undesireable outcome. If one of these situations occurs, the physician or employee is expected to report it using the PSLS. This is done through an electronic form in which the Reporter enters the event demographics (date, time, and location) along with a brief description of the event, the response to the event, and the perceived effects on the patient. Note that event information is provided via free text boxes, which serve to improve the contextual information without the constraints of a drop-down menu.

1.4.2 The clinical reviewer stage

The review process (both clinical and core review) is part of regular care, not study specific. In the TOH model, the clinical reviewers are physicians, or similarly qualified health professionals (i.e. a physician who trained outside of Canada) (The Ottawa Hosptial (2013)). The clinical reviewer is responsible for reviewing each event to determine whether it truly represents a patient safety event. Each hospital service is assigned at least one clinical reviewer who is a clinician familiar with the service and its patient care. The clinical reviewer is able to access and classify an event as soon as it is entered into the PSLS; they are notified by email once an event is ready for review. On average, it takes reviewers 3 months to classify and close events. The classification process performed by the clinical reviewer is illustrated in Figure 5-9 of Appendix B and Figure 1 of Appendix C.

This classification and its rating scales is consistent with that used in the seminal patient safety work conducted in the US, the UK, Australia and Canada. First, the reviewer is asked to rate whether the patient experienced an undesirable outcome. If “yes”, the reviewer uses a 6-point ordinal scale to rate whether the outcome was caused by healthcare processes (as opposed to the natural history of the disease). If the event is rated as being caused by healthcare (i.e. it is rated as a 4, 5, or 6 on the scale), the event is classified an adverse event. Otherwise, the outcome is considered to be a function of the patient’s underlying disease process or bad luck and it is rated a non- event. The clinical reviewer then reviews all adverse events to determine whether the outcome was preventable using another 6-point ordinal scale (in which a score above 3 indicates a preventable adverse event).

For reported events that the reviewer feels are not an undesireable outcome, the reviewer classifies whether the event had the potential to lead to harm in the patient. If the opinion is yes, then these events are termed potential events. Reported events with no potential to cause harm in the patient are considered non-patient safety events.

The distinction between true patient safety events (consisting of adverse events, preventable adverse events, and near misses) and non-patient safety events is a fundamental difference between the PSLS and other voluntary reporting systems and critical to the PSLS's success. This process will improve the quality of data for analysis and interpretation. In addition, it will improve the efficiency of subsequent actions as they will only be performed on true events.

1.4.3 The core reviewer stage

The Core Reviewers make up a small and centralized team consisting of classification experts within the hospital's risk management group, who had many years experience in determining the degree of severity of patient harm. They classify the adverse event's type and severity, the latter using a six-point ordinal scale ranging from nil to death. The type and severity scales were adapted from the WHO's Conceptual Framework for the International Classification for Patient Safety, Version 1.1.

1.4.4 Nurse manager/division manager stage

The Nurse/Division Manager is responsible for overseeing the day-to-day delivery of healthcare to patients on their ward. One of their tasks is to ensure the prompt recognition and response to adverse situations affecting patients on their unit. Within this function, they review all issues identified within the PSLS on patients under their care and ensure that identified issues are addressed and communicated to the patient and the care delivery team.

1.4.5 Data warehouse stage

As each case is resolved, it is logged into the Enterprise Data Warehouse, where it is linked with other pertinent hospital data such as patient and health system characteristics. It also allows us to distinguish between encounters with and without patient safety events. This provides us with meaningful denominator

information, allowing us to identify areas in the hospital where AEs are more common. Also, it allows analysts to conduct powerful causal analyses and produce meaningful AE statistics including prevalence and incidence.

1.5 Study rationale

As mentioned above, voluntary reporting has many limitations, many of which stem from poor data quality (Cullen, 1995; Wolf, 2001; Beckmann, 2003). When compared to other AE detection methods, voluntary incident reporting resulted in higher false-positive and false-negative rates (Cullen, 1995; Wolf, 2001; Beckmann, 2003). A recent study indicated that 25% of reports that were labeled as miscellaneous or other actually contained an adverse event (Gong, 2009). Underreporting is also a large issue; since reporting of adverse events is at the healthcare provider's discretion and many events go undetected. Underreporting of adverse events in the United States ranges from 50-96% annually (Barach and Small, 2000; Harper, 2005).

Previous literature has identified several reasons why healthcare providers do not report true events, the main barriers are:

1. **Fear of being reprimanded and fear of being ostracized by peers:** many providers, physicians in particular, are fearful of reporting true events because they feel that the medical culture is not supportive of incident reporting. Unfortunately, most incident reporting systems are used to direct blame and shame on healthcare providers, thus many are hesitant to report out of fear of job repercussions (Evans, 2006; Madsen, 2006; Braithwaite, 2008; Padmore, 2009; O'Connor, 2010; Mahajan,2010.; Hashemi, 2012; Hartnell, 2012; Hwang, 2012; Perez, 2014). If patient safety and quality improvement are not emphasized early in their training, many physicians will develop a 'deny and defend' approach to error reporting; they adopt the belief that only bad physicians make mistakes and become reluctant to report (Evans, 2006; Perez, 2014). Although various medical schools now include patient safety as part of their core

curriculum, many residents and junior doctors do not report due to the competitive atmosphere of medicine (Perez, 2014).

2. **Lack of time:** Several studies have found that many healthcare providers have positive attitudes towards incident reporting and intend to report, yet they find the reporting process too time consuming to fit in amongst their many other tasks, so the events go un-reported (Jeffe, 2004; Johnson, 2004; Kingston, 2004; Schectman, 2006; Braithwaite, 2008; Padmore, 2009; Patow, 2009; Travaglia, 2009, Hartnell, 2012).

3. **Lack of knowledge:** Another important barrier to incident reporting is a lack of consensus amongst providers on what constitutes an adverse event, and uncertainty on how to use electronic reporting systems (Kingston, 2004; Taylor, 2004; Schectman, 2006; Kaldijan, 2006; Kaldijan, 2008; Gonzalez, 2009; O'Connor, 2010; Mahajan, 2010; Hartnell, 2012; Hashemi, 2012; Hwang, 2012; Perez, 2014). These uncertainties have a two-fold effect on incident reporting: firstly, it will result in less events being reported, and secondly, it will cause over-reporting of non-events that are irrelevant to patient safety. For example, some providers report adverse outcomes (events that arise from the natural course of the disease and are not due to the care they received) rather than adverse events. There can also be duplicates of some events, for example if a change in a patient's medication caused an increase in blood pressure, that event might get reported by pharmacy, as well as that ward responsible for that patient's care. In addition, unrelated problems such as employee issues and conflicts may also be reported as adverse events. Ultimately, these issues result in a misrepresentation of true adverse event data. Most voluntary reporting systems cannot distinguish true patient safety events from non-events without manual review by a physician, which reduces the efficiency and accuracy of

voluntary reporting and AE analysis. Although many studies have discussed the barriers associated with underreporting, very few have addressed issues surrounding the relevancy and quality of data that gets reported.

4. **Apathy towards incident reporting:** Lastly, many providers do not report adverse events because they do not believe incident reports result in meaningful changes to patient care (Uribe, 2002; Jeffe 2004; Kingston, 2004; Evans, 2006; Kaldijan, 2006; Schectman, 2006; Sanghera, 2007; Braithwaite, 2008; Padmore, 2009; Travaglia, 2009; Mahajan, 2010; Hartnell, 2012; Hashemi, 2012; Hwang, 2012). Effective feedback is essential to improving patient safety and quality of care (Sanghera, 2007; Benn, 2009). Without a timely and appropriate response, incident reporting loses its effectiveness; providers view it as a 'black box' in which events are entered but no actions are carried out. Moreover, a delay in response does not allow providers to learn from their errors.

The PSLS has several unique features described above that, in theory, should overcome barriers associated with voluntary incident reporting. First, the PSLS is an anonymous system; it collects information on the location, type, and severity of event, but any personal identification of healthcare providers is not permitted. Previous studies have demonstrated that physicians are more likely to report when they believe there will be no punitive response or retaliation from peers (Shectman, 2006; Bolsin, 2011; Garbutt, 2008). Thus, an anonymous system that protects healthcare providers will lead to a more supportive patient safety culture and encourage true event reporting.

Second, most of the event information is entered into PSLS using pre-defined drop down menus, which are tailored to different events types; someone entering a near miss will answer a different set of questions than someone entering an adverse event. This will improve the efficiency of the reporting process, since providers will only have to answer questions that are pertinent to their event type.

Third, all events entered into the PSLS are reviewed by a Clinical Reviewer, who further classifies the event as a true patient safety event, or a non-event. This will help to quantify the extent of over-reporting of non-events, which will lead to clinical programs developing effective strategies to reduce it. In addition, all healthcare providers received PSLS training, where they were taught how to use the system and what type of events to report.

Lastly, after the Core Reviewer classifies all events, they alert the Manager in the department responsible for the event. It is then the manager's responsibility to 'close' the event by addressing it with their staff. This would enhance learning and create a feedback loop in which there was progressive education on patient safety events, and focus on the most common problems for quality improvement. Moreover, it demonstrates to healthcare providers that incidents are acted upon and that reporting can produce visible improvements in delivery of care.

Although the design of the PSLS offers some theoretical benefits, these have not been evaluated. In particular, it is unclear whether reporters are submitting events to the PSLS that represent true patient safety events in the opinion of the clinical reviewer. This is important because the submission of true events suggests that the staff and physicians understand the types of events influencing the safety of care, feel comfortable reporting, know how to report, and are motivated to contribute to the improvement of the safety.

We can use the result of the review process to make inferences regarding reporting behavior within the hospital. It is easy to determine whether reporters are submitting true patient safety events by comparing the proportion of true patient safety events (adverse events + near misses) to all reported events. Because our clinical reviewers have more education on patient health outcomes, processes of care, and patient safety than most others in the organization, they are better able to distinguish between true and non events. By evaluating patterns of reported events and in particular the true events we are able to determine the reporting behaviours of the staff.

Another feature of the PSLS that can help us define the validity of the reporting behavior is the ability to predict true events using other information. There are event, patient, and system level factors which have been shown to predict safety risk. If reporters are using the system correctly, then it would be expected that we could observe associations between these factors and the probability of reporting true events.

It is well described that overall patient risk is associated with the risk of adverse events. Therefore, if people were reporting events reliably and accurately, it would be expected that one could demonstrate an association between clinical factors and probability of there being a true patient safety event. Thus, one would expect to observe an association of probability of true patient safety event with hospital service, baseline probability of mortality, and co-morbidity level. In order to account for this, I included the following patient level variables in my analysis: age, sex, diagnosis, Charlson Index, Elixhauser, Escobar, LAPS score, elective admissions, emergency surgical admissions, emergency non-surgical admissions.

In addition to patient factors, system factors might also be beneficial in predicting event occurrence. Specifically, if a nursing unit has a particularly effective safety culture the staff may be more inclined to report events. Conversely, if the unit is very busy the staff may be less likely to report. Finally, event related factors are also relevant – when the event occurs – may be critically important. If it occurs on a night and weekend, the willingness and ability to report may be limited because of reductions in staff at these times. The PSLS has the capability of evaluating these factors because it links reported events with all other clinical and administrative data at the Ottawa Hospital. I included the following system level variables in my analysis: mean daily admissions, mean nightly admissions, mean daily nurse to patient ratio, mean nightly nurse to patient ratio, number of patients at midnight.

A final perspective one could use to evaluate the system is changes in reporting over time. One could assess whether the probability of events representing true patient safety events changed over time to determine whether staff are learning what to report. Various factors could be hypothesized to affect this probability - if the unit culture shifted as a result of findings from the PSLS, if event risk changed due to

patients changing or because of changes in the system (for example staffing levels). One could also assess the types of events and event types overall and overtime. We have an understanding of the events common in healthcare, as seen in table 3, they include medication-related events, falls, and events related to medical equipment and devices – if we are not seeing these events, then it suggests that reporters are not submitting them. I included the following event-level factors in my analysis: number of months the PSLS was available and time to event. In addition, I also measured the monthly incidence rates of total events reported, true events reported, and the 3 most common event types reported, by campus, program, and role of reporter.

Because of the unique feature of the PSLS, we are in a unique position to evaluate reporting behavior compared to all other voluntary reporting systems in other health systems. Specifically, because there is a clinical review process embedded within the program, it is possible to evaluate the positive predictive value of reported events for true patient safety events; because the PSLS data is combined with other clinical and administrative data, it is possible to determine association of clinical, system, and event factors with true patient safety event probability; and, because, a standard coding system is used by a single core reviewer, it is possible to determine whether event risks are meaningfully changing over time.

It must be re-iterated that almost all hospitals in the world require their staff to report events – yet there is very little research evaluating what people actually report. These evaluations will therefore be relevant to a large number of healthcare providers.

1.6 Study objectives

The primary purpose of this work was to evaluate the relationship between various clinical and system factors with the probability reported events represented true patient safety events. Specific objectives related to this purpose were: 1) to describe the probability that an event reported in PSLS is truly a patient safety event; 2) to identify factors associated with the classification of an incident reported in PSLS as a true

patient safety event; and, 3) to determine whether this probability can be accurately predicted using a multivariate multilevel regression model incorporating event, patient, reporter, and system data.

A secondary purpose of the work was to describe patient safety events after the introduction of the PSLS at the Ottawa Hospital. Specifically, the objectives related to this purpose were: 1) to determine the monthly incidence rate of *all* PSEs reported during the study period by campus, hospital program, and role of reporter, 2) to determine the monthly incidence rate of *true* PSEs during the study period by campus, program, and role of reporter; and, 3) to determine the monthly incidence rate of the 3 most frequent event classes by hospital program.

The results from this study will be useful for all hospitals that maintain a voluntary reporting system. These results can be used to validate the PSLS as an effective tool for patient safety events and to highlight the critical role of peer review process in the defining of patient safety events. By identifying patient, reporter, event, and health system characteristics associated with bad data quality (false positives), it will also highlight situations in which a peer-review process might be circumvented. Specifically, it might be possible to use data to predict whether the event is a meaningful one, if this is the case, then events with a high probability of being classified as true will not need to undergo Core Review. This will result in savings in human resources and improve the efficiency of the system. In turn, this information has the potential to change the way hospitals comply with this important regulatory requirement.

Secondly, by identifying trends in reporting over time, we can assess the impact the PSLS had on voluntary reporting rates. This information can be used to develop strategies and solutions for further improving voluntary reporting. If the PSLS is proven to be effective, it can be implemented within these hospitals to obtain more meaningful AE data. A key caveat to these assumptions is that the estimated probability of true patient safety events were taken into account in the analysis.

2.0 Methods

2.1 Study Design

I performed a retrospective cohort study using electronic health care data. The unit of analysis is a patient safety event entered by a staff or physician.

2.2 Setting

I performed the study at the Ottawa Hospital, a multi-campus teaching hospital in Ottawa, ON between April 1 2010 and September 30, 2011. April 1 2010 represents the 'go-live' date of the voluntary reporting module of PSLS. I chose September 30, 2011 as my end date because that was the point at which greater than 90% of PSLS events were closed (they had gone through the clinical and core review stage, and appropriate follow up action was carried out). I studied reported events from three campuses: the Civic Campus, the Heart Institute, and the General Campus.

2.3 Inclusion/exclusion criteria

I evaluated all reported patient safety events if they occurred in adults aged 18 and older, admitted to an inpatient ward at one of the three study campuses. I excluded patients if I was unable to link reported events to Ottawa Hospital data sources. This occurred because the person submitting a voluntary report did not enter correct information pertaining to the patient identity or location in the voluntary report form. I excluded these events because I could not link them to data from the Ottawa Hospital Data Warehouse (OHDW) required to create the study covariates.

2.4 Outcome variables

The primary outcome was a 'true patient safety event (PSE)', which consisted of preventable adverse events (AEs), non-preventable AEs, and near misses. AEs are patient outcomes caused by medical care. The subset of AEs caused by error are considered preventable. Near misses are process deviations that have the potential to cause harm. I used a standard approach to define these outcomes (PSLS white paper). In short, all submitted events underwent clinical reviewer. An AE was defined as any event the Clinical Reviewer scored as 4 or greater on the questions "was the degree to which the outcome or its severity influenced by medical management?" A preventable AE was the subset of AEs in which the Clinical reviewer rated a 4 or greater on the question "was the outcome caused by error?" All other AEs were defined as non-preventable. The sum of preventable and non-preventable events equals the number of AEs detected. Near misses were derived from the Initial Assessment, where the Clinical Reviewer did not agree that the patient experienced harm, but scored the event as 4 or higher when asked "what was the potential for causing harm?"

For the different objectives in this study, I expressed this outcome in different ways

2.4.1 True patient safety events

This was a binary outcome. Each reported PSE was classified by the clinical reviewer as a true event or a non-event.

2.4.2 Rate of true patient safety events

To adjust for the number of patients observed at different times and locations, we calculated the rate as the number of events divided by the number of patient days (multiplied by 1000). We assessed various units of analysis including months and hospital locations including programs, campus and reporters. In all cases, rate was calculated as events per 1000 patient days.

2.4.3 Proportion of true PSEs

The proportion of true PSEs was calculated by dividing the total number of preventable AEs, non-preventable AEs, and near misses by the total number of voluntary reported events. We assessed this outcome across various strata including: months, hospital program, and role of reporter.

2.4.4 Rate specific event classification

The core reviewer further classified the true event type using the Datix Common Classification System (CCS), level 1 (CCS 1) classification, which consists of 14 categories: Accident (no falls), behaviour, clinical administration, clinical process/procedure, documentation, equipment/product/medical device, fall, healthcare associated infection, laboratory, maternity care, medication/IV fluid, biological (includes vaccine), nutrition, transfusion medicine, vascular access lines, other. We calculated the proportion of CCS1 event classification by event type (preventable, non-preventable, and near miss). In addition, we calculated the monthly incidence rate of the 3 most frequent event classifications (using the same method as above), by hospital campus, program, and role of the reporter.

2.5 Overview of data sources used

2.5.1 Patient Safety Learning System (PSLS)

The PSLS provided all event information. The core of the PSLS consists of a transactional relational database, which facilitates workflow and stores information pertaining to cases, including how they are reported. Reporters, clinical reviewers, core reviewers and managers enter information into the PSLS.

To facilitate analyses of the system, PSLS administrators have developed a data extract containing all the event characteristics listed above. This extract also contains a patient and encounter unique identifier we can use for linking purposes.

2.5.2 Ottawa Hospital Data Warehouse (OHDW)

The OHDW is a database containing personal health data for the explicit use of secondary analyses. The OHDW integrates data from several sources; three sources provide data on every patient admitted to a TOH campus. vOacis contains information pertaining to demographics and services received, SMS provides a census history and ER tracking and includes service and bed information for patient encounters, and Med2020 contains data from Health Records Abstracts (contained within the Discharge Abstract Database or DAD). The OHDW also integrates important health system data such as capacity history (derived from SMS) and staffing time cards which are available for each campus, service, ward, and nursing unit (contained in The Environment for Scheduling and Payroll (ESP) data system). Date is extracted from the respective source systems and loaded into the OHDW using a single data model and standard definitions. The OHDW data model has five main entities: patient, encounters, services, reference, and facility.

I used data tables from the encounter, service, and facility categories. I extracted all patient-level variables from the Abstracts, Discharge Abstract, Diagnosis, and Lab Service tables. I derived all system-level variables from the Functional Center, Census History, and Staffing tables. The specific covariates obtained from each table is provided in table 5 below. A conceptual map of the different datasets available within the OHDW is provided in Appendix D. I chose my variables based on consultation with Dr. Forster, data availability, and their ability to be linked to an inpatient encounter at the Ottawa hospital.

Table 6 A complete list of covariates, both fixed and random, included in my study

	Type	**Source**	**Fixed/Random**
Reporter	Categorical-nominal	PSLS	Random
Program	Categorical-nominal	SMS	Random
Event-level			
Time PSLS was available	Categorical-Ordinal	PSLS	Fixed
Time to event	Categorical-Ordinal	DW-DAD	Fixed
Event severity	Categorical-Ordinal	PSLS	Fixed
Event type	Categorical-nominal	PSLS	Fixed
Patient-level			Fixed
Age	Continuous-ratio	DW-DAD	Fixed
Sex	Binary	DW-DAD	Fixed
Diagnosis class	Categorical-nominal	DW-DAD	Fixed
Off service patients	Binary	SMS	Fixed
Charlson Index	Categorical-ordinal	DW-DAD	Fixed
Escobar index	Continuous-ratio	DW-DAD	Fixed
Elixhauser index	Categorical-ordinal	DW-DAD	Fixed
LAPS score	Continuous-ratio	DW-	Fixed
Elective admissions	Binary	DW-DAD	Fixed
Emergency surgical admissions	Binary	DW-DAD	Fixed
Emergency non-surgical admissions	Binary	DW-DAD	Fixed
System-level			Fixed
Number of patients at midnight	Continuous-interval	SMS	Fixed
Mean daily admissions	Continuous-interval	SMS	Fixed
Mean nightly admissions	Continuous-interval	SMS	Fixed
Mean daily nurse to patient ratio	Continuous-interval	SMS; ESP	Fixed

2.6 Cohort derivation

I created the analytical dataset using data from the PSLS, and linked it to various tables in the Ottawa Hospital Data Warehouse (encounters, abstract, diagnosis, staffing level, and nursing unit). The final dataset consists of 3 nested levels: event and patient data, reporter data, and nursing and staffing data. The most granular level is the event variables, with each row of the final table representing a unique patient safety event (PSE). A conceptual map demonstrating how the individual datasets within the OHDW link to the PSLS is available in Appendix E.

2.6.1 Event data

First, I extracted all event data from the PSLS. There were 16,520 cases recorded within the PSLS between April 1 2010 and September 30 2011, of which 12,039 had undergone full classification and were considered 'closed' cases. I excluded the following types of events: hazards, security events, e-triggers and event affecting a visitor. Following these exclusions, there were 10,349 total reported events.

2.6.2 Patient and encounter data

Next, I linked PSLS data to encounter data within the Ottawa Hospital Data Warehouse using the patient's Medical Record Number (MRN). Since MRN is a sensitive field (it can be used to identify an individual patient), an analyst with the appropriate access level extracted it, and returned to me as a de-identified patient id (patwid). This patient id is also found within various datasets of the data warehouse. All patients without a valid MRN or patient ID were excluded from the study population.

Encounter information in the OHDW includes details about the patient collected throughout their hospital stay. Although the patient id can be found within the encounters table, the unique row is a single hospital encounter, denoted with a de-identified encounter id. Each row contains a start and end date

associated with the encounter, as well as an encounter status code. All encounters with a status code of 'Inpatient' whose start and end date overlapped a patient's event date were included. Therefore, some patients had more than 1 encounter associated with their event date; in order to identify the correct encounter, more information was needed.

I then abstracted additional patient variables such as age, sex, and most responsible diagnosis from the abstracts and diagnosis table using the patient id as a linking variable. Any inpatient under the age of 18 was excluded from our study. Furthermore, there are certain inpatient wards, such as Psychiatric and Rehab, for which abstract data is not available. Consequently, these patients were also excluded from our study.

2.6.3 Census History data

In order to create nursing unit and staffing variables for each PSE, I obtained the nursing unit each patient occupied during the time of their event. I extracted this information from the Census History table within the data warehouse, which tracks an inpatient's movement through the hospital within a single encounter. Each row represents a change in location (in this case nursing unit) for each encounter, and also includes a date and time that a patient entered and left that particular unit. Each unique encounter within the Census History table is also given an encounter id, which is identical to the encounter id found in the encounters table; this was used to link the census data to our cohort dataset. If the date of the PSEs did not coincide with the start and end date on a particular nursing unit, they were excluded from our study since they did not experience an inpatient event. If the patient experienced an event on the emergency department prior to their inpatient admission, they were excluded because the event did not occur on an inpatient ward, thus the aggregated system-level variables (i.e. nurse:patient ratio) would not be applicable.

The PSLS also contains a field to identify the location type of the event, as well as the actual location. The actual location field within the PSLS contains the most granular information on where the event took place; which is where the nursing unit is entered. The location type groups the event locations into more

general categories, including: Inpatient, Critical Care, Outpatient, Laboratory, Perioperative, Community, Medical Imaging, Pharmacy, and Non-Clinical Area. These fields were entered manually by the reporter, whereas the nursing unit within the census history table is recorded by clerks each time a patient is admitted to their ward. I included location variables from both sources in order to validate the data recorded within the PSLS.

Upon linking these two datasets, several issues occurred. Firstly, the PSLS location type classified several events as non-inpatient, even though the Data Warehouse identified them all as inpatient encounters. This is somewhat expected, since a patient could experience an event in a non-inpatient location during their inpatient stay. I excluded All location types classified as Community, Outpatient, Medical Imaging, or Non-Clinical Area since they are considered non-inpatient locations. Critical Care includes all events that occurred in ICU, and the Emergency Department; if the actual location was an ICU ward, the event was kept, whereas all events that occurred in the emergency department were excluded. I retained all Laboratory and Pharmacy events for further investigation.

The second, and more problematic issue was that the majority of PSEs had a different nursing unit recorded within the PSLS and the Data Warehouse. In order to address this issue, I created a new ordinal variable to assess how well these two variables matched. A level 1 was assigned to all PSEs in which the PSLS location matched the Data Warehouse location exactly. A level 2 was assigned to all PSEs whose nursing unit differed due to spelling and formatting errors. A level 3 was assigned whenever the nursing unit differed, but the service was the same (e.g. both units were from a medicine ward). A Level 4 was assigned whenever the 2 nursing units were completely unrelated, and a match 99 was given to all Laboratory and Pharmacy events, since we would not expect their location to match.

Further investigation revealed that the majority of the mismatches were due to formatting errors (e.g. the nursing unit 5 Est was recorded in the PSLS as 5EST, and in the data warehouse, it was recorded as 5E). In

order to resolve level 3 and 4 matches, a Core Reviewer and myself reviewed a subset of these cases to develop a decision rule for choosing the correct location.

The Data Warehouse location from Census History was used as the correct location for the majority of the cases since the process for recording locations is more reliable. However, there are certain units that Census History does a poor job of capturing patient flow. These include all birthing units: (F4DE) and all temporary/transitional units (E2, PACU, SDCU, PAU). Therefore, whenever the PSLS recorded one of these units as the actual location, I chose it over the nursing unit recorded in Census History. Furthermore, the most common mismatched unit within the PSLS was the ICU wards. Since this occurred at a much higher frequency than other nursing units, it was not likely due to random error, and is most likely the correct location. Our review confirmed this assumption to be correct. Therefore, whenever the PSLS recorded ICU as the actual location of the event, I also chose it over the Census History location.

In order to determine the true location of Pharmacy, Perioperative, and Lab events, the same Core Reviewer and myself reviewed a sample of these events. One of each level 2 CCS classification was chosen for review (9 from Laboratory, 10 from perioperative, and 6 from pharmacy). If the event was due to an error on the nursing unit rather than in the lab, perioperative area, or pharmacy, I included the event. (For example, all mis-labeled specimens identified by lab were considered to be an error that occurred on a nursing unit, whereas a post analytical error such as incorrect results reported could be attributed to the lab, and was therefore not included).

Lastly, a small percentage of my data still had two nursing units from the data Warehouse associated with one PSLS PSE. This occurred whenever a patient changed nursing units on the same day that they experienced an event. Although the PSLS does contain a field to record the time of the event, it was often left blank since it is not a mandatory field. Furthermore, TOH staff may be entering these events several hours after they occur, so the time recorded may not be accurate. If the PSLS location was not on a birthing unit, temporary unit, or ICU ward, the correct nursing unit was chosen as the Census History location with the

highest match level. If the two match levels were the same, the nursing unit from the first encounter was selected. This only occurred in a fraction of our total cases and is unlikely to bias my results.

2.6.4 Program data

I also included variables pertaining to patient volume and staffing levels at the aggregate level of the hospital program in order to determine if systemic-level factors were associated with true events. These variables could not be obtained directly; they were computed using intermediate variables stored within different datasets of the data warehouse.

2.6.4.1 Staffing data

All staffing data for the Ottawa Hospital (TOH) is stored within the Staffing Level table. Staffing data is not assigned to a particular nursing unit, but rather by cost centre. In order to identify the cost centres associated with each nursing unit, I created a reference table linking the nursing units from my study cohort to the Nunit table, which contains a complete list of all Ottawa Hospital nursing units and their corresponding cost centres.

Once these cost centres were obtained, I was able to extract my staffing data. I abstracted all shifts worked by Registered Nurses and Registered Practical Nurses during my study period, the cost centre they were allocated to, as well as the start and end time for each shift. Therefore, each unique row represented a single shift worked by a nurse.

2.6.4.2 Patient volume data

I used the census history table to extract all adult inpatients admitted to any of the nursing units included in my study from April 1 2010-September 30 2011. Similar to the staffing dataset, I also linked to the Nunit table to identify the appropriate cost centre that each inpatient was admitted to.

The patient volume and staffing tables were linked using the cost centre code as the common variable. Not all values could be retained because there were some cost centre codes within the patient volume dataset that were not found within the staffing level dataset. Patients are sometimes moved onto newly created cost centres for which there is no staff allocated, therefore those cost centres do not exist in the staffing dataset. Since no staffing data could be obtained for those centres, I excluded all events associated with those cost centres.

With the remaining valid cost centres, I calculated the daily nurse to patient ratio by dividing the total number of daily nursing hours by the total number of daily patient hours for each cost centre. The nightly nurse to patient ratio was calculated in the same manner.

2.6.4.3 Aggregating cost centers to programs

Cost centres can be aggregated into 9 hospital programs mentioned above: Critical Care, Geriatrics, Medicine, Neuroscience and Endoscopy, Surgery, Heart Institute, Cancer, Nephrology, Obstetrics and Gynecology, and Transitional Care. To increase the number of events per cluster, I aggregated each cost centre was into their respective programs, using a reference table supplied by the Ottawa Hospital Performance Engagement team. Therefore, within the final dataset, there were 9 unique values for mean daily admissions, mean nightly admissions, mean number of patients at midnight, mean daily nurse to patient ratio, and mean nightly nurse to patient ratio. I linked this dataset back to my study cohort dataset using the cost centre code.

2.6.4.4 Reporter characteristics

I obtained the role of the reporter from a field in the PSLS, where the reporter is required to identify their job title. I further classified the job title into 5 categories: Nurse, Doctor, Manager, Lab, and Other (includes, clerks, technicians, orderlies, and other members of TOH staff not specified above). Further

investigation revealed that there were only 7 events reported by doctors and managers, therefore they were grouped into Other. There were 39 events that were missing a job title and were excluded from the study cohort.

2.6.4.5 Composite indices

The Charlson index, and Escobar score were calculated for each unique PSE once the final cohort had been derived. The variables included in these indices are stored within various tables of the data warehouse. I used the comorbid macro, developed by the Ottawa Hospital Performance Innovation team, to extract the relevant data and to calculate a Charlson and Escobar score for my study dataset.

2.6.4.6 Denominator for rate calculations

In order to obtain the denominator used in the rate calculations, I created a separate dataset which included the total number of adult inpatients admitted to the nursing units found in my study, over the length of my study period (April 1 2010-September 2011). I used the data warehouse macro ptdays to calculate the total number of patient days per nursing unit, per month, for the specified time period. This macro also calculates the total number of patient who were admitted and discharged from a particular nursing in less than 24 hours. For the purpose of my study, the total patient days was calculated as the sum of these two values. I linked this denominator back to my cohort dataset through the nursing unit, and summarized these values at the reporter and program level.

2.7 Covariate measures

2.7.1 Event characteristics

2.7.1.1 Number of months the PSLS was available

I categorized the number of months PSLS was available as less than or equal to 3 months, 4-7 months, 8-12 months, and greater than 12 months. Less than or equal to 3 months was used as the reference category. I calculated this variable by subtracting the date of the PSE (obtained from incidents table in PSLS) from the go live date for the program where the event occurred.

2.7.1.2 Time to event

The time to event was classified as same day, 1-5 days, or greater than 5 days. I decided to classify time to event as a categorical variable to determine if there was a significant difference in true events between an acute stay and an extended stay. I created these cut-points based on the frequency distribution of the variable in order to obtain an equal amount of subjects in each category. I gave events that occurred on the same day their own category, because these patients may be at a higher risk for an adverse event, since healthcare providers would be less familiar with the patient. I calculated this variable by subtracting the date of inpatient admission (extracted from OHDW Abstracts table) from the date of the PSE.

2.7.1.3 Event classification

I obtained event classification from the incidents table in PSLS. It was categorized into predefined event types using a 3 level hierarchical classification. Level 1 categorizes each event into 1 of 14 categories: Accident, behavior, clinical administration, clinical process/procedure, documentation, equipment/product/medical device, fall, healthcare associated infection, laboratory, maternity care, medication/IV fluid/biological (includes vaccine), nutrition, transfusion medicine, and vascular access line.

Level 2 and 3 classifications provides a more specific and granular description of the type of event that occurred.

2.7.1.4 Event severity

I obtained event severity from the incidents table in PSLS. The Core Reviewer classified event severity using a six-point ordinal scale of Nil, Physiological Abnormalities, Symptoms, Transient Disability, Permanent Disability, and Death. Nil indicates that no harm was caused to the patient. Physiological Abnormalities is chosen when the event causes changes in laboratory parameters and/or physical signs without causing any symptoms in the patient. Symptoms is chosen when the event caused patient discomfort but did not impair the patient's capacity to perform Activities of Daily Living (ADLs). Transient disability is the classification used when the event transiently impaired a patient's ability to perform ADLs. Permanent disability was chosen when the event permanently impaired the patient's ability to perform ADLs. Finally, Death was chosen whenever the event caused a patient's death.

2.7.2 Patient characteristics

2.7.2.1 Age

I calculated patient age at time of event by subtracting the patient's date of birth (obtained from Abtracts table in OHDW) from the date of PSE.

2.7.2.2 Sex

I abstracted the sex of the patient directly from the OHDW Abstracts table.

2.7.2.3 Diagnosis class

The diagnosis classes were derived from the ICD-10 Disease Classification. I obtained this variable from the Diagnosis table in OHDW and linked it to the other patient variables form the Abstracts table using the encounter ID. I only selected the diagnosis code for the most responsible diagnosis. Ten of the 22 classifications were used in my study and they include: Diseases of the blood and blood-forming organs and disorders involving the immune mechanism, Diseases of the circulatory system, Endocrine, nutritional, and metabolic diseases, diseases of the eye and adnexa, Factors influencing health status and contact with health services, Certain infections and parasitic diseases, Mental and behavioural disorders, Neoplasms, Diseases of the nervous system, and Diseases of the respiratory system.

2.7.2.4 Off service patients

I created off service as a binary yes/no variable. An off service patient was defined as any patient who was assigned to a ward that differed from their admitting service. For example, if a patient was admitted under general medicine, but was moved to a surgical ward to receive care, they would be considered off service. I identified off service events by using a lookup table created by another Performance Measurement analyst that displayed all possible combinations of TOH services and nursing units. All nursing units that were not part of that particular service were assigned a value of 1 for the off service variable. I linked the off service variable back to my analytical dataset by matching it to the service and nursing unit of the PSE.

2.7.2.5 Patient comorbidity

I used 2 variables to measure a patient's severity of illness: the Charlson Index and the Escobar score. I also included Individual components of the Escobar score such as the LAPS score (Laboratory-based Acute Physiology *S*core), Elixhauser index, elective admissions, emergency surgical admissions, and emergency non-surgical admissions as separate covariates.

I included both the Charlson Index and Escobar score because they measure different aspects of a patient's condition. The Charlson Index is a discrete scoring system which uses 17 diagnostic categories to evaluate a patient's chronic condition (Khan, 2010). Each patient is assigned a weighted score, depending on the number and seriousness of comorbidities present. The majority of clinical populations score between 0 and 6; the Data Warehouse then groups these scores into 4 ordinal categories: 0, 1-2, 3-4, and 5 and greater; where a score of zero indicates no comorbidities, and 5 or greater indicates several severe comorbidities. Although the Charlson score can predict long term mortality with high accuracy, it performs worse when trying to predict a patient's mortality acutely. Needham et al conducted a systematic review of previous studies that evaluated the Charlson Index, and found that it could predict in-hospital mortality with a discrimination of 0.67. A much stronger discrimination was achieved when more acute measures were taken into consideration. Another potential pitfall of the Charlson Index is that the 17 diagnostic categories are based on ICD-9 codes. Certain conditions within the OHDW are coded poorly using ICD codes and may not be represented in a patient's overall Charlson score, thus under-estimating the complexity of their condition.

The Escobar score uses age, sex, the LAPS score, admission type, admission diagnosis, and the Elixhauser index to estimate inpatient and 30-day risk adjusted mortality (Escobar, 2008). It can predict a patient's 30-day in-hospital mortality with 0.88 discrimination (Escobar, 2008). In contrast to the Charlson Index, the risk adjusted inpatient mortality can be used to determine a patient's acute condition upon admission. The inclusion of a chronic mortality and acute mortality index allowed me to get a more robust representation of a patient's condition.

Like Charlson, the Elixhauser index is used to measure the number and severity of comorbidities present. However, the Elixhauser index uses 30 dichotomous variables rather than 17 to represent different comorbidity groups. When compared directly, some studies showed that Elixhauser was slightly statistically superior to Charlson at adjusting for comorbidity (Dominick, 2005; Stukenboug, 2001; Southern, 2004). A

revised version of the Elixhauser score developed by van Walraven et al was used, which summarizes all 30 comorbidities into a single number using a weighting system similar to Charlson (van Walraven et al, 2009).

2.7.2.6 LAPS score

I obtained the LAPS score from the Lab Service table in OHDW. The LAPS score is a continuous variable that integrates information from 14 laboratory tests taken in the 24 hours following hospitalization. A point score is assigned to each lab parameter based on its deviation from the normal range and the probability of mortality. The scores from each test are added together to produce a total score, where a higher the score indicates a greater probability of mortality.

2.7.2.7 Admission type

I obtained the admission type from the Discharge Abstract table of OHDW. Admission type was classified as 3 binary yes/no variables: Elective, emergent surgical, non-emergent surgical.

2.7.3 Program characteristics

2.7.3.1 Mean daily admissions

I obtained the numerator for mean daily admissions from the Census History table in OHDW. I divided the total inpatient admissions for each program by the number of days between April 2010-September 30 2011 to produce a mean rate per day. I defined a daily admission as the total number of inpatient admissions that occurred between 7:30 am and 7:30 pm.

2.7.3.2 Mean nightly admissions

I calculated the mean admission at night using the same method as above. I defined as nightly admission as any inpatient admission that occurred between 7:30 pm and 7:30 am.

2.7.3.3 Number of patients at midnight

I calculated the number of patients at midnight in two steps. First, the number of times each patient encounter crossed midnight was calculated and summed for each cost centre. Secondly, this number was divided by the total number of days between April 1 2010 and September 30 2011.

2.7.3.4 Daily nurse to patient ratio

For each program, I calculated the daily nurse to patient ratio by dividing the total number of nursing hours worked during a day shift by the total inpatient hours during the day. Similar to above, the day period was defined by the hours between 7:30 am - 7:30 pm.

2.7.3.5 Nightly nurse to staff ratio

I calculated nightly nurse to patient ratios using the same method as daily nurse to patient ratios, except I included the hours between 7:30 pm-7:30 am.

2.8 Statistical analysis

2.8.1 Statistical Software

I performed all statistical analyses using SAS 9.3.

2.8.2 Objective 1: Determine the positive predictive value of the PSLS

I calculated the positive predictive value by dividing the number of true events by the total number of patient safety events reported. I further subdivided the number of true events into the frequency and proportion of true event types reported (AEs, preventable AEs, non-preventable AEs, near misses).

2.8.3 Objective 2: Determine an optimal model that can accurately predict the probability of a true event being reported

2.8.3.1 Descriptive statistics

Before the model was generated, I conducted some preliminary analyses to assess the characteristics of my study population. I performed a separate bivariate analysis for each program, using the covariates listed above. For all categorical variables, I recorded the frequency and proportion of each level, and for all continuous variables I reported the mean and standard deviation, along with the median and IQR. Within each program there were 2 columns, the first column displayed descriptive statistics for all events reported for that particular program, while the second column contained true events only.

2.8.3.2 Simple Covariate Analysis

I conducted a simple covariate analysis of the above covariates to identify potential predictors of true events. Each estimate was adjusted by program and reporter, where each program was assigned a random intercept and each reporter a random slope. All estimates with a p value of less than or equal to 0.20 were included in the preliminary model. I did not force any variables into the model, because I only wanted to include variables that were statistically significant in my final model. If well established clinically sensible variables do not show up as significant in my final model, it would suggest that healthcare workers are not using the system appropriately.

2.8.3.3 Model selection

The desired model was a hierarchical logistic regression model, where each PSE is nested within the role of the reporter, and each reporter is nested within the program they belong to. Hospital data contains an inherent hierarchical structure. Reporters with the same job title are likely to record events in a similar way,

and reporters within the same program who are under the same clinical manager are also likely to have similar reporting habits. Therefore, the assumption made in traditional regression models that all observations are independent is clearly violated. Ignoring the effects of clustering would result in overestimating the number of independent observations that exist. This would, in turn lead to underestimation of the standard error, more narrow confidence intervals, and an underestimation of the p value.

Therefore, it is reasonable to group individual data into clusters. The most granular level of data included all event-level and patient-level variables. Although multiple events occurring in the same patient would be correlated, the majority of patients in my study dataset only have one or two events recorded. Thus, the size of patient clusters would be very small, which would significantly reduce the power to detect between-cluster differences.

Each unique event was clustered by the role of the reporter, which belonged to one of three categories: Nurse (including both RNs and RPNs), Lab staff, or Other. Each reporter was then grouped by their respective hospital program: Critical Care, Geriatrics and Short-term Rehab, Heart Institute, Integrated Cancer Program, Medicine/Neuroscience and Endoscopy, Nephrology, Obstetrics and Gynecology, Surgery and Perioperative Program, and Transitional Care.

The two approaches I considered for modeling the hierarchical data with a dichotomous outcome included: the Generalized Estimated Equations (GENMOD) and the Generalized Linear Mixed Models (GLIMMIX). The GENMOD procedure calculates the population averaged effect for each covariate so that one regression coefficient is used for all clusters. The correlation within a cluster is not known and not of interest. In contrast, the GLIMMIX procedure calculates cluster-specific effects, where each covariate has a different regression coefficient for each cluster. In this case, the correlation within clusters is known and of interest. For these reasons, the GLIMMIX model was chosen over GENMOD so that I could obtain the program and reporter-specific effects.

2.8.3.4 Model assumption

All model assumptions were validated before I began building my model. The assumptions for the GLIMMIX model are as follows: 1) All random effects are normally distributed with a mean zero and a non-zero covariance matrix G. 2) All error terms have a normal distribution with a mean of zero and an independent variance structure. 3) The random effects and errors are independent of each other.

I investigated the distribution of program and reporter random effects using the univariate procedure which produced histograms of the distribution of the random effect residuals. The p value from the goodness of fit test was also taken into consideration. The null hypothesis from this test is that the mean is equal to zero, therefore a p value of greater than 0.05 would indicate a failure to reject the null hypothesis, and we can conclude that the distribution of random effects is normal.

The G covariance matrix is a matrix of the variance of the random effects.
It measures the extent to which the outcome measures within a cluster are related.
Consider the equation for a generalized linear mixed model:

$y_{ij} = \beta_0 + \beta x_{ij} + \gamma_i$

Where y represents the outcome variable (true PSE), β_0 represents the intercept, βx_{ij} represents the fixed effects covariates for each observation, j within a cluster i, and γ_i are pair-specific random effects that model heterogeneity across clusters (in this case, across reporters and program). A covariance G matrix is then plotted for each possible pair-wise combination between clusters, as seen below:

$$\mathrm{Var}[\gamma] = \mathrm{Var}\begin{bmatrix} \gamma_1 \\ \gamma_2 \\ \gamma_3 \\ \vdots \\ \gamma_r \end{bmatrix} = \begin{bmatrix} \sigma^2_\gamma & 0 & 0 & \cdots & 0 \\ 0 & \sigma^2_\gamma & 0 & \cdots & 0 \\ 0 & 0 & \sigma^2_\gamma & \cdots & 0 \\ \vdots & \vdots & \vdots & \ddots & \vdots \\ 0 & 0 & 0 & \cdots & \sigma^2_\gamma \end{bmatrix}$$

In a traditional logistic regression model, where each observation is independent, the covariance matrix is zero.

In order to evaluate the G matrix, I conducted a covariance test on the intercept only model using the COVTEST option in the GLIMMIX model. The covariance test tests the null hypothesis that the G matrix is zero, meaning there is no correlation within clusters. A p value of greater than 0.05 indicates a statistically significant correlation between clusters and validates our assumptions that clustering by program and reporter is necessary. I conducted this test on three separate models; one including only the reporter as the random intercept, another which included only the program as the random intercept, and a third which included the program as a random intercept and the reporter as a random slope nested within each program. If the p value was greater than 0.05, and there was a sufficient sample size in each cluster (10 outcomes per cluster, per variable), then I used the GLIMMIX model as the final model, otherwise, I used a traditional logistic regression with a common intercept.

2.8.3.5 Model building

2.8.3.5.1 Selection of a candidate model

From the simple covariate analysis, I determined an optimal model using forward selection. I fit all models using restricted pseudo-likelihood. I added all covariates with a p value of less than 0.20, starting with the most granular level of data; I added significant event-level covariates first, followed by patient-level, then nursing unit. Within each level, the covariates were added in the order of increasing p value. I only included significant ($p<0.05$) covariates, or non-significant covariates with a significant Likelihood Ratio Test in the candidate multivariate model. I used the method=quad option to obtain the maximum likelihood estimates.

Charlson Index, Elixhauser Index, Escobar score, and components of the Escobar score are all measures of severity of a patient's condition; if more than one of these covariates were included in the final model, it

would constitute over-fitting. Therefore, I fitted each measure of severity that was significant in the univariate analysis into a different multivariate model. (There can be a maximum of four candidate multivariate models). I chose the best candidate model based on the diagnostic measures listed below.

2.8.3.5.2 Diagnostics

I used the Hosmer-Lemeshow test and AIC to assess the fit of the model. The Hosmer Lemeshow test orders each observation (in this case, each PSE) in order of increasing probability of an event along a chi squared distribution. These observations are then grouped into groups with a desired size, M equal to:

M= [0.1 + N + 0.5], where N is the size of the total sample.

The Hosmer-Lemeshow statistic is derived from a Pearson chi square test, which calculates the difference between the predicted and observed probabilities for each group. The equation is provided below

$$\chi^2_{HL} = \sum_{i=1}^{g} \frac{(O_i - N_i\bar{\pi}_i)^2}{N_i\bar{\pi}_i(1-\bar{\pi}_i)}$$

Where g is the total number of groups, O_i is the frequency of events in the ith group, and $N_i\pi_i$ is the predicted frequency of events in the ith group. (N_i is the sample size of the ith group, and π_i is the estimated probability of an event in the ith group). A low chi square statistic and a high p value indicate a small difference in the number of observed and predicted outcomes, and thus a model of good fit and calibration.

I evaluated the predictive ability of the model using the c statistic, which denotes the area under a sensitivity vs. 1-specificity graph. This number represents the proportion of times the model was able to correctly distinguish between a true event and a non-event.

I identified potential outliers using Pearson residual plots of all significant covariates, and DFBETA plots to identify any influential data points. The effects of these data points were investigated by conducting a

sensitivity analysis, in which the final model was re-run without these points. If the fixed regression coefficients changed by 10.0% or greater, I removed it from the model.

2.8.3.5.3 Iterations to the candidate model

After determining a candidate model, I performed the following iterations in order to achieve an optimal model. First, I re-introduced variables that were insignificant in the previous iterations; I retained them if the likelihood ratio test was significant, or if they had a p value of less than 0.05.

I also developed interaction terms between fixed effects a priori, which I introduced into the optimal candidate model if they were included as a single term. I investigated the following interactions: escobar and time to event, elixhauser and time to event, laps and time to event. If I chose logistic regression as the final model, I also considered the interaction of the role of the reporter with either day to event, laps, escobar, or elixhauser. I retained the interaction terms in the final model if they had a p value of less than 0.05, or a significant ($p < 0.05$) likelihood ratio test.

Next, if a GLIMMIX model was chosen as the candidate model, I considered the addition of a random slope term; if the AIC while using the method=QUAD option decreased, I retained the random slope term in the model.

Lastly, I also took sample size into consideration when selecting a final model. Some programs had a low number (less than 10), of outcomes per reporter and covariate, therefore a glimmix model may not be appropriate. For models with less than 10 outcomes per covariate and reporter, I used a traditional logistic regression model.

2.8.3.5.4 Data transformations

After the above iterations were carried out, I carried out data transformations when necessary. If a continuous variable was included in the candidate model, I produced loess plots to examine its linearity. When variables appeared to be non-linear, I performed the appropriate data transformation. If the likelihood ratio was significant, I retained the transformed variable in the final model.

2.8.3.5.5 Measures of variability

2.8.3.5.5.1 Median odds ratio (MOR)

In order to assess the relative impact of event and patient, reporter, and program level effects on the likelihood of a true event, the Median Odds Ratio (MOR) was used. The MOR computes all possible odds ratios for the likelihood of a true event between 2 observations from different clusters with similar event and patient characteristics. The distribution of all possible values is plotted against its probability density, and the median value is selected as the MOR. The MOR depicts the increased odds of a true event when an individual moves to a program or reporter with a greater likelihood of reporting a true event. The values range from 1 to infinity, since the cluster with the greater odds is always placed in the numerator. In practice, it is not necessary to compute all possible combinations of odds ratios; the MOR can be computed directly from the cluster-level variance using the following formula:

$$MOR = \exp[\sqrt{(2 \times V_A)} \times 0.6745]$$

Where V_A is the variance between clusters, and 0.6745 is the 75^{th} centile of the cumulative distribution function of the normal distribution with a mean 0 and variance 1.

The MOR has several advantages. Firstly, it is independent of the outcome prevalence and is only a function of the cluster-level variance. Secondly, it can be easily computed from an intercept only model as well as a full model. Lastly, it can be directly compared to the odds ratios from individual-level covariates so that the relative strength of each can be assessed. If the MOR is greater than individual level covariates, then cluster-level factors have a greater impact on the likelihood of an event (Merlo, 2006).

3.0 Results

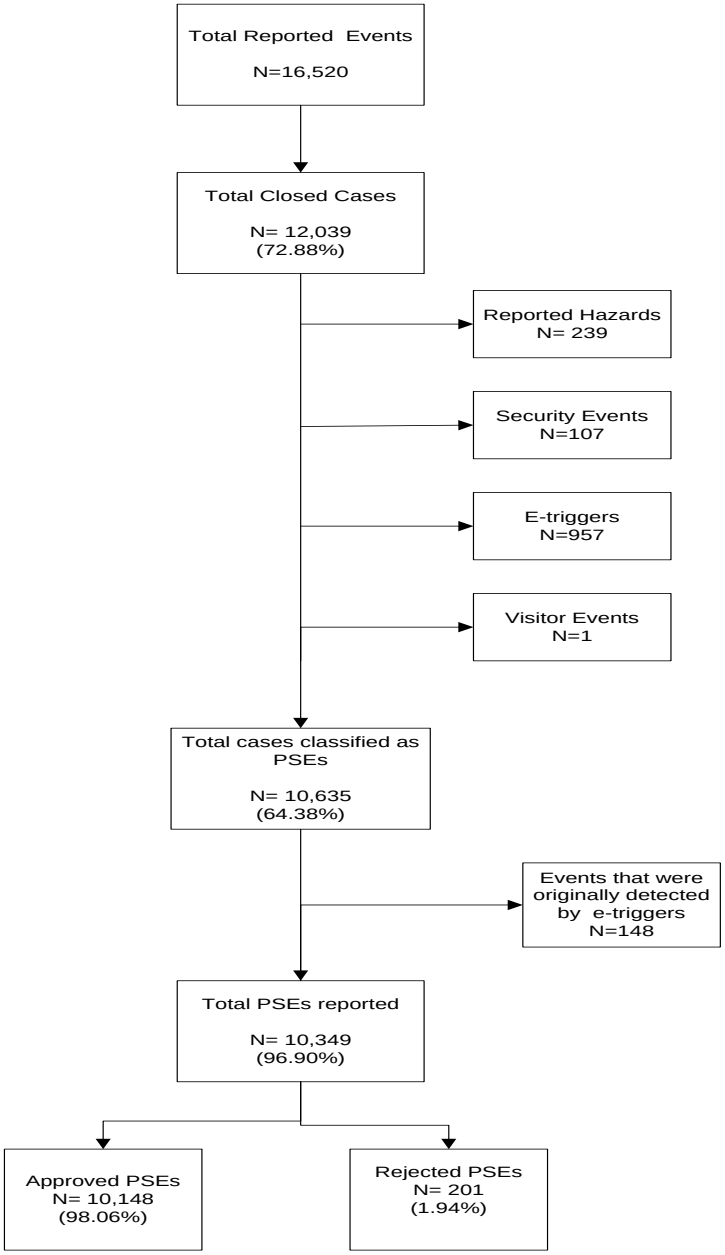
3.1 Cohort derivation

To define all relevant study variables, it was necessary to link data from several sources. This section describes this process by demonstrating the numbers of events identified and excluded at each stage of the linking process.

3.1.1 Extracting patient-level characteristics

Of the 16,520 events in the PSLS, there were 10,635 closed patient safety events. Of these, 201 events were rejected by the core reviewer as non PSEs, resulting in 10, 148 approved PSEs. E-triggers were excluded because these are events that are electronically detected with an algorithm, and do not represent events

reported to the PSLS by healthcare providers. The derivation of true PSEs from the PSLS dataset is depicted in Figure 3 below.



Number of reported events detected by the Patient Safety Learning System (PSLS) from Apr 1 2010 – Sept 30 2011

Figure 3 Total number of closed patient safety events reported to the Patient Safety Learning System from April 2010-September 30 2011

Next, I linked the PSLS dataset to the encounters table in the OHDW using patient MRN; the process is summarized in figure 4 below. Out of the 10,349 closed PSEs within the original cohort dataset, 1,715 did not have a valid mrn. This reduced our total number of valid events to 8,634 PSEs for 6,418 patients. I was able to retrieve encounter data for all patients except for 1, whose patient id was not found in the encounters table, therefore this patient was excluded. I excluded 1,807 patients because they did not have an encounter status of inpatient, or their event date did not coincide with their inpatient encounter start and end date. I excluded an additional 267 inpatients under the age of 18 and 280 inpatients without valid data in the abstracts dataset . Therefore, there were 4,063 remaining inpatients and 5,637 PSEs.

Since the PSLS and encounter dataset can only be linked by patient, there were multiple encounters that overlap with 1 PSE. Within our dataset, there were a total of 5,481 unique PSEs, and 56 PSEs that can be linked to more than 1 patient encounter. The correct encounter was identified once more information was collected.

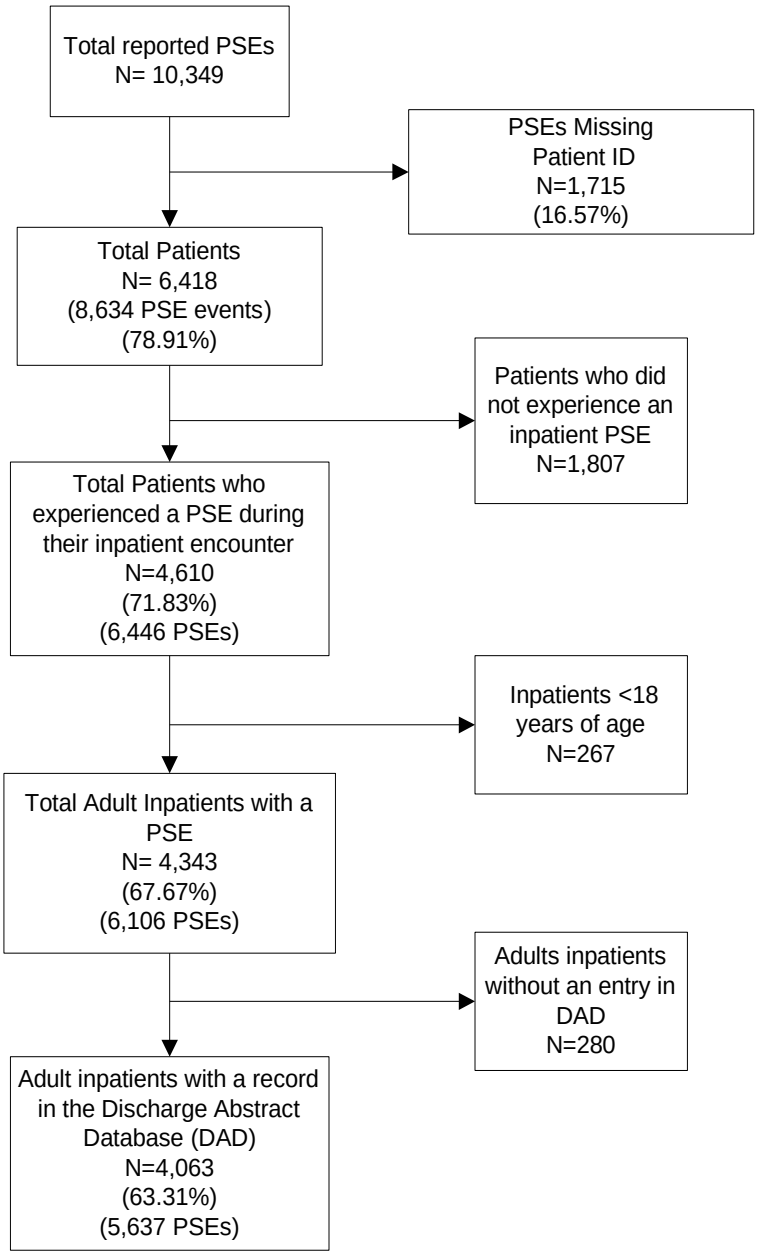


Figure Linking PSLS data to OHDW to obtain encounter and patient characteristics

***F*igure 4** Linking PSLS data to the OHDW encounters table to obtain encounter and patient characteristics

3.1.2 Mapping each event to a nursing unit and program

I obtained my program level variables by linking to the Census History table in OHDW using patient encounter id; the flowchart in figure 5 shows the derivation. When linking to the Census History dataset, 257

patients were excluded because their event date did not overlap with a start and end date for their nursing unit. There were 1,682 events that occurred during an inpatient stay but not on a nursing unit; in decreasing order of frequency, these included: critical care, perioperative, laboratory, outpatient, pharmacy, medical imaging, non-clinical areas, and community events. 711 of these events occurred in the emergency department, outpatient, medical imaging, community, and non-clinical areas and were excluded from our study cohort.

In the remaining 4,580 events, 1,361 had an exact match between the PSLS and Census History location (Level 1 match), 2,624 events differed due to a spelling or formatting error (level 2 match), 162 events differed on hospital service (Level 3 match), and 53 events had a PSLS and Census History location that were completely unrelated. Furthermore, 380 events were classified as Laboratory, Perioperative, or Pharmacy; 197 of these were identified as events that occurred on a nursing unit, while the remaining 183 were excluded.

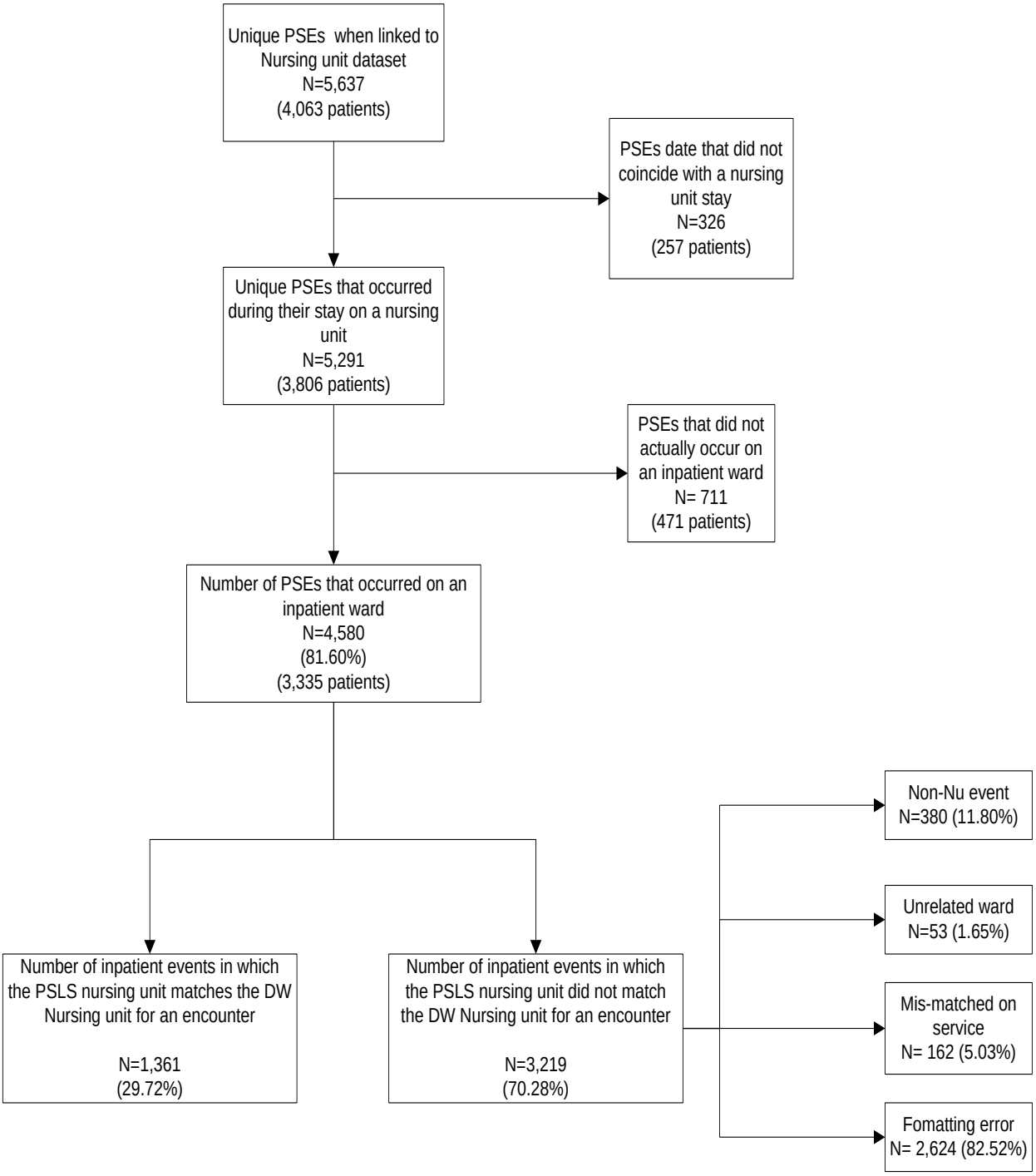


Figure 5 Linking PSLS data to the census history table in OHDW to obtain program level characteristics

3.1.3 Extracting staffing data for each hospital programs

When linked to the staffing dataset, 250 events did not have a valid cost centre code within the staffing level dataset; all of these events came from 6 nursing units: DCUS, C3PA, E1, SDON, C3SI, and PANU.

3.1.4 Final data quality checks

Furthermore, there were 42 events with an incorrect event classification, where the assessment of patient harm did not match the classification of event type (e.g. no patient harm was reported, however the classification for preventable vs. non-preventable events was filled out. Lastly, there were 39 events that were missing a job title, therefore the type of reporter could not be identified. These exclusions reduced my final cohort study dataset to 4,066 unique PSEs, 3,008 patients, 48 unique nursing units, and 41 cost centres. I included a flowchart of the final cohort derivation below in Figure 6.

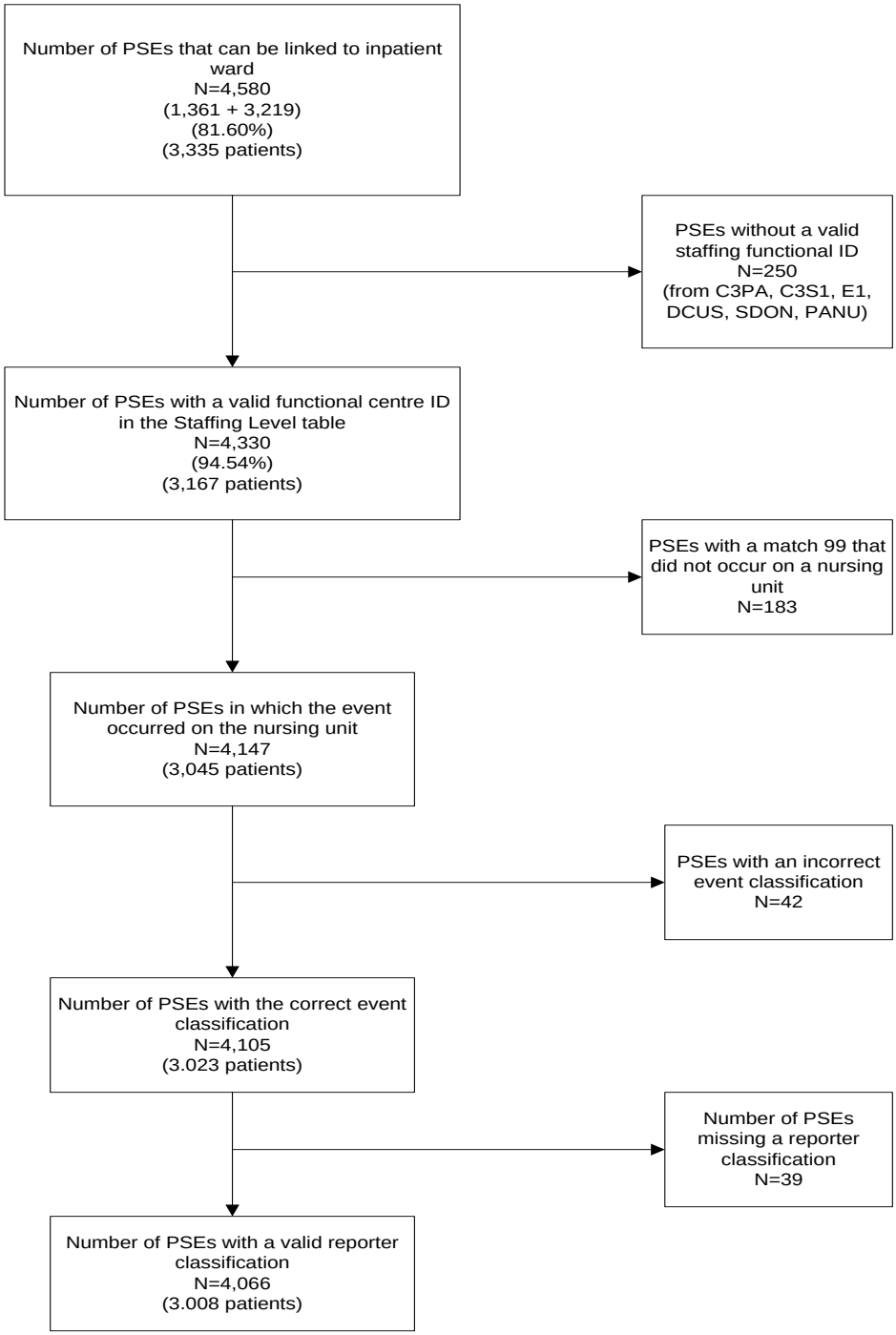


Figure Linking PSLS data to nursing unit and staffing level tables in OHDW to obtain program-level characteristics

Figure 6 Linking PSLS data to staffing level table to obtain staffing data, and final exclusions

3.2 Descriptive statistics by program

3.2.1 Proportion of true events and sample size

Table 7 depicts the frequency of total events and true events reported by hospital program. The sample size in each program varied substantially, which can be attributed to the differences in go live dates for different programs, as well as differences in reporting behaviours. Medicine and neurosciences was the only program that was available for more than 12 months; as a result, it had the highest number of events recorded (N=1,270). In decreasing order, the sample sizes for the remaining programs were: 882 events in Surgery and Perioperiative program, 456 events from Critical Care, 434 events in Obstetrics and Gynecology, 363 events in the Integrated Cancer Program, 335 events reported in the Heart Institute, 190 events in Nephrology, 92 events from the Transitional Care Unit, and only 44 events reported in Geriatrics and Short-Term Rehab. The proportion of true events ranged from 70.00% in Nephrology to 47.93% in Obstetrics and Gynecology.

Table 7 Bivariate analysis of reporting frequency by program

	Total events	**True events**
Critical Care	N=456	N=305 (66.9%)
Geriatrics and Short term Rehab	N=44	N=25 (56.8%)
Heart Institute	N=335	N=188 (56.1%)
Cancer	N=363	N=242 (66.7%)
Medicine	N=1,270	N=864 (68.0%)
Nephrology	N=190	N=133 (70.0%)
Obstetrics and Gynecology	N=405	N=187 (46.2%)
Surgery and Periops	N=911	N=574 (63.0%)
Transitional Care	N=92	N=51 (55.4%)
Total	**N=4,066**	**N=2,569**

3.2.2 Event type

Table 8 depicts the frequency of event types reported by program, since event type was only recorded for true events, I chose to show the results for true events only. Overall, near misses represented the majority of true PSEs reported (N=1,909, 74.3%). This was consistent across all programs; the range varied from 56.9% (N=29) in Transitional Care to 94.1% in Heart Institute (177). 15.1% (N=387) of all true PSEs were

preventable; this ranged from 1.6% (N=3) in the Heart Institute, to 33.3% (N=17) in Transitional Care. Lastly, 10.6% (273) of all true PSEs were classified as non-preventable; this varied from 4.3% (N=8) in the Heart Institute, to 11.1% (N=34) in Critical Care.

Table 8 Event type by program, true events only

	Near Miss	Preventable AE	Non-Preventable AE
Critical Care	252 (82.6%)	19 (6.2%)	34 (11.1%)
Geriatrics and Short term Rehab	19 (76.0%)	4 (16.0%)	2 (8.0%)
Heart Institute	177 (94.1%)	3 (1.6%)	8 (4.3%)
Cancer	188 (77.7%)	29 (12.0%)	25 (10.3%)
Medicine	561 (64.9%)	199 (23.0%)	104 (12.0%)
Nephrology	104 (78.2%)	17 (12.8%)	12 (9.0%)
Obstetrics and Gynecology	140 (74.9%)	23 (12.3%)	24 (12.8%)
Surgery and Periops	439 (76.5%)	76 (13.2%)	59 (10.3%)
Transitional Care	29 (56.9%)	17 (33.3%)	5 (9.8%)
Total	1,909 (74.3%)	387 (15.1%)	273 (10.6%)

3.2.3 Event class

Table 9 depicts the frequency of event types reported by program, since event type was only recorded for true events, I chose to show the results for true events only. Overall, laboratory events were the most common event reported, representing 46.0% (N=1,182) of all PSEs. This varied from 31.0% (N=268) in Medicine to 72.0% (N=18) in Geriatrics and short term Rehab and Heart Institute. Laboratory events were the most common PSE in all programs except for Transitional Care, in which Falls were the most common PSE.

Overall, falls were the second most common PSE, representing 17.6% (N=451) of all PSEs; this ranged from 6.6% (N=20) in Critical Care to 27.9% (N=241) in Medicine.

Medication-related events were the third most common event overall, representing 14.5% (N=372) of all PSEs; this ranged from 3.9% (N=2) in Transitional Care to 20.1% (N=174) in Medicine.

Table 9 Event class by program, true events only

	Missing	Laboratory	Fall	Medication/ IV fluid/ biological (includes vaccine)	Documentation	Clinical process/ procedure
Critical Care	1 (0.3%)	190 (62.3%)	20 (6.6%)	36 (11.8%)	10 (3.3%)	22 (7.2%)
Geriatrics and Short term Rehab	0 (0.0%)	18 (72.0%)	6 (24.0%)	1 (4.0%)	0 (0.0%)	0 (0.0%)
Heart Institute	0 (0.0%)	18 (72.0%)	6 (24.0%)	1 (4.0%)	0 (0.0%)	0 (0.0%)
Cancer	0 (0.0%)	124 (51.2%)	28 (11.6%)	28 (11.6%)	25 (10.3%)	12 (5.0%)
Medicine	1 (0.1%)	268 (31.0%)	241 (27.9%)	174 (20.1%)	68 (7.9%)	62 (7.2%)
Nephrology	0 (0.0%)	64 (48.1%)	18 (13.5%)	17 (12.8%)	19 (14.3%)	8 (6.0%)
Obstetrics and Gynecology	0 (0.0%)	66 (35.3%)	17 (9.1%)	23 (12.3%)	13 (7.0%)	28 (15.0%)
Surgery and Periops	1 (0.2%)	265 (46.2%)	96 (16.7%)	85 (14.8%)	55 (9.6%)	40 (7.0%)
Transitional Care	0 (0.0%)	19 (37.3%)	21 (41.2%)	2 (3.9%)	2 (3.9%)	0 (0.0%)
Total	**3 (0.1%)**	**1,182 (46.0%)**	**451 (17.6%)**	**372 (14.5%)**	**194 (7.6%)**	**174 (6.8%)**

Table 9 cont'd Event class by program, true events only

	Transfusion medicine	Equipment/ product/ medical device	Clinical administration	Vascular access lines	Accident (no falls)	Nutrition
Critical Care	9 (3.0%)	10 (3.3%)	2 (0.7%)	3 (1.0%)	1 (0.3%)	1 (0.3%)
Geriatrics and Short term Rehab	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Heart Institute	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cancer	7 (2.9%)	2 (0.8%)	5 (2.1%)	1 (0.4%)	2 (0.8%)	3 (1.2%)
Medicine	13 (1.5%)	7 (0.8%)	7 (0.8%)	6 (0.7%)	6 (0.7%)	3 (0.3%)
Nephrology	2 (1.5%)	1 (0.8%)	2 (1.5%)	1 (0.8%)	0 (0.0%)	0 (0.0%)
Obstetric and Gynecology	10 (5.3%)	8 (4.3%)	11 (5.9%)	0 (0.0%)	0 (0.0%)	2 (1.1%)
Surgery and Periops	13 (2.3%)	7 (1.2%)	3 (0.5%)	4 (0.7%)	3 (0.5%)	2 (0.3%)
Transitional Care	0 (0.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)	1 (2.0%)
Total	**59 (2.3%)**	**37 (1.4%)**	**30 (1.2%)**	**15 (0.6%)**	**13 (0.5%)**	**12 (0.5%)**

Table 9 cont'd Event class by program, true events only

	Behaviour	Maternity care	Healthcare associated infection	Sterilization/ disinfection	Illness
Critical Care	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Geriatrics and Short term Rehab	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Heart Institute	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cancer	2 (0.8%)	0 (0.0%)	3 (1.2%)	0 (0.0%)	0 (0.0%)
Medicine	4 (0.5%)	0 (0.0%)	4 (0.5%)	0 (0.0%)	0 (0.0%)
Nephrology	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)
Obstetrics and Gynecology	0 (0.0%)	8 (4.3%)	1 (0.5%)	0 (0.0%)	0 (0.0%)
Surgery and Periops	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Transitional Care	4 (7.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Total	**10 (0.4%)**	**8 (0.3%)**	**9 (0.4%)**	**0 (0.0%)**	**0 (0.0%)**

3.2.4 Event severity

Table 10 depicts the frequency of event types reported by program, since event type was only recorded for true events, I chose to show the results for true events only. Overall, 73.5% (N=1,888) of all true PSEs did not cause harm to the patient; this varied from 64.7% (N=559) in Medicine to 92.0% in Heart Institute.

Table 10 Bivariate analysis of event severity by program, true events only

	Missing	Death	Nil	Permanent disability	Physiological Abnormalities	Symptoms	Transient Disability	Unknown
Critical Care	1 (0.3%)	0 (0.0%)	239 (78.4%)	0 (0.0%)	8 (2.6%)	27 (8.9%)	1 (0.3%)	29 (9.5%)
Geriatrics and Short term Rehab	0 (0.0%)	0 (0.0%)	17 (68.0%)	0 (0.0%)	0 (0.0%)	6 (24.0%)	0 (0.0%)	2 (8.0%)
Heart Institute	0 (0.0%)	0 (0.0%)	173 (92.0%)	0 (0.0%)	0 (0.0%)	4 (2.1%)	0 (0.0%)	11 (5.9%)
Cancer	0 (0.0%)	0 (0.0%)	188 (77.7%)	0 (0.0%)	5 (2.1%)	35 (14.5%)	2 (0.8%)	12 (5.0%)
Medicine	1 (0.1%)	1 (0.1%)	559 (64.7%)	0 (0.0%)	32 (3.7%)	234 (27.1%)	12 (1.4%)	25 (2.9%)
Nephrology	0 (0.0%)	0 (0.0%)	101 (75.9%)	0 (0.0%)	4 (3.0%)	24 (18.0%)	0 (0.0%)	4 (3.0%)
Obstetrics and Gynecology	0 (0.0%)	1 (0.5%)	140 (74.9%)	1 (0.5%)	5 (2.7%)	29 (15.5%)	6 (3.2%)	5 (2.7%)
Surgery and Periops	0 (0.0%)	2 (0.3%)	439 (76.5%)	0 (0.0%)	10 (1.7%)	101 (17.6%)	3 (0.5%)	19 (3.3%)
Transitional Care	0 (0.0%)	0 (0.0%)	32 (62.7%)	0 (0.0%)	0 (0.0%)	18 (35.3%)	0 (0.0%)	1 (2.0%)
Total	**2 (0.1%)**	**4 (0.2%)**	**1,888 (73.5%)**	**1 (0.0%)**	**64 (2.5%)**	**478 (18.6%)**	**24 (0.9%)**	**108 (4.2%)**

3.3 Description of random effects

3.3.1 Role of reporter

Table 11 depicts the frequency of reporting by role of reporter. Nurses reported 44.4%(N=1,807) of all PSEs, Laboratory staff was responsible for 41.6% (N=1,690) of all PSEs reported, and other TOH staff reported 14.0% (N=569) of all PSEs. Nurses reported the majority of events in the Transitional Care Unit, Surgery and Periops, Obstetrics and Gynecology, Nephrology, and Medicine, with proportions ranging from 41.1% in Nephrology to 58.7% in Transitional Care Unit. Lab was responsible for the majority of events in the remaining programs; the proportion ranged from 45.7% in Integrated Cancer Program to 73.4% in the Heart Institute. Overall, only 4 cases resulted in death: 2 deaths were reported in Surgery and Periops, 1 death was reported from Medicine, and 1 death was reported from Obstetrics and Gynecology.

Table 11 Bivariate analysis of role of reporter, by program

	Lab		Nurse		Other	
	Total events	**True events**	**Total events**	**True events**	**Total events**	**True events**
Critical Care	253 (55.5%)	166 (54.4%)	124 (27.2%)	92 (30.2%)	79 (17.3%)	47 (15.4%)
Geriatrics and Short term Rehab	25 (56.8%)	14 (56.0%)	11 (25.0%)	6 (24.0%)	8 (18.2%)	5 (20.0%)
Heart Institute	246 (73.4%)	139 (73.9%)	17 (5.1%)	8 (4.3%)	72 (21.5%)	41 (21.8%)
Cancer	166 (45.7%)	117 (48.3%)	150 (41.3%)	102 (42.1%)	47 (12.9%)	23 (9.5%)
Medicine	408 (32.1%)	238 (27.5%)	737 (58.0%)	550 (63.7%)	125 (9.8%)	76 (8.8%)
Nephrology	75 (39.5%)	59 (44.4%)	78 (41.1%)	53 (39.8%)	37 (19.5%)	21 (15.8%)
Obstetric and Gynecology	122 (30.1%)	62 (33.2%)	209 (51.6%)	104 (55.6%)	74 (18.3%)	21 (11.2%)
Surgery and Periops	369 (40.5%)	237 (41.3%)	427 (46.9%)	275 (47.9%)	115 (12.6%)	62 (10.8%)
Transitional Care	26 (28.3%)	18 (35.3%)	54 (58.7%)	30 (58.8%)	12 (13.0%)	3 (5.9%)
Total	**1,690 (41.6%)**	**1,050 (40.9%)**	**1,807 (44.4%)**	**1,220 (47.5%)**	**569 (14.0%)**	**299 (11.6%)**

3.4 Description of fixed effects

3.4.1 Event-level covariates

3.4.1.1 Number of months PSLS was available

Table 12 depicts a bivariate analysis of the percentage of true events reported, by hospital program and number of months the PSLS was available. The overall frequency distribution of events recorded over time was as follows: 18.2% (N=738) of all events were recorded within 3 months of less of the PSLS being made available, 39.6% (N=1,611) were recorded within 4-7 months, 37.2% (N=1,513) of all events were reported within 8-12 months, and 5.0% (N=204) were reported after 12 months (all from Medicine). Critical Care, Geriatrics and Short-Term rehab, the Heart Institute, Obstetrics and Gynecology, Nephrology, as well as the Transitional Care Unit, all had the greatest proportion of PSEs recorded within 4-7 months of the PSLS being available, ranging from 46.8% in Nephrology to 52.3% in Geriatrics and Short Term Rehab. Within Medicine, Neuroscience and Endoscopy, Integrated Cancer program, and Surgery and Periops, the highest proportion of events was recorded within 8-12 months of the PSLS being available, ranging from 32.8% in Medicine to 52.9% in the Integrated Cancer program.

Table 12 Bivariate analysis of number of months the PSLS was available, by program

	3 months or less		4-7 months		8-12 months		Over 12 months	
	Total events	**True events**	**Total events**	**True events**	**Total events**	**True events**	**Total events**	**True events**
Critical Care	119 (26.1%)	90 (29.5%)	214 (46.9%)	158 (51.8%)	123 (27.0%)	57 (18.7%)	0 (0.0%)	0 (0.0%)
Geriatrics and Short term Rehab	13 (29.5%)	13 (52.0%)	23 (52.3%)	10 (40.0%)	8 (18.2%)	2 (8.0%)	0 (0.0%)	0 (0.0%)
Heart Institute	94 (28.1%)	76 (40.4%)	164 (49.0%)	93 (49.5%)	77 (23.0%)	19 (10.1%)	0 (0.0%)	0 (0.0%)
Cancer	48 (13.2%)	39 (16.1%)	123 (33.9%)	86 (35.5%)	192 (52.9%)	117 (48.3%)	0 (0.0%)	0 (0.0%)
Medicine	251 (19.8%)	143 (16.6%)	399 (31.4%)	307 (35.5%)	416 (32.8%)	295 (34.1%)	204 (16.1%)	119 (13.8%)
Nephrology	28 (14.7%)	26 (19.5%)	89 (46.8%)	65 (48.9%)	73 (38.4%)	42 (31.6%)	0 (0.0%)	0 (0.0%)
Obstetrics and Gynecology	48 (11.9%)	35 (18.7%)	191 (47.2%)	86 (46.0%)	166 (41.0%)	66 (35.3%)	0 (0.0%)	0 (0.0%)
Surgery and Periops	114 (12.5%)	96 (16.7%)	361 (39.6%)	246 (42.9%)	436 (47.9%)	232 (40.4%)	0 (0.0%)	0 (0.0%)
Transitional Care	23 (25.0%)	19 (37.3%)	47 (51.1%)	26 (51.0%)	22 (23.9%)	6 (11.8%)	0 (0.0%)	0 (0.0%)
Total	**738 (18.2%)**	**537 (20.9%)**	**1,611 (39.6%)**	**1,077 (41.9%)**	**1,513 (37.2%)**	**836 (32.5%)**	**204 (5.0%)**	**119 (4.6%)**

3.4.1.2 Day to event

Table 13 depicts a bivariate analysis of true events reported, by hospital program and time from admission to PSE. In total, 14.3% (N=581) of all events were recorded on the same day as an admission to an inpatient ward, 40.6% (N=1,651) were recorded within 1-5 days, and 45.1% (N=1,834) were recorded after 5 days. With the exception of Nephrology, Obstetrics and Gynecology, and Surgery, the majority of PSEs were reported after more than 5 days of admission, with proportions ranging from 46.7% in critical care to 97.8% in the Transitional Care Unit. In the remaining programs, more events were reported within 1-5 days of admissions, ranging from 48.4% in Surgery and Periops to 51.6% in Nephrology.

Table 13 Bivariate analysis of frequency of day to event, by program

	First day		1-5 Days		> 5 days	
	Total events	**True events**	**Total events**	**True events**	**Total events**	**True events**
Critical Care	44 (9.6%)	29 (9.5%)	199 (43.6%)	126 (41.3%)	213 (46.7%)	150 (49.2%)
Geriatrics and Short term Rehab	2 (4.5%)	1 (4.0%)	9 (20.5%)	5 (20.0%)	33 (75.0%)	19 (76.0%)
Heart Institute	71 (21.2%)	30 (16.0%)	128 (38.2%)	70 (37.2%)	136 (40.6%)	88 (46.8%)
Cancer	24 (6.6%)	14 (5.8%)	141 (38.8%)	95 (39.3%)	198 (54.5%)	133 (55.0%)
Medicine	42 (3.3%)	27 (3.1%)	460 (36.2%)	292 (33.8%)	768 (60.5%)	545 (63.1%)
Nephrology	19 (10.0%)	16 (12.0%)	98 (51.6%)	66 (49.6%)	73 (38.4%)	51 (38.3%)
Obstetrics and Gynecology	133 (32.8%)	59 (31.6%)	201 (49.6%)	90 (48.1%)	71 (17.5%)	38 (20.3%)
Surgery and Periops	67 (7.4%)	34 (5.9%)	442 (48.5%)	290 (50.5%)	402 (44.1%)	250 (43.6%)
Transitional Care	0 (0.0%)	0 (0.0%)	2 (2.2%)	1 (2.0%)	90 (97.8%)	50 (98.0%)
Total	**402 (9.9%)**	**210 (8.2%)**	**1,680 (41.3%)**	**1,035 (40.3%)**	**1,984 (48.8%)**	**1,324 (51.5%)**

3.4.1.3 Campus

Table 14 depicts a bivariate analysis of true events reported, by hospital program and campus. Overall, the General Campus reported 48.6% (N=1,977) of the total events and 48.9% of the true events (N=1,244). The Civic Campus reported 43.1% (N=1,754) of total events and 43.8% of true events (N=1,126). The Heart Institute reported the remaining 8.2% (N=335) of total events and 7.3% (N=188) of true events.

Table 14 Bivariate analysis of campus of PSE, by program

	Civic Campus		General Campus		Heart Institute	
	Total events	**True events**	**Total events**	**True events**	**Total events**	**True events**
Critical Care	227 (49.8%)	154 (50.5%)	229 (50.2%)	151 (49.5%)	0 (0.0%)	0 (0.0%)
Geriatrics and Short term Rehab	44 (100.0%)	25 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Heart Institute	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	335 (100.0%)	188 (100.0%)
Cancer	0 (0.0%)	0 (0.0%)	363 (100.0%)	242 (100.0%)	0 (0.0%)	0 (0.0%)
Medicine	869 (68.4%)	582 (67.4%)	401 (31.6%)	282 (32.6%)	0 (0.0%)	0 (0.0%)
Nephrology	0 (0.0%)	0 (0.0%)	190 (100.0%)	133 (100.0%)	0 (0.0%)	0 (0.0%)
Obstetrics and Gynecology	218 (53.8%)	106 (56.7%)	187 (46.2%)	81 (43.3%)	0 (0.0%)	0 (0.0%)
Surgery and Periops	367 (40.3%)	238 (41.5%)	544 (59.7%)	336 (58.5%)	0 (0.0%)	0 (0.0%)
Transitional Care	29 (31.5%)	21 (41.2%)	63 (68.5%)	30 (58.8%)	0 (0.0%)	0 (0.0%)
Total	**1,754 (43.1%)**	**1,126 (43.8%)**	**1,977 (48.6%)**	**1,255 (48.9%)**	**335 (8.2%)**	**188 (7.3%)**

3.4.2 Patient-level covariates

3.4.2.1 Age

Table 15 depicts the mean and median age of patient for each event reported, by hospital program and true event status. The overall mean age was 63.61 with a standard deviation of 18.58. Among programs, the mean (standard deviation) age varied from 43.65 (20.7%) among Obstetrics and Gynecology, to 83.64 (7.3%) in Geriatrics and Short Term Rehab.

Table 15 Bivariate analysis of mean and median age of each patient at the time of reported event, by program

	Mean ± SD		Median (IQR)	
	Total events	**True events**	**Total events**	**True events**
Critical Care	59.14 ± 16.76	58.97 ± 16.31	62.00 (50.00-71.50)	62.00 (51.00-71.00)
Geriatrics and Short term Rehab	83.64 ± 7.33	83.68 ± 7.03	84.00 (79.00-88.50)	84.00 (79.00-89.00)
Heart Institute	68.45 ± 13.23	68.96 ± 13.58	70.00 (60.00-78.00)	72.00 (59.00-79.00)
Cancer	61.97 ± 15.58	62.05 ± 15.63	64.00 (54.00-73.00)	65.00 (55.00-72.00)
Medicine	67.53 ± 17.55	68.02 ± 17.04	71.00 (55.00-82.00)	72.00 (57.00-82.00)
Nephrology	65.74 ± 15.33	66.80 ± 14.96	67.00 (57.00-77.00)	67.00 (59.00-77.00)
Obstetric and Gynecology	42.28 ± 20.36	45.25 ± 20.99	34.00 (28.00-55.00)	36.00 (29.00-58.00)
Surgery and Periops	66.00 ± 16.54	65.45 ± 16.98	69.00 (56.00-78.00)	69.00 (55.00-78.00)
Transitional Care	76.95 ± 11.79	75.82 ± 12.80	80.00 (70.00-85.00)	80.00 (70.00-85.00)
Total	**63.61 ± 18.58**	**64.47 ± 17.90**	**66.00 (53.00-78.00)**	**67.00 (54.00-79.00)**

3.4.2.2 Sex

Table 16 depicts a bivariate analysis of true events reported, by hospital program and sex. Overall, 50.1% of all events occurred in females, and 49.9% in males. Most programs had approximately equal proportions of males and females, with the exception of the Heart Institute (69.3% male and 30.7% female), Nephrology (64.7% male, 35.3% female), and Obstetrics and Gynecology (88.7% female, 11.3% male). All male patients from Obstetrics and Gynecology were off service medicine and oncology patients.

Table 16 Bivariate analysis of sex, by program

	Female		Male	
	Total events	**True events**	**Total events**	**True events**
Critical Care	193 (42.3%)	139 (45.6%)	263 (57.7%)	166 (54.4%)
Geriatrics and Short term Rehab	22 (50.0%)	11 (44.0%)	22 (50.0%)	14 (56.0%)
Heart Institute	103 (30.7%)	58 (30.9%)	232 (69.3%)	130 (69.1%)
Cancer	160 (44.1%)	107 (44.2%)	203 (55.9%)	135 (55.8%)
Medicine	637 (50.2%)	433 (50.1%)	633 (49.8%)	431 (49.9%)
Nephrology	67 (35.3%)	42 (31.6%)	123 (64.7%)	91 (68.4%)
Obstetric and Gynecology	385 (95.1%)	176 (94.1%)	20 (4.9%)	11 (5.9%)
Surgery and Periops	427 (46.9%)	267 (46.5%)	484 (53.1%)	307 (53.5%)
Transitional Care	43 (46.7%)	24 (47.1%)	49 (53.3%)	27 (52.9%)
Total	**2,037 (50.1%)**	**1,257 (48.9%)**	**2,029 (49.9%)**	**1,312 (51.1%)**

3.4.2.3 Diagnosis class

Table 17 depicts a bivariate analysis of true events reported, by hospital program and ICD-10 diagnosis class. The overall frequencies for diagnosis class were 1.6% (N=66) from the blood and immune system, 17.7% (N=721) pertaining to the circulatory system, 3.6% (N=146) endocrine and metabolic diseases, 0.1% (N=4) eye and ear, 45.6% (N=1,856) were factors influencing health status and health services, 6.5% (N=265) infectious and parasitic diseases, 1.8% (N=75) mental and behavioural diseases, 12.9% (N=525) neoplasms, 2.5% (N=100) nervous system, 7.5% (N=305) pertaining to the respiratory system, and 0.1% (N=3) that were missing a diagnosis class. Apart from the Heart Institute and Integrated Cancer program, the most common diagnosis class was Factors influencing health status and health services. Among these programs, the proportion ranged from 32.7% in Critical Care to 82.0% in Obstetrics and Gynecology. As expected, diseases of the circulatory system were the most common diagnosis class for the Heart Institute (83.3% of all events reported), and Neoplasms were the most common diagnosis class for the Integrated Cancer Program (42.4% of all cases).

Table 17 Bivariate analysis of ICD-10 Diagnosis class at time of reported event, by program

	Factors influencing health status and contact with health services		Circulatory system		Neoplasms	
	Total events	**True events**	**Total events**	**True events**	**Total events**	**True events**
Critical Care	149 (32.7%)	97 (31.8%)	76 (16.7%)	50 (16.4%)	48 (10.5%)	36 (11.8%)
Geriatrics and Short term Rehab	34 (77.3%)	19 (76.0%)	5 (11.4%)	3 (12.0%)	2 (4.5%)	2 (8.0%)
Heart Institute	42 (12.5%)	23 (12.2%)	279 (83.3%)	158 (84.0%)	3 (0.9%)	0 (0.0%)
Cancer	115 (31.7%)	81 (33.5%)	6 (1.7%)	4 (1.7%)	154 (42.4%)	102 (42.1%)
Medicine	510 (40.2%)	336 (38.9%)	253 (19.9%)	182 (21.1%)	95 (7.5%)	63 (7.3%)
Nephrology	107 (56.3%)	72 (54.1%)	23 (12.1%)	16 (12.0%)	8 (4.2%)	8 (6.0%)
Obstetrics and Gynecology	338 (83.5%)	148 (79.1%)	4 (1.0%)	3 (1.6%)	32 (7.9%)	19 (10.2%)
Surgery and Periops	510 (56.0%)	324 (56.4%)	63 (6.9%)	37 (6.4%)	180 (19.8%)	118 (20.6%)
Transitional Care	51 (55.4%)	32 (62.7%)	12 (13.0%)	7 (13.7%)	3 (3.3%)	2 (3.9%)
Total	**1,856 (45.6%)**	**1,132 (44.1%)**	**721 (17.7%)**	**460 (17.9%)**	**525 (12.9%)**	**350 (13.6%)**

Table 17 cont'd Bivariate analysis of ICD-10 Diagnosis class at time of reported event, by program

	Respiratory system		Infectious and parasitic		Endocrine, nutritional and metabolic	
	Total events	**True events**	**Total events**	**True events**	**Total events**	**True events**
Critical Care	66 (14.5%)	49 (16.1%)	87 (19.1%)	52 (17.0%)	11 (2.4%)	6 (2.0%)
Geriatrics and Short term Rehab	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Heart Institute	6 (1.8%)	4 (2.1%)	4 (1.2%)	2 (1.1%)	0 (0.0%)	0 (0.0%)
Cancer	17 (4.7%)	8 (3.3%)	25 (6.9%)	18 (7.4%)	5 (1.4%)	2 (0.8%)
Medicine	118 (9.3%)	79 (9.1%)	105 (8.3%)	70 (8.1%)	53 (4.2%)	37 (4.3%)
Nephrology	16 (8.4%)	13 (9.8%)	11 (5.8%)	10 (7.5%)	13 (6.8%)	8 (6.0%)
Obstetrics and Gynecology	13 (3.2%)	7 (3.7%)	5 (1.2%)	2 (1.1%)	6 (1.5%)	4 (2.1%)
Surgery and Periops	60 (6.6%)	29 (5.1%)	25 (2.7%)	14 (2.4%)	57 (6.3%)	40 (7.0%)
Transitional Care	9 (9.8%)	5 (9.8%)	3 (3.3%)	1 (2.0%)	1 (1.1%)	0 (0.0%)
Total	**305 (7.5%)**	**194 (7.6%)**	**265 (6.5%)**	**169 (6.6%)**	**146 (3.6%)**	**97 (3.8%)**

Table 17 cont'd Bivariate analysis of ICD-10 Diagnosis class at time of reported event, by program

	Nervous system		Mental and behavioural		Blood and immune system	
	Total events	**True events**	**Total events**	**True events**	**Total events**	**True events**
Critical Care	4 (0.9%)	2 (0.7%)	3 (0.7%)	3 (1.0%)	12 (2.6%)	10 (3.3%)
Geriatrics and Short term Rehab	1 (2.3%)	0 (0.0%)	2 (4.5%)	1 (4.0%)	0 (0.0%)	0 (0.0%)
Heart Institute	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.5%)	0 (0.0%)	0 (0.0%)
Cancer	10 (2.8%)	5 (2.1%)	0 (0.0%)	0 (0.0%)	4 (1.1%)	3 (1.2%)
Medicine	69 (5.4%)	51 (5.9%)	54 (4.3%)	39 (4.5%)	11 (0.9%)	5 (0.6%)
Nephrology	4 (2.1%)	3 (2.3%)	0 (0.0%)	0 (0.0%)	7 (3.7%)	3 (2.3%)
Obstetric and Gynecology	0 (0.0%)	0 (0.0%)	5 (1.2%)	4 (2.1%)	2 (0.5%)	0 (0.0%)
Surgery and Periops	4 (0.4%)	3 (0.5%)	1 (0.1%)	1 (0.2%)	7 (0.8%)	5 (0.9%)
Transitional Care	8 (8.7%)	2 (3.9%)	5 (5.4%)	2 (3.9%)	0 (0.0%)	0 (0.0%)
Total	**100 (2.5%)**	**66 (2.6%)**	**75 (1.8%)**	**54 (2.1%)**	**66 (1.6%)**	**42 (1.6%)**

Table 17 cont'd Bivariate analysis of ICD-10 Diagnosis class at time of reported event, by program

	10.Eye and ear		Missing	
	Total events	**True events**	**Total events**	**True events**
Critical Care	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Geriatrics and Short term Rehab	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Heart Institute	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cancer	27 (7.4%)	19 (7.9%)	0 (0.0%)	0 (0.0%)
Medicine	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)
Nephrology	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)
Obstetrics and Gynecology	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Surgery and Periops	4 (0.4%)	3 (0.5%)	0 (0.0%)	0 (0.0%)
Transitional Care	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Total	4 (0.1%)	3 (0.1%)	3 (0.1%)	2 (0.1%)

3.4.2.4 Off service patients

Table 18 depicts a bivariate analysis of true events reported, by hospital program and off service status. Overall, 12.4% (N=504) of all recorded PSEs came from patients who were off service. This rate differed greatly by program. Critical Care, Geriatrics and Short-Term Rehab, and Transitional Care Unit all had no off service patients. The highest was among the Nephrology Program, of which 41.1% of all PSEs reported came from an off service patient.

Table 18 Bivariate analysis of off-service, by program

	Total events	**True events**
Critical Care	0 (0.0%)	0 (0.0%)
Geriatrics and Short term Rehab	0 (0.0%)	0 (0.0%)
Heart Institute	3 (0.9%)	3 (1.6%)
Cancer	60 (16.5%)	41 (16.9%)
Medicine	81 (6.4%)	56 (6.5%)
Nephrology	78 (41.1%)	58 (43.6%)
Obstetrics and Gynecology	60 (14.8%)	37 (19.8%)
Surgery and Periops	222 (24.4%)	135 (23.5%)
Transitional Care	0 (0.0%)	0 (0.0%)
Total	**504 (12.4%)**	**330 (12.8%)**

3.4.2.5 Charlson index

Table 19 depicts a bivariate analysis of true events reported, by hospital program and Charlson score. The distribution of Charlson scores differed greatly by program. Overall, 31.0% of events (N=1,260) had a Charlson Score of 0, 27.3% (N=1,111) had a score between 1 and 2, 18.9% (N=770) had a score between 3 and 4, and 22.7% (N=925) had a score of 5 or greater. A score of 0 was most common among Obstetrics and Gynecology (73.1% of events), Surgery and Periops (35.7% of events), and Transitional Care unit (29.3%). Within Critical Care, Heart Institute, and Medicine, Neuroscience and Endoscopy, the majority of events had a score of 1-2 (33.8%, 34.9%, 27.6% respectively). In Nephrology, the majority of events reported had a

Charlson score between 3 and 4 (31.6% of all events). Geriatrics and Short Term Rehab, and Cancer had the most events recorded for a Charlson score of 5 or greater (31.8% and 43.3% respectively).

Table 19 Bivariate analysis of Charlson Index, by program

	0		1-2		3-4		≥5	
	Total events	**True events**	**Total events**	**True events**	**Total events**	**True events**	**Total events**	**True events**
Critical Care	121 (26.5%)	80 (26.2%)	154 (33.8%)	103 (33.8%)	90 (19.7%)	58 (19.0%)	91 (20.0%)	64 (21.0%)
Geriatrics and Short term Rehab	8 (18.2%)	3 (12.0%)	11 (25.0%)	6 (24.0%)	11 (25.0%)	6 (24.0%)	14 (31.8%)	10 (40.0%)
Heart Institute	73 (21.8%)	38 (20.2%)	117 (34.9%)	68 (36.2%)	75 (22.4%)	47 (25.0%)	70 (20.9%)	35 (18.6%)
Cancer	34 (9.4%)	20 (8.3%)	119 (32.8%)	87 (36.0%)	53 (14.6%)	32 (13.2%)	157 (43.3%)	103 (42.6%)
Medicine	337 (26.5%)	208 (24.1%)	351 (27.6%)	249 (28.8%)	277 (21.8%)	195 (22.6%)	305 (24.0%)	212 (24.5%)
Nephrology	39 (20.5%)	25 (18.8%)	41 (21.6%)	29 (21.8%)	60 (31.6%)	40 (30.1%)	50 (26.3%)	39 (29.3%)
Obstetrics and Gynecology	296 (73.1%)	124 (66.3%)	47 (11.6%)	22 (11.8%)	19 (4.7%)	10 (5.3%)	43 (10.6%)	31 (16.6%)
Surgery and Periops	325 (35.7%)	209 (36.4%)	248 (27.2%)	150 (26.1%)	160 (17.6%)	111 (19.3%)	178 (19.5%)	104 (18.1%)
Transitional Care	27 (29.3%)	18 (35.3%)	23 (25.0%)	14 (27.5%)	25 (27.2%)	11 (21.6%)	17 (18.5%)	8 (15.7%)
Total	**1,260 (31.0%)**	**725 (28.2%)**	**1,111 (27.3%)**	**728 (28.3%)**	**770 (18.9%)**	**510 (19.9%)**	**925 (22.7%)**	**606 (23.6%)**

3.4.2.6 Elixhauser score

Table 20 depicts a bivariate analysis of true events reported, by hospital program and mean and median Escobar score. The overall mean (stdev) Elixhauser score was 6.78 (7.39) with a median of 5 and IQR from 0.00-12.00). Within programs, the lowest mean (stdev) score was from Obstetrics and Gynecology, which was 2.76 (6.00), with a median and IQR of 0.00 and 0.00-4.00 respectively. The highest Elixhauser score was within the Integrated Cancer program, with a mean (stdev) of 11.19 (7.94) and median 12.00, with an IQR from 4.00-16.00.

Table 20 Bivariate analysis of mean and median Elixhauser score, by program

	Mean ± SD		Median (IQR)	
	Total events	**True events**	**Total events**	**True events**
Critical Care	7.05 ± 7.69	6.93 ± 7.71	5.00 (0.00-11.00)	5.00 (0.00-11.00)
Geriatrics and Short term Rehab	7.61 ± 7.08	7.72 ± 7.72	5.00 (1.00-14.00)	8.00 (0.00-14.00)
Heart Institute	7.49 ± 7.20	7.84 ± 7.15	6.00 (0.00-12.00)	7.00 (3.00-12.00)
Cancer	11.19 ± 7.94	11.36 ± 8.15	12.00 (4.00-16.00)	11.50 (4.00-16.00)
Medicine	7.35 ± 7.17	7.39 ± 7.30	6.00 (0.00-12.00)	6.00 (0.00-12.00)
Nephrology	7.02 ± 6.97	7.05 ± 7.06	5.00 (0.00-12.00)	5.00 (0.00-12.00)
Obstetrics and Gynecology	2.76 ± 6.00	3.88 ± 7.16	0.00 (0.00-3.00)	0.00 (0.00-6.00)
Surgery and Periops	5.72 ± 6.97	5.57 ± 7.03	4.00 (0.00-10.00)	4.00 (0.00-9.00)
Transitional Care	5.03 ± 6.54	4.94 ± 6.39	4.00 (0.00-8.00)	5.00 (0.00-8.00)
Total	6.78 ± 7.39	7.02 ± 7.53	5.00 (0.00-12.00)	5.00 (0.00-12.00)

3.4.2.7 Escobar index

Table 21 depicts a bivariate analysis of true events reported, by hospital program and mean and median escobar index. The overall mean (stdev) Escobar index score was 0.13 (0.16), with an overall median of 0.07 and IQR of 0.01-0.19. Therefore, on average, the risk of mortality within my study cohort was 13% and the median risk was 7.0%. The lowest score was within Obstetrics and Gynecology with a mean (stdev) of 0.04 (0.09) and a median of 0.00 with IQR from 0.00-0.03. The highest score was within Critical Care with a mean (stdev) of 0.23 (0.21), and a median of 0.16 with an IQR of 0.04-0.37.

Table 21 Bivariate analysis of mean and median Escobar score, by program

	Mean ± SD		Median (IQR)	
	Total events	**True events**	**Total events**	**True events**
Critical Care	0.23 ± 0.21	0.22 ± 0.20	0.16 (0.04-0.37)	0.15 (0.04-0.35)
Geriatrics and Short term Rehab	0.14 ± 0.15	0.16 ± 0.15	0.10 (0.02-0.16)	0.10 (0.03-0.29)
Heart Institute	0.11 ± 0.14	0.13 ± 0.16	0.06 (0.02-0.15)	0.08 (0.02-0.17)
Cancer	0.18 ± 0.16	0.18 ± 0.16	0.13 (0.04-0.28)	0.13 (0.04-0.29)
Medicine	0.15 ± 0.15	0.16 ± 0.15	0.10 (0.03-0.23)	0.11 (0.04-0.24)
Nephrology	0.13 ± 0.15	0.14 ± 0.16	0.07 (0.03-0.18)	0.07 (0.03-0.18)
Obstetrics and Gynecology	0.04 ± 0.09	0.05 ± 0.10	0.00 (0.00-0.01)	0.00 (0.00-0.05)
Surgery and Periops	0.09 ± 0.12	0.08 ± 0.12	0.04 (0.01-0.11)	0.04 (0.01-0.11)
Transitional Care	0.12 ± 0.10	0.12 ± 0.11	0.10 (0.04-0.17)	0.10 (0.03-0.14)
Total	0.13 ± 0.16	0.14 ± 0.16	0.07 (0.01-0.19)	0.08 (0.02-0.20)

3.4.2.8 LAPS score

Table 22 depicts a bivariate analysis of true events reported, by hospital program and mean and median LAPS score. The overall mean LAPS score was 37.68 with a standard deviation of 29.66. The median score was 34.0 with an IQR of 14.00-54.00. Within programs, the mean (std) score ranged from 17.52 (19.83) in Obstetrics and Gynecology with a median of 5.00 and IQR of 0.00-28.00, to a mean (stdev) of 59.66 (36.10) within Critical Care and median and IQR of 56.00 and 34.50-83.50 respectively.

Table 22 Bivariate analysis of mean and median LAPS score, by program

	Mean ± SD		Median (IQR)	
	Total events	**True events**	**Total events**	**True events**
Critical Care	59.66 ± 36.10	57.25 ± 36.37	56.00 (34.50-83.50)	55.00 (32.00-80.00)
Geriatrics and Short term Rehab	29.80 ± 22.92	33.28 ± 25.36	29.00 (5.50-50.50)	31.00 (7.00-54.00)
Heart Institute	36.81 ± 34.71	41.65 ± 37.07	29.00 (9.00-53.00)	35.50 (13.00-58.50)
Cancer	40.61 ± 24.42	42.19 ± 24.53	40.00 (28.00-55.00)	41.50 (28.00-57.00)
Medicine	42.82 ± 26.75	43.53 ± 27.67	40.00 (25.00-58.00)	41.00 (25.00-59.00)
Nephrology	48.98 ± 23.27	48.85 ± 23.64	52.00 (34.00-65.00)	50.00 (33.00-64.00)
Obstetrics and Gynecology	17.52 ± 19.83	19.12 ± 20.16	5.00 (0.00-28.00)	12.00 (5.00-30.00)
Surgery and Periops	26.00 ± 24.65	25.90 ± 24.45	23.00 (1.00-41.00)	23.00 (0.00-42.00)
Transitional Care	34.24 ± 22.63	31.37 ± 23.24	35.00 (16.00-51.00)	29.00 (5.00-51.00)
Total	37.68 ± 29.66	39.11 ± 30.00	34.00 (14.00-54.00)	37.00 (15.00-56.00)

3.4.2.9 Admission type

Table 23 depicts a bivariate analysis of true events reported, by hospital program and elective admissions. The overall average frequency for elective admissions was 16.0% (N= 649) and varied substantially between programs. The proportion ranged between 2.8% of total PSEs among the Medicine, Neuroscience and Endoscopy program, to 50.0% in Geriatrics and Short-Term Rehab.

Table 24 depicts a bivariate analysis of true events reported, by hospital program and non-surgical emergency admissions. Overall, 21.4% (N=869) of all PSEs reported were from an emergency surgical admission. This proportion ranged from 1.1% in the Integrated Cancer program to 47.3% in Surgery and Periops.

Table 25 depicts a bivariate analysis of true events reported, by hospital program and surgical emergency admissions. Overall, 62.6% (N=2,547) of all PSEs reported were from non-surgical emergency admissions. Surgery had the lowest proportion of emergency non-surgical admissions with 28.9% of all reported PSEs, and the highest was within Nephrology with 92.1% of all reported PSEs.

Table 23 Bivariate analysis of the frequency of elective admissions, by program

	Total events	**True events**
Critical Care	42 (9.2%)	29 (9.5%)
Geriatrics and Short term Rehab	22 (50.0%)	14 (56.0%)
Heart Institute	96 (28.7%)	46 (24.5%)
Cancer	52 (14.3%)	39 (16.1%)
Medicine	35 (2.8%)	24 (2.8%)
Nephrology	10 (5.3%)	5 (3.8%)
Obstetrics and Gynecology	172 (42.5%)	74 (39.6%)
Surgery and Periops	217 (23.8%)	140 (24.4%)
Transitional Care	3 (3.3%)	2 (3.9%)
Total	649 (16.0%)	373 (14.5%)

Table 24 Bivariate analysis of frequency of Emergency, non-surgical admissions, by program

	Total events	**True events**
Critical Care	285 (62.5%)	185 (60.7%)
Geriatrics and Short term Rehab	18 (40.9%)	10 (40.0%)
Heart Institute	170 (50.7%)	105 (55.9%)
Cancer	307 (84.6%)	200 (82.6%)
Medicine	1,066 (83.9%)	716 (82.9%)
Nephrology	175 (92.1%)	124 (93.2%)
Obstetrics and Gynecology	185 (45.7%)	87 (46.5%)
Surgery and Periops	263 (28.9%)	165 (28.7%)
Transitional Care	78 (84.8%)	42 (82.4%)
Total	**2,547 (62.6%)**	**1,634 (63.6%)**

Table 25 Bivariate analysis of the frequency of Emergency surgical admissions, by program

	Total events	**True events**
Critical Care	128 (28.1%)	91 (29.8%)
Geriatrics and Short term Rehab	4 (9.1%)	1 (4.0%)
Heart Institute	69 (20.6%)	37 (19.7%)
Cancer	4 (1.1%)	3 (1.2%)
Medicine	169 (13.3%)	124 (14.4%)
Nephrology	5 (2.6%)	4 (3.0%)
Obstetrics and Gynecology	48 (11.9%)	26 (13.9%)
Surgery and Periops	431 (47.3%)	269 (46.9%)
Transitional Care	11 (12.0%)	7 (13.7%)
Total	**869 (21.4%)**	**562 (21.9%)**

3.4.3 **System-level covariates**

Table 26 shows the averages for the system level variables. The number of patients at midnight ranged from 12.15 in Critical Care to 30.92 in Nephrology. Upon consultation with my supervisor, these values were concordant with the true average patient volumes for these respective programs. However, the nurse to patient ratios, which used staffing data, did not match with the true values for each program. Each program should have an excess number of patients compared to nursing staff, thus all ratios should be less than 1. Yet, they are reported as much higher within Critical Care and the Heart Institute (2.32 and 1.41 respectively).

Linking patient data to staffing data proved challenging for several reasons, which I discussed in section 2.6.4.2. Namely, I found a lack of consistency in the coding of functional centres within the patient and staffing datasets. There were functional centers created within the patient census dataset that did not exist in the staffing dataset, and vice versa. Given these data limitations, I concluded that I could not use these data tables to provide accurate estimates of nursing to patient ratios, and decided to exclude them from the analysis.

Table 26 Program-level variables by hospital program

	CC	GER	HI	CAN	MED	NEPH	OBS/GYN	SURG	TRANS
Mean Daily Admissions	1.00	1.11	2.20	1.86	1.31	2.80	4.50	3.05	0.73
Mean Nightly Admissions	0.77	0.00	0.83	0.93	0.81	2.46	3.47	1.76	0.05
Number of patients at midnight	12.15	21.78	11.95	27.73	16.29	30.92	14.49	26.32	33.41
Mean Daily nurse to patient ratio	2.32	0.21	1.41	0.36	0.63	0.33	0.89	0.37	0.26
Mean Nightly nurse to patient ratio	2.44	0.16	1.39	0.25	0.49	0.25	0.91	0.29	0.13

3.5 Primary Objective 1: Positive predictive value of PSLS

Table 27 shows the positive predictive value of the PSLS system, and the breakdown by event type. The positive predictive value of the PSLS was 63.18%, meaning that 63.18% (N=2,569) of all inpatient PSEs included in my study were classified as true events. The most common event type reported was near misses, which comprised 46.95% (N=1,909) of all true events. The remaining were adverse events (AEs), of which 273 (6.71%) were preventable and 387 (9.52%) were non-preventable.

Table 27 Positive Predictive value of PSLS		
	N	**% (95% CI)**
Total True Events	**2569**	**63.18 (61.7-64.66)**
Non- preventable	387	9.52 (8.62-10.42)
Preventable AEs	273	6.71 (5.94-7.48)
Near Misses	1909	46.95 (45.42-48.48)
Total Non-events	**1497**	**36.82 (35.34-38.30)**
Total	**4066**	**100**

Table 28 shows the results from my simple covariate analysis of all potential study covariates. From the simple covariate analysis, the following fixed covariates were selected for inclusion in the multivariate model: number of months PSLS was available, time to event, patient age, Charlson Index, Escobar Score, LAPS score, emergency surgical admissions, mean admits per day, and mean admits per night.

3.6 Primary Objective 2a: Generating a predictive model with GLIMMIX

3.6.1 Simple covariate analysis

Table 28 Simple covariate analysis of all predictor variables, adjusted by role of the reporter and

		OR (95% CI)
Event variables	**# Months PSLS was available**	
	>= 3 months	**.**
	4-7 months	**0.73 (0.60-0.89)**
	8-12 months	**0.40 (0.33-0.49)**
	>12 months	**0.39(0.27-0.54)**
	Time to event	
	Same day	**.**
	1-5 days	**1.27 (1.01-1.59)**
	>5 Days	**1.49 (1.18-1.87)**
Patient variables	**Patient age**	**1.00 (0.999-1.01)**
	Sex (male is ref)	0.97 (0.84-1.11)
	Diagnosis	
	Blood and immune system	0.91 (0.51-1.59)
	Circulatory system	1.22 (0.91-1.65)
	Endocrine, nutritional, and metabolic	1.15 (0.76-1.76)
	Eye and ear	1.68 (0.17-16.43)
	Factors influencing health status and contact	1.05 (0.81-1.36)
	Infectious and parasitic	0.97 (0.68-1.37)
	Mental and behavioural	1.40(0.79-2.46)
	Neoplasms	1.19 (0.88-1.62)
	Nervous system	1.01(0.62-1.63)
	Respiratory system	--
	Charlson Index	
	0	**--**
	1-2	**1.31(1.01-1.56)**
	3-4	**1.30(1.07-1.57)**
	>=5	**1.22(1.02-1.47)**
	Escobar Score	**1.56 (0.998-2.44)**
	LAPS score	**1.002 (1.00-1.005)**
	Elixhauser score	1.005 (0.996- 1.014)
	Elective Admission	1.08 (0.90-1.30)
	Emergency surgical Admission	**0.861 (0.73-1.02)**
	Emergency nonsurgical Admission	1.07 (0.92-1.24)
	Off Service Patient	0.90 (0.73-1.10)
System-Level Variables	**Mean admits/day**	**0.88 (0.77-1.01)**
	Mean admits/night	**0.89(0.74-1.06)**
	Patients at midnight	1.01 (0.99-1.03)
	Daily nurse to	0.97 (0.70-1.35)
	Nightly nurse to	0.967 (0.716-1.305)

* GLIMMIX models include role of reporter as a random intercept

** Bold terms had a p value < 0.20, and were the covariates included in iterations to determine the final model.

3.6.2 **Model Assumptions**

The COVTEST of independence was significant, which indicated that clustering by reporter and program was necessary. Thus, I used GLIMMIX to determine my final multivariate model.

3.6.3 **Diagnostics**

Table 29 depicts the diagnostics for the three candidate models. All three models had similar diagnostic statistics. The discriminatory ability (c-statistic) was 65%, meaning each model was able to distinguish an event from a non-event 65% of the time. This is considered poor discrimination. Moreover, the calibration of the model was poor, as indicated by the low p value from the Hosmer-Lemeshow test (p<0.001). Therefore, this model did not adequately fit the data, so I investigated other options.

Table 29 Model diagnostics used to choose a candidate model

	Charlson Index	**Escobar**	**Escobar components**
AIC	5171.67	5172.69	5172.69
-2 Log Likelihood	5149.67	5156.69	5156.69
Hosmer-Lemeshow (chisq(p-value))	53.83 (<0.0001)	45.00 (<0.0001)	45.00 (<0.0001)
c-statistic	0.653	0.65	0.65

3.6.3.1 Correction of poor calibration option 1: data transformations

Typically, data transformations are used to correct poor model calibration. However, bivariate analyses within each program showed that different covariates were significant across different programs. Therefore, a single multivariate model may not be appropriate; the relationship between true events and patient and event-level factors may need to be modeled for each program separately.

3.6.3.2 Correction of poor calibration option 2: model stratification

I took an alternative approach, in which each of the hospital programs were modeled separately, using the role of the reporter as the random intercept. Due to sample size constraints, Geriatrics and Short-Term Rehab, as well as the Transitional Care Unit could not be modeled separately.

I selected an optimal model for the remaining programs using the same logic as above. In the section below, I've included the results of the simple covariate analysis (Table 30) and the final multivariate models by program (Table 31), as well as the final model diagnostics (table 32). The intermediate steps for model building can be viewed in Appendix E.

3.6.4 Summary of results for individual models by program

3.6.4.1 Simple covariate analyses by hospital program

Table 30 Estimates (OR(95% CI)) from the simple covariate analysis for each individual program

	CC	**HI**	**CAN**	**MED**	**NEPH**	**OBS/ GYN**	**SURG**
Type of model used	logistic regression	logistic regression	GLIMMIX*	GLIMMIX*	logistic regression	logistic regression	Logistic regression
# Months PSLS was available							
≥ 3 months	--	--	--	--	--	--	
4-7 months	**0.91 (0.54-1.53)**	**0.08 (0.04-0.16)**	**0.46 (0.20-1.08)**	**2.73 (1.93-3.87)**	**0.21 0.05-0.95)**	**0.30 (0.15-0.61)**	**0.40 (0.23-0.70)**
8-12 months	**0.28 (0.16-0.48)**	**0.31 (0.17-0.57)**	**0.25 (0.11-0.58)**	**2.04 (1.46-2.85)**	**0.10 (0.02-0.47)**	**0.25 (0.12-0.50)**	**0.21 (0.13-0.37)**
>12 months	N/A	N/A	N/A	**1.23 (0.84-1.80)**			
Time to event							
Same day	--	--					
1-5 days	0.89 (0.45-1.77)	**1.65 (0.92-2.96)**	1.53 (0.63-3.74)	0.97 (0.50-1.89)	**0.39 (0.10-1.42)**	1.02 (0.65-1.58)	**1.85 (1.10-3.10)**

	CC	HI	CAN	MED	NEPH	OBS/ GYN	SURG
>5 Days	1.23 (0.62-2.45)	**2.51 (1.39-4.51)**	1.48 (0.62-3.55)	1.28 (0.66-2.48)	**0.44 (0.12-1.64)**	1.57 (0.90-2.75)	**1.60 (0.95-2.70)**
Patient age	0.998 (0.99-1.01)	1.01 (0.99-1.02)	1.00 (0.99-1.02)	1.00 (0.997-1.01)	**1.02 (1.00-1.04)**	**1.01 (1.00-1.02)**	**1.00 (0.986-1.003)**
Sex (male is ref)	**1.50 (1.01-2.25)**	1.01 (0.63-1.61	1.03 (0.66-1.61)	0.995 (0.78-1.26)	**0.59 (0.31-1.12)**	1.45 (0.59-3.58)	1.04 (0.79-1.36)
Diagnosis				did not converge			did not converge
Blood and immune system	1.74 (0.35-8.73)		2.32 (0.64-8.56)		0.17 (0.03-1.22)	<0.001 (<0.001->999.99)	
Circulatory system	0.67 (0.32-1.38)	0.65 (0.12-3.62	2.61 (0.36-18.87)		0.53 (0.11-2.46)	2.57 (0.21-31.71)	
Endocrine, nutritional, and metabolic	0.42 (0.11-1.54)		0.65 (0.08-5.10)		0.37 (0.07-1.99)	1.71 (0.23-12.90)	
Eye and ear	N/A	N/A	N/A	N/A	N/A	N/A	
Factors influencing health status and contact with health services	0.65 (0.34-1.24)	0.61 (0.10-3.67)	2.49 (0.88-7.11)		0.48 (0.13-1.78)	0.67 (0.22-2.03)	
Infectious and parasitic	0.52 (0.26-1.04)	0.50 (0.04-6.68)	2.58 (0.70-9.57)		2.31 (0.21-25.66)	0.57 (0.07-4.64)	
Mental and behavioural	>999.99 (<0.001->999.99)	>999.99 (<0.001->999.99)	2.89 (0.24-34.29)		>999.99 (<0.001->999.99)	3.43 (0.30-39.64)	
Neoplasms	1.04 (0.44-2.45)	>999.99 (<0.001->999.99)	1.98 (0.71-5.52)		0.69 (0.05-9.21)	1.25 (0.34-4.60)	
Nervous system	0.35 (0.05-2.66)	N/A	1.00 (0.21-4.86)		0.48 (0.13-1.78)	0.67 (0.22-2.03)	
Respiratory system (ref)	--	--	--		--	--	
Charlson Index							
0	--	--					
1-2	1.04 (0.63-1.71)	**1.28 (0.71-2.30)**	**1.94 (0.87-4.34)**	**1.49 (1.08-2.06)**	**1.35 (0.53-3.46)**	**1.22 (0.66-2.26)**	**0.85 (0.60-1.20)**

	CC	HI	CAN	MED	NEPH	OBS/ GYN	SURG
3-4	0.93 (0.52-1.65)	**1.55 (0.80-2.98)**	**1.15 (0.47-2.82)**	**1.41 (1.00-1.99)**	**1.12 (0.48-2.61)**	**1.54 (0.61-3.91)**	**1.26(0.84-1.90)**
≥5	1.21 (0.68-2.18)	**0.92 (0.48-1.78)**	**1.41 (0.65-3.05)**	**1.32 (0.94-1.84)**	**1.99 (0.78-5.06)**	**3.58 (1.77-7.25)**	**0.78 (0.54-1.14)**
Escobar Score	**0.48 (0.19-1.20)**	**16.3 (2.70-98.15)**	**1.68 (0.41-6.85)**	**2.50 (1.10-5.67)**	4.08 (0.42-39.88)	**9.00 (0.95-84.31)**	0.99 (0.97-1.01)
LAPS score	**0.99 (0.99-1.00**	**1.02 (0.99-1.05)**	**1.01 (0.999-1.02)**	**1.003 (0.998-1.00)**	0.999 (0.986-1.01)	**1.01 (0.998-1.02)**	0.56 (0.19-1.64)
Elixhauser score	0.99 (0.97-1.02)	1.02 (0.99-1.05)	1.01 (0.98-1.04)	1.01 (0.99-1.02)	1.00 (0.96-1.05)	**1.06 (1.03-1.10)**	1.00 (0.99-1.01)
Elective Admission (yes is ref)	1.12 (0.56-2.21)	**0.63 (0.39-1.01)**	**1.56 (0.80-3.07)**	**1.10 (0.53-2.28)**	**0.41 (0.11-1.46)**	0.80 (0.54-1.19)	1.10 (0.80-1.53)
Emergency surgical Admission (yes is ref)	1.31 (0.84-2.04)	0.88 (0.52-1.50)	1.59 (0.16-15.99)	**1.39 (0.96-2.01)**	1.73 (0.19-15.86)	1.44 (0.79-2.63)	0.95 (0.73-1.25)
Emergency nonsurgical Admission (yes is ref)	0.79 (0.52-1.18)	**1.60 (1.03-2.46)**	**0.63 (0.33-1.22)**	**0.74 (0.53-1.04)**	1.62 (0.55-4.79)	1.07 (0.72-1.58	0.98 (0.73-1.32)
Off Service Patient (yes is ref)	N/A	>999.99 (<0.001->999.9)	0.90 (0.49-1.64	0.94 (0.57-1.54)		**2.10 (1.19-3.67)**	

* GLIMMIX models include role of reporter as a random intercept

**Bold terms had a p value < 0.20, and were the covariates included in iterations to determine the final model

3.6.4.2 Final multivariate models by hospital program

Table 31 Estimates (OR(95% CI)) from the final multivariate model for each individual program

	CC	**HI**	**CAN**	**MED**	**NEPH**	**OBS/ GYN**	**SURG**
Type of model used	logistic regression	logistic regression	GLIMMIX*	GLIMMIX*	logistic regression	logistic regression	logistic regression
# Months PSLS was available							
≥ 3 months	--	--	--	--	--	--	--
4-7 months	0.90 (0.53-1.53)	0.23 (0.12-0.43)	0.46 (0.20-1.11)	2.74 (1.93-3.89)	0.10 (0.02-0.45	0.27 (0.13-0.57)	0.33 (0.19-0.60)
8-12 months	0.28 (0.16-0.48)	0.05 (0.02-0.11)	0.26 (0.11-0.61)	2.00 (1.43-2.80)	0.05 (0.05-0.996)	0.21 (0.10-0.45)	0.14 (0.08-0.25
>12 months	0	0		1.26 (0.86-1.86)	0	0	0
Time to event	-						
Same day	--	--	--	--	--	--	--
1-5 days	--	1.59 (0.80-3.16	--	--	0.36 (0.09-1.38)	--	2.15 (1.25-3.70)
>5 Days	--	3.60 (1.83-7.10)	--	--	0.42(0.11-1.64)	--	1.70 (0.99-2.91)
Patient age	--	--	--	--	**--**	--	--
Sex (female is ref)	--	--	--	--	1.83 (0.93-3.60)	--	--
Charlson Index							
0	--	--	--	--	--	--	--
1-2	--	--	--	1.47 (1.05-2.03)	--	--	--
3-4	--	--	--	1.45 (1.02-2.06)	--	--	--

	CC	HI	CAN	MED	NEPH	OBS/ GYN	SURG
≥5	--	--	--	1.31 (0.93-1.85)	--	--	--
Escobar Score	0.4 (0.15-1.05	--	--	--	--	--	--
LAPS score	--	--		--	--	--	--
Elixhauser score		--	--	--	--	1.04 (1.00-1.08)	--
Elective Admission (yes is ref)		--	--	--	--	--	--
Emergency surgical Admission (no is ref)		--	--	--	--	--	--
Emergency nonsurgical Admission (no is ref)		2.39(1.41-4.06	1.91 (0.96-3.83)	0.79 (0.56-1.14)	--	--	--
Off Service Patient (no is ref)		--	--	--	--	1.7 (0.9-3.19)	--
Role of Reporter							
Other	--	--	--	--	--		--
Lab	1.16 (0.67-1.99)	--	--	--	--	2.14 (1.11-4.12)	1.41 (0.90-2.23)
Nurse	1.72 (0.92-3.24)	--	--	--	--	2.80 (1.52-5.15)	2.43 (1.54-3.83)
MOR for intercept only model			1.46	2.13			
MOR for final model			1.85	1.48			

3.6.4.3 Final model diagnostics by hospital program

Table 32 Summary of final model diagnostics by hospital program

	CC	HI	CAN	MED	NEPH	OBS/ GYN	SURG
AIC	552.965	388.214	455.74	1535.17	223.81	530.971	1141.1
-2 Log Likelihoo	540.965	376.214	439.53	1517.17	211.81	516.971	1127.1 41
Hosmer-Lemesho w (chisq(p-	4.8497 (0.7735)	3.9265 (0.7882)	10.1095 (0.2574)	8.9307 (0.3482)	4.9176 (0.6700)	2.3414 (0.9386)	9.3369 (0.3147)
c-statistic	0.65	0.769	0.648	0.662	0.696	0.671	0.656
Outliers	none	none	none	none	2-retained*	1-retained*	None

*** I retained outliers if their removal did not change parameter estimates by ≥10%**

3.6.4.4 Summary of results

Each program had its own significant set of predictors; the only covariate common to each final model was number of months the PSLS was available. With the exception of Medicine, the relationship was an inverse negative relationship, where the likelihood of a true PSEs being reported decreased over time. The negative linear relationship still existed for Medicine, Neuroscience and Endoscopy, however the odds ratios were all above 1 and trended towards null. Therefore, later months captured more true events than at 3 months or less, however the difference became less significant over time. Other significant covariates included day to event, severity of illness, sex, and admission status.

I used a GLIMMIX as the final multivariate model for Medicine and Cancer programs, and traditional logistic regression model for the remaining programs. Both Obstetrics and Gynecology, as well as Surgery and Periops, had a significant COVTEST of independence, however, there were not a significant number of outcomes within the reporter role other to create clusters. Therefore, I used a traditional logistic regression model.

For each final model, the calibration was excellent (p value less than 0.05). Model discrimination improved for all programs, yet remained poor (less than 70%) for all programs except the Heart Institute.

3.7 Secondary Objective: Rates of reporting

3.7.1 Monthly rate of total PSLS events reported

There was some initial fluctuation in reporting rates when the PSLS was first introduced, however, from January 2011 and onwards, reporting rates were fairly constant from month to month. Monthly reporting rates were similar across all three campuses and programs. Nurses had slightly higher monthly reporting rates than Lab staff or Other.

3.7.1.1 By campus

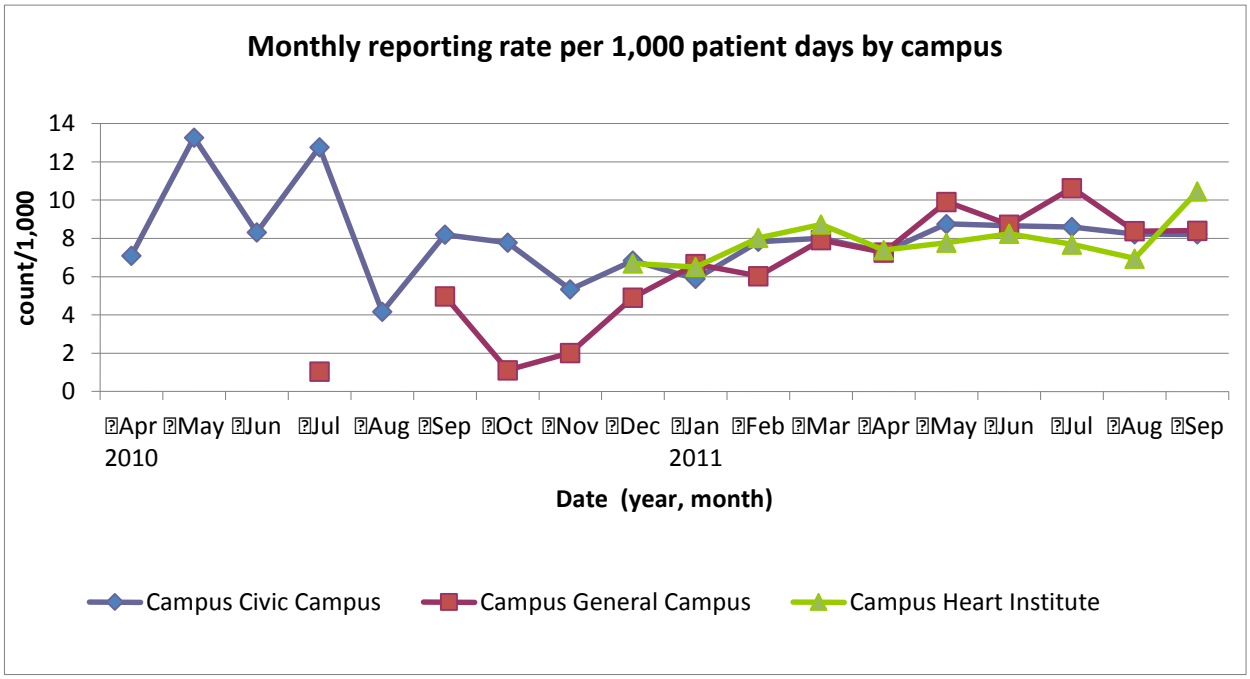


Figure 7 Monthly incidence rate of total PSEs reported from April 2010-September 2011 by campus

3.7.1.2 By program

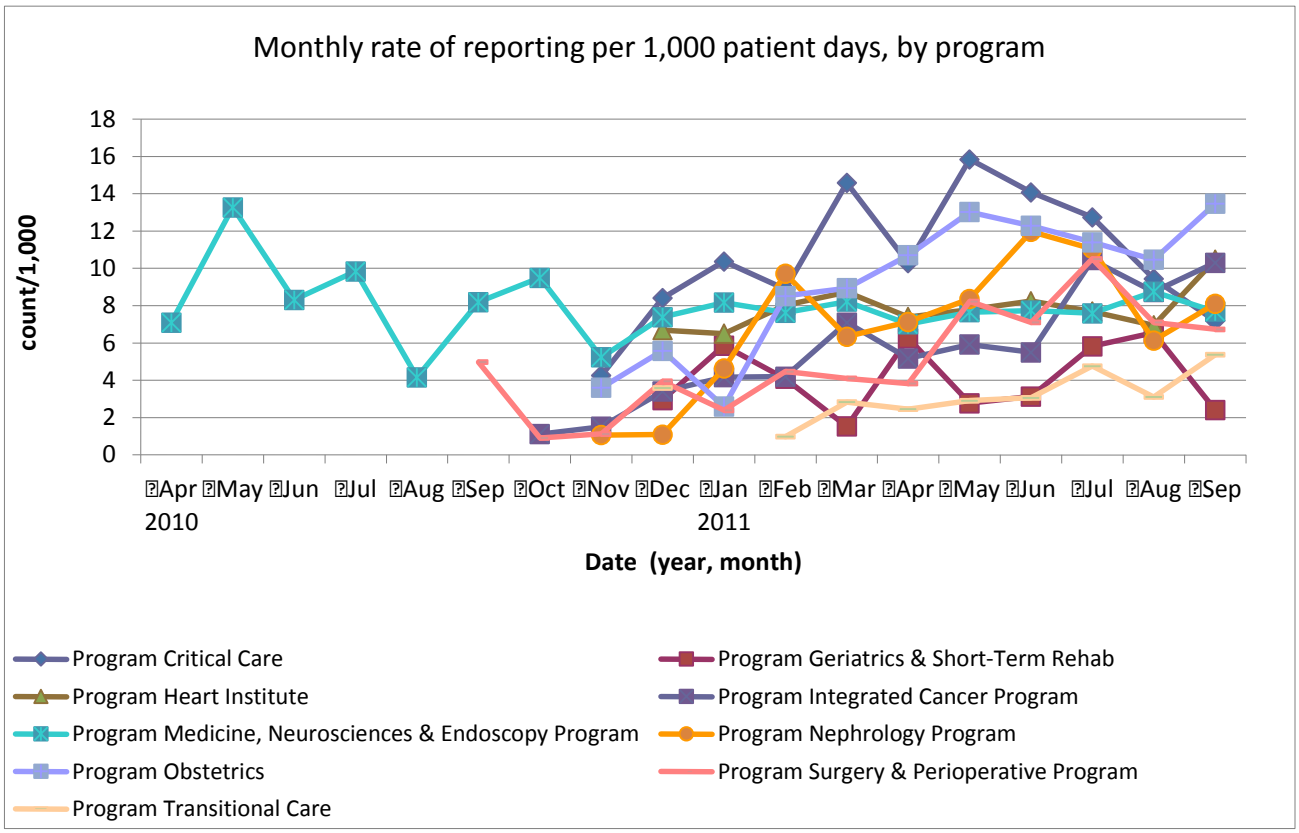


Figure 8 Monthly Incidence rate of total PSEs reported from April 2010-September 2011 by program

3.7.1.3 By reporter

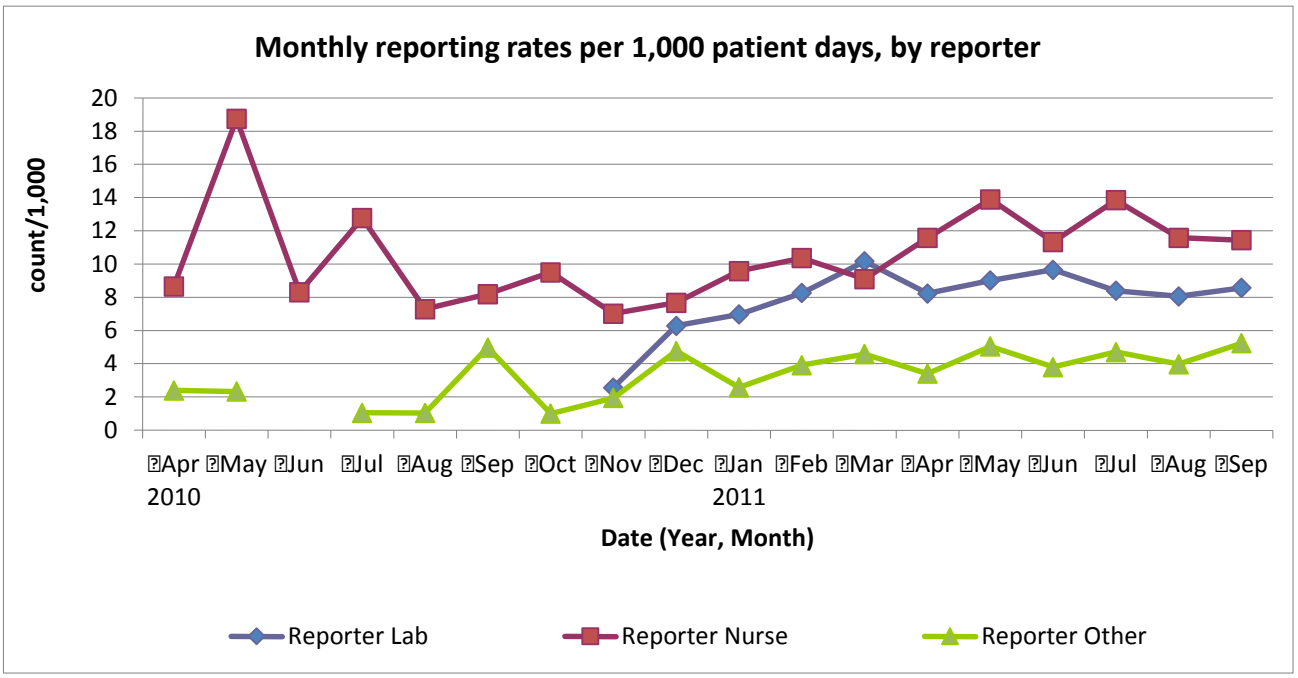


Figure 9 Monthly Incidence rate of total PSEs reported from April 2010-September 2011 by reporter

3.7.2 Monthly rate of true events reported

After initial fluctuations in reporting, the rate of true events stabilized after January 2011 and steadily decreased over time. Reporting rates were similar across campuses, programs, and reporter roles.

3.7.2.1 By campus

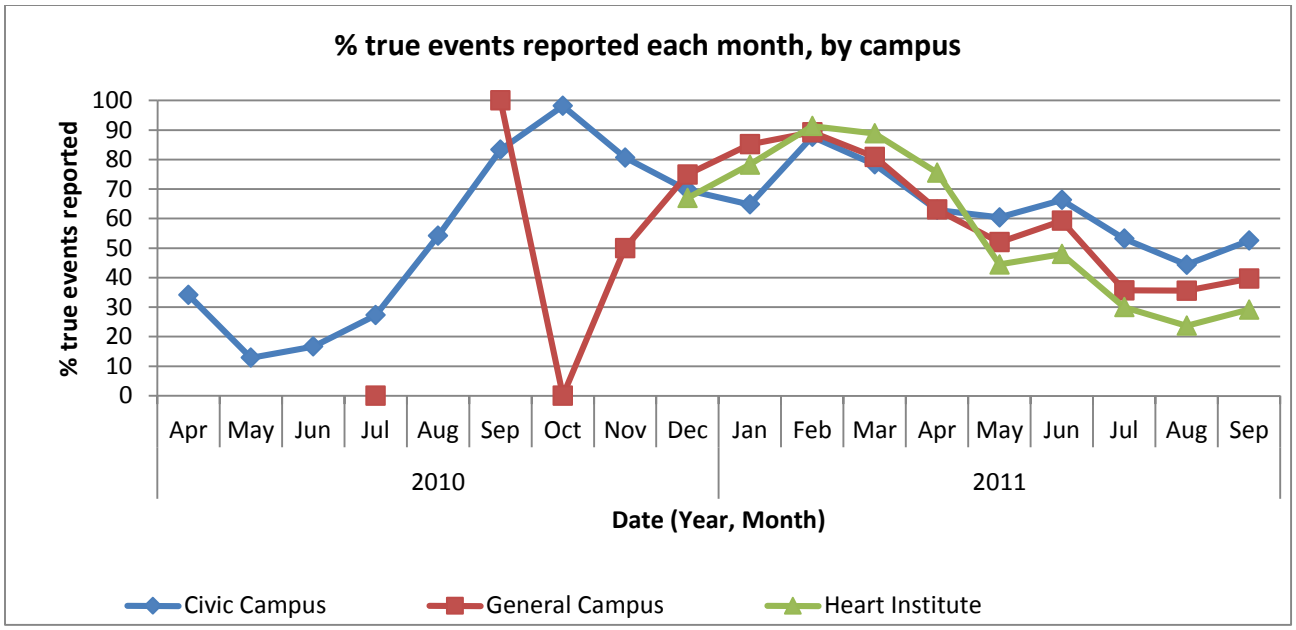


Figure 10 Monthly Incidence rate of true PSEs reported from April 2010-September 2011 by campus

3.7.2.2 By Program

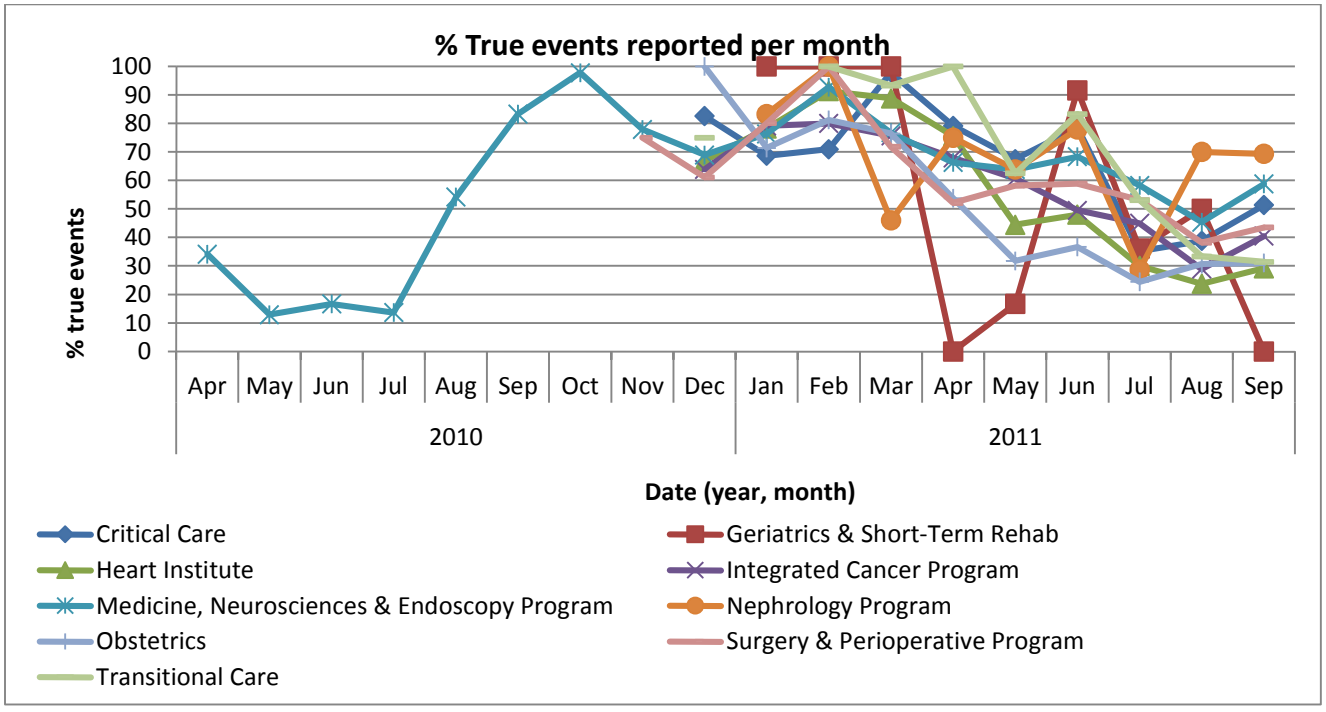


Figure 11 Monthly Incidence rate of true PSEs reported from April 2010-September 2011 by program

3.7.2.3 By reporter

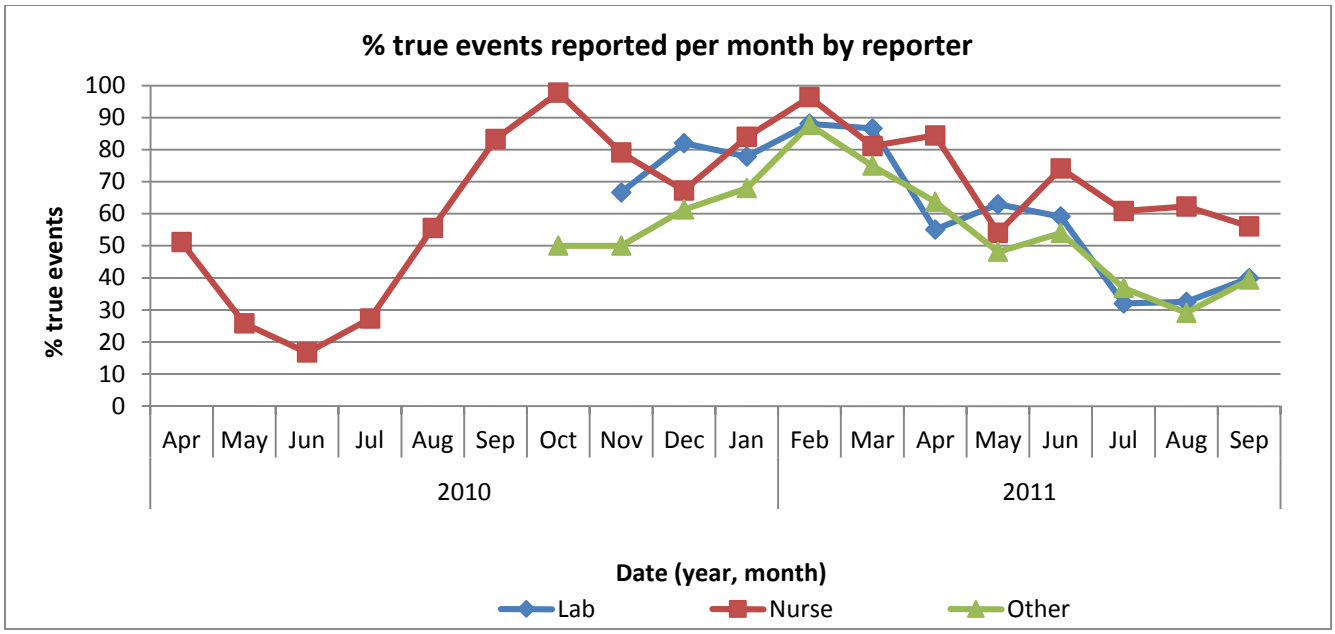


Figure 12 Monthly Incidence rate of true PSEs reported from April 2010-September 2011 by reporter

3.7.3 Raw counts of event classes by event type

Table 33 Raw counts of true PSEs by type and event class

	Non-Preventable	Preventable	Near Miss	Total Events
Laboratory	5	31	1146	1182
Fall	348	75	28	451
Medication / IV fluid / biological (includes vaccine)	1	55	316	372
Documentation		12	182	194
Clinical process / procedure	11	78	85	174
Transfusion Medicine		1	58	59
Equipment / product / medical device	2	12	23	37
Clinical administration		2	28	30
Vascular access lines	1	1	13	15
Accident (no falls)	9	4		13
Nutrition		2	10	12
Behaviour	3		7	10
Healthcare associated infection			9	9
Maternity care	6		2	8
Missing	1		2	3
Total	**387**	**273**	**1909**	**2569**

Trends among event types were similar. Overall, Laboratory events were the most common true event reported, representing 46.0% of all true events. The second was Falls, which represented 17.6% of all true events reported. The least common event class reported was Illness and Sterilization/disinfection; none of the true events were classified into one of these categories. Among adverse events (AEs), Fall were the most prevalent type of true event reported (89.92% of all non-preventable events and 27.47% of all preventable events). The majority of near misses were Laboratory events (60.03% of all true events).

3.7.4 Monthly rate by event class

I reported the monthly rates of true PSEs for the top 3 most frequent events: Laboratory, Falls, and Medication. The remaining programs did not have sufficient data to graph meaningful monthly trends.

3.7.4.1 Lab

3.7.4.1.1 By campus

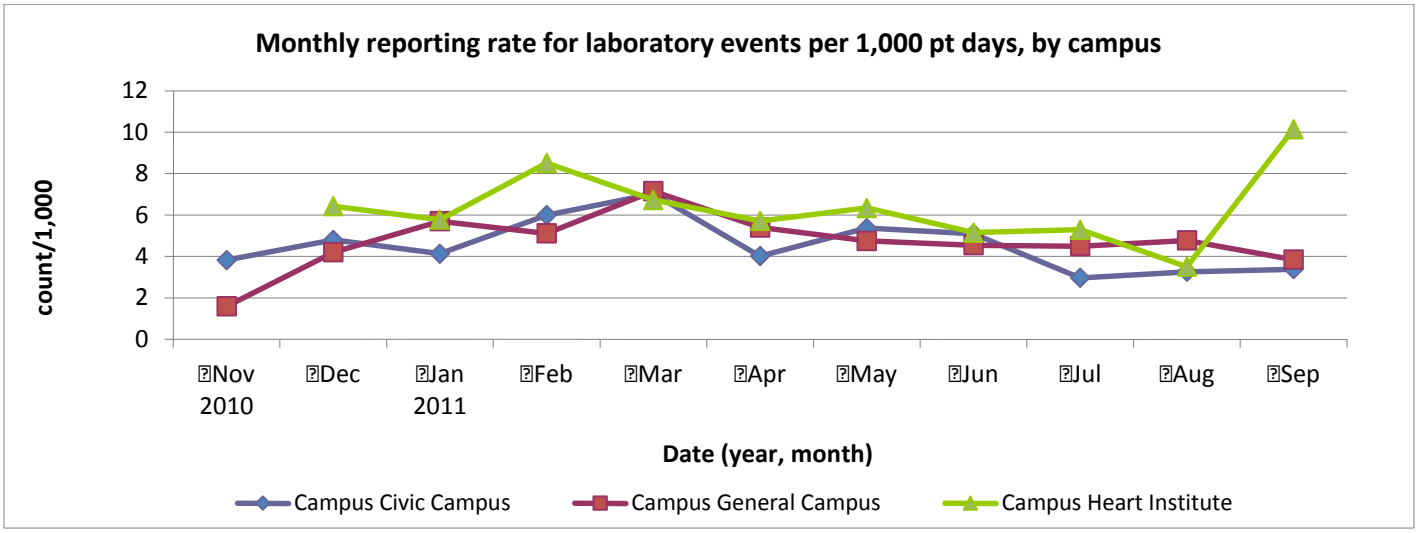


Figure 13 Monthly incidence rate of true laboratory events from April 2010-September 2011 by campus

3.7.4.1.2 By program

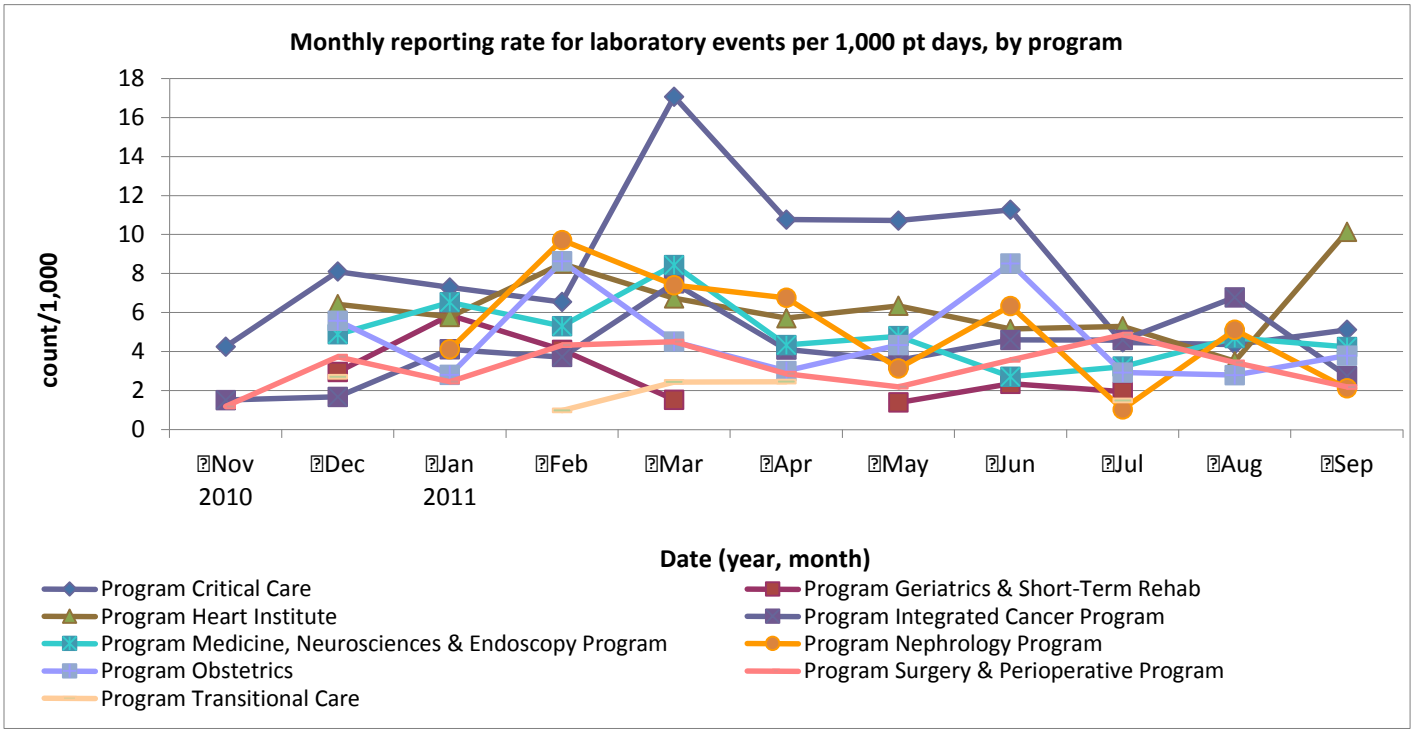


FIgure 14 Monthly incidence rate of true laboratory events from April 2010-September 2011 by program

3.7.4.1.3 By reporter

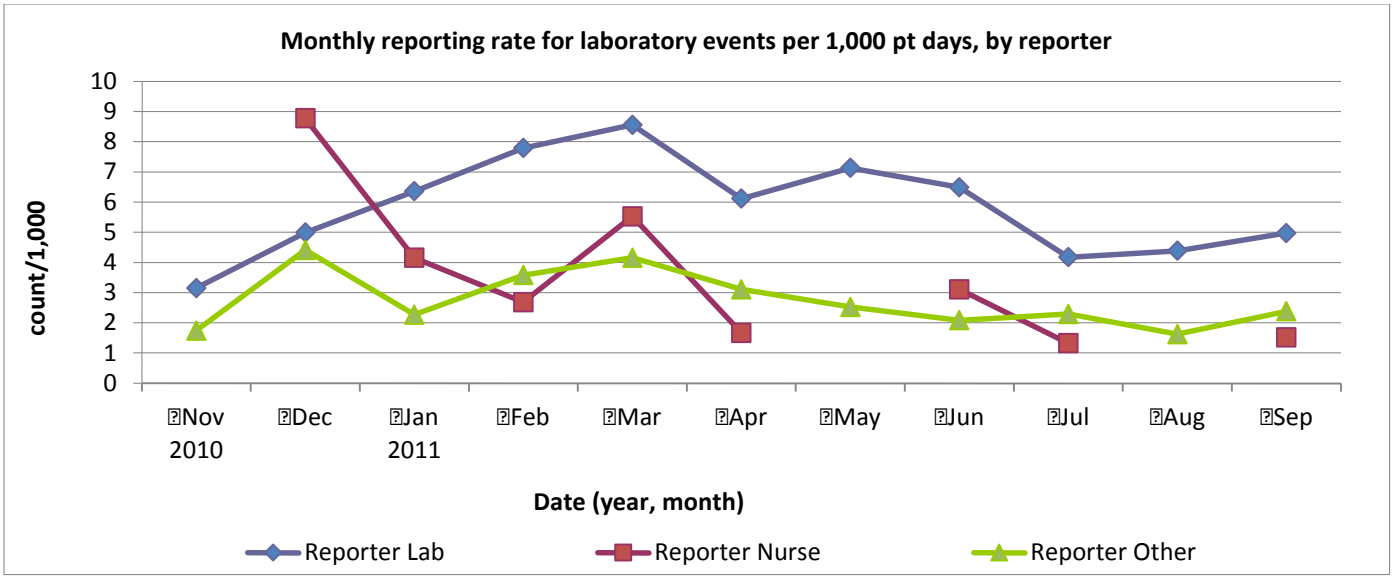


Figure 15 Monthly incidence rate of true laboratory events from April 2010-September 2011 by reporter

3.7.4.2 Falls

3.7.4.2.1 By campus

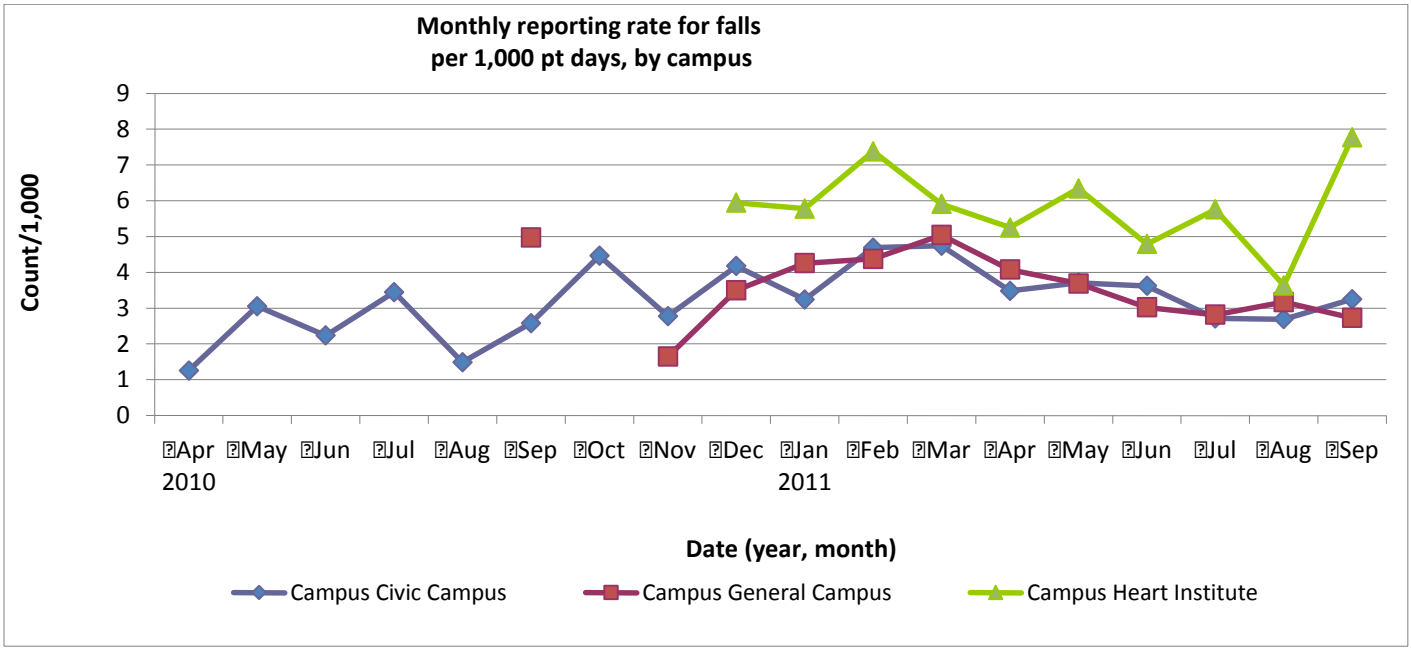


Figure 16 Monthly incidence rate of true falls from April 2010-September 2011 by campus

3.7.4.2.2 By program

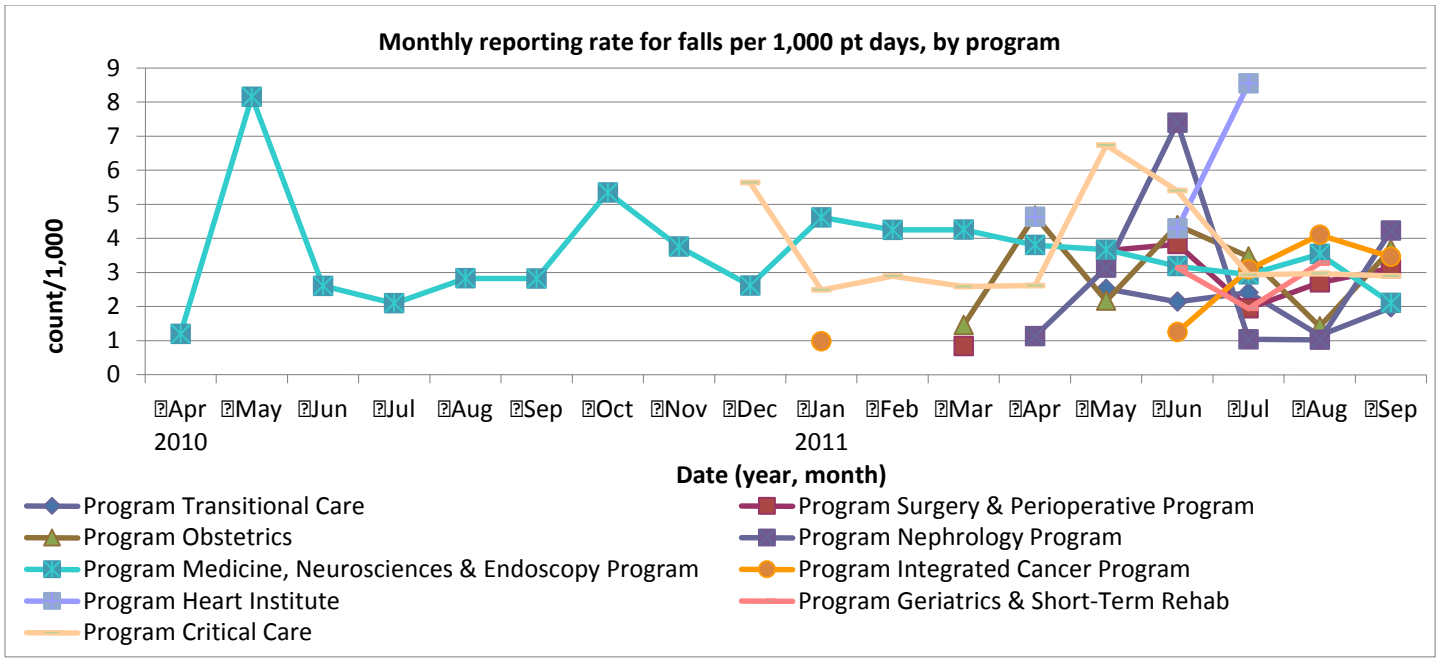


Figure 17 Monthly incidence rate of true falls from April 2010-September 2011 by program

3.7.4.2.3 By reporter

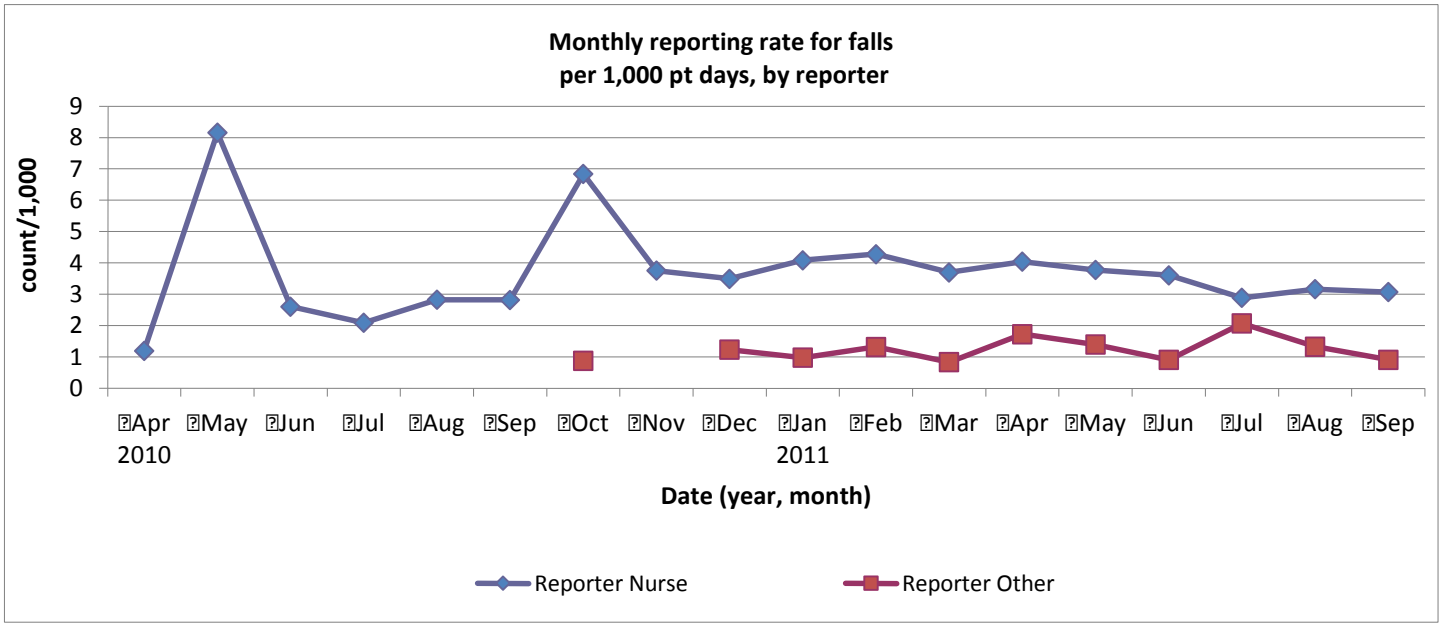


Figure 18 Monthly incidence rate of true falls from April 2010-September 2011 by reporter

3.7.4.3 Medication

3.7.4.4 By campus

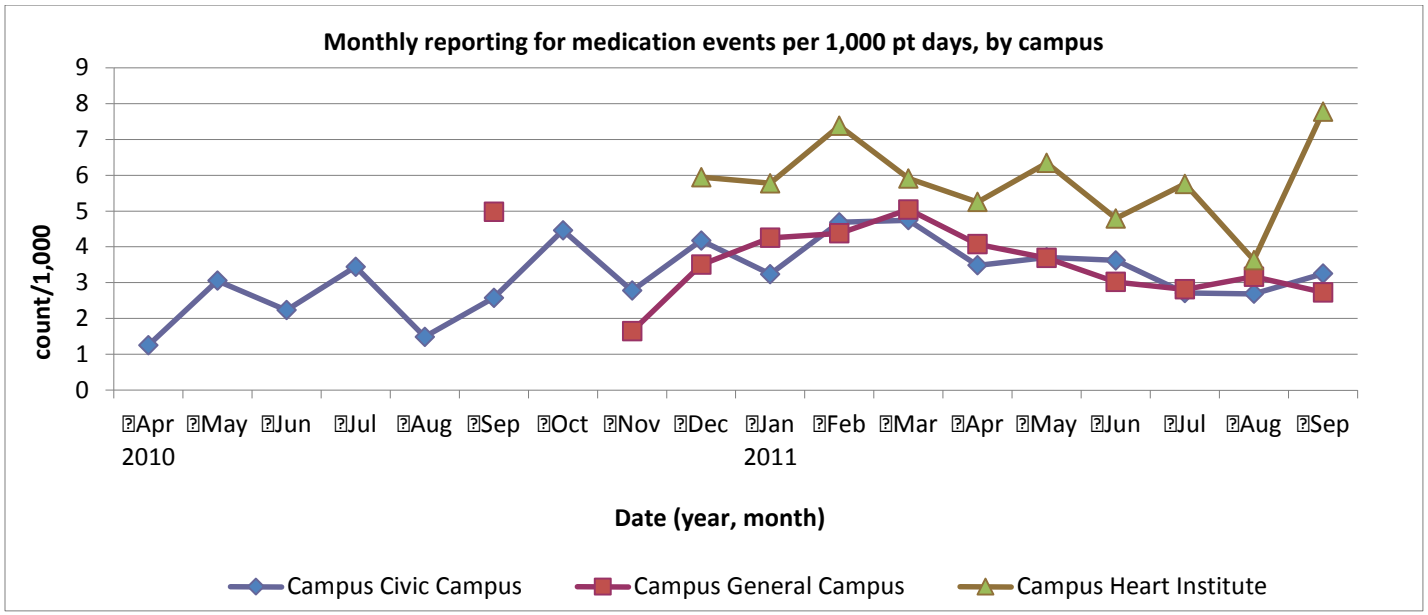


Figure 19 Monthly incidence rate of true medication events from April 2010-September 2011 by campus

3.7.4.5 By program

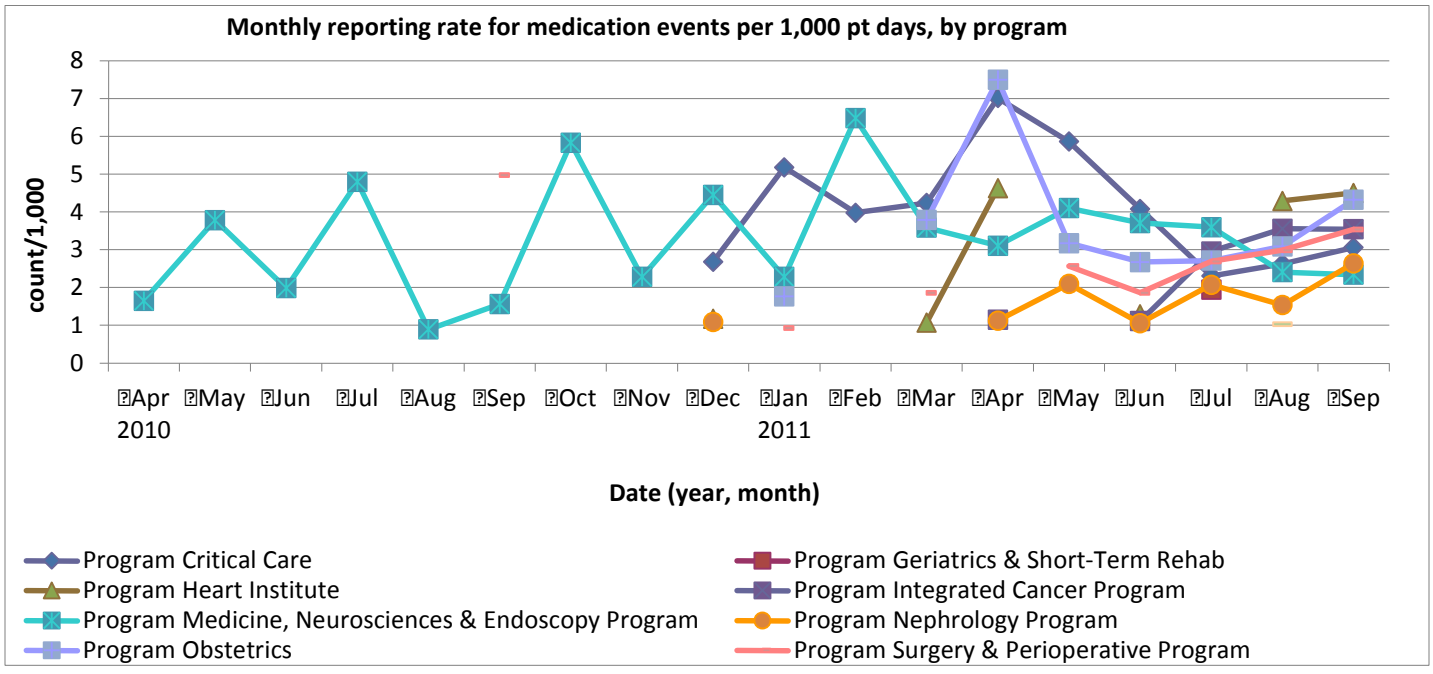


Figure 20 Monthly incidence rate of true medication events from April 2010-September 2011 by program

3.7.4.6 By reporter

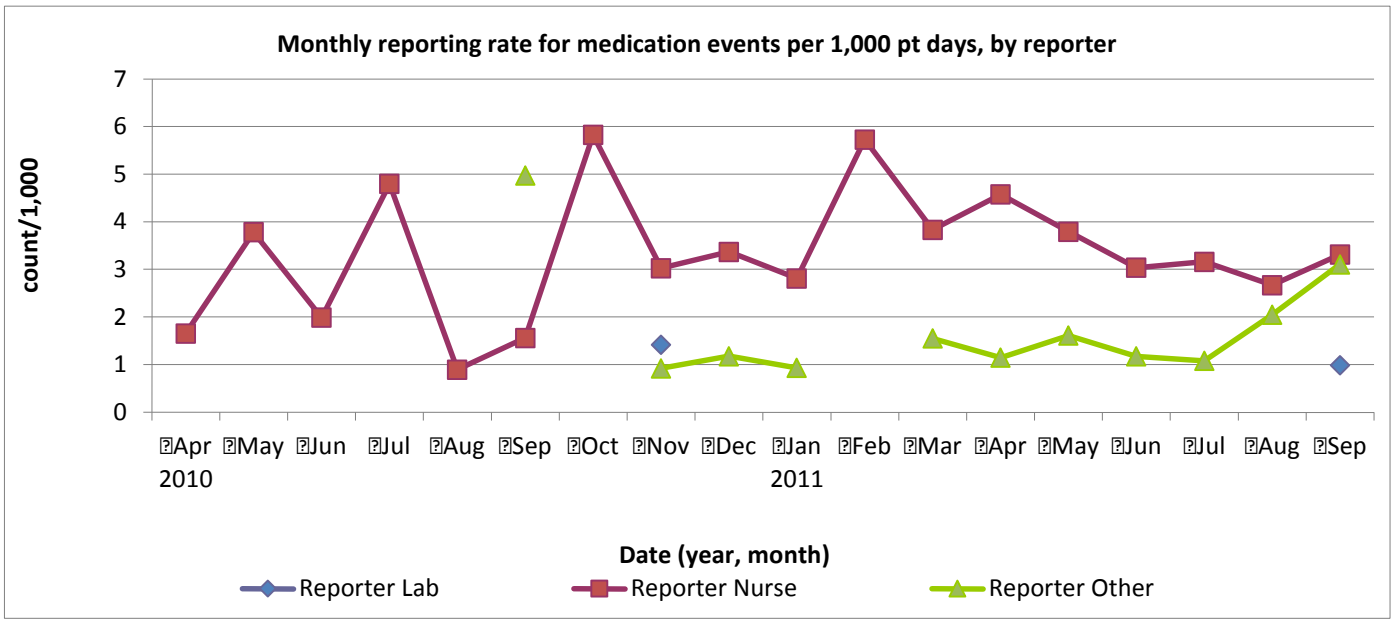


Figure 21 Monthly incidence rate of true medication events from April 2010-September 2011 by reporter

4.0 Discussion

4.1 Primary Findings

4.1.1 Primary objective 1: Positive Predictive Value of PSLS

Over the 18 months that the PSLS was in place at the Ottawa Hospital there were 10,349 voluntarily reported patient safety events. Linking these events to other hospital data highlighted many of the challenges of using voluntary reporting as a method of tracking safety. From a technical perspective, a large proportion of events could not be linked to other hospital data for a variety of reasons – some of which are a function of the underlying technical infrastructure and some because of the care delivery system at the hospital. Related to technical issues, a large number of events had to be excluded because of the absence of patient identifiers or because the identifying information included on the form was inconsistent with other hospital systems. Processes related to data validation could be used to address these issues. Related to care delivery systems at the hospital – this study highlighted the diffuse nature of the services provided at TOH – as large numbers of events were excluded because they occurred in children or in outpatients.

Once I linked all events to inpatient encounters, there were 4,066 patient safety events to evaluate. Of these, the core review function identified 2,569 events (63% (95% CI 62-65%)) as 'true patient safety events'. Of true patient safety events, 660 (25% (95% CI 24-26%)) were associated with some form of adverse patient outcome (termed adverse events), including 273 (10% (95% CI 9-12%)) that were considered preventable. The remaining 1,909 (74% (95% CI 73-76%)) true patient safety events, were what are considered to be near misses.

The PPV of having a true patient safety event for all events was (63% (95% CI 62-65%)). I saw some important variations in PPV. By program, Nephrology had the highest positive predictive value of 70.0%, while Obstetrics and Gynecology had the lowest, with only 47.93% true events reported. The values in the remaining programs ranged from 55.43% to 68.03%.

I observed that as the duration of having the PSLS increased, we found that the PPV decreased.

4.1.2 Primary objective 2: Generating a predictive model to identify factors associated with true events

Despite access to several conceptually appealing predictive factors and assessment of different analytic approaches, I was unable to define an accurate, clinically relevant, and universal approach to predicting the presence of true patient safety events. The models I built all had poor discrimination with c-statistics less than 0.7. The variables that were included in the model did not relate to clinical factors – the most consistent variable was time since PSLS implementation. Most importantly, we were unable to demonstrate a consistent set of predictors across clinical programs.

A full model that fitted all programs as a random intercept with reporters nested within had a poor calibration and discrimination, and therefore was not a suitable model. This may be due to the small sample size of some of the programs. I then conducted a simple covariate analysis for each program separately, which revealed that each program had a unique set of significant predictors. In light of this information, I did not feel that creating one model and generalizing it to all hospital programs was appropriate. Thus, I generated a different predictive model for each program, using the role of the reporter as the random intercept. Consequently, I could not include system-level covariates in my final model. Stratification improved the calibration and the discriminatory ability of all programs, except Integrated Cancer Program. However, the difference was negligible (0.65 in original model vs. 0.648 in integrated Cancer Program.

I fit the final multivariate models for Integrated Cancer Program and Medicine, Neuroscience and Endoscopy using GLIMMIX, and logistic regression for the remaining programs. Although both Obstetrics and Gynecology and Surgery and Periops both had significant covariance matrices, sample size constraints prevented me from using a hierarchical model. However, I feel that hierarchical modeling should be considered for these two programs in future studies.

Although I was able to obtain a good calibration from all 7 stratified models, the discriminatory ability remained poor (less than 70%) in all models except Heart Institute. Overall, it ranged from 0.65 in Critical Care

to 0.769 in the Heart Institute. Therefore, the overall utility of these models to predict patient safety events is limited.

The traditional patient and system-level covariates, which are used to predict adverse outcomes with high accuracy, are far less accurate at predicting adverse events. This may be because the relationship between clinical factors and adverse events is less direct than the relationship between clinical factors and adverse outcomes. In order to establish an association between clinical factors and adverse events, the patient must first posses a clinical factor that would pre-dispose them to an adverse outcome, the patient must then experience an adverse outcome due to medical care (adverse event), the adverse event must be acknowledged by a healthcare worker, and finally, the healthcare worker must report the event. There are many variables between the clinical factor and reporting the adverse event that can complicate the association. Human and behavioural factors, rather than clinical factors may play a larger role in predicting true event reporting. Factors such as a reporter's understanding of patient safety events, their views on the effectiveness of incident reporting, their level of comfort reporting adverse events, and previous social norms, are also important factors that are difficult to quantify.

Given that we were unable to predict which reported events were true patient safety events using existing system information, it will be necessary to continue the clinical review process. Since the discriminatory ability of all of my final models was poor; clinical reviewers are needed to identify true patient safety events.

4.1.3 Secondary objective 1: Incidence of overall reporting rates over time

Overall, the rate of patient safety events reported for inpatients were 6.39 per 1000 patient days. After an initial learning period, from April 2010-January 2011, in which rates were low, reporting rates *increased and* stabilized; remaining constant from month to month. This was similar across campuses, programs, and reporters. This suggests that these rates may not be reflective of the incidence of true patient safety event rates because they failed to change over time. A perhaps more accurate picture would show fluctuations over time in response to changes in the environment, such as: the introduction of new patient safety initiatives, patient population, staff and patient volume. An alternative finding would be that healthcare managers were not able to address the findings either because they did not explicitly address them or because their efforts for improvement were ineffectual.

4.1.4 Secondary objective 2: Incidence of true PSE reporting rates over time

Similar to overall reporting rates, the rate of true event reporting fluctuated greatly from April 2010 to January 2011. However, the proportion of true events reported each month steadily decreased from January to September of 2011. This trend was also observed across all campuses, programs, and role of reporter. This finding could be a function of effects at the reporter or reviewer role.

When considering the decrease in true events over time from the perspective of the reporter, there are two hypotheses that could explain this trend. The first is that the composition of reporters has changed over time. If the same reporters had been using the system consistently, I would have expected both reporting rates to be constant. Over time, it is possible that more providers will report events as the PSLS becomes a more recognized tool. In turn, this could lead to a decrease in PPV if there are a constant number of true events occurring. Also, as number of potential reporters increase, the need for education on the system and safety concepts also increases. There may be inconsistent opinions on what constitutes a true patient safety event, as more reporters come on line, the PPV will decrease because it becomes increasingly difficult to maintain consistency in reporting.

The second hypothesis is that the composition of reporters has remained constant, and changes in clinical and system-level factors have influenced their reporting behaviours. These could include patient volumes, or organizational changes that may have altered the way reporter view patient safety events. The anonymity of reporters was protected, so I cannot determine whether the composition of reporters had changed over the course of my study.

Pertaining to reviewer role, an individual's classifications may change over time. It is possible that the reviewer becomes more discriminating as time goes by –becoming more focused on certain types of events. This would decrease the overall PPV.

4.1.5 Type of events reported over time

4.1.5.1 Event type

Near misses were the most common event type, representing 45.95% of all events reported, and 74.31% of all true events. Previous literature identified fear of being reprimanded as one of the main barriers to incident reporting (Jeffe, 2004; Coyle, 2005; Madsen, 2006; Padmore, 2009; O'Connor, 2010; Mahajan, 2010; Hwang, 2012; Hartnell, 2012; Hashemi, 2012). Thus, healthcare workers would be more inclined to report events in which the patient did not experience any actual harm.

Although near misses do not result in patient harm, I feel they still represent useful quality improvement opportunities. Near miss reporting has been used in many other high risk institutions, such as aviation, space, and nuclear power, and have been successful in reducing adverse events (Barach, 2000). Barach et al highlighted several advantages to near miss reporting: 1) they occur much more frequently (in other institutions), which allows for quantifiable analysis, 2) there are fewer barriers to data collection, 3) recovery strategies can be studies to enhance proactive interventions and to de-emphasize the culture of blame, 4) there is less hindsight bias (after an event has occurred, you are more likely to view it as preventable) (Barach, 2000). Near misses allow for pro-active resolution of hazards: they identify lapses in

patient care, and provide healthcare staff with the opportunity to correct them before it causes harm to a patient. Furthermore, near miss reporting can engage healthcare workers in incident reporting, increase their safety ownership, and help them develop positive attitudes surround safety.

4.1.5.2 Event class

The most common class of events reported were lab events, followed by falls, then medication errors. Similar to nurses, the laboratory staff members were highly engaged in incident reporting and enthusiastic about the PSLS, so it is not surprising that the majority of true events reported were lab-related or nursing-sensitive. 80-90% of all diagnoses in the hospital are made based on lab results (Agarwal, 2013) and thus laboratory events should be regarded as useful quality improvement opportunities. Laboratory-related adverse events could lead to a delay in diagnosis, or a miss-diagnosis, which could have a significant impact on patient outcome.

4.1.5.3 Event severity

Given near misses were the most common event type, it was not surprising that the majority of PSEs also resulted in no harm (49.2% of total events, and 73.5% of true events). Death occurred in 0.1% of total events and 0.1% of true events.

4.1.5.4 Comparison to previous literature

45.5% of previous studies from tables 2-5 listed near misses as the majority of patient safety events reported. It is worthwhile to note that 100% of previous studies conducted on a single ward reported near misses as a majority, while only 40.0% of studies conducted on all hospital services reported near misses as a majority. This highlights that discrepancies in reporting behaviours between hospital services exist; it is not an anomaly in my study.

Falls and medication errors were common in-hospital adverse events in previous literature, but not laboratory events. The high prevalence of laboratory events in my study is likely due to the increased participation of laboratory staff compared to other departments, rather than a true high prevalence of laboratory-related events at TOH. As mentioned previously, PSLS is an anonymous reporting system, so I was not able to determine the proportion of laboratory staff using PSLS.

4.1.6 Frequency of reporting, by role of the reporter

Overall, the largest proportion of total events and true events were reported by nurses (44.4% of total events, 47.5% of true events), followed by lab staff (41.6% of total events, 40.9% of true events), and the remaining were reported by Other healthcare workers (14.0% of total events, 11.6% of true events). Out of the 5 programs that were modeled using logistic regression (Critical care, Heart Institute, Nephrology, Obstetrics and Gynecology, and Surgery and Periops), Obstetrics and Gynecology, and Surgery and periops included the role of the reporter as a statistically significant fixed effect in their final model. In both programs, lab and nurse staff were more likely to report true events compared to other healthcare workers. In Cancer and Medicine, which used the GLIMMIX model, nurses had the strongest median odds ratio in both programs (Cancer: 1.85, Medicine: 1.48). I was not surprised by this finding; although both laboratory and nursing staff had high reporting rates, nurses have traditionally done the majority of incident reporting (Kingston 2004; Wild, 2005; Schectman,2006; Evans, 2006; Hirose, 2007; Braithwaite 2008; Nuckols, 2009; Gong, 2011; Bodina, 2014). All healthcare workers received the same PSLS training, but I would expect nurses to be more proficient at detecting true PSEs due to previous experience.

There were some significant variations in PSLS participation between reporter roles and between programs; the most obvious was the Heart Institute, where nurses were only responsible for 5% of event reporting. One of the biggest concerns with these findings is the low participation of physicians. As mentioned previously in section 2.6.4.4 of the methods, only 7 events were reported by physicians. This is not

surprising, given the findings from the previous studies listed in table 4. Out of the 12 studies that recorded reporting frequency by provider role, 8 had the nurse as the main reporter, 2 listed other non-physician healthcare staff as the main reporter, and only 2 listed the physician as the main reporter. Previous literature has alluded to many reasons why physicians typically under-report adverse events. Junior doctors, residents, and medical students are often uncomfortable reporting on senior colleagues (Goldie 2003; Perez 2014). Senior doctors may also fear looking foolish in front of junior colleagues and also fear loss of self-esteem (Kaldjian, 2006; Perez, 2014). Furthermore, incident reporting was traditionally done by the nursing administration, and many doctors still view it as a nurses' responsibility to report ((Kingston 2004; Wild, 2005; Schectman,2006; Evans, 2006; Hirose, 2007; Braithwaite 2008; Nuckols, 2009; Gong, 2011; Bodina, 2014). Although physicians are less likely to report, they are more likely to report more serious events than nurses and other healthcare staff (Hirose, 2007; Braithwaite 2008; Evans, 2006; Rowin, 2008). Their lack of participation in the PSLS suggests that the system is not capturing many of the more severe, true PSEs.

Discrepancies in participation by role of reporter has important implications in terms of patient safety culture, PSLS training, and the types of events that get reported. I will discuss these implications in section 4.2, Implications of findings.

4.1.7 Comparison of PSLS data to baseline values in the total TOH inpatient population

The descriptive statistics suggest that the data reported to PSLS is not representative of the true inpatient population at TOH. Specifically, there were some notable discrepancies in event severity, comorbidities, and diagnosis.

In terms of event severity, no AEs resulted in deaths in critical care. This was somewhat surprising since Critical Care patients have a much higher risk of in-hospital mortality compared to other wards**.** This suggests that healthcare workers may not be comfortable reporting events that had a significant impact on the patient, and we are likely missing an important portion of true patient safety events occurring in the

hospital. In England, reporting patient death became mandatory June 1, 2010, between the quarter where death reporting was voluntary, and where death reporting became mandatory, incident reports increased by 17% (Donaldson, 2014).

With respect to comorbidity, 56% of true events in Critical Care were reported from patients with a Charlson Score of <=2, which is much lower than the average score in the true population. High overall scores were seen in Nephrology.

In terms of diagnosis, the most common diagnosis was factors influencing health status and contact with health services. According to ICD-10, this represents occasions when circumstances other than a disease, injury or external cause classifiable to categories A00-Y89 are recorded as "diagnoses" or "problems". This can arise in two main ways:

1) When a person who may or may not be sick encounters the health services for some specific purpose, such as to receive limited care or service for a current condition, to donate an organ or tissue, to receive prophylactic vaccination or to discuss a problem which is in itself not a disease or injury.
2) When some circumstance or problem is present which influences the person's health status but is not in itself a current illness or injury. Such factors may be elicited during population surveys, when the person may or may not be currently sick, or be recorded as an additional factor to be borne in mind when the person is receiving care for some illness or injury. (ICD-10)

This diagnosis class represents patients who are not severely ill and are much less clinically complex. Again, these findings highlight that healthcare workers are reluctant to report severe AEs in which significant harm occurred to the patient.

4.2 Implications of findings

In summary, we found that approximately 1/3rd of reported events were not true patient safety events. This implies that healthcare providers are not reporting adverse events appropriately, and that a clinical review process is necessary for a hospital voluntary reporting system to identify safety threats. Further, this implies that the reporting system requires reporters to provide sufficient documentation to enable the appropriate classification of the event. We also found that there was difficulty discerning true events from all events using a predictive model. Again, this implies the need to have every case be reviewed by a clinical review process to ensure we are not falsely classifying cases.

I found that patient safety events did not change over the era of the study – in frequency, type, or severity. This is somewhat discouraging for those responsible for system administration. It suggests that healthcare teams are not able to use this information to evaluate meaningful change.

My results show that the data captured in the PSLS is not representative of the true TOH population, and thus is not providing managers with accurate, representative information on patient safety events. This was deduced from descriptive statistics on event severity, patient comorbidity, patient diagnosis on admission, and well as reporting frequency by role of provider and by program. At the time I collected my data, the PSLS was only active 1 year and may not have been widely disseminated throughout all hospital programs and healthcare providers, which may also account for some of the discrepancies in reporting rates and accuracy of event reporting. However, I still feel that these data discrepancies are a reflection on TOH culture, PSLS training, and types of events reported, and I will discuss each of these implications below.

The higher rates of reporting among lab and nursing staff compared to previous studies indicates that they have created a culture that is more supportive of incident reporting. Low reporting rates among physicians and other healthcare workers may be due to cultural barriers. Davies et al identified 3 factors that are imperative to successful implementation of a new technology, all of which can influence a healthcare provider's decision to use the PSLS. The main categories are:

1) perceived usefulness: Physicians and other healthcare staff may be apathetic towards incident reporting because they feel that it will not result in any meaningful change.

2) perceived ease of use: Some reporters may find the system difficult to use, or difficult to incorporate incident reporting into their normal workflow. This may be especially difficult for healthcare providers who were not engaged in incident reporting in the past.

3) subjective norms: If reporting among physicians was not encouraged in the past, they will be less likely to adopt it. Previous studies have found that nurses are responsible for the majority of incident reporting (Kingston 2004; Wild, 2005; Schectman,2006; Evans, 2006; Hirose, 2007; Braithwaite 2008; Nuckols, 2009; Gong, 2011; Bodina, 2014). Other healthcare providers may be reluctant to report because they feel it is not their responsibility.

All TOH staff receive the same PSLS training, the higher level of reporting amongst lab and staff speaks to the point that they are more engaged with the PSLS system. Although reporting rates between the roles of reporter differed, the proportion of true events, the event types, and severity were similar across all reporting roles. This suggests that all healthcare workers struggle with identifying true events, or may be reluctant to report them. This highlights the need for better training, with emphasis on what constitutes an actual patient safety event. It may be necessary to have follow up sessions throughout the year to ensure that healthcare workers are clear on what to report. Training should also focus on incorporating incident reporting into everyday workflow, since many healthcare providers have not had previous experience with incidence reporting, I will discuss strategies on how to improve PSLS training in the paragraphs below.

Again, the data discrepancies described above re-iterate the point that voluntary reporting may not be represent the true proportion of adverse events in the population. Previous studies have shown that healthcare providers preferentially report events they are familiar with. Thus, lab-related events will be over-represented, and more severe events will under-represented in my study. This results in skewed picture of adverse event data.

My findings have important implications from the perspectives of a hospital CEO, a patient safety researcher, and as a member of the public. I will address each of them in the paragraphs below.

As a hospital CEO, I would be hesitant to use the results from the PSLS as true indicators of hospital performance and safety. I would work towards improving the validity of the PSLS system by engaging in conversations with the board of trustees, clinical program heads, patient safety researchers, and frontline staff to address the underlying themes associated with poor incident reporting.

The first theme I would investigate would be culture of incident reporting within each clinical program. Ginsburg et al identified 6 dimensions that should be used to measure healthcare providers' perceptions of patient safety culture: organizational leadership support for safety, incident follow-up, supervisory leadership for safety, unit learning culture, judge-free environment, and job repercussions of error. I would identify deficiencies in any of these domains and collaborate with patient safety researchers to develop strategies to improve them.

Next, I would develop strategies to increase reporting rates among physicians, residents and medical students. As mentioned above, this can lead to a participation bias and skewed event data. Several studies have stated that physician engagement in incident reporting is essential to the effectiveness of a hospital reporting system (Johnson, 2003; Hatfield, 2005; Anderson, 2006; Nuckols, 2009; Chassin, 2013). Increasing their input would result in a broader spectrum of events reported and provide a more accurate depiction of PSE frequency. To increase physician engagement in the PSLS system, I would advocate for the inclusion of quality improvement and patient safety into the core curriculum of medical students and residents. If patient safety is emphasized across their medical education, they will be more willing to contribute to patient safety initiatives. I would also ensure that senior physicians receive adequate education on PSLS reporting, so that the skills that residents acquire during training are re-enforced in the hospital setting.

I would also evaluate the effectiveness of current patient safety education and PSLS training. Previous studies have shown that many healthcare providers are unclear on what constitutes a true patient safety

event (Taylor, 2004; Kingston, 2004; Schectman, 2006; Gonzalez, 2009; Majahan, 2010; Hashemi, 2012; Hwang 2012). Wong et al conducted a systematic review of the current patient safety programmes for residents and found that patient safety education was very effective at changing residents' attitudes and knowledge of incident reporting, yet it did not produce any changes in behaviour. Similar results were also seen in a study conducted with registrars (Jansma, 2010). Thus I would attempt to bridge the gap between education and behaviour change.

Davis and Bauchner both published papers on factors that influence behavior change among physicians, and concluded the following:

1) Physicians often oversestimate how good their own practice adheres to national guidelines.
2) Traditional didactic lecturing, continuing medical education, and passive distribution of information and guildelines does little to change behavior
3) Having information available to physicians is necessary, although not sufficient
4) Audit and feedback is only modestly effective in changing physician behaviour. Greater improvement is obtained with feedback is combine with specific recommendations. Source and purpose of feedback will also affect how successful it is
5) Interventions with the most success at improving physician behavior are: educational outreach with local opinion leaders, multidisciplinary clinical paths, and reminders (both computerized and manual)
6) Financial incentives are powerful drivers of physician behaviour under certain circumstances.

Using these findings, and principles of knowledge translation, I would implement effective strategies to increase reporting amongst physicians, and improve the rate of true event reporting among all healthcare workers. The Pathman-Preceed model for knowledge translation is depicted in figure 22 below.

Table 2 Pathman-PRECEED model for knowledge translation

	Perspective of target (policy maker, consumer, or clinician)			
Intervention*	**Awareness**	**Agreement**	**Adoption**	**Adherence**
Predisposing	Distribution of printed information; journals; media campaigns; lectures, rounds; academic detailing			
Enabling		Opinion leaders; small group sessions for clinicians	Small group sessions for clinicians; patient education methods; clinical flowcharts or algorithms; academic detailing	
Reinforcing			Small group sessions for audit and feedback	Reminders (professional and patient), multiple interventions

*Perspective of healthcare or educational system.

Figure 22 Pathman-PRECEED model of knowledge translation

The Pathman-PRECEED model includes 3 factors for an effective intervention: Predisposing, Enabling, and Reinforcing, in turn, these factors lead the target consumer to move through 4 stages: Awareness, Agreement, Adoption, and Adherence,

I would address each of these in the following way:

1) Predispose to change by increasing knowledge or skills: This can be accomplished by disseminating results from the monthly PSLS reports to healthcare workers. Although this method alone is not sufficient to cause behavior change, it can be used to make healthcare workers aware of current issues in event reporting.
2) Enable change by promoting conductive conditions in the practice and elsewhere: Enabling tools are needed for healthcare workers to move from awareness to agreement and adoption. This can include small group sessions with opinion leaders, such as patient safety experts within TOH, who can speak about the importance of incident reporting. Flow charts, and quick diagrams could also be included in the PSLS system, to help healthcare workers identify true events.
3) Re-enforce change once it is made: Adherence to appropriate incident reporting can be achieved by reminders, audit, and feedback sessions. Clinical managers could do a monthly audit on incident reporting rates, the percentage of true events, and event types.

Lastly, I would develop strategies to drive behaviour change in incident reporting. Firstly, I would consider designating reporter 'champions' within each hospital program. Historically, organizational champions have been effective in driving cultural shifts and behaviour change in the healthcare setting (Hendy, 2012). Preferably, the champion would be a provider in a senior position with expertise in incident reporting who can educate their staff on how to identify true events, and will encourage incident reporting across all provider roles.

Secondly, I would also work with clinical managers to improve the closing of patient safety events. More emphasis should be placed on communicating the end result of patient safety events to their staff. This is complicated by anonymity: the identity of the reporter and the individuals involved in the patient safety event are protected, so managers cannot follow up with individual reporters after they have submitted an event. Currently, monthly reports are generated on the types of events reported to the PSLS. These monthly reports could be improved by showing the percentage of true events reported each month, and a summary of the actions taken by managers to close each true patient safety event. This would make frontline healthcare providers aware of the accuracy of their reports, and also enforce the notion that each patient safety event is investigated on an administrative level.

Thirdly, I would include examples of positive deviance in PSLS training sessions. If healthcare providers are aware of the success of other incident reporting programs, they may be more inclined to report, and more astute to identifying true patient safety events.

Lastly, I would also consider introducing incentive programs to get frontline staff more engaged in incident reporting.

As a patient safety researcher, I would investigate any barriers to true event reporting, and factors that influence reporting behaviours at the individual and institutional level. The technology acceptance model,

developed by Davis, identifies three main themes that are necessary for technology acceptance among healthcare workers: perceived usefulness, perceived ease of use, subjective norms (pressure from co-workers and senior leaders to use the technology) (Davis, 1989). Furthermore, Gordin et al conducted a systematic review to identify factors that predict healthcare provider behaviour. The five strongest predictors were: Intention, beliefs about consequences, beliefs about capabilities, social influences, and past behaviour. I would investigate each of these by conducting focus groups and qualitative analyses across different healthcare providers.

At the Individual level, I would investigate the following:intention: the extent to which providers want to report; knowledge of the PSLS system: provider's proficiency with PSLS and their ability to distinguish true events from non-events; healthcare provider's attitudes towards the PSLS and incident reporting: perceived ease of use, perceived usefulness, beliefs about consequences; and past behaviour: I would determine how often providers used previous incident reporting systems, and whether they have been engaged in previous quality improvement initiatives.

At the Institutional level, I would investigate social influences. Junior doctors, residents, and medical students are often uncomfortable reporting on senior colleagues(Goldie 2003; Perez 2014). Senior doctors may also fear looking foolish in front of junior colleagues and also fear loss of self-esteem (Kaldjian, 2006; Perez, 2014). Furthermore, incident reporting was traditionally done by the nursing administration, and many doctors still view it as a nurses' responsibility to report. I would further investigate the 6 domains mentioned by Ginsburg et al to determine whether the hospital culture is supportive of incident reporting. I would also examine this at the Ottawa Hospital overall, and within individual programs. Lastly, I would collaborate with hospital CEO on strategies for behaviour modification and organizational change.

As a member of the public, I would be reluctant to trust patient safety statistics reported from the PSLS system. I would like to see more emphasis placed error reporting and improving safety culture.

4.3 Study Strengths

The Patient Safety Learning System has several unique features making it potentially more useful than other voluntary reporting systems. First, it contains a peer review stage, in which all entered events are assessed using standardized criteria. This has enabled me to distinguish true patient safety events from non-events, and identify predictive factors and trends. To my knowledge, this is the first study that has attempted to develop a predictive model for voluntary reporting behaviour. Second, it requires reporters to enter other patient and encounter data which can be used to link it to system data. This in turn can be used to determine other system factors which might be associated with safety events. It can also be used to determine the fidelity of data entry by reporters. This is the first study to evaluate a system from these perspectives.

The PSLS was able to rectify some of the weaknesses of previous incident reporting systems. Firstly, the overall quality of data was high (with the exception of missing MRNs, which as mentioned above, has been rectified). Many previous incident reporting systems lacked sufficient contextual and denominator information, whereas the PSLS had many mandatory fields, ensuring that all relevant information was captured. The PSLS created extensive fields that allowed the reporter to provide meaningful event and patient level data pertaining to the PSE. Most of this data was entered using drop down menus, which improved the standardization of data across all events.

Secondly, the free text boxes gave reporters the freedom to describe the unique aspects of the patient event. This improved the contextual information available, which helped to distinguish true PSEs from non-events. The true events had very little missing data, so there was sufficient information to identify clinically important trends in event reporting, and to follow up with true PSEs.

Lastly, this study also linked data from the PSLS to the Data Warehouse, which allowed me to obtain event, patient, and system-level factors associated with an adverse event.

4.4 Study Limitations

Although some progress has been made, there are many important issues that still need to be addressed. First, the data consistency between the PSLS and the OHDW can be improved. Although the data entered within the PSLS was consistent, there were some discrepancies in common data fields between the PSLS and the OHDW. The 3 main data quality issues that arose were: missing patient MRNs, discrepancy in the location of the event between the PSLS and OHDW, and inaccurate patient volume and staffing metrics. The former issue has been resolved for all future events reported. Further investigations are needed to resolve the latter issue; this will allow us to conduct more powerful analyses. From the point of view of my study, this gap led to the exclusion of a large number of events. In turn, this decreased the power of my study and could be one factor leading to my finding of a model with weak discrimination.

Furthermore, I also found some inconsistencies between data tables within the OHDW, mainly the patient and staffing tables. As a result, I excluded higher system-level variables from my study, which are likely to influence reporting behaviours. However, my analysis also revealed that a single set of event and patient-level predictors could not be applied across all programs to achieve a good fit. Ultimately, I created a separate model for each hospital program, which eliminated the system-level variables from my model. Thus, regardless of the quality of the data, the system-level variables would have been excluded. Although these data discrepancies do highlight the challenges and limitations of administrative database research, and may have contributed to the limited utility of my model, they do not affect the PPV of the PSLS, and the decrease in true events reported over time.

Data consistency between large administrative databases is challenging for several reasons. Data is captured from a variety of different sources; consistency across all of them requires continued collaboration among staff members of different roles and departments. In addition, existing codes are continuously changed and updated. As seen with the coding for functional centers, new functional centers can be created within the nursing unit tables to solve an overflow issue, or nursing units can be re-assigned to a different

hospital program. This layer of complexity exacerbates the difficulty of maintaining consistent data across different sources.

The second weakness not addressed by the PSLS was the underreporting of true patient safety events. Due to a lack of a gold standard for incident reporting, it is difficult to determine the true number of patient safety events that occurred. Thus, I cannot quantify the sensitivity of the PSLS system, nor extent of event under-reporting. In previous literature, rates of under-reporting ranged from 5-95% (Barach, 2000; Kim, 2006; Milch, 2006).

Thirdly, the core reviewer is not a true 'gold' standard. Thus, its classifications are subject to error, making it increasingly difficult to develop a predictive model. This could be improved by introducing more core reviewers to ensure more accurate event classification. This approach is not feasible in this setting but could be achieved if we had a research study. This factor again may have contributed to my inability to identify factors associated with the outcome: if ratings themselves are inconsistent then the ability of a model to find an association is reduced.

Lastly, the main weakness of the PSLS was the over-reporting of non-events;(36.82%) of events recorded were not true patient safety events, and the proportion of true events being reported has decreased over time. This suggests that there may have been systematic changes in how the PSLS was used by frontline healthcare providers as the system matures. It is possible that once the system has stabilized there will be different results.

5.0 Conclusion

A total of 63% of all events reported within the PSLS were true events; the proportion varied by program. Thus, the overall reporting rate of true events was low, and decreased over time. The discrimination of the final models were poor; clinically relevant event, patient, and unit level factors that are commonly used to predict adverse outcomes were not accurate predictors of true patient safety

events. This suggests that a clinical review process as embedded within the PSLS is a critical component of the program. The PSLS has the potential to be a valid learning tool and to reduce patient safety events. The use of a clinical and core reviewer is extremely valuable, since it identifies which reported events are truly associated with patient safety. It can also serve as useful feedback to managers to determine if healthcare providers are using the system appropriately. The detailed denominator information can be used to identify meaningful trends in patient safety events, and can also highlight lapses in care. This can be used to assist managers in streamlining their quality improvement initiatives. However, given the stable reporting rates and the consistency of event frequency, type and severity over time and within programs – it does not appear to be achieving this promise as of yet. It is possible that many different individual and institutional barriers are limiting its effectiveness as these have been found elsewhere to be important challenges to success. The issues of incident reporting systems are complex and multi-faceted, and transformational change is often very slow. Initiatives targeting effective patient safety education and behaviour modification are necessary to galvanize changes in reporting attitudes and behaviours.

6.0 References

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7.0 Abbreviations

Abbreviation	Full Description
AIC	Akaike's Information Criterion
CC	Critical Care
CAN	Integrated Cancer Program
GER	Geriatrics and Short-Term Rehabilitation
HI	Heart Institute
MED	Medicine, Neuroscience, and Endoscopy
NEPH	Nephrology
OBS/GYN	Obstestrics and Gynecology
SURG	Surgery and Perioperative period
TRANS	Transitional Care
PSE	Patient Safety Event
PSLS	Patient Safety Learning System
SAS	Statistical Analysis Software
TOH	The Ottawa Hospital
TOHDW	The Ottawa Hospital Data Warehouse
WID	Warehouse identifier

8.0 Appendices

APPENDIX A

The Patient Safety Learning System-Implementation and progress to date

In 2009, the Ottawa Hospital developed the Patient Safety Learning System in response to advice from Accreditation Canada to implement a number of required organizational practices pertaining to patient safety before the 2010 audit. In May of 2009, a consultant was hired to assist the Ottawa Hospital in selecting a commercial vendor to implement a voluntary incident reporting system. The consultant recommended Datix Ltd, a software company that has been providing incident reporting systems for patient safety since 1986. In July 2009, Datix agreed to work with TOH to incorporate the PSLS into their existing commercial product. Over the next year, Datix and experts at TOH collaborated to develop this unique product. The project officially began in January 2010, current state analysis was conducted from February 2010-April 2010 to prepare for the launch of the pilot. The Voluntary Reporting pilot was launched on the Internal Medicine floors (A5 and B5) at the Civic Campus and at the Radiation Therapy Treatment Centre in the Cancer Centre from April 2010-May 2011. Corporate clinical rollout began in June 2010 and ended in June 2011, where the PSLS was implemented in various wards across the Ottawa Hospital. Table 1 provides a list of go-live dates for specific wards.

PROGRAM	Go Live Date
Mental Health	Sept 7th
Pharmacy	Sept 14/10
Medicine – CTU, Endoscopy, Neurosurgery, Neurology	Nov 22nd Neurosurgery March 28

Critical Care, Emergency	ICU Dec 13 ER March 7
Laboratory Medicine	Nov 29/10
Diagnostic Imaging	Dec 20th
Obstetrics Gynecology, Newborn Care	March 14 and March 21(for Riverside)
Nephrology Programs	Arpil 11TH Civic and General MAY 11TH Riverside (Off site tbd)
Surgery & Periops	May 2/11
Transitional Care and ALC programs	May 9, 2011
Ambulatory Care and Eye Care	May 16
Geriatrics & Physio	June 6th
Spiritual Care & Social Work	go live June 6
Cancer Care	June20

Rehabilitation and Family Health Team	June 20/11
Professional Services	June 27/11
Heart Institute	Tbd
Non clinical areas	Tbd

Currently, TOH is working on a plan to identify non-clinical staff that require access to PSLS; however a timeline has yet to be determined. Over the summer, TOH hopes to upgrade the existing application to the most recent version in order to reflect changes expressed by analysts and upper management.

APPENDIX B

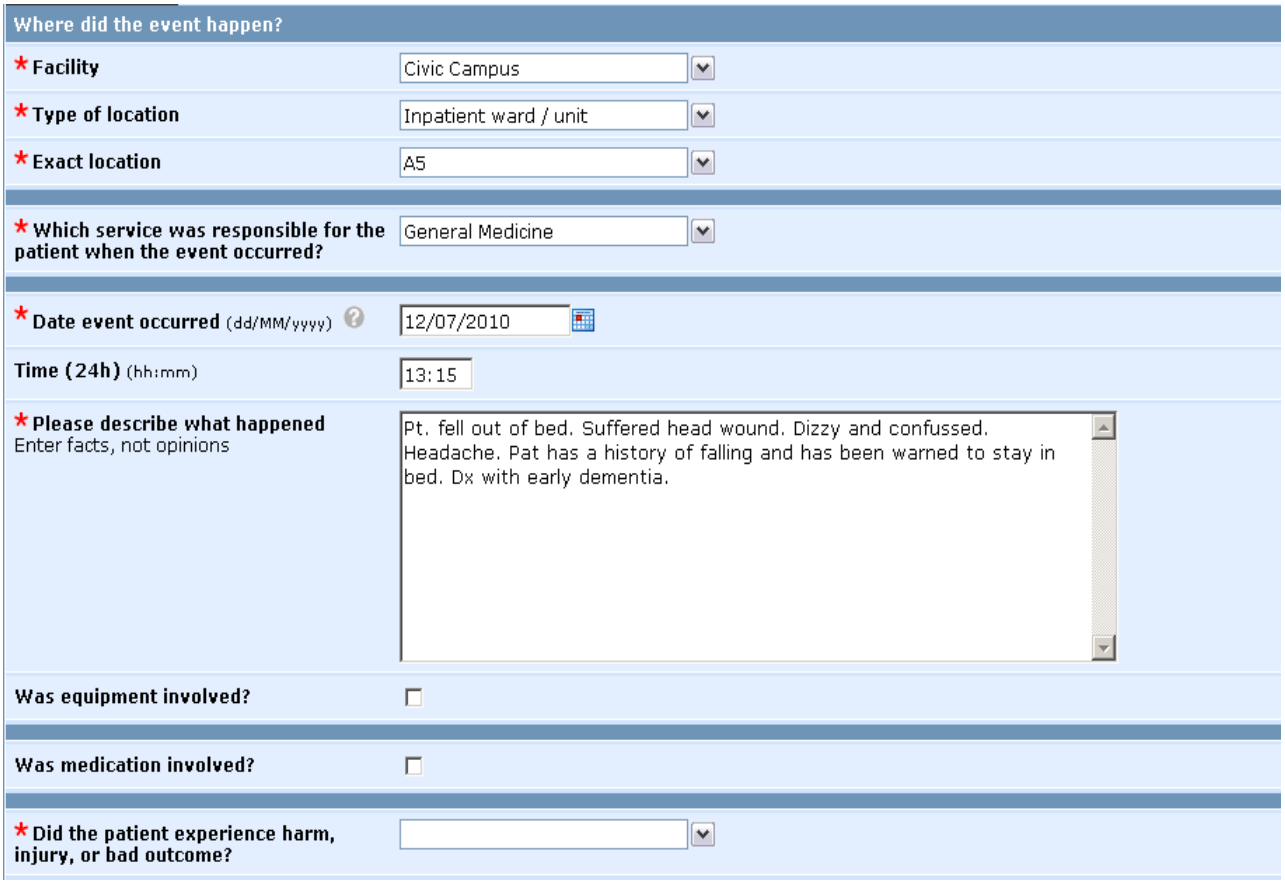


Figure 1: The Voluntary Reporting Stage- Where and what

Figure 2: The Voluntary Reporting Stage- No harm

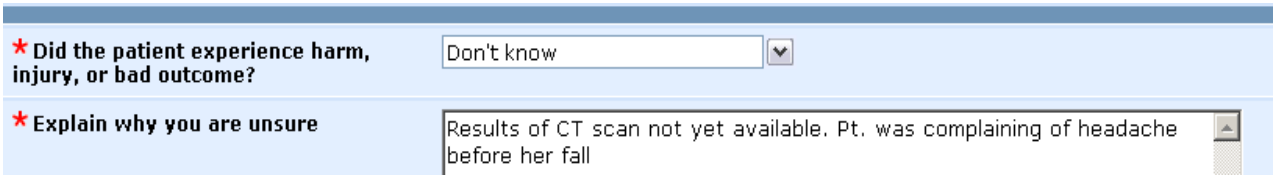


Figure 3: The Voluntary Reporting Stage- Don't know if harmed.

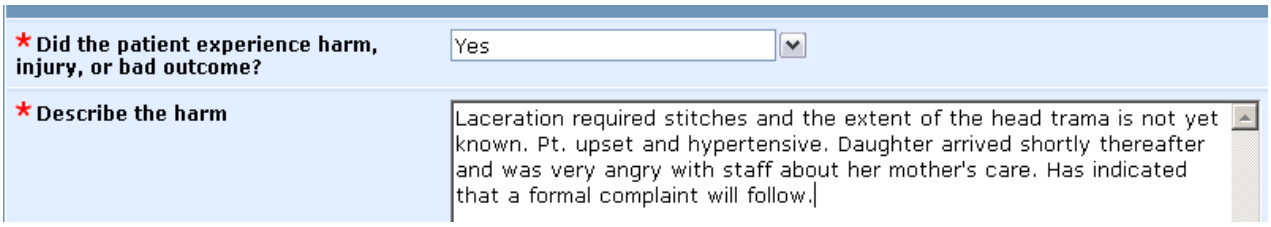


Figure 4: The Voluntary Reporting Stage- Yes to harm

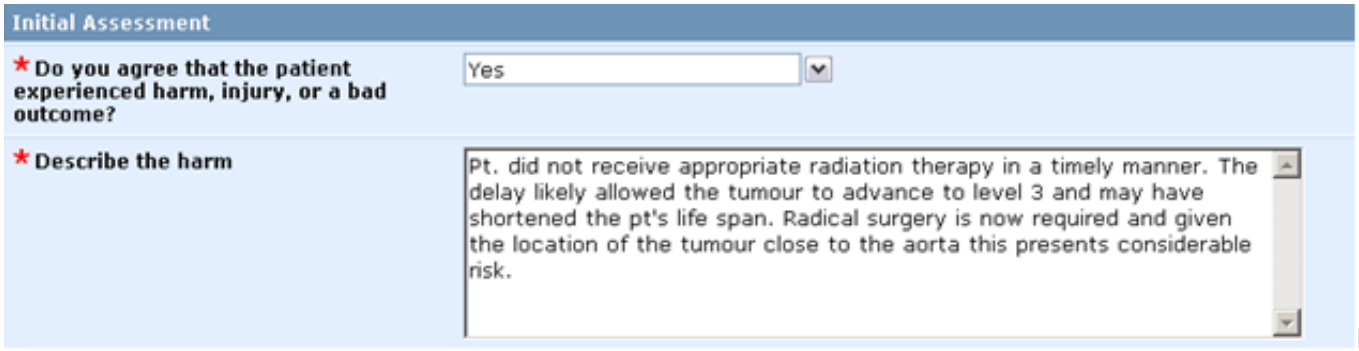
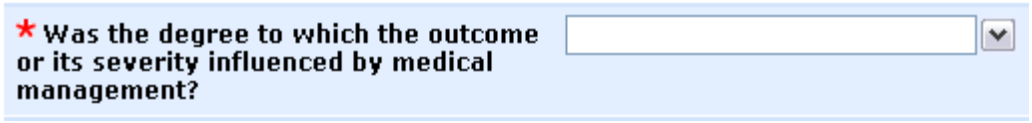


Figure 5: The Clinical Review Stage- Agreement of harm



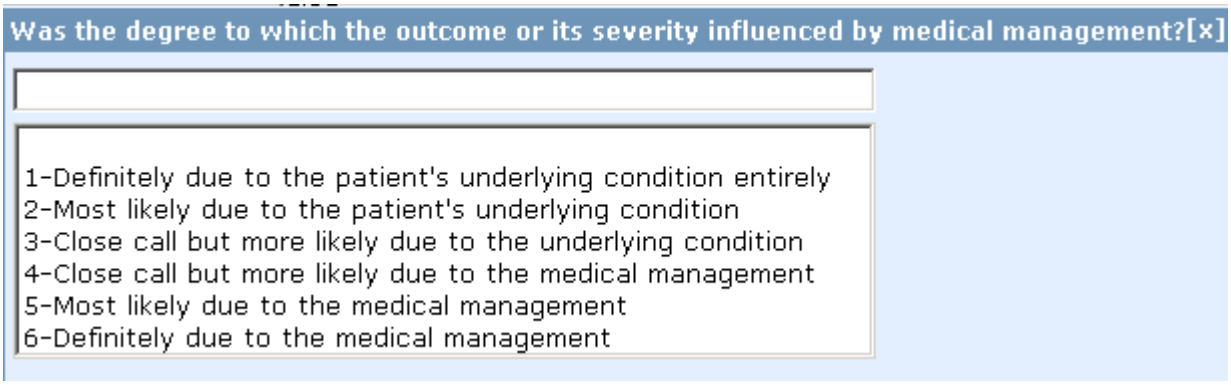


Figure 6: The Clinical Review Stage- Assessing preventability by medical management

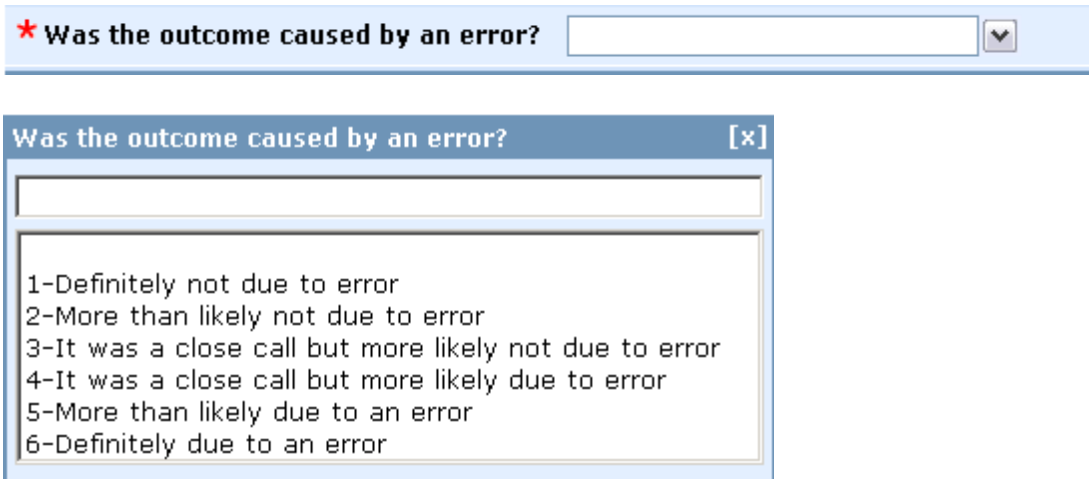
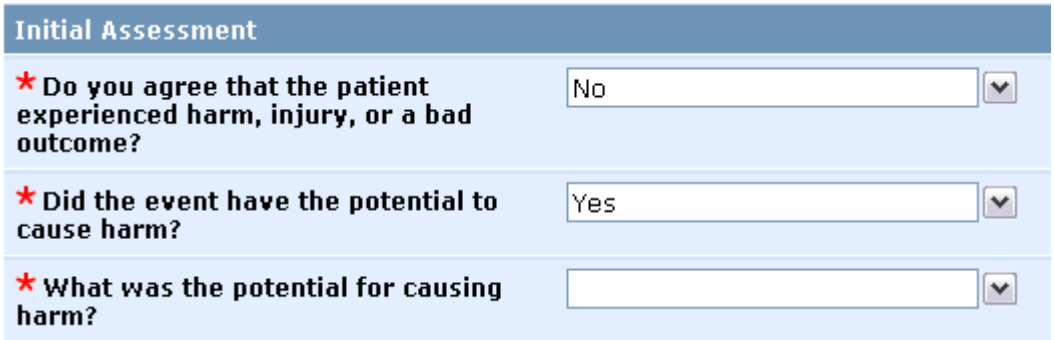


Figure 7: The Clinical Review Stage- Assessing preventability by medical error



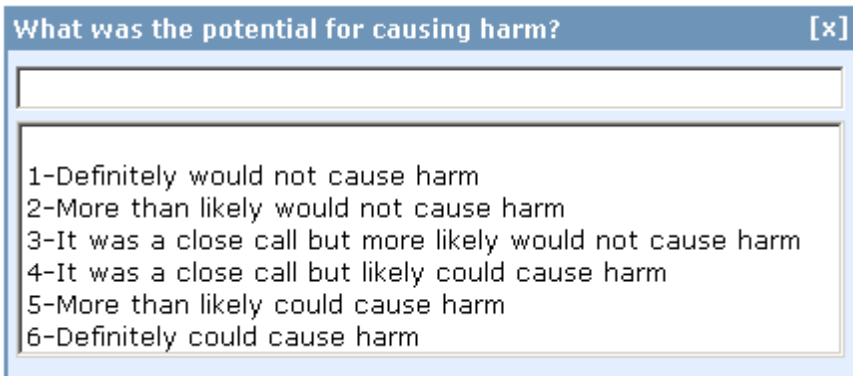


Figure 8: The Clinical Review Stage– No harm, assessing potential harm

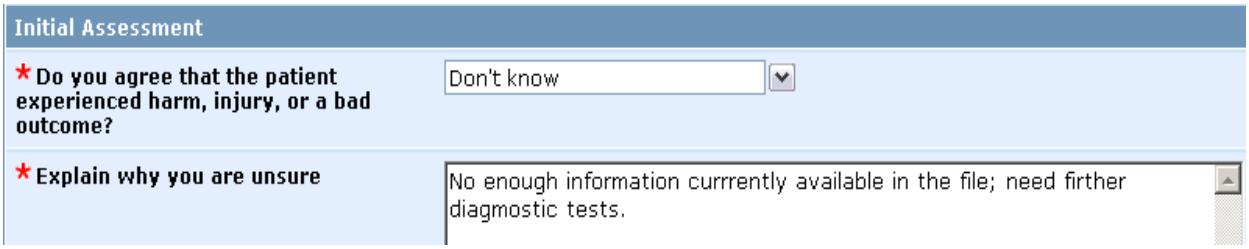


Figure 9: The Clinical Review Stage– Don't know if patient harm occurred

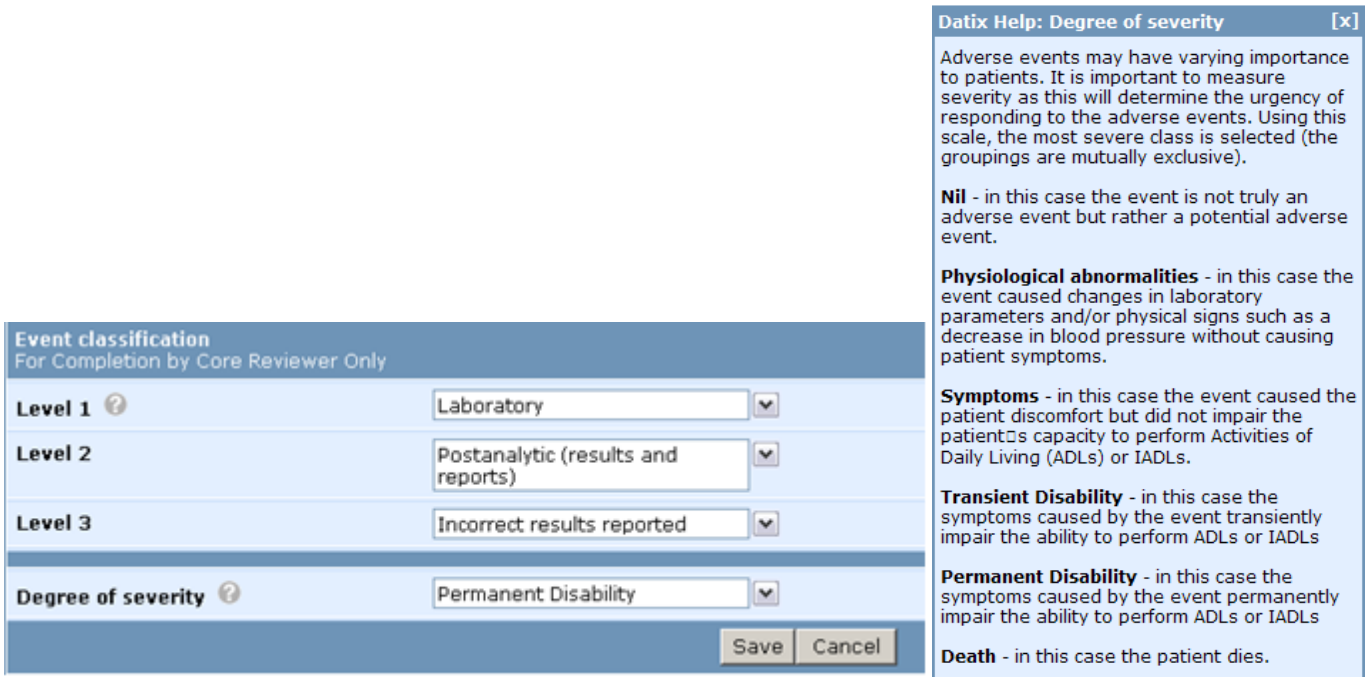


Figure 10: The Core Reviewer Stage- Assessing severity of event

APPENDIX C

Figure 1- Flow chart of PSLS event classification

APPENDIX D

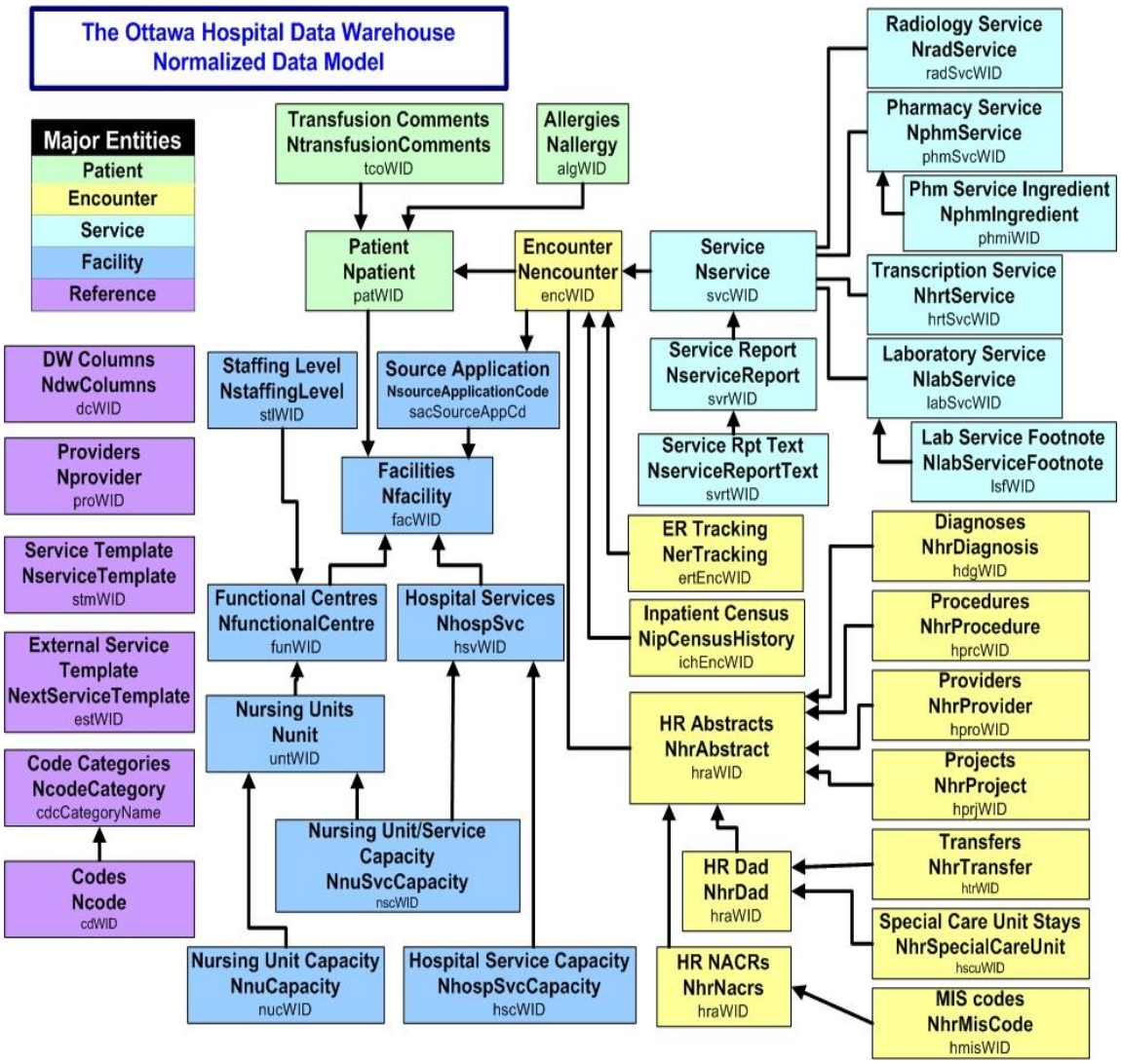


Figure 1- Conceptual Map of OHDW

APPENDIX E

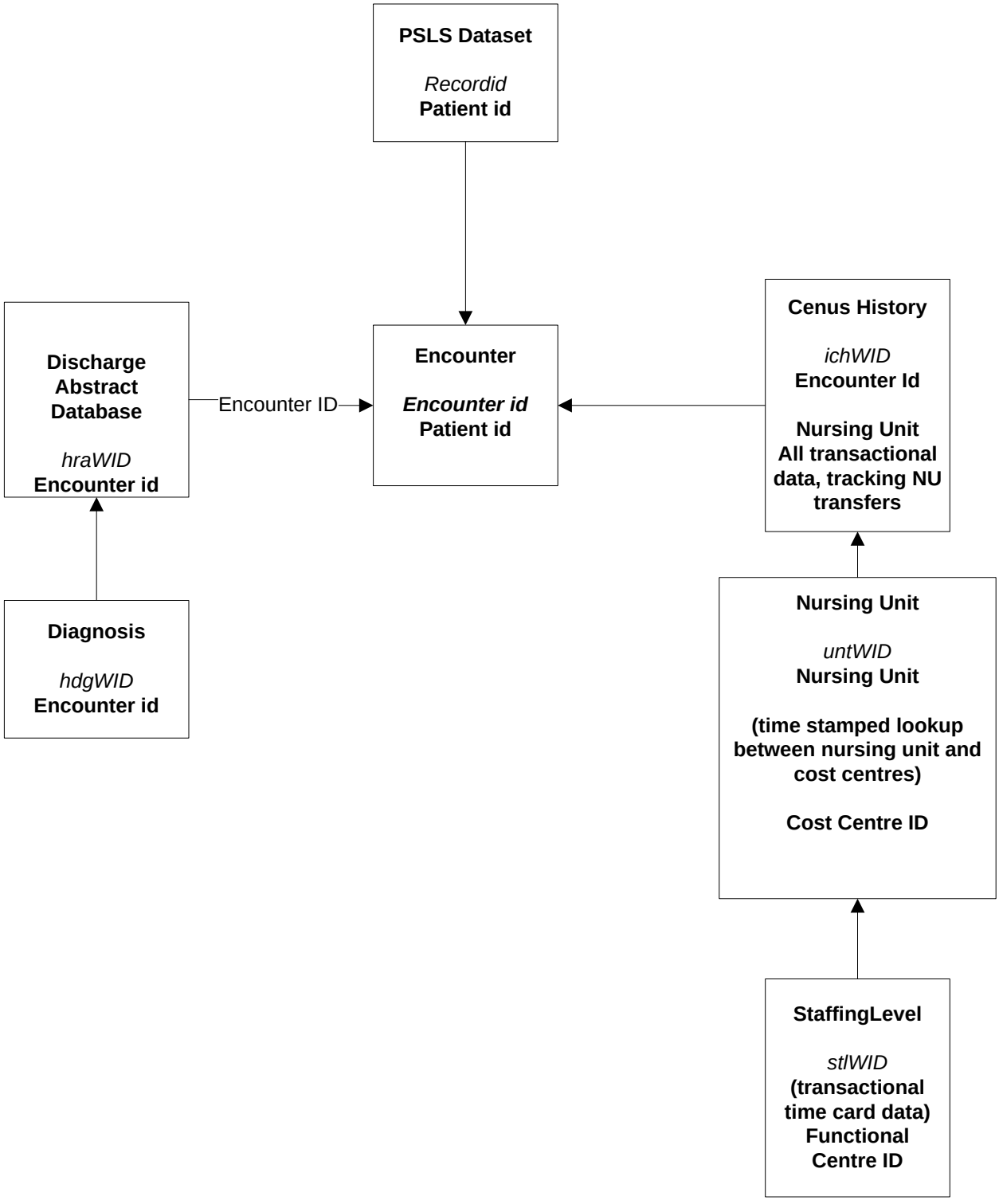


Figure 1- Conceptual map to demonstrate the variables used to link the different datasets from my study together

*variables in italics are the unique rows of each table, the variables in bold are what I used to link two tables together

APPENDIX F

8.1.1 Predictive model including program and reporter as a random intercept

8.1.2 Model assumptions

Histogram plots and p values for the distribution of random effect residuals revealed that they were normally distributed. The p value from the covtest was less than 0.05, therefore the null hypothesis that the G matrix for covariance structure is zero was rejected. Therefore, I concluded that there is significant covariance between clusters of programs and reporter, and it is necessary to take these covariances into account when constructing my model. Hence, the GLIMMIX model, in which the role of the reporter and hospital program are modeled as random effects, was appropriate.

Table Covariance between reporters in the intercept only model

Covariance Parameter Estimates

Cov Parm	Subject	Estimate	Standard Error
Intercept	**program**	0.06447	0.06051
Reporter	**program**	0.105	0.055

Table Covariance test of independence in the intercept only model

Tests of Covariance Parameters

Based on the Residual Pseudo-Likelihood					
Label	**DF**	**-2 Res Log P-Like**	**ChiSq**	**Pr > ChiSq**	**Note**
No G-side effects	2	17706	88.07	<.0001	MI

8.1.3 Selection of a candidate model

Charlson Index, escobar score, and the escobar components LAPS score and emergency surgical admissions met the significant criteria of a p-value of less than 0.20. Therefore, I fit three different candidate models. They are shown below.

Table Candidate Model 1: Using Charlson Index as a measure of severity of illness

	Estimate	**Standard Error**	**Pr > |t|**
Intercept	0.4622	0.1765	0.0307
Number of months PSLS was available			
>12 Months	-0.8626	0.1767	<.0001
8-12 Months	-0.8411	0.1038	<.0001
4-7 Months	-0.2558	0.1011	0.0115

< 3 Months	0	.	.
Day to event			
> 5 days	0.2185	0.1188	0.0658
1-5 Days	0.3283	0.1217	0.007
First Day	0	.	.
Charlson Index			
>5	0.1546	0.09726	0.112
3-4	0.1951	0.1024	0.0568
1-2	0.2242	0.09099	0.0138
0	0	.	.

Table Candidate Model 2: Escobar score as a measure of severity of illness

Effect	**Estimate**	**Std Error**	**P value**
Intercept	0.5735	0.1716	0.0102
# Months PSLS was available			
>12 Months	-0.8645	0.177	<.0001
8-12 Months	-0.8388	0.1042	<.0001
4-7 Months	-0.2561	0.1013	0.0115
< 3 Months	0	.	.
Day to event			

> 5 days	0.2362	0.1191	0.0473
1-5 Days	0.3674	0.1209	0.0024
First Day	0	.	.

Candidate model 3: Escobar components as a measure of severity

None of the escobar components were significant ($p<0.05$) in the multivariate model, therefore, I obtained the same results as using escobar as a whole (number of months the PSLS was available and days to event were included)

8.2 Predictive model for Critical Care

8.2.1 Model assumptions

Table Covariance between reporters in the intercept only model for Critical Care			
Covariance Parameter Estimates			
Cov Parm	**Subject**	**Estimate**	**Standard Error**
Intercept	**Reporter**	0.05933	0.1043

Table Covariance test of independence in the intercept only model for Critical Care

Tests of Covariance Parameters

Based on the Residual Pseudo-Likelihood

Label	DF	-2 Res Log P-Like	ChiSq	Pr > ChiSq	Note
Independence	1	1987.5	1	0.1588	MI

Table Covariance between reporters in the full final model for Critical Care

Covariance Parameter Estimates

Cov Parm	Subject	Estimate	Standard Error
Intercept	**Reporter**	0	.

Table Covariance test of independence in the full final model for Critical Care

Tests of Covariance Parameters

Based on the Residual Pseudo-Likelihood

Label	DF	-2 Res Log P-Like	ChiSq	Pr > ChiSq	Note
Independence	1	2036.21	0	1	MI

8.2.2 Selection of a candidate model

	Table Candidate Model 1 for Critical Care: Using Escobar components as a measure of severity of illness		
Parameter	**Estimate**	**Std err**	**P value**
Intercept	1.1315	0.3482	0.0012
# Months PSLS was available			
8-12 months	-1.2915	0.2856	<.0001
4-7 months	-0.1028	0.2681	0.7014
3 months or less	0		.
Escobar	-0.9163	0.4938	0.0635
Reporter			
Lab	0.1445	0.2771	0.6021
Nurse	0.5439	0.3216	0.0908
Other	0		.

Table Candidate Model 2 for Critical Care: Escobar components as a measure of severity of illness

Parameter	**Estimate**	**Std err**	**P value**
Intercept	1.307	0.3913	0.0008
# Months PSLS was available			0.6193
8-12 months	-1.3298	0.2923	0.0057
4-7 months	-0.1344	0.2705	<.0001
3 months or less	0		.
Laps	-0.0082	0.00295	0.0008
Sex (female is ref)	-0.3006	0.2164	0.1647
Reporter			
Lab	0.1519		0.5871
Nurse	0.5793		0.0741
Other	0		.

8.2.3 Diagnostics

Table Comparison of diagnostic statistics between the candidate models for Critical Care		
	Escobar	**Escobar components**
AIC	552.965	548.876
-2 Log L	540.965	534.876
Hosmer-Lemeshow (chisq(p-value))	4.8497 (0.7735)	15.7941 (0.0454)
c-statistic	0.65	0.675

Although model 2, including escobar components only had the highest discriminatory ability, the p value from the Hosmer-Lemeshow test was less than 0.05, indicating poor model calibration.

8.3 Fixed effect interactions

I considered the interaction between Escobar score and role of the reporter, since it is plausible that certain reporters are more likely to report events on more severe patients, and may also be more likely to report a true event. The results are shown below.

Table Candidate model for Critical Care, with the addition of an interaction between Escobar score and reporter			
Parameter	**Estimate**	**Std err**	**P value**
Intercept	1.3203	0.4269	0.002
# Months PSLS was available			
8-12 months	-1.3022	0.2865	<.0001
4-7 months	-0.1015	0.2684	0.7053
3 months or less	0	.	.
Escobar	-1.6891	1.12	0.1315
Reporter			
Lab	-0.05	0.4154	0.9042
Nurse	0.2186	0.4871	0.6536
Escobar*Lab	0.8086	1.2867	0.5297
Escobar*Nurse	1.3712	1.5504	0.3765

Table Comparison of diagnostic statistics between the candidate model and candidate model with interaction, for Critical Care		
	Candidate model	**Candidate model +interaction between escobar and reporter**
AIC	552.965	548.876
-2 Log L	540.965	540.165
Hosmer-Lemeshow (chisq(p-value))	4.8497(0.7735)	16.1308 (0.0405)

c-statistic	0.65	0.66

The interaction term was not significant ($p<0.05$), and the Likelihood Ratio Test demonstrated that it does not make a significant contribution to the model. Furthermore, this model also had poor calibration, as indicated by the Hosmer-Lemeshow test. Therefore, I did not retain it.

8.3.1.1 Sample size considerations

Table Frequency of outcomes for each categorical fixed covariate included in the candidate model for Critical Care		
	Non-Events	**Events**
	N=151	**N=305**
# Months PSLS was available		

3 months or less	29 (19.2%)	90 (29.5%)
4-7 months	56 (37.1%)	158 (51.8%)
8-12 months	66 (43.7%)	57 (18.7%)
Reporter		
Lab	87 (57.6%)	166 (54.4%)
Nurse	32 (21.2%)	92 (30.2%)
Other	32 (21.2%)	47 (15.4%)

For each of our covariates, there were more than 10 outcomes, therefore our sample size was sufficient and I did not remove any additional variables.

8.3.2 Outliers and influential data points

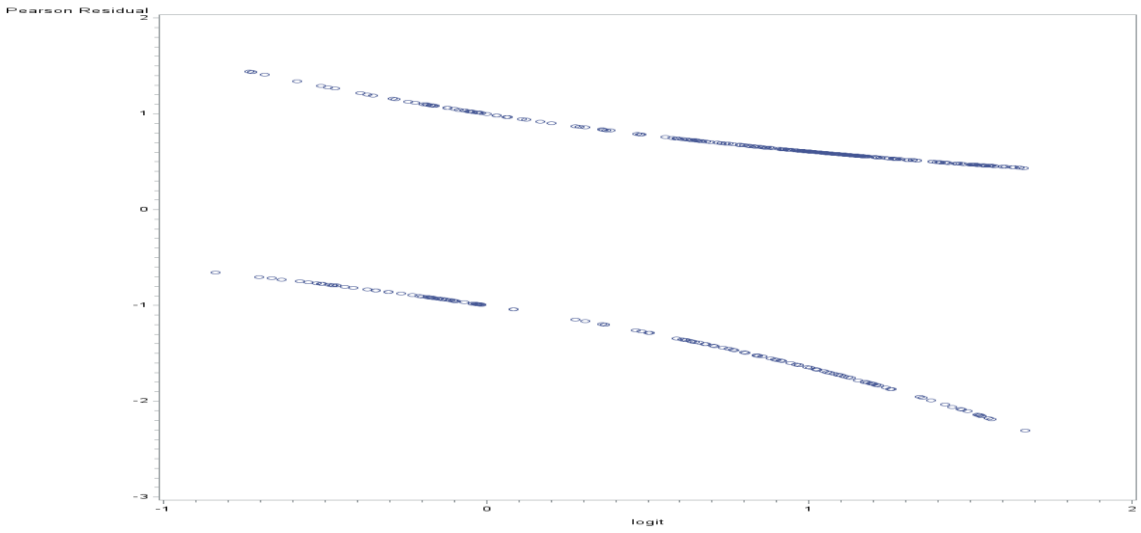


Figure residual plot of the candidate model for Critical Care

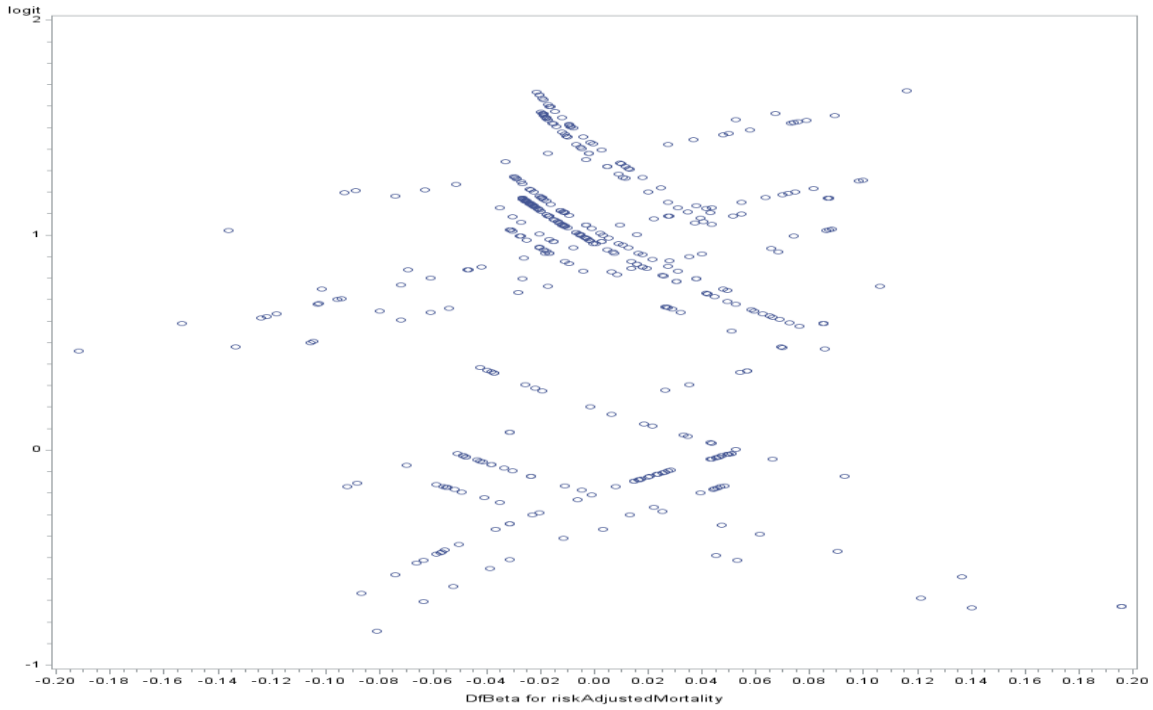


Figure DFBETA plot for escobar in the candidate model for Critical Care

Based on the above figures, there were no data points that stood out as extreme. Therefore, I did not remove any.

8.3.3 Data transformations

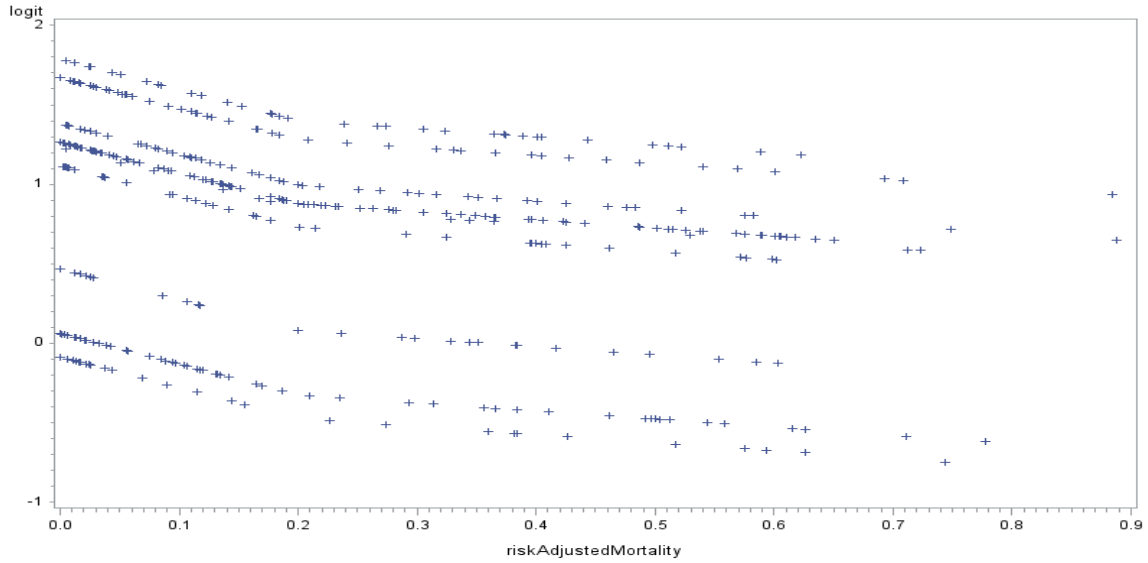


Figure logit vs. Escobar for candidate model within Critical Care

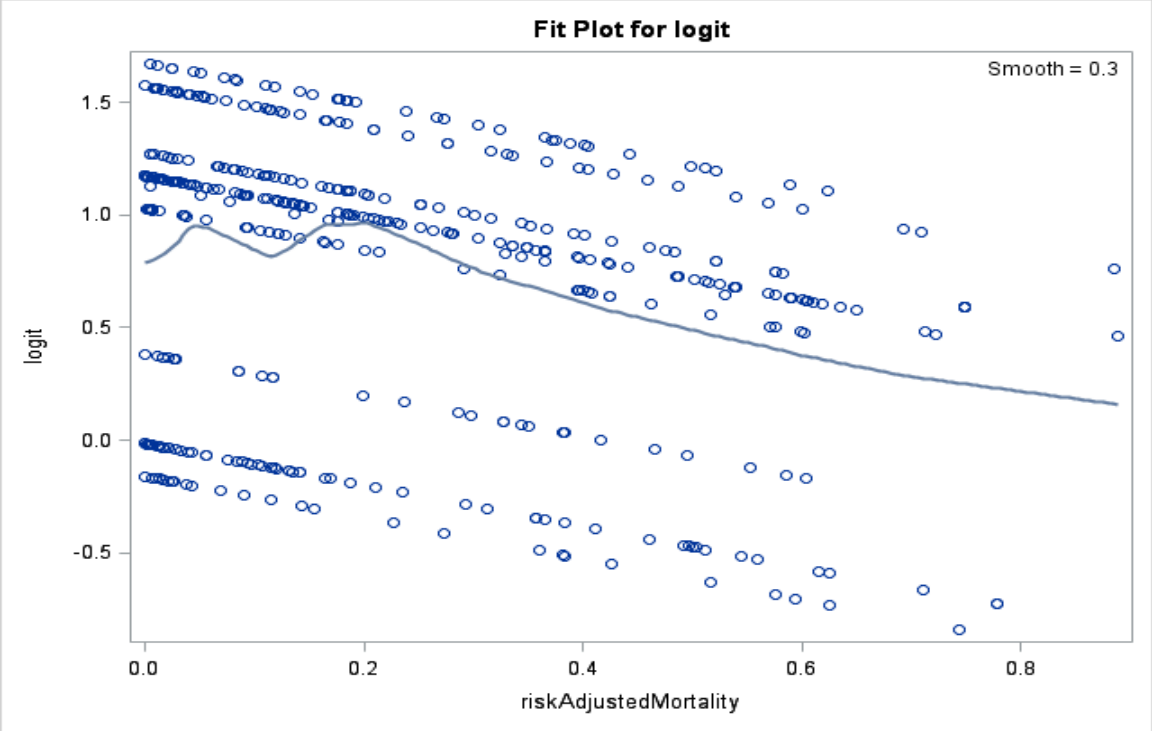


Figure loess plot of logit vs.Escobar for Critical Care

The loess plot indicated that escobar is non-linear for values of 0.20 and less. The logit plot also showed that the slope for values of 0.20 and less differed from those greater than 0.20. Therefore, I fit the candidate model with a spline term for Escobar, with a knot at 0.20.

Table Candidate model for Critical Care, with the addition of a			
Parameter	**Estimate**	**Standard Error**	**Pr > ChiSq**
Intercept	1.235	0.3878	0.0015
# Months PSLS			
4-7 months	-0.1183	0.2692	0.6603
8-12 months	-1.3215	0.29	<.0001
Reporter			
Lab	0.1479	0.2772	0.5935
Nurse	0.5528	0.3222	0.0862
Escobar <0.20	-1.9376	1.7428	0.2662
Escobar >0.20	-0.5055	0.8345	0.5447

I evaluated the fit of the new model by comparing the diagnostic statistics of the candidate model to the new model with the added spline term.

Table Comparison of diagnostic statistics between the candidate		
	Candidate model	**Spline escobar**
AIC	552.965	554.59
-2 Log Likelihood	540.965	540.59
Hosmer-Lemeshow	4.8497(0.7735)	3.7646 (0.1522)
c-statistic	0.65	0.67

Although the addition of a spline term for escobar improved the discriminatory ability of the model by 1.5%, the likelihood ratio test, using 1 degree of freedom, and the AIC, indicated that it did not significantly improve the fit of the model. Therefore, I chose not to include it.

8.3.4 Final model

Table: Final multivariate logistic regression model for critical care

Effect	Estimate	Std err	Pr > |t|	OR (95% CI)
Intercept	1.1315	0.3482	0.0012	
# Months PSLS was available				
>12 Months	0	0	0	
8-12 months	-1.2915	0.2856	<.0001	0.28 (0.16-0.48)
4-7 months	-0.1028	0.2681	0.7014	0.90(0.53-1.53)
≤3 months	0	.	.	0
Escobar	-0.9163	0.4938	0.0635	0.4 (0.15-1.05)
Role of Reporter				
Lab	0.1445	0.2771	0.6021	1.16 (0.67-1.99)
Nurse	0.5439	0.3216	0.0908	1.72 (0.92-3.24)
Other	0	.	.	0

8.4 Predictive model for Heart Institute

8.4.1 Model assumptions

Table Covariance between reporters at the Heart Institute in an intercept-only model

Covariance Parameter Estimates			
Cov Parm	**Subject**	**Estimate**	**Standard Error**
Intercept	**Reporter**	0	.

Table Covariate test of independence between reporters at the Heart Institute in an intercept-only model

Based on the Residual Pseudo-Likelihood					
Label	**DF**	**-2 Res Log P-Like**	**ChiSq**	**Pr > ChiSq**	**Note**
No G-side effects	1	1422.73	0	1	MI

Table Covariance between reporters at the Heart Institute in the full final model

Covariance Parameter Estimates			
Cov Parm	**Subject**	**Estimate**	**Standard Error**

Intercept	**Reporter**	0	.

Table Covariate test of independence between reporters at the Heart Institute in the full final model

Tests of Covariance Parameters

Based on the Residual Pseudo-Likelihood

Label	DF	-2 Res Log P-Like	ChiSq	Pr > ChiSq	Note
No G-side effects	1	1531.41	0	1	MI

8.4.2 Selection of a candidate model

Table Candidate Model 1 for Heart Institute: Using

Effect	Estimate	Std err	Pr > |t|
Intercept	15.0197	1154.3	0.9896
# Months PSLS			

>12 Months	**0**	**0**	**0**
8-12 months	-1.4352	0.3262	<.0001
4-7 months	-2.816	0.3946	<.0001
<3 months	0	.	.
Day to event			
> 5 days	0.6701	0.3365	0.0464
1-5 Days	1.2099	0.3424	0.0004
First Day	0	.	.
Patient Age	0.0126	0.00961	0.1897
Off service Days	-15.0017	1154.3	0.9896

Charlson index was not significant in the multivariate model, and was therefore not retained.

Table Candidate Model 2 for Heart Institute: Using Escobar as a measure of severity of illness

Effect	**Estimate**	**Standard Error**	**Pr > |t|**
Intercept	0.6331	0.3393	0.062
Number of months PSLS was available			
>12 Months			
8-12 Months	-1.3127	0.3215	<.0001
4-7 Months	-2.7147	0.392	<.0001
≤ 3 Months			
Day to event			
> 5 days	0.6243	0.3388	0.0654
1-5 Days	1.1763	0.345	0.0006
First Day			

Escobar	2.0363	1.0384	0.0499

Candidate Model 3 for Heart Institute: Escobar components as a measure of severity of illness

Effect	Estimate	Std err	Pr > |t|
Intercept	-2.3953	0.4217	<.0001
Number of months PSLS was available			
>12 Months	0	0	0
8-12 Months	2.9616	0.4047	<.0001
4-7 Months	1.455	0.3242	<.0001
≤ 3 Months	0	.	.

Day to event			
> 5 days	0.4413	0.3517	0.2096
1-5 Days	1.2516	0.3465	0.0003
First Day	0	.	.
Non-surg Emergency (yes if ref)	0.8876	0.2711	0.0011
Off Service Days	14.8889	1168.3	0.9898

8.4.3 Diagnostics

Table Comparing diagnostic statistics for the three potential candidate models			
	Charlson Index	**Escobar score**	**Escobar**
AIC	396.21	394.782	387.035
-2 Log L	382.492	382.782	373.035
Hosmer-Lemeshow	7.0383(0.5325)	8.5184(0.3845)	3.9603(0.7843)
c-statistic	0.765	0.773	0.774

The model obtained from using escobar components as a measure of illness severity had the highest discriminatory ability and the lowest AIC, therefore I chose it as the candidate model.

8.4.4 Sample size considerations

Table Frequency of outcomes for each categorical fixed covariate included in the candidate model for Heart Institute		
	Non-event	**Event**
	N=147	N=188
# months PSLS was available		
3 months or less	18 (12.2%)	76 (40.4%)
4-7 months	71 (48.3%)	93 (49.5%)

8-12 months	58 (39.5%)	19 (10.1%)
Day to event		
1-5 Days	58 (39.5%)	70 (37.2%)
> 5 days	48 (32.7%)	88 (46.8%)
First day	41 (27.9%)	30 (16.0%)
Off-service	0 (0.0%)	3 (1.6%)
Emergency non-surgical admissions	65 (44.2%)	105 (55.9%)

8.4.5 Iterations to candidate model

The initial iterations included off service in the candidate model, however the p value was non-significant. Furthermore, only three off service encounters experienced an event, so it's confidence interval is likely to be very wide and imprecise, and it is likely to introduce instability into the model. Therefore, I considered removing off -service from the model.

Table Candidate model for Heart Institute without off service			
	Parameter	**Standard**	**Pr > ChiSq**

	Estimate	Error	
Effect			
Intercept	0.5555	0.3423	0.1046
Number of months PSLS was available			
>12 Months	0	0	0
8-12 Months	-2.9638	0.4049	<.0001
4-7 Months	-1.4742	0.3262	<.0001
< 3 Months	0	.	.
Day to event			
> 5 days	0.4615	0.351	0.1885
1-5 Days	1.2826	0.3458	0.0002
First Day	0	.	.
Non-surg Emergency	0.8716	0.2703	0.0013

Table Comparison of diagnostic statistics between original candidate model for		
	Original Candidate model	**Candidate model without**
AIC	387.035	388.214
-2 Log Likelihood	373.035	376.214
Hosmer-Lemeshow	3.9603(0.7843)	3.9265 (0.7882)
c-statistic	0.774	0.769

The likelihood ratio test, using 1 degree of freedom, showed that off service does not make a statistically significant contribution to the model. Therefore, I chose to remove it. However, off-service patients should be considered as a potential predictor in future studies. Based on table, all other fixed covariates have a sufficient sample size, therefore no other covariates were removed.

8.4.6 Outliers and influential data points

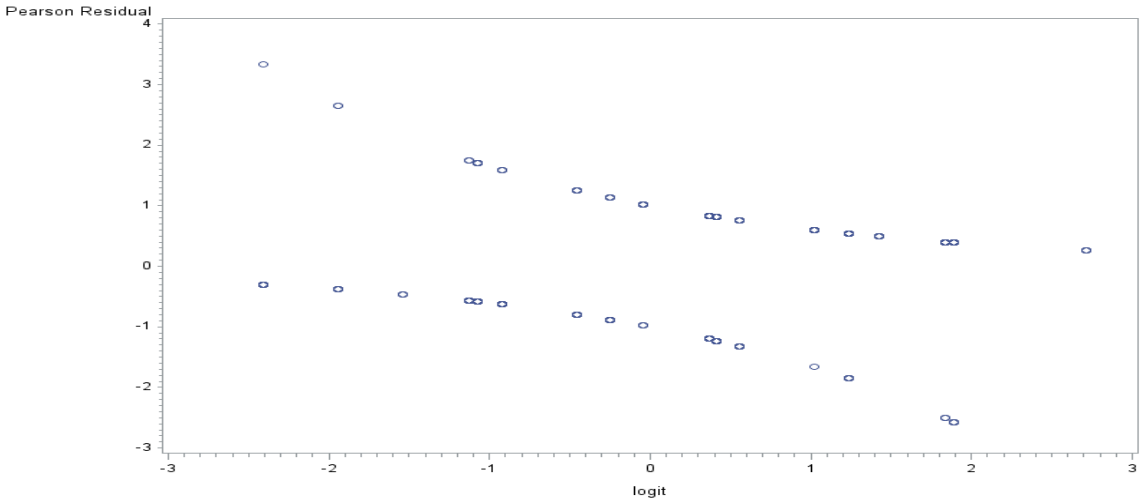


Figure Pearson residuals vs. logit for the current candidate model at the Heart Institute

There were no observations that stood out as outliers, therefore I did not remove any data.

8.4.7 Data transformations

I did not have any continuous variables included in my candidate model; therefore no transformations were executed.

8.4.8 Final model

Table: Final multivariate logistic regression model for the Heart Institute

Effect	Estimate	Std err	Pr > |t|	OR (95% CI)
Intercept	0.5555	0.3423	0.1046	
Number of months				
PSLS was available				
>12 Months	0	0	0	
8-12 Months	-2.9638	0.4049	<.0001	0.05 (0.02-0.11)
4-7 Months	-1.4742	0.3262	<.0001	0.23 (0.12-0.43)
≤ 3 Months	0	.	.	
Day to event				
> 5 days	1.2826	0.3458	0.0002	3.60 (1.83-7.10)
1-5 Days	0.4615	0.351	0.1885	1.59 (0.80-3.16)
First Day	0	.	.	

Non-surg Emergency	0.8716	0.2703	0.0013	2.39(1.41-4.06)

8.5 Predictive model for Integrated Cancer Program

8.5.1 Model assumptions

Table Covariance between reporters in an intercept-only model within the Integrated Cancer Program

Covariance Parameter Estimates			
Cov Parm	**Subject**	**Estimate**	**Standard Error**
Intercept	**Reporter**	0.1597	0.2277

Table Covariance test of independence in an intercept-only model between reporters within the Integrated Cancer Program

Tests of Covariance Parameters

Based on the Residual Pseudo-Likelihood

Label	**DF**	**-2 Res Log P-Like**	**ChiSq**	**Pr > ChiSq**	**Note**

Independence	1	1586.44	2.28	0.0655	MI

Table Covariance between reporters in the full final model within the Integrated Cancer Program

Covariance Parameter Estimates			
Cov Parm	**Subject**	**Estimate**	**Standard Error**
Intercept	**Reporter**	0.4145	0.4956

Table Covariance test of independence in the full final model between reporters within the Integrated Cancer Program					
Tests of Covariance Parameters Based on the Residual Pseudo-Likelihood					
Label	**DF**	**-2 Res Log P-Like**	**ChiSq**	**Pr > ChiSq**	**Note**

No G-side effects	1	1627.40	6.13	0.0052	MI

8.5.2 Selection of a candidate model

Table Candidate Model 1 for Integrated Cancer Program: Using Charlson Index as a measure of illness severity

Solutions for Fixed Effects			
Effect	**Estimate**	**Std err**	**Pr > |t|**
Intercept	1.5332	0.5354	0.1034
Number of months PSLS was available			
>12 Months			
8-12 Months	-1.4028	0.4349	0.0014
4-7 Months	-0.7701	0.4287	0.0733
≤ 3 Months	0		.

The Charlson Index was non-significant when the model was also adjusted for the number of months PSLS was available therefore it was removed.

Table Candidate Model 2 for Integrated Cancer Program: Escobar components as a measure of severity of illness

Effect	**Estimate**	**Std err**	**Pr > |t|**
Intercept	1.7149	0.6344	0.114
# Months PSLS was available			
>12 Months	0	0	0
8-12 months	-1.3617	0.4385	0.0021
4-7 months	-0.7787	0.4305	0.0713
<3 months	0	.	.

Emergency non-surgical no if ref)	-0.6488	0.3523	0.0664
laps	0.008903	0.004966	0.0739

Although the LAPS score and non-surgical emergency admissions were not significant, they increased the discriminatory ability of the model from 0.627 to 0.649, therefore they were retained in the model.

8.5.3 Diagnostics

Table Comparison of diagnostic statistics between the candidate models for Integrated Cancer Program		
	Charlson Index	**Escobar components**
AIC	457.32	455.74
Likelihood	449.32	439.53
Hosmer-Lemeshow Test (chisp(p-value))	2.7509 (0.7383)	10.1095 (0.2574)
c-statistic	0.627	0.648

Since model 3, using escobar components had the highest c-statistic and the lowest AIC, I chose it as the candidate model for the integrated cancer program.

8.5.4 Iterations to the candidate model

8.5.4.1 Addition of a random slope

Table Covariance between reporter random intercepts and slopes for Integrated Cancer Program

Covariance Parameter Estimates

Cov Parm	Subject	Estimate	Standard Error
Intercept	**Reporter**	0.2689	0.4361
Reporter	**Reporter**	0.08357	.

Table Comparing model fit with and without the introduction of a random slope between reporters for Integrated Cancer Program		
	Candidate model with random intercept only	**Candidate model with random intercept and random slope**
AIC	457.53	459.53

The initial candidate model, including a random intercept only had a lower AIC than the model that introduced a random slope. Since a lower AIC is indicative of a better fit, I did not include a random slope for the role of the reporter.

8.5.4.2 Addition/removal of non-significant fixed covariates

Table Comparison of diagnostic criteria between		
	Candidate Model	**Candidate Model**
AIC	455.74	457.53
Likelihood	439.53	439.53
Hosmer-	10.1095 (0.2574)	4.1649 (0.8420)
c-statistic	0.648	0.663

The addition of Charlson index to the candidate model increased the AIC slightly by 1.79, indicating a worse fit. Furthermore, likelihood ratio test, with 3 degrees of freedom, indicated that it does not make a significant contribution to the model. Therefore, I did not retain Charlson Index in the candidate model.

8.5.5 Sample size considerations

Table Frequency of outcomes for each categorical fixed covariate included in the candidate model		
	Non-event	**Event**
	N=121	N=242
# months PSLS was available		
3 months or less	9 (7.4%)	39 (16.1%)
4-7 months	37 (30.6%)	86 (35.5%)
8-12 months	75 (62.0%)	117 (48.3%)
Emergency non-surgical admissions		
No	14 (11.6%)	42 (17.4%)

Yes	107 (88.4%)	200 (82.6%)

8.5.6 Outliers and influential data points

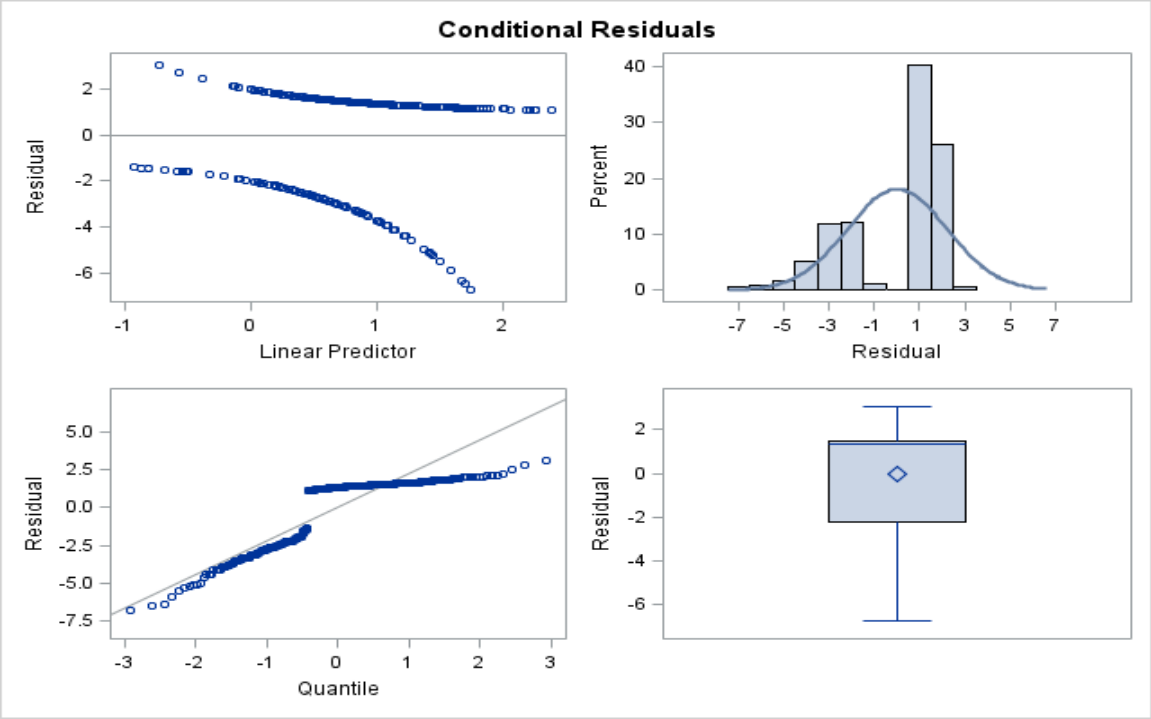


Figure Residual plot of the random effects for the candidate model for the integrated cancer program

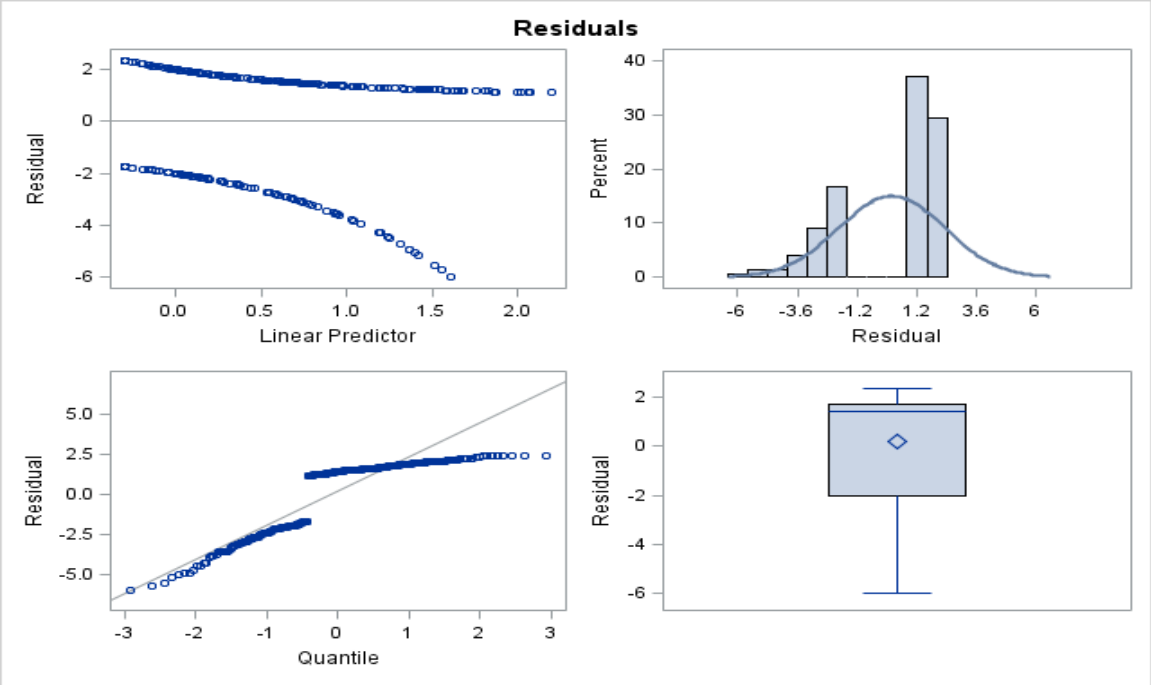


Figure Residual plot of the fixed effects in the candidate model for the integrated cancer program

There were no extreme data points; therefore I did not remove any observations.

8.5.7 Data transformations

I examined the linearity of the LAPS score to determine whether data transformations were necessary.

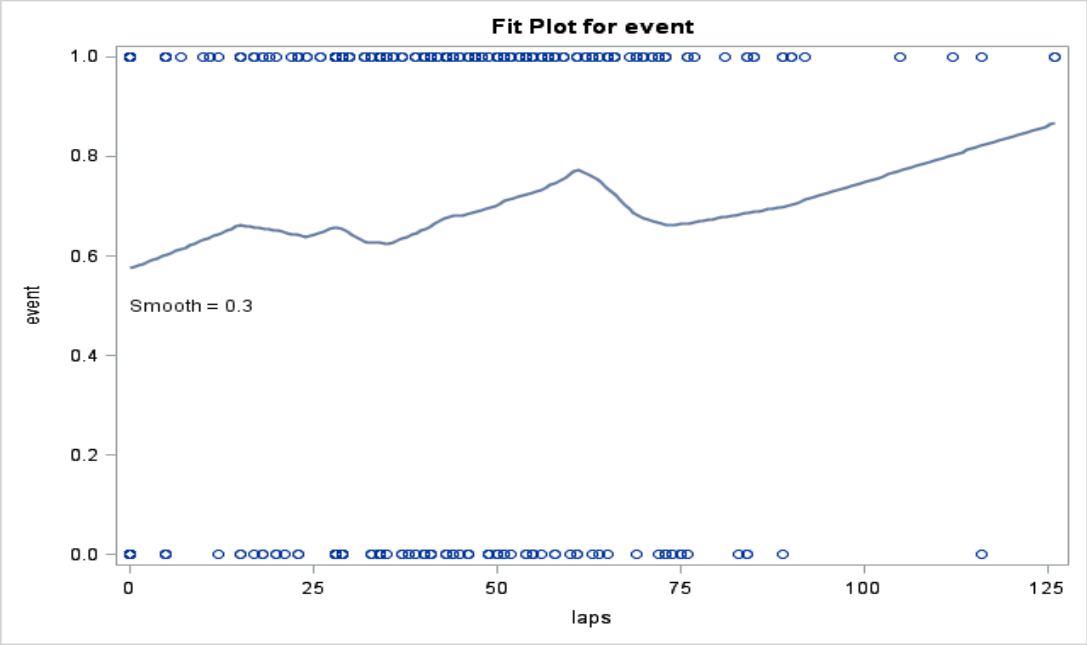


Figure Loess plot of LAPS score and probability of an event for Integrated Cancer Program

Based on the plot above, the slope was fairly linear (with the exception of values between 50 and 75), and the shape of the line did not appear to fit other functions (e.g. quadratic, logarithmic). Therefore, I decided not to perform any transformations on the LAPS score.

8.5.8 Final model

Table: Final GLIMMIX model for Integrated Cancer program, adjusted by the role of the reporter

	Intercept-only model	Patient and event level covariates			
	Estimate	st err	p value	OR (95% CI)	

Event variables	**Intercept**		1.7149	0.6344	0.114	
	# Months PSLS was available					
	8-12 months		0	0	0	0.26 (0.11-0.61)
	4-7 months		-1.362	0.4385	0.0021	0.46 (0.20-1.11)
	≥3 months (ref)		-0.779	0.4305	0.0713	
Patient variables	**LAPS score**		0.0089	0.005	0.0739	1.01 (0.999-1.02)
	Emergency nonsurgical Admission		-0.649	0.3523	0.0664	1.91 (0.96-3.83)
	c	0.648				
	MOR	1.46	1.85			
	PCV (%)		61.47			

8.6 Predictive model for Medicine, Neuroscience and Endoscopy

8.6.1 Model assumptions

Table Covariance between reporters in an intercept-only model within the Medicine, Neuroscience and Endoscopy program

Covariance Parameter Estimates			
Cov Parm	**Subject**	**Estimate**	**Standard Error**

Intercept	**Reporter**	0.1597	0.2277

Table Covariance test of independence in an intercept-only model within the Medicine, Neuroscience and Endoscopy program

Tests of Covariance Parameters Based on the Residual Pseudo-Likelihood					
Label	**DF**	**-2 Res Log P-Like**	**ChiSq**	**Pr > ChiSq**	**Note**
Independence	1	1586.44	2.28	0.0655	MI

Table Covariance between reporters in the full final model within the Medicine, Neuroscience and Endoscopy progam

Covariance Parameter Estimates			
Cov Parm	**Subject**	**Estimate**	**Standard Error**
Intercept	**Reporter**	0.1674	0.1778

Table Covariance test of independence in the full final model within the Medicine, Neuroscience and Endoscopy program					
Tests of Covariance Parameters Based on the Residual Pseudo-Likelihood					
Label	**DF**	**-2 Res Log P-Like**	**ChiSq**	**Pr > ChiSq**	**Note**
No G-side effects	1	5681.7	28.63	<.0001	MI

8.6.2 Selection of a candidate model

Three separate models were created to investigate the effect of severity of illness on true events. The first contained all significant non-related covariates, and the Charlson Index, the second model replaced the Charlson Index with the significant Escobar components, and the third incorporated both the Charlson Index and Escobar components.

Table Candidate Model 1: Charlson Index as a measure of severity of illness			
Effect	**Estimate**	**Std err**	**Pr > |t|**
Intercept	-0.1541	0.2872	0.6451

# Months PSLS was available			
> 12 Months	0.2026	0.1962	0.3019
8-12 months	0.698	0.1716	<.0001
4-7 months	1.01	0.1786	<.0001
<3 months	0	.	.
Charlson Index			
5	0.245	0.1731	0.1573
3-4	0.3602	0.1784	0.0437
1-2	0.3936	0.1675	0.019
0	0	.	.

Table Candidate Model 2:Escobar score as a measure of severity of illness

Effect	**Estimate**	**Std err**	**Pr > |t|**
Intercept	-0.01946	0.2786	0.9507
# Months PSLS was available			
> 12 Months	0.2054	0.1957	0.2941
8-12 months	0.6944	0.1714	<.0001
4-7 months	0.9893	0.1781	<.0001

<3 months	0	.	.
Escobar	0.751	0.424	0.0768

Model 3: Escobar components LAPS, emergency surgical, and emergency non-surgical as measures of severity

Effect	**Estimate**	**Std err**	**Pr > |t|**
Intercept	-0.06387	0.33	0.8644
# Months PSLS was available			
> 12 Months	0.2415	0.1978	0.2225
8-12 months	0.694	0.1718	<.0001
4-7 months	1.0146	0.179	<.0001
<3 months	0	.	.
Charlson Index			
5	0.219	0.1775	0.2175
3-4	0.343	0.1798	0.0567
1-2	0.3683	0.1683	0.0288
0	0	.	.
LAPS	0.003999	0.00251	0.1114
emerg_nonsurg	0.3019	0.1873	0.1073

Similar to the cancer program, both LAPS and non-surgical emergency admissions were non-significant but they improved the c statistic from 0.651 to 0.657 and improved the calibration of the model from poor (p=0.0298) to good (p=0.1828) , therefore I retained them in the model.

8.6.3 Diagnostics

Table Comparing diagnostic statistics between three potential candidate models for Medicine			
	Charlson Index	**Escobar**	**Escobar components**
AIC	1534.78	1534.30	1534.48
-2 Log Likelihood	1518.78	1522.25	1520.48
Hosmer-Lemeshow Test (chisp(p-value))	25.8087 (0.0022)	8.5273 (0.3837)	11.3480 (0.1828)
c-statistic	0.661	0.657	0.657

Although the model with the Charlson Index had the highest discriminatory ability, the p value from the Hosmer-lemeshow test indicated that the model was a poor fit ($p<0.05$). I chose the model 3, with the escobar components as a candidate model since it had the best fit and discriminatory ability.

8.6.4 Iterations to the candidate model

8.6.4.1 Addition of a random slope

Table Comparing the fit of the random intercept-only model for Medicine, Neuroscience and Endoscopy, with the new model adding a random slope term		
	Random intercept model	Random intercept + random slope model
AIC	1535.2	1537.2

Table Covariance between reporter intercepts and slopes in the candidate model for Medicine, Neuroscience and Endoscopy

Covariance Parameter Estimates			
Cov Parm	**Subject**	**Estimate**	**Standard Error**
Intercept	**Reporter**	0.1613	0.1778
Reporter	**Reporter**	0.006117	.

The random intercept-only model had a smaller AIC, which indicates a better fit. Therefore, I did not include a random slope in my final model.

8.6.4.2 Addition/removal of non-significant fixed covariates

I added the Charlson Index to the candidate model, which cause the LAPS score to become non-significant, so I removed LAPS score from the candidate model. The results are shown in the table below.

Table Candidate model for Medicine, Neuroscience and Endoscopy, with Charson Index added			
Effect	**Estimate**	**Std err**	**Pr > |t|**
Intercept	0.03348	0.2929	0.9194
# Months PSLS was available			
> 12 Months	0.2269	0.1978	0.2516
8-12 months	0.6903	0.1718	<.0001
4-7 months	1.0078	0.1788	<.0001
<3 months	0	.	.
Charlson Index			
5	0.2728	0.1745	0.1182
3-4	0.3739	0.1789	0.0368
1-2	0.3813	0.168	0.0234
0	0	.	.
Emerg surg (yes is ref)	0.2287	0.1817	0.2085

I then compared this model to the previous candidate model using the LAPS score and emergency non-surgical admissions, using the same 4 diagnostic criteria used above.

Table Comparison of diagnostic statistics between the original candidate model for Medicine, Neuroscience and Endoscopy, and the candidate model with Charlson Index added		
	Candidate Model	**Candidate model + Charlson Index**
AIC	1534.48	1535.17
Likelihood	1520.48	1517.17
Hosmer-Lemeshow Test (chisp(p-value))	11.3480 (0.1828)	8.9307 (0.3482)
c-statistic	0.657	0.662

Since the addition of Charlson Index improved the discriminatory ability of the model, I decided to retain it. Therefore, the new candidate model included the number of months the PSLS was available, the Charlson Index, and emergency surgical admissions.

8.6.5 Sample size considerations

Table Frequency of outcomes for each categorical fixed covariate included in the candidate model						
	Non-event			**Event**		
	Lab	**Nurse**	**Other**	**Lab**	**Nurse**	**Other**
	N=170	**N=187**	**N=49**	**N=238**	**N=550**	**N=76**

# Months PSLS was available	16 (9.4%)	76 (40.6%)	16 (32.7%)	39 (16.4%)	90 (16.4%)	14 (18.4%)
3 months or less	46 (27.1%)	34 (18.2%)	12 (24.5%)	80 (33.6%)	207 (37.6%)	20 (26.3%)
4-7 months	61 (35.9%)	50 (26.7%)	10 (20.4%)	84 (35.3%)	184 (33.5%)	27 (35.5%)
8-12 months	47 (27.6%)	27 (14.4%)	11 (22.4%)	35 (14.7%)	69 (12.5%)	15 (19.7%)
Over 12 months						
Charlson Index						
0	61 (35.9%)	51 (27.3%)	17 (34.7%)	63 (26.5%)	126 (22.9%)	19 (25.0%)
1-2	39 (22.9%)	45 (24.1%)	18 (36.7%)	76 (31.9%)	152 (27.6%)	21 (27.6%)
3-4	36 (21.2%)	42 (22.5%)	4 (8.2%)	51 (21.4%)	126 (22.9%)	18 (23.7%)
5+	34 (20.0%)	49 (26.2%)	10 (20.4%)	48 (20.2%)	146 (26.5%)	18 (23.7%)
Emergency surgical admissions	143 (84.1%)	169 (90.4%)	38 (77.6%)	200 (84.0%)	459 (83.5%)	57 (75.0%)

All fixed covariates currently included have more than 10 outcomes per reporter, therefore I did not need to remove any covariates due to sample size.

8.6.6 Outliers and influential data points

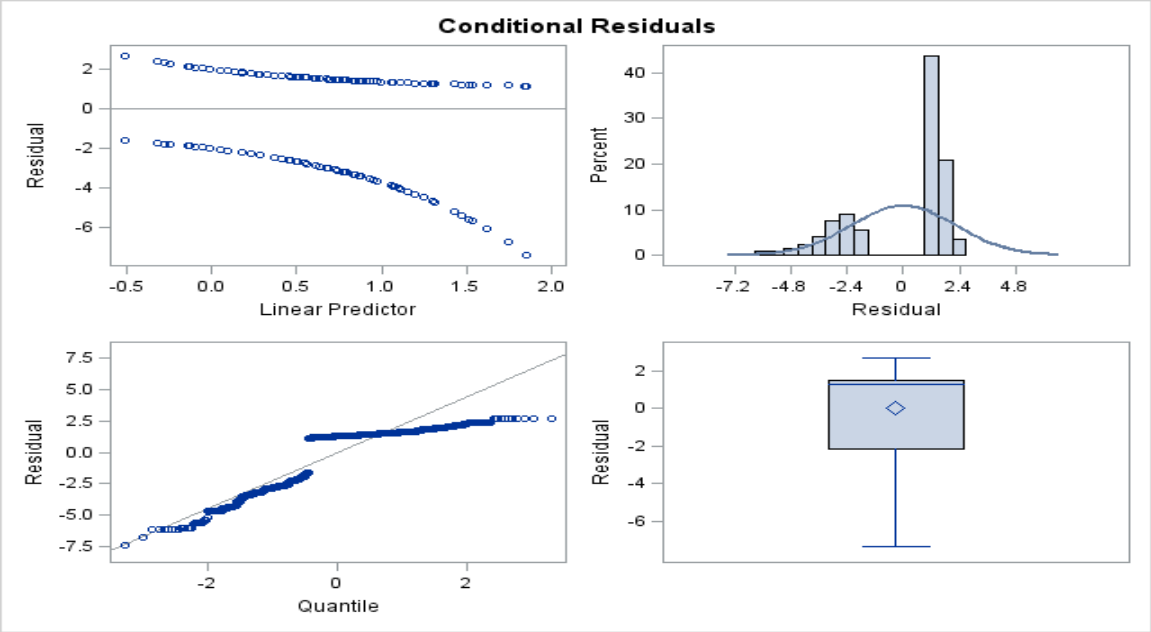


Figure Residual plot of random effects for the current final model for Medicine, Neuroscience and Endoscopy

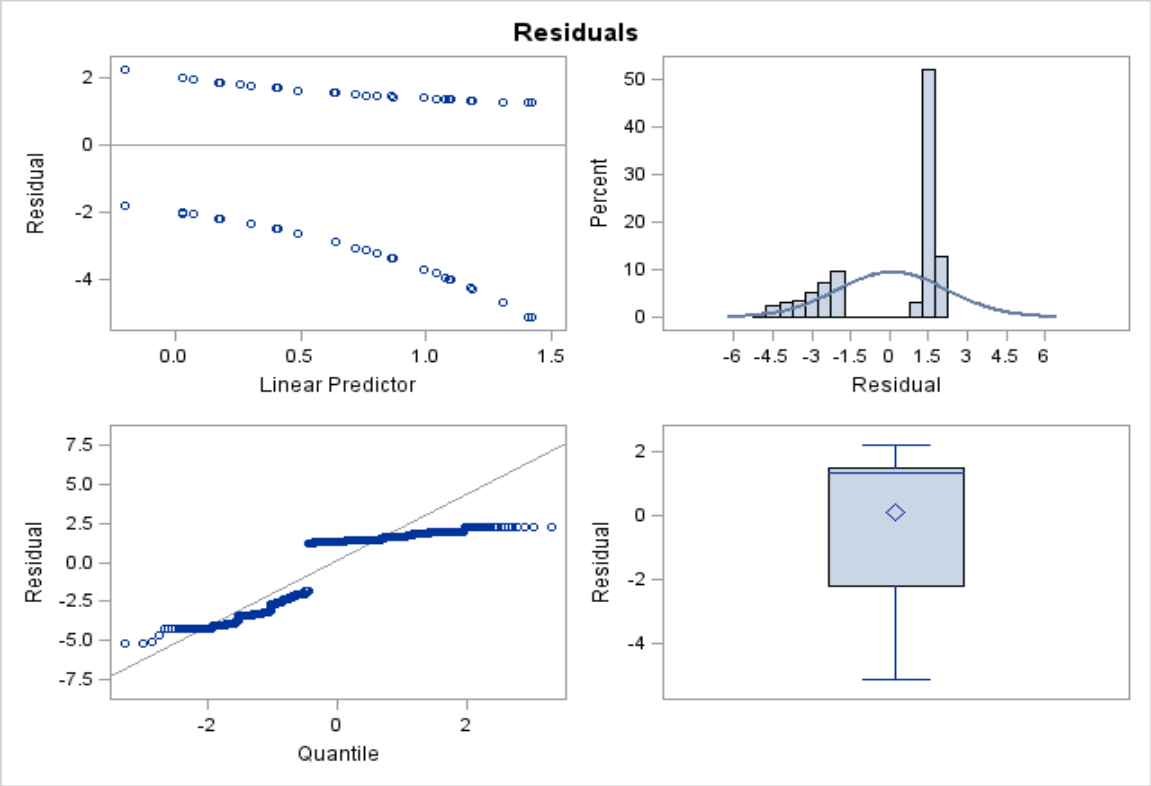


Figure Residual plot of fixed effects for the current final model for Medicine, Neuroscience and Endoscopy

No extreme outlying data points were detected, therefore I did not remove any observations.

8.6.6.1 Final model

Table: Final model for Medicine, Neuroscience and Endoscopy, adjusted by role of reporter

Effect	Intercept-only	Event and patient-level covariates			
		Estimate	Std err	Pr > |t|	OR (95% CI)
Intercept		0.02902	0.3239	.	

Event level covariates	# Months PSLS was available						
	> 12 Months			0.2308	0.1975	0.2427	1.26 (0.86-1.86)
	8-12 months			0.6918	0.1716	<.0001	2.00 (1.43-2.80)
	4-7 months			1.0083	0.1787	<.0001	2.74 (1.93-3.89)
	≤3 months			0	.	.	
Patient level covariates	Charlson Index						
	5			0.2704	0.1744	0.1213	1.31 (0.93-1.85)
	3-4			0.3718	0.1788	0.0377	1.45 (1.02-2.06)
	1-2			0.3802	0.1679	0.0238	1.46 (1.05-2.03)
	0			0	.	.	
	Emergency nonsurgical			-0.2302	0.1817	0.2054	0.79(0.56-1.14)
	c		0.662				
	H-L (chisq, pvalue)		10.0854(0.2591)				
	MOR	2.13	1.48				
	PCV (%)		-275.51				

8.6.7 Predictive model for Nephrology

8.6.7.1 Model assumptions

Table Covariance between reporters in an intercept-only model for Nephrology

Covariance Parameter Estimates			
Cov Parm	**Subject**	**Estimate**	**Standard Error**
Intercept	**Reporter**	0.102	0.2251

Table covtest of independence for the intercept only model for Nephrology

Tests of Covariance Parameters Based on the Residual Pseudo-Likelihood					
Label	**DF**	**-2 Res Log P-Like**	**ChiSq**	**Pr > ChiSq**	**Note**
Independence	1	868.53	0.45	0.2519	MI

Table Covariance between reporters in the full final model for Nephrology

Covariance Parameter Estimates

Cov Parm	Subject	Estimate	Standard Error
Intercept	Reporter	0	.

Table covtest of independence for the full final model for Nephrology

Tests of Covariance Parameters Based on the Residual Pseudo-Likelihood					
Label	DF	-2 Res Log P-Like	ChiSq	Pr > ChiSq	Note
No G-side effects	1	889.51	0	1	MI

Similar to Medicine, three separate models were conducted to measure severity of illness, one with the Charlson Index, one with Escobar components, and another with both the Charlson index and significant Escobar components.

8.6.7.2 Selection of a candidate model

Model 1: Charlson Index as a measure of severity of illness

Effect	Estimate	Std err	Pr > |t|

Intercept	1.2112	0.272	<.0001
# Months PSLS was available			
>12 Months	0	0	0
8-12 months	-1.027	0.3053	0.0008
4-7 months	-0.2532	0.3048	0.4061
<3 months	0	.	.
Sex (female is ref)	0.3123	0.1715	0.0686

Model 2: Escobar components as a measure of severity of illness

Effect	**Estimate**	**Std err**	**Pr > |t|**
Intercept	0.7635	0.4198	0.069
# Months PSLS was available			

>12 Months	0	0	0
8-12 months	-1.2667	0.3395	0.0002
4-7 months	-0.3312	0.3259	0.3095
<3 months	0	.	.
Day to event			
>5 days	-0.3647	0.3143	0.2459
1-5 days	-0.5052	0.3011	0.0934
Same day	0	.	.
Sex	0.3118	0.1771	0.0782
Elective Admits	-1.0317	0.4027	0.0104

8.6.7.3 Diagnostics

Table Comparison of diagnostic statistics between the two candidate models for Nephrology		
	Charlson Index	**Escobar components**
AIC	222.384	218.957
-2 Log Likelihood	214.384	204.957

Hosmer-Lemeshow Test (chisp(p-value))	1	6.3057(0.613)
c-statistic	0.679	0.722

Based on the diagnostics above, I chose model 2 with escobar component elective admissions as my candidate model.

8.6.7.4 Sample size considerations

Table Frequency of outcomes for each categorical fixed covariate included in the candidate model for Nephrology		
	Non-event	Event

	N=57	N=133
# Months PSLS was available		
3 months or less	2 (3.5%)	26 (19.5%)
4-7 months	24 (42.1%)	65 (48.9%)
8-12 months	31 (54.4%)	42 (31.6%)
Day to event		
1-5 Days	32 (56.1%)	66 (49.6%)
> 5 days	22 (38.6%)	51 (38.3%)
First day	3 (5.3%)	16 (12.0%)
Non-elective admits	52 (91.2%)	128 (96.2%)
Elective admits	5 (8.8%)	5 (3.8%)
Sex		
Female		
Male		

All covariates had more than 10 outcomes per covariates except for elective admits. Therefore, I removed it from the final model. However, elective admissions should be considered as potential predictor in future predictive models within a cardiac institute.

8.6.7.5 Outliers and influential data points

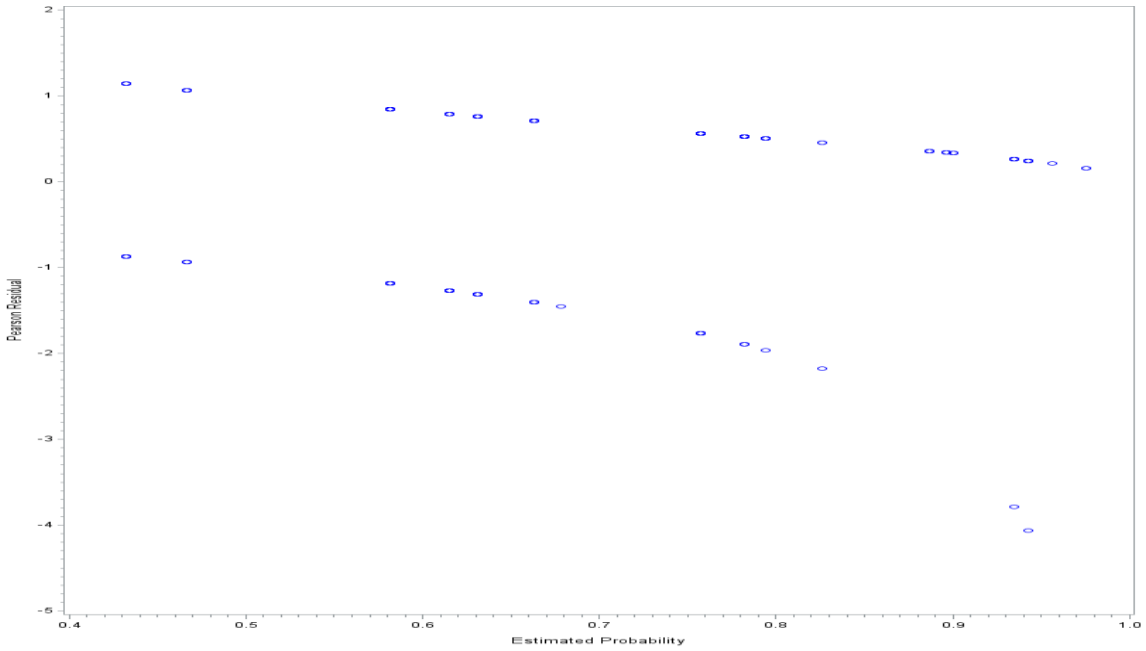


Figure Pearson residuals vs. logit for candidate model within Nephrology

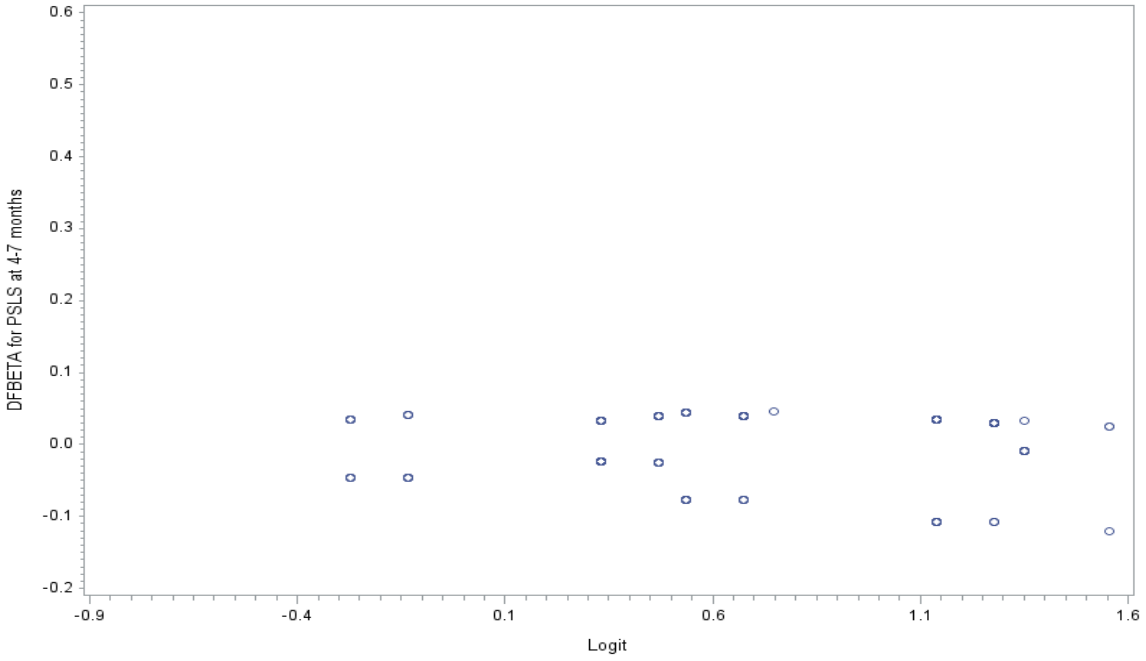


Figure DFBETA plot for PSLS available from 4-7 months for Nephrology

I identified two outliers with residuals of -3.79 and -4.06. Removal of these observations resulted in quasi-complete separation; I also investigated the fixed covariates of interest and did not see any unusual values. Therefore I chose to retain them in the model.

8.6.7.6 Final model

Table Final multivariate logistic regression model for Nephrology

	Estimate	Std err	p value	OR (95%CI)
Intercept	1.4624	0.329	<.0001	
# Months PSLS was available				
8-12 months	-1.0477	0.307	0.0006	0.05 (0.05-0.996)
4-7 months	-0.2388	0.3057	0.4348	0.10 (0.02-0.45)
<3 months	0	.	.	0
Day to event				
>5 days	-0.2468	0.2909	0.3962	0.42(0.11-1.64)
1-5 days	-0.3863	0.2771	0.1633	0.36 (0.09-1.38)
Same day	0	.	.	0
Sex (female is ref)	0.3012	0.1733	0.3012	1.83 (0.93-3.60)

8.6.8 Predictive model for Obstetrics and Gynecology

8.6.8.1 Model assumptions

Table Covariance between reporters for an intercept-only model in Obstetrics

Covariance Parameter Estimates			
Cov Parm	**Subject**	**Estimate**	**Standard Error**
Intercept	**Reporter**	0.2264	0.2777

Table Covtest of independence for an intercept-only model in Obstetrics

Tests of Covariance Parameters Based on the Residual Pseudo-Likelihood					
Label	**DF**	**-2 Res Log P-Like**	**ChiSq**	**Pr > ChiSq**	**Note**
No G-side effects	1	1731.95	5.45	0.0098	MI

Table Covariance between reporters for the full final model in Obstetrics

Covariance Parameter Estimates			
Cov Parm	**Subject**	**Estimate**	**Standard Error**
Intercept	**Reporter**	0.228	0.281

Table Covtest of independence for the full final model in Obstetrics

Tests of Covariance Parameters Based on the Residual Pseudo-Likelihood					
Label	**DF**	**-2 Res Log P-Like**	**ChiSq**	**Pr > ChiSq**	**Note**
No G-side effects	1	1764.91	5.67	0.0086	MI

8.6.8.2 Selection of a candidate model

Three separate models were conducted to compare the Charlson index to Escobar, to Escobar components.

Table Candidate Model 1: Charlson Index as a measure of severity of illness for Obstetrics andGynecology

Effect	**Estimate**	**Std err**	**Pr > |t|**
Intercept	0.3537	0.2111	0.0939
# Months PSLS was available			
8-12 months	-0.614	0.1696	0.0003

4-7 months	-0.342	0.1624	0.035
<3 months	0	.	.
Charlson Index			
5	0.6881	0.3019	0.0226
3-4	-0.165	0.3759	0.6603
1-2	-0.224	0.2765	0.4181
0	0	.	.
Off service days	0.2732	0.1631	0.0938
Reporter			
Lab	0.1691	0.1671	0.3117
Nurse	0.4289	0.1512	0.0046
Other			

Table Candidate Model 2: Elixhauser score as a measure of severity of illness

For Obstestrics and Gynecology

Effect	Estimate	Std err	Pr > |t|
Intercept	0.0547	0.2002	0.7845
# Months PSLS was available			
8-12 months	-0.607	0.1689	0.0003
4-7 months	-0.345	0.1622	0.0336
<3 months	0	.	.
Elixhauser	**0.0409**	0.0196	0.0363
Off service days	0.269	0.159	0.0907
Reporter			
Lab	0.1649	0.1654	0.3188
Nurse	0.432	0.1498	0.0039
Other	0	.	.

Table Candidate Model 3: Escobar score as a measure of severity of illness for Obstetrics and Gynecology

Effect	Estimate	Std err	Pr > |t|
Intercept	0.2499	0.1785	0.1616

# Months PSLS			
was available			
8-12 months	-0.622	0.1678	0.0002
4-7 months	-0.375	0.1608	0.0197
<3 months	0	.	.
Off service days	0.375	0.1497	0.0122
Reporter			
Lab	0.2016	0.1637	0.2181
Nurse	0.4313	0.1491	0.0038
Other	0	.	.

Table Candidate Model 4: Escobar components as a measure of severity of illness for Obstetrics and Gynecology

Effect	**Estimate**	**Std err**	**Pr > |t|**
Intercept	0.2499	0.1785	0.1616
# Months PSLS			
was available			
8-12 months	-0.622	0.1678	0.0002
4-7 months	-0.375	0.1608	0.0197
<3 months	0	.	.
Off service days	0.375	0.1497	0.0122
Reporter			
Lab	0.2016	0.1637	0.2181
Nurse	0.4313	0.1491	0.0038

Other	0	.	.

Neither Escobar, nor its components were significant in a multivariate model, therefore I did not retain them.

8.6.8.3 Diagnostics

Table Comparing diagnostic statistics between the four potential candidate models

	Charlson Index	**Elixhauser**	**Escobar**	**Escobar components**
AIC	532.456	530.971	533.507	533.507
Likelihood	514.456	516.971	521.507	521.507
Hosmer-Lemeshow Test (chisp(p-value))	4.5432 (0.7155)	2.3414 (0.9386)	2.4200 (0.7885)	2.4200 (0.7885)
c-statistic	0.675	0.671	0.658	0.658

Since model 2, using the Elixhauser score had the lowest AIC score, good calibration, and the higher discriminatory ability, I chose it as the candidate model.

8.6.8.4 Iterations of the candidate model

8.6.8.4.1 Fixed effects interactions

I considered the interaction between the role of the reporter and a patient's Elixhauser score, since it is possible that certain reporters are more likely to report and/or detect events among sicker patients.

Table Candidate model for Obstetrics with the addition of an interaction between Elixhauser score and role of reporter

Effect	Estimate	Std err	Pr > |t|
Intercept			
# Months PSLS was available	0.0662	0.201	0.7421
8-12 months	-0.6178	0.1696	0.0003
4-7 months	-0.3472	0.1628	0.033
<3 months	0	.	.
Elixhauser	0.0266	0.0241	0.2688
Off service days	0.2473	0.1612	0.1251
Reporter			
Lab	0.1663	0.1834	0.3645
Nurse	0.3735	0.1609	0.0203
Other	0	.	.
Elixhauser*Lab	0.00786	0.0295	0.7896
Elixhauser*Nurse	0.0314	0.0284	0.2676

I compared the diagnostic statistics of the original candidate model to the new model with the interaction term, the results are shown below.

Table Comparison of diagnostic statistics between the original candidate model for Obstetrics and Gynecology to the candidate model with an interaction term

	Candidate model	**Candidate model + interaction**
AIC	530.971	533.649
Likelihood	516.971	515.649
Hosmer-Lemeshow Test (chisp(p-value))	2.3414 (0.9386)	2.4697 (0.9294)
c-statistic	0.671	0.671

The addition of an interaction term was not statistically significant ($p>0.05$) in the candidate model; in addition, the Likelihood Ratio Test, using two degrees of freedom, also showed that it did not contribute significantly to the model. Therefore, I did not retain it.

8.6.8.5 Sample size considerations

Table Frequency of outcomes for each categorical fixed covariate included in the candidate model for Obstetrics and Gynecology		
	Non-Event	**Event**
	N=218	**N=187**
# months PSLS was available		
3 months or less	13 (6.0%)	35 (18.7%)
4-7 months	105 (48.2%)	86 (46.0%)
8-12 months	100 (45.9%)	66 (35.3%)
Off service		
No	195 (89.4%)	150 (80.2%)
Yes	23 (10.6%)	37 (19.8%)
Reporter		
Lab	60 (27.5%)	62 (33.2%)
Nurse	105 (48.2%)	104 (55.6%)
Other	53 (24.3%)	21 (11.2%)

All covariates had greater than 10 outcomes, therefore I did not have to remove any variables due to low sample size.

8.6.8.6 Outliers and influential data points

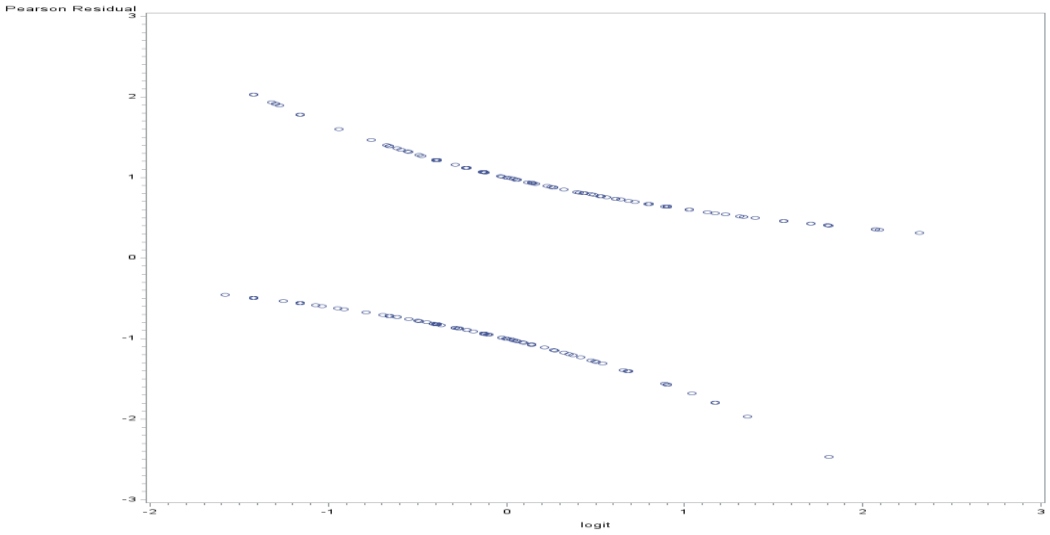


Figure Pearson Residual vs. logit for candidate model within Obstetrics

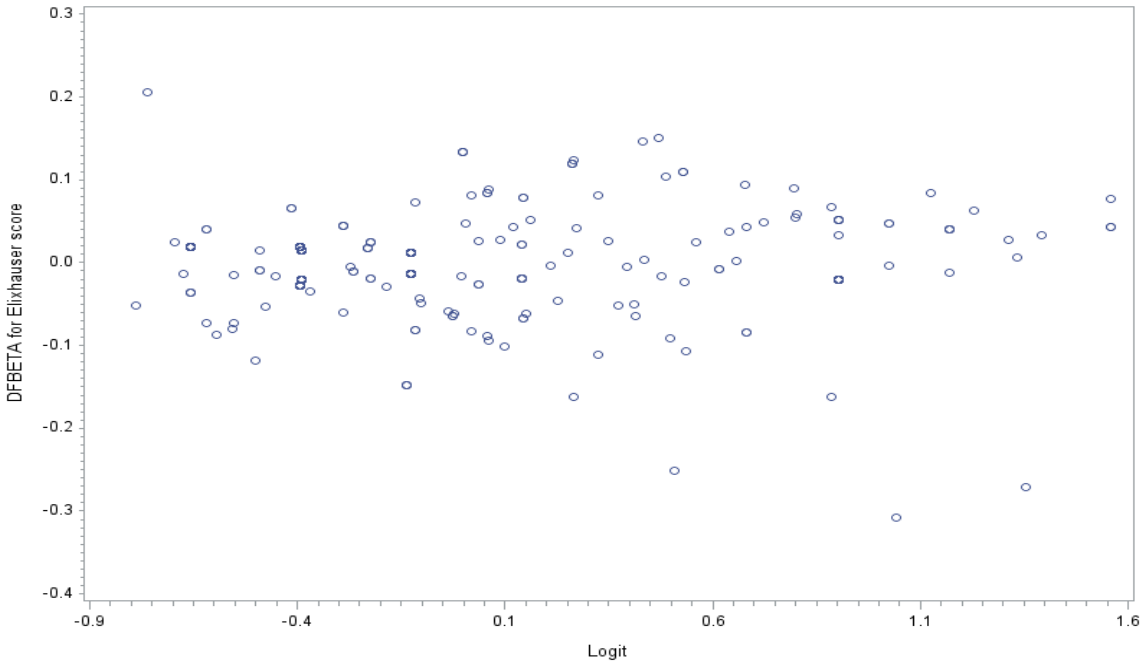


Figure DFBETA plot for Elixhauser score within Obstetrics

I identified one potential outlier with a residual of -2.47. I removed this observation from my dataset and examined its effect on the model.

Table Candidate model for Obstetrics after the removal of an outlier

Effect	Estimate	Std err	Pr > |t|	% change
Intercept	0.1109	0.2034	0.5857	

# Months PSLS was available				
8-12 months	-0.6437	0.1716	0.0002	3.71
4-7 months	-0.3766	0.1647	0.0223	3.18
<3 months	0	.	.	
E**lixhauser**	0.0411	0.0197	0.0369	-0.02
Off service days	0.3037	0.1607	0.0588	-3.47
Reporter				
Lab	0.1788	0.1663	0.2824	-1.39
Nurse	0.4321	0.1505	0.0041	-0.01
Other	0	.	.	

The removal of the outlier did not significantly change the fixed estimates, therefore, I chose to retain it.

8.6.8.7 Final model

Table Final model for Obstetrics, using traditional logistic regression

Effect	**Estimate**	**Std err**	**Pr > |t|**	**OR (95% CI)**
Intercept	0.0547	0.2002	0.7845	

# Months PSLS was available				
8-12 months	-0.607	0.1689	0.0003	0.21 (0.10-0.45)
4-7 months	-0.345	0.1622	0.0336	0.27 (0.13-0.57)
<3 months	0	.	.	.
Elixhauser	**0.0409**	0.0196	0.0363	1.04 (1.00-1.08)
Off service days	0.269	0.159	0.0907	1.7 (0.9-3.19)
Reporter				
Lab	0.1649	0.1654	0.3188	2.14 (1.11-4.12)
Nurse	0.432	0.1498	0.0039	2.80 (1.52-5.15)
Other	0	.	.	

8.6.9 Predictive model for Surgery and Periops

8.6.9.1 Model assumptions

Table Covariance between reporters in an intercept only model for Surgery and Periops

Covariance Parameter Estimates			
Cov Parm	**Subject**	**Estimate**	**Standard Error**
Intercept	**Reporter**	0.02323	0.05402

Table Covtest of independence in an intercept-only model for Surgery and Periops

Tests of Covariance Parameters Based on the Residual Pseudo-Likelihood					
Label	**DF**	**-2 Res Log P-Like**	**ChiSq**	**Pr > ChiSq**	**Note**
Independence	1	3917.37	0.35	0.2773	MI

Table Covariance between reporters in the full final model for Surgery and Periops

Covariance Parameter Estimates			
Cov Parm	**Subject**	**Estimate**	**Standard Error**
Intercept	Reporter	0.1686	0.1929

Table Covtest of independence in the full final model for Surgery and Periops

Tests of Covariance Parameters
Based on the Residual Pseudo-Likelihood

Label	**DF**	**-2 Res Log P-Like**	ChiSq	Pr > ChiSq	Note
No G-side effects	1	4008.84	11.49	0.0003	MI

8.6.9.2 Selection of a candidate model

Similar to the models above, I built separate models for both the Charlson index and Escobar index.

Table Candidate Model 1: Charlson Index as a measure of severity of illness for Surgery and Periops			
Effect	**Estimate**	**Std err**	**Pr > |t|**
Intercept	1.2543	0.4385	0.1036
# Months PSLS was available			
>12 Months	0	0	0
8-12 months	-0.9282	0.1256	<.0001
4-7 months	-0.1108	0.1213	0.3608
<3 months	0	.	.
Day to event			
>5 days	0.1136	0.1198	0.3428
1-5 days	0.3537	0.1172	0.0025

Same day	0	.	.
Patient age	-0.00621	0.00454	0.1712
Charlson Index			
5	-0.3115	0.2032	0.1257
3-4	0.1898	0.2203	0.3892
1-2	-0.1646	0.1826	0.3677
0	0	.	.
Role of reporter			
Nurse	0.4742	0.1119	<.0001
Lab	-0.0581	0.111	0.6008

Since none of the other composite indices for severity were significant, I only had one candidate model.

8.6.9.3 Diagnostics

Table Diagnostic statistics for the candidate model for Surgery and Periops	
AIC	1142.01
Likelihood	1120.01
Hosmer-Lemeshow Test (chisp(p-value))	8.4693 (0.389)

c-statistic	0.663

8.6.9.4 Iterations of the candidate model

8.6.9.4.1 Addition/removal of non-significant fixed covariates

Since the Charlson index was non-significant in the multivariate model, I removed it and examined its effect on the model.

Table Candidate model for Surgery and Periops without Charlson Index				
Effect	**Estimate**	**Std err**	**Pr > |t|**	**% change**
Intercept	1.0166	0.3142	0.0012	
# Months PSLS was available				
>12 Months	0	0	0	0
8-12 months	-0.9337	0.1254	<.0001	0.55
4-7 months	-0.0958	0.1207	0.4274	-1.5
<3 months	0	.	.	.
Day to event				
>5 days	0.1095	0.1166	0.3477	0.41
1-5 days	0.3328	0.1161	0.0042	2.09
Same day	0	.	.	.
Patient age	-0.00605	0.0044	0.1691	-0.016

Role of reporter				
Nurse	0.4857	0.1113	<.0001	-1.15
Lab	-0.0665	0.1102	0.5459	-3.49

Table Comparison of diagnostic statistics between the candidate model for Surgery and Periops, and the candidate model without Charlson Index		
	Candidate Model	**Candidate model without Charlson Index**
AIC	1142.01	1141.141
-2 Log Likelihood	1120.01	1127.141
Hosmer-Lemeshow Test (chisp(p-value))	8.4693 (0.389)	14.1645(0.0776)
c-statistic	0.663	0.66

The Likelihood Ratio test, using 3 degrees of freedom was non-significant (p>0.05), and none of the fixed covariates changed by greater than 10%. Therefore, I concluded that the Charlson Index did not make a significant contribution to the multivariate model and removed it.

Patient age was also non-significant, so I removed it from the candidate model and examined its effect.

Table Candidate model for Surgery and Periops without patient age				
Effect	**Estimate**	**Std err**	**Pr > |t|**	**% change**
Intercept	0.6221	0.1253	<.0001	

# Months PSLS was available				
>12 Months	0	0	0	0
8-12 months	-0.9346	0.1253	<.0001	0.09
4-7 months	-0.0907	0.1205	0.4518	-0.51
<3 months	0	.	.	.
Day to event				
>5 days	0.095	0.1159	0.4122	1.45
1-5 days	0.3361	0.1159	0.0037	-0.33
Same day	0	.	.	
Reporter				
Lab	-0.0654	0.11	0.5523	5.935
Nurse	0.4762	0.1109	<.0001	0.95
Other	0	.	.	.

Table Comparison of diagnostic statistics between the candidate model for Surgery and Periops, and the candidate model without Charlson Index

	Candidate Model + Charlson index removed	**Candidate model + Charlson Index and patient age removed**
AIC	1141.235	1141.141

-2 Log Likelihood	1125.235	1127.141
Hosmer-Lemeshow Test (chisp(p-value))	14.1645(0.0776)	9.3369(0.3147)
c-statistic	0.66	0.656

The likelihood ratio test, with 1 degree of freedom indicated that the addition of patient age was non-significant. Furthermore, none of the fixed covariate estimates were altered by more than 10% when patient age was removed. Thus, I chose not to include it in my final model.

Table Frequency of outcomes for each categorical fixed covariate included in the candidate model for Surgery and Periops		
	Non-event	**Event**

	N=337	N=574
# Months PSLS was available		
3 months or less	18 (5.3%)	96 (16.7%)
4-7 months	115 (34.1%)	246 (42.9%)
8-12 months	204 (60.5%)	232 (40.4%)
Time to event		
First day	152 (45.1%)	290 (50.5%)
1-5 Days	152 (45.1%)	250 (43.6%)
> 5 days	33 (9.8%)	34 (5.9%)
Reporter Role		
Lab	132 (39.2%)	237 (41.3%)
Nurse	152 (45.1%)	275 (47.9%)
Other	53 (15.7%)	62 (10.8%)

8.6.9.5 Sample size considerations

All covariates have greater than 10 events, therefore I did not have to remove any variables due to low sample size.

8.6.9.6 Outliers and influential data points

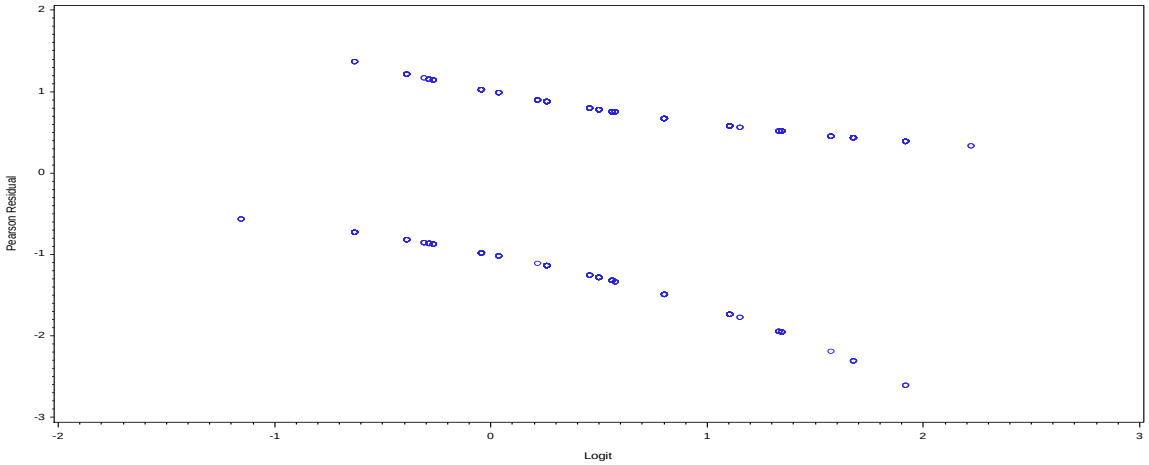


Figure Residual plot of random effects for the candidate model of surgery and periops

There were no extreme outliers in my surgical cohort, therefore I did not remove any observations.

8.6.9.7 Final model

Table Final multivariate logistic regression model for Surgery and Periops

Effect	**Estimate**	**Std err**	**Pr > |t|**	**OR (95% CI)**
Intercept	0.6221	0.1253	<.0001	
# Months PSLS was available				
>12 Months	0	0	0	0
8-12 months	-0.9346	0.1253	<.0001	0.14 (0.08-0.25)
4-7 months	-0.0907	0.1205	0.4518	0.33 (0.19-0.60)

<3 months	0	.	.	.
Day to event				
>5 days	0.095	0.1159	0.4122	1.70 (0.99-2.91)
1-5 days	0.3361	0.1159	0.0037	2.15 (1.25-3.70)
Same day	0	.	.	
Reporter				
Lab	-0.0654	0.11	0.5523	1.41 (0.90-2.23)
Nurse	0.4762	0.1109	<.0001	2.43 (1.54-3.83)
Other	0	.	.	

Appendix G

Table 1 Demographic data of previous literature on incident reporting in an adult hospital setting

	Setting	Time Period	Data collection	Type of reporter
Bates 1995 United States	2 General Medical Units, 1 ICU	Oct-Nov, 1992 51 days	Mixed methods: prospective data collection, retrospective review Medication errors detected by self report from pharmacy and chart review by nurses ADEs were detected by incident reporting	All event identified by pharmacists and nurses, then reviewed by 2 independent clinical reviewers (doctor)
Beckers 2003 Netherlands	22 Regional hospitals	Jan 1 2001- Dec 31 2002	Mixed methods: Prospective data collection, retrospective review	Hospital hemovigillance officers

Beckmann 2003 Australia	Tertiary care, ICU	Mar 15 1999-May 15 1999	Descriptive, cross-sectional comparison of Incident reporting and chart review	All Healthcare staff
Benson 2000 Germany	Anesthesiology and ICU: >14 yrs	Jan 1998-Dec 1998	Cross-sectional comparison of incident reporting with automatic triggers	Anesthesiologists
Bodina 2014 Italy	Teaching hospital	Jan 2011-Dec 2012	Mixed methods: prospective data collection, retrospective review	
Chen 1998 Hong Kong	Tertiary referral teaching hospital: Anesthesia, Acute Pain Service	May 1996 – April 1997	Incident reporting	All healthcare staff
Davies 2010 England	NHS hospitals	6 months prospective study period	Mixed methods: prospective data collection, retrospective review	Not stated

Donaldson 2014 England	National database of all hospitals in England: all adult deaths > 16 yrs	Jun 1 2010 – Oct 31 2012	Mixed methods: prospective data collection, retrospective review	All healthcare staff, mandatory reporting of deaths
	Setting	**Time Period**	**Data collection**	**Type of reporter**
Freestone 2008 Australia	Tertiary public teaching Hospital	Aug 2001-Feb 2004	Mixed methods: prospective data collection, retrospective review	Anesthesia registrars and their training supervisor
Gurjar 2011 England	District general hospital: Adult inpatients, general surgery	Apr 2002-Mar 2007	Mixed methods, prospective data collection, retrospective review	
Hart 1994	Anesthesia, ICU			
Haw 2011 England	Chartiable specialist psychiatric facility, all ages	Mar 1 2008-Feb 28 2010	Mixed methods, prospective data collection, retrospective review	Not stated

Ito 2003 Japan	44 Private psychiatric hospitals	Oct 1 2000 - Nov 2000	Mixed Methods: cross sectional self report survey, retrospective record review	All healthcare staff
Kobus 1996				Not stated
Khorsandi 2012 Scotland	Teaching Hospital: surgery	May 2004 - Dec 2009	Mixed Methods: cross sectional self report survey, retrospective record review	All healthcare staff
Kirke 2009 Ireland	8 Irish hospitals	Jan 1 2006 – Jun 30 2007		Not stated
Kuo 2012 Taiwan	Teaching hospital	2004 – Apr 2007	Mixed Methods: cross sectional self report survey, retrospective record review	Nurses

Levtzion-Korach 2009 United States	Tertiary care academic hospital: inpatient and outpatient	May 10 2004- Nov 30 2006	Mixed methods: prospective data collection, retrospective review	All healthcare staff
	Setting	**Time Period**	**Data collection**	**Type of reporter**

Levtzion-Korach 2010 United States	Tertiary care teaching hospital	May 10 2004 - Feb 28 2006	Comparison of incident reporting to other systems: patient complaints, risk management, medical malpractice claims, executive walk round	All healthcare staff
Linden 2000 United States	256 nationwide Transfusion services	Jan 1 1990-Dec 31 1999		Not stated
Lipshutz 2015 United States	Academic quaternary care hospital: Anaesthesia ICU	Jan 1 2009-Dec 301 2011	Near miss reporting system	All anaesthesia providers can report: physicians, nurses, residents, fellows, faculty
Liu 2009 China	2 Teaching hospitals: Adults only	Hospital A: Apr 2007-June 2007 Hospital B: Dec 2007-Jan 2008	Retrospective cohort	Nurses only

	Setting	**Time Period**	**Data collection**	**Type of reporter**

Manias 2013 Australia	Systematic review: Hospital setting	June 2012	Systematic review of the types of events reported to different systems: Chart review, claims data review, computer monitoring, Direct care observation, interviews, prospective data collection, incident reporting	Not stated
Mark 2009 United States	8 Hospitals participating in University Health System Consortium Patient Safety Net	Jan 1 2004- Dec 31 2004	Mixed methods: prospective data collection, retrospective review	Not stated
McElroy 2014 United States	Tertiary care kidney transplantation center	Apr 2010 - Apr 2011	Prospective: Comparison of incident reporting	All healthcare staff

			to web-based debriefing tool	
Merino 2012 Spain	76 hospitals ICU	22 Mar 2007- 23 mar 2007	Observational, prospective, 24 hour cross-sectional study with self-reporting	Not stated
Minato 2013 Japan	Laboratories			
Morimoto 2004 United States	Inpatient		Practice data, Self reports from health professionals, Survey of patients	All healthcare staff
Nakajima 2005 Japan	Government run teaching hospital	Jun 1 2001 – Mar 31 2004	Observational	All healthcare staff
Narasethkamol 2011 Thailand	Thai University Hospital: anaesthesia	Jan 1 2007- Dec 21 2007	Retrospective: Each event reviewed by 3 reviewers	Attending anesthesia staff
Nuckols 2007 United states	2 US Hospitals: 1 Academic hospital, 1 Community hospital	Jan 1 2001- Dec 31 2001	Observational:	Not stated

			16,575 randomly selected patients from the hospitals Retrospective review of events	
	Setting	**Time Period**	**Data collection**	**Type of reporter**
O Breathnach 2011 Ireland	Surgical wards	Jan 1 2004 – May 30 2010	Mixed methods: Prospective data collection. Retrospective review	All healthcare staff
Olsen 2007 England	NHS district hospital: adult acute medical and surgical units		Prospective cohort comparing AEs reported by chart review and incident reporting	Not stated
Pagnamenta 2013 Switzerland	Public, non-university, multicentre teaching hospital: ICU	May 2004 - Apr 2006	Prospective, control before and after	All healthcare staff
Pronovost 2006 United States	23 ICUs in the United States 13 academic medical centers 9 community teaching hospitals	Jul 2002 - Jun 30 2004	Mixed methods: Prospective data collection,	All healthcare staff

	1 community hospital		retrospective review	
Rakha 2006 England	Hospital Trust, Department of Cellular Pathology	Jan 1 2009 – Dec 31 2010	Retrospective review	All cellular pathology staff
Sawamura 2005 Japan	132 long-term psychiatric units	Oct 1 2000 – Nov 2000	Multivariate model to determine variables associated with ADRs	All healthcare staff
Schildmeijer 2013 Sweden	University hospital: Orthopedic department	2009	Retrospective review of 350 randomly selected admissions	All healthcare staff
Sevadis 2010 UK: England and Wales		Nov 2003 – 10 Oct 2005	Retrospective review of diagnostic errors reported to UK's National Reporting and Learning System	Not stated

Spigelman 2005 Australia		12 AIMS users surveyed of 11 days: in Nov 2002	AIMS system Analysis of weaknesses in incident reporting	All Healthcare staff
Taylor 2014 England	30 Critical Care units	2009-2012	Prospective data collection, retrospective review	All healthcare staff
Tuttle 2004 United States	Teaching hospital- all clinical areas	Jan 1 2002 - Dec 31 2002	Control before and after	All healthcare staff
	Setting	**Time Period**	**Data collection**	**Type of reporter**
Weignart 2000 United States	Teaching hospital, inpatient: Medicine	Aug 1997 – Nov 1997	Prospective data collection in the form of interviews, participation voluntary Compared with incident reporting system and chart review	House officers: frontline healthcare workers, responsible for admitting all patients to a unit

Weignart 2001 United States	Teaching hospital: cardiac step down unit, oncology unit, medical ICU	Mar 1999 – Jun 1999	Prospective interviews Retrospective review and coding of events	Medical officers: PGY-2 and PGY-3 residents offered a $100 honorarium
Weignart 2010		Through Dec 31 2007	Systematic review of the medication errors reported in chemotherapy	
Welker, 2014 Germany	Inpatient: Anaesthesiology, ED, ICU, pain therapy	Apr 2010 – Feb 2011	Mixed methods: Prospective data collection from volunteered participants Retrospective review	All healthcare staff

Table Descriptive event data from previous incident reporting systems in adult hospital settings				
	Types of events	**Event Classification**	**Event Frequency**	**Reporting rates**
Bates 1995	ADEs	Bates model- same as my study	**530 medication errors** **25 ADEs:**	**Incidence rate of reporting:** 5.3 errors/100 orders

			5 (0.9%) associated with medication errors, all preventable **35 Near miss** **Severity** **ADEs:** 1 (4.0%)Life threatening 24 (96.0%) Serious/significant **Near Miss:** 4 (11.4%) Life threatening 31 (88.6%) Serious/significant	0.3 errors/ pt day, or per 1.4 admission
Beckers 2003	Transfusion incidents	SHOT guidelines	362 events 101 (27.9%) FNHTRL: Febrile non-hemolytic transfusion reaction 78 (21.5%) Product incidents 57 (15.7%) DHTR:	

			Delayed hemolytic transfusion reactions	
Beckmann 2003	Incidents and Adverse Events	Incidents: unintended event or outcome Adverse Events: unintended event or outcome caused my medical care	**Incident reporting: 30 AEs** only 1 related to ICU **Event class:** 12 (40.0%) Other 5 (16.7%) Circulatory and organ failure/sepsis 3 (1.0%) Management/planning education problems 3 (1.0%) Treatment/diagnosis delay **Severity:** Potential of harm: 49% minimal 51% significant **Chart Review: 132 AEs** 47 related to ICU 20 (15.2%) Other	**% Reporting by provider:** 49% Nurse 51% Physician

			10 (7.6%) Circulatory and organ failure/sepsis: 10 (7.6%) Pneumonia	
	Types of events	**Event Classification**	**Event Frequency**	**Reporting rates**
Benson 2000	AEs	N/A	**Hypotension:** Manual: Automatic: 1,276 **Hypertension:** Manual: 183 Automatic:1,009 **Bradycardia:** Manual: 408 Automatic: 623	Not reported
Bodina 2014 **Italy**	AEs and near misses	AE and near misses Near misses not reported separately	963 events reported	Majority was made by nurses

Chen 1998	Incidents relating to pain management	Incident: An event that affected, or could have affected the safety and well being of the patient whilst receiving a pain relief method that is supervised by the anaesthesia	53 incidents **Event type:** 81.4% preventable **Event class:** 14 (26.4%) Infusion delivery 14 (26.4%) Pump 12(22.6%) Drug administration **Event Severity:** 21 (39.6%) No physiological change 16 (30.2%) minor trauma 7 (13.2%) major physical change	**Incidence reporting rate:** 53 critical incidents in 1275 patients **% Reporting by provider:** 65.1% Pain Team 23% Nurses 7% Anesthetist
Davies 2010	ADRs	ADRs and severity: NPSA: National Patient Safety Agency	733 ADRs **Event severity:** 537 (73.3%) Low 181 (24.7%) Moderate, no permanent harm	Not reported

			12 (1.91%) Severe, permanent harm 12 (1.6%) Death	
Donaldson 2014	Adults deaths All deaths, not necessarily those due to medical care??	Patient safety incident: National Patient Safety Agency: Any unintended or unexpected incident which could have, or did, lead to harm for one of more patients receiving NHS care	2,010 incidents **Event Class:** 462 (23.0%) Failure to act on or recognize deterioration 206 (10.2%) Inpatient falls 202 (10.0%) Healthcare associated infections	Not reported
	Types of events	**Event Classification**	**Event Frequency**	**Reporting rates**
Freestone 2008	Anesthesia-related near misses	Anesthetic and safety literature	156 events **Event type:** 72 (46.2%) Near Miss **Event class:**	**% Reporting by provider:** 3.54% anesthetists

			66 (42.3%) Airway 34 (21.8%) Cardiovascular 11 (7.1%) Respiratory 11 (7.1%) Equipment	
Gurjar 2011	AEs occurring from acute and elective inpatient general surgical admissions	Event severity: Datix Common Classification System	461 events **Event class:** 239 (51.8%) Communicative or administrative 102 (22.1%) Nursing related 52 (11.3%) Surgery/theatre related **Event severity:** 207 (44.9%) No injury 184 (39.9%) Near miss 6 (1.3%) Serious near miss 4 Death or very serious incident	**Incident rate of reporting**: 2/100 admissions
Hart 1994	Incidents	Any event that caused harm to the patient	390 Incidents **Event severity:** 284 (72.8%) Potential harm	

			105 (26.2%0) Harm 1 (0.3%) Death	
Haw 2011	Medication Events: Medication errors ADEs Near miss	Error classification: NPSA (National Patient Safety Agency)	406 medication errors 40 near miss 0 ADE **Event severity:** 6.3% moderate or serious	Not reported
Ito 2003	ADRs	Event Severity: Ohio State University Medical Center ADE: any event that could be harmful to patients on participating units, whether the incident was intercepted or not	221 events **Event class:** 142 (62.3%) Other 79 (35.7%) Wrong Drug administered 44 (19.9%) Wrong time 35 (15.8%) Missed dose **Event severity:** 125 (56.6%) Clinically insignificant 33 (14.9%) potentially significant	**Incidence rate of reporting:** 0.79/1,000 pt days

			63% (28.5%) potentially serious	
	Types of events	**Event Classification**	**Event Frequency**	**Reporting rates**
Kobus 1996	AEs and near misses in critical care		116 AEs	
Khorsandi 2012	Surgical AEs		3,142 events **Event class:** 24 (29.6%) Staff shortage 16 (19.7%) MRSA infection 7 (8.6%) Central venous catheter complications **Event severity:** 81 (2.58%) severe	Not reported
Kirke 2009	ADEs		6,179 reports	

			Event class: 47% prescribing stage 40% administration stage 9% pharmacy dispensing stage **Event Severity:** 95% did not involve patient harm	
Kuo 2012	All AEs		984 events **Event class:** 390 (39.6%) Falls 239 (24.3%) Pressure Ulcers 72 (7.3%) Laboratory **Event severity:** 898 (91.3%) Minor or minimal 6 (0.6%) Serious/Major 1 (0.1%) Death	

	Types of events	**Event Classification**	**Event Frequency**	**Reporting rates**
Levtzion-Korach 2009	All AEs		14,179 reports **Event Class:** 30.4% Lab related 17.2% Falls 10.9% blood **Event severity:** 3,463 (24.4.%) Near miss 8,8602 (60.7%) No harm 2,024 (14.35) Temporary harm 63 (0.4%) Permanent harm 13 (0.1%) Death	**Incidence reporting rate:** 19.7 reports/1,000 pt days 0.09/admission **% Reporting by provider:** 7% eligible physicians submitted reports

Levtzion-Korach 2010	All AEs	National Quality Forum	Little overlap between the systems 8,616 Incident reports 1,003 Risk management reports 4,722 Patient complaints 61 Executive walk rounds 322 Malpractice claims **Incident reporting:** 2,102 (24.4%) Identification 1,447 (16.8%) Falls 1,226 (14.7%) Medication errors and ADEs **Patient complaints:** 1,029 (21.8%) Communication problems 613 (13.0%) Administration 580 (12.3%) Clinical Judgment **Malpractice claims:**	**% Reporting by provider:** **Risk Management reports:** 50% physicians I**ncident reporting:** 2.5% physicians Majority of reporting was done by nurses

			78 (24.3%) Clinical judgment 55 (17.1%) Communication 36 (11.2%) Medical records **Walk rounds:** 9 (15.7%) Equipment and supplies 7 (12.2%) Medical records 7 (12.2%) Infrastructure	
	Types of events	**Event Classification**	**Event Frequency**	**Reporting rates**
Linden 2000	Tranfusion-related AEs	New York State Department of Health	462 events **Event class:** 259 (56.1%) Non-blood bank error alone 135 (29.2%) Blood bank error alone 67 (14.5%) Compound error 1 (0.2%) Could not be determined **Event severity:** 237 had severity rating: 111 (46.8%) No harm	

			112 (47.3%) Acute hemolytic reaction, non-fatal 1 (0.4%) Acute hemolytic reaction, fatal 1 (0.4%) Low grade fever 8 (3.4%) Death due to underlying condition	
Lipshutz 2015	Near miss only	Near miss classification: Joint Commission patient Safety Event taxonomy: Technical, non-technical, equipment, system errors, human errors, poor safety culture	1,811 near misses 22 (1.2%) from ICU **Event class, ICU near misses:** 4 (16.0%) Skill based: failure to execute a task appropriately 3 (12.0%) Poor communication 3 (12.0%) Rule based: failure to perform routine task	Not reported
Liu 2009	Nursing-related patient safety events	Any event that is related, directly for indirectly to nursing/nurses.	141 events **Event type** 96 (68.0%) Preventable	Not reported

		And cause harm of potential harm to patient	**Event class:** 32 (22.6%) Medication error 26 (18.3%) Swelling or bleeding or IV puncture site 12 (8.5%) Inappropriate nursing procedure **Event severity:** 2 (1.4%) Death	
	Types of events	**Event Classification**	**Event Frequency**	**Reporting rates**
Mark 2009	All AEs	IoM's definitions of AEs and medical errors Event subtypes classified using Patient Safety Net taxonomy: Medication error ADR Equipment Fall	25,300 Incidents reported 3,381 (13.3%) AEs **Event class:** 344 (10.2%) Medication error 266 (7.9%) ADRs 115 (3.4%) Equipment/supplies **Event severity:** 109 (0.4%) Death	**Incidence reporting rate:** 1.57 % of admissions

		Procedure/treatment/test Complication of procedure/treatment/test Transfusion Behavioural Skin integrity Care coordination/records Other		
McElroy 2014	Medical errors and AEs	WHO International Classification of Patient Safety Reportable circumstance: significant potential for harm, no incident occurred	**Debriefing responses:** 334 patient safety issues 179 Safety incidents **Event type:** 31 (17.3%) AEs 19 (10.6%) No-Harm incidents 9 (5.0%) Near miss 120 (67.0%) reportable circumstances	**% Reporting by provider:** **Debriefing responses:** 40.3% Nurse 31.1% Attending physician **Incident reports:** 77.2% Nurse

		Near miss: event that could have resulted in unwanted consequences but did not, event did not reach the patient No harm incident: event reached the patient, but no harm discerned AE: harmful incident resulting in harm to a patient, resulting from medical intervention	**Event class:** 29 (28.4%) Resource/Organizational Management 39 (21.8%) Medical Device/ Equipment 36 (20.1%) Clinical Process/Procedure **Incident reporting:** 92 Patient safety issues **Event type:** 56 Safety incidents 12 (21.4%)AEs 17 (30.4%) No Harm 9 (16.1%) Near miss 14 (25.0%) reportable circumstances **Event class:** 16 (28.6%) Medical Device/ Equipment 13 (23.2%) Patient accidents	12.2% Physician assistant

			10 (17.9%) Documentation	
	Types of events	**Event Classification**	**Event Frequency**	**Reporting rates**
Merino 2012	All AEs	WHO International Classification for Patient Safety AE: incident that resulted in harm to the patient Near miss: event that did not reach the patient, or did reach the patient, but no harm was discerned Event severity: Ruiz-Jarabo Group's classification	1,424 incidents **Event type:** 481 (33.8%) AEs 943 (66.2%) Near Miss **Event class:** **AEs:** 126 (26.2%) Nursing care 116 (24.1%) Nosocomial infection 56 (11.6%) Medication 29% permanent damage 4% Death **Severity:** 115 (23.9%) Could not be determined 185 (38.5%) Temporary harm	

			172 (35.8%) Permanent harm 9 (1.9%) Death **Near Miss:** 294 (31.2%) Medication 207 (22.0%) Equipment 133 (14.1%) Accidental withdrawal of catheters or tubes **Event severity:** 168 (17.8%) Detected/corrected before event occurred 596 (63.2%) No harm, did not require monitoring/intervention 179(19.0%) No harm, required monitoring/intervention	

	Types of events	Event Classification	Event Frequency	Reporting rates
Minato 2013				
Nakajima 2005	All AEs	Not specified	6,041 Incidents **Event class:** 2,815 (46.6%) Medication 1,147 (19.0%) Lines and tubes 826 (13.7%) Falls and slips	**Rate of reporting by provider:** 84.7% Nurse of midwife 10.2% Physician 2.3% Pharmacist
Narasethkamol 2011	Anesthesia-related adverse events		191 incidents Event type: 89 (46.5%) Preventable Event class 43 (22.5%) Oxygen saturation 26 (13.6%) Arrythmia needing treatment 24 (12.6%) Equipment malfunction	

Nuckols 2007			2,244 unique incidents (results weighted to represent all patients) **Event type:** 9% of patients had at least 1 incident 59.0% Preventable 8.7% Non-Preventable 32.3% Preventability unclear **Event class:** 29% Medication incident 14% Falls 15% Operative incidents **Event severity:** 806 (20.8%) No harm 394 (10.2%) Minor to moderate 74 Severe (1.9%) 109 Death (2.8%) 638 (16.5%) Unknown	**Incidence** **reporting rate:** 17 incidents/ 1,000 pt days **Reporting rate** **by provider:** 89% Nurses 8.9% Other 1.9% Physicians

			1855 (47.9%) Did not rate harm	
	Types of events	**Event Classification**	**Event Frequency**	**Reporting rates**
O Breathnach 2011	All AEs on surgical wards reported to CIS (Clinical Idemnity Scheme)	Clinical incident: CIS: "an event arising as a consequence of, provisions of, or failure to provide clinical care that resulted in injury, disease, disability, death, or prolonged hospital stay for the patient."	42,094 AEs 19, 343 (46.0%) General Surgery 11,307 (26.8%) Orthopedic surgery 11,444 (27.2)% Remaining wards **Event class:** 32% Slips/trips/falls 2nd most common: Medication error	**% Reporting by provider:** 85% Nurse/midwife 4% Physicians

			3rd most common: Perioperative Incident **Event severity:** 18,528 (80.1)% No harm	
Olsen 2007	All AEs		**Chart Review**: 26 AEs 40 Near Miss **Incident reporting:** 0 AEs 11 Near Miss **Pharmacy surveillance:** 10 medication errors, all near miss Very little overlap between systems	
Pagnamenta 2013	AEs	AEs: unintentional event due to healthcare management that caused or could	2,047 events **Event class:** 984 (48.1%) Drug related 245 (12.0%)	**Incidence rate of reporting:** 32/100 ICU admissions

		have caused patient harm	Indwelling lines, catheters, and drains 213 (10.4%) Communication and planning **Event severity:** 265 (12.9%) No detectable harm 1,155 (56.4%) Minimal, temporary harm 302 (14.8%) Minimal permanent harm 5 (0.2%) Severe harm 0 Death	117.4/ 1000 ICU pt days **% Reporting by provider:** 1,757 (85.8%) Nurse 269 (13.1%) Physician 21 (1.0%) Other
	Types of events	**Event Classification**	**Event Frequency**	**Reporting rates**
Pronovost 2006	Incidents: Any event that could or did lead to patient harm	Incidents: Any event that could or did lead to patient harm Adverse events: incidents causing harm	2,075 incidents 5 Hospital submitted 58% of reports **Event class:** 864 (41.6%) Medication/therapeutics	**Reporting rate:** Median 3 reports/ICU/month **Reporting rate by provider:**

		Near miss: incidents causing no harm	416 (20.0%) Incorrect/incomplete care deliver 320 (15%) Equipment/medical device **Event severity:** 42% Harm 5% Death	69% Nurse 11% physician 4% Pharmacist
Rakha 2006	Cellular pathology: booking and specimen labelling		584 incidents **Event class:** 285 (48.5%) Booking-related incidents 136 (23.2%) Machine/processing-related 51 (8.7%) Cytology (recall- time) related 345 (59.1%) Pre-analytical 133 (22.8%) Analytical 106 (18.2%) Post analytical **Event severity:**	Not reported

			462 (79.1%) Near miss, no harm 108 (18.5%) Actual harm 14 (2.4%) Harm undertermined	
	Types of events	**Event Classification**	**Event Frequency**	**Reporting rates**
Sawamura 2005	Potential ADR	Potential ADRs: medication-related event that could have been	221 incident reports **Event class:**	Not reported

		harmful to patients Event severity: Ohio State University Medical Center	160 (72.4%) Incorrect administration 61 (27.1%) Incorrect drugs **Event severity** 22 (24.9%) intercepted before reaching the patient 125 (56.6%)Clinically significant 34 (15.4%) Potentially significant 52 (23.5%) Potentially serious	
Schildmeijer 2013	No harm incidents relating to orthopedics	WHO: Event or circumstance that could have or has resulted in unnecessary harm to patient	118 No harm incidents **Event type:** 94 (79.7%) Preventable **Event class:** 66 (55.9%) Drug therapy 18 (15.3%) Nursing care, excluding drugs 12 (10.2%) System related	Not reported Length of stay significantly associated with near miss admissions (compared to

				admissions with no near-miss)
Sevadis 2010	**Diagnostic errors**	National Patient Safety Agency: any unintended or unexpected incident which could have, or did lead to patient harm	1,674 diagnosis related incidents (0.5% of total incidents reported) 926 (55.3%) No harm 4 (0.2%) Harm not reported Diagnosis-related incidents more likely to be associated with harm ($p<0.001$)	Not reported
Spigelman 2005				Medical staff reported only 5% of events in AIMS database When medical staff reported incidents, they were associated with a more serious outcome

				Voluntary incident reporting did not capture all incident data and information was often too generic for root cause analysis
	Types of events	**Event Classification**	**Event Frequency**	**Reporting rates**
Taylor 2014	All ADEs	Classification of ADEs: UK Intensive Care Society: incidents where patients were harmed, or could have been harmed as a result of their care."	2,238 ADEs **Event type:** 1,461 (65.3%) Preventable **Event severity:** 452 (20.2%) Temporary/ more than temporary harm 497 (22%) Potentially major or life threatening	**Incidence reporting rate:** (/1,000 pt days) 2009: 5.9 2012: 6.6
Tuttle 2004	All AEs:		2,843 events	**% Reporting by provider:**

	Medication events Adverse clinical events, falls, administrative		**Event class:** 1,126 (39.6%) Medication/infusion events 851 (29.9%)Adverse clinical events 693 (24.4%) Falls 137 (4.8%) Administrative **Event severity:** 292 (10.3%) Near Miss 1,531 (54.0%) No Harm 623 (21.9%) Harm	70% Nurse 2% Physician 3% Pharmacist 25% Other
Weignart 2000	All AEs		**House Officer reports:** 110 Events 29 (26.4%) AEs 52 (47.3%) Near Miss 29 (26.4%) Other quality problems **Incident reporting:** Detecting only 1 house officer report **Chart Review:**	

			Corroborated 72.9% events	
	Types of events	**Event Classification**	**Event Frequency**	**Reporting rates**
Weignart 2001	**All AEs and near misses**		88 events **Event type:** 5 AEs (0.5% of admissions) 48 Near miss in (4.9% of admissions) 35 Other quality problem (3.5% of admissions) **Event class:** 23 (26.1%) Therapy 19 (21.4%) Other process problems 18 (20.4%) Clinical Services	**% Reporting rate provider:** 55% Physicians 15% Radiology 11% Laboratory 84% corroborated with reported events in medical record

			Event severity: 39 (44.3%) No Harm 5 (5.7%) Injury 22 (25.0%) Delayed diagnosis 15 (17.0%) Delayed treatment 7 (8.0%) Difficult discharge	
Weignart 2010	**Medical errors** **ADEs** **Near miss**	Error: WHO:the failure of a planned action to be completes as intended AEs: Bates	508 incidents **Event type:** 99 (19.5%) ADEs 322 (63.4%) Near Miss 87 (17.15%) Medical errors **Event severity, AEs:** 20 (20.8%) serious or life threatening 52 (52.5%) Significant 25 (25.3%) minor **Event severity, Near misses:** 2 (0.6%)risk of serious harm	

			187 (58.1%) Risk of significant injury 132 (41.0%) risk of minor injury **Event severity, overall:** 12 (2.4%) Death 1 (0.2%) Permanent disabiilty **ADEs detected from** **different sources:** literature search: 73.1% Hospital safety reports 58.8%	

	Types of events	**Event Classification**	**Event Frequency**	**Reporting rates**
Welker, 2014 **Findland**	All AEs reported to anesthesiology, emergency medicine, ICU, pain therapy	WHO and National Patient Safety Agency taxonomy Event severity: American Society of Aneasthesiologists (ASA)	1,548 reports 1,347 (87.0%) contain ASA event classification **Event class:** 443 (28.6%) Clinical processes 347 (22.4%)medication 530 (34.2%) medical devices **Severity:** 238 (15.4%) ASA I (No Harm) 436 (28.2%) ASA II (Mild Dx) 467 (30.2%) ASA III (Severe Dx)	**% Reporting by provider:** 68.6% Physicians 68.6% Nurses

			191 (12.3%) ASA IV (Incapacitating Dx) 15 (1.0%) ASA V (Dying) 201 (13.0%) N/A	

Table 3 Previous literature that compared incident reporting to other methods of adverse event detection, in a hospital setting with an adult population

	Types of events	**Event Classification**	**Event Frequency**	**Reporting rates**
Beckmann 2003	Incidents and Adverse Events	Incidents: unintended event or outcome Adverse Events: unintended event or outcome caused my medical care	**Incident reporting: 30 AEs** only 1 related to ICU **Event class:** 12 (40.0%) Other 5 (16.7%) Circulatory and organ failure/sepsis	**% Reporting by provider:** 49% Nurse 51% Physician

			3 (1.0%) Management/planning education problems 3 (1.0%) Treatment/diagnosis delay **Severity:** Potential of harm: 49% minimal 51% significant **Chart Review: 132 AEs** 47 related to ICU 20 (15.2%) Other 10 (7.6%) Circulatory and organ failure/sepsis: 10 (7.6%) Pneumonia	
	Types of events	**Event Classification**	**Event Frequency**	**Reporting rates**
Benson 2000	AEs	N/A	**Hypotension:** Manual: 339 Automatic: 1,276	Not reported

			Hypertension: Manual: 183 Automatic:1,009 **Bradycardia:** Manual: 408 Automatic: 623	
Levtzion-Korach 2010	All AEs	National Quality Forum	Little overlap between the systems 8,616 Incident reports 1,003 Risk management reports 4,722 Patient complaints 61 Executive walk rounds 322 Malpractice claims **Incident reporting:** 2,102 (24.4%) Identification 1,447 (16.8%) Falls 1,226 (14.7%) Medication errors and ADEs	**% Reporting by provider:** **Risk Management reports:** 50% physicians I**ncident reporting:** 2.5% physicians Majority of reporting was done by nurses

			Patient complaints: 1,029 (21.8%) Communication problems 613 (13.0%) Administration 580 (12.3%) Clinical Judgment **Malpractice claims:** 78 (24.3%) Clinical judgment 55 (17.1%) Communication 36 (11.2%) Medical records **Walk rounds:** 9 (15.7%) Equipment and supplies 7 (12.2%) Medical records 7 (12.2%) Infrastructure	
	Types of events	**Event Classification**	**Event Frequency**	**Reporting rates**
McElroy 2014	Medical errors and AEs	WHO International Classification of Patient Safety	**Debriefing responses:** 334 patient safety issues 179 Safety incidents	**% Reporting by provider:**

		Reportable circumstance: significant potential for harm, no incident occurred Near miss: event that could have resulted in unwanted consequences but did not, event did not reach the patient No harm incident: event reached the patient, but no harm discerned AE: harmful incident resulting	**Event type:** 31 (17.3%) AEs 19 (10.6%) No-Harm incidents 9 (5.0%) Near miss 120 (67.0%) reportable circumstances **Event class:** 29 (28.4%) Resource/Organizational Management 39 (21.8%) Medical Device/ Equipment 36 (20.1%) Clinical Process/Procedure **Incident reporting:** 92 Patient safety issues **Event type:** 56 Safety incidents 12 (21.4%)AEs 17 (30.4%) No Harm	**Debriefing responses:** 40.3% Nurse 31.1% Attending physician **Incident reports:** 77.2% Nurse 12.2% Physician assistant

		in harm to a patient, resulting from medical intervention	9 (16.1%) Near miss 14 (25.0%) reportable circumstances **Event class:** 16 (28.6%) Medical Device/ Equipment 13 (23.2%) Patient accidents 10 (17.9%) Documentation	
	Types of events	**Event Classification**	**Event Frequency**	**Reporting rates**

Olsen 2007	All AEs		**Chart Review**: 26 AEs 40 Near Miss **Incident reporting:** 0 AEs 11 Near Miss **Pharmacy surveillance:** 10 medication errors, all near miss Very little overlap between systems	
Weignart 2000	All AEs		**House Officer reports:** 110 Events 29 (26.4%) AEs 52 (47.3%) Near Miss 29 (26.4%) Other quality problems **Incident reporting:** Detecting only 1 house officer report	

			Chart Review: Corroborated 72.9% events	
Weignart 2010	**Medical errors** **ADEs** **Near miss**	Error: WHO:the failure of a planned action to be completes as intended AEs: Bates	508 incidents **Event type:** 99 (19.5%) ADEs 322 (63.4%) Near Miss 87 (17.15%) Medical errors **Event severity, AEs:** 20 (20.8%) serious or life threatening 52 (52.5%) Significant 25 (25.3%) minor **Event severity, Near misses:** 2 (0.6%)risk of serious harm 187 (58.1%) Risk of significant injury 132 (41.0%) risk of minor injury **Event severity, overall:** 12 (2.4%) Death	

			1 (0.2%) Permanent disabiilty **ADEs detected from** **different sources:** literature search: 73.1% Hospital safety reports 58.8%	