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Adverse Events among Patients Registered in High Acuity Areas of the Emergency Department: A Prospective Cohort Study

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Adverse Events among Patients Registered in High Acuity Areas of the Emergency Department: A Prospective Cohort Study

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Thesis submitted to the Faculty of Graduate and Postdoctoral Studies
in partial fulfillment of the requirements for MSc degree in Epidemiology

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1.0 ABSTRACT

Introduction:

Little is known about patient safety issues in the emergency department (ED). The goal of this study was to determine the proportion of patients with adverse events in high acuity areas of the ED.

Methods:

This was a prospective cohort study in two Ottawa EDs. All consenting consecutive patients had a telephone interview at 14 days if discharged or chart review if admitted. Three emergency physicians assessed flagged outcomes (such as death, return ED visits) for adverse events. An adverse event was a flagged outcome associated with health care management. Descriptive statistics and multiple logistic regression analysed the adverse events.

Results:

Over 4 months, 518 patients were enrolled. Seventy-three percent were discharged and 27% admitted. Of 135 flagged outcomes, 43(8.5%) patients had adverse events. None of the variables examined were statistically associated with adverse events.

Conclusion: This study suggests that adverse events are important considerations in the ED.

2.0 INTRODUCTION

Patient safety has become an important topic in medicine as awareness of adverse events has increased. The concept of patient safety has been defined as "freedom from accidental injury" while adverse events are unintended injuries that result from health care management.[1] Previous population-based studies estimated that 3% of all adverse events occur in the emergency department, suggesting it is a low priority area in patient safety.[2] These studies may have underestimated the true rate due to their focus on inpatients. The emergency department patient population is complex with high acuity presentations and system pressures to establish diagnoses and administer therapies in a short period of time. Conducting research in this setting is challenging because of these issues and the diversity of the population, the majority of whom are discharged into the community with limited follow-up. As a result, emergency patient safety studies have focused on the most severe adverse events or specific patient sub-populations. Few have looked comprehensively at the population as a whole.

This prospective cohort study aimed to determine the proportion of high acuity patients with adverse events in two Ottawa emergency departments. Consecutive patients were enrolled during a stratified random sampling of the 24 hour, 7 days a week service provided in the emergency department. Those patients who were discharged from hospital received phone follow-up in 10-14 days while those who were admitted had their charts reviewed. Discharged patients who experienced unexpected death, unscheduled admissions to hospital, unscheduled emergency

department visits and new or worsening symptoms were flagged for further review. Admitted patients who experienced unexpected death, were transferred to a higher acuity area, underwent unplanned emergency surgery, and suffered falls or adverse drug effects were flagged for further review. Those patients with flagged outcomes had their emergency and inpatient charts summarized as well as the data from telephone interviews. Three emergency physicians blinded to patient and treating physician identity independently reviewed all flagged outcomes. They utilized a structured, previously validated approach to determine the presence of adverse events, their preventability and severity. In this way, this thesis attempted to rigorously identify and describe adverse events among some of the sickest patients presenting to emergency departments.

2.1 Statement of the Problem

Adverse events are unintended injuries that result from health care management.[2] Examples of adverse events related to emergency department care include post-lumbar puncture headaches and missed myocardial infarctions. It is accepted that a given proportion of adverse events are not preventable and are expected complications from health care interventions. There is a subset of adverse events, however, which are **preventable** and arise from an error in health care management. An error is defined as a failure of a planned action to be completed as intended or use of a wrong plan to achieve an aim.[1] Not all adverse events are due to error but it is those that are preventable that become targets for interventions to improve patient safety.

Emergency department care is an important component of the health care system. There are an estimated 800 emergency departments in Canada with an estimated 14 million patient visits per year.[3;4] Of these, 80% are discharged home, while 11% are admitted per year (the rest left without being seen).[4] These emergency departments are staffed by emergency specialists in urban centers and mostly family physicians in rural regions. Emergency departments are also a key component in medical training with most large urban departments serving as an educational setting for physician learners.

Emergency department care may be associated with inherent risks since these are areas of high patient acuity with increasing pressures in terms of overcrowding and limited resources. Understanding that large numbers of patients need to be triaged, assessed, diagnosed and treated in a short period of time with limited information leads one to intuitively conclude that it is a ripe environment for patient safety concerns. Patients are unstable, undifferentiated and unscheduled. Physicians working in the emergency department are challenged by multiple interruptions, overcrowding, shift work and a lack of continuity of care.[5] The complexity of the patient encounter in the emergency department has been previously described[6] and this contributes to the challenge of studying adverse events in the emergency department.[5]

To date, few researchers have taken up this challenge and as a result there is very little data describing adverse events in the emergency department. A review of the literature reveals that most patient safety studies have been conducted on

hospitalized inpatients. No published emergency medicine studies have attempted to assess the overall incidence of adverse events in the emergency department. Those patient safety studies that have been conducted in emergency medicine have focused on quality assurance or specific populations.

We cannot prioritize emergency department patient safety efforts until we have a good estimate of the incidence and type of adverse events. The goal of this thesis is to determine the proportion of patients with adverse events among those triaged to the high acuity areas of the emergency department. Furthermore, an attempt will be made to characterize the population most at risk for adverse events in the emergency department. This will establish a foundation for planning future patient safety interventions.

2.2 Literature Review

The literature discussed in this Introduction was generated via a search of the Medline database (1966-2004) for articles relating to adverse events and patient safety in the emergency department. Initially a structured search strategy was created with the assistance of a library scientist (see Figure A).

This search strategy was repeated and expanded in August 2006 as part of another project, a systematic literature review of patient safety interventions in the emergency department. Articles found to be relevant to this thesis were included in the present review. Specifically, the themes of patient safety theory, adverse event measurement and patient safety studies in emergency medicine were sought.

The Medline database search was supplemented through hand searching of the reference lists of retrieved articles, the table of contents of major emergency medicine journals and conference proceedings from the years 2000-2006. The website AHRQ Patient Safety Network (http://psnet.ahrq.gov) and the libraries of one of the thesis supervisors (AF) and another patient safety expert, Dr. Kaveh Shojania, were also searched for relevant studies. While this does not constitute a formal systematic literature review, it does represent an attempt to obtain a comprehensive picture of the patient safety literature in emergency medicine.

2.3 Background

2.3.1 Overview

Since the publication of the Institute of Medicine's landmark report, "To Err is Human: Building a Safer Health System" in 1999, patient safety has become an area of public debate and research interest.[1] The report identified common medical errors such as adverse drug effects, improper blood transfusions, wrong site surgery and pressure ulcers. The authors indicated that preventable medical errors were not only financially costly but also led to a loss of trust by patients and diminished morale among health care providers. One of the reports main conclusions was that medical error was mostly due to faulty systems rather than "individual recklessness".[1] There were four main recommendations issued: 1) establish a Center for Patient Safety to create leadership and facilitate research; 2) develop a national mandatory reporting system; 3) set explicit performance standards via licensing and certifying bodies; 4) encourage the development of a "culture of safety" among health care organizations. This seminal report was viewed by many

as a turning point in patient safety awareness among health care providers and the public.

The Institute of Medicine report gained the public's attention because it estimated the incidence of medical adverse events was equivalent to one jumbo jet crashing every 4 days. The analogy to the aviation is pertinent since this industry is well-known for their work in the prevention of undesirable outcomes. For example, it is common to use simulators to enhance team performance and also employ root-cause analysis of mishaps.[7] The methodologies used by this industry are becoming relevant to patient safety in medicine. While the differences between the two realms are obvious, many common lessons can be learned. Some critical care fields such as anesthesia have already begun to adopt the safety principles used in aviation.[7] Emergency medicine is another critical care area that may benefit from similar approaches.

Since patient safety has received much coverage in the press, it has become a readily identifiable issue amongst the lay public. This is important as previously the consumers of health care were largely unaware of the attendant risks of becoming a patient.[1] The Canadian Institute for Health Information's 2004 annual report included a survey of 1,000 Canadians.[8] They found that 24% had experienced a preventable adverse event related to their care or that of a family member. Of those who had experienced an event, about half (52%) said that the most recent event had had serious consequences. One must interpret these results with care as patients often do not have full information behind the reason that a certain

healthcare decision was made. In addition, sometimes a patient's interpretation of a serious adverse event is quite different from that of a clinician. Nonetheless, it has been suggested that patient satisfaction with health care is closely linked to previous experience of adverse events.[9] This survey highlights that patient safety is part of the public consciousness and thus creates expectations that these concerns are being addressed by the health care system.

Given this background on the emergence of patient safety as an important theme in health care, the following subsections describe relevant patient safety theory and research related to adverse events both overall in terms of the health care system and specifically with respect to emergency medicine. This review of the literature will provide the rationale for this thesis and its methodology.

2.3.2 Patient Safety Theory

Dr. James Reason, a respected British safety expert, has written extensively on safety in industry including health care.[10;11] Dr. Reason proposed a "system-based approach" to patient safety. His model of the health care system described a "blunt end" and a "sharp end". The blunt end represented upper levels of the organization such as hospital administrators and managers, whereas the sharp end represented the interface between health care provider and patient. Problems with the sharp end usually had immediate effects, whereas problems with the blunt end could have latent, trickle down effects resulting in many adverse events over years. Dr. Reason postulated that medicine has been focusing on the sharp end, the wrong "end", of the system when it comes to patient safety.

Traditionally, medicine has had a "blame-oriented" culture which has been oriented towards the sharp end.[12] The idea being that if one identified the "bad apple" that the patient safety issues would be resolved. This has been deeply ingrained in medicine as witnessed by mortality and morbidity rounds where the tendency of the audience can be to find fault with the involved physicians' management rather than looking at the broader system issues.[13] The system-based approach of patient safety concentrates on work conditions and environments that contribute to patterns of adverse events. Examples of system issues that could contribute to adverse events include: time pressures, equipment inadequacies and understaffing. The basic premise is that humans are fallible and adverse events should be expected – even in the best organizations. Thus to assign blame becomes counterproductive; rather, the goal should be to create a system that can withstand the operational dangers (i.e. expected rate of adverse events with minimal impact on patients) while still achieving its objectives. In order to create such a system, a series of defences need to be in place.

Dr. Reason described built-in barriers to adverse events in his "Swiss Cheese Model" (see Figure B).[10] The Swiss Cheese Model suggests that every system has multiple barriers to adverse events. Examples in the emergency department include: triage, assessments by multiple providers, documentation, investigations and follow-up. Each barrier has a series of "holes" in it - but unlike Swiss cheese, these holes open and close and change position over time. In order for an adverse event to occur, the holes in each barrier must line up. The corollary to this is that adverse events occur in predictable patterns.

While the system-based approach has been widely embraced among patient safety advocates, another fundamental piece to patient safety theory is the cognitive processes of the individual. As previously mentioned, the patient encounter in the emergency department is frequently complex and clinicians have a tendency to recurrently encounter the same "pitfalls" in diagnosis and management. These pitfalls have been described as "cognitive dispositions to respond" and are felt to be contributors to the occurrence of adverse events.[14] Examples of such cognitive dispositions to respond include: anchoring (tendency to fixate on features of presentation too early in diagnostic process), confirmation bias (tendency to look for confirming evidence to support a hypothesis) and fundamental attribution error (tendency to blame people when things go wrong rather than circumstances).[14] Dr Croskerry, an emergency physician who has documented these phenomena, also proposes some strategies to reduce adverse events caused in part by these cognitive dispositions to respond. One such solution is a cognitive forcing strategy, which implies awareness of cognitive dispositions to respond and directly addressing them. An example is the physician who diagnoses a fracture on X-ray - instead of stopping there, a cognitive forcing strategy would be to search for the "second fracture" as this is frequently missed. Thus, the clinician can reflect upon her or his role in the system contribution to adverse events by engaging in such 'meta-cognition" to help avoid predictable pitfalls in clinical decision making.

If adverse events are so predictable, it would seem logical that one could design features in the system to account for this. The field of human factors engineering endeavours to achieve this very thing. Human factors engineering aims to design

technology such that it decreases errors, while still being user friendly. For example, a cardiac monitor should be sensitive to abnormal cardiac rhythms and yet still be capable of competing with ambient noise. While these principles have traditionally been applied to technology, they have more recently been applied to entire systems. An example is the attempt to reduce adverse drug events in a hospital.[15] The human factors principles applied included: reduction of reliance on memory, simplification, standardization, reduction of hand-offs, increase in feedback, decrease in multiple entry and reduction in "look-alike" drugs. Human factors engineering has been used to attempt to limit the incidence of adverse events while still allowing for a system that can better contain the damaging effects of adverse events.

Donald Norman, an author of human factors engineering based design models, proposed four main principles behind preventing error utilizing design: 1) understand the causes of error and design to minimize those causes; 2) make it possible to undo actions or make it harder to do what cannot be undone; 3) make it easier to discover and to correct the errors that occur; 4) change the attitude towards error.[16] Dr. Norman posits that the admission and study of mistakes are what permit improvement. These four principles can be used to guide research and intervention planning in patient safety.

In this thesis, we will endeavour to understand the causes of adverse events utilizing a system-based approach. When examining the risk factors for adverse events in the emergency department, we plan on collecting baseline data not only about the

patient involved, but also the level of training of the health care providers, the triage assignment, time of day of registration, the estimated mean waiting time to be assessed by a physician and the number of admitted patients in the emergency department at the time of enrolment. The latter two variables aim to get a sense of the "busy-ness" of the emergency department as a measure of some of the pressures on clinical decision making. If we identify an association between some of the system factors in the emergency department and adverse events, this could lead to system-based interventions. In this way, we are incorporating patient safety theory into the methodology.

2.3.3 Patient Safety Studies

2.3.3.1 Major Studies

In order to create effective interventions to reduce adverse events, one must first be able to measure the rate of such events. Previous studies in the United States,[2;17] Great Britain,[18] Australia,[19] New Zealand[20] and, more recently, in Canada,[21] demonstrated that the incidence of adverse events among hospitalized in-patients is concerning, with estimates ranging from 2.9-16.6%. There are few published studies measuring adverse events in the emergency department and most focus on specific sub-populations. A pilot study to the current thesis was performed by Dr. Alan Forster and found an adverse event proportion of 6.0%.[22] This latter study will be discussed in detail in a later section.

The first landmark study was the Harvard Medical Practices Study which utilized nurses and medical chart analysts to screen a non-random weighted sample of

30,121 charts from 51 New York state acute care hospitals in 1984.[2] The goal was to describe injury cases that were potential malpractice suits. Two physicians independently reviewed all the charts that passed the screening criteria and judged whether they constituted adverse events. Adverse events occurred in 3.7% of hospitalizations with the most common type being adverse drug effects (19.0%) and wound infections (14.0%). The largest number of adverse events resulted from treatment in the operating room (47.7%), while the emergency room was the site of adverse events for 3.0% of the admitted patients. On a secondary analysis of the data, it was found that 69.6% of all adverse events were preventable. The highest proportion of preventable adverse events (93.3%) occurred in the emergency room.

When in 1995, another group of Harvard investigators chose to apply the Harvard Medical Practices Study methodology to Utah and Colorado; they found an adverse event rate of 2.9% of hospitalizations.[17] After reviewing 14,052 randomly selected inpatient charts from 28 hospitals, they concluded that just over half (52.0%) of the identified adverse events were preventable. The majority of adverse events were operative (44.9%) followed by adverse drug effects (19.3%). They also found 3.0% of adverse events occurred in the emergency room. A large proportion (52.6%) of adverse events in the emergency department was considered preventable.

Investigators in Australia also applied similar methods to investigate 31 hospitals in that country.[19] Wilson et al found that 16.6% of the randomly selected sample of 14,179 admissions was judged by twenty-one reviewer physicians to have adverse events. Most were related to surgical procedures (50.3%) and diagnostic error

(13.6%) while adverse drug effects comprised only 10.8% of adverse events. They documented 51.0% of their adverse events as preventable.

Similar studies outside of the United States have also found different rates of adverse events. In New Zealand, investigators used similar methods to the American and Australian studies among the inpatient population and documented an adverse event incidence of 11.2%.[20] In Britain, research using the same methodology found an adverse event incidence of 11.7%.[18] The Canadian Adverse Events Study randomly sampled Canadian hospitals and retrospectively reviewed charts to determine an incidence of 7.5% among hospitalized in-patients.[21] The Ottawa Hospital Patient Safety Study utilized the same methodology to document an adverse event incidence rate of 12.7% among admitted patients.[23] Thus all of the studies conducted outside of the United States documented higher rates of adverse events than that country. The wide adoption of the Harvard Medical Practices Study methodology resulted in a standardized method of adverse event determination.

2.3.3.2 General Methods of Adverse Event Detection

The Harvard Medical Practices study methodology was designed to reduce the subjectivity of adverse event detection.[2] Patients' charts were reviewed for a predefined series of screening criteria that had been found to be associated with an increased likelihood of medical injury. Examples included death, transfer to a special care unit and readmission to hospital. Reviewers were then asked to review all the charts flagged by these screening criteria to determine whether these constituted adverse events. This was a three step process during which reviewers were asked

to determine: 1) whether definable injury was caused at least in part by medical management; 2) if the injury produced measurable disability or prolonged length of stay; 3) whether the injury was unintended. All three conditions had to be satisfied to be considered an adverse event. Judgement of causation was determined using a six point Likert scale:

1. little or no evidence of management causation or negligence
2. slight evidence
3. not quite likely (less than 50:50 odds but a close call)
4. more likely than not (greater than 50:50 odds but a close call)
5. strong evidence
6. virtually certain evidence.

The authors indicated that by using these explicit criteria, the aim was to determine adverse events more objectively.

In order to examine the reasons for the discrepancy in adverse event rates between the U.S. and Australia, both groups of authors jointly published a comparison of the two studies.[24] Both studies used the same Likert scale for adverse event determination as described above. In the Utah and Colorado study, a confidence score of more than or equal to four (more than 50:50 chance of management causation but close call) constituted an adverse event.[17] The Australian study used a confidence threshold of more than one (little or no evidence of management causation or negligence) as per the Harvard Medical Practices study.[19] When comparing the two studies, the authors found that despite accounting for differences in the confidence threshold used to define an adverse event, the number of

physician reviewers (two versus one) and inclusion of different types of adverse events, the proportions of adverse events remained separated by three orders of magnitude (3.2% for Utah & Colorado and 10.6% for Australia). Their explanations for this persistent difference included the possibilities of lower quality of care in Australia or differing reviewer behaviour.

2.3.3.3 Limitations of Adverse Event Determination Methodology

These studies had a number of limitations including the retrospective nature of the data collection. The reliance upon documentation in the medical record can result in under-reporting of adverse events. Despite the standardization of the review process, physician judgement against local standards of care is ultimately applied. Kappa scores assessing the reliability of physician judgements were moderate in all of the studies (from 0.4-0.6). The other limitation of retrospective chart review is that all of the adverse events are identified by health care professionals.[25] By relying on the health care professional perspective, adverse events may be under-reported as there may be concerns regarding punitive repercussions. Furthermore, they may not accurately represent the perspective of the patient. Some have argued that focusing on the outcome does not give a full picture of medical error.[25] The example given is that of the "near-miss", whereby an error is identified and corrected before a patient is harmed. Nonetheless, identifying adverse events provides a focused picture of the most clinically significant outcomes which are likely to be most important both to the patient and the clinician.

Overall, these studies have helped define a method of identifying adverse events in health care. The low proportion of adverse events in the emergency department identified in the Harvard Medical Practice and Utah and Colorado studies may be misleading given that only inpatients were reviewed and this comprises a small segment of the emergency department population.[2;17] What is remarkable; however, are the high rates of preventability among emergency department adverse events compared to those for other groups. This could be due to the unique challenges and complexities of the emergency department environment as described in the above section, "Statement of the Problem". It is clear that more focused study of the emergency department environment is required to get a more complete sense of adverse events in this setting. This thesis aims to achieve such an objective by adapting these methods of adverse event detection to the unique situation of the emergency department.

2.3.4 Patient Safety Studies in Emergency Medicine

Research into adverse events in emergency medicine is in its infancy. Much of the emergency patient safety literature is grounded in a quality assurance approach. Studies have focused on malpractice claims, death audits, return emergency department visits and phone follow-up. A few more recent studies have attempted to document medical errors in the emergency department. There have also been several population specific assessments of patient safety in the emergency department such as trauma deaths,[26-30] missed myocardial infarctions[31-34] and adverse drug effects.[35;36] Only the unpublished pilot study to this thesis has

examined the overall emergency department population in terms of measuring adverse events.[22]

These studies have highlighted that diagnostic issues are a major concern in the emergency department. Voluntary reporting of medical errors has suggested that the actual number of adverse events is low. Standardization of trauma care has decreased the number of deaths but missed myocardial infarctions continue to be an issue for emergency physicians. These studies have been limited by narrow, non-standard definitions of adverse events, the use of implicit judgements and focus on specific sub-populations. The settings of these studies have been primarily the United States or other countries where emergency department care differs in many ways to current Canadian emergency department conditions. The following subsections describe emergency patient safety studies under the themes of quality assurance and specific populations as well as limitations to the methodologies used.

2.3.4.1 Quality Assurance Studies

Studies of malpractice claims

Just as for the general inpatient population, some early emergency patient safety studies have evaluated malpractice claims. In 1993, Karcz and colleagues sought to describe the characteristics of 144 closed malpractice claims against emergency physicians in Massachusetts.[37] This retrospective review found that wounds, fractures and chest pain were the most commonly represented presenting complaints. The authors had one reviewer judge the preventability of the claim and found the rate to be 43%. Missed myocardial infarctions constituted the highest

monetary loss. Another American emergency malpractice study retrospectively reviewed 122 closed malpractice claims involving a missed or delayed diagnosis in the emergency department.[38] The most common themes associated with diagnostic issues were failure to order a test or conduct an appropriate history and physical. This study also found missed fractures, infections and myocardial infarctions as the most common types of cases. The authors utilized a single reviewer who was an internal resident staff person or resident not emergency physician peers. The preventability of the claims was rated as 65%. Review of closed malpractice claims represent a narrow picture of the most severe adverse events and are oriented towards finding negligence in physician care; they do provide, however, a sense of the populations at risk.

Death audits

Another type of study that selects the most severe adverse events is the audit of the deaths of emergency patients. Italian emergency researchers sought to search for clinical errors in their department over a one year period.[39] They created an ad hoc review committee to examine the charts of all patients who died in the emergency department or who were transferred to the intensive care unit within 24 hours of their admission to the emergency department. While the definition of "error" was not described and it is unclear how many cases were uncovered, the authors provided 4 examples of what they felt were preventable deaths due to an error in management. Each was a case of missed or delayed diagnosis that was felt to contribute to the death of that patient. The cases involved aortic dissection, pulmonary embolisms and subarachnoid hemorrhage. There was no indication that the reviewers were

blinded to physician or patient identity which may have influenced judgements of what constituted error. Given the paucity of description of the methods, it is possible selection bias and misclassification bias could have been present in this study.

Lu et al improved on the methodology used by the Italian group when performing a retrospective chart review of deaths in their Taiwanese emergency department.[40] The authors used 2 reviewers to independently categorize the deaths' preventability and further whether they were due to missed diagnosis, delayed diagnosis or inappropriate medical management. They identified 124 cases for review; all patients died in hospital and there was no follow-up of discharged patients. Reviewers considered 26% of the death preventable, the majority secondary to inappropriate medical management. Limitations included selection bias as only inpatient deaths were considered; therefore, one could potentially miss patients who subsequently died in the community or other at other institutions.

Other North American studies have also examined patients who died in the emergency department but specifically looking at diagnostic accuracy by comparing the final emergency department diagnosis with autopsy results.[41] Major diagnostic disagreement has been documented in 4-15% of cases. Furthermore, improvements in diagnostic technologies do not seem to have impacted on diagnostic accuracy among deceased patients.[41]

Studies of return emergency department visits

While malpractice and deaths are clearly of concern to emergency medicine researchers, another population of interest is those patients who return to the emergency department for the same complaint. Investigators in Memphis, Tennessee retrospectively reviewed the charts of all patients who returned to the emergency department within 48 hours over a 3 month period.[42] The cases were independently reviewed by three emergency physicians un-blinded to patient and treating physician identity. Three percent of patients (569/17,214) with return visits were identified. Reviewers categorized these visits as patient-related returns (e.g. left without being seen on first visit), physician-related returns (e.g. missed diagnosis), health care system related returns (e.g. referred by private physician's office) and illness-related returns (e.g. progression of disease). More than half of the return visits (53%) were found to be patient-related, 25% disease-related, 18% physician-related and 4% system-related. As with the previous emergency studies described, there were issues with selection bias since patients could have returned to other institutions or developed complications and chosen not to return. Furthermore, there was no assessment of the preventability of these return emergency department visits.

British investigators took a prospective approach to assessing the return emergency department visit population.[43] They administered a questionnaire to 235 patients who had unscheduled return visits within a one month period (235/8036 total visits, 2.9%). Almost two-thirds of the patients (62%) returned for persistent symptoms and 13% for a complication of treatment. A minority (9%) had conditions missed on

the first visit with fractures figuring most prominently. The authors indicated that care was inappropriate on the first visit in 8% of cases although their method for determining this was not described. Half of the patients did not require further hospital treatment and the authors felt these patients could have been treated by general practitioners. The low acuity and severity of the cases described in this study bring the generalizability of this work into question. A study using the same methods in a smaller British Accident and Emergency Department found that of 113 unscheduled return emergency department visits (113/5811 total visits, 1.9%), the most common reason was due to inadequate communication.[44] They also found 6 patients who required admission on the second visit, 2 cases due to missed myocardial infarction and one due to delay in diagnosing testicular torsion. The authors indicated that 80% of cases were due to a deficiency in care provided at the initial visit though their methods for determining this were not described. While these studies used a prospective methodology and patient-oriented perspective, the methods for identifying adverse events and preventability were ill-defined.

Telephone follow-up studies

All of the emergency patient safety studies described thus far refer to the population of emergency department patients either admitted to hospital or re-presenting to the same institution. The majority of patients seen in the emergency department are discharged home and little is known about this population. Two studies have attempted to evaluate this group of patients using telephone follow-up protocols. In 1986, investigators in Akron, Ohio implemented such a system by having an emergency physician conduct a daily review of patient charts seen in the previous

24 hours.[45] Those patients meeting inclusion criteria such as undiagnosed chest pain or abdominal pain, infections requiring antibiotics, syncope, head trauma and unscheduled return emergency department visits were flagged. These physicians selected 281 (39%) of these 723 cases for phone follow-up with a success contact rate of 81%. They found that the majority (77%) of patients felt their condition had improved, 20% were unchanged and seven patients felt worse. Of the latter group, six patients required direct medical intervention and two were admitted to hospital. While the study suffered from selection bias since they did not describe the criteria used to select patients for follow-up, some negative outcomes were identified. Whether these outcomes were associated with health care management or were preventable was unclear as this was not measured. The total number of cases from which the follow-ups were selected was not reported; for these reasons we cannot conclude what proportion constituted adverse events.

A more recent phone follow-up study from Taiwan had explicit patient safety objectives whereby the authors sought to determine the impact of a quality improvement program on adverse events.[46] The intervention in this before and after study was the provision of direct feedback to physicians on their patients' outcomes. Patients were selected for phone follow-up if they had "high risk conditions" such as stroke, undiagnosed chest pain, asthma, gastrointestinal bleeding, infections or intoxications. The authors also screened the charts of all patients returning to the emergency department within three days of first presentation. Clinically significant adverse events were defined as those patients who returned to the emergency

department and found to have either a missed diagnosis or an erroneous management plan. The authors had an 81% success rate in phone follow-up.

The Taiwanese authors enrolled 566 high risk patients of 4,139 discharged patients (14%) in the before group and 397 of 3,507 (11%) in the after group. When comparing the before and after periods, they found a statistically significant decrease in the return emergency department rate from 10% (57/566) to 5% (19/397) with an associated reduction in clinically significant adverse events of 4.1% (23/566) to 1.5% (6/397). The most common types of adverse events were related to the complaints of abdominal pain, infections and cardiovascular disease. A majority (74%) of patients with clinically significant adverse events were attributed to missed diagnoses. This study had a very narrow definition of adverse events as it was confined to those patients who returned to the emergency department with specific diagnostic or management issues. Those patients who may have died in the community, did not re-present for their symptoms or had other potential causes for return were not described. The high risk criteria could also lead to selection bias as these criteria had not been previously validated. Nonetheless, this is one of the few studies of the discharged emergency department population and demonstrated a significant impact of a feedback system to emergency physicians.

Voluntary medical error reporting

While previous patient safety emergency medicine studies have utilized retrospective chart review, questionnaires and phone follow-up to assess for adverse events, others have adopted a prospective approach to document medical

errors as they occur. In the United States, Fordyce et al approached all emergency department staff every 3-4 hours during all shifts over a one week period to actively solicit medical error reports.[47] These written reports were requested for all suspected medical errors irrespective of whether an adverse event had occurred. The observation period was preceded by an educational intervention that reviewed definitions of medical error and emphasized the lack of liability in reporting. The authors found a medical error rate of 18% (346/1935 visits) with an adverse event rate of 0.4%. Most errors were noted to carry a low risk of adverse event and involved issues surrounding documentation and labelling of medications. Patients with errors were noted to be older than the general emergency department population. Limitations of this study included the use of a voluntary reporting system which may have been subject to a reluctance of health care providers to report errors. The study was conducted over a brief period of time at a single center and did not assess the outcomes of patients after discharge or admission to hospital. This may have been why the adverse event rate was so low as errors may not have all been detected as they occurred.

The same group of investigators repeated the study over a one month period one year later but without the active solicitation component.[48] Medical error reporting forms were made available to emergency department personnel who were encouraged to fill them out at the time they noted an error, near-miss or adverse event. This time they documented a lower error rate of 2% (203 errors/9308 patients) and found a preponderance of older female patients were involved. One third of the errors were medication-related and another third involved

miscommunication. Staff were asked to determine the preventability of the error and felt this was the case 75% of the time. Near-misses accounted for 47% of errors and 15% of errors resulted in adverse events. The adverse events were not explicitly defined in the article and included repeat blood draws and repeat x-rays. Limitations were similar to the previous study in terms of selection bias and the voluntary nature of the reporting. The categorization of errors was performed by the reporting health care providers rather than trained reviewers.

Investigators in a rural Australian hospital implemented a multi-pronged approach to addressing medical error and sought to determine the impact on adverse events.[49] They created a clinical risk management model that included inpatient and emergency department record review, incident reporting, coroner reports, media reports and patient complaints. Any identified medical errors or adverse events were assessed for a contributing "risk" which was prioritized and relevant system changes implemented if feasible. They then evaluated the impact of these system changes using the same methods for identifying errors and adverse events over a seven year period. All emergency department charts were screened for deaths, unplanned return emergency department visits, length of stay more than six hours and the transfer to an acute care facility. These flagged charts were evaluated by a clinical risk manager (unclear if this was a physician) for an adverse event which they defined as "an untoward patient event, where under optimal conditions, is not a consequent of a patients' disease or treatment". They found an overall adverse event rate of 1.2% (250/20,050) in the emergency department. Quarterly measurements of adverse event rates over the time that the risk management model

was being implemented showed a reduction in adverse events from 3.3% of all emergency visits to 0.5%.

The Australian authors indicated that their study supported a system-based approach to event analysis with a demonstrable impact on adverse events. The advantage to this study is the use of multiple methods of adverse event detection for the hospital as a whole, although only retrospective chart review was specified as being used for the emergency department. The flagging criteria were limited to deaths, return visits, transfers or prolonged length of stay. Those patients re-presenting to other institutions, or having complications in the community and not re-presenting at all, were not measured. In addition, the use of a single reviewer for adverse event determination potentially increases the subjectivity and decreases the accuracy of these measurements.

2.3.4.2 Specific Population Studies

The previously described emergency patient safety studies all adopted a quality assurance approach. Other investigations in this field have studied specific patient subpopulations such as trauma, missed myocardial infarctions and those suffering adverse drug effects.

Trauma studies

With the advent of Advanced Trauma Life Support standardization of care, some authors have published data demonstrating a reduction in preventable deaths in their systems.[26-30] Yates et al described a trauma audit system to track the impact

of implementing Advanced Trauma Life Support training and creating trauma teams at a British accident and emergency department in 1994.[26] They documented a yearly reduction in mortality rates as a result. American investigators utilized a retrospective chart review of a random sample of trauma deaths to determine that regionalization of trauma to a tertiary care center reduced the number of preventable deaths by 19%.[50] These studies suggest that the implementation of standardized care resulted in enhanced patient safety among the trauma population.

Missed myocardial infarction studies

Another population at risk of diagnostic error is the chest pain population. Some emergency researchers have focused on the patients discharged home with missed myocardial infarctions. Most recently, Canadian investigators looked at a specific population of patients who presented with chest discomfort. Christenson et al conducted a prospective cohort study of this patient group and determined that 5.3% had acute coronary syndrome and were discharged from the emergency department.[33] One patient died. These investigators used pre-defined electrocardiogram, serology, stress test and angiography criteria to define their outcome. The study was limited by the fact that patients with symptoms other than chest discomfort (for example, shortness of breath) were excluded. In addition, not all discharged patients had a diagnostic work-up; thus, some patients with acute coronary syndrome may not have been diagnosed. The study described a small but important segment of the emergency department population.

Other investigators have suggested a profile of the patient who tends to be discharged with missed myocardial infarction.[31] Pope et al describe women younger than 55 who are non-white, presenting with shortness of breath as the chief complaint as a high risk population for misdiagnosis. In this American series of 10,000 emergency department patients, the rate of missed myocardial infarction was 2.0%. Similarly, McCarthy and colleagues performed a multi-center case-control study of United States coronary care unit patients admitted via the emergency department.[34] They compared those patients discharged with chest pain to those admitted and found a missed myocardial infarction rate of 1.9%. Twenty-five percent of these patients had ST segment changes on their electrocardiograms that were not diagnosed by the emergency physician and hence felt to be preventable adverse events.

Adverse drug event studies

While chest pain is a common emergency department presenting complaint, another increasing segment of the population are the elderly. More and more patients are presenting with a multitude of comorbidities and medications. This has caused increased concern regarding adverse drug events. Hohl et al conducted a prospective observational study in Vancouver to determine the accuracy of emergency physicians in identifying adverse drug events amongst elderly patients.[35] They found an incidence of 16.2% adverse drug events among 161 patients. Of these, the treating emergency physician recognized over half (51.2%). In particular, physicians were apt to recognize adverse drug events related to the presenting complaint or that were severe in nature.

A recent study described the results of active surveillance of emergency department visits for outpatient adverse drug events through a national database.[36] All initial emergency department visits among 63 American hospitals were screened for injuries, poisonings and adverse drug events. Adverse drug events were defined as "an incident emergency department visit for a condition that the treating physician explicitly attributed to the use of a drug or a drug-specific effect". This included allergic reactions, adverse effects and secondary effects (for example falls, choking). Adverse drug events represented 0.6% of all emergency department visits. The most common drug types involved were insulins, opioid analgesics, anticoagulants, amoxicillin-containing agents and antihistamines. This study did not examine the preventability or severity of these events.

2.3.4.3 Limitations of Patient Safety Studies in Emergency Medicine

The patient safety studies in emergency medicine share many limitations. The emergency department patient population is difficult to study since a large proportion is discharged home and it is often unknown what happens to them once they leave the hospital. Thus, it is easier to study the most severe events such as death or malpractice or those patients who return to the same institution. The risk is selection bias and missing adverse events which could be just as severe but occur in the community or at another institution. Likewise, retrospective chart review allows one to attempt to uncover errors once the outcome is known. This is subject to hindsight bias, the tendency to simplify situations examined after knowing the outcomes.[16] As a result, there may be an inclination to overcall errors.

The determination of adverse events is ultimately one of clinical judgement. The Harvard Medical Practices study methodology attempts to reduce some of the subjectivity of this judgement through a structured approach.[2] Unfortunately, none of the emergency medicine patient safety studies utilized this approach as many did not clearly define adverse events and used single reviewers to make determinations in an unstructured fashion. While documenting the rate of adverse events is important, ultimately the preventability of these events is paramount when one comes to planning interventions. Few studies addressed this element and did not describe a systematic approach.

Much of the patient safety research in emergency medicine has focused on specific populations. We do not know the actual overall rate of adverse events in the emergency department for the entire population seen. Current estimates are based on retrospective review of admitted patients only which comprise approximately 11% of the total population seen in the emergency department. Most studies have also been conducted in the United States or countries other than Canada. There are many differences in the staffing, organization and triage of emergency departments internationally and this may significantly limit the generalizability to the Canadian setting. This thesis will study both the admitted and discharged patients in two Canadian emergency departments in order to determine the proportion of patients with adverse events using a structured and system-based approach.

2.3.5 Pilot Study

To date, there has been one prospective pilot study that has focused on measuring the incidence of adverse events for patients discharged from the emergency department.[22] This prospective cohort study conducted at The Ottawa Hospital by Forster et al. enrolled a convenience sample of emergency department patients during day shifts over a ten week period. Patients were then administered a structured telephone interview two weeks post-discharge. Patients were asked about their overall state of health, and whether they had visited a physician's office, emergency department or were admitted to hospital. If a patient presented to another institution, data was collected based upon the patient's description and the charts were not obtained. Those patients who died, were readmitted to hospital, returned to an emergency department or suffered new or worsening symptoms were evaluated for adverse events. Two physicians, an internist and an emergency physician, reviewed the cases using a modification of the Harvard Medical Practices Study approach.[2] The reviewers had to have a confidence level of at least three on the six point Likert scale (evidence of causation is 50-50 but more unlikely) to be considered an adverse event. Preventability and the causative error were assessed.

The investigators documented an adverse event incidence of 6% (24 adverse events) of which 71% were judged as preventable. There was one death, 4% admitted to hospital, 5% return emergency visits and 5% developed new symptoms. The most common errors identified were management, diagnostic, or inadequate follow-up. They did not find any statistically significant associations between preventable adverse events and demographics. Although this study attempted to

include the whole population of discharged emergency patients, the fact that it was a non-consecutive convenience sample introduces the potential for selection bias. Hindsight bias may have also played a role in the adverse event determinations although the more structured Harvard Medical Practices methodology was used to reduce subjectivity.[2] In addition, patient outcomes were evaluated by an internist and an emergency physician who were not blinded to the treating physician or patient identities.

This thesis improved on the methodology of the previous pilot by including both admitted and discharged patients from the high acuity areas of more than one emergency department. Consecutive patients were enrolled during randomly selected shifts to represent the 24 hour, 7 day-a-week service provided in the emergency department. Thus, we accounted for the highest volume times by including patients registering in the evening and night rather than just during the day. The structured telephone interview was modified and improved upon, and three emergency physicians reviewed all flagged outcomes. These reviewers were blinded to patient and treating physician identity and were trained in a standardized fashion to use a modified Harvard Medical Practices Study method for adverse event determination.[2] In implementing these methodological changes, a more comprehensive and potentially more accurate emergency department adverse event study resulted.

2.4 Rationale

Patient safety research has highlighted that our health care systems need to be improved to reduce preventable adverse events. If we can strengthen the systems to reduce these outcomes we will lower the number of preventable deaths and medical complications as well as potentially increase health care provider morale and patient satisfaction. In fact a recent survey found a strong link between the number of patient safety concerns a consumer had and their level of satisfaction with health care received.[51]

Emergency departments are an important area of focus for patient safety research because of the high risk features of this practice environment.[52] Emergency physicians are dealing with increasingly complex patients in need of rapid, detailed evaluation with high expectations for extensive diagnostic work-up.[6] As the population ages, emergency department overcrowding increases and waiting times become more prolonged, the potential for adverse events becomes an increasing concern.[6;16] As a result of these unique features, ensuring patient safety in the emergency department may require different processes than in the rest of the hospital.[16] In order to determine how to proceed, we need a more comprehensive picture of emergency adverse events as well as a capability to measure these events before implementing interventions.[15;53;54] An understanding of the risk factors for adverse events is required to prevent future emergency adverse events.[54] Thus far, patient safety research has focused on inpatients and those few studies conducted in the emergency department have focused on specific populations with little comparability to modern Canadian emergency medicine practice. Though

these studies had many limitations, they do suggest that emergency department care has a small but important risk of preventable adverse events. Given the high volume of patients seen in emergency departments this could translate to a large number of potentially affected patients.

Several editorials in leading emergency medicine journals have called for increase research into emergency adverse events in a systematic way.[6;54-56] There have also been comments in the emergency medicine literature that researchers should focus on "reducing adverse events by enhancing human performance in the emergency department" rather than concentrating on error.[57] The language of error has been criticized as promoting blame rather than system improvement.[16] This thesis endeavours to improve on previous adverse event determination methodology and use the language of patient safety and adverse events rather than error. We will also be utilizing emergency physicians peer reviewers as advocated by the literature.[6] Through the employment of a structured, system-based approach, we will obtain an overall sense of adverse events among high acuity emergency department patients.

This thesis will confirm risk estimates, address previous methodological concerns and improve knowledge regarding system influences on patient safety. By identifying the proportion of patients with adverse events, their preventability and risk factors, we can begin to plan interventions and measure their effectiveness. There is room for improvement in the emergency department as to date, most departments have little automation, little task standardization, few forced functions and

questionable team coordination.[6] This thesis will establish the groundwork for planning future interventions such as the electronic medical record, computerized order entry, practice guidelines and teamwork simulations. In doing so, there is the potential to have a significant impact on mortality and morbidity, system efficiencies, health care provider performance and patient satisfaction.

3.0 OBJECTIVES

3.1 Overall Goal

The overall goal is to develop a better understanding of the proportion of patients with adverse events among those triaged to high acuity areas of the emergency department. Furthermore, the goal is to determine risk factors for adverse events in order to contribute to the planning of future preventative strategies.

3.2 Specific Objectives

The specific objectives are to:

1. Describe the population of patients triaged to high acuity areas of the emergency department who may be at risk for adverse events.
2. Determine the proportion of patients with adverse events among those triaged to high acuity areas of the emergency department.
3. Determine the proportion of these adverse events that are preventable.
4. Describe and categorize the types of adverse events.
5. Assess the association between patient characteristics and adverse events.
6. Assess the association between system characteristics and adverse events.
7. Evaluate the relationship between multiple patient and system characteristics and adverse events.
8. Determine the proportion of adverse events among specific patient subgroups.

4.0 METHODS

4.1 Study Overview

In order to determine the proportion of patients with adverse events in the high acuity areas of the emergency department, we first enrolled all consecutive patients presenting to these during randomly selected enrolment shifts. We conducted telephone interviews of those patients discharged from the emergency department and chart reviews of those patients admitted. We then constructed case summaries for pre-defined flagged outcomes. These summaries were reviewed by three experienced emergency physicians who determined whether the flagged outcomes were associated with health care management and if so, whether these adverse events were preventable or not.

4.2 Study Design

The study design was a dual-center prospective analytic cohort study conducted at two large emergency departments in Ottawa representing approximately 112,000 patient visits per year. The unit of analysis was the emergency department patient triaged to the high acuity areas of the department.

4.3 Target Population

The target population was that population to which the study findings could be generalized.[58] In this study, the target population included all eligible patients who were discharged home or admitted from the high acuity areas of the emergency department.

4.4 Study Population

The study population, defined a priori, was the subset of the population with the condition of interest as defined by the eligibility criteria.[59] In this case, the study population consisted of patients registered to the resuscitation or observation areas of the two emergency departments of The Ottawa Hospital (Civic and General Campuses) who subsequently suffered an adverse event. The resuscitation and observation areas represented those patients of highest acuity. Acuity was measured by the Canadian Triage Acuity Score (CTAS), a validated tool to determine the urgency by which the patient should be seen.[60] A score from the 5 point scale is assigned by the triage nurse at the time of registration such that 1="resuscitation", 2="emergent", 3="urgent", 4="less urgent", 5= "non-urgent". High acuity patients were those with a score of 1-3 who most often arrived by ambulance or were non-ambulatory, requiring assessment on stretchers.

In the pilot study, patients located in the high acuity areas of the emergency department were at higher risk for adverse events than those located in the ambulatory areas.[22] Thus, we chose to study this higher risk population. Also, due to department layout it was more feasible for consecutive patient recruitment to focus on the high acuity areas. At the General campus, some higher acuity patients were physically located in another area of the department if there was overflow. As a result, we planned a priori to broaden our recruitment to intermittently search for those patients requiring stretchers who were located in the area called "corridor".

4.5 Sampling Method

It was not feasible, without considerable resources, to conduct this study 24 hours a day, 7 days a week. We felt it important, however, to include patients from different times during the day and week when staffing levels vary. In order to accomplish this, we used a stratified random sampling scheme. We obtained independent random samples from the following time strata: day shifts (0800-1600h), evening shifts (1600-0000h), modified night shifts (1800-0200h or 0700-1500h) and weekends. Peak volumes of patient registration occurred during the evening shift; therefore, we sampled this stratum more heavily. We modified the night shift due to the low volume of patients who are discharged or admitted between 0200-0700h. Due to feasibility issues, we sampled night and weekend shifts less heavily. The ratio of days:evenings:nights:weekends was 2:6:1:1. We randomly assigned the campus location.

4.6 Enrolment of Subjects

We considered all consecutive patients registered in the resuscitation and observation areas of the emergency departments during the sampling time frame to be eligible for the study.

4.6.1 Inclusion Criteria

We included the following patients:

- older than age 18,
- capable of providing informed consent – or had an available substitute decision maker capable of providing informed consent, and

- patient was treated in the resuscitation or observation areas of the emergency department.

4.6.2 Exclusion Criteria

We excluded patients if they met any of the following criteria:

- cognitive impairment due to an organic brain process or major psychiatric illness and no available substitute decision maker,
- critically ill or in too much distress to be capable of informed consent,
- unable to complete a telephone interview in English or French (or their substitute decision maker was unable), or
- discharged home and did not have a telephone or who were otherwise unavailable for follow-up two weeks later (as determined at enrolment)

4.7 Recruitment Strategies

At the beginning of an enrolment shift, a research nurse obtained permission from the attending emergency physician to approach each consecutive patient registered to the resuscitation or observation areas of the emergency department who was alert and capable of providing informed consent (see Figure 1 for patient flow). At the General campus, the research nurse routinely screened patients for eligibility in the section called "corridor" at the time of the study to account for overflow of higher acuity patients. She explained the study objectives and follow-up procedures to each patient as well as the benefits of the study in terms of knowledge gain. As outlined further in the Ethics section below, the nurse indicated there were no

physical risks to the patient, only a potential inconvenience of a 5-10 minute follow-up phone call. She explicitly stated that participation in the study would not impact on clinical care and that withdrawal from the study could occur at any time. She also emphasized the preservation of confidentiality. She collected baseline data on all patients (or their substitute decision makers) who consented in writing (see Appendix B for consent form) to participate in the study. She asked each patient to provide two telephone numbers (their preferred number and a 'back-up' number) and three times of day when they preferred to be called.

4.8 Outcome Measures

4.8.1 Primary Outcome

We explicitly defined the outcomes a priori in consultation with the thesis committee and other emergency medicine experts. These are defined in Figure 3 and the hierarchy applied to these definitions is presented in Figure 4. The proportion of patients with **adverse events** among those discharged or admitted from the high acuity areas of the emergency department was the primary outcome of interest. In order to arrive at this final outcome, we conducted a telephone interview or chart review and physician reviewers evaluated any flagged outcomes.

We defined **flagged outcomes** depending on patient disposition. For those patients discharged home, flagged outcomes included:

- new or worsening symptoms
- unscheduled return emergency department visit

- unscheduled admission to hospital
- death

We excluded any flagged outcomes that were scheduled emergency department visits or hospital admissions. For those patients admitted to hospital, we used the flagged outcome criteria based on the Harvard Medical Practices Study.[2] These included:

- unplanned transfer from another acute care hospital
- unplanned transfer to the acute monitoring area, neuro-observation unit or intensive care unit
- unplanned transfer/return to the operating room
- organ damage/removal during surgery
- hospital complications
- development of new neurological deficits during admission
- hospital-acquired infection
- hospital incurred accident or injury
- adverse drug reaction
- dissatisfaction with care
- litigation
- unplanned re-admission to hospital
- death

Three emergency physician reviewers independently judged the association with provided care by analysing the case summary (further described below). **Adverse events** were classified as those flagged outcomes deemed to be associated with health care management by the reviewers (see definitions, Figure 3).

In addition, the reviewers categorized adverse events as preventable and non-preventable. For the purpose of this study, we defined **preventable adverse events** as adverse events caused by a health care management problem such as a diagnostic issue, management issue, unsafe disposition decision or suboptimal follow-up. Preventable adverse events also included medication adverse effects and procedural complications. The hierarchy of the definitions used in the outcome measures is represented in a flow diagram in Figure 4.

Adverse event: a flagged outcome associated with health care management

Preventable adverse event: an adverse event caused by a health care management problem such as a diagnostic issue, management issue, unsafe disposition decision or suboptimal follow-up

Diagnostic issue: not acting on documented signs, symptoms, laboratory tests or imaging or not ordering an indicated diagnostic test

Management issue: suboptimal management plan despite accurate diagnosis or based on an inaccurate diagnosis

Unsafe disposition decision: patient placed at unnecessary risk of experiencing death or major disability by being sent home

Suboptimal follow-up: problems with follow-up arrangements led to the development of new symptoms, unnecessary prolongation of symptoms, an unscheduled return visit to the emergency department or a subsequent unscheduled hospitalization. (this could be due to inadequate availability of follow-up appointment, or due to inappropriate follow-up arrangements)

Medication adverse effect: patient experiences a symptom related to a medication regardless of whether the medication was appropriately prescribed or taken

Procedural complication: patient experiences adverse consequences of a procedure

4.8.2 Secondary Outcomes

Secondary outcomes of interest included the classification of the **causes of the preventable adverse events** as: diagnostic issues, management issues, unsafe disposition decision, suboptimal follow-up, medication adverse effects, procedural complications, infection or fall. The reviewers categorized the **severity of the outcomes** as symptoms only, laboratory abnormality, requiring medical or surgical

intervention, visit to the emergency department, admission to hospital, visit to health professional's office, transfer to critical care or death.

4.9 Data Collection

Baseline data were collected and entered into a handheld device (Palm Personal Digital Assistant using Pendragon software) while the patient was present in the emergency department (see Appendix C for baseline data collection form). Baseline variables included:

- age and sex
- campus site and location in emergency department
- presenting complaint and Canadian Triage Acuity Scale score
- comorbidities (past medical history of any chronic illness)
- medications (recorded as a categorical variable such that any patient on at least one medication scored positively for this variable)
- number of emergency physicians involved in patient care
- level of training of primary assessor
- discharge diagnosis
- time of registration and discharge
- estimated waiting time when patient was registered (as determined by asking the care facilitator registered nurse in the emergency department)
- number of admitted patients in department at time of discharge (also determined by asking the care facilitator registered nurse in the emergency department)

We collected outcome data via telephone interviews or chart review.

4.9.1 Telephone Interview

A trained research nurse conducted the structured telephone interview (see Appendix D) by 10-14 days after discharge. If the patient could not be reached at that time, she conducted the interview as soon as contact was made with the patient. She asked patients whether they had returned to an emergency department, been admitted to hospital or visited a health professional. She recorded the timing of these flagged outcomes with respect to the index emergency department visit. She asked whether the initial problem had resolved and whether there were any new or worsening symptoms. She then asked how much these symptoms affected physical functioning and what was done to resolve them. For each patient who identified that their problem had not resolved or that they felt worse, the study nurse confirmed the contact information and indicated she would call back with recommendations from the study physician (LC). The study physician was consulted in each case and she recommended either a return to the emergency department or follow up with their primary care provider as appropriate. We modified the data collection sheet and structured telephone interviews which were both previously piloted.

4.9.2 Chart Review

A trained medical student conducted the chart review by using a structured data collection sheet adapted from the Harvard Medical Practices study to screen inpatient charts for flagged outcomes as outlined above.[2]

4.9.3 Database

In order to facilitate data cleaning and analysis, we created a Microsoft Access database to allow entry of baseline data, telephone follow-up data and chart review data. The database permitted linking of these data tables and the creation of data entry forms. We entered the baseline emergency department visit data via a handheld personal digital assistant and subsequently transferred this to the database. We photocopied each emergency record of treatment. We abstracted data from return emergency visits or admission records and entered these into the database.

4.9.4 Follow-up

We endeavoured to obtain all records of return emergency department visits or admissions when this occurred at centers other than The Ottawa Hospital. In some cases, this required separate ethics approval from the relevant institution. In the event a patient could not be reached for follow-up, we searched the records of The Ottawa Hospital to determine whether that patient may have been admitted to hospital or died.

4.9.5 Case summaries

The medical student and primary author created narrative case summaries for each identified flagged outcome. The case summary began with baseline characteristics including age, presenting complaint, Canadian Triage Acuity Scale score and location in the emergency department. The case summaries excluded the name and gender of the patient as well as the identity of the treating physicians. We

summarized the history of presenting illness, findings on physical examination, laboratory results and treatments administered. We then described the timing, course and response to the outcome. Where documentation was lacking, this was mentioned in the case summary as not documented. The reviewer could review any electrocardiograms and the index emergency department visit record of treatment if desired. The patient's name and treating physician identity were masked on the electrocardiograms and medical record. We subjected every flagged outcome case summary to a formal outcome assessment.

4.10 Outcome Assessment

The outcome assessors consisted of three emergency physicians each with at least 5 years of clinical experience and a total of 25 years experience combined. Two of the physicians were Fellows of the Royal College of Physicians and Surgeons of Canada and one was trained in emergency medicine through the College of Family Physicians of Canada. All were attending emergency physicians at both campuses of The Ottawa Hospital. These emergency physicians independently reviewed each case summary for the flagged outcomes. They completed a structured, previously piloted and subsequently modified outcome assessment form created on Microsoft Access (Appendix E). Each reviewer underwent a training session whereby we reviewed standardized definitions and practiced examples to aid in standardizing interpretations (further described below).

We broke down each flagged outcome assessment into components to guide the reviewer through a structured process when arriving at the conclusion that the outcome was an adverse event. This determination was performed in eight steps.

1. We asked the reviewers to confirm that they felt that this case summary was indeed a flagged outcome (they were asked to check a box from a list - see Appendix E).

2. We asked the reviewer to consider the timing of the flagged outcome relative to health care management. Reviewers indicated whether they felt the timing of the event suggested a relationship between the flagged outcome and the health care management (as likely, possibly and unlikely).

3. The reviewer rated the probability that there was another reasonable competing explanation for this flagged outcome (high, moderate, low)

4. We asked the reviewer to consider whether there was an opportunity to prevent the flagged outcome (yes, possibly, no)

5. The reviewer judged whether there was an opportunity to reduce the severity of the flagged outcome (yes, possibly, no)

6. We asked the reviewer whether there was recognition that this kind of flagged outcome could result from the treatment received (widely recognized, not recognized)

7. The reviewer indicated whether the outcome responded to a change in management (convincing response, suggestive response, no response, unable to determine)

The goal of these initial steps was to have the reviewer consider each component for the flagged outcome and finally be ready to make a judgement on whether the adverse event was associated with health care management.

The final step of the adverse event determination was based on that utilized by previous landmark adverse event studies such as the Harvard Medical Practices study, and the Quality in Australian Health Care study.[2;19] These studies utilized a validated 6 point Likert scale to determine the confidence of the reviewer in health care management causation of the outcome. All the scales previously used had the following components:

1. no evidence for management causation
2. slight evidence for management causation
3. management causation not likely, less than 50-50 but close call
4. management causation more likely than not, more than 50-50 but close call
5. strong evidence for management causation
6. certain evidence for management causation

Since this scale has been accepted in the patient safety literature as the gold standard method of determining the presence of an adverse event, this was the method we utilized. If two out of three reviewers had a level of certainty greater than 4/6 (i.e. 5/6 or 6/6), we classified the flagged outcome as an adverse event. In order to evaluate the sensitivity of these judgements, the author and a thesis supervisor (AF) independently reviewed these adverse events. Final determination of an adverse event was based on agreement between four out of five reviewers.

For all identified adverse events, the reviewers further determined the severity of the adverse event and whether it was preventable based on their clinical judgement. They then classified the preventable adverse events as diagnostic issues, management issues, medication adverse effect, procedural complication or other (see Figure 3 for definitions).

4.11 Blinding

We blinded the reviewers to the treating emergency physician, patient name and gender. The cases were summarized in detail so as to reduce the need to look at the actual record of treatment (ROT) and risk handwriting recognition. We explicitly asked reviewers at the end of each outcome assessment whether they had reviewed the record of treatment and if they knew the identity of the treating physician. In the secondary review by the author and thesis supervisor, patient identity, gender and treating physician identity remained masked.

4.12 Quality Assurance

We performed periodic checks on the accuracy of baseline data collection. Key variables such as hospital unique identifier were double-entered. The author regularly reviewed case summaries and outcomes assigned to ensure definitions were being met. All attempts were made to complete any missing variables. Data cleaning of the database was undertaken in multiple phases prior to analysis by looking for duplicates and verifying some basic logic rules as well as reviewing frequency distribution and summary statistics using the proc freq procedure in SAS.

4.12.1 Training

We trained the **research nurse** on using the data collection form and in the principles of informed consent. We also provided training on performing structured telephone interviews with emphasis placed on impartial question posing without using leading vocabulary or unstructured prompting. This approach was adapted from the Dillman survey methodology.[61]

We trained the **medical student chart reviewer** on the definitions of the flagged outcomes and data abstraction using sample charts and scenarios.

We trained the **emergency physician outcome assessors** using cases from the pilot study. We provided a package which included an abstract summary of the project, operational definitions, patient flow diagrams and explicit guidelines (see Figure 5 for reviewer guidelines).

4.13 Sample Size Calculation

The primary outcome was the occurrence of an adverse event. The pilot study conducted at the Civic campus of The Ottawa Hospital documented an adverse event proportion of 6%.[22] The Ottawa Hospital Civic site had 45,595 patients seen and discharged from April 2003 to March 2004. The Ottawa Hospital General site had 45,503. The sample size calculation was based on the Civic site and assuming that 40% of the patients seen and discharged were assessed in the resuscitation/observation area. This would result in 18,238 patients. The sample size for each stratum was calculated taking into account the differential cost for

collecting data for each time stratum and assuming variance was fixed for each stratum.

The strata were:

- Days (D) 0800-1600h
- Evenings (E) 1600-0000h
- Modified night (N) shifts (1800-0200h or 0700-1500h)
- Weekends (W) Saturday and Sunday

An independent random sample was drawn for each stratum in order to maintain the following proportion: D:E:N:W = 2:6:1:1. The sample size calculations were performed utilizing the formula for stratified random samples to estimate proportions described by Scheaffer et al (Appendix A for full sample size calculation).[62]

The calculated sample sizes for each time stratum (for both sites) were:

1. days (0800-1600h) – 131
2. evenings (1600-0000h) – 322
3. nights (0000-0800h) – 49
4. weekends – 49

Therefore the expected sample size for one site was 551, and for two sites was 1102.

4.14 Statistical Analyses

4.14.1 Analysis for Objective 1 (Description of Population)

We used descriptive statistics to characterize the population of patients enrolled in the study from high acuity areas of the emergency department. This analysis was taken from the baseline characteristic data gathering.

4.14.2 Analysis for Objective 2 (Proportion of Patients with Adverse Events)

We calculated the proportion of patients with adverse events as the number of patients with adverse events divided by the number of patients enrolled. We calculated both the point and 95% confidence interval estimates for this proportion.

4.14.3 Analysis for Objective 3 (Proportion of Preventable Adverse Events)

We calculated the proportion of preventable adverse events by dividing the number of preventable adverse events by the overall number of adverse events. We calculated both the point and 95% confidence interval estimates for this proportion.

4.14.4 Analysis for Objective 4 (Types of Adverse Events)

We presented the types and severity of adverse events using frequency distributions as well as numerical descriptive statistics.

4.14.5 Analysis for Objective 5 (Associations with Patient Characteristics)

We examined the association between patient characteristics and adverse events using the chi square test. We reported associations with a p value less than 0.05 as statistically significant.

4.14.6 Analysis for Objective 6 (Associations with System Characteristics)

We examined the association between patient characteristics and adverse events using the chi square test. We reported associations with a p value less than 0.05 as statistically significant.

4.14.7 Analysis for Objective 7 (Relationship to Multiple Patient and System Characteristics)

We created a multiple logistic regression model to examine the influence of the following baseline variables on the primary outcome: age, sex, Canadian Triage and Acuity Scale (CTAS) level, time stratum, location in the emergency department, presenting complaint, discharge diagnosis, seen by medical student, resident or staff, number emergency physicians involved in care, more than one medication, more than one co-morbidity, site location, number of patients admitted in the emergency department at time of assessment, estimated waiting time for patients at time of assessment. We conducted initial univariate analyses for each variable and those with p values less than 0.25 or of great clinical meaning were included in the model.

We entered variables using stepwise selection with a p value of entry of 0.05. We reported those variables with statistically significant associations as odds ratios. We assessed statistical significance of independent variables using the likelihood ratio test (with a p value of <0.05 as statistically significant). We measured goodness of fit using the classic or the Hosmer-Lemeshow approach depending on the final number of observations used.

4.14.8 Analysis for Objective 8 (Specific Patient Subgroups)

The patients presenting with chest pain, shortness of breath, headache, fever, palpitations, neurological symptoms and abdominal pain represent groups of special interest and we chose these a priori for further analysis to determine whether they were higher risk groups. We planned to examine the associations between these risk factors and adverse events by repeating the above analyses for these subgroups.

4.14.9 Inter-rater Reliability

We calculated kappa scores to determine the degree of agreement between the three outcome assessors and reported these as a measure of inter-rater reliability. We used the procedure for multiple raters as outlined by Fleiss for these calculations.[63]

4.15 Ethics

There were no risks of harm to patients for this study as it was observational and did not interfere with patient care. We addressed the issue of privacy of the patient information by obtaining informed consent from the attending physician and individual patient for collecting and analysing the data. We rigorously concealed patient identity during the outcome assessment phase. When reporting the results, we also took care that patients would not be identifiable. The Ottawa Hospital Research Ethics Board approved the study. If a patient presented to another institution on follow-up, ethics approval was sought if required by that institution to obtain a copy of the medical record.

5.0 RESULTS

Analysis by Objective

5.1 Summary of Patient Population (Objective 1)

5.1.1 Overview of Enrolment and Patient Flow

Patient and enrolment flow are summarized in Figures 1 and 2 respectively. All patients registered in the Resuscitation or Observation areas of the Emergency Department were initially considered for the study. After excluding those who did not meet the inclusion criteria, 518 patients were enrolled from August to December 2004. Of these, 73.0% were discharged home and 26.6% were admitted. Two patients withdrew their consent. Of the patients discharged, nine patients could not be reached for phone follow-up despite multiple attempts (more than 10 calls per patient). Four admitted patients had charts which could not be located by medical records despite multiple attempts. Thus the overall loss to follow-up was 2.5%. The final number of patients analysed was 503.

5.1.2 Baseline Characteristics

In Table 1a the baseline characteristics (patient factors) are provided for all patients who were enrolled and subsequently admitted or discharged. Overall, the patients enrolled in the study were older (median age 57) with an equal distribution between genders (female 50.5%) and presenting most commonly with chest pain, weakness or abdominal pain. In terms of acuity, the Canadian Triage Acuity Scores (CTAS) were predominantly emergent and urgent. This reflects the fact that critically ill patients (often triaged as CTAS=Resuscitation) were excluded. The majority

(85.6%) was taking at least one medication and had at a past medical history of at least one chronic illness (77.7%).

When comparing admitted and discharged patients in terms of patient characteristics, they were similar in terms of age and sex. They also had similar levels of acuity (as measured by Canadian Triage Acuity Scale), rates of medication use and co-morbid illnesses. The presenting complaints were similar among all groups. The majority of Canadian Triage Acuity Scores were emergent or urgent. The discharge diagnostic categories were similar between groups with the exception of proportionately more patients with infection diagnoses being admitted than discharged (12.7% vs. 6.2%).

In terms of system factors (Table 1b), most patients were located in resuscitation and observation and most enrolled patients were cared for by one emergency physician. In more than half of the cases (56.1%), there was 0-2 patients admitted in the emergency department awaiting inpatient beds. Just under half of the patients (48.7%) were primarily assessed by a staff physician rather than a physician learner and nearly half were registered during the day. The estimated waiting time represented the head nurse's estimate of how long patients were waiting to be assessed by an emergency physician. Each time a patient was enrolled, the research nurse approached the care facilitator (the head nurse in the emergency department) and asked her to estimate how long patients were waiting for physician assessment. The median estimated waiting time was 30 minutes.

When comparing system factors among admitted and discharged patients (Table 1b), a higher proportion of discharged patients were located in the resuscitation area of the emergency department. The majority of patients in all groups were under the care of only one emergency physician. The proportion of patients admitted in the emergency department awaiting beds on the floor was not available for admitted patients since the disposition decision often occurred much later than the time of enrolment and the decision to discharge is often known much sooner than the decision to admit (thus this often occurred after the enrolment shift and was obtained retrospectively the following day). In terms of the level of training of the assessors, staff physicians were more likely to see admitted patients and non-emergency medicine residents were more likely to see patients who were ultimately discharged. Emergency medicine residents and medical students had similar proportions of admitted and discharged patients. The time of registration and estimated waiting time did not markedly differ between admitted and discharged patients.

5.2 Proportion of Patients with Adverse Events (Objective 2)

In table 2 the proportion of patients with adverse events among all enrolled, those admitted and those discharged is outlined. There were 43 patients with adverse events, a proportion of 8.5% (95% confidence interval (95% CI): 8.1%, 8.9%). When comparing admitted and discharged patients, the proportion of all adverse events was almost evenly split with almost 50% in each group (22 admitted and 21 discharged). All of the adverse events were deemed attributable to emergency department care in the discharged group whereas only 18.2% of patients' adverse events were attributable to emergency department care in the admitted group.

5.3 Proportion of Preventable Adverse Events (Objective 3)

Of all adverse events identified, 24(55.8%) were preventable. Relative to the overall sample size, this represents a proportion of preventable adverse events of 4.8% (95% CI: 4.5%, 5.1%). In terms of preventability, 71.4% of the adverse events in discharged patients were preventable, whereas 40.9% of admitted patients' adverse events were deemed preventable.

5.4 Characterizations of Adverse Events (Objective 4)

5.4.1 Adverse Event Type

The most common types of adverse events (Table 3) were management issues (n=18, 41.9%), procedural complications (n=13, 30.2%) and diagnostic issues (n=10, 23.3%) (see Figure 3 for definitions). The breakdown of most common types of adverse events differed between discharged and admitted patients. Among admitted patients, the most common types were: procedural complications (n=11, 50.0%), management issues (n=8, 36.4%) and medication adverse effects (n=6, 27.3%). For discharged patients, management issues (n=10, 47.6%), diagnostic issues (n=7, 33.3%) and unsafe disposition decisions (n=4, 19.0%) figured more prominently. The lack of patients in the unsafe disposition and suboptimal follow-up categories amongst admitted patients is logical as these patients have assured follow-up and safer disposition in hospital.

5.4.2 Adverse Event Severity

A summary of the severity of adverse events overall and for discharged and admitted patients is provided in Table 4. There was one adverse event that was an unexpected death (described in Table 6 as a diagnostic issue). In terms of response to the severity of the adverse event (Table 5), nearly half (46.5%) of adverse events required some form of intervention. Just under a third (27.9%) was admitted to hospital and 9.3% had return emergency department visits. Only the most severe outcome was counted if patients had more than one outcome severity - for example, many patients had return emergency department visits and subsequently were admitted (these patients would have been counted as admissions to hospital).

The most severe example of each type of adverse event is presented in Table 6. An example of a diagnostic issue was a 55 year old patient who presented with chest pain radiating to the back and had documented unequal blood pressures in each arm. There was 7 hour delay in the diagnosis of aortic dissection as these signs were not acted upon and an indicated diagnostic test was not ordered. The patient eventually died, possibly related to this delay in diagnosis. An example of an unsafe disposition decision was a 70 year old patient with history of chronic obstructive pulmonary disease who presented with shortness of breath. They were noted to be in moderate respiratory distress with a respiratory rate of 36, were treated with Ventolin and Atrovent and discharged on inhaled medications (no oral steroid or antibiotics). The patient returned eight hours later in severe respiratory distress requiring BiPAP and admission to hospital for 10 days. All adverse events are described in Appendix F.

5.5 Risk Factors for Adverse Events (Objectives 5 and 6)

5.5.1 Univariate Analysis

5.5.1.1 Patient Factors

Before conducting the univariate analysis, the differences between characteristics of patients with adverse events versus all patients enrolled in the study were examined (Table 7a). Patients with adverse events were similar to the overall group enrolled in terms of age, sex, acuity, use of medications and presence of comorbidities. The presenting complaints were similar between patients with adverse events and all those enrolled. The proportion of patients with shortness of breath was larger in those with adverse events compared to all patients enrolled (16.3 vs. 9.1%) whereas all patients enrolled had a higher proportion of patients with chest pain (27.2% vs. 16.3%). Patients with a cardiac discharge diagnosis were proportionately more represented (37.0 vs. 27.9%) among all patients enrolled rather than those with adverse events.

The relationship between patient factors and the occurrence of an adverse event was examined using chi square analysis, as presented in Table 7b. None of the patient factors were found to be statistically significantly associated with having an adverse event (using a p value of 0.05). Within presenting complaint there was a trend towards more adverse events amongst those with shortness of breath and weakness.

Table 7c displays the results of the univariate associations between patient risk factors and *preventable* adverse events. Age was the only statistically significant

association. While more non-preventable adverse events occurred in the older age groups, higher rates of preventable adverse events were found in the younger age groups. These numbers are small, so a cautious interpretation is warranted. None of the other patient factors were statistically significantly associated with a preventable adverse event; however, the numbers were very small.

5.5.1.2 System Factors

When examining the differences in system factors between those with adverse events and all of the patients enrolled (Table 8a), the proportion of patients located in cubicles/corridor (11.6 vs. 5.2%) was higher among those with adverse events. The majority of patients both with and without adverse events were cared for by one emergency physician. The proportion of patients admitted in the emergency department awaiting inpatient beds was higher for those patients with adverse events (32.5% with 2-4 patients waiting for bed) than for the overall patients who were enrolled in the study (26.3%). A higher proportion of patients with adverse events were seen primarily by staff physicians (60.5%) than those who were enrolled overall (48.7%). There were no differences between adverse event and overall enrolled patients in terms of the time of registration and the estimated waiting time.

The univariate analysis of the relationships between system factors and the occurrence of an adverse event are presented in Table 8b. Two factors approach statistical significance: location in the emergency department and level of training of the assessor. Patients with adverse events tended to be less often located in the

resuscitation area of the emergency department and more often located in cubicles relative to those who did not have adverse events. Those with adverse events were more likely to be primarily assessed by a staff physician rather than a learner physician relative to those without adverse events. That being said, none of the system factors were statistically significantly associated with the occurrence of an adverse event (using a p value of significance of 0.05). There was a trend towards more adverse events occurring when 2-8 patients were admitted in the emergency department awaiting inpatient beds.

Table 8c displays the results of the univariate associations between system risk factors and *preventable* adverse events. None of the system risk factors examined were found to be statistically significantly associated with preventable adverse events.

5.6 Multivariate Analysis (Objective 7)

In performing the multivariate analysis, variables were examined for missing data and zero cells. Those categorical variables with zero cells had their categories collapsed if possible and if clinically logical. Appropriate variables were selected for multivariate analysis taking into account missing data and statistical significance in univariate analysis. A cut-off p value of 0.25 was used for inclusion in the multivariate analysis. Initially, the patient and system factors were examined independently, and then any significant variables out of these analyses were planned to be combined. Tables 9a-e summarize the odds ratios and 95% confidence intervals for the multivariate analyses for the occurrence of adverse

events and preventable adverse events. Patients with preventable adverse events were compared to patients with non-preventable adverse events. This comparison was considered the most sensible since these patients would be more similar than those patients who did not experience any adverse events. None of the odds ratios achieved statistical significance.

5.6.1 Patient Factors

5.6.1.1 Risk Factors for Adverse Events

Presenting complaint was the only patient risk factor that met the inclusion criteria for multivariate analysis for the occurrence of adverse events (Table 9a). The presenting complaint variable was transformed using dummy variables such that each presenting complaint, for example chest pain, had a value of 1 if present and 0 if absent. When presenting complaint was assessed as a single variable using logistic regression (see Appendix G, Figure Ga for SAS output), the resultant equation was: logit(ae) = -2.4 - 0.5(chest pain) + 0.7(shortness of breath) - 0.03(abdominal pain) +0.8(weakness/neuro symptoms) - 0.8(palpitations) + 0.2(trauma). The Hosmer-Lemeshow goodness of fit statistic had a p value of 1.00 and was thus a good fit. None of the coefficients was statistically significant by the Wald statistic and the odds ratios were all small with 95% confidence intervals crossing one. Thus presenting complaint was not statistically significantly associated with the occurrence of an adverse event.

5.6.1.2 Risk Factors for Preventable Adverse Events

In terms of *preventable* adverse events (Table 9b), three patient risk factors met inclusion criteria for multivariate analysis: age, presenting complaint and discharge diagnosis. Goodness of fit testing was not performed since the sample size was small (43); this also limits the stability of logistic regression for these outcomes.

Age

The age variable was collapsed from decade to groups of 20 years to reduce zero cells. The model of logit(preventable aes) = intercept + age was examined comparing each category to the lowest age category. When age was assessed as a single variable using logistic regression (see Appendix G, Figure Gb for SAS output), the resultant equation was: logit(preventable aes) = 1.5 - 1.0(age 40-60) - 2.2(age 61-80) - 1.8(age 81-100). Although one age group (61-80) reached statistical significance, since age is a categorical variable, we cannot interpret one category in isolation with respect to preventable adverse events. One can only conclude that age was not a significant risk factor since none of the odds ratios generated from this model were statistically significant and the confidence intervals were wide.

Presenting complaint

The presenting complaint variable was transformed using dummy variables similar to the approach used to assess the occurrence of adverse events. When presenting complaint was evaluated as a single variable using logistic regression (see Appendix G, Figure Gc for SAS output), the resultant equation was: logit(preventable aes) =

0.9 - 0.04(chest pain) - 1.8(shortness of breath) - 0.9(abdominal pain) - 2.3(weakness/neuro symptoms) - 0.2(trauma). None of the coefficients were statistically significant by the Wald test and the odds ratios all approached one and were not statistically significant.

Discharge diagnosis

When discharge diagnosis was assessed as a single variable using logistic regression (see Appendix G, Figure Gd for SAS output), the resultant equation was: logit(preventable aes) = 0.9 + 0.6(cardiac) - 0.1(infection) + 1(neurological) + 1(trauma) + 1.9(gastrointestinal). None of the coefficients were statistically significant by the Wald test and none of the odds ratios were statistically significant with some very wide confidence intervals.

Combining patient risk factors

Logistic regression was performed including all three variables and selection was conducted in forward, backward and stepwise fashion (see Appendix G, Figure Ge for SAS output for stepwise selection). In all three cases, only one variable emerged in the final model: age. Thus the equation was: logit(preventable aes) = 1.9 - 0.03(age). The odds ratio estimate was 0.966 with a narrow, though non-significant confidence interval.

5.6.2 System Risk Factors

5.6.2.1 Risk Factors for Adverse Events

Four system factors were included in the multivariate analysis for the occurrence of adverse events (Table 9c): location in the emergency department, number of patients waiting for beds, level of training of the primary assessor and number of emergency physicians involved in patient's care. The number of emergency physicians involved in patient's care was excluded since 90% of the patients were cared for by one physician, there were insufficient numbers in the second category (2 physicians) to permit a logistic regression.

Location in emergency department

Location in the emergency department was transformed into numeric variables such that each location, for example resuscitation, was assigned a numeric value (see Appendix G for SAS output, Figure Gf). The smallest number of observations was in the cubicles/corridor category, and this was chosen as the reference variable. The resultant model was: logit(ae) = -2.1 -0.3(observation) - 1.8(resuscitation). The odds ratios were all small with wide confidence intervals crossing one hence this variable was not statistically significantly associated with the occurrence of adverse events. Goodness of fit could not be assessed because of low numbers of observations in the cubicles category.

Number of patients waiting for beds

This variable was an attempted measure at the "busy-ness" of the emergency department as it represented the number of beds being occupied by admitted

patients awaiting beds on the floor. The analysis of this variable was interpreted cautiously since 26% of the observations were missing for this variable. This was a continuous variable and the resultant model (see Appendix G for SAS output, Figure Gg) was: logit(ae) = -3.3 +0.4(number of patients waiting for beds). The odds ratio was 1.5 and the 95% confidence interval was (0.95, 2.5) hence this variable was not statistically significantly associated with the occurrence of an adverse event. Goodness of fit could not be assessed because of a small number of observations in the one patient waiting for beds category.

Level of training of primary assessor

Level of training of primary assessor was transformed into numeric variables such that each level of training, for example medical student, was assigned a numeric value such as 1. The smallest number of observations was in the medical student category, and this was chosen as the reference variable. The resultant model (see Appendix G for SAS output, Figure Gh) was: logit(ae) = -2.9 -1.2(emergency medicine resident) + 0.4(non-emergency medicine resident) +0.3(staff). The model was a good fit with a p value of 1.00. The odds ratios ranged from 0.3 to 1.3 and all the confidence intervals crossed one. Thus this variable was also not statistically associated with adverse events.

Combining system risk factors

All three system factors were combined in a logistic regression model using forward, backward and stepwise selection methods. The only variable to emerge in the model was the location of resuscitation. The final model (see Appendix G for SAS output

for stepwise selection, Figure Gi) was: logit(ae) = -2.4 -1.4(resuscitation location). The odds ratio was 0.237 with a 95% confidence interval of (0.068, 0.824), achieving statistical significance. This must be interpreted with caution, however, since only one category out of the location variable was statistically significant and the location variable should be considered as a whole. The location variable overall was not statistically significantly associated.

5.6.2.2 Risk Factors for Preventable Adverse Events

For preventable adverse event system risk factors (Table 9d), three met inclusion criteria: number of patients waiting for inpatient beds, number of emergency physicians involved in the patient's care and the estimated waiting time when the patient was assessed. The number of patients waiting for inpatient beds variable was excluded because 50% of the data were missing for this variable. This could be attributed to the fact that this data was not collected for admitted patients, who constituted one half of the adverse events identified. The second variable of number of physicians involved in the patient's care was also excluded because nearly all preventable adverse events had only one physician involved. As such the second category of two physician involvement had only one patient. The last variable of estimated waiting time was examined using logistic regression.

This was a continuous variable with a skewed distribution towards less than one hour. Logistic regression on this variable (see Appendix G, Figure Gj for SAS output) resulted in the following equation: logit(preventable aes)= -0.04 +

0.41(estimated waiting time). The regression coefficient was not statistically significant and the odds ratio of 1.5 had a wide confidence interval.

5.6.3 Combining Patient and System Risk Factors

For the occurrence of adverse events, none of the patient or system risk factors in multivariate analysis were statistically associated, thus no combination analysis was attempted.

In terms of preventable adverse events (Table 9e), a final multivariate analysis was performed combining the only significant patient risk factor variable with the system risk factor analysed. Logistic regression was conducted on age and estimated waiting time. The resultant model (see Appendix G, Figure Gk for SAS output) was logit (preventable aes)= -1.5 + 0.03(age) - 0.3(estimated waiting time). None of the regression coefficients were statistically significant, nor were the odds ratio estimates.

5.7 Adverse Events among Patient Subgroups (Objective 8)

The patients presenting with chest pain, shortness of breath, headache, fever, palpitations, neurological symptoms and abdominal pain were identified a priori as groups of special interest. These were to be further analysed to determine whether these were higher risk groups than other patients. Chest pain, shortness of breath, palpitations, neurological symptoms and abdominal pain have already been analysed and determined not to be statistically significantly associated with

preventable adverse events (with the caveat that the numbers were small). None of the patients with adverse events presented with headache or fever.

Another subgroup became of interest during the analysis, and this was comparing the admitted and discharged patients. There were differences in patient factors between admitted and discharged patients among those with adverse events (Table 10a). Admitted patients with adverse events tended to be older than those discharged (median age 70 vs. 53) and a smaller proportion had comorbidities (72.7 vs. 90.5%). A higher proportion of admitted adverse event patients had a cardiac discharge diagnosis (36.4 vs. 19.0%) whereas a higher proportion of discharged patients had infection (19.0 vs. 4.5%) and neurological (14.3 vs. 0%) diagnoses.

When comparing differences in system factors for those adverse event patients who were admitted and discharged (Table 10b), admitted patients were more likely to be located in corridor/cubicles (18.2 vs. 4.8%). A higher proportion of admitted adverse event patients were assessed by staff physicians (68.2% vs. 52.4%) and a lower proportion by non-emergency medicine residents (13.6 vs. 33.3%). A higher proportion of admitted patients were registered in the evening time period (40.9 vs. 33.3%) whereas a lesser proportion were registered at night (4.5 vs. 9.5%).

Univariate analyses examining the relationship between patient or system factors for admitted patients and the occurrence of adverse events did not uncover any statistically significant associations. Likewise, a repeat analysis for discharged patients failed to reveal any statistically significant associations.

5.8 Challenges to Internal Validity of Methods

5.8.1 Inter-rater Reliability

Since the determination of adverse events was conducted by multiple reviewers, the degree of inter-rater reliability was examined. When considering the 135 flagged outcomes, on 18 occasions (13% of the time) the three original reviewers universally agreed that the outcome was an adverse event (seeTable 11). If one includes agreement among the majority (2 out of 3) this occurred on 42 occasions or 31% of the time. The kappa value for the three reviewers evaluating the 135 flagged outcomes was 0.26 (95%CI: 0.20, 0.32). This was calculated as described by Fleiss et al for multiple ratings per subject with different raters.[63] This represents a moderate level of agreement.

An alternate statistic for calculating the level of agreement among reviewers has been proposed by Localio et al.[64] These authors performed a secondary analysis on the ratings of the Harvard Medical Practice Study and calculated a statistic that they felt recognizes that the "agreement about whether a patient's condition is normal (no adverse event) is usually greater than agreement about whether a patient has a disease or abnormal condition".[64] In addition this statistic is less influenced by the prevalence of the result being scored (i.e. proportion of adverse events) than the kappa score. Using the formula:

$$\text{Level of agreement} = \frac{\text{number of cases of universal agreement among reviewers}}{\text{numerator + number of cases of extreme disagreement}}$$

We defined extreme disagreement as cases where only one reviewer rated a flagged outcome as an adverse event. The level of agreement in this case was 0.39 (18/46).

We believe the outcomes judged to be adverse events by the reviewers have face validity (see Appendix F for a description of all adverse events) and that requiring three reviewers to agree on the determination of an adverse event could have led to an under-inclusion of adverse events. This is further addressed in the Discussion.

5.8.2 Adequacy of Blinding of Reviewers

When reviewers were asked to review the flagged outcomes for each patient, there were methodological concerns surrounding the potential for the physician reviewers to recognize patient or treating physician identity. In order to reduce the possibility of this, case summaries were created. But because some details can only be gleaned from examining the original treatment record, this was available as a pdf file for the reviewer to examine *only* if they felt they had insufficient detail from the case summary. Reviewers looked at the original treatment record 21.2% of the time. In addition, at the end of each review, each reviewer was asked to indicate whether they suspected the identity of the treating physician. This was the case 5.0% of the time.

6.0 DISCUSSION

This thesis consisted of a successfully run prospective cohort study that enrolled a large number of patients from the high acuity areas of the emergency department. We found a similar proportion of patients with adverse events in our study as documented in the pilot study of discharged emergency patients and previous Canadian adverse event studies of hospitalized inpatients.[22;65] Our proportion of patients with adverse events was higher than that predicted to occur in the emergency department by the Harvard Medical Practices inpatient study.[2] The preventability of our adverse events was similar to that documented in the Utah and Australian inpatient studies.[17;19] Overall, there was a low level of morbidity and mortality in the adverse events we recorded. This was the first full-scale evaluation of adverse events in Canadian emergency department patients.

We noted several differences between the admitted and discharged patients. There was a higher proportion of adverse events among the patients admitted in our study; but a low proportion of these were attributable to emergency department care. Admitted patients had a higher proportion of adverse events due to management issues or procedural complications whereas discharged patients had relatively more diagnostic issues and unsafe disposition decisions. We noted that proportionately more preventable adverse events were seen in the discharged population, suggesting that this group may be the most appropriate to target for preventive interventions. This study was unique in that it prospectively addressed patient safety issues with a structured, system-based approach in a population in much need of description and study. Our work helps to establish a methodology of

measuring adverse events in the emergency department and plan for future patient safety interventions.

6.1 Population Description (Objective 1)

One goal of this study was to obtain a representative sample of high acuity emergency department patients in order to examine some patient and system factors that could contribute to adverse events. We chose this patient group because intuitively these patients seemed at high risk for adverse events. We were particularly concerned about those patients who were triaged as having a potentially significant medical problem but who were subsequently sent home. These are the patients that many emergency physicians worry about at the end of a shift: "did that patient I sent home with chest pain really have a significant cardiac problem?" Previous emergency medicine studies in patient safety have focused on quality assurance or subgroup populations such as trauma deaths,[26-30] missed myocardial infarctions[31-34] and elderly patients on multiple medications.[35;36] To date, no study has taken a comprehensive view of high acuity patients presenting to the emergency department.

We took care in our study to enrol consecutive patients who presented to the emergency department during our enrolment shifts. We noted 73% of the 503 patients were discharged home and achieved a follow-up rate of 98%. Overall, the study population was older with a high rate of comorbidities and medication use, reflecting what we would expect to see as clinicians. We believe we've obtained a

representative sample of the population of interest that enhances the robustness and validity of our results.

We studied system factors for this study population based on James Reason's model of a system-based approach to patient safety.[10] Previous concerns have been documented in the literature surrounding errors made during handover from physician to physician[66;67] and the potential impact of the "busy-ness" of the emergency department on clinical decision making.[68;69] We were surprised that the rate of handover was low in our study as 91% of patients enrolled were cared for by only one emergency physician. As an indirect measure of "busy-ness" of the emergency department, we measured the number of patients admitted in the department awaiting inpatient beds. Since sicker patients often require admission, when larger numbers of these patients are registered, more emergency department beds are occupied as those admitted await inpatient beds. This creates a phenomenon known colloquially as "bed block" - it limits the number of beds available to assess patients when there are high volumes of high acuity patients. These translate into increased pressures on emergency physicians to promote flow of patients through the department. To our surprise, most of the time (56%) there were two or fewer patients waiting for inpatient beds at the time of enrolment. These data may explain why we failed to find an association between the number of emergency physicians involved in a patients' care or the "busy-ness" of the emergency department and adverse events.

Other system factors examined in this study included estimated waiting time and level of training of the primary assessor. The Canadian Triage and Acuity Scale (CTAS) provides guidelines for time to physician assessment based on the acuity assigned to the patient at triage.[60] For CTAS levels 2 and 3, the recommended time to assessment is 15 and 30 minutes respectively. It is often felt by emergency physicians that with the current state of overcrowding in emergency departments these targets are infrequently met. We found a mean estimated waiting time for physician assessment of 30 minutes for our CTAS 2 and 3 patients which reinforces this view.

The Ottawa Hospital is a teaching hospital that involves multiple levels of learners in daily health care practices. Some have speculated that clinical experience may be associated with error rates among emergency physicians.[69;70] We found that 50% of patients were assessed by junior physician learners (medical students or residents) and this was not subsequently associated with adverse events. Emergency physicians commonly perceive that prolonged waiting times, and the involvement of learner physicians can pose a threat to patient safety. Our study did not demonstrate these as particularly prominent issues. This could be related to secular trends, i.e. our four month period of enrolment was not a particularly busy time in the emergency department or it is possible that our perceptions of the importance of these factors is somewhat exaggerated. Our study was unique in the consideration of these system factors when evaluating patient safety in emergency medicine.

6.2 Proportion of Patients with Adverse Events (Objective 2)

This study is the first to comprehensively evaluate both admitted and discharged high acuity emergency patients. The primary outcome of interest was the proportion of patients with adverse events. Our finding of 8.5% is comparable to the only other similar emergency medicine patient safety study, the pilot study by Forster et al, who documented 6% adverse events among discharged emergency patients.[22] The two other emergency patient safety studies that reported adverse event rates, the Taiwanese phone follow-up study of discharged patients, and the Australian retrospective chart review of pre-selected "high risk" emergency patients found rates of 4% and 1% respectively.[46;49] These latter two studies were limited by restrictive definitions of adverse events and non-standardized approaches to adverse event detection.

In terms of hospital inpatient studies, our result is comparable to the Canadian Adverse Events study which found an incidence of 7.5% among inpatients through retrospective chart review.[65] The Ottawa Hospital Patient Safety Study used similar methods for the same population as the Canadian Adverse Event study and found a higher adverse event incidence of 12.7%.[23] These differing adverse event rates are likely because the Canadian Adverse Events study reviewed charts from 20 hospitals including teaching and community hospitals and noted a higher rate in teaching hospitals; whereas the Ottawa Hospital study was conducted at a single teaching hospital. The proportion of patients with adverse events in our study is half that documented in Australia (17%) but twice that found in the Harvard Medical Practices Study (4%).[19;2] As discussed in the introduction, the investigators of both

of the latter studies compared their data and speculated that the difference between the two adverse event rates were likely related to different reviewer behaviour or potentially quality of care. Our study assessed a different population as we focused on high acuity emergency patients and evaluated prospectively both those who were discharged and those who were admitted. Overall, one can conclude that the number of emergency patients with adverse events is not markedly different from that of the Canadian inpatient population. As a result, the emergency department should receive similar emphasis in safety improvement initiatives as other areas of the health care system. In fact, given that significantly more patients visit emergency departments than are admitted to hospital, one could argue that more investments are required in this area.

6.3 Proportion of Preventable Adverse Events (Objective 3)

Overall, our result of 56% preventability of adverse events is on par with previous studies documenting 50% preventability for inpatients.[17;19] In our study, there were marked differences in preventability between admitted (41%) and discharged (71%) patients. The only emergency patient safety studies to assess preventability of adverse events among discharged patients were the pilot study and two British studies[44] of unscheduled return emergency department visits.[22;43] The pilot study utilized the same methodology for determining preventability as we did and found that 71% of adverse events in discharged patients were preventable. The British investigators' methods for determining and defining preventability were not described but they found 8% preventability in one study and 80% in the other.[43;44] Considering our findings and these previous studies, it would seem that the

discharged population may be a more appropriate target for preventative interventions in the emergency department such as policy change, use of technological tools or clinical management algorithms.

In terms of the hospital inpatient population, it is interesting that the Harvard Medical Practices study found that 93% of the 73 adverse events occurring in the emergency department were preventable.[2] The preventability in the Harvard study is much higher than the 41% (n=9) preventable adverse events we documented in our admitted population. This could either be due to the focus on malpractice or differing reviewer behaviour as the adverse event rate in this study was markedly different from other inpatient studies. The number of adverse events studied in both cases is small and larger studies would be required to assess more accurately the preventability of adverse events among patients admitted from the emergency department.

6.4 Types of Adverse Events (Objective 4)

Overall, we found management issues, which can include diagnostic issues, as the most common type of adverse event. For example, the case of the patient who was diagnosed as atypical chest pain, discharged and subsequently returned 11 days later and required urgent coronary artery bypass surgery included several issues around diagnosis, management and follow-up. Procedural complications was the next most common type and this was predominantly among the admitted patients who typically receive more procedural interventions as they are sicker and are often admitted for diagnostic testing. Nevertheless, diagnostic issues were still an

important category, comprising 23% of adverse events. This type of adverse event was particularly important in the discharged versus admitted group. Previous authors[69] have highlighted diagnostic issues as being the most common contributor to adverse events in the emergency department.[39] Our study suggests that in the emergency department, adverse events can be related to many issues, likely secondary to the complexity of the patient encounter.

The literature has often focused on adverse drug events. A recent article in the Journal of the American Medical Association is the largest study on this topic and reported on a national database of 21, 298 adverse drug events.[36] They found that adverse drug events accounted for 0.6% of emergency department visits. In our study 9 (21%) adverse events were due to medication adverse effects (representing 1.8% of all patients enrolled) and only three of these occurred in discharged patients. Only in one case did the patient return to the emergency department. The numbers in our study are too small to draw definitive conclusions; however, one might speculate that adverse drug events should not be the first priority in patient safety interventions in the emergency department.

In terms of the severity of adverse events, our study documented an overall low level of severity as a minority of adverse events (7%) resulted in disability or death. This is a similar trend to that documented in the Quality in Australian Health Care inpatient study which found 3% of adverse events resulting in disability or death.[19] The Harvard Medical Practices inpatient study and Utah and Colorado inpatient study had higher proportions of disability or death with 30% and 40% of adverse

events respectively, perhaps because of their focus on malpractice cases.[2;17] None of the emergency patient safety studies assessed overall adverse event severity, rather they tended to select the more severe groups and only study these. Although we found a low risk of severe adverse events, the high volume of patients treated in the emergency department means that potentially large numbers of patients could be severely affected.

A high proportion of patients in our study (47%) required some form of medical or surgical intervention to treat the adverse event and this was primarily seen in the admitted group where 86% of adverse events required intervention. This reflects the higher proportion of procedural complications and adverse drug effects in this group - two adverse event types more likely to require an interventional response.

6.5 Association between Patient Characteristics and Adverse Events (Objective 5)

In our study we found that age was statistically associated with preventable adverse events but in an opposite direction to what had previously been observed. Age more than 61 years was not statistically associated with the occurrence of an adverse event and in fact a smaller proportion of patients in this age group had preventable adverse events compared to the younger age groups. Possible explanations for this would include that the sample was skewed towards younger age groups. The frequency distribution histogram for age (Appendix H), however, demonstrates that in fact the age distribution was slightly skewed towards the older age groups. Some of the inpatient studies had age distributions much more skewed

to older age groups than ours and this could exaggerate the age trends they observed in their studies.[20;71;72]

Another possibility is that the elderly population is more likely to have non-preventable adverse events since as a sicker population receiving more medical care, they could be higher risk overall. But our data on adverse event occurrence does not bear this out. It is also possible that health care providers have predisposed notions of certain age groups, such that we do not expect younger patients to be as sick. An example is the 40 year old patient who presents with chest pain and no cardiac risk factors. Clinicians typically view these patients as low risk for cardiac disease and are more likely to discharge them home with fewer investigations. While in many cases this may constitute appropriate care, it is possible that this age-based judgment may lead to under-investigation of this population. Finally, given the small number of adverse events it is entirely possible that the trend we observed with age is due to chance.

Previous hospital inpatient studies have evaluated associations between a few basic demographic factors (particularly age and sex) and adverse events.[20;23;65;71-73] Several have assessed administrative data and found only increased age was associated with adverse events while gender was not. [20;23;65;73] Interestingly, the two prospective studies examining patients discharged after hospital admission found no association between age and adverse events. [71;72] The pilot study was the only emergency patient safety study to assess associations between adverse events and demographics and found none to be statistically significant.[22] A larger study of the

emergency department population would be required to confirm these findings. This would also be useful for examining the many other patient factors we considered in our study but for which no statistical association with adverse events was found.

6.6 Association between System Characteristics and Adverse Events (Objective 6)

We found a trend towards an association between level of training of the primary physician assessor and adverse events, though not in the way we expected. A higher proportion of patients with adverse events were seen by attending staff physicians rather than learner physicians. This could be due to staff physicians seeing the more complex and sick patients but may also represent the pressure for rapid disposition decisions that staff physicians feel in order to maintain flow through the emergency department. One previous study has suggested that more experienced emergency physicians make fewer errors but the methodology was fraught with difficulty as it was a single institution retrospective peer review process used to make this determination.[70]

There was also a trend towards patients located in the cubicles/corridor area and an adverse event. This finding is interesting since in optimal conditions, high acuity patients should be seen in the high acuity geographic areas of the emergency department (resuscitation and observation). It is not uncommon for these patients to be placed in lower acuity areas when the high acuity areas are full or overflowing with patients. This can lead to a health care provider's initial impression of a patient in this area as not being very ill since they have been triaged into the low acuity

area. Dr. Croskerry refers to this process as anchoring.[14] Hence, physicians may be more likely to "down-play" a patient's presentation when seeing them in a low acuity area and this could increase their risk of having an adverse event.

Finally, the variable designed to assess the "busy-ness" of the emergency department, the number of patients admitted awaiting beds, trended towards being associated with adverse events when two to four patients were awaiting inpatient beds. This reflects the concept of "bed block" when the number of available beds in the emergency department is reduced and emergency physicians feel increased pressure to make rapid disposition decisions.

Despite all of these trends towards association between system factors and adverse events, none of them proved to be statistically significant. This was also true for preventable adverse events. No previous adverse event studies have explicitly linked system characteristics to the occurrence of adverse events. Authors have speculated that level of experience of physicians, overcrowding of emergency departments and prolonged waiting times may contribute to adverse events in the emergency department.[69] One Spanish study assessed the effect of emergency department overcrowding on deaths in the emergency department and return emergency department visits.[74] This was a prospective cohort study over 2 years that used the number of visits per week as a measure of overcrowding (i.e. the department was designed for 100 visits per day and when this threshold was exceeded it was defined as overcrowding). They found a linear statistically significant relationship between overcrowding and death in the emergency

department. The authors did not specify whether expected deaths and scheduled returned emergency visits were included. Furthermore, they did not evaluate the deaths or return visits for associations with health care management therefore it is unclear how many of these were in fact adverse events.

Our study documented some interesting trends among system factors and their relationship to adverse events. The lack of statistical significance could be because there is no such association, despite popular perception. Alternatively, our attempts to measure system factors may not have accurately represented system conditions. Another strong possibility is that these trends were not statistically significant due to the low number of adverse events and further larger studies would be required to confirm the hypotheses we have generated.

6.7 Relationship between Multiple Patient and System Factors and Adverse Events (Objective 7)

None of the multivariate analyses examining the patient and system factors individually or in combination yielded statistically significant associations with adverse events (preventable or non-preventable). No other studies looked at system factors or their relationship with patient factors and adverse events. Our findings are likely due to the low number of events and a larger study with higher event rate would be required to further explore this issue.

6.8 Adverse Events among Patient Subgroups (Objective 8)

As previously discussed, the majority of existing adverse event studies have been based upon either inpatients or discharged emergency patients. This study afforded an opportunity to examine differences between patients admitted from the emergency department versus those discharged home. Some thought-provoking trends emerged among those with adverse events in these groups. Admitted patients tended to be older, discharged with a cardiac diagnosis and a higher proportion were seen by attending staff. As mentioned earlier, we found that admitted patients had a higher proportion of adverse events (16 vs. 6%) which were more commonly management issues, procedural complications or diagnostic issues. The patients with these adverse events had higher rates of intervention (86 vs. 5%) but only 18% of these events were attributable to emergency department care. These results are not surprising since the admitted population is an acutely sicker population exposed to more interventions and thus are at higher risk of complications.

In contrast, discharged patients had a higher proportion of comorbidities and tended to be proportionately more often discharged with neurological or infection diagnoses. These patients were seen in higher proportion by resident physicians and while they had a lower proportion of adverse events, the preventability was much higher (71 vs. 41%). Diagnostic and unsafe disposition decision issues figured more prominently in this group. Diagnostic issues have been previously highlighted in the literature as significant issues for emergency physicians and it follows that since disposition decisions are often made based upon limited information in a short period of time

that these could result in adverse events.[69] It is somewhat reassuring that the adverse event rate among discharged patients is lower given difficulties with continuity of care in this group. Nonetheless, there is clearly room for improvement. These findings lead one to hypothesize that there are distinct differences between high acuity emergency patients who are admitted and discharged. The strategies employed to prevent adverse events in these groups should consequently be tailored to these differences. A larger study examining these populations would help reinforce these findings and further develop potential preventative interventions.

6.9 Methodological Issues

This study had much strength as one of the few prospective evaluations of patient safety in emergency medicine. We minimized selection bias by employing a prospective, consecutive patient enrolment during randomly sampled time frames. We had a very high follow-up rate of 98% for an ambulatory population that is typically difficult to follow.[45] The process of determining adverse events was based on the methods of several landmark adverse event studies and had high face validity. The outcome assessors were emergency specialists who were well blinded to patient and treating physician identity. By collecting data on over 500 patients, we were able to achieve high precision on our adverse event estimate with narrow 95% confidence intervals of +/- 0.4%.

Inter-rater reliability

There are limitations to this study however, in terms of inter-rater reliability, small number of adverse events, hindsight bias and generalizability. Despite our rigorous

attempts to train the outcome assessors and utilize the same principles of adverse event determination as previous inpatient studies the inter-rater reliability amongst our three reviewers was moderate at 0.3.[2;17;19;23;65] In reviewing the kappa scores for previous adverse event studies, the following table summarizes the results:

Study	Number of Reviewers	Kappa statistic for agreement among reviewers of adverse event rating
Brennan et al[2]	2	0.61
Wilson et al[19]	2	0.42
Thomas et al[17]	1 with a random sample reviewed by second reviewer	0.4
Baker et al[65]	2	0.47

Our kappa statistics were lower than previous studies; however, we had three reviewers rather than two which made universal agreement more challenging. Previous literature has suggested that inter-rater reliability increases with the experience of the reviewers.[64] Our reviewers had not performed adverse event determinations before and there were no emergency physicians available at our center with this experience so we were unable to overcome this limitation. Interestingly, another factor found to decrease inter-rater reliability is the type of adverse event being analysed.[64] Less agreement was found for ratings involving diagnostic and management issues as opposed to ratings for wound infections or adverse drug reactions. The studies with greater inter-rater agreement included a higher proportion of wound infections and adverse drug reactions than our study, in

which diagnostic and management issues figured more prominently. This could possibly explain why we experienced a lower kappa statistic.

Localio et al studied agreement between reviewers for the retrospective chart review performed in the Harvard Medical Practices Study because of concerns on the difficulty of achieving consensus when clinical judgment is involved.[64] In a secondary analysis, they calculated an alternate statistic to the kappa (as outlined in the results section 5.8.1) which they felt was more robust in the setting of adverse event determinations. Their calculation of inter-rater agreement using this method was 0.44 and they found that universal agreement was 10%. This is similar to our study when we performed the same calculation and found a level of agreement of 0.39 with universal agreement 13% of the time.

Concerns have been expressed about the inter-rater reliability of adverse event determinations and some solutions proposed.[17] One was standardized training - several of the previous adverse event studies had reviewer training conducted at different times by different investigators. We had a single session with all 3 reviewers conducted by the author. Second was to have a quality control process whereby a sample of the reviews was re-reviewed by investigators and false positives and false-negatives eliminated. We did this in our study. The author and a supervisor (AF) reviewed all of the flagged outcomes rated as adverse events. In order to be included as an adverse event, we required agreement among four out of five reviewers. While this was designed to increase the specificity of the adverse event determinations, it likely did so at the cost of under-inclusion of adverse events.

We believe we did achieve high specificity with our process as borne out with the high face validity of the adverse events we documented. Thus, recognizing the potential subjectivity of adverse event ratings, we did our utmost to attempt to overcome these issues based on recommendations of previous experienced researchers.

Small number of adverse events

Our univariate, multivariate and subgroup analyses failed to uncover any statistically significant associations with adverse events and this is most likely due to the fact that we only had 43 patients with adverse events in our study. While this low proportion is favourable in terms of quality of care, it does limit the stability of detailed analyses. We prospectively collected data on more than 500 patients and stopped short of our goal of 1102 because of time limitations and minimal gains in precision for the primary outcome. We reassessed sample requirements after four months of data collection. Assuming an adverse event proportion of 6% as seen in the pilot study, the 95% confidence interval for the same proportion for the 378 discharged patients enrolled thus far was 3.91 to 9.02. It was determined that if 1000 patients were enrolled, this would only be a gain in precision of 2% overall (95% CI of 4.65, 7.70). Even if the adverse event proportion was twice that in the pilot study, the gain in precision by enrolling 1000 patients would only be 2.7%. This was discussed with the thesis committee and not felt to be clinically significant. It was felt that time would be better invested in working on the methodology for flagged outcome evaluation and pursuing the chart review for admitted patients to

increase the overall sample size to 500. By including admitted patients we would have a more comprehensive sense of all patients registered in the high acuity areas.

We also suspected there could be important differences between the admitted and discharged patients which had not been previously described. The methodology for chart review for inpatients had been well established in several landmark patient safety studies and we chose to adopt this methodology to strengthen our planned methods. Future studies will require much larger samples to further delineate the patient and system risk factors for adverse events.

Hindsight bias

Our study is subject to both hindsight bias and outcome bias; both are recognized limitations of adverse event investigations.[75-78] Hindsight bias is the tendency of people with outcome knowledge to exaggerate the extent to which they would have predicted an event beforehand.[78] Outcome bias is the influence of outcome knowledge on the evaluations of decision quality.[78] These biases reflect the concept that a poor outcome does not necessarily reflect a poor decision but that a negative outcome causes a reviewer to search harder for a problematic decision.[75] It has been demonstrated experimentally that knowledge of the outcome influences the judgements of appropriateness of care.[77] Caplan et al asked 112 anesthesiologists to evaluate 21 cases of adverse events based upon malpractice claims.[77] Each case was replicated to have a permanent disability outcome and a temporary disability outcome. They randomly assigned one version of each case to the reviewers. They found that when original cases of temporary injury were changed to

permanent injury, overall ratings of appropriate care decreased by 31%, a statistically significant finding. Likewise, when investigators altered the outcome from permanent to temporary, they found ratings of appropriate care increased by 28%. Of note, these reviewers were asked to make implicit judgements on the cases provided.

There are several suggested methods to handling hindsight and outcome bias. One is to blind the reviewers to the outcome.[78] We were unable to do this as the outcomes were used to identify the cases and were essential components in understanding the events that occurred and the health care provided. It is recognized that outcomes can be required to evaluate decision quality.[75] Another option is to ask reviewers to consider only information that would have been available to the decision maker at the time. We did this via our reviewer guidelines (Figure 5). A further possibility is to ask the reviewers to consider how other possible outcomes could have occurred. We did this during the adverse event determination phase by asking reviewers to rate the probability that another reasonable competing explanation could be the cause of the flagged outcome (see Appendix E for outcome assessment form). Lastly, rather than rely on implicit judgements, it is preferable to have a structured approach. The method for adverse event determination we used was based upon the Harvard Medical Practices inpatient study and these investigators validated this approach explicitly to reduce the reliance on implicit judgement.[2;79] In the end, one cannot completely avoid hindsight or outcome bias with this type of research; however, we feel we made

earnest attempts to reduce the impact of these influences on reviewer decision making.

Generalizability

Finally, this study was conducted in two emergency departments of one hospital and this limits the generalizability of the results. We have shown that the proportion of patients with adverse events we measured is similar to previous adverse event studies albeit of different populations. The Canadian Adverse Event Study conducted retrospective chart review of inpatients at multiple different hospitals and found a trend towards more adverse events in teaching hospitals rather than large community of small hospitals.[65] It is unknown whether the same would hold true for high acuity patients in the emergency departments of these hospitals.

6.10 Future Directions

Clinical implications

Our study has several implications for clinical care in Canadian emergency departments. The proportion of patients with adverse events we documented indicates that these are not common occurrences but that there is definite room for improvement with half of the events being preventable. If one extrapolates our results to all Canadian emergency departments, this would translate into 1.2 million adverse events per year with 400,000 preventable adverse events among discharged patients. Of the latter group, almost 80% returned to hospital for an emergency visit or admission, incurring further health care costs. One in twenty discharged patients with adverse events suffered a permanent disability

corresponding to almost 28,000 Canadians annually. While these results need to be reproduced in a larger multi-center study to draw any firm conclusions, it suggests that patient safety in emergency medicine, particularly in the discharged population, should be an urgent priority.

As with other areas of medicine, it is important to increase the awareness of patient safety among the emergency medicine community if we are to decrease iatrogenic morbidity and mortality. Future work needs to include the emergency department in creating a culture of safety. We have demonstrated differences between those patients who are admitted from the emergency department and those who are discharged home. We have also described key adverse event types that could be targeted for more study and future interventions. Physicians need to be aware of the different issues facing these populations and become involved in designing interventions to reduce adverse events. Before implementing such interventions, however, a reliable and reproducible method of adverse event determination should be established.

Methodological studies

Future studies based on this thesis work should include methodological investigations, reproducing this study on a larger scale and considering future patient safety interventions. In terms of methodological work, Forster and colleagues have utilized computer modelling to look at the impact of the number of reviewers on inter-rater reliability and accuracy.[80] They have found that three reviewers are superior to one in terms of sensitivity and specificity of adverse event

ratings. The authors suggest future work needs to focus on the variability of the accuracy of physician judgements. A potential study could use theoretical adverse event scenarios where specific patient and system characteristics are altered in order to determine what the most influential factors are on reviewer judgment. Once this is understood, it may be possible to reduce these influences by blinding reviewers to certain factors or making the adverse event determinations even more structured.

Multi-center study

Despite the fact that we enrolled over 500 patients in our study, we still had a relatively small number of patients with adverse events. A larger, multi-center study of the high acuity population would increase the number of events available for analysis as well as address the issue of generalizability. This would allow confirmation of our findings in terms of differences between admitted and discharged patients as well as a re-assessment of the role of patient and system factors in terms of increasing risk of adverse events. Furthermore, this type of study could be used to make comparisons between teaching and community hospitals or urban and rural hospitals. Our study did not identify a particularly high risk patient group in terms of presenting complaint, but a larger study might identify patients, presenting with chest pain or abdominal pain for example, as groups in which to focus future study.

Another approach would be to study the **discharged population** since this group had a higher proportion of preventable adverse events for which 100% were

attributable to emergency department care. This study could be used to evaluate the specific system characteristics which trended to being associated with adverse events in our study. Level of training of the assessor, waiting time, number of admitted inpatients and location in the emergency department could all be assessed. This data would allow for planning of specific interventions for this potentially high risk population.

Interventional studies

Finally, once the proportion of patients with adverse events has been confirmed on a larger scale, some specific interventional studies could be considered. These could include evaluating feedback to physicians, the creation of handover guidelines and optimizing the use of the electronic record. Emergency physicians already tend to feel vulnerable with the lack of follow-up they have on the patients they manage. Part of enhancing quality of care and patient safety is to close this feedback loop.[81] One previous study in Taiwan has evaluated the use of **phone follow-up** to obtain feedback for emergency physicians.[46] They performed daily chart reviews of patients seen in the emergency department and screened these for those they deemed to be high risk. The results of the phone follow-up were communicated to the treating physicians. In their before and after study, they documented a statistically significant reduction in return visits due to diagnostic, management errors or unsafe disposition decisions. This intervention likely merits further evaluation as our study indicated we are able to identify adverse events in the discharged population with a high rate of follow-up. One could envision a "patient safety officer" in the emergency department charged with the task of daily chart

review and phone follow-up and utilize our structured adverse event detection methodology to capture a broader sense of adverse events rather than just return emergency visits. We could also get a better sense of the types of adverse events we identified in the discharged population such as diagnostic issues and unsafe disposition decisions. While this is a potentially resource-intensive intervention, it would be interesting to see if the impact on adverse events could be replicated in a Canadian setting.

While our study did not have a high rate of handover since most patients were seen by only one emergency physician, the reality is that due to the shift work nature of emergency medicine, handovers are inevitable. We may have underestimated this variable since the timing of our enrolment shifts coincided with the emergency physician duty shifts. Authors have highlighted the potential pitfalls in **handover communication**.[66-68] There is concern regarding the lack of standardization of handover procedures within and between institutions and that critical information can be lost in the handover process.[66;67] Many methods of handover have been described, from the passing on of written documentation, tape recordings, computerized exchange of information and face-to-face communication.[66;67] One study of nursing handover on a Canadian general medicine ward demonstrated that involving nurses in the creation of handover guidelines increased the success of their implementation.[67] The impact of these guidelines on adverse events was not measured. In the emergency department, a relatively low cost intervention could involve the creation of handover guidelines and measuring the impact on adverse events using our methodology. This type of intervention could potentially reduce

diagnostic and management issues by enhancing the amount of information provided to the receiving physician. This study would likely require an altered enrolment strategy to maximize inclusion of patients registered in the department at the time of shift change. Several authors have proposed recommendations for deriving appropriate handover guidelines.[66;67;68] If this intervention demonstrated an impact on adverse events, it would be relatively simple to implement similar guidelines in other emergency departments.

Lastly, another interventional study of interest would be the utilization of an **electronic medical record** to enhance adverse event detection and implement treatment algorithms and guidelines. Many emergency departments across the country are transitioning to electronic medical records. These systems have the benefit of increasing access of health care providers to the medical record, reducing issues of handwriting illegibility and standardizing documentation of the emergency assessment and treatment. Another benefit is the creation of a searchable database. This could lead to the creation of software that would hunt for "key words" to identify adverse events. One could also use such a database to search for deaths, unscheduled return emergency visits and more easily link these to the emergency department visit records. A study could be constructed to compare the accuracy of this method of adverse event detection to our current more resource-intensive method. This intervention would involve a significant outlay cost for hardware and software but potentially reduced long term costs in terms of ongoing adverse event surveillance. While this strategy has been proposed in the emergency medicine literature, we were unable to find any studies that have

evaluated this approach.[16] Thus, this is an area of emergency patient safety research that may facilitate adverse event detection and surveillance in the future.

Another link to the electronic record could be the implementation of **treatment algorithms** or **clinical practice guidelines**. Rather than physicians relying on memory of evidence or having to look it up during their shift, when a patient presented with shortness of breath, for example, an icon could appear that would allow the physician to access a risk stratification model for pulmonary embolism. Pediatric emergency departments have implemented similar strategies. One Australian group implemented clinical pathways for managing gastroenteritis, asthma and croup using their computerized medical record system.[82] In their before and after study they documented a reduction in admission rate and length of hospital stay as well as a reduction in unscheduled return emergency department visits. The authors indicated they did not uncover any adverse events though their methods for measuring these were not described. The same group of investigators performed a more detailed study of the croup protocol and specifically measured unexpected airway obstruction and persistent fever as adverse events.[83] They utilized an established critical incident reporting system to measure these outcomes. They did not identify any adverse events in either group so it is unknown whether this protocol impacted on this variable for the 267 patients enrolled.

If the multi-center study identifies potentially high risk groups such as chest pain and abdominal pain, diagnostic and management algorithms or guidelines could be developed and implemented in a similar way to these pediatric studies but utilizing

our adverse event detection system to determine if this has an impact. This particular study is potentially quite challenging as some presenting complaints such as chest pain and abdominal pain can be quite complex and difficult to summarize into an algorithm. If the electronic medical record is already in place, it would be a relatively low cost intervention to investigate.

In summary, this thesis has generated many hypotheses that could serve as the basis for future investigations. More research is needed on the method of adverse event determination to increase the inter-rater reliability. While it is tempting to immediately explore preventative interventions, further work to confirm our results is required. A larger multi-center study would ensure the adverse event proportion is replicable and the trends in differences between admitted and discharged patients bear out. Interventions that hold promise include direct feedback to emergency physicians, implementation of handover guidelines, electronic adverse event detection and electronic clinical practice guidelines.

7.0 CONCLUSIONS

In conclusion, we found a similar proportion of patients with adverse events among the high acuity emergency department population as the Canadian inpatient population. The fact that one half of our events were preventable suggests that much could be improved in emergency department care to reduce adverse events. Although we found a low risk of severe adverse events, the high volume of patients treated in the emergency department implies that potentially large numbers of patients could be severely affected. While the admitted population had

proportionately more adverse events, the discharged population had a higher degree of preventability. We hypothesize that strategies to reduce these events would be different for discharged and admitted patients.

While our findings are comparable to previous adverse event studies of inpatients, this thesis was unique in several ways. We studied the high acuity emergency department population and included both admitted and discharged patients. Patients were enrolled over randomly selected shifts to represent the 24 hour-a-day service provided by the emergency department. Unlike previous emergency adverse event studies, we utilized a structured adverse event detection approach based upon the validated Harvard Medical Practices study methodology.[2] As recommended by the emergency medicine literature, we employed peer emergency physicians to review the flagged outcomes. We also used three reviewers rather than one to increase the robustness of adverse event detection. This study was the first to try and correlate system factors with adverse events in the emergency department.

We conclude that patient safety deserves high priority in emergency medicine research and quality improvement initiatives. Much work remains to be done, including replicating the current results on a larger scale and confirming our hypotheses regarding admitted and discharged patients. We recommend that future studies focus on the discharged population who may benefit the most from preventative interventions. Future interventions to consider include increasing feedback to physicians, creating handover guidelines and incorporating the

electronic medical record into adverse event detection and clinical practice guideline implementation. The key to successfully implementing these interventions is measuring the impact upon adverse events. Only those demonstrating a clinically significant effect should be considered for broader implementation. By advancing emergency patient safety research, we can work towards achieving the goals of reducing patient morbidity and mortality, increasing health care provider morale and improving patient satisfaction with their health care experience.

LIST OF TABLES AND FIGURES

Figure A: Literature Search Strategy

Database: Ovid MEDLINE(R) <1966 to July Week 4 2004>
Search Strategy:

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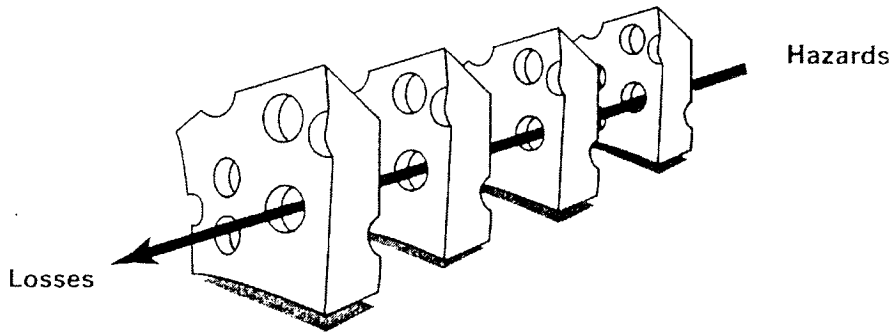
1 exp medical errors/ or diagnostic errors/ or medication errors/ or observer variation/ (42885)
2 Safety Management/ (3779)
3 (patient adj2 safety).tw. (3068)
4 (adverse adj2 (event$ or reaction$ or effect$)).tw. (84416)
5 ((medical or surgical or diagnostic or medication or procedur$) adj2 (mistake$ or error$)).tw. (4911)
6 malpractice/ (19535)
7 or/1-6 (151401)
8 exp emergency service, hospital/ or trauma centers/ (22468)
9 (emergency adj2 (service or unit or department or room)).tw. (21714)
10 Emergency Medical Services/ (17876)
11 or/8-10 (50101)
12 7 and 11 (2018)
13 limit 12 to english language (1882)

Figure B: The Swiss Cheese Model



Source: BMJ 2000[10]

Permission obtained from British Medical Journal Publishing for reproduction of this figure (see Appendix I)

Figure 1: Patient Flow

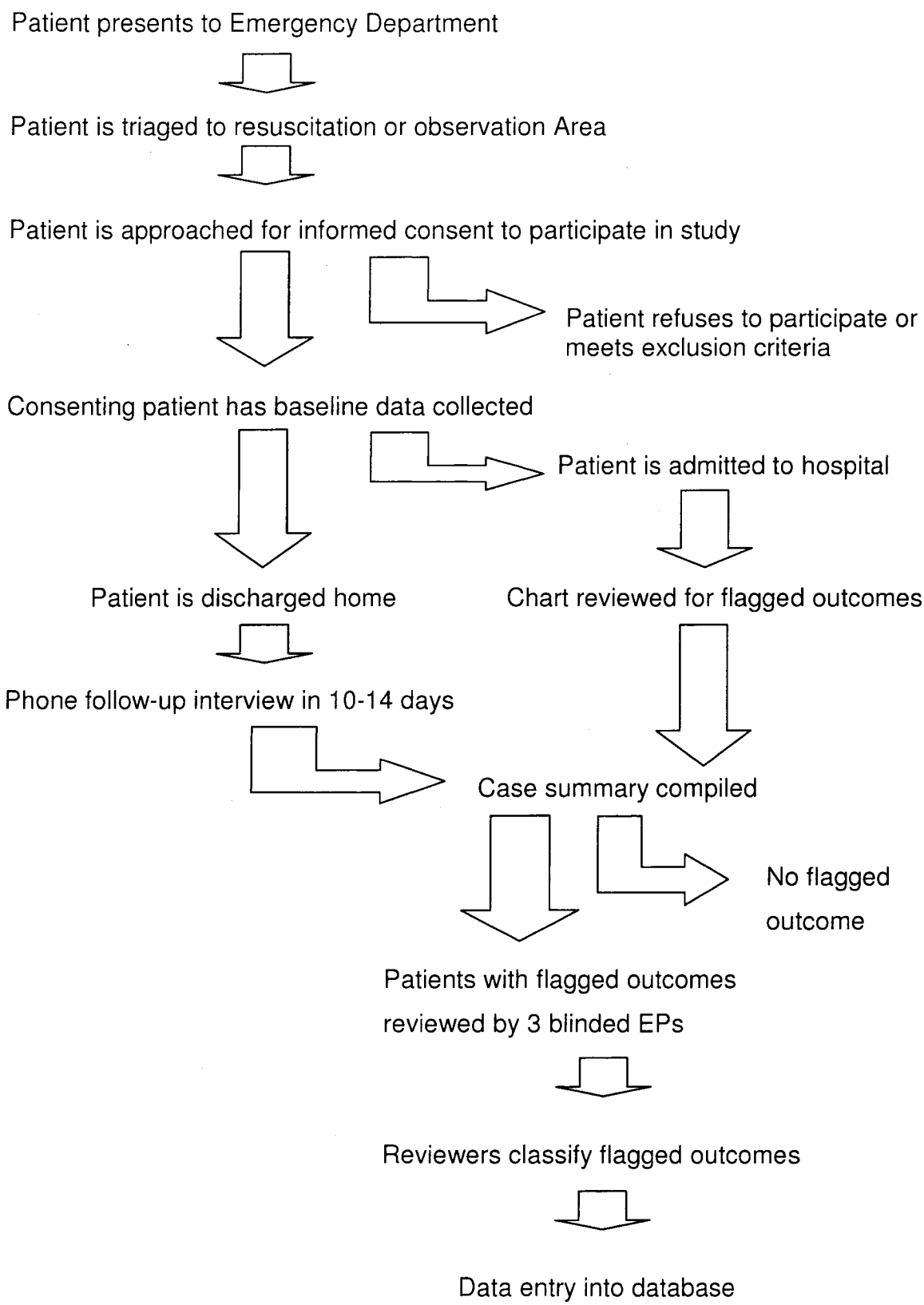


Figure 2: Enrolment Flow

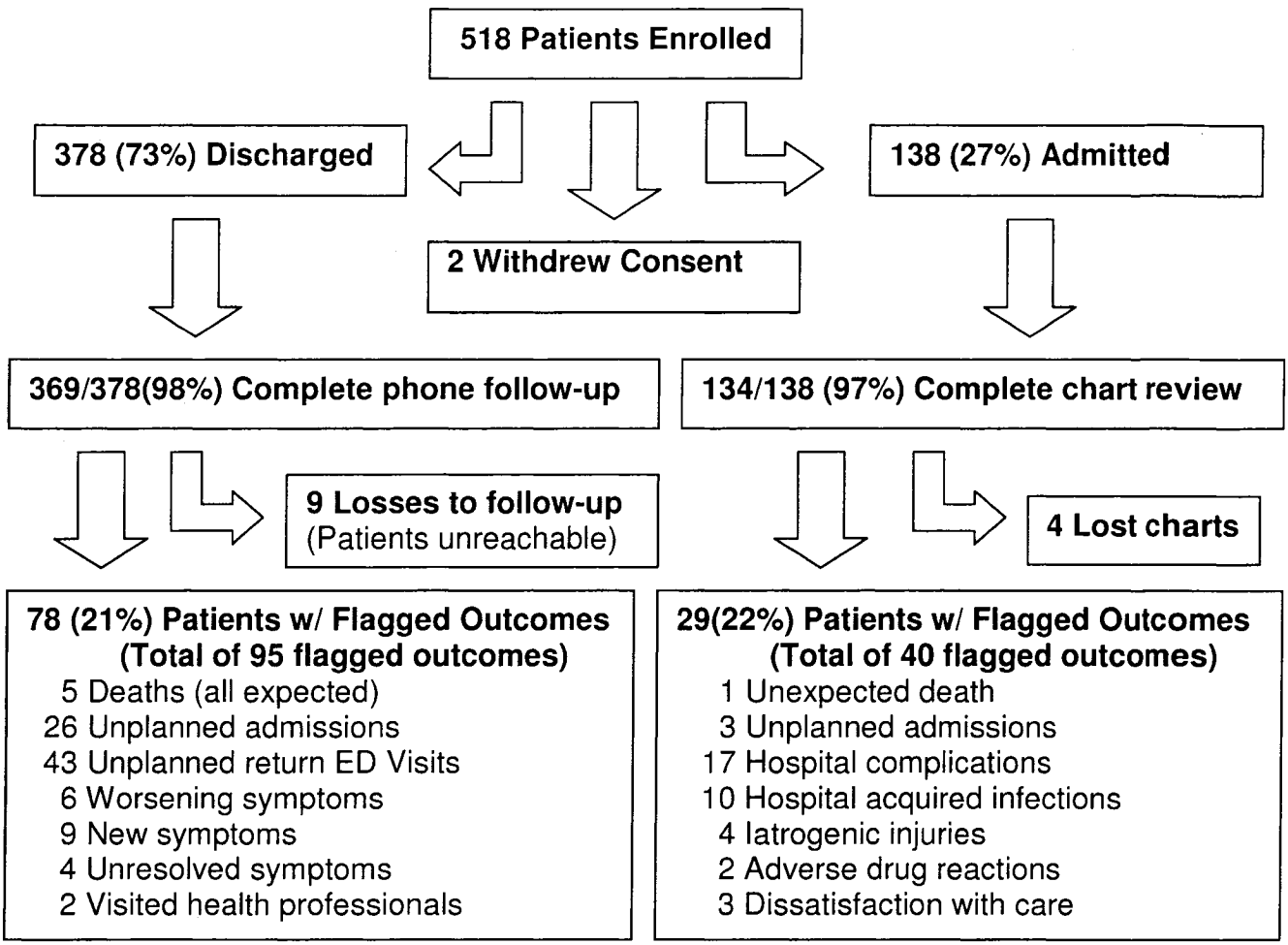


Figure 3: Definitions

Flagged outcome: the definition depends upon the status of the patient at the end of the emergency department visit:

- If *discharged* from the emergency department - patient experiences any of the following:
  - new/worsening symptoms
  - an unscheduled visit to an emergency department or health professional
  - an unscheduled admission to hospital
  - death
- If *admitted* to hospital from the emergency department - patient experiences any of the following:
  - unplanned transfer from another acute care hospital
  - unplanned transfer to acute monitoring area/ neuro-observation area/ intensive care unit
  - unplanned transfer/return to operating room
  - organ damage/removal during surgery
  - hospital complications
  - development of new neurological deficits during admission
  - hospital-acquired infection
  - hospital incurred accident or injury
  - adverse drug reaction

Figure 3: Definitions - continued

Adverse event: a flagged outcome associated with health care management

Preventable adverse event: an adverse event caused by a health care management problem such as a diagnostic issue, management issue, unsafe disposition decision or suboptimal follow-up

Diagnostic issue: not acting on documented signs, symptoms, laboratory tests or imaging or not ordering an indicated diagnostic test

Management issue: suboptimal management plan despite accurate diagnosis or based on an inaccurate diagnosis

Unsafe disposition decision: patient placed at unnecessary risk of experiencing death or major disability by being sent home

***Suboptimal follow-up*:** problems with follow-up arrangements led to the development of new symptoms, unnecessary prolongation of symptoms, an unscheduled return visit to the ED or a subsequent unscheduled hospitalization. (this could be due to inadequate availability of follow-up appointment, or due to inappropriate follow-up arrangements)

Medication adverse effect: patient experiences a symptom related to a medication regardless of whether the medication was appropriately prescribed or taken

Procedural complication: patient experiences adverse consequences of a procedure

Figure 4: Flow Diagram of Outcome Definitions

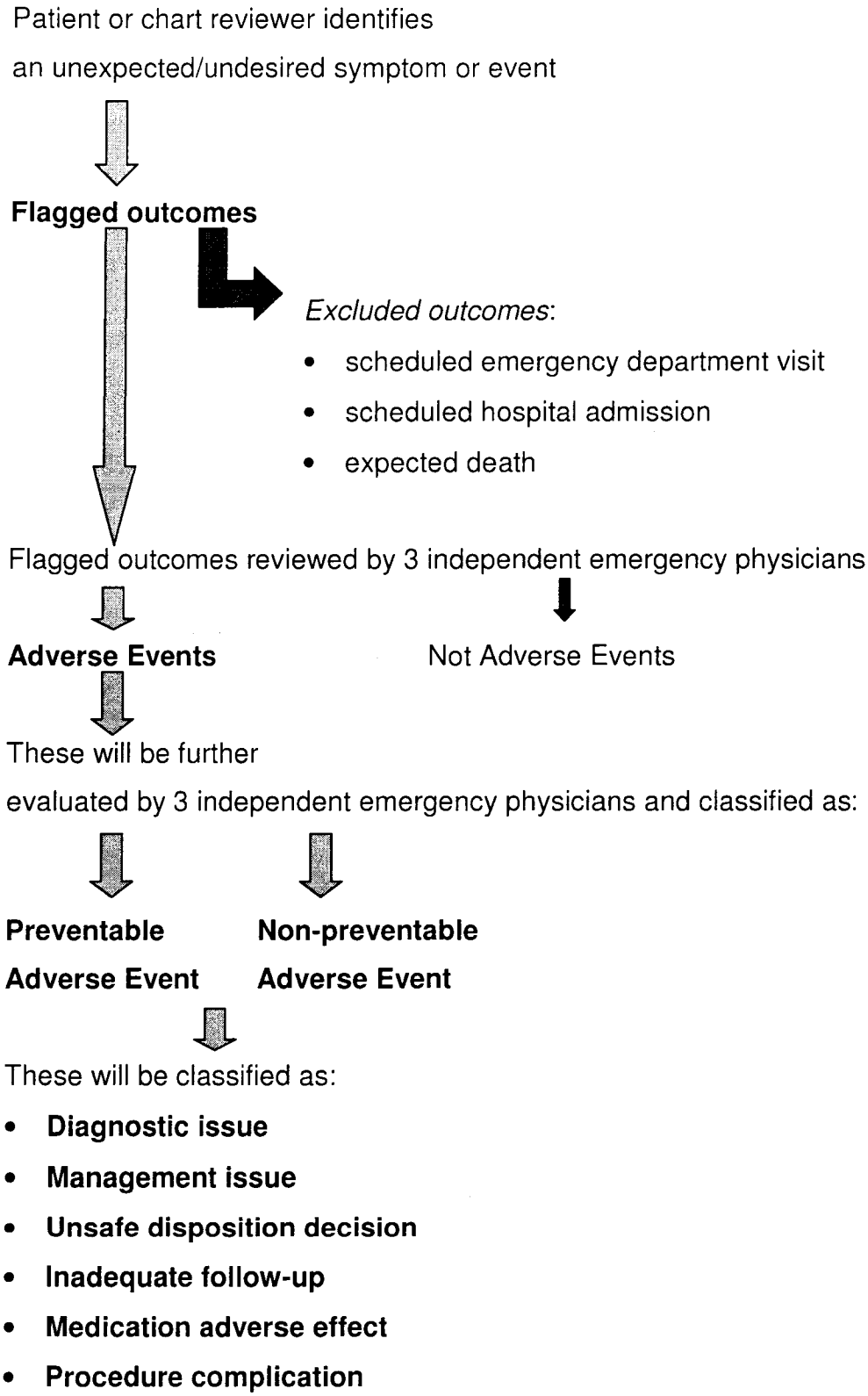


Figure 5: Reviewer Guidelines

1. Remember that a flagged outcome ≠ an adverse event.
    - Flagged outcomes are markers picked up in the review of all cases
    - An association with health care management is required for it to be an adverse event
    - Progression of disease is not an adverse event

2. Try and look at all cases from the patient rather than the physician's perspective
    - Remind yourself that we are interested in system issues, not blaming individual physicians

3. Try to consider the cases from a broad system perspective. i.e. avoid focusing only on ED care but all components of care

4. Think about what factors in the case are influencing your decision
    - i.e. if the management was different, would you still make the same judgement?

5. Bear in mind what is reasonable to have known at the index visit
    - This is retrospective, we have access to information that was not available initially

6. Expect uncertainty – you are not expected to say for certain that it is an adverse event, more to estimate the probability that it is one.

Table 1a: Baseline characteristics of patients enrolled - patient factors

	All patients (N=503)	Admitted (N=134)	Discharged (N=369)
PATIENT FACTORS			
Age (median, range)*	57, 18-98	64, 19-98	57, 18-94
Sex (% female)	254(50.5%)	68 (50.8%)	186 (50.4%)
Presenting complaints (top 5)			
Chest pain	137 (27.2%)	29 (21.6%)	108 (29.3%)
Weakness/dizziness	53 (10.5%)	13 (9.7%)	40 (10.8%)
Abdominal pain	46 (9.1%)	14 (10.4%)	32 (8.7%)
Shortness of breath	44 (8.7%)	14 (10.4%)	30 (8.1%)
Trauma	30 (6.0%)	8 (6.0%)	22 (6.0%)
Canadian Triage Acuity Score (CTAS)			
1 Resuscitation	5 (1.0%)	1 (0.8%)	4 (1.1%)
2 Emergent	224 (44.5%)	57 (42.5%)	167 (45.3%)
3 Urgent	243 (48.3%)	68 (50.7%)	175 (47.4%)
4-5 Less/Non-urgent	13 (2.6%)	7 (5.2%)	6 (1.6%)
Taking medications†	429 (85.6%)	115 (85.8%)	314 (85.1%)
Has chronic illnesses‡	391 (77.7%)	90 (67.7%)	301 (81.6%)
Discharge diagnostic categories (top 5)			
Cardiac	186 (37.0%)	39 (29.1%)	147 (39.8%)
Gastrointestinal	73 (14.5%)	21 (15.7%)	52 (14.1%)
Infection	40 (8.0%)	17 (12.7%)	23 (6.2%)
Neurological	35 (7.0%)	5 (3.7%)	30 (8.1%)
Trauma	28 (5.6%)	6 (4.5%)	22 (6.0%)

* age had a slightly skewed distribution to the older age groups - see Appendix H
† taking medications = patient was on at least one medication at presentation
‡ has chronic illnesses = patient had past medical history of at least one chronic illness

Table 1b: Baseline characteristics of patients enrolled - system factors

	All patients (N=503)	Admitted (N=134)	Discharged (N=369)
SYSTEM FACTORS			
Civic Campus	347 (69.0%)	98 (73.1%)	249 (67.5%)
Location in emergency department			
Resuscitation	186 (37.0%)	36 (26.9%)	150 (40.7%)
Observation	291 (57.9%)	81 (60.4%)	210 (56.9%)
Cubicles/corridor	26 (5.2%)	17 (12.7%)	9 (2.4%)
Number of emergency MDs involved in care			
1	459 (91.3%)	126(94.0%)	333 (90.2%)
2	38 (7.6%)	6 (4.5%)	32 (8.7%)
3	3 (0.6%)	0	3 (0.8%)
Number of patients waiting for beds *†			
0	98 (19.5%)	-	98 (26.6%)
1	79 (15.7%)	-	79 (21.4%)
2	105 (20.9%)	-	105 (28.5%)
4	27 (5.4%)	-	27 (7.3%)
5	26 (5.2%)	-	26 (7.0%)
6	9 (1.8%)	-	9 (2.4%)
8	12 (2.4%)	-	12 (3.3%)
Level of training of primary assessor			
Staff	245 (48.7%)	81(60.4%)	164 (44.4%)
Non-emergency medicine resident	111 (22.1%)	12 (9.0%)	99 (26.8%)
Emergency medicine resident	86 (17.1%)	22 (16.4%)	64 (17.3%)
Medical student	59 (11.7%)	18 (13.4%)	41 (11.1%)
Time of registration			
Day (0800-1600h)	243 (48.3%)	69 (51.5%)	174 (47.2%)
Evening (1600-0000h)	218 (43.3%)	51 (38.1%)	167 (45.3%)
Night (0000-0800h)	42 (8.3%)	14 (10.4%)	28 (7.6%)
Estimated waiting time (median, range)*‡	0.5h , 0-6h	-	0.9h, 0-6h

*Data were unavailable for admitted pts

†Number of patients waiting for beds = number of patients in emergency department admitted and awaiting inpatient beds at the time of enrolment

‡Estimated waiting time = ascertained from care facilitator registered nurse i.e. estimated waiting time for physician assessment when patient was enrolled in the study

Table 2: Proportion of adverse events, preventability and relation to emergency department care

	All patients (N=503)	Admitted (N=134)	Discharged (N=369)
Adverse events	43 (8.5%)	22 (16.4%)	21 (5.7%)
Preventable adverse events	24 (4.8%)	9 (6.7%)	15 (4.1%)
Attributable to emergency department care	25 (5.0%)	4 (3.0%)	21 (5.7%)

Table 3: Types of adverse event

Adverse Event Types*†	All patients with adverse events (N=43)	Admitted with adverse events (N=22)	Discharged with adverse events (N=21)
Management Issue	18 (41.9%)	8 (36.4%)	10 (47.6%)
Procedural Complication	13 (30.2%)	11 (50.0%)	2 (9.5%)
Diagnostic Issue	10 (23.3%)	3 (13.6%)	7 (33.3%)
Medication Adverse Effect	9 (20.9%)	6 (27.3%)	3 (14.3%)
Infection	6 (14.0%)	6 (27.3%)	0
Unsafe Disposition Decision	4 (9.3%)	0	4 (19.0%)
Suboptimal Follow-up	2 (4.7%)	0	2 (9.5%)
Fall	3 (7.0%)	2 (9.1%)	1 (4.8%)
TOTALS	65	36	29

*Some adverse events had more than one type; all are counted and reported here

†Definitions of adverse event types can be found in Figure 3

Table 4: Severity of adverse events

Severity*	All patients with adverse events (N=43)	Admitted with adverse events(N=22)	Discharged with adverse events (N=21)
Lab abnormality requiring treatment	6 (14.0%)	6 (27.3%)	0
Up to 1 day of symptoms	18 (41.9%)	8 (36.4%)	10 (47.6%)
More than 1 day of symptoms	16 (37.2%)	7 (31.8%)	9 (42.9%)
Non-permanent disability	1 (2.3%)	0	1 (4.8%)
Permanent disability	1 (2.3%)	0	1 (4.8%)
Death	1 (2.3%)	1 (4.5%)	0

*Note, if a patient had multiple severity classes only the most severe was counted

Table 5: Response to adverse event

Response*	All patients with adverse events (N=43)	Admitted with adverse events (N=22)	Discharged with adverse events (N=21)
Symptoms only (no treatment)	10 (23.3%)	8 (36.4%)	2 (9.5%)
Required medical/surgical intervention	20 (46.5%)	19 (86.4%)	1 (4.8%)
Visit to MD office	2 (4.7%)	n/a	2 (9.5%)
Emergency department visit	4 (9.3%)	n/a	4 (19.0%)
Admission to hospital	12 (27.9%)	n/a	12 (57.1%)
Death	1 (2.3%)	1 (4.5%)	0
TOTALS	49	28	21

*Note, if a patient had multiple response classes only the most severe was counted; however, if a patient had multiple adverse events, all are reported here

Table 6: Examples of adverse event type

Adverse Event Type*	Index Emergency Department Visit	Outcome
Management Issue	49 year old patient with history of coronary artery disease, diabetes and hypertension presented with pleuritic chest pain radiating to left shoulder. Treated with morphine and gravol. EKG, CXR, d-dimer all negative. Initial troponin T 0.04, repeat 4 hours later 0.01. Discharged as atypical chest pain with a question of angina.	Eleven days later awoke in night acutely short of breath. Presented with fever and diffuse edema despite increasing lasix themselves night previous. Admitted with CHF and underwent triple bypass surgery 3 weeks later complicated by renal failure, respiratory failure, pneumonia, cholecystitis and leg ulcers resulting in prolonged hospital stay.
Procedural Complication	80 year old patient presented with chest pain intermittently over a few days relieved by nitro but some present at rest. Admitted with unstable angina and underwent cardiac catheterization 5 days later which revealed severe diffuse disease.	Coronary bypass surgery performed 3 days after angiography without difficulty. Next day patient developed anemia secondary to post-operative hemorrhage and was transfused 3 units of blood.
Diagnostic Issue	55 year old patient presented to peripheral hospital ED with 10/10 chest pain similar to usual angina unrelieved by nitroglycerin. Nurse notes pain radiates to back. EKG unremarkable and troponin was positive. Admitted with unstable angina and treated with heparin. Cardiologist notes systolic and diastolic murmur. Next day cardiologist recommended angiography which patient refused - left against medical advice. Presented to TOH ED few hours later. Physician notes blood pressures were unequal in each arm at peripheral hospital but unclear if these were repeated. Nurse notes chest pain 1/10 radiating to back with left sided weakness and numb all over. EKG showed inferior ST deviation and CXR noted as nil acute. Cardiology referral made with diagnosis of rule out acute coronary syndrome.	Five hour delay between emergency physician consultation and cardiology assessment. Senior cardiologist performed bedside echo 7 hours after consultation requested and diagnosed an ascending aortic dissection with a flap extending to the abdominal aorta. Patient treated with metoprolol, nitroprusside. Referred the following day to cardiac surgery and taken to the operating room - difficulties coming of cardiac bypass pump - chest was left open and closed 48 hours later. 4 days later sudden respiratory distress and high lactate, suspected dissection of gut vessels and severe ischemia leading to death.

*Definitions are found in Figure 3

Adverse Event Type	Index Emergency Department Visit	Outcome
Medication Adverse Effect	28 year old patient presented with one week of confusion. Had recent change in psychiatric medications and also recently started on steroids for asthma exacerbation. Patient found to be hyperglycemic and treated with IV insulin infusion. Steroids were discontinued and psychiatric drug dosing reduced.	Patient became hypokalemic shortly after insulin initiated. Initial K was 3.5, then 3.0 before KCl elixir initiated.
Nosocomial Infection	69 year old patient recently diagnosed with squamous cell carcinoma of the esophagus presented with dysphagia. Admitted for esophageal resection.	Total esophagectomy with gastric pull-up performed 5 days later. 1 week later developed sinus tachycardia and noted to have purulent fluid draining from surgical wound. Cultures grew Candida and Peptostreptococcus. Patient was treated with Vancomycin, Pip/taxo and underwent endoscopy. Patient recovered over next month.
Unsafe Disposition Decision	70 year old patient with history of chronic obstructive pulmonary disease and coronary artery disease presented with increasing shortness of breath, chest pain and fever. Noted to be in moderate respiratory distress (RR 36 SaO2 97% R/A) and wheezing at bases. Treated with Ventolin & Atrovent with improvement. No acute changes on EKG/CXR. Discharged as COPD exacerbation on Ventolin, Atrovent and Symbicort.	Returned 8 hours later in severe respiratory distress requiring BiPAP, Ventolin, Solumedrol. Had a pCO2 of 81 and pH of 7.19. Was admitted to hospital and treated with BiPAP for 48 hours, antibiotics and steroids. Discharged from hospital 10 days later.
Suboptimal Follow-up	53 year old patient with history of smoking, hypertension and coronary artery disease. Presented with left arm tingling, weakness and throbbing associated with chest tightness. Decreased strength and reflexes in left arm. CT head, CXR and EKG all negative. Cardiac enzymes drawn at presentation negative. Discharged as left arm weakness not yet diagnosed for neurology follow-up in 2-3 weeks.	On phone follow-up 2 weeks later patient stated left arm weakness and numbness had worsened such that they are unable to work. Had not yet received neurology follow-up appointment.

Adverse Event Type	Index Emergency Department Visit	Outcome
Fall	98 year old patient presented feeling generally unwell and short of breath. Diagnosed with NSTEMI, congestive heart failure and renal failure.	No documentation if universal fall precautions in place in ED or on ward. Next day patient fell in bathroom - nurse found patient on floor with IV pulled out and patient being very confused and frightened. No injury occurred. Fall deemed multifactorial - related to poor vision and physical deconditioning. Physio and occupational therapy initiated and fall precautions instituted.

Table 7a: Patient factor characteristics of those with adverse events vs. all patients enrolled

	Patients with Adverse Events (N=43)	All patients enrolled in study (503)
Age (median, range)	56, 23-98	57, 18-98
Sex (% female)	23 (53.5%)	254(50.5%)
Presenting complaint (top 5)		
Chest pain	7 (16.3%)	137 (27.2%)
Shortness of breath	7 (16.3%)	46 (9.1%)
Weakness	5 (11.6%)	53 (10.5%)
Abdominal pain	4 (9.3%)	44 (8.7%)
Trauma	3 (7.0%)	30 (6.0%)
Canadian Triage Acuity Score (CTAS)		
1 Resuscitation	0	5 (1.0%)
2 Emergent	22 (51.2%)	224 (44.5%)
3 Urgent	20 (46.5%)	243 (48.3%)
4-5 Less/Non-urgent	0	13 (2.6%)
Taking medications*	39 (90.7%)	429 (85.3%)
Has chronic illnesses†	35 (81.4%)	391 (77.7%)
Discharge Diagnostic Categories (top 5)		
Cardiac	12 (27.9%)	186 (37.0%)
Gastrointestinal	6 (14.0%)	73 (14.5%)
Infection	5 (11.6%)	40 (8.0%)
Neurological	3 (7.0%)	35 (7.0%)
Trauma	3 (7.0%)	28 (5.6%)

* taking medications = patient was on at least one medication at presentation
† has chronic illnesses = patient had past medical history of at least one chronic illness

Table 7b: Univariate analysis of patient factors for adverse events

Patient Characteristic	Patients with adverse events (N=43)	Patients without adverse events (N=460)	Chi square test statistic, P value
Age			
20-40	11 (25.6%)	99 (21.5%)	
41-60	13 (30.2%)	153 (33.3%)	
61-80	12 (27.9%)	143 (31.1%)	
81-100	7 (16.3%)	60 (13.0%)	0.8315, p=0.8419
Gender			
Female	23 (53.5%)	231 (50.2%)	
Male	20 (46.5%)	229 (49.8%)	0.1683, p=0.6816
Presenting Complaint*† (top 5)			
Chest Pain	7 (16.2%)	130 (28.3%)	
Shortness of breath	7 (16.2%)	37 (8.0%)	
Weakness	5 (11.6%)	25 (5.3%)	
Abdominal pain	4 (9.3%)	42 (9.1%)	
Trauma	3 (7.0%)	27 (5.9%)	6.8920, p=0.1417
Canadian Triage Acuity Score*‡			
1 Resuscitation	0	5 (1.1%)	
2 Emergent	22 (51.2%)	202 (43.9%)	
3 Urgent	20 (46.5%)	223 (48.5%)	
4-5 Less/Non-urgent	0	13 (2.8%)	0.3140 p=0.2974
Taking medications			
Yes	39 (90.7%)	390 (84.8%)	
No	4 (9.3%)	68 (14.8%)	0.9821, p=0.3217
Has chronic illnesses			
Yes	35 (81.4%)	356 (77.4%)	
No	8 (18.6%)	103 (22.4%)	0.3358, p=0.5622
Discharge Diagnosis*† (top 5)			
Cardiac	12 (27.9%)	173 (37.6%)	
Gastrointestinal	6 (14.0%)	66 (14.3%)	
Infection	5 (11.6%)	35 (7.6%)	
Neurological	3 (7.0%)	31 (6.7%)	
Trauma	3 (7.0%)	25 (5.4%)	1.1717, p=0.2791

*Because of low numbers in cells the Mantel-Hanzel chi square value was used
† Not all patients are represented in this category as only the 5 most common types of presenting complaints are displayed (the same is true for discharge diagnoses)
‡When zero cells were removed the p value was still not significant (p=0.5482)

Table 7c: Univariate analysis of patient factors for *preventable* adverse events

Patient Characteristic	Patients with preventable adverse events (N=24)	Patients with non-preventable adverse events (N=19)	Chi square test statistic, P value
Age*			
20-40	9 (37.5%)	2 (10.5%)	
41-60	8 (33.3%)	5 (26.3%)	
61-80	4 (16.7%)	8 (42.1%)	
81-100	3 (12.5%)	4 (21.1%)	4.7030, p=0.030
Gender			
Female	14 (58.3%)	10 (52.6%)	
Male	10 (41.7%)	10 (52.6%)	0.5125, p=0.474
Presenting Complaint*†			
Chest Pain	5 (20.8%)	2 (10.5%)	
Shortness of breath	2 (8.3%)	5 (26.3%)	
Abdominal pain	2 (8.3%)	2 (10.5%)	
Weakness/neuro Sx	1 (4.2%)	4 (21.1%)	
Trauma	2 (8.3%)	1 (5.3%)	1.4027, p=0.2363
Canadian Triage Acuity Score (CTAS)			
1 Resuscitation	0	0	
2 Emergent	14 (58.3%)	8 (42.1%)	
3 Urgent	10 (41.7%)	10 (52.6%)	0.7995, p=0.375
4-5 Less/Non-urgent	0	0	
Discharge Diagnosis*			
Cardiac	7 (29.2%)	5 (26.3%)	
Infection	2 (8.3%)	3 (15.8%)	
Neurological	2 (8.3%)	1 (5.3%)	
Trauma	2 (8.3%)	1 (5.3%)	
Gastrointestinal	5 (20.8%)	1 (5.3%)	0.0001, p=0.9924

*because of low numbers in cells the Mantel-Hanzel chi square value was used
† Not all patients are represented in this category as only the 6 most common types of presenting complaints are displayed (the same is true for discharge diagnoses)

Table 8a: System factor characteristics of those with adverse events vs. all patients enrolled

	Patients with Adverse Events (N=43)	All patients enrolled (N=503)
SYSTEM FACTORS		
Civic Campus	28 (65.1%)	347 (69.0%)
Location in emergency department		
Resuscitation	11 (25.6%)	186 (37.0%)
Observation	27 (62.8%)	291 (57.9%)
Cubicles/corridor	5 (11.6%)	26 (5.2%)
Number of emergency MDs involved in care		
1	42 (97.7%)	462 (91.8%)
2	1 (2.3%)	38 (7.6%)
3	0	3 (0.6%)
Number of patients waiting for beds*		
0	5 (11.6%)	98 (19.5%)
1	1 (2.3%)	79 (15.7%)
2	13 (30.2%)	105 (20.9%)
4	1 (2.3%)	27 (5.4%)
5	0	26 (5.2%)
6	0	9 (1.8%)
8	0	12 (2.4%)
Level of training of primary assessor		
Staff	26 (60.5%)	245 (48.7%)
Non-emergency medicine resident	10 (23.3%)	111 (22.1%)
Emergency Medicine resident	1 (2.3%)	86 (17.1%)
Medical student	6 (14.0%)	59 (11.7%)
Time of Registration		
Day (0800-1600h)	24 (55.8%)	243 (48.3%)
Evening (1600-0000h)	16 (37.2%)	218 (43.3%)
Night (0000-0800h)	3 (7.0%)	42 (8.3%)
Estimated Waiting Time (median, range)	0h, 0-4.8h	0.5h , 0-6h

* 50% of data missing for adverse events and 27% missing for all enrolled patients as data was not collected for admitted patients

Table 8b: Univariate analysis of system factors for adverse events

System Factor	Patients with adverse events (N=43)	Patients without adverse events (N=460)	Chi square test statistic, P value
Campus			
Civic	28 (65.1%)	319 (69.3%)	
General	15 (34.9%)	141 (30.7%)	0.3291, p=0.5662
Location in emergency department			
Resuscitation	11 (25.6%)	175 (38.0%)	
Observation	27 (62.8%)	264 (57.4%)	
Cubicles/corridor	5 (11.6%)	21 (4.6%)	5.6446, p=0.0595
Number of emergency MDs involved in care*			
1	42 (97.7%)	417 (90.7%)	
2-3	1 (2.3%)	40 (8.7%)	2.1524, p=0.1423
Number of patients waiting for beds †			
0-1	6 (14.0%)	171 (37.2%)	
2-8	14 (32.6%)	165 (35.9%)	3.2960, p=0.0694
Level of training of primary assessor			
Staff	26 (60.5%)	219 (47.6%)	
Non-emergency medicine resident	10 (23.3%)	101 (22.0%)	
Emergency medicine resident	1 (2.3%)	85 (18.5%)	
Medical student	6 (14.0%)	53 (11.5%)	7.5357, p=0.0566
Time of Registration			
Day (0800-1600h)	24 (55.8%)	219 (47.6%)	
Evening (1600-0000h)	16 (37.2%)	202 (43.9%)	
Night (0000-0800h)	3 (7.0%)	39 (8.5%)	1.0620, p=0.5880
Estimated Waiting Time*			
0-2h	36 (83.7%)	395 (85.9%)	
2-5h	3 (7.0%)	49 (10.7%)	0.4164, p=0.5188

*because of low numbers in cells the Mantel-Hanzel chi square value was used
†50% of data were missing for this variable (for all admitted patients)

Table 8c: Univariate analysis of system factors for *preventable* adverse events

System Factor	Patients with preventable adverse events (N=24)	Patients with non-preventable adverse events (N=19)	Chi square test statistic, P value
Campus			
Civic	16 (66.7%)	12 (63.2%)	
General	8 (33.3%)	7 (36.8%)	0.0575, p=0.811
Location in emergency department*			
Resuscitation	7 (29.2%)	4 (21.1%)	
Observation	15 (62.5%)	12 (63.2%)	
Cubicles/corridor	2 (8.3%)	3 (15.8%)	0.7121, p=0.399
Number of emergency MDs involved in care*			
1	24 (100.0%)	18 (94.7%)	
2	0	1 (5.3%)	1.2632, p=0.255
Number of patients waiting for beds* †			
0-1	3 (12.5%)	3 (15.8%)	
2-4	11 (45.8%)	3 (15.8%)	1.5510, p=0.213
Level of training of primary assessor*			
Staff	15 (62.5%)	11 (57.9%)	
Non-emergency medicine resident	5 (20.8%)	5 (26.3%)	
Emergency medicine resident	1 (4.2%)	0	
Medical student	3 (12.5%)	3 (15.8%)	0.2075, p=0.649
Time of Registration*			
Day (0800-1600h)	12 (50.0%)	12 (63.2%)	
Evening (1600-0000h)	10 (41.7%)	6 (31.6%)	
Night (0000-0800h)	2 (8.3%)	1 (5.3%)	0.7005, p=0.403
Estimated Waiting Time			
0-2h	18 (75.0%)	18 (94.7%)	
2-5h	0	3 (15.8%)	2.7143, p=0.100

*because of low numbers in cells the Mantel-Hanzel chi square value was used
†50% of data were missing for this variable

Table 9a: Multivariate analysis for patient risk factors - adverse event vs. no adverse event

Significant Variable	Odds Ratio	95%CI	Goodness of fit p value*
Patient Risk Factors			
Presenting complaint			1.00
Chest pain	0.59	(0.23, 1.47)	
Shortness of breath	2.06	(0.79, 5.36)	
Abdominal pain	1.04	(0.33, 3.26)	
Weakness/neuro symptoms	2.18	(0.73, 6.46)	
Palpitations	0.44	(0.06, 3.42)	
Trauma	1.21	(0.33, 4.43)	

*Hosmer-Lemeshow goodness of fit test was used

Table 9b: Multivariate analysis for patient risk factors - *preventable* adverse events

Significant Variable	Odds Ratio	95%CI
Patient Risk Factors		
Age	0.97	(0.94, 0.99)
Presenting complaint		
Chest pain	1.04	(0.15, 7.28)
Shortness of breath	0.17	(0.02, 1.16)
Abdominal pain	0.42	(0.05, 3.84)
Weakness/neuro symptoms	0.10	(0.01, 1.18)
Trauma	0.83	(0.06, 11.42)
Discharge diagnosis		
Cardiac	1.87	(0.39, 8.89)
Infection	0.89	(0.11, 7.11)
Neurological	2.67	(0.19, 36.76)
Trauma	2.67	(0.19, 36.76)
Gastrointestinal	6.67	(0.61, 73.02)

Table 9c: Multivariate analysis for system risk factors - adverse event vs. no adverse event

Significant Variable	Odds Ratio	95%CI	Goodness of fit p value*
System Risk Factors			
Location in emergency department			-†
Resuscitation	0.17	(0.02, 1.80)	
Observation	0.70	(0.08, 5.92)	
No. patients waiting for beds	1.55	(0.95, 2.53)	-†
Level of training of primary assessor			1.00
Staff	1.30	(0.27, 6.19)	
Emergency medicine resident	0.31	(0.03, 3.55)	
Non-emergency medicine resident	1.48	(0.29, 7.44)	

*Hosmer-Lemeshow goodness of fit test was used

†Because of low cell numbers (<5 in one group), the goodness of fit statistic could not be calculated

N.B. Number emergency physicians involved in care was excluded because of low numbers in the adverse event cells

Table 9d: Multivariate analysis for system risk factors - preventable adverse events

Significant Variable	Odds Ratio	95%CI
System Risk Factors†		
Estimated waiting time	1.51	(0.68, 3.35)

†Despite the fact that the number of patients waiting for beds met the p<=0.25 cut-off, this variable was excluded as 50% of the data for this variable were missing. The number of emergency physicians involved in the patients care was also excluded because of a low cell count of 1 for the only other category >1

Table 9e: Multivariate analysis for patient and system risk factors - preventable adverse events

Significant Variable	Odds Ratio	95%CI
Combining patient & system factors		
Age & estimated waiting time		
Age	1.03	(0.99, 1.07)
Estimated waiting time	0.70	(0.33, 1.52)

Table 10a: Baseline characteristics of patients with adverse events - patient factors

	Patients with adverse events (N=43)	Admitted patients with adverse events(N=22)	Discharged patients with adverse events(N=21)
PATIENT FACTORS			
Age (median, range)	56, 23-98	70, 23-98	53, 24-82
Sex (% female)	23 (53.5%)	13 (59.1%)	10 (47.6%)
Presenting complaint (top 5)			
Chest pain	7 (16.3%)	4 (18.2%)	3 (14.3%)
Shortness of breath	7 (16.3%)	4 (18.2%)	3 (14.3%)
Abdominal pain	4 (9.3%)	2 (9.1%)	2 (9.5%)
Trauma	3 (7.0%)	3 (13.6%)	0
Weakness	5 (11.6%)	3 (13.6%)	2 (9.5%)
Canadian Triage Acuity Score			
1 Resuscitation	0	0	0
2 Emergent	22 (51.2%)	11 (50.0%)	11 (52.4%)
3 Urgent	20 (46.5%)	11 (50.0%)	9 (42.9%)
4-5 Less/Non-urgent	0	0	0
Taking medications	39 (90.7%)	20 (90.9%)	19 (90.5%)
Has chronic illnesses	35 (81.4%)	16 (72.7%)	19 (90.5%)
Discharge Diagnostic Categories (top 5)			
Cardiac	12 (27.9%)	8 (36.4%)	4 (19.0%)
Gastrointestinal	6 (14.0%)	3 (13.6%)	3 (14.3%)
Infection	5 (11.6%)	1 (4.5%)	4 (19.0%)
Neurological	3 (7.0%)	0	3 (14.3%)
Trauma	3 (7.0%)	3 (13.6%)	0

Table 10b: Baseline characteristics of patients with adverse events - system factors

	Patients with adverse events (N=43)	Admitted patients with adverse events(N=22)	Discharged patients with adverse events (N=21)
SYSTEM FACTORS			
Civic Campus	28 (65.1%)	15 (68.2%)	13 (61.9%)
Location in emergency department			
Resuscitation	11 (25.6%)	7 (31.8%)	4 (19.0%)
Observation	27 (62.8%)	11 (50.0%)	16 (76.2%)
Cubicles/corridor	5 (11.6%)	4 (18.2%)	1 (4.8%)
Number of emergency MDs involved in care			
1	42 (97.7%)	21 (95.5%)	21 (100.0%)
2	1 (2.3%)	1 (4.5%)	0
Number of patients waiting for beds *			
0	5 (11.6%)	-	5 (23.8%)
1	1 (2.3%)	-	1 (4.8%)
2	13 (30.2%)	-	13 (61.9%)
4	1 (2.3%)		1 (4.8%)
Level of training of primary assessor			
Staff	26 (60.5%)	15 (68.2%)	11 (52.4%)
Non-EM resident	10 (23.3%)	3 (13.6%)	7 (33.3%)
EM resident	1 (2.3%)	0	1 (4.8%)
Med student	6 (14.0%)	4 (18.2%)	2 (9.5%)
Time of Registration			
Day (0800-1600h)	24 (55.8%)	12 (54.5%)	12 (57.1%)
Evening (1600-0000h)	16 (37.2%)	9 (40.9%)	7 (33.3%)
Night (0000-0800h)	3 (7.0%)	1 (4.5%)	2 (9.5%)
Estimated Waiting Time (median, range)*	0h, 0-4.8h	-	0.75h, 0-4.8h

*data was unavailable for admitted pts

Table 11: Agreement among reviewers for all flagged outcomes

Outcome Rated as an Adverse Event			Frequency n (%) (N= 135)
Reviewer 1	**Reviewer 2**	**Reviewer 3**	
Yes	Yes	Yes	18 (13.3%)
Yes	Yes	No	15 (11.1%)
Yes	No	Yes	7 (5.2%)
Yes	No	No	38 (28.1%)
No	Yes	Yes	2 (1.5%)
No	Yes	No	6 (4.4%)
No	No	Yes	2 (1.5%)
No	No	No	47 (34.8%)

APPENDICES

Appendix A: Sample Size Calculation

The Ottawa Hospital Civic site had 45,595 patients seen and discharged from April 2003 to March 2004. The Ottawa Hospital General site had 45,503. The sample size calculation was based on the Civic site and assuming that 40% of the patients seen and discharged were assessed in the resuscitation/observation area. This would result in 18,238 patients. The sample size for each stratum was calculated taking into account the differential cost for collecting data for each time stratum and assuming variance was fixed for each stratum.

The strata were:

- Days (D) 0800-1600h
- Evenings (E) 1600-0000h
- Modified night (N) shifts (1800-0200h or 0700-1500h)
- Weekends (W) Saturday and Sunday

An independent random sample shall be drawn for each stratum in order to maintain the following proportion: D:E:N:W = 2:6:1:1

The following assumptions were made:

- the estimated proportion of adverse events ($\hat{p}$)of 0.06 (6% as documented in the pilot study) , where $\hat{q} = 1 - \hat{p} = 0.94$
- the bound on the error estimate (B) is 0.02 (2%)
- the cost for collecting data for each stratum is differential such that evenings, nights and weekends are more expensive. The following estimates were made regarding the relative costs of these time periods:
    - days, cost (c_1) = 1
    - evenings, cost (c_2)= 1.5

- nights, cost (c_3)= 2
- weekends, cost (c_4)= 2

i.e. collecting data in the evening costs 1.5 times collecting data during the day, while collecting data at night or on the weekend costs twice as much as during the day

The sample size calculations were performed utilizing the formula for stratified random samples to estimate proportions described by Scheaffer et al.[62]

$$n = \frac{\sum_{i=1}^{4} \frac{N_i^2 \hat{p}_i \hat{q}_i}{w_i}}{N^2 D + \sum_{i=1}^{4} N_i \hat{p}_i \hat{q}_i}$$

If N=18,238 (40% of patients discharged in one year at the Civic site), then to divide this population proportionally among our time strata:

N_1 (days) = 20% = 3,647

N_2 (evenings) = 60% = 10,942

N_3 (nights) = 10% = 1,823

N_4 (weekends) = 10% = 1,823

then

$$\sum_{i=1}^{4} N_i \sqrt{\hat{p}_i \hat{q}_i / c_i} = \left[3,,647\sqrt{(0.06)(0.94)/1}\right] + \left[10,942\sqrt{(0.06)(0.94)/1.5}\right] + 2\left[1,823\sqrt{(0.06)(094)/2}\right]$$

$$= 866.1 + 2,121.7 + 612.3$$

$$= 3,600.1$$

and

$$n_i = n\frac{N_i\sqrt{\hat{p}_i\hat{q}_i / c_i}}{\sum_{i=1}^{4} N_i\sqrt{\hat{p}_i\hat{q}_i / c_i}}$$

$$n_1 = n\frac{866.1}{3{,}600.1} = n(0.24)$$

$$n_2 = n\frac{2121.7}{3{,}600.1} = n(0.59)$$

$$n_3 = n\frac{306.2}{3{,}600.1} = n(0.09)$$

$$n_4 = n\frac{306.2}{3{,}600.1} = n(0.09)$$

Thus w_1=0.24 w_2=0.59 w_3=0.09 w_4=0.09

$$\sum_{i=1}^{4}\frac{N_i^{\,2}\hat{p}_i\hat{q}_i}{w_i} = \left[\frac{(3{,}647)^2(0.06)(0.94)}{0.24}\right] + \left[\frac{(10{,}942)^2(0.06)(0.94)}{0.59}\right] + 2\left[\frac{(1{,}823)^2(0.06)(0.94)}{0.09}\right]$$

$$= 3{,}125{,}643.1 + 11{,}445{,}124.3 + 4{,}165{,}239.0$$

$$= 18{,}736{,}006.4$$

$$\sum_{i=1}^{4} N_i\hat{p}_i\hat{q}_i = [(3{,}647)(0.06)(0.94)] + [(10{,}942)(0.06)(0.94)] + 2[(1{,}823)(0.06)(0.94)]$$

$$= 205.7 + 617.1 + 205.6$$

$$= 1{,}028.4$$

$$D = \frac{B^2}{4} = \frac{(0.02)^2}{4} = 0.0001$$

$$N^2D = (18{,}238)^2(0.0001) = 33{,}262.5$$

Finally

$$n = \frac{\sum_{i=1}^{4} \frac{N_i^2 \hat{p}_i \hat{q}_i}{w_i}}{N^2 D + \sum_{i=1}^{4} N_i \hat{p}_i \hat{q}_i} = \frac{18{,}736{,}006.4}{33{,}262.5 + 1{,}028.4} = 546.4$$

and

$$n_1 = n(0.24) = (546.4)(0.24) = 131$$

$$n_2 = n(0.59) = 322$$

$$n_3 = n(0.09) = 49$$

$$n_4 = n(0.09) = 49$$

In summary, the sample sizes for each time stratum (for both sites) were:

5. days (0800-1600h) – 131
6. evenings (1600-0000h) – 322
7. nights (0000-0800h) – 49
8. weekends – 49

Therefore the expected sample size for one site is 551, and for two sites was 1102.

Appendix B: Consent Form

OTTAWA HEALTH RESEARCH INSTITUTE

INSTITUT DE RECHERCHE EN SANTE D'OTTAWA

AN INSTITUTE OF • UN INSTITUT DE

Information and Consent Form

Improving Emergency Department After-Care Study

Investigators: Dr. Lisa Calder, Dr. Ian Stiell, Dr. Alan Forster

The goal of the "Improving Emergency Department After-Care Study" is to improve patient care after patients go home from the Emergency Department. In particular, the investigators wish to identify potentially preventable problems related to heath care delivery. These problems can sometimes become noticeable after patients leave the Emergency Department.

If you agree to participate in this study, we will review your medical record (emergency room chart and any records of subsequent hospitalizations) and perform a brief telephone interview approximately 10-14 days after your emergency room visit. The main purpose of the interview is to find out how you are doing. It will take approximately 5 minutes to complete and we will call you at a time that is convenient for you. You will not be needed to do anything else for this study. If you choose not to participate, this decision will in no way impact upon your health care in the emergency department. You can withdraw from the study at any time.

There are no direct benefits to you for participating in the study. However, if we identify that you are having a problem when we telephone you, then we will refer you to the appropriate health care provider (your family doctor or the emergency department). We will ensure that all the information you provide will remain confidential.

Thank you for considering participation in our research study. We believe it will help improve the health care of patients like you. If you have any questions or comments regarding the study, please contact the principal investigator, Dr. Lisa Calder, through her pager at (613)368-6095.

☐ I agree to participate in this study

Name of Patient (please print)	Signature	Date
Home phone number	Alternate phone number	
Best time to call #1	Best time to call #2	Best time to call #3
Name of investigator/delegate	Signature	Date

Appendix C: Baseline Data Collection Form

Form Name: ED_after_care2**

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Field: 1	Last_name	Parameters:	Field Type: Freeform text
Field: 2	First_name	Parameters:	Field Type: Freeform text
Field: 3	MRN	Parameters:	Field Type: Numeric
Field: 4	MRN2	Parameters:	Field Type: Numeric
Field: 5	Campus	Parameters: Civic General	Field Type: Popup list
Field: 6	Year_of_Birth	Parameters:	Field Type: Numeric
Field: 7	Month_of_Birth	Parameters:	Field Type: Numeric
Field: 8	Day_of_Birth	Parameters:	Field Type: Numeric
Field: 9	Gender (1=Female, 0=Male)	Parameters:	Field Type: Numeric
Field: 10	Phone_number1	Parameters:	Field Type: Numeric

Field: 11	Phone_number2	Parameters:	Field Type: Numeric
Field: 12	Best time of day for phone call	Parameters:	Field Type: Time
Field: 13	Next best time for phone call	Parameters:	Field Type: Time
Field: 14	Third best time for phone call	Parameters:	Field Type: Time
Field: 15	CTAS acuity score	Parameters: Resuscitation Emergent Urgent Less urgent Non urgent	Field Type: Popup list
Field: 16	Date and time of ED registration	Parameters:	Field Type: Date and Time
Field: 17	Predicted waiting time when patient is registered in the ED (in hours)	Parameters:	Field Type: Numeric
Field: 18	Presenting Complaint	Parameters: Chief complaint	Field Type: Lookup list
Field: 19	Location in the ED	Parameters: Corridor Observation Resuscitation	Field Type: Popup list
Field: 20	Was patient on medications prior to the ED visit?	Parameters:	Field Type: Yes or No

Field: 21	Does the patient have at least one chronic medical condition?	Parameters:	Field Type: Yes or No
Field: 22	Was there a consultation sought?	Parameters:	Field Type: Yes or No
Field: 23	Provisional diagnosis group - pick list	Parameters: ED Diagnoses	Field Type: Lookup list
Field: 24	Provisional diagnosis description	Parameters:	Field Type: Freeform text
Field: 25	Level of training of primary assessor	Parameters: Medical student Resident (non EM program) Resident (EM program) Staff	Field Type: Popup list
Field: 26	Number of Emergency Physicians involved in patients care	Parameters:	Field Type: Numeric
Field: 27	Number of patients waiting for inpatient beds at the time patient was discharged from the ED	Parameters:	Field Type: Numeric
Field: 28	Is this form completed?	Parameters:	Field Type: Completion checkbox
Field: 29	Date and time of ED discharge	Parameters:	Field Type: Date and Time

Appendix D: Structured Telephone Interview

Hello,

May I speak to _____ *(patient's name)*?

Hi _____,

My name is Mélanie Courtney.

If patient has died, try to determine:

*date of death:*_____

*cause of death:*_____

You may recall we met in The Ottawa Hospital Emergency Department on _____ *(date of discharge)*
At that time we enrolled you in Improving Emergency Department After-Care Study.

The goal of this study is to improve patient care after patients go home from the Emergency Department.

It will take approximately 5 minutes to answer a few questions and your answers will be kept confidential.

When we met you told us that this would be a good time for us to call.
Is it still a good time for you now?

If not, is there another time I could call back which would be more convenient?

1. Since your emergency room visit on _____*(date)*, have you:

a. returned to an emergency department? ***No*** **Yes** : i. Which Emergency Department did you visit?

- ☐ Civic
- ☐ General
- ☐ Montfort
- ☐ Queensway-Carleton
- ☐ Other:_____

ii. Please describe the reason for your visit

_____

iii. Do you remember the date? ____

proceed to question 1 b

1. Since your emergency room visit on _____ *(date)*, have you:

b. been admitted to hospital? ***No*** **Yes** : i. To which hospital?

- ☐ Civic
- ☐ General
- ☐ Montfort
- ☐ Queensway-Carleton
- ☐ Other:_____

ii. Please describe the reason for your admission

_____

_____

_____

_____

iii. Do you remember the date?

_____

proceed to question 1c

1. Since your emergency room visit on _____ *(date)*, have you:

c. seen a health professional? ***No*** **Yes** : i. What type of health professional did you see?

- ☐ family doctor
- ☐ specialist:_____
- ☐ chiropractor
- ☐ physiotherapist
- ☐ other:_____

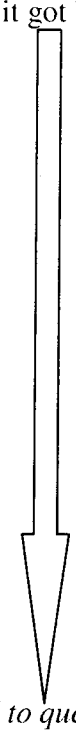
ii. Please describe the reason for your visit_____

_____

proceed to question 2

2. Did the problem you had on your emergency room visit resolve?

Yes
(so it got better?)



Proceed to question #3

No: i. Tell me what happened:

_____

_____

_____

_____

ii. What did you do?

_____

_____

3. Since your emergency room visit, have you had any new health problems develop?

No

Proceed to question #4

Yes:

a. Please describe the problem. *(When did it start?)*

_____

b. How did this limit your daily activities?

_____

_____

c. On a scale from 0-5 (0=not serious at all, 5=very serious), how seriously is this problem affecting your life?

0 1 2 3 4 5

d. What do you think the cause is?

_____

_____

e. What did you do about it?

_____

_____

4. Since your emergency room visit, have you had any worsening of pre-existing health problems?

No

end of interview

Yes:

a. Please describe the problem. *(When did it start?)*

_____

_____

_____

b. How did this limit your daily activities?

_____

_____

c. On a scale from 0-5 (0=not serious at all, 5=very serious), how seriously is this problem affecting your life?

0 1 2 3 4 5

d. What do you think the cause is?

_____

_____

_____

e. What did you do about it?

_____

_____

_____

End of interview

This concludes the interview.

Thank you very much for your time.

Do you have any comments for us?

_____

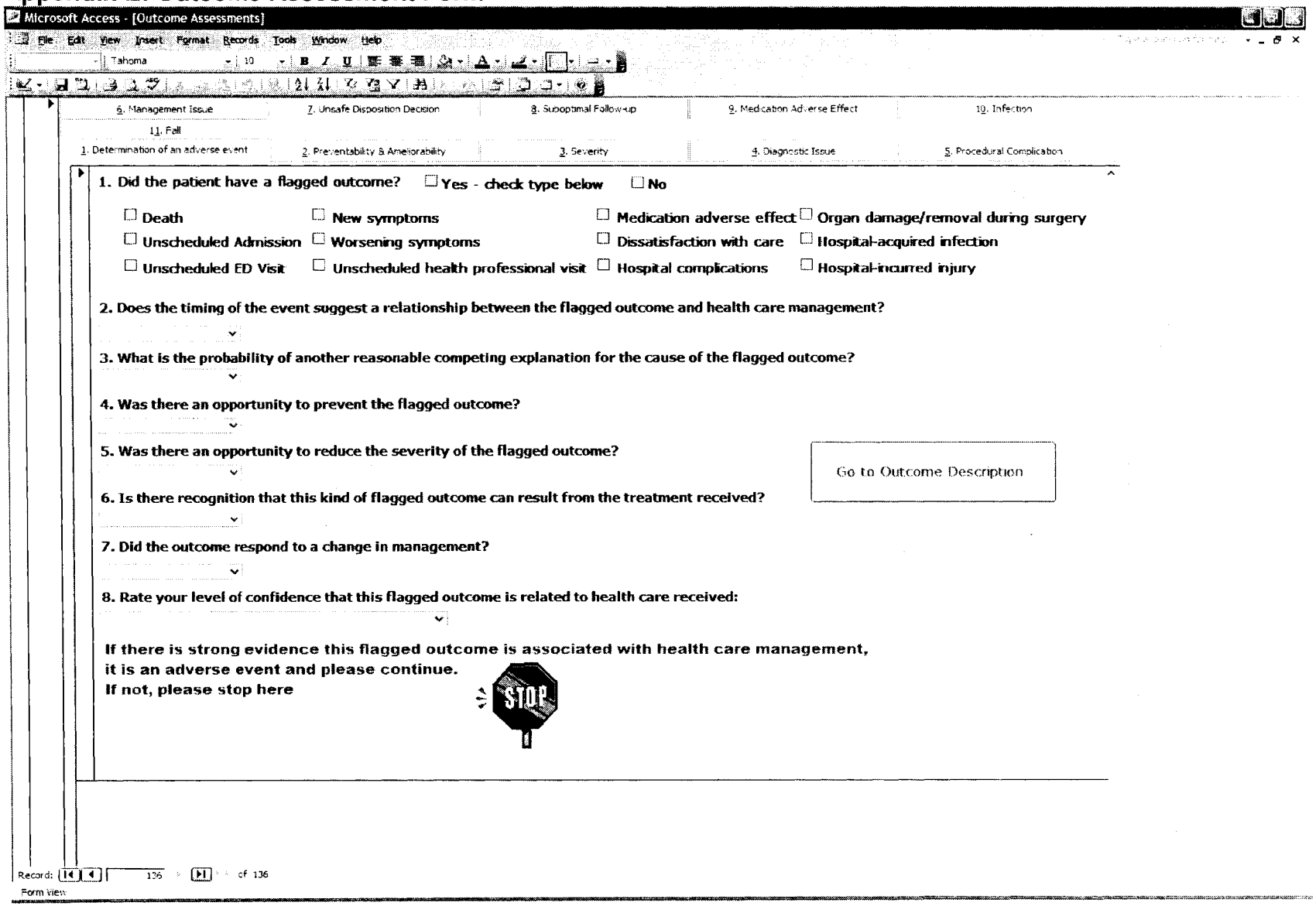
_____

_____

_____

_____

Appendix E: Outcome Assessment Form



Appendix F: Description of All Adverse Events

Reason for visit/admit	Course	Type of outcome	Description of outcome	Documented explanation	Response to outcome
Patient with Hx of COPD, strokes, and 5-6 silent MI's in last 5-6 years. Comes to ED 1500h with 2 days of increasing SOB, left sternal chest pain, and fever. Mod resp distress, RR 36 SaO2 97% R/A. Patient has diffuse, deep, wheezing sound at lung bases.	Patient treated with ventolin & atrovent with much improvement. ECG compared to old but no acute changes. CXR showed no acute changes. Patient d/c at 12am with a dx of acute COPD exacerbation and with Ventolin, Atrovent, & Symbicort puffers prn.	Admission	Presents to ED 8am the following day with same symptoms and complaining of severe dyspnea; also coughing up green sputum. Treated with ventolin, solumedrol, and BiPAP in ED and admitted to hospital. PCO2 81 and blood pH of 7.19.	Patient had an acute exacerbation of chronic obstructive pulmonary disease secondary to pneumonia.	CXR showed a RLL pneumonia. Req'd BiPAP for first 48 hours. Treated with Levaquin, Lasix, and intravenous steroids. Patients condition gradually improved; slowly requiring less and less BiPAP. PCO2 came down to 45 and patient discharged.
Patient came to ED at 1830h with 3 day history of fever, nausea, vomiting, and diarrhea. Unable to keep anything down. Has a dry tongue. No note of presence or absence of CVA tenderness or of urinary symptoms. Temp 38.8	Patient treated with Maxeran, Tylenol, and Gravol with much relief. Blood cultures sent. No urine dip done. Patient feeling better so discharged at 2300h with diet instructions and given some Tylenol and Gravol. Diagnosis of gastroenteritis.	ED Visit	Following day blood cultures came back positive for E. coli bacteria. Patient called back to ED and returned at 1000h. Still having fever, nausea, vomiting, and diarrhea. Now having mild SOB, joint pains, and epigastric & CVA tenderness.	Pyelonephritis	Urine cultures taken; positive for E. coli, WBC, and blood. Patient treated with IV Gravol and po Tylenol II. Started on IV ciprofloxacin. Patient feeling much better and discharged at 1400h with 10 days Cipro, to F/U with GP. To return if Sx worsen.

Reason for visit/admit	Course	Type of outcome	Description of outcome	Documented explanation	Response to outcome
Patient presented with crampy peri-umbilical pain for 2 days. Vomited once, normal bms. Presented to ED at 1735h. No fever, anorexia, CVA tenderness, urinary symptoms. Abdomen soft, diffusely tender, no peritonitis.	Treated with IV fluids, gravol and morphine. Abdo x-ray noted as normal in chart. Patient d/c at 2200h with diagnosis of gastroenteritis with advil and f/u with GP. Unclear if pain-free at d/c.	Admission	Patient called back to ED 5 days later for air-fluid levels seen on x-ray done Nov. 25. Still having abd pain, vomiting, & diarrhea. Abdomen is very distended; diffuse peritoneal signs. CT showed small bowel obstruction; unknown cause. Patient admitted.	Perforated appendicitis.	Patient brought to OR for laproscopic exploration of possible peritonitis and proximal ileal obstruction. Discovered pus throughout abdomen from a perforated appendicitis; performed laproscopic appendectomy. Patient recovered and discharged.
Hx of progressive ovarian cancer. Finished chemo 4 mos ago, undergoing radiation Tx. Presents at 1430h with rectal pain, bloody/mucousy diarrhea, fever, vomiting that morning. Feeling unwell since yesterday. T 39.1, HR 125, RR18, BP 142/64, dry MM.	Patient given 100cc/hr saline, Tylenol, and Toradol. Wbc 9.0, Hb 105. Blood and stool cultures sent. Patient discharged home on ciprofloxacin. Unclear if tachycardia resolved. Final diagnosis of fever- NYD.	Admission	Blood culture from ED came back positive for Clostridium perfringens 0900h following day. Patient not home when called but was admitted from cancer clinic (there for radiation Tx) with a diagnosis of radiation enteritis. Patient is still febrile (37.9).	Radiation enteritis due to palliative radiation treatment for ovarian cancer.	Started on Pip/Tazo for bacteremia. Found to be anemic on admission (HGB 92); given RBC transfusion and HGB remained stable for rest of admission. GI consult treated with Asacol for Hx of ulcerative colitis. Symptoms improved over course of admission.

Reason for visit/admit	Course	Type of outcome	Description of outcome	Documented explanation	Response to outcome
PMx of MI in '94, and a CABG x2 in '94 to LAD and marginal branch. Awoke at 0300h with chest "fluttering" and pain to shoulder blades similar to previous MI. Relieved with nitro X1 at 0830h. Recurred 1100h; came to ED at 1200h ongoing 1/10 pain.	Patient treated with nitro which gave some relief to symptoms. ECG and CXR didn't show any acute abnormalities. TnT & CK done at 12:30h negative. Patient discharged home at 1500h with nitro&ASA; return if increase in CP. Impression: GERD vs. angina	Admission	Pain returned next day at 01:30h with pain relieved by nitro. Pain back 04:30h; nitro gave no relief. Presented to ED at 0700h. Immediately given aspirin, nitrox3. CK was 1159 and troponin peaked at 2.02. Diagnosis of acute inferior MI.	Acute ST elevation myocardial infarction (inferior wall).	Patient admitted and treated with ACEi, statin, aspirin, and heparin. Angiogram revealed an occluded LAD, 70% circumflex, and 2 lesions in RCA. Transferred on Sept. 24 to the heart institute for successful angioplasty and stenting; d/c 2 weeks later.
PMHx ulcerative colitis. Last week one episode of bloody diarrhea and abdo cramps. Saw GP who prescribed prednisone. Came to ED at 1600h with vomiting x2 after taking meds, abdo cramps, fever 100. O/E: T36, HR 89, BP 132/84, dry MM, tender LLQ	Initially assessed at 1645h and given normal saline bolus. Reassessed at 1900h, patient feeling much better and able to keep down oral fluids. Patient discharged at 2100h with a diagnosis of ulcerative colitis; to follow up with GI.	Admission	Following day patient began feeling very weak and unwell and had frankly bloody stools. Came to a different ED at 0300h 2 days after index visit. Patient was assessed in the ED and it was decided that, since they could not keep down oral steroids, they would be admitted.		Patient was started on IV solumedrol. Severe abdominal pain and bloody diarrhea did not subside. Patient had an urgent surgical assessment and it was decided that patient would benefit from a subtotal colectomy with ileostomy. Patient had a post-op wound infection which was treated successfully. Patient was discharged home diagnosis of ulcerative colitis.

Reason for visit/admit	Course	Type of outcome	Description of outcome	Documented explanation	Response to outcome
Patient had uncomplicated total hysterectomy last week. Started to have vaginal bleeding POD 10 for which they visited ER and saw obs/gyn - deemed patient OK to go home. Presented to ED at 11am 2 days later after waking up at 3am bleeding again.	Patient was assessed in ED and given normal saline and Tylenol. Gyne consulted, vaginal packing was placed which was removed in the office the following day revealing adequate hemostasis.	Admission	Patient returned to ED 5am following day after bleeding started again at 10pm night before. Bleeding got worse around 3am and was passing large clots. Hb was 112 on previous visit - now 82. Patient was started on normal saline at 6:30am. Gyne consulted.	Post-op bleeding. Complication of hysterectomy.	Gyne seen at 8am patient taken to the OR at 9am for examination under general anaesthesia. Source of bleeding found and repaired with 3 sutures along vaginal vault, adequate hemostasis observed. Given 2 RBC transfusions during recovery and discharged.
Patient was at community centre and had a near syncope and a "blackening" of their visual fields. Had a short period of blurred vision afterward. Came to ED via ambulance at 11:30am.	CXR was -ve. Urine microscopy +ve for bacteria dip +ve for leukocyte esterase. Treated with Cipro 400 IV. Patient d/c at 4:30pm with dx of UTI. To take cipro 500 BID x 7 days.	New Problem	On phone follow-up 2 weeks later patient described developing a yeast infection. Stated that infection did not limit activity in any way. (Patient had -ve blood culture and urine culture was +ve for S. agalactiae.)	Yeast infection caused by the cipro treatment started in ED.	GP put patient on medication to treat the infection.

Reason for visit/admit	Course	Type of outcome	Description of outcome	Documented explanation	Response to outcome
Patient left GP's office and began feeling very anxious at 6pm. Had chest pain but feels it was caused by anxiety. Feels anxious because GP was questioning them about drug addiction. Came to ED at 7pm; no chest pain at present.	TnT and CK measured at 8:30pm and 2am. TnT negative both times and CK was high on both occasions. ECG: no acute findings. Patient discharged at 3am with diagnosis of anxiety +/- angina. F/u w/ GP - consider testing TSH and increasing beta blocker.	New Problem	On f/u phone interview 2 weeks later patient claims they were hurt during ED visit by fall from bed. Unable to ask questions, pt repeated same story over and over. Claims was verbally abused by nursing staff & will file a report.	None given.	None
PMHx htn, smoking, ?CAD. 3 day hx of left-sided shoulder ache. Today began having tingling, weakness, throbbing to left arm that is worse with effort & awakes at night. Has some tightness in chest during left arm pain. Came to ED at 5pm.	4/5 strength LUE, decreased DTR LUE. Treated with nitro. CXR, CThead, ECG all negative. TnT and CK done at 5:30pm, both negative. Patient discharged with dx of left arm weakness NYD. To have neuro f/u in 2-3 weeks. RtER prn.	Problem Worsened	On phone follow-up 2 weeks later, pt has worsened L side numbness & weakness. Patient rates its severity to be a 4/5 and is unable to work. Was to see neurologist but has not been called with appt.	None.	Patient is taking morphine for pain (not prescribed at ED visit).

Reason for visit/admit	Course	Type of outcome	Description of outcome	Documented explanation	Response to outcome
Patient has history of benign prostatic hyperplasia; seen by urology 4 years ago at Civic. Patient getting up 3-4 times during night to urinate but only voids very small amounts. Feels pressure and pain and unable to sleep. Patient came to ED at 7am.	Patient given a Foley catheter with a leg bag. Physical exam revealed a markedly enlarged prostate. Discharged home at 12pm with a diagnosis of nocturia secondary to benign prostatic hyperplasia. Foley in place. To follow up with urology.	Visited HP	On phone f/u 2 weeks later, patient describes returning to ED 3 days after initial visit claiming catheter was not functioning. ED physicians determined that is was functioning and discharged patient. Patient went to family doctor stating catheter inserted in ED was uncomfortable.	Catheter was uncomfortable.	Family doctor removed the catheter. Patient still having problems urinating and is waiting to see urologist.
Presented at 1pm with right flank pain that radiates to the abdomen that awoke patient at 3am. No note of absence or presence of fever or CVA tenderness.	Patient treated with morphine, toradol, and gravol. Sent for abdominal and pelvic CT; revealed dilated right ureter but no stones. Patient discharged with a diagnosis of UTI and a prescription for 7 days of cipro. Urine cultures taken (+ve for E coli).	Admission	Patient returned to ED one day later with increasing flank pain radiating to stomach and a fever of 39.9. Had suprapubic tenderness and costovertebral angle tenderness. Urine was cloudy with blood and leukocytes. Admitted with pyelonephritis.	Patient had a pyelonephritis that did not respond to initial antibiotic treatment but did respond well to the IV antibiotics.	Patient's antibiotics changed to IV Cefotaxime and Vancomycin. Repeat urine cultures positive for cipro-sensitive E. coli. Patient was stable throughout the 1-day admission and flank pain was much better. Discharged home with cipro and percocet.

Reason for visit/admit	Course	Type of outcome	Description of outcome	Documented explanation	Response to outcome
PMHx high cholesterol, FHx CAD. Patient presents at 12:00pm with 2-day history of crushing anterior chest pain radiating to the throat and has associated SOB. Occurs at rest, lasts about 10 minutes, and resolves spontaneously.	Patient was given ASA and nitro. EKG done - no interpretation on ROT. D-dimer positive at 574. Patient discharged w/ Dx R/o PE at 4:30pm with thrombosis f/u. No documentation if fragmin received.	New Problem	While at thrombosis clinic following day, ongoing chest pain. Referred to ED who Dx unstable angina. Referred to cardiology, admitted - cardiac catheterization 3 days later: normal. After d/c patient developed a rash due to scarlet fever. Is bed ridden (severity=5/5).	Strep infection in lungs.	Patient given antibiotics by GP.
Hx of DM & MI 4 mos prior. Presents to ED with nausea, vomiting, non-bloody diarrhea. Increasing SoB on RN note. Denies chest pain. Notes redness to R groin at site of angio patient had 3 months prior.	Blood work drawn, wbc 11.1, CK 72. EKG documented as normal by EP. Given 1L NS bolus and subsequently felt better, so was d/c'd home. No f/u instructions documented.	ED Visit	Awoke at 0400h with severe SoB, worse supine. No chest pain. No resp distress on exam, SaO2 96% room air, no RR doc'd. Chest clear to auscultation, jvp 3-4cm.	mild CHF	CXR showed cardiomegaly, L effusion. CK, d-dimer at 1930h both negative. Given lasix 40mg IV at 1630h, noted to be walking around comfortably at that time. D/c'd home at 1700h with f/u with GP and to return if worse.

Reason for visit/admit	Course	Type of outcome	Description of outcome	Documented explanation	Response to outcome
Has right frontal lobe tumor that causes seizures. Patient feeling dizzy 2 weeks since changing seizure medication from Topomax to Keppra. Patient fell today, couldn't get up. Has left-sided weakness.	Patient was found to have Tegretol level greater than 71.5 and dose was reduced from 2000 to 1600. Also given prescription 10-day course of Baclofen and discharged home.	Admission	Two weeks later patient developed rash that appeared at dinnertime & was gone by morning. Patient developed fevers, bilateral MCP pain, and had a seizure 2 days later. Rash, fever, & pain were persistent until ER presentation 2 weeks after index visit.	Fever and rash were an allergic reaction to Baclofen. Low Na could either be the result of SIADH or it was a side-effect of the Tegretol treatment.	Rash responded well to Benadryl treatment. Also found to be hyponatremic (Na=126) on presentation; was treated successfully with IV normal saline (Na on discharge= 131). Patient discharged Nov. 2 with instructions to follow-up with family physician.
Patient had been trying to get pregnant. Diagnosed with ectopic pregnancy 2 days prior and d/c'd home. Now has increasing pain and BhCG of 1897, and passing clots.	Gyne consulted and prescribed methotrexate injection at this time. Discharged home with diagnosis of ectopic pregnancy.	Admission	At 2:30pm began to have sudden increase in LLQ pain and passing small clots. Had changed pad 11 times since the ED visit the previous day.	Ectopic tubal pregnancy.	Patient admitted for observation overnight. Pain treated with Tylenol and Advil. Given IV D5W/NS. Gyne decided to treat ectopic medically vs. surgically. Patient discharged home with a gyne follow-up in a few days.
Patient has history of high BP came to ED at 6pm. Has 3 week history of headache on left side of head, numbness in left arm/left side of face (worse in am), blurred vision on/off, ringing in ears (especially left), & nausea. Also 25lbs wt loss	Patient had a head CT done which revealed a sella tursica enlarged with water density material (MRI recommended to investigate pituitary). Treated with Stemetil and Benadryl. Patient discharged home at 10pm with diagnosis of migraine H/A to F/U with GP.	Admission	Patient returned to ED still having headaches, weight loss, weakness, blurred vision, and is also hypertensive. Patient admitted so that they could be worked up for possible cyst on pituitary gland.	Empty sellar syndrome.	Patient was consulted by endocrinology and had an MRI done Dec. 16 which did not reveal any intrasellar lesions. Extra CSF was seen in the sella tursica. Headaches resolved spontaneously. Patient d/c home to follow up with neurosurgeon.

Reason for visit/admit	Course	Type of outcome	Description of outcome	Documented explanation	Response to outcome
Patient presented at 12:30h with 8/10 pain in upper left shoulder, chest, and axilla that worsens on deep breathing. Patient has history of MIx2, type II DM, and hypertension.	Patient treated with gravol and morphine. CXR, D-dimer, and ECG performed but were all negative. TnT 12:50=0.04, TNT 16:45=0.01. Patient discharged at 22:00h with the diagnosis of atypical chest pain and a question of angina.	Admission	Patient woke up during night gasping for air (better when sitting than lying). Presented to ED next evening at 5pm with fever (101.9) & diffuse edema - despite increasing Lasix themselves night before. Admitted to hospital with the diagnosis of CHF.	Patient had congestive heart failure.	3 weeks later went for CABG x 3 (LAD, acute marginal, 2nd marginal) and LV aneurysm repair. Post-op patient had many complications including: acute on CRF, resp. failure, cholecystitis, pneumonia, and ulcers on legs and feet resulting in a long hospital stay.
PMHx Alzheimer's dementia, CVA, low thyroid. Presents with L facial droop, garbled speech for 10 minutes, now resolved. No headache/chest pain. No deficits on exam.	EKG NSR 67, bloodwork unremarkable. D/c'd home with a change of ASA to Aggrenox and f/u with GP, outpt echo/carotid Doppler	New Problem	On phone f/u wife describes "bleeding from stomach" but further clarification is difficult because she has a marked hearing impairment.	none	Has appointment with family doctor
Patient had a 5-day history of crushing retrosternal chest pain that radiated to back and left arm; worse on exertion. Had a stress test that morning. Presented to ED at 1200h with a superventricular tachycardia.	Patient was treated with adenosine,fentanyl, propofol, and versed. Electrocardioverted around 1330h; reverted back to sinus tachycardia of 112. Chest pain recurred 1945h-referred to cardiology. 2100h patient left hospital against medical advice.	ED Visit	After leaving hospital patient continued to have the same chest pain. Presents to ED at 1000h with 10/10 chest pain, dizziness, and nausea. SVT has returned, 162 on arrival.	Unstable SVT.	Patient given same meds as last visit and then cardioverted at 50, 70, and 100J all only giving temporary relief of SVT. Cardiology consult. Patient discharged at 1400h. To take sotalol and to follow up with cardiology next day.

Reason for visit/admit	Course	Type of outcome	Description of outcome	Documented explanation	Response to outcome
Patient known liver cirrhosis secondary to HCV & EtOH. Patient has developing shortness of breath and peripheral edema. Abdomen very distended. Came to ED at 10:30h to get paracentesis (direct to GI). Last paracentesis 6 weeks ago removed 3L of fluid.	Patient underwent paracentesis in ED removing 6-7L of fluid. Also transfused with 2 units of albumin. Biochemistry tests revealed high AST, GGT, and ALP. Patient discharged home at 1600h.	ED Visit	Patient returned to ED 2 days later at 1400h. States that fluid is leaking from previous paracentesis sites (x2). Slight SOB and abdo remains distended.	Ascites due to liver cirrhosis secondary to EtOH abuse.	GI consulted. Patient once again underwent paracentesis which was unsuccessful in draining any fluid. Stoma bag placed over drainage site. Patient discharged at 1700h; is to have U/S guided paracentesis next week.
Aug 23rd peripheral ED @11:30h with 10/10 CP similar to angina, no relief w/ nitro. RN note radiates to back. BP doc'd R arm 130/50. CXR- ?result, EKG nil acute, +trop. Rx heparin referred to cardio Dx UA. Cardio noted syst&diast M, Dx UA/NSTEMI, admitted tele.	In am, cardio rec. angiography - pt refused. Attempted Tx to HI unsuccess. Pt left AMA, to TOH ED Aug 24 12:00pm. EP notes unequal BPs in periphery - ? if repeated; fem pulses = . RN: CP 1/10 radiates to back, wk Lside and numb all over. EKG infQ, ST dev	Unexpected death	PCXR nil acuteCardio referral r/o ACS@ 1455h, accepted 1520h, assessed 2010h. Sr cardio 2210h, bedside echo 2320h: acute AI, inf asc aortic dissection, flap to abd aorta. Metop, nitroprusside. Seen by CVS Sx Aug 25th ?time, plan for OR in am. OR Aug 25th.	Dissection extended from ascending aorta to R femoral art. Long OR w/ probs coming off pump. Chest left open 48h then closed. Aug 30 sudden resp distress, high lactate, low pH. Suspected dissection of gut vessels and severe ischemia leading to death.	Comfort measures

Reason for visit/admit	Course	Type of outcome	Description of outcome	Documented explanation	Response to outcome
Patient presented to emergency with 5 days of bilateral leg weakness followed by sudden onset of paresthesias. CT chest 3 days prior showed lung Ca with lymphadenopathy. MRI spine showed pathological fractures T4,6 with spinal cord compression.	Patient was started on IV Decadron in ED. They had a Foley catheter inserted and were referred to Neurosurgery. Patient went for surgery to relieve pressure on spinal cord on the day of admission. Patient remained in hospital for radiation treatment.	Hospital acquired infection	Foley catheter that was inserted in emergency was replaced 11 days later. Patient had cloudy, foul-smelling urine at that time. UTI confirmed by E. coli growth in urinary culture.	None given.	Patient treated with Po septra.
Patient was admitted for midsternal pain and discomfort. Pain had been on and off for a few days and is relieved with administration of nitro. Some pain at rest.	Patient was stabilized in ER and admitted. Underwent a cardiac nuclear scan and a cardiac catheterization 5 days later revealing severely stenosed coronaries. Patient went to OR for CABG 3 days later and returned to ward for recovery.	Hospital complication developing during admission	Patient developed anemia secondary to post-op hemorrhage one day following the CABG surgery.	Anemia was due to blood loss during the surgery.	Patient was transfused with 3 units of RBC's
Patient was admitted for midsternal pain and discomfort. Pain on and off for a few days and is relieved with administration of nitro. Some pain at rest.	Patient was stabilized in ER and admitted. Had a cardiac nuclear scan (Nov. 22), a cardiac cath(Nov. 23) revealing severely stenosed coronaries. Patient went to OR for CABG (Nov. 26) and returned to ward for recovery.	Hospital complication developing during admission	Patient developed recurrent bouts of atrial fibrillation (AF) starting 1 day following the CABG surgery. AF occurred on and off up until discharge.	None given.	Monitor the patient for any other cardiac complications.

Reason for visit/admit	Course	Type of outcome	Description of outcome	Documented explanation	Response to outcome
Patient fell in a restaurant parking lot and landed on concrete barrier resulting in a fractured hip.	It was decided that the patient would not undergo surgery to repair hip. They were admitted so that they could be monitored until a plan as to where and by what means their recovery and rehabilitation would occur. Patient developed pneumonia 11 days later.	Hospital complication developing after admission	Patient presented with right pleuritic chest pain and a drop in O2 saturation. Investigations revealed a DVT in the left leg and multiple bilateral pulmonary embolisms.	Thought that the DVT was related to the fracture and that the PE was a result of the DVT.	Patient was treated with Fragmin and pain resolved.
Patient was admitted to hospital with digoxin toxicity and renal failure. Heart rate on admission was 30-60.	Patient's digoxin was stopped, metoprolol held and monitored. Patient was aggressively hydrated with improvement in toxicity symptoms and renal failure. Patient found to be anemic likely due to chonic disease. Patient was discharged home.	Hospital acquired infection	Began having loose bowel movements starting on 2 weeks later and had a stool culture positive for Clostridium difficile.	Contracted infection in the hospital.	The patient was isolated, treated with Flagyl, and taught the precautions necessary to avoid transmitting the bacteria.
Patient was admitted for midsternal pain and discomfort. Pain had been on and off for a few days and is relieved with administration of nitro. Some pain at rest.	Patient was stabilized in ER and admitted. Underwent a cardiac nuclear scan and a cardiac catheterization 5 days later revealing severe CAD. Patient went to OR for CABG 3 days later and returned to ward for recovery.	Unplanned removal/injury/repair of organ/structure during surgery	Three days following CABG surgery patient developed a post-operative pneumothorax on the right side - felt to be secondary to operation.	Complication following the CABG surgery.	None.

Reason for visit/admit	Course	Type of outcome	Description of outcome	Documented explanation	Response to outcome
No note of universal fall precautions in ER chart. Patient admitted feeling generally unwell, short of breath, and fatigued. Found to have a NSTEMI, CHF,and acute on chronic renal failure.	Patient was not experiencing any chest pain and heart failure was stable. Patient declined dialysis treatment for kidney failure. Patient was monitored and awaiting results of tests.	Hospital incurred accident or injury	No document'n that universal fall precautions were in place. Patient fell in bathroom shortly after admission. Nurse found patient on floor with IV ripped out of arm, blood all over patient and floor, and the patient was very confused and frightened.	Felt that the patient's fall was likely a multifactorial problem, due to a combination of poor vision and poor walking ability.	Physiotherapy and occupational therapy consulted. Assessed patient's ability to abulate safely and comfortably. Patient given a walker and a commode was placed at bedside to reduce the risk of a fall.
Patient admitted with severe chest pain, dizziness and nausea. Patient signed self out of peripheral hospital and came to TOH.	Patient came to hospital at 12:00pm. Saw the ER physician who noted patient had unequal BPs documented in periphery. Femoral pulses noted to be equal, PCXR nil acute. Referred to cardiology as r/o ACS.	Documentation of patient/family dissatisfaction with care	At 7:30pm patient stated: "I'm fed up! I've been waiting too long". Patient was very rude and told nurses to go away. Patient eventually diagnosed as having an aortic dissection. Patient died of multi-organ failure.	Patient not happy with the length of time it was taking to see a cardiologist.	Cardiology resident came down to assess the patient.
Patient had a fall followed by syncope and is now having difficulty walking because of pain. Patient had suffered a broken hip.	Patient stabilized in hospital and awaiting surgery to repair broken hip. Moore's arthroplasty performed.	Hospital complication developing during admission	Patient had an acute post-hemorrhagic anemia (hemoglobin fell to 94 from following surgery to repair fractured femoral neck.	Anemia due to operative site hemorrhage.	Patient was transfused with 1 unit of RBC's

Reason for visit/admit	Course	Type of outcome	Description of outcome	Documented explanation	Response to outcome
Patient admitted for abscesses at intravenous drug abuse injection sites on right shoulder, both forearms, and ankles. Patient wanted help for morphine addiction.	Patient was found to be anemic and was transfused. Patient was slowly being weaned off of morphine, resulting in some withdrawal symptoms. Abscesses getting better but patient left hospital without permission a number of occasions during hospital stay.	Unplanned admission as a result of health care management	Patient returned to ER 2 weeks later with left leg cellulitis and diagnosed with a DVT of IVC and PE.	The possibility of a DVT was a concern for physicians all along but patient's inability to follow orders of the health care workers made it difficult to do a proper workup on previous admission.	Cellulitis was treated with oral antibiotics but did not improve dramatically until IV antibiotics were started. The DVT and PE were treated with Coumadin and Fragmin.
Patient had a 2 month history of diarrhea (up to 10x per day) that was not responding to antibiotic treatment. Patient also had right lower quadrant cramping pain.	Patient rehydrated and medicated for pain control. Continued diarrhea (up to 20x/d) Undergoing diagnostic tests. C. difficile positive during admission - started on Flagyl.	Adverse drug reaction	Patient developed diffuse pruritic maculopapular rash all over body 1 day after starting Flagyl treatment.	Thought to be an allergic reaction to Flagyl.	Patient treated with Benadryl and Flagyl was discontinued.
Patient has history of smoking, dyslipidemia, and peripheral vascular disease. Admitted because of 1 week history of squeezing chest pain radiating into throat. Dx NSTEMI	Patient underwent cardiac catheterization 4 days later revealing severely stenosed LAD and circumflex coronary arteries. Had a double CABG surgery on 2 days later. Patient returned from OR for recovery.	Hospital complication developing after admission	Patient developed post-surgical atrial fibrillation 1 day after double CABG surgery.	Complication of the surgery.	Atrial fibrillation treated with amiodarone and beta blocker.

Reason for visit/admit	Course	Type of outcome	Description of outcome	Documented explanation	Response to outcome
Patient presented with severe diarrhea and vomiting. Recent diagnosis of Hepatitis B. Also has cramping pains in upper abdomen.	Patient on IV fluids and morphine for abdominal pain control. Symptoms improving slightly.	Documentation of patient disatisfaction with care	Patient asked nurse to make food during the night. Nurse explained kitchen is closed and can only offer snacks. Patient complained that nurse "would not help" and that patient "hadn't eaten in 5 days" and asked to have another nurse.	None given.	Charge nurse explained to patient that they can help themselves as well and that they would be going home soon.
Patient fell in a parking lot at restaurant and landed on concrete barrier resulting in a fractured hip. No mention of any respiratory signs or symptoms.	Patient not operative candidate -reason not documented. Patient admitted for monitoring until a plan as to where and by what means recovery and rehabilitation would occur. O2 sats consistently in low to mid 90's.	Hospital acquired infection	Patient became very short of breath due to a bibasilar pneumonia. On further investigation a left pleural effusion was also discovered.	No explanation given for the pneumonia but thought that the pleural effusion could be caused by the pneumonia even though the location of the effusion did not correspond to the pneumonia.	Patient was treated with Cefuroxime and Biaxin.
86 yr patient found on B/R floor at home; came to ER with dizziness, confusion, and an episode of loss of consciousness for 30min that morning. Patient has history of high BP & previous strokes.	Patient being worked up for possibility of seizures or syncope. Previous day patient had CXR which only showed a slight atelectasis and had a head CT which showed a very atrophied brain. Both done in the ED upon presentation.	Hospital complication developing during admission	With daughter at bedside, patient hallucinated then began to have a seizure; all muscles stiffened. BP increased to 210/90 and patient became cyanotic and incontinent.	Thought that seizure may have been the result of alcohol or drug withdrawal as the patient had a history of alcohol abuse and possible ativan abuse.	Patient started on IV dilantin. Patient did not have any more seizure-like episodes during their stay but was confused and disoriented much of the time. Patient discharged to geriatrics unit.

Reason for visit/admit	Course	Type of outcome	Description of outcome	Documented explanation	Response to outcome
Patient came to emergency complaining of increasing confusion for a week and a half. Patient had recently changed medications for psychiatric problems (now taking Seroquel-900mg). Also on steroids for recent asthma exacerbation.	Patient was found to be hyperglycemic and was treated in ED with IV insulin (11am). Seroquel dose was decreased to 500mg. Patient was taken off prednisone treated with po antibiotics for respiratory infection.	Hospital complication developing during admission	Patient became hypokalemic shortly after IV insulin infusion. IVF had KCl added in ED. Patient had two separate low potassium measurements. Lowest was 3.0 mol/L potassium (4:30pm) and the other was 3.5 mol/L.	Thought that this was due to the large amounts of insulin that were being infused causing a potassium shift intracellularly.	Patient was treated with KCl elixir and K-Dur.
Previously healthy patient presented to ED with few month history of dysphagia and sternal chest pain. Recent blood work showed a white count of 56.8 and GP referred patient to ED.	Patient was admitted to hospital and was diagnosed with M2 AML. Patient underwent idarubicin/AraC chemo.	Hospital complication developing during admission	Bloodwork done throughout chemo. 3 days after start of induction chemo noticed patient's INR=2.01, PTT=33, and fibrinogen=0.7; all increased. Patient diagnosed with a low grade DIC.	None given.	Patient transfused with 4 units of cryo. Fibrinogen was up to 1.3 next day, no further transfusions were needed. AML persisted and patient was treated successfully with bone marrow transplant
Previously healthy patient presented with few months of dysphagia and retrosternal chest pain. Blood work showed a white count of 56.8 and GP referred for possible leukemia.	Patient was admitted to hospital and was diagnosed with M2 AML. Patient underwent idarubicin/AraC chemo. Bone marrow match was found and patient received stem cells	Hospital complication developing after admission	Dysphagia due to pain/mucus. Diagnosed with significant mucosinusitis. Feeding tube inserted 2 weeks later - subsequently missed 2 of 4 methotrexate treatments.	Thought to be an acute episode of patient's chronic sinusitis diagnosed by CT scan.	Patient treated with Pip/Tazo and symptoms improved. Feeding tube removed patient's symptoms continued to improve.

Reason for visit/admit	Course	Type of outcome	Description of outcome	Documented explanation	Response to outcome
Patient with history of CHF presented to ED with 1-week increasing SOB on exertion. Has some orthopnea and peripheral edema. Needed BiPAP in ER and was admitted.	Tests and examination revealed patient to have pulmonary edema, LBBB (old), a-fib, and an elevated CK. Patient's Furosemide was increased, b-blocker changed from acebutolol to metoprolol, and started on aspirin and ramipril.	Hospital complication developing after admission	Patient developed an acutely sore left foot. Complained of aching feet and had some redness in left foot. Needed a lot of assistance for ambulation because of pain.	Diagnosed with an acute gout attack.	Treated successfully with a tapering dose of prednisone and physiotherapy consulted. At discharge patient was able to ambulate well.
Patient was recently diagnosed with squamous cell carcinoma of the esophagus. No evidence of metastatic disease. Came to ED having difficulty swallowing solid foods - last meal 2 weeks prior. Referred to Medicine.	Patient underwent cardiopulmonary evaluation to see if could tolerate esophageal resection. Five days later patient had total esophagectomy with gastric pull-up. Patient recovering from surgery on floor; thought to tolerate procedure well.	Hospital Acquired Infection	Patient developed a tachycardia (>100/min) which developed over the last 2 days. Also had purulent fluid draining from surgical neck wound. Culture results showed growth of both Candida albicans and Peptostreptococcus species.	Infection of surgical site.	Patient underwent exploratory endoscopy to ensure stomach was still viable. Was started on therapy with Vancomycin and Pip/Tazo. Patients recovery was slow with multiple fevers but wound did eventually heal satisfactorily. Patient discharged.
Patient was recently diagnosed with squamous cell carcinoma of the esophagus. No evidence of metastatic disease. Came to ED having difficulty swallowing solid foods.	Patient underwent cardiopulmonary evaluation to see if could tolerate esophageal resection. Five days later patient had total esophagectomy with gastric pull-up. Patient had infection of neck wound one week later (on antibiotic therapy for it).	Unplanned injury of organ or structure during surgery	Patient underwent many post-op chest x-rays after esophagectomy. One month post-op chest x-ray revealed that patient had a right pneumothorax.	Complication of surgical procedure.	There was no specific treatment. The pneumothorax resolved spontaneously.

Reason for visit/admit	Course	Type of outcome	Description of outcome	Documented explanation	Response to outcome
Patient was recently diagnosed with non-small cell metastatic lung cancer. Presented to ED with chest pains and increasing bone pain.	Chest pain due to multiple PE's and started on Fragmin. Bone pain secondary to many bone metastases, visualized by spiral CT, so patient given morphine for pain control and monitored for DVT/PE.	Hospital Acquired Infection	Patient developed shortness of breath 2 days earlier. CXR: possible bilat pneumonia. CXR 1 week after admission: possible consolidation in RLL.	None given.	Patient started on Levaquin therapy. Was discharged one day later so final outcome is not known.
Patient has end-stage renal disease and is being followed pre-hemodialysis. Presents with increasing SOB, peripheral and pulmonary edema for last 4 weeks.	Patient started on dialysis via an A-V fistula. Cardio work-up done which ruled out any acute cardiac cause.	Hospital complication developing during admission	Patient developed a hematoma on left AV fistula 4 days later. Fistula was noted to be fragile.	Hemodialysis damaged fistula.	Ice applied to fistula but alternate hemodialysis route needed. A right IJ PermCath inserted with tip in patient's right atrium without complications. Patient to receive dialysis through this access until hematoma resolved. Patient discharged home.
Patient has history of diabetes (on insulin), hypertension, knee problems, and arthritis. Fell down stairs at home and hit head. Came to ED and was confused, disoriented, and shaky.	Patient worked-up at General then transferred to Civic neurosurgery. Had head and spine CT and brain MRI done which revealed no tumour but a right intracranial bleed. Being investigated as to reason for change in mental status and fall.	Hospital incurred accident or injury	Patient had an unwitnessed fall 5 days after admission and was found to be very confused and disoriented 3 days later.	Patient had poor balance and a 1-year history of falls. Patient also had periods of delirium and dementia with possible left neglect apraxia.	Patient was transferred to Geriatric Assessment Unit for safe assessment of cognition. Despite patient being seen as high fall risk they fell recurrently. Patient discharged home.

Reason for visit/admit	Course	Type of outcome	Description of outcome	Documented explanation	Response to outcome
Patient admitted for a 3 day history of squeezing chest pain under left arm, left breast, and neck. Also had diarrhea that started around the same time.	Patient underwent a spiral CT scan and had their D-dimer, INR, PTT, CK, and TnT tested. All results were normal so patient admitted for likely pericarditis (suggested by ECG results). Patient was on Tylenol 3, IV Morphine, and Dilaudid for pain control.	Adverse drug reaction	Patient stated that drugs were not sufficient to control her pain. Dilaudid dose was increased 1 week after admission. Three days later patient became drowsy and began having both visual and auditory hallucinations.	Patient taking too high of a dose of narcotics.	Stop narcotics.
Patient was admitted with a right lower lobe pneumonia as well as atrial fibrillation.	Patient was gradually getting better. Still coughing but not as short of breath as on admission.	Hospital acquired infection	Ten days later patient began having diarrhea. Stool culture results came back positive for C. difficile.	None given.	Patient was treated with a 7-day course of Flagyl
Patient left peripheral hospital that morning after common bile duct stone diagnosis by abdominal US. Presented to TOH ER at 6pm with right upper quadrant pain which was increasing in intensity.	Patient was seen in ED and then was sent for endoscopic retrograde cholangio-pancreatography (ERCP). Returned from ERCP at 6:30pm same day. Patient still having some right upper quadrant pain.	Hospital complications developing during admission	By the evening of the following day the patient had developed a post-ERCP pancreatitis indicated by a large increase in lipase levels (greater than 2000).	Complication of endoscopic procedure.	Admit and observe.

Appendix G: SAS Output

Figure Ga: Logistic regression of presenting complaint relative to the occurrence of an adverse event

Analysis of Maximum Likelihood Estimates

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept	1	-2.3865	0.2612	83.4500	<.0001
PCCP	1	-0.5351	0.4678	1.3089	0.2526
PCSO	1	0.7216	0.4880	2.1865	0.1392
PCAP	1	0.0351	0.5849	0.0036	0.9522
PCWK	1	0.7772	0.5552	1.9597	0.1615
PCPA	1	-0.8321	1.0526	0.6249	0.4292
PCTR	1	0.1892	0.6623	0.0816	0.7751

Odds Ratio Estimates

Effect	Point Estimate	95% Wald Confidence Limits	
PCCP	0.586	0.234	1.465
PCSO	2.058	0.791	5.355
PCAP	1.036	0.329	3.259
PCWK	2.175	0.733	6.458
PCPA	0.435	0.055	3.424
PCTR	1.208	0.330	4.425

Figure Gb: Logistic regression of age as a single variable relative to preventable adverse events

Analysis of Maximum Likelihood Estimates

Parameter		DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept		1	1.5040	0.7817	3.7017	0.0544
agegr	40	1	-1.0340	0.9675	1.1422	0.2852
agegr	60	1	-2.1972	0.9930	4.8957	0.0269
agegr	80	1	-1.7917	1.0929	2.6877	0.1011

Odds Ratio Estimates

Effect	Point Estimate	95% Wald Confidence Limits	
agegr 40 vs 20	0.356	0.053	2.369
agegr 60 vs 20	0.111	0.016	0.778
agegr 80 vs 20	0.167	0.020	1.420

Figure Gc: Logistic regression of presenting complaint as a single variable relative to preventable adverse events

Analysis of Maximum Likelihood Estimates

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept	1	0.8755	0.5323	2.7051	0.1000
PCCP	1	0.0408	0.9916	0.0017	0.9672
PCSO	1	-1.7918	0.9916	3.2648	0.0708
PCAP	1	-0.8755	1.1328	0.5972	0.4396
PCWK	1	-2.2617	1.2383	3.3362	0.0678
PCTR	1	-0.1823	1.3354	0.0186	0.8914

Odds Ratio Estimates

Effect	Point Estimate	95% Wald Confidence Limits	
PCCP	1.042	0.149	7.275
PCSO	0.167	0.024	1.164
PCAP	0.417	0.045	3.838
PCWK	0.104	0.009	1.180
PCTR	0.833	0.061	11.416

Figure Gd: Logistic regression of discharge diagnosis as a single variable relative to preventable adverse events

Analysis of Maximum Likelihood Estimates

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept	1	-0.2877	0.5401	0.2838	0.5943
DDHE	1	0.6242	0.7966	0.6140	0.4333
DDIN	1	-0.1178	1.0607	0.0123	0.9116
DDNE	1	0.9808	1.3385	0.5369	0.4637
DDTR	1	0.9808	1.3385	0.5369	0.4637
DDGI	1	1.8970	1.2213	2.4126	0.1204

Odds Ratio Estimates

Effect	Point Estimate	95% Wald Confidence Limits	
DDHE	1.867	0.392	8.894
DDIN	0.889	0.111	7.107
DDNE	2.667	0.193	36.756
DDTR	2.667	0.193	36.756
DDGI	6.666	0.609	73.017

Figure Ge: Stepwise logistic regression of both patient risk factors relative to preventable adverse events

Analysis of Maximum Likelihood Estimates

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept	1	1.9049	0.8653	4.8460	0.0277
agegr	1	-0.0350	0.0166	4.4532	0.0348

Odds Ratio Estimates

Effect	Point Estimate	95% Wald Confidence Limits	
agegr	0.966	0.935	0.998

Figure Gf: Logistic regression of location in emergency department relative to the occurrence of an adverse event

Analysis of Maximum Likelihood Estimates

Parameter		DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept		1	-2.0794	1.0607	3.8436	0.0499
loc	2	1	-0.3629	1.0922	0.1104	0.7397
loc	3	1	-1.7848	1.2105	2.1739	0.1404

Odds Ratio Estimates

Effect	Point Estimate	95% Wald Confidence Limits	
loc 2 vs 1	0.696	0.082	5.917
loc 3 vs 1	0.168	0.016	1.800

loc 1 = cubicles/corridor
loc 2 = observation
loc 3 = resuscitation

Figure Gg: Logistic regression of number of patients waiting for beds relative to the occurrence of an adverse event

Analysis of Maximum Likelihood Estimates

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept	1	-3.3440	0.4154	64.8085	<.0001
NumberOfPatientsWait	1	0.4386	0.2500	3.0770	0.0794

Odds Ratio Estimates

Effect	Point Estimate	95% Wald Confidence Limits	
NumberOfPatientsWait	1.550	0.950	2.531

Figure Gh: Logistic regression of level of training of primary assessor relative to the occurrence of an adverse event

Analysis of Maximum Likelihood Estimates

Parameter		DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept		1	-2.9444	0.7255	16.4725	<.0001
lot	2	1	-1.1664	1.2421	0.8819	0.3477
lot	3	1	0.3905	0.8248	0.2242	0.6359
lot	4	1	0.2634	0.7957	0.1096	0.7406

Odds Ratio Estimates

Effect	Point Estimate	95% Wald Confidence Limits	
lot 2 vs 1	0.311	0.027	3.554
lot 3 vs 1	1.478	0.293	7.442
lot 4 vs 1	1.301	0.274	6.190

lot1 = medical student
lot2= emergency medicine resident
lot3= non-emergency medicine resident
lot4= staff

Figure Gi: Stepwise selection logistic regression of location in emergency department, number of patients waiting for beds and level of training of primary assessor relative to occurrence of adverse events

Analysis of Maximum Likelihood Estimates

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept	1	-2.4243	0.2530	91.7847	<.0001
LEDR	1	-1.4399	0.6359	5.1278	0.0235

Odds Ratio Estimates

Effect	Point Estimate	95% Wald Confidence Limits	
LEDR	0.237	0.068	0.824

Figure Gj: Logistic regression of estimated waiting time relative to preventable adverse events

Analysis of Maximum Likelihood Estimates

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept	1	-0.0383	0.3666	0.0109	0.9168
PredictedWaitingTime	1	0.4116	0.4065	1.0255	0.3112

Odds Ratio Estimates

Effect	Point Estimate	95% Wald Confidence Limits	
PredictedWaitingTime	1.509	0.680	3.348

Figure Gk: Logistic regression of age and estimated waiting time relative to preventable adverse events

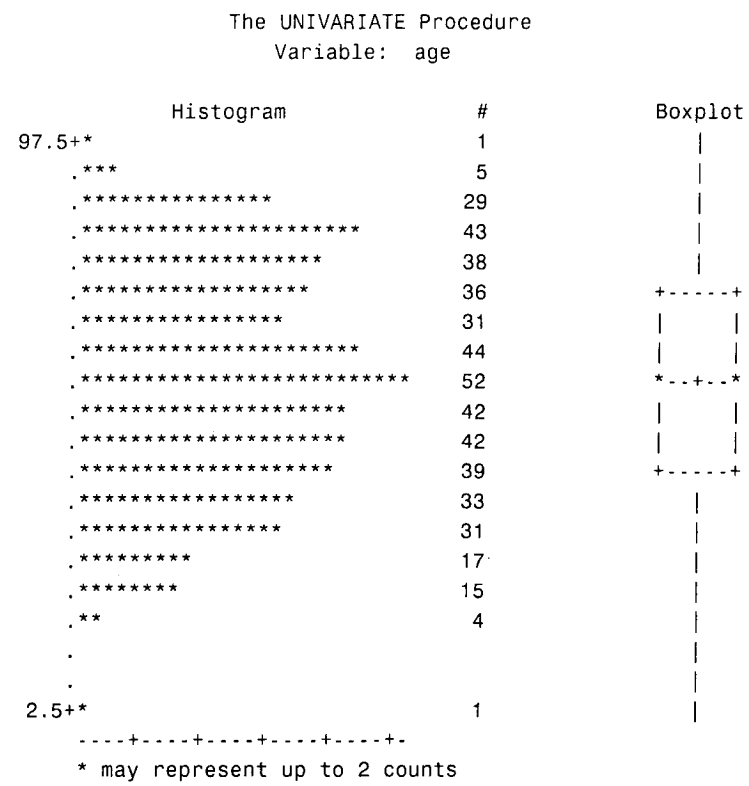
Analysis of Maximum Likelihood Estimates

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept	1	-1.5310	0.9182	2.7805	0.0954
agegr	1	0.0319	0.0169	3.5391	0.0599
PredictedWaitingTime	1	-0.3547	0.3930	0.8148	0.3667

Odds Ratio Estimates

Effect	Point Estimate	95% Wald Confidence Limits	
agegr	1.032	0.999	1.067
PredictedWaitingTime	0.701	0.325	1.515

Appendix H: Frequency distribution histogram of age for all patients enrolled n=503



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