An Exploratory Study of the Fundamental Characteristics Influencing the Analysis and Communication Activities of Health Care Incident Reporting Systems

by

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A thesis submitted in conformity with the requirements for the degree of Master of Health Science in Clinical Engineering
Institute of Biomaterials and Biomedical Engineering
University of Toronto

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Abstract

Incident reporting systems offer rich opportunities for learning from errors in health care. However, little attention has been given to understanding how the implementation of reporting system characteristics impact analysis and communication activities. This research explored the characteristics of reporting systems that promote analysis and communication activities. Ten characteristics were identified through a comprehensive literature review. Two reporting systems were then compared to assess how differences in the implementation of the characteristics impact the contents of the database. The results demonstrated that differences in the characteristics’ implementation have an effect on the ability to extract information essential to analysis activities. Next, the reporting processes of the two systems were mapped onto a hierarchical framework to highlight how the characteristics influence the communication of incident information across the health care system. The presented work furthers the understanding of characteristics needed to design reporting systems more effective at promoting learning.
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# Table of Contents

Acknowledgments......................................................................................................................... ii

Table of Contents............................................................................................................................ iv

List of Tables ....................................................................................................................................... viii

List of Figures ....................................................................................................................................... x

List of Appendices ............................................................................................................................ xiii

List of Abbreviations ........................................................................................................................ xiv

1 Introduction ........................................................................................................................................ 1

1.1 Prevalence of Incidents in Health Care ....................................................................................... 1

1.2 Incident Reporting Systems ......................................................................................................... 1

1.3 Objective ....................................................................................................................................... 4

1.4 Study Goals ................................................................................................................................... 4

1.5 Chapter Outline ............................................................................................................................ 5

2 Background ....................................................................................................................................... 7

2.1 Incident Terminology ..................................................................................................................... 7

2.2 Why Incidents Occur .................................................................................................................... 7

2.3 Collecting Information about Incidents in Health Care ............................................................... 9

2.4 The Evolution of Incident Reporting Systems ............................................................................ 11

2.5 Differences in Incident Reporting Between Industry and Health Care ..................................... 12

2.6 Barriers of Health Care Incident Reporting Systems ................................................................. 13

2.7 Chapter Summary ....................................................................................................................... 15

3 Fundamental Characteristics of Incident Reporting Systems .......................................................... 16

3.1 Objective ....................................................................................................................................... 16

3.2 Methodology ................................................................................................................................ 16

3.3 Literature Findings ....................................................................................................................... 18
3.3.1 Reporting Culture ......................................................... 20
3.3.2 Classification of a ‘Reportable Event’ .................................. 23
3.3.3 Operational Aspects ....................................................... 26
3.3.4 Collecting Versus Analyzing Incident Data .......................... 33
3.3.5 Description of an Event ................................................... 37
3.3.6 Consistency of Language & Standardization .......................... 44
3.3.7 Accessibility & Ability to Search the System ....................... 46
3.3.8 Timeliness of Reporting .................................................. 48
3.3.9 Feedback & Dissemination of Information ............................ 49
3.3.10 Denominator & Numerator Issues ..................................... 51
3.4 Chapter Summary ............................................................. 53

4 Comparison of Two Existing Databases Based on the Ten Fundamental Characteristics .... 57
4.1 Objective .............................................................................. 57
4.2 Introduction to the Example Databases ..................................... 57
  4.2.1 FDA’s MAUDE Database .................................................. 58
  4.2.2 ISMP Canada’s Medication Incident Database ...................... 60
4.3 Comparison of the Systems Using the Ten Identified Fundamental Characteristics ....... 61
  4.3.1 Reporting Culture Discussed in Terms of the Goal of the Reporting System ..... 61
  4.3.2 Classification of a ‘Reportable Event’ .................................. 64
  4.3.3 Operational Aspects ....................................................... 65
  4.3.4 Collecting Versus Analyzing Incident Data .......................... 68
  4.3.5 Description of an Event ................................................... 70
  4.3.6 Consistency of Language & Standardization .......................... 72
  4.3.7 Accessibility & Ability to Search the System ....................... 74
  4.3.8 Timeliness of Reporting .................................................. 75
  4.3.9 Feedback & Dissemination of Information ............................ 77
4.3.10 Denominator & Numerator Issues ................................................................. 80

4.4 Chapter Summary ................................................................................................. 81

5 Investigating Whether Structural Differences Impact the Database Contents .......... 84

5.1 Objective .............................................................................................................. 84

5.2 Chapter Overview ............................................................................................... 84

5.3 Case Study: Multiple Intravenous Infusion Incidents ....................................... 86

5.4 Methodology ....................................................................................................... 88

5.4.1 Querying the Systems ..................................................................................... 89

5.4.2 Coding the Query Results .............................................................................. 91

5.4.3 Analysis of the Coding Results ..................................................................... 99

5.5 Results ................................................................................................................ 99

5.5.1 Applicability .................................................................................................. 99

5.5.2 Location .......................................................................................................... 100

5.5.3 Impact ............................................................................................................ 101

5.5.4 Cause .............................................................................................................. 103

5.5.5 Overall Ability to Identify Information in the Three Fields ....................... 105

5.6 Discussion .......................................................................................................... 106

5.7 Chapter Summary ............................................................................................... 115

6 Applying a Framework for Exploring the Incident Reporting Process ................. 117

6.1 Objective ............................................................................................................ 117

6.2 Rasmussen’s Risk Management Framework ..................................................... 117

6.3 Applying the Framework to the Example Databases ........................................ 123

6.3.1 Mapping the MAUDE Reporting Process onto the Framework ................. 123

6.3.2 Mapping the ISMP Canada Medication Incident Database Reporting Process onto the Framework ................................................................. 128

6.3.3 Examples of Using the Framework to Explore Aspects of the Fundamental Characteristics ........................................................................................................... 132
<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.3.4</td>
<td>Using the Framework to Assess How the Systems Provide the Mechanisms for Promoting Their Goals</td>
<td>140</td>
</tr>
<tr>
<td>6.4</td>
<td>Chapter Summary</td>
<td>152</td>
</tr>
<tr>
<td>7</td>
<td>Discussion and Limitations of the Study</td>
<td>154</td>
</tr>
<tr>
<td>7.1</td>
<td>Discussion</td>
<td>154</td>
</tr>
<tr>
<td>7.2</td>
<td>Limitations</td>
<td>160</td>
</tr>
<tr>
<td>7.2.1</td>
<td>Development of the Ten Fundamental Characteristics</td>
<td>160</td>
</tr>
<tr>
<td>7.2.2</td>
<td>Comparison of the Two Existing Databases</td>
<td>161</td>
</tr>
<tr>
<td>7.2.3</td>
<td>Investigating the Contents of the Two Example Systems</td>
<td>161</td>
</tr>
<tr>
<td>7.2.4</td>
<td>Applying the Framework for Exploring the Incident Reporting Process</td>
<td>162</td>
</tr>
<tr>
<td>8</td>
<td>Future Directions</td>
<td>163</td>
</tr>
<tr>
<td>9</td>
<td>Conclusions</td>
<td>168</td>
</tr>
<tr>
<td></td>
<td>Bibliography</td>
<td>170</td>
</tr>
<tr>
<td></td>
<td>Appendix A: Literature Search Methodology</td>
<td>180</td>
</tr>
<tr>
<td></td>
<td>Appendix B: Incident Database Assessment Methodology</td>
<td>182</td>
</tr>
<tr>
<td></td>
<td>Appendix C: Database Coding Inter-rater Reliability Results</td>
<td>191</td>
</tr>
</tbody>
</table>
List of Tables

Table 1: Notable benefits and goals of effective incident reporting systems ........................................... 2

Table 2: Methods used to collect health care error information ..................................................................... 9

Table 3: Reason’s cultural components of a ‘safe’ organizational culture ..................................................... 22

Table 4: Summary of the ten fundamental characteristics identified from the literature search as important consideration for analysis and communication activities in incident reporting systems .................................................................................................................................................. 53

Table 5: Summary of manufacturer and user facility mandatory reporting requirements to the MAUDE reporting system ........................................................................................................................................................................... 66

Table 6: The goal of the FDA’s MAUDE database and ISMP Canada’s Medication Incident Database and the operating organization’s punitive authority over the reporters ......................................................... 81

Table 7: Summary of the structural differences between the MAUDE and ISMP Canada Medication Incident Database based on the fundamental characteristics .............................................................................................................. 82

Table 8: Fundamental characteristics relevant to the extraction of Location, Impact, and Cause information from system reports ................................................................................................................................. 85

Table 9: Breakdown of the Cause field into its general categories and specific Cause coding options ........................................................................................................................................................................ 94

Table 10: Distribution of event Impact between the MAUDE and ISMP database (unknown harm category excluded) ........................................................................................................................................................................ 103

Table 11: Result of coding the Cause field of the reports found applicable to multiple IV infusion incidents within the MAUDE and ISMP Canada Medication Incident Database ........................................... 104

Table 12: Specific causes of multiple IV infusion incidents in which ISMP Canada’s Medication Incident Database and the FDA’s MAUDE database contained a significantly larger percentage of their incidents related to ......................................................................................................................... 108
Table 13: Typical organizational levels present within Rasmussen’s (1997) framework and examples of how they can be represented within the context of health care............................... 119

Table 14: The 10 fundamental characteristics of incident reporting systems that influence a system’s usefulness as a tool for incident analysis and communication ......................... 155

Table 15: Incident reporting systems in health care literature review summary ..................... 180

Table 16: Incident reporting systems in industry literature review summary ....................... 180

Table 17: Multiple IV infusion incident keywords with Microsoft Access query formatting.... 183

Table 18: Definitions and notes used in the identification of applicable reports and the first pass coding of the Impact and Location fields .......................................................... 184

Table 19: Terms used to denote if a report is suspected to be related to a multiple IV infusion issue, but does not explicitly mention multiple medications being delivered ..................... 187

Table 20: Further rules used to instruct the coding teams when to code a reports as "Suspected" applicability.................................................................................................................. 188

Table 21: Second pass coding options for the Cause field and rules used by the coding teams for the coding processes .................................................................................................. 188

Table 22: Fleiss’ Kappa results for establishing inter-rater reliability ........................................ 191
List of Figures

Figure 1: Reason’s “Swiss cheese” model of incident causation (adapted from Reason, 2000 and Vincent, 1998) .......................................................... 8

Figure 2: Health care incident data collection methods and their relative ability to detect latent conditions, active errors, and adverse events (adapted from Thomas & Petersen, 2003) .......... 10

Figure 3: Hierarchy of reporting (adapted from To Err is Human) .............................................. 29

Figure 4: Hierarchy of incident reporting system analysis techniques ........................................ 35

Figure 5: Multiple infusion setups A) Secondary “piggyback” infusion, B) Multichannel pump concurrent infusion, C) Multi-pump concurrent infusion, and D) Secondary and concurrent infusion ............................................................................................................ 87

Figure 6: Separation of the incident Cause based on its location within the IV administration setup (example shown for a piggyback infusion set-up) ......................................................... 94

Figure 7: Results of identifying the applicability (i.e. applicability as a multiple IV infusion incident) of the reports returned from the keyword search of the MAUDE and ISMP Canada Medication Incident Database ................................................................................................................................. 100

Figure 8: Results of coding the Location of the reports found applicable to multiple IV infusion incidents within the MAUDE and ISMP Canada Medication Incident Database ............. 101

Figure 9: Results of coding the Impact of the reports found applicable to multiple IV infusion incidents within the MAUDE and ISMP Canada Medication Incident Database ................. 102

Figure 10: Results of how often the reports of the MAUDE and ISMP Canada systems contained sufficient descriptive information to identify the Location, Impact, and Cause of an incident... 106

Figure 11: Notable differences between the ISMP Canada and MAUDE databases in the prevalence of multiple IV infusion incident causes related to infusion pump issues ............. 109

Figure 12: Hierarchical levels of a complex socio-technical system involved in risk management (adapted from Rasmussen (1997)) ............................................................................................................. 118
Figure 13: Legend for identifying the fundamental characteristics and other notable aspects in the reporting system frameworks

Figure 14: The FDA’s MAUDE incident reporting process mapped onto Rasmussen’s (1997) framework

Figure 15: ISMP Canada’s Medication Incident Database reporting process mapped onto Rasmussen’s (1997) framework

Figure 16: MAUDE framework highlighting the components related to the accessibility of the system to the public

Figure 17: ISMP Canada Medication Incident Database framework highlighting the components related to the accessibility of the system to the public

Figure 18: MAUDE framework highlighting the components related to the feedback of information to the reporter(s)

Figure 19: ISMP Canada Medication Incident Database framework highlighting the components related to the feedback of information to the reporter(s)

Figure 20: MAUDE framework highlighting the mechanisms related to promoting the specific goals of the MAUDE

Figure 21: MAUDE framework highlighting the mechanisms related to promoting the general four goals of incident reporting systems

Figure 22: ISMP Canada Medication Incident Database framework highlighting the mechanisms related to promoting the specific goals of the ISMP Canada system

Figure 23: ISMP Canada Medication Incident Database framework highlighting the mechanisms related to promoting the four general goals of incident reporting systems

Figure 24: Literature search strategy applied to the search for publications related to incident reporting in health care
Figure 25: Literature search strategy applied to the search for publications related to incident reporting in industry.
List of Appendices

Appendix A: Literature Search Methodology................................................................. 180
Appendix B: Incident Database Assessment Methodology............................................. 182
Appendix C: Database Coding Inter-rater Reliability Results....................................... 191
List of Abbreviations

AIMS – Advanced Incident Monitoring System
ASRS – Aviation Safety Reporting System
CMIRPS – Canadian Medication Incident Reporting and Prevention System
FAA – Federal Aviation Administration
FDA – Food and Drug Administration
FD&C Act – Federal Food, Drug, and Cosmetic Act
FMEA – Failure Modes and Effects Analysis
HTSRT – Health Technology Safety Research Team
ICPS – International Classification for Patient Safety
IOM – Institute of Medicine
ISMP – Institute for Safe Medication Practices
IV - Intravenous
JCAHO – Joint Commission on Accreditation of Health Organizations
MAUDE – Manufacturer and User Facility Device Experience
MDR – Medical Device Reporting
NASA – National Aeronautics and Space Administration
NCC MERP – National Coordinating Council for Medication Error Reporting and Prevention
NPSA – National Patient Safety Agency
NRLS – National Reporting and Learning System
NTSB – National Transportation Safety Board
SMDA – Safe Medical Devices Act
WHO – World Health Organization
1 Introduction

1.1 Prevalence of Incidents in Health Care

Studies based in various countries have estimated that approximately 2.9% to 16.6% of all hospital admissions are complicated by some form of adverse event.\textsuperscript{1-4} In the United States alone it is estimated that 44,000 to 98,000 fatalities and 1.3 million injuries occur each year as a result of medical errors.\textsuperscript{5,6} In Canada it was estimated that between 141,250 and 232,250 adverse events occurred in 2000, with 20.8% resulting in death.\textsuperscript{3} Furthermore, an estimated 36.9% of the incidents which occurred were judged to be preventable had adequate action been taken.\textsuperscript{3}

Despite the severity of this problem, incidents in health care seldom generate public attention. Unlike airline crashes that typically gain media attention, health care incidents tend to go unacknowledged as they usually occur one patient at a time in thousands of different locations spread across the country.\textsuperscript{7} Evaluating and understanding the types of incidents and why they occur is an essential component for developing effective strategies for improving safety in health care.\textsuperscript{4,8} Only within the past few decades have authors begun to highlight the need for more concern and efforts at error prevention.\textsuperscript{7,8}

1.2 Incident Reporting Systems

The Institute of Medicine’s (IOM’s) 1999 report \textit{To Err is Human, Building A Safer Health System} played a key role in bringing the public’s attention to issues of errors and incidents in health care in the United States and abroad.\textsuperscript{9} One of the primary recommendations of this report was the implementation of incident reporting systems. This recommendation was further highlighted by reports from the U.K., Australia, and Canada (\textit{An Organization with a Memory}\textsuperscript{10}, \textit{The Quality in Australian Health Care Study}\textsuperscript{11}, and \textit{Building a Safer System}\textsuperscript{12} respectively). These reports helped to make patient safety and incident reporting a major academic pursuit.\textsuperscript{9}

Incident reporting systems collect data about error events in a structured format for the detection, collation, and analysis of incidents.\textsuperscript{1,13} These systems serve as tools for detecting patterns, discovering underlying factors, focusing attention, and guiding actions.\textsuperscript{13,14} In addition, they serve to create a collaborative arena for understanding risks and generating solutions for preventing further incident occurrence.\textsuperscript{14} Incident reporting systems can guide retrospective
analysis of factors contributing to system failures, as well as prospective analysis for identifying potential risk factors and prompting mitigation strategies/actions.\textsuperscript{15} While incident analysis can be used as both a reactive and proactive tool, its strength lies in its ability to look at root causes and apply these findings to the future.\textsuperscript{16} Several key benefits of incident reporting systems as proposed in the literature are listed in Table 1.\textsuperscript{1,17} These benefits can also be considered goals of incident reporting systems that maximize their effectiveness as a tool for improving patient safety.

Table 1: Notable benefits and goals of effective incident reporting systems

<table>
<thead>
<tr>
<th>Benefits &amp; Goals of Effective Incident Reporting Systems</th>
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<tbody>
<tr>
<td>✓ Allow monitoring of underlying trends and patterns, encouraging early identification of incidents</td>
</tr>
<tr>
<td>✓ Support timely investigations of incidents</td>
</tr>
<tr>
<td>✓ Provide feedback to health care staff, patients, and administrative personnel regarding the nature of the incident and considerations underway to prevent future occurrence</td>
</tr>
<tr>
<td>✓ Promote learning from incidents, including near misses and adverse events</td>
</tr>
</tbody>
</table>

To this end there are four essential activities in incident reporting, which are often carried out in an iterative loop.\textsuperscript{8} These activities are:

1) **Collecting** incident information from those interacting within the system
2) **Identifying** and **analyzing** safety issues from the collected information
3) **Communicating** the findings and recommendations to people who can implement system changes
4) **Implementing** strategies which prevent future occurrence of similar events

In general, patient safety and health care literature has primarily focused on the act of collecting incident reports.\textsuperscript{4} However, limited focus has been given to the equally, if not more important, activities of analyzing and then communicating information from these reports.\textsuperscript{16,18} Collecting incident reports converts easily into numbers, trends, and targets, but this information by itself reveals comparatively little about causes and prevention strategies, which are the more important aspects of incident reporting.\textsuperscript{16,19} Reporting alone does not necessarily improve patient
safety.\textsuperscript{20,21} Simply counting reports is of relatively little utility while the analysis phase turns an incident report into a lesson.\textsuperscript{8,20,22}

Following incident analysis is the equally important activity of communicating these lessons. One of the World Health Organization’s (WHO’s) four core principles in its draft guidelines for Adverse Event Reporting and Learning Systems is that reporting is only of value if it leads to a constructive response.\textsuperscript{23,24} There are two primary paths where communication is required. The first is providing feedback on the findings and any mitigating strategies to the people who reported the issue in the first place. Keeping staff upraised of the actions being undertaken by providing robust, regular, and direct feedback is essential to successful incident reporting.\textsuperscript{8} However, most current reporting systems have a long way to go with regards to providing feedback.\textsuperscript{8} Typically what is experienced by reporters, rather than feedback or system change, is either no response or a punitive response.\textsuperscript{22} If reporting does not produce a constructive response, the concern is that front-line personnel may lose interest in continuing to provide reports, or simply report because ‘someone’ requires it, rather than trying to bring attention to issues requiring system change.\textsuperscript{22,25}

The second communication pathway leads to the fourth activity of incident reporting, implementing strategies to prevent reoccurrence. This pathway relays the analysis findings to people who can implement strategies to prevent similar incidents from occurring again, preferably not just at a local level but across the health care system. Simply generating periodic reports on incident reporting findings does not lead to improvements in system effectiveness.\textsuperscript{25} Incident reporting systems must stimulate changes and improvements in patient safety.\textsuperscript{25} Few efforts have been undertaken to evaluate if, and if so how, incident data is being used to improve patient safety.\textsuperscript{18} These lapses in effective communication may be partially responsible for health care staff in general, and physicians in particular, not acknowledging the importance of incident reporting systems.\textsuperscript{26}

Despite diligent efforts, most incident reporting systems in health care are still in their infancy.\textsuperscript{18} The groundwork has been laid by the IOM and other reports, but progress stemming from it has been slow.\textsuperscript{9} To reap the full benefits of incident reporting, there is a need to turn our attention to the activities of analysis and communication, items 2 and 3 from the list of four incident reporting activities listed above. By exploring and building on our understanding of these

activities of incident reporting, work can be undertaken to reinforce and strengthen them, thereby creating incident reporting system which live up to their full potential as patient safety tools.

1.3 Objective

This thesis is aimed at exploring and discussing the fundamental characteristics of incident reporting systems that are important influences on the usefulness of reporting systems in health care with regards to analysis and communication activities. While these characteristics may be implemented through different methods, they provide the mechanisms which impact the ability of a system to identify and analyze common underlying incident issues, learn from incidents and develop patient safety recommendations, and communicate this knowledge to those that can use it to prevent future occurrences. This work doesn’t aim to provide consensus on the best methods for implementing these characteristics, but rather explore the considerations surrounding these characteristics and the different methods through which they have been implemented. To this end, two incident reporting systems will be presented as case studies to explore the various considerations regarding the implementation of the fundamental characteristics. One consideration to be explored is how the characteristics may be structurally built into and represented within different reporting systems. The presented work then aims to explore how differences in the structural implementation of several of the characteristics impact the contents of the system and the ability to extract information useful for analysis activities. Finally, the interaction of the fundamental characteristics across the various organizational levels involved in the reporting process will be explored using a framework. The framework is also intended to help explore how a system’s implementation of the characteristics creates mechanisms for promoting the goals of the reporting system and communication of incident information. Overall, this work provides a concerted effort to explore characteristics related to analysis and communication activities that impact the usefulness of incident reporting systems in health care. This type of study has been suggested in the To Err Is Human report as an important area of exploration due to its potential for advancing the knowledge of how current systems could be made more effective.5

1.4 Study Goals

This study is primarily exploratory and will aim to investigate the following topics related to incident reporting systems in health care:
1. Through systematically examining literature on the use of incident reporting in health care and in high risk industries (e.g. aviation, chemical processing, and nuclear power generation), devise a list of the fundamental characteristics which are considered essential elements, providing the mechanisms for making incident reporting systems effective tools for incident analysis and communication.

2. Compare and contrast the structural design of two existing incident reporting databases based on the methods used to structurally implement the fundamental characteristics identified from the literature search.

3. Investigate if differences in the structural implementation of several of the fundamental characteristics in the two example databases impact the type of reports and the quality of information contained within the systems.

4. Map the incident reporting process of the two example databases onto a framework to highlight the portrayal of the fundamental characteristics across the various levels, individuals, and organization involved in the overall incident reporting system. The framework will also provide an avenue to explore the communication of incident information and the mechanisms incorporated into the systems for promoting the goals of the incident reporting.

1.5 Chapter Outline

In Chapter 2 of the presented work, background information regarding the nature of incidents and the adoption of incident reporting practices into health care settings is presented. Chapter 3 presents a systematic literature review which develops a list of fundamental characteristics that impact the analysis and communication activities of incident reporting systems. With the list of characteristics developed, Chapter 4 compares and contrasts how the characteristics have been structurally implemented within two existing health care incident reporting systems. These two incident reporting systems serve as examples of currently existing reporting systems and were used to explore the fundamental characteristics in the remainder of the presented work. Using the comparison findings, Chapter 5 presents an investigation exploring if structural differences of the two example reporting systems impact the type of reports and quality of information contained in the systems. In Chapter 6 a framework is presented for modeling incident reporting systems across an organizational hierarchy. The reporting process of the two example incident reporting systems introduced in Chapter 4 are mapped onto the framework and discussed with
regards to how the implementation and interaction of the fundamental characteristics create the mechanisms for promoting the reporting system’s goals. Chapter 7 discusses the important considerations stemming from the work presented in the previous chapters, as well as the limitations of the presented work. Following from this discussion, Chapter 8 presents directions for future work building upon the observations and finding from the presented research. Chapter 9 concludes the study and provides a summary of the work and the implications it has for the use of incident reporting systems in health care.
2 Background

2.1 Incident Terminology

When referring to incidents in health care there are a variety of terms used, each with slightly different meanings. The terms “error”, “event”, and “incident” are broad terms often used to encompass all forms of events in which an act does not achieve its intended outcome or resulted, or could have resulted, in unnecessary harm to a patient. Adverse events” are incidents in which there is physical or psychological injury or harm to a patient resulting from medical management rather than an underlying condition of the patient. “Near misses” are events in which the error has the potential to cause an adverse event, but fails to do so because of chance or because it is intercepted.

2.2 Why Incidents Occur

Health care is a complex, adaptive system involving 24-hour a day activity, the need for quick and difficult decisions, team coordination, and trade-offs between service and safety. As a result, the occurrence of incidents in health care environments is not surprising. There are two broad classifications of error: human error and systemic error. Human error can be isolated incidents due to an individual’s personal behavior or occur regularly due to an underlying undetected cause. With the rare exception of malicious acts, most errors are not caused by careless people or human error, but rather systemic errors. Systemic errors occur due to system flaws or organizational failures which create hidden conditions that eventually lead to errors on the front line.

Causes of errors are often further broken down and discussed in terms of “active failures” or “latent conditions”. Active failures arise only a short time before an incident occurs at the front line during the provision of direct patient care and often have immediate adverse consequences. Active failures can be hard to detect and are often knowledge, rule, skill, or technical based, being comprised of lapses, slips, mistakes, or procedural violations. Conversely, latent conditions are the result of upstream organizational factors, such as design and planning decisions, which create a situation where errors can arise. Latent conditions may exist unrecognized in the underlying system for a long time before resulting in an adverse
event. However, since they continually exist, by taking a proactive risk management approach they can be identified and remedied before resulting in an adverse event.  

In general, most adverse events are the result of a combination of active failures and latent conditions. Errors typically arise from a chain of circumstances, with a wide variety of contributory factors, which align in time and space in such a way as to lead to an incident. Reason’s “Swiss cheese” model of incident causation (shown in Figure 1) illustrates how latent conditions, active failures, and contextual factors align to allow hazardous situations to penetrate system defenses, barriers and safeguards, leading to an incident.

---

**Figure 1: Reason’s “Swiss cheese” model of incident causation (adapted from Reason, 2000 and Vincent, 1998)**

In general, major health care incidents are rare and when they do occur they gain attention by health care staff in the facility where the incident occurred and on occasion gain media attention. However, unspectacular incidents which occur far more frequently typically go unrecognized. Far from being random isolated incidents, these unspectacular incidents tend to fall into recurrent patterns with the same set of circumstance continually provoking similar errors, regardless of the people involved. H.W. Heinrich in 1941 studied industrial accidents and calculated that for every 300 near misses there would be 29 minor injuries and 1 major injury (now called the Heinrich ratio). While the methodology and numbers of Heinrich’s work have been challenged, the concept still remains valid and applicable to health care. Near miss events occur far more frequently, but the factors that allow for these near misses occasionally align for a major accident...
to occur. Thus, the collection of information about incidents and near misses is a much-needed element for understanding and preventing safety issues.

### 2.3 Collecting Information about Incidents in Health Care

There are many approaches that health care organizations may use to gather information on safety issues.\(^{4,34}\) Several common methods are described in Table 2.\(^{2,4,34-36}\)

**Table 2: Methods used to collect health care error information**

<table>
<thead>
<tr>
<th>Method</th>
<th>Advantages</th>
<th>Limitations</th>
<th>Commonly Documented Error Types</th>
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<tbody>
<tr>
<td><strong>Direct Observation</strong></td>
<td>• Identifies a large number of event types</td>
<td>• Labor intensive</td>
<td>• Medication</td>
</tr>
<tr>
<td>Observation of health care</td>
<td>• Real time</td>
<td>• Expensive</td>
<td>• Compliance</td>
</tr>
<tr>
<td>staff as they perform tasks</td>
<td></td>
<td>• Observer bias</td>
<td>• Procedure</td>
</tr>
<tr>
<td><strong>Chart Review</strong></td>
<td>• Reliably captures actual events (not near misses)</td>
<td>• Retrospective</td>
<td>• Medication</td>
</tr>
<tr>
<td>Review of written records</td>
<td></td>
<td>• Less reliable than direct observation</td>
<td>• Treatment</td>
</tr>
<tr>
<td>documenting patient care</td>
<td></td>
<td></td>
<td>• Procedures and monitoring</td>
</tr>
<tr>
<td><strong>Malpractice Claims</strong></td>
<td>• Captures rare, but serious events</td>
<td>• Retrospective</td>
<td>• Clinical judgment</td>
</tr>
<tr>
<td>Review of factors contributing to the allegation or initiation of a claim/suit</td>
<td></td>
<td>• Selection bias</td>
<td>• Communication</td>
</tr>
<tr>
<td><strong>Patient Complaints</strong></td>
<td>• Identifies problems about patient experience</td>
<td>• Retrospective</td>
<td>• Technical skills</td>
</tr>
<tr>
<td>Documented complaints, concerns, or suggestions by patients or their family</td>
<td></td>
<td>• May be dismissed as “service problems”</td>
<td></td>
</tr>
<tr>
<td><strong>Executive Walk Rounds</strong></td>
<td>• Bidirectional feedback</td>
<td>• Fear of blame</td>
<td>• Equipment</td>
</tr>
<tr>
<td>Executive leadership visits a site of patient care and engages with staff about safety concerns</td>
<td>• Stimulated conversation</td>
<td>• Tempting to focus on easy fixes</td>
<td>• Infrastructure</td>
</tr>
<tr>
<td></td>
<td>• Inexpensive</td>
<td></td>
<td>• Electronic records technology</td>
</tr>
<tr>
<td><strong>Incident Reporting</strong></td>
<td>• Captures a wide range of events and near misses</td>
<td>• Underreporting</td>
<td>• Falls</td>
</tr>
<tr>
<td>Mandatory or voluntary</td>
<td></td>
<td>• Less reliable than direct observation</td>
<td>• Medication problems</td>
</tr>
<tr>
<td>reporting of errors to risk management by health care staff</td>
<td></td>
<td></td>
<td>• Patient identification</td>
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Comparison of incidents detected by the different methods shows relatively little overlap between sources.\textsuperscript{34,36} Each method tends to provide its own unique view of safety problems in health care, with no single method adequately detecting the full range of target events.\textsuperscript{25,36} The picture of patient safety depends on the method(s) used to generate it, with each method having its own advantages and limitations.\textsuperscript{34,35} Figure 2 shows the relative ability of the various methods at detecting latent conditions, active errors, and adverse events.\textsuperscript{37}

![Figure 2: Health care incident data collection methods and their relative ability to detect latent conditions, active errors, and adverse events (adapted from Thomas & Petersen, 2003)](image)

Methods to the left of this continuum tend to capture more contextual information which surrounds errors and are thereby good at identifying latent conditions.\textsuperscript{37} To the right of the continuum are methods which provide precise and accurate estimates of error in a prospective fashion. However, these methods are poor at detecting latent conditions as contributory factors may have occurred at a different time or place than that of the error.\textsuperscript{37}

It is infeasible for hospitals to use all these methods to gather safety information. Therefore most hospitals only use a combination of a couple of the methods mentioned. However, incident reporting has become a cornerstone for assessing and improving safety.\textsuperscript{4} In various countries around the world, including the U.S., U.K., Australia, and Canada, incident reporting systems have become a centerpiece of national patient safety policies.\textsuperscript{21}
2.4 The Evolution of Incident Reporting Systems

Accidents in high-risk industries, such as nuclear power technology, chemical processing, aviation, or military operations, can cost many lives, damage the environment, and generate a lot of public concern. In addition, incidents can be expensive in terms of their direct and indirect costs, as well as reputation. As such, it is easy to understand why these industries were relatively quick to uptake the practice of incident reporting. In these fields, incident reporting serves to identify unanticipated risks in the planning and design of operations which would not otherwise be captured in audit or assurance programs. Incident reporting in aviation dates back to 1954 when assessing the causes of airplane crashed during World War II. The perceived effectiveness of incident reporting in industry can partially be attributed to its ability to capture contextual information and by providing insights in local problems, used to highlight regional and national patterns of failure.

The apparent success of incident reporting systems such as these served as models and the motivation for developing similar systems in health care. Around 1965, risk managers started adapting incident reporting practices into hospitals. However, rather than aiming to improve patient safety, these ‘risk management’ systems were intended to prevent and prepare for litigation. Doctors and nurses were encouraged to report potentially litigious events in order to build a better defense in case of litigation. This trend continued as malpractice litigation rates grew through the 1970’s.

Anesthesia departments were the first to begin to shift the focus away from litigation and back towards reducing accidents and improving safety. Anesthesiologists led the way in recognizing system factors as the causes of errors and implementing fail-safe systems and error training programs. In 1991, the publication of the Harvard Medical Practice Study drew attention to the magnitude of errors in the health care system. This report found that 3.7% of hospitalized patients in New York City sustained unintended injuries due to their treatment. Following this publication, the emphasis on patient safety gained momentum through the 1990’s as other authors began writing about successful safety strategies in other high-risk industries. The publication of To Err is Human in 1999 made the general public aware of the magnitude of errors in health care and helped trigger worldwide political efforts to improve patient safety. Over the past couple of decades political initiatives, hospital associations, professional societies,
and accrediting bodies have been successful in encouraging consequential changes in incident reporting systems worldwide. Within the last several years numerous countries have undertaken initiatives to established national or system-wide incident reporting and analysis systems. However, compared with other high-risk industries, health care incident reporting systems remain relatively immature, with fragmented reporting processes and poor sharing of information.

2.5 Differences in Incident Reporting Between Industry and Health Care

Despite evolving from incident reporting systems in high-risk industries such as aviation, nuclear power, and chemical processing, health care is a very different field with unique characteristics that aren’t always taken into account. Policy makers and risk management often look to the apparent success of incident reporting systems in aviation to support the transfer of methods to the development of health care systems. However, while there are several similarities between the two fields there are contextual differences that influence the feasibility of identifying, analyzing, and learning from incidents.

Unlike incidents in aviation or nuclear power which are infrequent, highly visible, and may involve massive loss of life, incidents in health care happen to individual patients, one at a time, and seldom receive public attention. While the human cost of a single error in industry has the potential to be on the scale of hundreds, in health care the human cost typically is much less for a single error. However, these seemingly single errors in health care may occur numerous times in hundreds of institutions across the country. As a result, the error rates in health care are estimated to be nearly 100,000-fold greater than in industry. Therefore, methods and processes which aviation uses for managing the number of incident reports they receive may not be feasible to implement in health care. Put into perspective, in 2005 there were 2,015 aviation incidents reported to the National Transportation Safety Board (NTSB) occurring within the U.S. and international airspace. The U.K. National Reporting and Learning System (NRLS) for health care incidents receives approximately this number of reports every 36 hours.

Fields of industry and health care both involve highly trained professionals working as teams and depend on technology to complete tasks with potentially harmful outcomes. However, there are significant difference in the complexity and variability of the tasks being performed between the
fields. Tasks in industry are often routine, with standardized procedures, and sometimes assisted by some level of automation. In contrast, standardization and task design in health care can vary widely. Tasks in the operating room have become highly refined and standardized, but in patient care units it is harder to standardize tasks with the variability of patient characteristics, treatment regimens, recovery times, etc.

Health care also presents a very distinct legal, ethical and regulatory environment. The threat of malpractice lawsuits and legal action is what initially brought about the use of incident reporting in health care. Health care professionals continuously make decisions which will impact a patient’s well being. As such they are held to a certain standard and have trust placed on them. This sort of responsibility also carries with it the very prominent risk of legal action if any sort of error occurs, resulting in incident reporting being intertwined with a fear of the legal environment. In health care incident reporting, there is also the ethical responsibility surrounding the patient’s privacy and restrictions in place for disclosing patient information, presenting a unique risk of liability for clinicians. Finally, unlike industry which is often highly regulated by a single, centralized oversight body, health care tends to be a mix of monitoring agencies, accreditation bodies, government licensing bodies, and numerous specialized professional associations which are responsible for setting standards. This makes assigning responsibilities with respect to incident reporting in health care a difficult task.

Safety concerns in health care are similar enough to those in high-risk industries to warrant learning from each other, but this should not go as far as importing programs, procedures, and practices directly from one field into the other. Health care is a very unique field and needs to develop its own solutions for dealing with incident reporting. The experience of other systems, such as those in aviation, can be used as a template for developing the systems, but it is fundamentally a transfer of principles rather than practices and procedures.

2.6 Barriers of Health Care Incident Reporting Systems

Commonly reported barriers to the process of reporting incidents by health care staff include:

- Fear of blame, litigation, and disciplinary action for error
- Lack of awareness or disagreement over whether or not a reportable error had occurred
- The effort and time required to submit a report
- Perception of a limited management response from reports
- Lack of feedback

For example, a survey by Evans et al. found the most common barriers to reporting noted by doctors were lack of feedback, the reporting form taking too long to complete, and a belief that an event was too trivial to report. For nurses the survey found the biggest barriers were lack of feedback, belief that there is no point in reporting near miss events, and forgetting to report when too busy. Another issue is “defining away” an incident based on the perception that it does not fit with an organization’s definition of a reportable incident. These barriers affect one group of users of incident reporting systems which are the front line staff reporting information into the system. These barriers at the collection stage of incident reporting have an impact throughout the entire flow of incident information.

With regards to incident reporting systems themselves, barriers commonly identified include:

- Underreporting
- The subjective nature of the reports
- Low quality of documented information
- Insufficient resources available (financial/human)
- Lack of consistency and standard approaches

Underreporting of incidents remains a significant issue for incident reporting systems, with estimates that as many as 95% of adverse events go unreported. Participation bias is another identified issue and refers to the limited reporting of some health care professions. Nurses are the most frequent contributors to incident reports, largely due to their substantial direct interaction with patients. Physicians tend to report incidents less than nurses and as such it biases the distribution of incidents more towards nursing related tasks. Overall, uptake and compliance of incident reporting among health care professionals has been low and inconsistent. Another fundamental issue with reporting systems is they can generate thousands of reports, but lack denominators to serve as a basis to assess the actual prevalence of events. These barriers affect the second group of users of incident reporting systems and those are the
analysts tasked with identifying error trends and developing solutions to help prevent future occurrence.

2.7 Chapter Summary

With rare exceptions, incidents are generally the result of hidden conditions within a system as opposed to careless people or human error. Incidents typically arise due to an alignment of contributory factors involving latent conditions, active failures, and contextual factors which allow for hazardous situation to become errors. Collecting information about these errors and incidents offers opportunities for understanding and learning from these problems to create safer systems. While there are several methods which promote this, incident reporting has become a centerpiece of national patient safety policies in a variety of countries. Incident reporting started in high-risk industries such as aviation, and eventually migrated to the health care system. While health care and high-risk industries may share some similarities, health care is a very unique and complex environment. Therefore, health care needs to develop its own practices and strategies for implementing and using incident reporting systems and cannot directly transfer these from other successful industry based systems. Overall, incident reporting systems in health care are still relatively immature, fragmented, and have a variety of barriers preventing their effective use. As such, there is a need to explore incident reporting systems in more detail to understand how to make the systems more effective. To this end the next chapter provides a detailed search of the literature to explore the fundamental characteristics important to performing the analysis and communication activities vital to successful incident reporting systems.
3 Fundamental Characteristics of Incident Reporting Systems

3.1 Objective

The objective of this systematic literature search is to develop a list of the fundamental characteristics commonly cited as important influences on the usefulness and effectiveness of incident reporting systems with regards to analysis and communication activities. Literature with respect to incident reporting systems in both health care and high-risk industrial settings was targeted by this review process. Incident reporting systems within high risk industries, such as aviation, chemical processing, and nuclear power generation were included in this process as some of the systems and reporting practices have been around for longer than those in health care.

3.2 Methodology

A systematic review of the literature was carried out by searching online literature databases for relevant publications discussing the use or design of incident reporting systems for the purposes of incident analysis, building of safety recommendations, or communicating incident information. The review was divided into two parts, with the first part focusing on incident reporting in health care and the second part focusing on reporting systems in other industries such as aviation, nuclear safety, and chemical processing. Articles from any country were considered, but only articles published in English were included in the review. To correspond to the publishing of *To Err is Human* and similar national reports in the late 1990’s, articles published between 1996 and January 2011 were included in the literature review.

All the articles returned from the search are reviewed against a set of inclusion and exclusion criteria. The inclusion and exclusion criteria were developed by the researcher. The inclusion criteria are based on the need to capture publications which referred to the characteristics and concepts surrounding the design and/or use of incident reporting systems. The exclusion criteria were developed to remove publications that only focus on collecting incident reports or superficially use incident reporting data without reference to any characteristics or concepts important to analysis and communication activities. The inclusion and exclusion criteria are presented below:
Articles which discussed the following themes were included in the relevant literature

- Analysis of incident reports with reference to characteristics of the system which affect the analysis process
- Implementation or evaluation of an incident reporting system
- Comparison of multiple incident reporting systems with regards to differences in how the system is operated or designed
- Discussion of concepts or elements that affect the use of incident reporting systems for collecting or analyzing reporting data

Articles which focused solely on the following topics without reference to any component of the inclusion criteria categories were excluded from the relevant literature

- Safety/reporting culture
- Assessment of an event type which only superficially made use of incident data

Table 15 and Table 16 within Appendix A document the literature databases and search terms used in the two-part literature search. Information Specialists from the University Health Network Library and the University of Toronto Engineering & Computer Science Library were consulted regarding the literature databases most relevant to the topic of incident reporting. Figure 24 and Figure 25 in Appendix A summarize the literature search process.

A total of 476 citations were found from the incident reporting in health care literature search and 541 citations from the literature search of incident reporting in industry. These values do not take into account articles duplicated between the literature databases. After reviewing all the article titles and abstracts returned from the database search, all sources were assessed against the established inclusion and exclusion criteria leaving 82 health care related articles and 74 industry related articles. Upon reading these articles fully and assessing against the inclusion and exclusion criteria the articles were further reduced to 78 and 41 publications respectively. A substantial number of publications relevant to incident reporting in industry were excluded at this point as they tended to focus on specific incident case studies rather than concepts which affect the usefulness of the reporting systems.

After removing any duplicated publications between the literature databases a total of 51 and 31 non-duplicated citations where found from the health care and industry searches respectively. Bibliographic references which were commonly cross-referenced between the search results
were retrieved and reviewed against the inclusion and exclusion criteria. Publications that were deemed relevant were added to the collection of applicable articles. This process resulted in an additional 32 articles and reports being added to the comprehensive review. This includes papers from organizations and governmental bodies such as the World Health Organization, Institute of Medicine, and Canadian Patient Safety Institute. At the end of the literature review process 114 publications had been identified as relevant to exploring the elements which are considered to be essential for effective incident reporting systems. Thematic analysis was used to extract and group common topics and ideas presented within these publications. This grouping of topics and ideas served to develop the list of fundamental characteristics for incident reporting systems with regards to the analysis and communication of incident information. These characteristics are explored and characterized in the following sections.

3.3 Literature Findings

Several authors have put forth properties and characteristics for successful incident reporting systems. For example, drawing on published literature Leape (2002) adapted a list suggesting that successful incident reporting systems in health care are exemplified by the following characteristics:

1) Nonpunitive
   - Reporters do not fear punishment from others as a result of reporting
2) Confidential
   - The identities of the patient, reporter, and institution are not revealed to a third party
3) Independent
   - An independent organization without the power to punish the reporter or organization analyzes the system data
4) Supported by Expert Analysis
   - Reports are analyzed by experts experienced in identifying underlying system causes and have an understanding of clinical circumstances
5) Timely Feedback to System Users
   - Reports are analyzed promptly with feedback quickly disseminated to staff where the report originated and those who can implement system change
6) Systems-Oriented
   - Recommendations arising from report analysis focus on changing systems, processes, or products, rather than on individual performance

7) Responsive
   - Disseminated recommendation are acted upon by participant organization whenever possible

This list presents some of the characteristics of a successful incident reporting system and is supported by numerous authors, but is not necessarily comprehensive. For example, the WHO Draft Guidelines for Adverse Event Reporting and Learning Systems supported this list of characteristics, but also added that systems must be credible. Credibility comes from the combination of independent and expert analysts helping to validate the recommendations to facilitate their acceptance. The WHO also noted that successful systems must lead to meaningful analysis and constructive response, be supported by adequate human and financial resources, and capable of disseminating recommendations.

Runciman (2002) proposed that national reporting and learning systems: be independent; utilize common, agreed standards and terminology; use a single clinically useful classification; provide reporters with anonymity and legal privilege; provide rapid feedback and evidence of action. Other authors have put forth other considerations that complement Leape’s and Runciman’s characteristics including the organizational culture, denominator data, dedicated system personnel, standardized coding and terminology, and data analysis methodology. The following sections aim to explore the fundamental characteristics highlighted by these and other authors as important elements which impact the structure and effectiveness of incident reporting systems. The benefits, limitations, and alternative approaches surrounding the concepts are explored with regard to their role in the effective analysis of incident reports. Many of the characteristics can be portrayed through multiple methods and in many cases there is no consensus regarding which method is superior in all situations. Therefore, this review aims to explore the characteristics and the main methods by which they have been implemented without drawing conclusions as to the optimal method of implementation.
3.3.1 Reporting Culture

The reporting culture is the organizational climate in which people are prepared to report errors. The culture of medicine is deeply rooted and places emphasis on high standards of performance by trained and skilled autonomous individuals. Therefore, when incidents occur there is a conflict with this cultural perception of high standards of performance and skilled professionals which plays a major role in the willingness of health care staff to report incidents. A number of publications have been devoted to how the culture affects reporting practices and how to promote a culture that is more conducive to reporting. The literature has primarily focused on the reporting culture as it relates to the reporting activities of incident reporting systems. However, the impact at the level of reporting will affect the number and quality of reports within the system, thereby influencing the capacity to carry out meaningful analysis.

The cultural aspects which influence reporting incidents in health care can be broken down into a number of categories which include the following proposed by Chamberlain (2008):

- Fear
  - Despite the widely disseminated message in various reports in the past decade that incidents typically result from system failures, there still remains a perception that incidents reflect incompetent staff. There are multiple dimensions of fear associated with incident reporting including fear of embarrassment, fear of punishment of self, fear of punishment of others, and fear of litigation. Health care incident reporting systems having initially evolved to prevent and prepare for litigation has not helped this perception as there remains a level of fear that reports are used to assign blame. Providing legal protection from data discoverability may help alleviate the fear of litigation, but not necessarily the other aspects of fear. As a result, people tend to resist reporting events that they can easily hide.

- Medical Culture
  - Medicine can be a very individualistic and competitive field. As such, health care staff may view their errors as a failure of character; that they weren’t careful enough or they didn’t try hard enough. This is similarly observed in other competitive occupations, such as test pilots. This attitude can result in a
reluctance to admit mistakes in order to maintain an aire of infallibility and not appear foolish or incompetent in the eyes of their colleagues.\textsuperscript{17,60}

- **Individual Factors**
  - Individual factors are those that are perceived to discourage the act of reporting by demonstrating no benefit or reward to reporting. Reporters may not perceive any kind of reward for reporting or in some cases may be actively discourage from reporting\textsuperscript{17} Pay schemes do not often reflect participation in incident reporting and those individuals who don’t report may seem more competent as they are perceived as having lower incident rates\textsuperscript{17} In some cases, there is a lack of clarity regarding what to report, disclosure and legal issues, and how the data is used, all of which impact the staff’s willingness to use reporting systems\textsuperscript{17}

- **Organizational Factors**
  - Hospitals and health care facilities can be reluctant to discuss and disclose incident information that could bring public attention to their organization.\textsuperscript{17} Admission of even a few errors, or reporting of average error rates, can be misinterpreted by an un-informed public as a high prevalence of errors.\textsuperscript{17} This in turn can lead to adverse publicity and liability for the organization and loss of public confidence.\textsuperscript{17} Trial by media can be particularly detrimental to incident reporting and work to enforce a blame and shame culture.\textsuperscript{17} While accountability and transparency are important to the public, it can be hard on incident reporting systems.

- **Knowledge Factors**
  - Not all health care workers believe incidents in health care are as big a problem as has been published.\textsuperscript{17} Some individuals don’t believe they are capable of making a mistake or that incident reporting is capable of bringing about constructive change.\textsuperscript{17,22} Physicians in particular may see incident reporting as inferior qualitative research and not supported by ‘hard’ scientific evidence.\textsuperscript{17,63}

A 2000 survey of 182 intensive care staff in several countries found that errors are not acknowledged or discussed due to: risk to personal reputation (76%), the threat of malpractice suits (71%), high expectations of the patients’ family or society (68%), possible disciplinary
actions by licensing boards (64%), threat to job security (63%) and expectations or egos of other team members (61% and 60%).

Aviation was a leader in building an open, blame-free, and supportive reporting culture, realizing that such a culture is likely to encourage reporting much better than a punitive system. Aircraft designers have acknowledged early on that errors and failures are inevitable and therefore design systems to “absorb” errors. Designers build in multiple buffers, automation, and redundancy in preparation for errors, pilots go through rigorous checklist prior to takeoff, and there are standardized procedures and protocols which are followed for trip planning, operations, and maintenance. Instead of blaming individuals for forgetfulness, carelessness, or moral weakness this systems approach to safety management sees errors as opportunities to improve and build a better system.

A similar culture of safety has been building in health care, having recognized that reporting is more likely to gain acceptance if individuals reporting errors do not need to worry about blame or adverse consequences to themselves or others. A blame culture or even the perception of a blame culture is detrimental to the incident reporting process as it can prevent reporters from elaborating and providing rich details about incidents or even reporting an error at all. Reason (1997) identified four interconnected components to establishing a ‘safe’ organizational culture, shown in Table 3.

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<th>Table 3: Reason’s cultural components of a ‘safe’ organizational culture</th>
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<td><strong>Cultural Component</strong></td>
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<td>Reporting Culture</td>
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<tr>
<td>Just Culture</td>
</tr>
<tr>
<td>Learning Culture</td>
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<td>Flexible Culture</td>
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Organizations have begun to acknowledge that it is difficult to change the human condition and it is much more effective to focus on the conditions under which humans work.\textsuperscript{32} This greatly contrasts the traditional ‘blame and shame’ mindset which sees errors as the result of unwanted variability in human behavior and that staff need “to try harder” or “be more careful”.\textsuperscript{32,51} A culture of no-blame does not mean individuals can be careless; they are still responsible for their actions.\textsuperscript{5} However, when errors do occur the main focus is on preventing someone else from committing the same error, not punishing the responsible individual.\textsuperscript{5} Nevertheless, reporting cannot be completely blame-free.\textsuperscript{57} Health care organizations need to be accountable and sanctions imposed against those violating patient safety.\textsuperscript{57} However, this level of risk of blame can be justifiable if only serious violations are targeted and the reporting system provides useful information back to participating organizations.\textsuperscript{57}

**Characteristic Summary: Reporting Culture**

In summary, the reporting culture refers to the consequences that individuals or facilities perceive may be leveled against them by supervisory groups or organizations for their involvement in an incident. A blame-free culture may have no consequences for involvement in an incident. In contrast, adverse consequences such as fines or being fired may influence reporters to hide incidents rather than risk the consequences. The reporting culture surrounding the system will impact the willingness of people to report events.

### 3.3.2 Classification of a ‘Reportable Event’

The classification and definition used to define what is encompassed by the term ‘reportable event’ varies between incident reporting systems and influences whether an event is recognized and reported or ignored.\textsuperscript{13,54} Definitions of a reportable event can range from specific (e.g. medication or surgical errors) to very broad (e.g. all incidents within a facility) and reflect the type or severity of an event.\textsuperscript{18} In addition, a study by Tamuz et al. (2004) found the classification of an error by those reporting is also influenced by where the event was detected in the process of delivering care (e.g. pharmacy versus the patient’s bedside).\textsuperscript{54} This issue is further complicated by lack of clear and consistent definitions, reporter perceptions and judgments, and conceptual misunderstandings.\textsuperscript{18,54,67} Incident reporting systems need clarity about the system’s
purpose and a clear definition of what events are considered reportable.\textsuperscript{8,17,18,54} This is not an easy task as it requires a balance to be struck between capturing as many significant events as possible while not overburdening the reporters and analysts, who may not have the time or resources to manage a large number of reports.\textsuperscript{1,62} However, incidents need to be submitted into the system in sufficient quantity as to ensure the detection of non-spurious events and contributing factors.\textsuperscript{68}

### 3.3.2.1 Reportable Incidents Defined By Patient Impact

Classifying reportable incidents by the severity of the event’s impact on the patient is one way of fixing the scope of an incident reporting system. Major adverse events and accidents, also called sentinel events, in which an event leads to death or serious physical or psychological injury tend to grab headlines and draw a lot of attention and concern.\textsuperscript{69} The outcomes of these event types are usually tangible and tend to be very recognizable for reporting purposes.\textsuperscript{18} Sentinel events include surgery on the wrong patient or wrong body part, unintended retention of a foreign object in a patient after surgery, and infant abduction.\textsuperscript{23} The U.S. Joint Commission on Accreditation of Healthcare Organizations (JCAHO) operates a voluntary system called the Sentinel Event Reporting System which collects only sentinel events. While these types of events are very concerning, fortunately they occur relatively rarely.\textsuperscript{69} Therefore, concentrating solely on sentinel events means relatively few cases to analyze, which can make trending harder, but frees resources to allow for more detailed analysis on a case by case basis. A limitation of this is the potential to implement ad-hoc corrective measure after each individual event rather than solutions that can be distributed across the health care system.\textsuperscript{69} This issue arises due to the database size being too small to generate statistically effective preventive measures.\textsuperscript{69}

As the severity of the incident decreases the number of errors tends to increase. For example, medication errors resulting in minor to no patient harm outnumber adverse drug events by about 100:1.\textsuperscript{70} At the other end of the impact spectrum from sentinel events are near misses. Near misses are events or near-events in which no harm occurs or a potentially harmful error is intercepted before resulting in harm. Although these incidents have no significant consequences they can still help identify system deficiencies and vulnerabilities.\textsuperscript{71} However, while near misses occur in far greater numbers than adverse events, they are often invisible and harder to detect.\textsuperscript{67,69,72} Studies of commercial aviation have shown that the causal path and root causes of
near misses are likely to be similar to those of that develop into a severe incident.\textsuperscript{69} It is assumed that the same is true for near misses in medicine.\textsuperscript{67,69} The greater number of near misses than adverse and sentinel events and the similarities in causal paths offers incident reporting systems a way to expand their dataset. Reporting of near misses may also act to lessen the fear of blame for those reporting since no actual patient harm occurred.\textsuperscript{73} Therefore, near misses provide information on system improvements without having to suffer the consequences of a full adverse event.\textsuperscript{8,38,67} However, since no harm occurred or the event was quickly rectified some staff believe near misses to be too trivial to be worth reporting.\textsuperscript{8,67,74} A survey by Evans et al. (2006) found that when compared to events with immediate outcomes, such as patient falls and medication errors requiring corrective treatment, near misses were the least likely to be reported.\textsuperscript{53}

### 3.3.2.2 Reportable Incidents Defined By Type of Event

A second way of classifying reportable incidents is by defining the type of incidents the system is targeted towards. Some systems are broad and open to all types of incidents, such as the National Reporting and Learning System (NRLS) in England and Wales, the Australian Advanced Incident Monitoring System (AIMS), and the Confidential Incident Reporting & Analysis System of the UK rail industry.\textsuperscript{5,62} However, reporting systems commonly tend to be more focused in scope, looking at the reporting of specific kinds of incidents.\textsuperscript{5,43} Specialty systems group incident categories based on shared features and common natures.\textsuperscript{27} Examples of specialty based reporting systems include the U.S.A. MedMARx\textsuperscript{SM}, the Canadian Medication Incident Reporting Prevention System (CMIRPS), and ISMP’s Medication Error Reporting Program which are all targeted at medication incidents. Specialty based reporting systems provide information on factors and error patterns associated with events within unique specialties.\textsuperscript{29,75} In general, these systems aim to provide relevant expert feedback for understanding a particular domain of health care and can be tailored to clinicians’ specific concerns.\textsuperscript{23,62} Leape (2002) proposes that systems that are specialty based or system-wide are much more feasible than national reporting systems.\textsuperscript{57} However, specialty based systems tend to be more valuable for gaining a deeper understanding of problems than discovering new areas of vulnerability.\textsuperscript{23} In addition, separation of reporting systems based on incident type may divide data from interdependent process components and thereby restrict the ability to identify trends.
and causal factors. For example, medication and technology aspects of drug administration may be separated into two different systems.

A survey by Evans et al. (2006) noted that staff are more likely to report incidents which are habitually reported, often witnessed, and usually associated with immediate outcomes. As a result, slips, trips and falls account for a large number of incidents reported as they typically are highly noticeable with the patient impact almost immediately known and often cannot be attributed to the actions of the clinical staff. Due to the ease at which reports of this nature can be submitted their numbers can easily contribute to a large portion of the incident reporting dataset. While this can provide rich information for targeting a common incident trend it can swamp the system with reports that make it difficult to identify less prominent, yet critical issues. Aviation is aware of this issue of ‘over-reporting’ where pointless or trivial reports are continuously submitted which can overwhelm the system. Therefore, however the system defines a ‘reportable event’, it must be constructed to ensure that the incidents collected reflect those that pose the greatest threats to patient safety.

**Characteristic Summary: Classification of a ‘Reportable Event’**

Overall, the classification of a ‘reportable event’ refers to the definition used to describe the incidents that should be reported to the system. Identifying a specific patient impact, (e.g. death or no harm), event type (e.g. medication or surgical error), or combinations of an impact and event type (i.e. medication errors resulting in death) can create systems targeted at collecting specific groupings of incidents. This characteristic not only influences what gets reported to the systems, but also what does not.

### 3.3.3 Operational Aspects

There is much discussion regarding the management of incident reporting systems and how a system should be operated to collect reports with rich and useful data without heightening the fear associated with reporting. Reporting systems are typically implemented with two functions in mind:

1) Provide information that leads to improved safety
2) Hold providers accountable for performance

While these two functions on a conceptual level seem to complement one another, in reality they prove difficult to satisfy simultaneously.\(^5\) As a result two broad ways of classifying the operation of systems has emerged: mandatory and voluntary reporting. Mandatory systems require individuals or organizations to submit incident reports as mandated by law, policy/regulation, or other formal means.\(^5,76\) Voluntary systems do not have an external authority mandating individuals to submit reports, but creates a medium to allow people to freely submit and share reports without compulsion.\(^5,76\) Whether a system is voluntary or mandatory will influence how incidents are captured in the reporting system.\(^46\) The operation of a reporting system can also be defined by how the identification of the reporter is handled. Identifying systems provide information regarding the care provider(s) who submitted and were involved in the reported incident. In contrast, anonymous systems contain no identifiable details of the care provider(s). Confidential reporting systems are a composite of the other two identification techniques in which reports contain identifiable details visible only to the individuals responsible for analyzing the reports. For all other users of the reporting system the report is de-identified. The following sections explore the benefits and limitations of the aforementioned aspects of the operation of incident reporting systems.

### 3.3.3.1 Voluntary and Mandatory Reporting

**Mandatory Reporting**

Mandatory reporting systems are typically governed by bodies that either implicitly or explicitly hold someone accountable for ensuring safe practice.\(^23,46\) As a result they are often targeted at specific types of incidents, taking an outcome-oriented approach by capturing events resulting in severe harm or death.\(^5,46,73,77\) These types of accountability systems are built on the belief that the government has a responsibility to the public to ensure that health care organizations adhere to necessary safety precautions and regulations to ensure care if provided safely.\(^23\) Mandated oversight by a government agency helps maintain the public’s trust in the system.\(^23\) In fact, surveys of the public have found a large majority favor the use of mandated reporting system.\(^78\) U.S. based surveys saw that 62-73% of Americans believe it is the public’s right to have information on adverse events publicly available.\(^23\) In addition, some believe that only by
mandating reporting will the full importance of reporting errors be conveyed to clinical staff.\textsuperscript{79} One of the recommendations stemming from \textit{To Err is Human} was the implementation of nationwide mandatory reporting programs with standardized reporting formats for serious adverse events.\textsuperscript{5}

Mandatory systems want full disclosure of incident information and may be used to identify unsafe practices by practitioners and facilities, potentially imposing citations, penalties, or sanctions.\textsuperscript{23,46,80} Due to this emphasis on individuals and error outcomes, rather than corrective actions, these systems can come into conflict with the notion of a blameless safety culture.\textsuperscript{23,80} The risk of sanctions and blame create a reluctance to report events which can be concealed, which results in accountability systems receiving relatively few reports.\textsuperscript{23} In addition, since most regulatory agencies lack the resources to perform full external investigations on all but a select few reports most submitted reports elicit no response.\textsuperscript{23} With only the risk of punishment and little to no constructive feedback, organizations may view mandatory reporting as all risk and no gain.\textsuperscript{23}

Examples of mandatory systems include adverse event reporting systems in a number of states in the United States.\textsuperscript{5} Not all states have systems in place and those that do have variable characteristics. However, all state systems mandate reporting of unexpected deaths and some mandate wrong-site surgery.\textsuperscript{23} The degree and method of public disclosure of system information varies between states.\textsuperscript{23} A common barrier cited with these systems is insufficient staff and resources for analyzing data, resulting in little aggregation of data and identification of trends.\textsuperscript{5,23}

\textbf{Voluntary Reporting}

It is argued that all reporting systems are fundamentally voluntary since mandating reporting using policies and laws cannot guarantee that people will not try and hide events they do not wish to report.\textsuperscript{5,61} Voluntary systems encourage staff to share experiences and document events for the purpose of continuous learning and bringing about safety improvements.\textsuperscript{23,80} To this end voluntary systems typically cover a wide range of reportable events, but usually collect more near misses and errors rather than adverse events.\textsuperscript{46,77} However, they also tend to collect a large percentage of mundane events\textsuperscript{25} which are not necessarily target problems for most risk management systems. Figure 3 illustrates the events capture by voluntary and mandatory
reporting systems and the patient impact of the most commonly captured incidents by each. The nature of the event types collected by voluntary systems makes them particularly good at discovering latent system failures, process information, and encouraging learning from incidents.\textsuperscript{46,77}

![Figure 3: Hierarchy of reporting (adapted from To Err is Human)](image)

Allowing staff to report as they see fit and emphasizing the role of learning from incidents helps alleviate some fear of blame and punishment associated with incident reporting.\textsuperscript{80} The depth of information and quality of the contextual information provided in reports may also be heightened by voluntary reporting.\textsuperscript{18,80} Some people only report to mandatory systems because some external body forces them to.\textsuperscript{80} As such, reporters may only provide enough information detailing a reportable event to meet the mandated reporting requirements while neglecting additional information which may be useful in understanding the event.\textsuperscript{80} It is hoped that those reporting to voluntary systems are doing so to help others avoid similar errors and therefore provide rich, contextual information to encourage learning.\textsuperscript{80} It has been proposed that voluntary systems provide more useful information regarding errors and their causative factors than mandatory programs.\textsuperscript{80} While \textit{To Err is Human} placed more emphasis on the need for mandatory systems, it also encouraged the continued development of voluntary reporting efforts.\textsuperscript{5} Voluntary systems were seen as complementary to mandatory reporting systems, due to their utility in capturing more near miss events than mandatory systems.\textsuperscript{5}
However, voluntary reporting requires continuous support of those submitting reports to the system. Since people aren’t forced to report the motivation for reporting is their individual professional ethic and belief that they are helping bring about change. Without seeing visible changes in practices to make health care safer staff may come to feel the time and effort required to complete a report is of no benefit and so stop reporting.

The National Reporting and Learning Service (NRLS) for England and Wales is one example of a voluntary reporting system. Reports are collected on any incidents that could have or did result in patient harm. The system is run by the National Patient Safety Agency (NPSA) which aggregates reports to understand the frequency of incident types, pattern and trends, and underlying contributory factors. The NPSA has no power to become involved in discipline or performance management. Another example of a voluntary system is the Australian AIMS which collects all events ranging from hazards and near misses to sentinel events. Similar to the NRLS this system has no punitive power and aggregates reports for trending purposes. The JCAHO Sentinel Event Reporting System, mentioned in a previous section, is another example of a prominent voluntary reporting system, targeted at sentinel events. JCAHO cannot penalize an organization’s accreditation status for reporting, but requires all submitted reports to provide a root cause analysis.

### 3.3.3.2 Identification of the Reporter’s Identity

How the identification of the individual, or organization in some cases, submitting an incident report is handled is an element that the literature has explored in some detail. There are three types of reports which are associated with this issue of reporter identification: identifying, anonymous, and confidential reports. Each type has some impact on the culture of safety, quality of information, and usefulness of the overall reporting system. Identifying reports disclose the reporter’s identity within the report for anyone reviewing the incident to take note of. This method allows the reporter to be contacted for further information regarding the incident, which can be very useful in obtaining a complete and rich description of the event. However, providing the identities of those involved with an incident carries with it a heightened fear of blame. Identifying reports clearly link individual personnel with an incident which can influence reporters to not report incidents which they can hide to avoid any potential embarrassment or punishment.
In contrast, anonymous reports contain no identifying information. While this negates the fear of being linked to the reported incident it also removes any opportunity to follow-up with the staff involved to expand on the details of the incident.\footnote{1} While the willingness of staff to participate in anonymous reporting systems is greater than with identifying reports, the ability to capture detailed information may suffer.\footnote{1,20} For example, anonymous reports often contain insufficient information to understand the root cause of an incident.\footnote{83} As a result there exists a trade-off between providing anonymity and the quality of useful information which can be obtained.\footnote{62} In addition, since these systems do not identify those involved, whether it is a person or an organization, they have been criticized for lack of accountability and transparency.\footnote{84}

Confidential reporting systems aim to combine the strengths of identifying, and anonymous, reporting. Confidential reports collect identifying information, but upon reviewing the report and contacting the reporter for further information, identifying details are stripped from the report.\footnote{76} As a result, confidential reporting systems tend to contain more complete incident information than anonymous systems.\footnote{76,83} In addition, typically those reviewing the confidential reports prior to removing the identifying information have no punitive authority over those reporting. Therefore, the fear of blame or punishment is limited and reporters tend to feel less personal risk when sharing incident information.\footnote{23} This aspect of an independent body, with no punitive authority over those reporting, has been shown to be helpful in aviation reporting and is often proposed in the literature as a component for more effect health care incident reporting systems as well.\footnote{23,57,58} In addition, if the independent body is composed of expert analysts who follow-up and act on incident reporting it goes a long way to establishing credibility to the incident reporting process.\footnote{23}

A study by Fernald et al. (2004) gave reporters the option to report anonymously or confidentially and found that two-thirds choose confidential reporting.\footnote{85} This could be attributable to the ease and time required to submit a confidential report since only minimal information was required upfront and then a telephone interview allowed further details to be captured. Meanwhile, anonymous reporting required the reporter to answer a few multiple-choice questions and fill in the blank questions. This study also found that confidential reports were significantly more likely to contain code-able data than the anonymous reports.\footnote{85} One of the oldest and most prominently discussed confidential reporting systems is the Aviation Safety
Reporting System (ASRS); it is discussed briefly below as an example of how confidential and independent reporting has successfully been implemented.

**Confidential & Independent Reporting System Example – The ASRS**

The aviation industry has led the way and shown that confidential, voluntary near miss reporting systems are important in assessing safety. In 1975 the U.S. Federal Aviation Administration (FAA), the body responsible for regulating all aspects of flying, implemented the Aviation Safety Reporting Program as a voluntary and confidential system for reporting unsafe occurrence and hazardous situations. However, pilots were reluctant to report incidents to a regulatory authority that could revoke licenses and impose fines so after four months of operation, the National Aeronautics and Space Administration (NASA) took over the collecting and analysis of reports and the system become the ASRS. The FAA still funds the system, but NASA serves as a highly respected reviewing and analytical body, independent of the other stakeholders in aviation safety. Reports are submitted confidentially to the ASRS where expert analysts follow up on the incident, contacting the reporter and investigating if more information is required, then any identifying information is removed and the report is maintained anonymously in the database. Reports which are submitted anonymously are not accepted by the ASRS.

Since its inception the ASRS has received more than 500,000 incident reports. The ASRS notes patterns, disseminates alerts, prints regular features in several pilots’ magazines, and publishes monthly widely-distributed safety bulletins and semiannual safety topic publications. However, the ASRS does not propose or advocate specific solutions to their findings. As a result some problems are acted upon by manufacturers and the FAA, while others are not. Overall, aviation’s cultivation of a safety culture has lead to great improvements in aviation practices. For example, the chances of dying per domestic jet flight is currently one in eight million, four times lower than the chances in 1967-1976. Charles Billings, the architect of the ASRS, attributes its success to three factors: reporting is safe (pilots are protected from disciplinary and legal consequences if they report promptly), simple (a one page report is made), and worthwhile (experts analyze the confidential reports and disseminate recommendations to pilots and the FAA). However, while the usefulness of the database as a qualitative tool is generally accepted, its acceptance as a quantitative tool has been less enthusiastic.
Nevertheless, the ASRS is widely regarded as one of the most successful, large-scale incident reporting systems.\textsuperscript{47}

It is important to note however that the ASRS is not the only reporting system responsible for U.S. aviation safety. The U.S. also has a mandatory system for all accidents in which death or serious injury occurs, or an aircraft receives substantial damage.\textsuperscript{5} This system is operated by the National Transportation Safety Board (NTSB) which is responsible for investigating all accidents.\textsuperscript{7}

\textbf{Characteristic Summary: Operational Aspects}

In summary, the operational aspects of the system is in reference to the aspects which dictate how reporting to the system is managed. Reporters may be mandated to report by an oversight organization or allowed to voluntarily share event information as they see fit. In addition, reporters may be required to identify themselves (i.e. their name) when submitting a report (identifying). Other systems don’t require the reporter’s identity (anonymous) or remove the reporter’s identity after contacting the report for further information (confidential).

\textbf{3.3.4 Collecting Versus Analyzing Incident Data}

Some people believe that a primary goal of incident reporting systems should be to increase the number of reported events and errors collected by the system.\textsuperscript{68} While a larger dataset may provide an increasingly rich source of information the volume of reports collected by itself does not indicate a successful system.\textsuperscript{5,68} An increasing number of reports is actually more likely to indicate improved practices in capturing events, which while potentially beneficial does not necessarily promise success.\textsuperscript{77}

In general, incidents are simply accumulated in health care reporting systems which is insufficient to achieve the ultimate goal of improving patient safety.\textsuperscript{68,89} Systems tend to place too much emphasis on the act of reporting and collecting reports and relatively little focusing on the vital aspect of analyzing and effectively using the data.\textsuperscript{68,89} Simply collecting reports without analysis turns incident reporting systems into merely tools for collecting statistics, which does little to improve safety.\textsuperscript{90,91} In addition, with issues such as under-reporting, variations in
reporting patterns, and a lack of denominator data, these statistics and rates are not necessarily accurate predictors of safety and underlying hazards.\textsuperscript{25,46} Incidents are also often multi-factorial and the underlying causes and contributing factors are not typically discernable from the simple trending of events.\textsuperscript{69} Regarding the U.K. National Patient Safety report, John Stepe, a former senior auditor with the National Audit Office, argues that it is\textsuperscript{90}:

"[...] nothing more than an exercise in accounting. There’s lots of tables and charts of numbers that summarize basic data, but nothing seems to have moved on. There’s no information at all on root causes of things that go wrong. There’s very little therefore that can be used for learning. When you read the report you realize that it simply adds nothing to patient safety."

Collecting incident reports to just develop statistics and trends, without carrying out further analysis is of little value.\textsuperscript{5,23} While aviation, oil, and nuclear industries have formal investigation and analysis practices\textsuperscript{92} health care is lagging in this respect. The most common failure of governmentally run health care reporting systems is the provision of inadequate resources (e.g. funding, staff, etc.) to analyze the reports they collect.\textsuperscript{23} It is no trivial task to analyze the hundreds and thousands of reports being gathered by national and international reporting schemes.\textsuperscript{47} Analysis is probably the lengthiest phase of incident reporting and requires the right tools, expertise, and funding to be effective.\textsuperscript{5,8,46} The tools required include those needed to carry out analysis techniques and of course the reports themselves. The data collected in the reports must have all the information necessary to understand an incident and how it occurred. Those involved in operating incident reporting systems believe that it is better to have high quality information on a few cases than poor information on many cases.\textsuperscript{5} Analysts should be comprised of experts who understand the practices, clinical significances, system issues, and potential preventive measures for the issues brought up in the reports.\textsuperscript{23} This often requires an interdisciplinary group comprised of nurses, physicians, pharmacists, and technicians amongst others.\textsuperscript{20} For example, the U.S. ASRS has dedicated teams of trained coders whose role is to analyze and follow up on each incident submitted to the system.\textsuperscript{41} ASRS analysts are comprised of experienced pilots, air traffic controllers, and mechanics as well as teams with human factors and psychology experience.\textsuperscript{93}

There are multiple analysis techniques which may be applied to incident reporting systems.\textsuperscript{16,18,23} The depth of analysis may be selected based on the resources available, the number of reports the
system receives, or if the goal is to produce frequency data versus detailed analysis of events. Figure 4 shows a hierarchy of the different incident reporting analysis techniques, based on those presented within the World Alliance for Patient Safety’s draft guidelines for adverse event reporting and learning systems.\(^{23}\)

![Figure 4: Hierarchy of incident reporting system analysis techniques](image)

High-level analysis may be performed at national levels to look at the number and types of incidents which occur and then disseminate the information widely. This type of analysis is good for highlighting areas for improvement across the system (or systems), raising awareness, and focusing attention for further studies and actions.\(^{8}\) However, on their own these high-level analyses do little to improve safety at the local level.\(^{8}\) Therefore, more detailed analyses are extremely important for understanding the root causes of incidents and how to prevent similar events from occurring in the future.\(^{8}\) More in-depth analysis may look at the chronological course of events leading up to the incident, the errors made along the way, and the contributing factors.\(^{20}\) However, the greater the depth of the analysis required, the less feasible it is for high-volume reporting systems, such as those at a national level, as detailed analyzes can be labor-intensive.\(^{46}\) As technology improves it may offer opportunities to assist in the process of analyzing reports in high-volume reporting systems.\(^{18,46}\) For example, some systems are using or developing data-mining software for clustering incidents into categories and helping to highlight
hazards for further investigation.\textsuperscript{46} Other software tools are used in other industries, but haven’t yet migrated to health care, such as statistical processing of text, natural language processing, data visualization, statistical measures of association, and mapping incident reports onto process maps.\textsuperscript{18} While technology may assist in the analysis process, expert analysis is typically required to evaluate and understand implications presented in the reports which technology can’t detect or understand.\textsuperscript{18}

Issues arise in the analysis of health care incidents with regard to the number of reports submitted to the systems. Health care reporting systems receive far more reports than those in other industries.\textsuperscript{26} For example, the ASRS spends about $3 million annually to analyze approximately 30,000 reports, equating to about $100 per case.\textsuperscript{41} If the same were assumed for health care, the cost to analyze the estimate 850,000 reports submitted to the NRLS would be infeasible.\textsuperscript{41} Many hospitals are already overwhelmed by the number of reports they receive.\textsuperscript{35} A study by Tuttle et al. (2004) found that 72\% of all events from 2002 at an academic medical center continued to remain “new” or “open” by August of the following year.\textsuperscript{68} This is a concerning issue as it is unlikely that systems can employ enough dedicated analysts to handle all the reported events without a great deal more funding.\textsuperscript{41} As such there may be some need for frameworks to help prioritize interventions based on the cost and complexity of the target problem.\textsuperscript{35}

Typically incident analysis has been seen as retrospective\textsuperscript{16} with techniques such as Failure Modes and Effects Analysis (FMEA) seen as prospective. Health care has primarily adopted a reactive posture to risk management, responding to individual events, often with superficial solutions rather than looking for underlying system problems.\textsuperscript{34,35} However, with better classification and analysis structures in place incident reporting systems may be more capable of undertaking proactive risk management measures rather than a reactive approach. There is a need to shift the emphasis from reactive risk management to proactive assessments of patient safety concerns to prevent errors before they occur.\textsuperscript{16,90}

\textbf{Characteristic Summary: Collecting Versus Analyzing Incident Data}

Overall, this characteristic is focused around how the reports and reporting information contained within the system are used. Some system use the data to develop statistics for events
which get reported and other systems analyze the data (e.g. causal analysis) looking for detailed causal factors. How the system chooses to use the reports impacts the role the system plays in building recommendations for improving safety.

### 3.3.5 Description of an Event

In order to analyze incident data there must be sufficient detail contained within the reports to identify the key issues and understand the factors which precipitated the incident. Incomplete and inaccurate reports are not useful, potentially misleading, and cannot help incident reporting systems bring about change.\(^{13,89,90}\) Good ‘quality’ reports are a prerequisite for meaningful analysis.\(^{8}\) In a review of adverse event reporting and learning systems literature, White (2007) made note of the following items which the U.K. NPSA identified as the minimum dataset that should be included in an incident report.\(^ {76}\)

- What happened (description, severity of actual or potential harm, people and equipment involved)
- Where it happened (location/specialty)
- When it happened (date/time)
- How it happened (immediate causes)
- Why it happened (underlying causes)
- What action taken or proposed (immediate and longer term)
- Impact of event (harm to the organization, patient, other)
- Factors that did, or could have, minimized impact

Vincent (2000) proposes that from the information presented in the reports analysts should be able to draw out information on the clinical context, patient factors, and contributory factors.\(^ {92}\) Contributory factors should include those specific to the event and general ones which are longstanding features that impact safe and effective operation of the unit, hospital, or system where the incident occurred.\(^ {92}\) However, current incident reporting systems vary widely in the amount of useful information contained within their reports and how this information is presented.\(^ {18,46}\) Information presented can range from structured classification fields to descriptive recounts of the event or any combination thereof.\(^ {46}\)
Structured Classification Information

Structured information within an incident report requires specific elements to be identified within defined fields typically using check boxes or pull down menus. The defined, clinically meaningful elements combine to form the taxonomy of the system. Taxonomies classify various dimensions or aspects of an incident including but not limited to:

- **Error Type – What Happened**
- **Patient Impact/Outcome – Level of Harm**
- **Domain/Setting – Location of the Event**
- **Stage of Care Process – Laboratory Results, Ordering, Delivery, etc.**
- **Personnel Involved**
  - Staff
  - Patient Characteristics
- **Product or Equipment Information**
- **Causal Factors – Proximal (Obvious) Causes, Underlying Causes, Contributing Factors**
- **Probability of Recurrence**
- **Prevention Strategies - Measures Taken or Proposed to Correct Error**

Reporting systems may use any combination of these and other factors to provide a meaningful structure for describing, explaining, and understanding an event. The taxonomy and classification structure can vary widely between incident reporting systems. However, taxonomies typically fall into one of three major categories: classification by event, by risk, or by causation. Grouping similar topics can aid in managing the data, identifying trends, counting the number of reports of a certain type, and highlighting potential priority areas. Structured classification makes it very easy and less costly to yield counts of errors grouped into the categories and cross compare categories, such as patient outcome and event type or domain. However, these classification methods by themselves are not always ideal for understanding an event to target safety improvements.

The classification process often results in events being collapsed into a simple descriptor category (e.g. “medication error”) and the cause being noted by an equally general and simplistic category (e.g. “communication failure” or “staffing issue”). As a result the quality of
information gained can be quite limited. Adding subcategories to provide greater detail is a common approach to improving the level of specificity of a structured event report.\textsuperscript{18} Providing more options increases the likelihood of the reporter finding a classification that matches their event.\textsuperscript{41}

However, having a very detailed schema of subcategories may prove a hindrance to the system. Reporters may feel overwhelmed by the list of detailed categorization options which may serve to decrease the likelihood of submitting reports.\textsuperscript{25} Having an exhaustive list of options also generally results in a small number of events in each category which may prove meaningless when trying to target common underlying system issues.\textsuperscript{18} In addition, if little guidance is given on the definition of the various categories and subcategories busy reporters rely on training and their own judgments to select a category, which introduces a risk of inaccurate and inconsistent classification coding.\textsuperscript{13,68,94} Reduced consistency in how different reporters or investigators classify similar events may be exacerbated by using a more exhaustive taxonomy with a larger number of options.\textsuperscript{41,47}

If relatively few categories are used and reporters understand the options then the reporting processes can be relatively quick for staff.\textsuperscript{23} The definitions and classification schemes can have a profound impact on the system’s capacity to collect accurate and detailed reports.\textsuperscript{54} Therefore, care and thought must be given during the development or implementation of the system taxonomy. Specialty-specific taxonomies may be beneficial for reporting systems targeted at a single realm of practice or error type, such as anesthesia or medication errors, to capture more topic specific details.\textsuperscript{28} However for systems capturing all types of events it may be easier to use a broader, less specific taxonomy. There is a balance that needs to be considered regarding the appropriate level of abstraction in a taxonomy. For example, the use of broad categories may reduce the time to report and analyze the incident, while also increasing the level of consistency in the use of the reporting scheme.\textsuperscript{47} But on the other hand, using more specific categories helps to distinguish more detailed incident causes and can help build better-educated recommendations.\textsuperscript{47} The WHO draft guidelines for adverse event and reporting systems suggest that when designing a classification system the following factors should be considered\textsuperscript{23}:

- The purpose of the reporting system
What is the expected product? How will the classification scheme facilitate analysis that will produce the desired outcome?

- The types of data that are available.
  - Are reporters expected to have carried out an investigation and analysis of the event?

- Resources
  - The more detailed and elaborate the classification system is, the more expertise will be required, and the costlier the system will be to maintain.

In addition, over time as systems evolve the taxonomy may need to change as well to incorporate new subcategories or new definitions and this can create issues. Changes may mean that previously classified reports from past years may need to be reclassified and updated to reflect the updated taxonomy which can be a demanding, time consuming process. Therefore, developing a complete and robust taxonomy at the onset of the system can minimize the need for change in the future.

One taxonomy of note is that used by the Australian Advanced Incident Monitoring System (AIMS). This system is used by over 50% of the Australian public health care system and collects voluntary and confidential reports on a broad range of events including sentinel events, near misses, and equipment failures. The taxonomy used is very sophisticated and expansive, consisting of 20,000 predefined terms which can be configured into over one million permutations. The system guides reporters through a cascade of structured questions, prompted by the report’s previous responses. This process allows the reporter to deconstruct the incident into very detailed, structured pieces of information about an incident. The system aims to translate incident information into a common language which can be compared with other reports and can be analyzed as part of a larger dataset. The AIMS is an example of a very complex and expansive structured classification system and most other taxonomies consist of far fewer terms.

Other notable taxonomies which have been used to classify incidents include the JCAHO patient safety taxonomy which uses four root nodes (impact, type of event, causes, and domain) to classify incidents resulting from patient care regardless of the setting or type of event. The four root nodes are broken down into 14 secondary classifications and then into 140 coded...
categories. The Eindhoven Classification Model is another example which categorizes events as either involving latent errors or involving active errors. Another example is the Victoroff Multiaxial Taxonomy which was used to develop the Applied Strategies for Improving Patient Safety (ASIPS) primary care reporting system. The ASIPS system consists of five domains and ten axes with detailed description for: outcome (including harm and resultant interventions), course of event (including event type, location, intent, event process, cause, and system), participants (participants and contributions), and event discoverer. The WHO is also in the preliminary stages of developing an international patient safety taxonomy. This taxonomy aims to be adaptable across cultures and languages for the entire spectrum of health care in order to provide a standardized classification to promote learning across systems.

**Free-Text Classification Information**

In contrast to the highly structured taxonomy method of providing incident information is the use of detailed free-text narratives. Narrative reports allow reporters to provide contextual information about the event in their own words and detail the progression of the event including the conditions that contributed to the event. This type of information can provide meaningful insight into exploring and understanding the nature of underlying system issues. As a result some experts and authorities argue that the value of incident reports lies only in drawing lessons from report narratives. The U.S. aviation reporting system acknowledges the importance of narratives as rich sources of information about contributing factors and actionable insights. Reporters may even describe contributing factors without recognizing them as such. In addition, allowing reporters the chance to tell their view of events may help reporters feel more involved as it implicitly values their observations.

However, since detailed narratives are unstructured and do not typically specify defined data elements there is a risk of incomplete or missing information with inconsistent levels of detail. Reports with inadequate information documented add nothing to the understanding of incidents. Understanding of narratives can also be complicated by misspellings, abbreviations, and acronyms. Narratives also require reporters to recall more detailed information about the event than structured taxonomies which just require the selection of the best fit coding option. As such narrative reports can be more time consuming to complete as well as requiring timely reporting lest memories begin to fade. In addition, open-ended, narrative
texts are harder to process automatically\textsuperscript{98} and require additional resources for analyzing and interpreting the data.\textsuperscript{23}

**Free Versus Structured Text Information**

The relative benefit of free-text narratives versus structured classification systems is unknown.\textsuperscript{18} Structured reporting formats which place more strictures on reporters\textsuperscript{98} are easier to aggregate, develop summary statistics, and recapitulate data efficiently.\textsuperscript{46} Therefore those who believe the role of incident reporting systems to be one of classification and triage may see the benefit in a purely structured system.\textsuperscript{25} However, those with the belief that the goal of reporting systems lies in detailed analysis may find the richer source of data provided by free-text narratives to be of more benefit.\textsuperscript{4,46} However, a majority of current systems use some combination of both free-text and structured elements to collecting incident information.\textsuperscript{18,23}

**Quality of Information**

While categorizing incidents into similar groups, whether by a structured taxonomy or through summarizing narrative text, is helpful for managing incident data it is not crucial for the success of incident reporting systems.\textsuperscript{20} Of primary importance is the quality of data that can be extracted from a report and used to direct safety improvements. However, the level of detail and quality of information provided through incident reporting is variable.\textsuperscript{14,16,91,99} Reports are often brief and fragmented which can make the task of classifying and analyzing data difficult.\textsuperscript{16}

For example, significant information has been noted as missing from reports submitted to the U.K.’s NRLS.\textsuperscript{91,94} As of mid-July 2005, only 11 of every 100 incident reports were estimated to contain information on causal factors and underlying issues.\textsuperscript{14} Also, despite the purported success of the ASRS, the quality and extent of information provided in their initial reports is also often of minimal and limited quality.\textsuperscript{14,39} Reports tend to be brief, technical statements, potentially only a couple lines long, and deal with events which the reporter may only have partially observed.\textsuperscript{39} However, the ASRS typically uses follow-up interviews with the reporter to obtain detailed information, without which the event sometimes cannot even be understood.\textsuperscript{14} Systems like the NRLS do not have the ability follow-up with reporters as they are anonymous, so the information submitted in the report is all the information they get. This results in many
reports of relatively limited use. In narrative reports the credibility of the information can also be compromised by the reporters trying to deflect or lessen the blame attributable to them.\textsuperscript{73}

Another issue with the quality of information is the miscoding of structured taxonomy data elements.\textsuperscript{68} Miscoding may be the result of poor design, lack of reporter knowledge, no standard nomenclature, or limited accountable oversight.\textsuperscript{68} Even with explicit criteria and definitions the inter-rater reliability for classifying events into the predefined categories has been found to be relatively low.\textsuperscript{94} A U.K. study noted that reporters inconsistently use categories, submit incomplete reports/missing information, and use the ‘other’ classification excessively without expanding on the details.\textsuperscript{94} It was also noted that of the 24 cases which were classified as ‘other’, 16 had no alternate description suggested by the reporters and 9 could be classified into a predefined category provided by the system.\textsuperscript{94} Excessive use of ‘other’ or ‘miscellaneous’ options is a common issue with structured taxonomy reports\textsuperscript{100} and can lead to a loss of useful information.\textsuperscript{101} For example, a study looking at the medication error reporting system at Johns Hopkins Children’s Center in Baltimore found 59\% of the time reports used the non-descript ‘other’ category for the error subtype classification.\textsuperscript{102} In another example, Gong (2009) looked at voluntary incident reports and found 32.8\% of the incident type fields reported as ‘miscellaneous’ and 41.3\% with ‘other’ listed in the error description field.\textsuperscript{13} About 25\% of the reports were coded as ‘miscellaneous’ incident types with ‘other’ error descriptions simultaneously.\textsuperscript{13} Even events that were easily distinguishable as a fall incident were reported as ‘miscellaneous’.\textsuperscript{13} In addition, upon reviewing and analyzing the event summaries they found that those reports coded as ‘miscellaneous’ or ‘other’ could often be placed into categories already existing in the system’s taxonomy.\textsuperscript{13} This study made note of the following possible reasons why the ‘other’ or ‘miscellaneous’ options are often used\textsuperscript{13}:

- No Matches
  - Reports do not match any of the predefined classification category options
- Multiple Matches
  - Reports could be classified into multiple category options
- Partially Matched Without Immediate Outcome or Cause
  - Reports contain limited information on the outcomes or causes so choosing the optimal category can be time consuming, therefore “miscellaneous” or “other” is selected as a safe choice
• Predefined Category Does Not Match the Reporter’s Mental Model of the Incident Type
  o Reports which conflict with the reporter’s mental model of a specific incident type and the predefined definition of the category

As a result of the issue caused by miscoding of events, Thomas et al. (2009) recommends a situation similar to the ASRS where incidents should be submitted as a two-stage process.\(^9\) This would entail, staff witnessing the incident providing the initial information and clinicians experienced with the taxonomy following-up with staff to record detailed classification information.\(^9\)

**Characteristic Summary: Description of an Event**

In summary, reports are only of use if information can be extracted from them to understand what occurred during the event and if possible the steps leading up to it. Systems may use structured taxonomies, free-text narratives, or a combination to assist in describing an event. These methods will influence the quality and usefulness of information contained within the reports.

### 3.3.6 Consistency of Language & Standardization

The understanding of patient safety literature and incident reporting has been compromised by an inconsistent use of language.\(^2,27\) Similar terms and concepts have different names, such as near miss and close call, while identical terms are used to denote several different concepts, such as error for errors, violations, and system failures.\(^2,27\) Comparison of rates of reporting for specific categories between systems is often of little use because of a lack of standardized definitions, inconsistent language, and local influences on reporting.\(^4,28,34,61\) The use of terminology may even differ between departments in the same organization.\(^5\) The complex array of professional associations and accreditation agencies, each using their own terminology may also further complicate the issue of inconsistent language.\(^48\) This has led to many situations where there are many different local schemes which rarely interface or relate to one another for sharing data.\(^91,103\) The need for stable classification and language throughout the entire system cannot be understated.\(^10\)
The inability to combine interrelated incident information between systems limits the potential for learning and developing a complete understanding of risks and strategies for improving performance.\(^{59}\) In one survey, 17 definitions were found for the term ‘error’ and 14 for the term ‘adverse event’.\(^{104}\) Another review found 24 definitions for the term ‘error’.\(^{105}\) A study by Yu et al. (2005) found 119 different terms used for patient safety purposes, including various definitions for adverse event, medical error, and near miss.\(^{106}\) Various terms and definitions combine to form more than 150 different terminology systems used around the world to describe the various medical domains.\(^{61}\) The inconsistent use of terminology and definitions\(^{61,107}\) has led many to support the need for a common, standardized terminology set or taxonomy for discussing patient safety and incident reporting.\(^{18,28,59,61,107}\)

It is important to adopt a taxonomy with standardized key concepts, terms, and definitions applicable to the full spectrum of health care.\(^{27,28}\) Such a taxonomy in place and accepted worldwide offers greater opportunities for researchers to better understand each other’s work and allow comparisons between facilities, jurisdictions, and countries.\(^{27}\) The WHO has taken a leadership role in developing the International Classification for Patient Safety (ICPS), a standardized taxonomy for classifying events in all health care domains.\(^{96,107}\) The ICPS is being collaboratively developed to consist of standardized concepts, terms, and definitions that are applicable regardless of country or culture and allow for meaningful, useful and appropriate classification of patient safety data.\(^{96}\) The aim is to provide an internationally acceptable classification to facilitate the description, comparison, measurement, monitoring, analysis and interpretation of information to improve learning and patient care.\(^{96}\) While a conceptual framework for the ICPS has been published, the classification systems itself is far from developed.\(^{18,96}\)

Beyond a standardized taxonomy and definitions, some also propose the need for standardized reporting methods, data models, and feedback mechanisms.\(^{107}\) For example, *To Err is Human* recommends implementing a standardized reporting format in the U.S. to define what should be reported and how it should be documented.\(^5\) Current systems vary in the extent to which and how they use structured data and free-text narratives which raises issues when trying to combine similar data from different systems.\(^{59}\) The *To Err is Human* report proposes that a standardized reporting format should allow improved tracking and combination of data, lessen the burden on
multi-site health care organizations or those required to submit reports to an external agency, and facilitate communication on patient safety.\textsuperscript{5}

**Characteristic Summary: Consistency of Language & Standardization**

This characteristic refers to the consistent use of language, terms, and definitions between incident reporting systems and the resultant impact on the sharing and comparison of incident data between systems. The lack of accepted terms and definitions has resulted in terms being used in different ways across systems, confusing the language used to discuss incidents. Standardized terminology aims to create a consistent language for the discussion of incidents in health care.

### 3.3.7 Accessibility & Ability to Search the System

A lesser explored element of incident reporting systems is who has access to viewing them and how easily past reports can be searched. Of course risk management teams responsible for handling and analyzing the system have access to view reports, but there is less agreement on the importance and benefit of allowing the public access to view reports.\textsuperscript{23} As stated in a previous section, a survey found that 62-73\% of Americans felt it was the public’s right to have access to health care incident information for accountability purposes.\textsuperscript{23} However, while accountability requires some form of public disclosure, it doesn’t necessarily mean providing access to incident reports themselves.\textsuperscript{23} As such, some systems make publically available investigation results or summary reports while others make the events themselves available.\textsuperscript{23} For example, the FDA MAUDE and ASRS make their reports available to the public via the internet. Meanwhile systems such as the AIMS, NRLS, JCAHO’s Sentinel Event Reporting System, and ISMP’s reporting database provide newsletters, publications, or safety alerts to highlight safety concerns, summaries, or trends.

Another seldom acknowledged aspect of accessibility is the ability to search for, retrieve, and review reports once they have been entered into a large-scale reporting system.\textsuperscript{103} The aim of information retrieval is to collect all documents from a database that are relevant to a user’s need.\textsuperscript{98} This topic of information retrieval is of particular importance to researchers and those
trying to locate specific types of events which may not be easily found by simply sorting by the taxonomy classification options. Currently, much of the information entered into reporting databases are simply never retrieved.\textsuperscript{108} This is partly because systems lack the capacity locate and compile incident data based on specific event queries.\textsuperscript{41} Queries are precisely structured requests for specific information to be found and retrieved within electronic information systems or databases. With increasing amounts of reports being submitted, reporting systems are relatively unprepared for dealing with the full amount of data which has been accumulated over time.\textsuperscript{41}

Effective information retrieval systems are concerned with the performance measures of precision and recall.\textsuperscript{41,47,103} Precision is the proportion of documents returned from a query that the user considers relevant to their request.\textsuperscript{41} Meanwhile, recall is the proportion of documents returned from a query relevant to the request compared to the total number of relevant documents in the entire system.\textsuperscript{41} Therefore, recall is a measure of the query’s sensitivity in relation to the system. Mathematically these two measures are defined as:

$$
\text{precision} = \frac{\{\text{relevant documents}\} \cap \{\text{retrieved documents}\}}{\{\text{retrieved documents}\}}
$$

$$
\text{recall} = \frac{\{\text{relevant documents}\} \cap \{\text{retrieved documents}\}}{\{\text{total relevant documents in the system}\}}
$$

Systems with high recall and relatively low precision result in a large number of relevant and irrelevant documents being retrieved from a query.\textsuperscript{41,103} This means that the user may have the time consuming task of manually filtering the relevant from irrelevant documents. Conversely, systems with high precision and low recall result in only relevant documents being returned from the query, but it misses a number of other potential targets that are not retrieved.\textsuperscript{41,103} This can potentially result in the user failing to identify a complete picture of the event being targeted by the query.

**Characteristic Summary: Accessibility & Ability to Search the System**

Overall, this characteristics looks at who (e.g. the public or a private organization) has access to viewing reports within the reporting system. This impacts who is capable of using the system to
investigate issues. The characteristic also reflects the ability and effort to search the system to investigate and review reports of specific events.

### 3.3.8 Timeliness of Reporting

Staff in health care are often working in busy, time-critical, and multi-tasking environments, as such finding time to complete an incident report and provide meaningful detail can be limited.\(^{13,25,41}\) Therefore, the motivation (e.g. improving safety or mandated to report), severity of the incident, and perceived utility of submitting a report are all factors taken into account when deciding whether to submit or not.\(^{25,41}\) As such, the aspect of how long it takes to report an incident is intertwined with what gets reported, the quality of information, the system culture, and how the reporting system demonstrates its usefulness.

Systems that do not allow follow-up interviews with the reporters require all-important information to be captured in the initial incident report. As such there is a balance that needs to be struck that optimizes the ease of and time required to report and the amount of important information that must be obtained.\(^{4,109}\) A survey by Fukuda et al. (2010) of teaching hospitals in Japan found that decreasing the time required to complete an incident report could increase reporting by 27% for physicians and 22% for nurses.\(^{109}\) A focus group study carried out by Karsh et al. found that participating physicians and clinical assistants agreed that the reporting time should not require more than 5 minutes and preferred approximately a 2-minute timeframe.\(^{110}\) This isn’t much time to complete a detailed description of an event in some cases. Therefore, one characteristic of importance is the number of fields required to be filled out.\(^{4}\) In reporting forms that identify required and optional fields reporters tend to complete only those that are required.\(^{4}\) One study found that their system’s contributing factor’s field, which was nonobligatory, was only completed in 74% of the reports.\(^{4}\)

Also factoring into this aspect is the greater the time lapse between an incident occurring and the documentation of the incident the more likely there will be a selective loss in the reporting of! incidents that causes minor or no patient harm.\(^{76}\) Therefore, another aspect is how quickly staff can gain access to the reporting forms, whether electronic or paper based, after an event. Currently it is unclear whether electronic formats or paper-based systems are superior at eliciting
more reports. However, the accessibility to paper versus electronic reporting is likely dependent on the local conditions and the differences between the clinical staff involved. As such it is generally preferred by staff to have variable mediums available for reporting, such as electronic and paper forms or by telephone. Whichever method is used the human factors associated with the reporting interface has the potential to affect the reporting rate, completeness of the report, and the accuracy of the information.

Adjacently linked with this issue of timely reporting is the problem that some incidents don’t become apparent until its outcomes occur, which could be over a matter of hours or days. This may results in multiple staff over a couple shifts being aware of different components of the overall incident pathway. Issues arise here in deciding who should report the event and ensuring the complete picture is obtained. Unclear guidelines delegating responsibility can lead to multiple individuals submitting reports for the same event or no one reporting, thinking it is not their responsibility.

**Characteristic Summary: Timeliness of Reporting**

This characteristic refers to the time required to complete and submit a report to the system. Reporters tend to be busy and have limited time to submit a report. Therefore, a balance must be struck with regard to the ease and time require to report and the amount of information to be captured in the report. In addition, reports must be submitted in a timely manner as contextual knowledge about and incident fades as time passes.

### 3.3.9 Feedback & Dissemination of Information

Staff are only likely to put their time and effort into reporting events they are not mandated to if they believe that it will bring about improved health care outcomes. If no response or action based on submitted reports is observed, staff will become increasingly less likely to take the time to report incidents. It is extremely important that staff can see positive improvement coming from incident reporting otherwise it creates a vicious circle in which reporting decreases and consequently the systems don’t collect enough data to suggest improvement actions. Therefore, feedback to staff and the sharing of data and lessons are often considered an essential
action and argument for implementing incident reporting system regardless of the industry or field. Incident follow-up and detailed feedback in other industries are used as mechanisms for encouraging participative safety regulation. Establishing a way to provide feedback to reporters helps demonstrate that their efforts are worthwhile and information isn’t disappearing into an administrative black hole. This in turn helps guard the staff’s willingness to continue to report incidents and near misses. Feedback should be supportive and provide information on action progress and outcomes. In addition, it is vital that feedback is provided to the reporters in a timely manner to keep them involved in the safety improvement process. Effectively using feedback mechanisms has been demonstrated to increase the rate of reporting.

However, in health care, feedback is seen as a weakness in the incident reporting process. One survey found that the lack of feedback was the greatest deterrent to reporting incidents as noted by doctors and nurses. Even feedback on the clarity of what to report, definitions for the various event codes, and disclosure issues has been seen as limited. In general, incident information is being collected by not fed back to staff in any useful manner.

Beyond the reporting staff, different stakeholders in patient safety, including researchers, regulatory agencies, and even the public, will have different needs when it comes to incident information. The real challenge in incident reporting is not necessarily related to the quantity or quality of reports, but rather the degree to which professionals and organizations use the information to learn and bring about change. Simply disseminating information internally to those in the organization where the reports originated typically only makes health care worker aware of the major hazards. However, disseminating information externally, beyond the organization’s reporting system allows lessons to be shared so multiple facilities can benefit from the experience, avoid making the same mistakes, and even collaborate to develop concrete mitigating strategies. Sharing information and findings externally helps to increase the sample size, which in turn helps identify potential risk patterns that while infrequent in a single institution may denote a serious issue across the domain of health care. Therefore sharing information such as trends, what happened in critical incidents, internal investigation results, planned changes, and any measures of how safety improved as a result of implemented changes can be important items for dissemination. However, there has been little published literature addressing methods for sharing safety improvements between multiple organizations.

Information shared in published journal articles are primarily about the collection or analysis of
events, but little information is included about implementing changes based on study findings or if patient safety was improved. Other fields, such as the chemical processing sector, have noted similar issues where the knowledge needed to learn from and prevent incidents is often available, but the lack of a structured communication system for disseminating knowledge is limiting the systems full potential.

Experience in aviation incident reporting has demonstrated the real value of incidents is their ability to bring widespread attention to areas where safety is weakest. Once identified they can help trigger participative and collaborative investigations, alert personnel to potential risks, and develop resolutions to risk areas. However, this is harder to achieve in health care where there is no centralized regulatory oversight organization like the FAA in aviation. The complex array of professional associations and accreditation agencies in health care make disseminating information to the right people a much harder task. However, learning in isolation is inefficient and less effective, especially considering that multiple institutions are most likely undertaking similar efforts.

Characteristic Summary: Feedback & Dissemination of Information

This characteristic refers to the extent to which information stemming from reporting systems is communicated. Reporters must be fed back information to keep them engaged in reporting. In addition, information about incidents and lessons learned must be disseminated to bring attention to issues and ensure learning from incidents is not isolated.

3.3.10 Denominator & Numerator Issues

In order to have accurate and valid measurements of the rates of various incidents systems require a robust definition of events (the numerator) and a baseline value of those situations where there is a risk for the event (the denominator). However, a fundamental issue with incident reporting systems is they generate numerators, but don’t capture the denominators. For example, systems may state how many patients bled while receiving anticoagulants or received wrong-site surgery, but they don’t reveal the total number of patients that were administered anticoagulants or received surgery. The lack of denominators can obscure what
the numerators reveal about incident rates. For example, a high number of incidents may reflect a practice that is continuously unsafe or a fraction of times when a very common practice resulted in an incident. It is difficult to analyze and compare incidents without some context as to the denominator measure.\textsuperscript{1} However, obtaining a denominator value can be a hard measure to determine without some form of standard and active surveillance system.\textsuperscript{46}

Numerator values are far easier to obtain, however the accuracy and validity of these values is questionable. Incident reporting is selective and is plagued with issues of under-reporting.\textsuperscript{13,15,109} Under-reporting is estimated to range from 50-96\% annually\textsuperscript{13,109} thus the frequency of reports likely does not represent true incidence of errors. Fluctuation in reporting practices can also influence the numerators which when interpreted can be perceived as changes in patient safety. For example, reporting may increase for a period as new staff arrive and are enthusiastic to report and bring about change.\textsuperscript{25} However, if they start to lose interest and report less, from a numbers perspective this could be interpreted as fewer incidents occurring and therefore an increase in patient safety.\textsuperscript{25} Furthermore, some systems detect such a small number of target events that even a small increase or decrease in reporting can produce a seemingly large change is the apparent incidence of the events.\textsuperscript{25} Another example of a numerator interpretation issue involves the fact that nurses tend to report more incidents than other health care staff which can be partially attributable to their substantial direct interaction with patients.\textsuperscript{41,56,59} However, when looking at the distribution of safety data related to profession there is a bias introduced that can be interpreted as nurses being involved in more incidents if the level of practitioner exposure to patients is not taken into consideration.\textsuperscript{41,56,59}

These numerator and denominator issues conflict with the use of incident reporting systems to count incidents and develop statistics. The numbers being derived from incident reporting systems reflect reporting characteristics for the system more so than actual incident prevalence and rates. As such, a meeting of patient safety experts from 8 countries in 2008 agreed that the information in incident reporting system should not be expressed or interpreted as a valid rate or incident occurrence.\textsuperscript{46}
Characteristic Summary: Denominator & Numerator Issues

Overall this characteristic is focused on the problems with under-reporting and the inability to collect reliable numerator and denominator data. These problems create issues in some cases when interpreting incident rates and results. In turn, these issues limit the usefulness and validity of incident data when expressed in terms of number values.

3.4 Chapter Summary

The ten fundamental characteristics highlighted in Chapter 3.3 are exhibited within all incident reporting systems in some manner. These ten characteristics are summarized in Table 4. These ten characteristics, developed from the literature search, influence all health care incident reporting systems with regards to their ability to carry out analysis and communication activities vital for effective reporting systems.

Table 4: Summary of the ten fundamental characteristics identified from the literature search as important consideration for analysis and communication activities in incident reporting systems

<table>
<thead>
<tr>
<th>Fundamental Characteristic</th>
<th>Description†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reporting Culture</td>
<td>The consequences that individuals or facilities perceive may be leveled against them by supervisory groups or organizations for their involvement in an incident. A blame-free culture may have no consequences for involvement in an incident. In contrast, adverse consequences such as fines or being fired may influence reporters to hide incidents rather than risk the consequences. The reporting culture surrounding the system will impact the willingness of people to report events.</td>
</tr>
</tbody>
</table>

† The summary statements made in this table are based on the characteristics discussed in Section 7.3 where the relevant literature citations have been documented to support these statements.
<table>
<thead>
<tr>
<th>Fundamental Characteristic</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Classification of a ‘Reportable Event’</strong></td>
<td>The definition used to describe the incidents that should be reported to the system. Identifying a specific patient impact, (e.g. death or no harm), event type (e.g. medication or surgical error), or combinations of an impact and event type (i.e. medication errors resulting in death) can create systems targeted at collecting specific groupings of incidents. This characteristic not only influences what gets reported to the systems, but also what does not.</td>
</tr>
<tr>
<td>- Defined by Event Impact</td>
<td></td>
</tr>
<tr>
<td>- Defined by Event Type</td>
<td></td>
</tr>
<tr>
<td><strong>Operational Aspects</strong></td>
<td>Aspects which dictate how reporting to the system is managed. Reporters may be mandated to report by an oversight organization or allowed to voluntarily share event information as they see fit. In addition, reporters may be required to identify themselves (i.e. their name) when submitting a report (identifying). Other systems don’t require the reporter’s identity (anonymous) or remove the reporter’s identity after contacting the report for further information (confidential).</td>
</tr>
<tr>
<td>- Voluntary vs. Mandatory Reporting</td>
<td></td>
</tr>
<tr>
<td>- Identification of the Reporter’s Identity</td>
<td></td>
</tr>
<tr>
<td><strong>Collecting Versus Analyzing Incident Data</strong></td>
<td>How the reports and reporting information contained within the system is used. Some system use the data to develop statistics for events which get reported and other systems analyze the data (e.g. causal analysis) looking for detailed causal factors. How the system chooses to use the reports impacts the role the system plays in building recommendations for improving safety.</td>
</tr>
<tr>
<td><strong>Description of an Event</strong></td>
<td>Reports are only of use if information can be extracted from them to understand what occurred during the event and if possible the steps leading up to it. Systems may use structured taxonomies, free-text narratives, or a combination to assist in describing an event. These methods will influence the quality and usefulness of information contained within the reports.</td>
</tr>
<tr>
<td>- Free-text vs. Structured Classification Information</td>
<td></td>
</tr>
<tr>
<td><strong>Consistency of Language &amp; Standardization</strong></td>
<td>The inconsistent use of language, terms, and definitions between incident reporting systems impacts the sharing and comparison of incident data between systems. The lack of accepted terms and definitions has resulted in terms being used in different ways across systems, confusing the language used to discuss incidents. Standardized terminology aims to create a consistent language for the discussion of incidents in health care.</td>
</tr>
</tbody>
</table>
The ten fundamental characteristics listed are important factors to consider when creating, implementing, or using any incident reporting system regardless of what field the system is implemented in. Many of these characteristics have two or more methods by which they can be implemented and the choice of method can have a profound impact on the structure of the reporting system. Overall, the literature review process reveals a lack of consensus on which methods of implementing the various characteristics is superior for all situations. Therefore, despite all ten characteristics being important elements in all reporting systems, the ways in which they are implemented and portrayed can vary significantly depending on the goals of the reporting system. The lack of agreement on the optimal methods of implementation of these characteristics has resulted in reporting systems being composed of a variety of different methods.
combinations of methods for portraying the fundamental characteristics. The next chapter aims to explore and compare two existing incident reporting systems with regards to how each structurally exhibits the implementation of the ten fundamental characteristics.
4 Comparison of Two Existing Databases Based on the Ten Fundamental Characteristics

4.1 Objective

The previous chapter served to establish the ten fundamental characteristics which contribute to the effectiveness of analysis and communication activities of incident reporting systems. However, the chapter also notes that these characteristics can often be implemented through different methods (e.g. mandatory vs. voluntary reporting, free-text vs. structured information fields, etc.). This chapter aims to use the ten characteristics (summarized in Table 4) to compare two example databases. The two databases selected are ISMP Canada’s Medication Incident Database and the Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database. Both databases are prominent, national systems, but they each exhibit different structures, operational policies, and objectives. In addition, many of the characteristics have been implemented using contrasting methods. The outcome goal of this chapter is to present a comparison of how these two databases structurally exhibit the ten fundamental characteristics. How the databases structurally exhibit or implement a characteristic refers to the way in which the characteristic has been defined within the system as an invariable component of the incident database or the reporting process. Policies, regulations, reporting and process guidelines, reporting forms, and the physical layout of the database itself are all aspects of the reporting system which may define how certain characteristics are structurally implemented. As such the comparison is presented with reference to these concrete aspects of the two systems and their reporting process. The websites for the two systems, as well as any documents published by the operating organization detailing the reporting guidelines, were used to provide information for performing this comparison. The “forms” used to report to the two systems were also investigated to provide insight for the comparison. Finally, Roger Cheng, a Project Leader at ISMP Canada, was contacted to provide clarifying information regarding ISMP Canada’s system and reporting processes for use in the comparison.

4.2 Introduction to the Example Databases

The FDA’s MAUDE and ISMP Canada’s Medication Incident Database, discussed below, are national incident reporting systems that serve as the two case studies for comparison in the
presented work. The two systems were selected due to the ease with which they could be accessed and assessed for the purposes of the present study. The MAUDE was selected because it is a prominent reporting system that is easily accessible online to the general public. The ISMP Canada’s Medication Incident Database was selected because a joint project between ISMP Canada and the Centre for Global eHealth Innovation offered the opportunity to consult with ISMP Canada and utilize their reporting system. These incident reporting systems were also selected as their differing structures and goals (which are discussed in this section) provide an opportunity to compare and contrast the diversity with which the ten characteristics can be structurally implemented within incident reporting systems.

4.2.1 FDA’s MAUDE Database

Mandated by the FDA, the MAUDE includes reported events in which a medical device may have been involved in an adverse event. The MAUDE aims to provide post-market surveillance of any product which falls under the definition of a medical device as defined by section 201(h) of the Federal Food, Drug, and Cosmetic (FD&C) Act.\textsuperscript{112,113} The FD&C Act defines a device as:

“an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is –

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.”

This definition provides a clear distinction between medical devices and pharmaceutical products.
The MAUDE database, which is updated quarterly, includes reports which involve a medical device malfunctioning or causing severe injury or death.\textsuperscript{113} Reports submitted to the MAUDE database are accessible online to the general public at:

\url{http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm}

In addition, the website allows the public to download files of yearly MAUDE report data which can be implemented into database programs such as Microsoft Access to construct personalized databases with the MAUDE data.

Regulations regarding the establishment and requirements of medical device reporting are put forth in Section 519 of the FD&C Act.\textsuperscript{112} Mandatory reports (for severe incidents) are required to be submitted by manufacturers, importers/distributors, and device user facilities such as hospitals, nursing homes, ambulatory surgical facilities, outpatient diagnostic facilities, and outpatient treatment facilities.\textsuperscript{114} User facilities are required to submit incidents resulting in serious injury to the manufacturer and those resulting in death to both the FDA and manufacturer. Incidents due to a device malfunction must be reported to the manufacturer as well. In addition to the mandatory reports, voluntary reports can be submitted to the system through the FDA’s “MedWatch” program. While the database is primarily U.S. based, reports can be submitted regarding incidents in other countries resulting from products manufactured in the U.S.

The manufacturer has an obligation to submit initial reports of death, serious injury, and malfunction to the FDA along with any supplemental reports. The manufacturer must also carry out investigations of each event to determine the cause and provide all reasonably known information about the event to the FDA. This includes any information from the user about the event and any results from analysis, testing, or other evaluation.\textsuperscript{114}

Depending on an incident’s severity and rate of occurrence, the FDA occasionally disseminates information by issuing notices, public health advisories, and safety alerts. In extreme cases the FDA may impose product recalls. However, the FDA typically relies on the manufacturer to initiate solutions to the problems or start any regulatory actions such as recalls or retrofits.\textsuperscript{115}
**Overall System Goal:**

As an organization the FDA’s purpose is to protect the public health by assuring safety, efficacy, and security of items such as drugs, medical devices, cosmetics, and food. The MAUDE’s purpose as part of the FDA is to provide post-market surveillance and monitoring of significant adverse events involving medical devices, with the goals of detecting and correcting problems in a timely manner.

**4.2.2 ISMP Canada’s Medication Incident Database**

ISMP has branches in both the U.S. and Canada and is a national not-for-profit organization which has been a strong and vocal proponent of voluntary error reporting programs. ISMP focuses on the reporting of adverse drug events and hazards in medication delivery and management with the goal of identifying medication risks and improving medication safety in health care. In Canada, ISMP works with provincial, national, and international patient safety organizations, regulatory agencies, the pharmaceutical industry, and the health care community to promote safe medication practices. The organization has dedicated analysts who review and analyze medication incidents and near miss reports to create recommendations for the prevention of harmful medication incidents.

The Medication Incident Database managed by ISMP Canada is a voluntary, anonymous and confidential reporting system, with reports of incidents, near misses, and hazards submitted by health care professionals and hospitals. The system is only targeted at events which involve some form of medication related error. This includes cases where a wrong medication or dose was given to a patient, as well as problems such as confusing labeling of drug products which could lead to errors. ISMP’s definition of medication is broadened to include prescription and non-prescription drugs, natural health products, imported products, and devices and equipment used to administer medications.

Viewing of the reports submitted to ISMP Canada’s database is not accessible to the general public. However, ISMP Canada releases and distributes bi-weekly safety bulletins which highlight hazards and medication safety information based on incidents submitted to their system.
**Overall System Goal:**

ISMP Canada states its purpose is “to identify risks in medication use systems, recommend optimal system safeguards, and advance safe medication practices.” With regards to their work with incident reporting their goal is “to review and analyze medication incident and near miss reports …, identify contributing factors and causes and make recommendations for the prevention of harmful medication incidents.”

### 4.3 Comparison of the Systems Using the Ten Identified Fundamental Characteristics

#### 4.3.1 Reporting Culture Discussed in Terms of the Goal of the Reporting System

In Chapter 3 the first characteristic was the reporting culture. However, when using this characteristic to compare different systems from a structural perspective there are some difficulties. A major component of the reporting culture characteristic is how reporters’ perceive their reporting will impact them; however this is more based on personal perceptions and not necessarily a structural characteristic of the database. However, the goal of the system and the punitive authority the operating organization has over the reporting organizations or individuals are structural parts of the system which influence the reporters’ perceptions and the reporting culture. For example, if the system’s goal is to maintain accountability or the operating organization can impose corrective action on a reporter (e.g. disciplinary action or termination of employment) the reporter may perceive a high risk of being punished, hence the reporter possibly perceiving a blame culture. Therefore, to compare the two databases structurally using some element of the reporting culture characteristic this section aims to explore the goals of the reporting systems and what power the operating organization has over the reporters with regards to imposing punitive measures.

**FDA MAUDE**

The MAUDE database is overseen and operated by the FDA, a governmental agency responsible for protecting public health by regulating and supervising a broad spectrum of food, drug, and device related products. As such it is responsible for enforcing laws and regulations, which
carries with it the possibility of holding people and organizations accountable for their actions. Legislation under the Safe Medical Devices Act (SMDA) of 1990 was enacted by the U.S. Congress to increase the amount of information the FDA and device manufacturers receive about problems with medical devices.\textsuperscript{116} In addition, the SMDA provided the FDA with post-marketing activities for monitoring products after they had been cleared for use.\textsuperscript{113} Under the SMDA, device manufacturers and user facilities are mandated to report deaths and serious injuries in which a medical device has or may have caused or contributed to an event.\textsuperscript{116} As such, the MAUDE database came into place to allow for this post-market surveillance of medical devices.\textsuperscript{113}

Regarding how the FDA handles and perceives reports, it has regulations surrounding the reporting of medical device incidents which can be enforced through legal sanctions authorized by the Federal Food Drug & Cosmetic (FD&C) Act.\textsuperscript{116} In addition, the FDA holds that once a device malfunction has contributed to a death or serious injury it is presumed that the malfunction is likely to contribute to more deaths or injuries.\textsuperscript{116} The FDA holds this presumption until no further deaths or serious injuries have resulted from the malfunction for two years, or if the manufacture can show the likelihood of another death or serious injury is remote.\textsuperscript{116} The FDA may take the following actions to enforce its regulations on device manufacturers: product recalls, monetary penalties, warning letters, seizure of goods, citations, injunctions, or criminal prosecution.\textsuperscript{116} Towards user facilities, failure to comply with reporting requirements may result in criminal or civil penalties.\textsuperscript{116} While reporting does not always lead to any of these consequences they are possibilities. The MAUDE database is not governed to try to blame or punish manufacturers and user facilities for their involvement in an incident. The MAUDE is more targeted at enforcing the accountability of medical device manufacturers.

\textit{ISMP Canada Medication Incident Database}

Unlike the FDA, ISMP is not a governmental agency. ISMP has no regulatory, licensing, inspecting, or accrediting authority.\textsuperscript{117} ISMP may work with accreditation bodies, manufacturers, policy makers, regulatory bodies, and standards-setting organizations\textsuperscript{117}, but at no point does it have the power to bring about any sort of blame or enforcing action on reporters. Reporting to the system is completely voluntary and reporters are free to report events which they want to
share. The impetus for this is the hope that people share information for the purpose of informing others of risks and attempting to bring about safety improvements. The database is used by ISMP to conduct research and develop recommendations for improving medication safety. Through use of the reports submitted to their database, ISMP publishes Safety Bulletins on issues, holds educational programs on safety, and works with other organizations to developing safe, evidence-based practices.

Overall learning and sharing recommendations is the guiding goal of the ISMP Canada Medication Reporting System. The goal is not to collect events in preparation for litigation or to hold health care professional accountable. The database is intended for use as a tool for learning about incidents, using that information to develop safe medication practices, and share that information with those capable of encouraging change.

**Comparison Summary: Goal of the Reporting System**

The reporting culture is not entirely a structural characteristic of the incident reporting system. One aspect of the reporting culture is the perception of the culture by those reporting to the system, which cannot be assessed structurally. However, this perception is influenced by the goal of the system and the punitive power the organization operating the system has over the reporters, which can be structurally assessed. The MAUDE is tasked with providing post-market surveillance for identifying and monitoring significant adverse events involving medical devices. The FDA itself has the power to enforce reporting through legal sanctions as well as impose punitive actions (e.g. product recalls) onto manufacturers regarding products that pose a threat to public health. In comparison, ISMP Canada’s system is tasked with reviewing and analyzing medication incident reports, then using this information to identify contributing factors and recommend system safeguards. ISMP Canada has no authority to enforce reporting or to punish any reporting individuals or organizations.
4.3.2 Classification of a ‘Reportable Event’

How the database phrases its definition of a reportable event is an important component of the system’s design. This attribute will play a large role in influencing what type of information the system captures, as well as the type of information that may be overlooked.

**FDA MAUDE**

With regards to the type of events to report, the MAUDE mandates that:

“A user facility must report to the device manufacturer and FDA whenever the facility has information that reasonably suggests a device has or may have caused or contributed to a patient’s death. If a facility has information that reasonably suggests a device has or may have caused or contributed to a patient’s serious injury, it must report this information to the device manufacturer.” ¹¹⁶

The device manufacturer is then required to report any device-related deaths, serious injuries, and malfunctions to the FDA whenever they become aware of the event.¹¹⁶ Regarding what is to be considered as a medical device, the FD&C Act provides a very specific definition.¹¹² Therefore the MAUDE’s definition of a reportable event clearly defines the type (medical device incidents) and impact (serious harm and death) of the incidents to be reported. However, voluntary reports of device malfunctions resulting in less severe impacts can also be submitted to the system.

**ISMP Canada Medication Incident Database**

ISMP Canada’s database is targeted at the reporting of medication incidents and near misses. Their definition of a medication incident is adapted from the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) and is defined as:

“Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Medication incidents may be related to professional practice, drug products, procedures, and systems, and include prescribing, order communication, product labeling/ packaging/
nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.”\textsuperscript{117}

This is a very specific definition of a wide arching type of health care incident. This definition also gives a glimpse into the impact of the events targeted by this system as it makes note of events that “may cause or lead to” an incident. This implies that all events from no harm or near miss events to incidents resulting in death are equally accepted into the ISMP database. Therefore, ISMP Canada’s definition of a reportable event clearly classifies the type of events as those related to medication issues, but does not identify a specific target incident impact, instead it openly accepts incidents of any impact (e.g. hazardous conditions, harm, death, etc.).

**Comparison Summary: Classification of a ‘Reportable Event’**

The MAUDE database is primarily concerned with events which can be classified as having resulted in the serious injury or death of a patient which was contributed to by some interaction with a medical device. In contrast, ISMP Canada’s system does not specify an impact that it classifies as a ‘reportable event’ but rather welcomes reports anywhere from warnings about hazardous conditions to events resulting in death. However, the type of events reported to ISMP Canada’s system must be classifiable as a medication related event.

4.3.3 Operational Aspects

The two databases have very different operational aspects with regards to both their style of reporting and how they deal with indentifying the reporter.

**FDA MAUDE**

The MAUDE is a highly regulated mandatory reporting system. Reporting to the MAUDE database is mandated by the FDA as regulated by the FD&C Act, SMDA, and Medical Device Reporting (MDR) regulations. These regulations require device manufacturers and user facilities to report post-marketing complaints and incidents in which a medical device may have malfunctioned or contributed to serious injury or death.\textsuperscript{116} In addition, user facilities are required
to submit annual reports summarizing their adverse event reports and manufacturers must submit annual certification of regulation compliance.\textsuperscript{116} Table 5 summarizes the mandatory reporting requirements for manufacturers and user facilities, including who they are supposed to report to. User facilities are required to submit reports through the manufacturer to notify them of the incident. User facilities must also notify the FDA in cases of patient death. Manufacturers are expected to review user facility reports and then submit the completed report to the FDA. A “good faith effort” is required by the manufacturer to try and obtain more information from the user facility if required.\textsuperscript{116} This entails at least one documented follow-up attempt for more information.

Table 5: Summary of manufacturer and user facility mandatory reporting requirements to the MAUDE reporting system

<table>
<thead>
<tr>
<th>Reporter</th>
<th>What to Report</th>
<th>Who to Report To</th>
<th>When to Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>User Facility</td>
<td>Serious Injuries</td>
<td>Manufacturer</td>
<td>Within 10 work days</td>
</tr>
<tr>
<td></td>
<td>Death</td>
<td>FDA and Manufacturer</td>
<td>Within 10 work days</td>
</tr>
<tr>
<td></td>
<td>Annual Summary Report</td>
<td>FDA</td>
<td>January 1</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>30 Day Reports of Deaths, Serious Injuries, and Malfunctions</td>
<td>FDA</td>
<td>30 days from becoming aware of the event</td>
</tr>
<tr>
<td></td>
<td>5 Day Reports For Those Requiring Remedial Action to Prevent Harm to Public Health</td>
<td>FDA</td>
<td>Within 5 work days</td>
</tr>
<tr>
<td></td>
<td>Annual Certification</td>
<td>FDA</td>
<td>When firm submits annual registration</td>
</tr>
</tbody>
</table>

User facilities are also encouraged, but not required, to report events to the manufacturer that do not result in death or serious injury.\textsuperscript{116} These voluntary reports aim to provide additional sources of information to the manufacturer and FDA concerning device safety, but aren’t governed by any sort of regulatory policy. Therefore, while the MAUDE is primarily governed by mandatory reporting, it also accepts voluntary reports of less severe device malfunctions.
As per the U.S. Freedom of Information Act any report in the FDA’s control is subject to full public disclosure in response to a Freedom of Information request.\textsuperscript{116} However, prior to public disclosure the FDA will delete from the report: trade secrets; confidential, commercial or financial information; personal, medical and similar information; and identifying information of a third party voluntarily submitting a report.\textsuperscript{116} User facilities are required to identify a contact person with whom the FDA can correspond, but will only disclose the identity of the user facility when requested. The FDA will not disclose the identities of physicians or other user facility employees. Manufacturer information, including the manufacturer name and contact information, is made publically identifiable on all MAUDE reports. As such, the MAUDE system can be considered to contain information identifying the reporter (i.e. the user facility and manufacturer).

\textit{ISMP Canada Medication Incident Database}

There are no laws or regulations mandating reporting to ISMP Canada’s Medication Incident Database, nor does ISMP Canada have any authority to enforce reporting. As such, reporting to this database is completely voluntary and offers health care professionals and hospitals a place to submit event information for the purposes of learning and research rather than accountability. Therefore, all the strict guidelines which are in place for reporting to the MAUDE are non-existent in this system. Reporters submit what they want, when they want.

Regarding reporter identification in the ISMP Canada database, it is anonymous by default. However when submitting a report, reporters are given the option to leave contact information and to provide consent for follow-up by ISMP Canada (Roger Cheng, Project Leader – ISMP Canada, personal communication, July 19, 2011). This allows ISMP Canada to contact the reporter for further elaboration on an event in cases where ISMP Canada requires or wants more information. However, any information identifying the reporter is only visible by ISMP Canada and is held in strict confidence. Therefore, while the system is anonymous by default, it allows for optional confidential reporting as well.
Comparison Summary: Operational Aspects

The MAUDE is a highly regulated mandatory reporting system with strict guidelines and policies for reporting. The MAUDE also welcomes reports submitted voluntarily. Submitting a report to the MAUDE requires the reporter, user facility, and manufacturer of the device involved in the incident to provide identifying information. However, the public can only view the manufacturer’s information or request the user facilities information. The reporter is not identified in any publically disclosed reports. The ISMP Canada Medication Incident Database is nearly the complete opposite of the MAUDE in terms of the operational aspects characteristic. That is, ISMP Canada’s system is a voluntary system and reporting is anonymous by default, but reporters are encouraged to provide contact information confidentially.

4.3.4 Collecting Versus Analyzing Incident Data

The way in which a system chooses to use the reports after they have been collected reflects how the final data from the incident reporting process is presented. The methods used can dictate whether information is simply collected with no additional processing, used to develop trends and statistics, or analyzed in detail to build recommendations and targeted safety improvements.

FDA MAUDE

The MAUDE is primarily a post-market surveillance system. As such its function is to collect reports of all events in which a medical device caused or contributed to severe injury or death. Analysis of the reported events doesn’t play a primary role in this function. If the FDA receives an influx of reports about a particular device or a situation they feel threatens public health they may request more information or issue notices, but this task is more akin to hazard identification than an analysis process.

The manufacturer and user facility play a larger role in developing information for the system, although the consistency and level of “analysis” is not fixed across every report. User facilities may carry out some investigation of an event after it has occurred at their organization. This may include sending the device to their medical engineering department for inspection to try and
determine the cause. However, the user facility is only mandated to report information that is “reasonably known” to it.\textsuperscript{116} Reasonably known information includes that found in facility documents and available as a result of reasonable follow-up within the facility.\textsuperscript{116} The manufacturer is also to submit information that is ‘reasonably known’ and it includes information that can be obtained by contacting a user facility, distributor and/or initial reporter, any information in the manufacturer’s procession, or any information that can be obtained by analysis, testing or other evaluation of the device.\textsuperscript{116} However, the FDA has no legal authority to require the user facility to return the involved device in the incident to the manufacturer or allow the manufacturer access to the device for investigation and evaluation.\textsuperscript{116} Therefore, the amount of actual analysis the manufacturer can perform without the device and only relying upon the user facility reports may be limited.

Overall, the system does not have a large emphasis on mandatory event analysis, although it does encourage the collection of as much information about each incident as reasonably obtainable. The MAUDE regulates, mandates, and focuses on the collection of incident information and less on the analysis processes following reporting. The database is primarily a surveillance system, which is used to collect reports, notify manufacturers of issues with their products, and allow the FDA to monitor for situations that pose potential risks to public health.

\textit{ISMP Canada Medication Incident Database}

One of ISMP Canada’s goals is to “review and analyze medication incident and near miss reports according to a hazard identification model, identify contributing factors and causes and make recommendations for the prevention of harmful medication incidents.”\textsuperscript{117} ISMP Canada employs analysts whose job it is to search their database and carry out meaningful analysis of reporting information. As such, ISMP Canada analysts are composed of clinicians who have clinical knowledge and experience relevant to understanding medication practices, such as pharmacists, pharmacy technicians, and nurses. ISMP Canada prioritizes its review and analysis of incoming incident reports by utilizing an analysis prioritization matrix (Roger Cheng, Project Leader – ISMP Canada, personal communication, July 19, 2011). ISMP reviews all reports submitted by individual practitioners and events resulting in patient harm submitted by hospitals. While reports classified as lower priority may not be initially reviewed when they are received, they are
used when investigating focused safety topics. In these studies ISMP will search their database and perform an aggregate analysis of all the relevant reports.

Root cause analysis, and failure mode and effects analysis are analytic tools used by ISMP Canada for investigating selected medication incidents. The results from ISMP Canada’s analysis efforts are regularly used to publish safety alerts and recommendations. Bi-weekly Safety Bulletins are published by ISMP Canada which alert those involved in health care of safety risks and provide recommendations for improving medication safety. In addition, for some of its projects ISMP Canada may work with regulatory agencies, policy makers, or manufacturers to bring about changes based on their findings. Overall, ISMP Canada has the goal of reviewing and analyzing medication incidents submitted to their system with the aim of determining recommendations to prevent further incidents from occurring.

Comparison Summary: Collecting Versus Analyzing Incident Data

Overall, the MAUDE has more policies and guidelines in place highlighting the processes for collecting incident reports and investigating them in a timely manner than it does for analysis activities. To this end the MAUDE appears to set out to capture a great deal of information about events which aims to allow manufacturers to correct issues with their products, but also allows the FDA to provide surveillance of medical devices and identify hazards to public safety. Meanwhile ISMP Canada’s system is much more focused on analysis tasks. ISMP Canada employs expert analysts who use a number of analysis techniques (e.g. aggregate data analysis of reports, root cause analysis, etc.) to learn from their reports and build recommendations for preventing harmful medication incidents.

4.3.5 Description of an Event

Understanding what has occurred from the information contained within an incident report is an extremely important part of an effective reporting system. Information without sufficient quality to ascertain the details about what occurred makes learning from past errors a near impossible task. In addition, the combination of free-text narratives and structured classification fields can make drawing information from reports a variable process between databases.
**FDA MAUDE**

The information presented in the MAUDE is done using short free-text information fields as well as check boxes with structured classification options, and free-text narratives. The short free-text information fields are mainly used for information about the device involved in the incident, such as the device name, manufacturer name, and model number. Structured classification is used for items such as the event outcomes, location, and type of device problem. A majority of the details about an incident are contained within the free-text narrative of the incident report. Since both user facilities and manufacturers typically contribute to reporting an event there is often one main narrative for the user facility to describe the event and then at least one field for the manufacturer to describe their follow up assessment of the event.

**ISMP Canada Medication Incident Database**

Similar to the MAUDE, information in the ISMP Canada database is composed of a combination of structured fields, short free-text information fields, and free-text narratives. However, a majority of the information in ISMP Canada’s database is in the form of structured classification elements. For example, defining the event type, location, impact, and contributing factors are based on elements selected by reporters from drop down or check box menus. The few short free-text information fields included in each report are mainly used to identify the medications involved in the incident, including information about its strength, route of administration, manufacturer, etc. Similar to the MAUDE, most of the descriptive information about the event is presented in the free-text narrative.

**Comparison Summary: Description of an Event**

The MAUDE and ISMP Canada systems do not differ to much with regards to the methods they use to capture incident information. Both systems present information via a combination of short-free text information fields, structured option fields (e.g. check boxes or drop down menus), and free-text narrative fields. Where they differ is with regards to the relative number of these types of fields. ISMP Canada tends to use structured option fields more than the MAUDE does. Meanwhile the MAUDE tends to use more short-free text information fields. In both
systems free-text narratives provide a majority of the descriptive information detailing what occurred during the event.

### 4.3.6 Consistency of Language & Standardization

This section aims to compare how the databases use consistent and clear terminology or definitions to provide structure to their reporting process. However, while consistent terminology within the system itself is important, it is also important to note how the terms and definitions match or conflict with those in other reporting systems.

**FDA MAUDE**

As a highly regulated body the FDA has detailed, documented definitions for most aspects of their reporting process. Most of the general terminology is laid out in the Code of Federal Regulations – Title 21 – Food and Drugs. In addition, the reporting guidelines for manufacturers and user facilities provide lengthy and specific definitions for terms that are particularly important for those reporting to the MAUDE. These definitions include what is meant by “MDR reportable events”, “malfunction”, “manufacturer”, “user facility”, “serious injury/serious illness”, and “caused or contributed to”. A very clear definition is also given in the FD&C Act of what constitutes a medical device. All of the documented definitions work towards maintaining a clear and consistent use of terminology with regards to what is reported to the database.

With regards to the fields requiring completion by the reporters within the reports themselves, they are not based on any predefined taxonomy. Many of the required fields appear to be fairly specific to the MAUDE reporting process, although there are sections for noting common descriptive element such as the event impact and location. However, the impact field offers a very broad classification of the impact (i.e. death, serious injury, malfunction, or other) when compared to other taxonomies. As a result of the limited standardization the MAUDE does not appear to lend itself well to comparing its data with other databases beyond using the free-text information and possibly the impact and location classifications.
**ISMP Canada Medication Incident Database**

ISMP Canada posts on their website a glossary of several terms it considers essential for discussing medication incidents. Definitions are included for terms such as “adverse drug event”, “harm”, “near miss or close call”, and “no harm event”. In addition, the definition provided for a “medication incident” is very well structured and incorporates a broad range of medication related issues to help guide the reporter in determining what is considered a reportable event. However, while these definitions provide a clear understanding of the relevant terms, the definitions are taken from a variety of different sources such as government publications and journal articles. This patchwork collection of definitions helps in illustrating the issue of no single standardized set of health care incident reporting terminology with which to consistently reference.

ISMP Canada’s database adapts components of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Taxonomy of Medication Errors to inform what information fields are included in the reports submitted to their reporting system. As the NCC MERP is composed of 27 national organizations it provides a strong basis for developing a standardized way of presenting medication errors. While ISMP Canada’s database doesn’t use all the taxonomy elements and uses slightly different coding options it still provides some level of standardization. The semi-standardized way of recording and tracking medication errors within their system has the potential for allowing ISMP Canada to cross compare their incident data with other systems using the same base taxonomy fairly easily.

**Comparison Summary: Consistency of Language & Standardization**

The MAUDE has very detailed terminology as defined within the policies and regulations governing the FDA. However, the terms used are somewhat unique to the MAUDE and not utilized across multiple incident reporting systems. This is also the case with regard to the use of information fields within their reporting forms, which do not appear to be based on any recognized standard. ISMP Canada in comparison provides a variety of definitions from recognized sources, but forms a patchwork collection of definitions that illustrates the lack of a single location for clear health care incident reporting terminology. With regard to the fields used
to report incidents, ISMP Canada has adapted them from the *NCC MERP* Taxonomy of Medication Errors, which is recognized by a number of other national organizations.

### 4.3.7 Accessibility & Ability to Search the System

Investigations like that described in the next chapter of this study, looking for reports surrounding specific types of events, are only possible if a database is accessible and searchable by researchers. The researchers may be part of the operating organization in which case access to the database may not be an issue. Difficulties arise however for external researchers and the public whom are not always allowed access to view reported incidents.

**FDA MAUDE**

Medical device reporting data is made available for public use under the U.S. Freedom of Information Act.\(^\text{119}\) The MAUDE database is available on the FDA’s website as a searchable database. People can use a variety of predefined fields, including brand of device, device manufacture, and event type, to initiate a search of the database. This process allows clinicians the ability to investigate specific devices when considering the use of a new medical device or looking into issues with their current devices.\(^\text{119}\) The public nature of the database also has allowed a number of researchers to undertake searches of the MAUDE data in attempts to summarize various device related events.\(^\text{119}\) In addition to the online search, downloadable files containing incident data from previous years can be accessed online for the public to use as they see fit. This option is beneficial as it allows users with some database experience to construct a database which offers more customizable search options.

**ISMP Canada Medication Incident Database**

The ISMP database is only accessible by ISMP Canada analysts; the public has no way to access individual event reports submitted to the system. However, while the public cannot view events, ISMP Canada employs expert clinicians whose job it is to analyze incidents and search through their database. Because of this emphasis on analysis ISMP Canada’s database is designed to be easily searchable using their predefined category fields as well as the free-text narratives of
reports. However, the inability for the public to review reports in the ISMP Canada database is definitely a limiting barrier as to who can use the data to assist in investigating incidents and potentially helping develop safety improvement strategies.

**Comparison Summary: Accessibility & Ability to Search the System**

The MAUDE is a publically accessible system which allows the public to search for and review incident reports submitted to the system. An online search is available, but the FDA also posts downloadable files containing all incident data which can be used to construct a customized database with MAUDE data. This can allow for more complex and detailed searching of the MAUDE reports. In comparison, ISMP Canada’s Medication Incident Database is not available to the public and only ISMP Canada has access to searching and reviewing submitted reports. However, as ISMP Canada is focused on analyzing and using their data for research they have implemented it in such a way to allow easy searching of it to perform aggregate data analysis.

### 4.3.8 Timeliness of Reporting

For the purposes of comparing the timeliness of a system’s reporting process it is important to note the effort required on the part of the reporter to submit a report. As mentioned in the literature search section, staff preferred that the time required to report not exceed five minutes. Therefore assessment of this characteristic involves looking at what elements are included in the report, how these elements are portrayed (i.e. free-text or predefined fields), and how easy it is to access the reporting system to submit the report.

**FDA MAUDE**

As with most aspects of the MAUDE the reporting process is highly regulated. Table 5 presented in the Operational Aspects comparison section (Section 4.3.3) displays the strict time requirements the FDA imposes for reporting. The reporting process for the MAUDE is form based, either through paper or electronic submissions. To report an event, user facilities must complete FDA Form 3500A, or some approved facsimile thereof, within 10 working days from the time that any medical personnel of the facility becomes aware of a reportable event. This
two-sided form requires user facilities to document information about the patient, a description of the event, the medical device information, the initial report information, and the user facility information. The further fields on the form are required to be filled out by the manufacturer and include the manufacturer’s information, their evaluation of the event and any remedial action taken. The manufacturer is responsible for providing any information missing from the form, including missing event codes or patient information that may not have been included by the user facility. The form uses a combination of check boxes, single phrase written responses, and a couple of free-text narratives. There are fields for event problem codes and evaluation codes, which requires referring to a coding manual developed by the FDA which contains hundreds of codes for adverse events. In these cases the user facility and manufacturer are required to enter codes which most accurately describe the event. There is also a field for the “common device name” which corresponds to a product code assigned to the device. If the product code of the device is unknown a generic or common name can be used. However, the FDA has classified approximately 1,700 generic categories of devices. A voluntary reporting form, MedWatch Form 3500, is also available for consumers and health care professionals to submit reports of device malfunctions or errors not resulting in serious injury or death. This form contains similar fields to that of the mandatory form.

The MAUDE has a very structured and clearly defined reporting processes, but it is not a simple and fast process. In fact the FDA has prepared an 18 page document to provide instructions for completing the form. The form itself consists of about 60 fields for reporting a device related event. Collection of the information required to submit the report is estimated by the FDA to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering the data needed, and completing and reviewing the collection information.

**ISMP Canada Medication Incident Database**

Individual practitioners can submit reports online while hospital facilities can use a Windows like interface program called Analyze-Err to submit reports. Both reporting methods are similar and consist of about eight mandatory fields and then voluntary sections for the event date, intervention and follow-up information, basic patient information, reporter contact information,
and contributing factors of the event. The reporter is also given the option to upload pdfs or photos to help illustrate the event or hazardous situations, although only through the online interface. Filling out information uses a combination of check boxes, drop-down menus, and relatively few free-text fields. ISMP Canada has about 24 fields total for reporting and only eight of these are required fields. In addition, a majority of the fields are check boxes or drop-down menus rather than text-based responses.

**Comparison Summary: Timeliness of Reporting**

The reporting form for the MAUDE is a substantial length consisting of a large number of fields to provide information on the event. As a result the FDA estimates that an average of 66 minutes is required per response in order to complete the report. In contrast, ISMP Canada requires far fewer fields to provide information when submitting a report. The reporting format of the ISMP Canada database is much more conducive to being completed in 5 minutes, even if the reporter fills in both the voluntary and mandatory fields.

**4.3.9 Feedback & Dissemination of Information**

Incident information should not only flow into the incident database, but also be shared and distributed through feedback and dissemination practices. As feedback is often seen as a weakness in the reporting process, it offers a good attribute with which to examine and compare the two databases. In addition, examining dissemination practices offers insight into how the databases integrate into the health care system as a whole or if the database serves as an isolated structure.

**FDA MAUDE**

Unlike most systems where a single person reports the event, reporting to the MAUDE involves multiple people (i.e. the user facility and manufacturer). Therefore, feedback relates to information being passed back to both parties. However, there generally is no formal feedback mechanism in place which requires manufacturers to inform the user facility of any follow-up measures or findings that they may have uncovered regarding the reported event. The
manufacturer may try to contact the user facility for further information about an event, but in the strictest sense this is not a form of feedback. The user facility having to report to the MAUDE through the manufacture may be considered some form of feedback to manufactures about the operation of their products, but this could also simply be considered a form of product surveillance. The FDA itself is not required to provide any direct feedback to manufacturers either. The FDA may contact the user facility or manufacturer for more information, but again this is not feedback in the strictest sense of the term. The closest thing to feedback is the FDA issuing warnings or notices to the manufacturer about issues they are noticing which require corrective action. Nearly all of the responsibility for following up on incidents is on the manufacturer.

The reporting process of the MAUDE itself can potentially be seen as a mechanism for disseminating information about device issues to the manufacturers in order to promote safety improvements. User facilities are mandated to report specific events to manufactures, which can be seen as disseminating knowledge about a safety concerns and keeping manufacturers informed about issues with their products. It is then up to the manufacturers to decide how to react to these incidents, but they are being kept informed about their product’s use in the market.

To disseminate information to the general public the FDA also occasionally issues notices, public health advisories, and safety alerts on products that they believe pose risks to public health. The FDA website is also used to post information about device issues and recall information. However, what is often disseminated by the FDA is not typically recommendations for better safety practices, but more akin to warnings about products that their database has suggested may prove harmful. The database being publically accessible can also be considered as another way in which the MAUDE disseminates its findings, but not necessarily any recommendations. This mechanism provides the raw data for the general public to explore specific devices or types of incidents.

**ISMP Canada Medication Incident Database**

Being primarily an anonymous reporting system makes providing feedback to the reporters a near impossible task. However, for reporters who provide their contact information and have provided consent for follow-up, ISMP Canada will contact reporters (Roger Cheng, Project
Leader – ISMP Canada, personal communication, July 19, 2011). In certain situations ISMP Canada may follow-up with a reporter by providing them with published Safety Bulletins regarding events similar to the one the reporter submitted. In other situations ISMP may follow-up to request more information about an event or get the reporter’s consent to use the incident in a publication. Finally, in some situations ISMP will follow-up to simply thank the reporter for contributing. While these later two follow-up strategies are not suggestions or recommendations for the reporter to use for improving safety, they are feedback that shows that the reporter’s effort is appreciated and that the report is not disappearing into an administrative black-hole.

One of ISMP Canada’s operational goals is the publishing and disseminating of information on safe medication practices for knowledge translation.\textsuperscript{117} As such they use the information arrived at through analyzing the reports in their database to provide tools and educational programs for improving patient safety. ISMP Canada also freely posts and distributes bi-weekly Safety Bulletins which are aimed at sharing information they receive about incidents and suggest improvement strategies for enhancing patient safety.\textsuperscript{117} ISMP Canada also distributes, for a fee, monthly Medication Safety Alert! publications targeted at specific professionals such as nursing, acute care, and community health professionals.\textsuperscript{117} In addition, ISMP Canada often works with regulatory agencies, policy makers, and manufacturers to help facilitate change in medication practices.

**Comparison Summary: Feedback & Dissemination of Information**

In the MAUDE, feedback is generally not given to the user facility and manufacturers expect when the FDA issues notices to the manufacturers regarding products they perceive as requiring corrective action to fix a threat to public health. Regarding dissemination practices of the FDA, information may be passed along via public notices, health advisories, or safety alerts published or posted on their website. The fact that the MAUDE is publically available itself also opens up dissemination opportunities as the public and researchers can carry out their own investigations of device related issues if they so choose. With regards to the ISMP Canada system, feedback is always given in some form to individual practitioners who submit confidentially. With regards to dissemination practices, ISMP Canada publishes bi-week Safety Bulletins to highlight noted safety issues or safety recommendations. ISMP Canada also forms partnerships with external
organizations to help disseminate lessons learnt and bring about improvements in medication safety.

4.3.10 Denominator & Numerator Issues

The issue of denominator and numerator problems is difficult to compare between databases because under-reporting rates and the number of times procedures are performed safely and unsafely are very difficult to determine. Therefore, with regards to denominator and numerator issues this section looks at how the organizations operating the databases acknowledge the existence of these limitations in the use of their database.

**FDA MAUDE**

The FDA posts a disclaimer on their website stating “MAUDE data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices”\(^{113}\). This statement demonstrates that the FDA is aware of the limitations involved with using numbers and rates as statistics to draw conclusions from their data and want users of their data to be aware as well. The FDA is more focused on reports regarding specific devices and if the outcome severity or the number of events reaches a certain point where it may affect public safety.

**ISMP Canada Medication Incident Database**

As a voluntary reporting system with nothing governing individuals to report there is no way to prevent issues of under-reporting. There is also no way for ISMP Canada to measure the total number of practices related to the reported event to serve as a denominator value. As such, ISMP Canada does not tend to focus on statistics or rates. ISMP Canada may use numbers in some of their publications, but only for contextual purposes when describing or assessing a group of events, but not as a standalone value. Overall, ISMP Canada takes a more qualitative approach rather than a quantitative approach to managing and discussing its data (Roger Cheng, Project Leader – ISMP Canada, personal communication, July 19, 2011).
Comparison Summary: Denominator and Numerator Issues

Both systems are the same in regards to their acknowledgement of the issue caused by denominator and numerator problems. As such both systems don’t utilize rates or prevalence’s of incidents when discussing results of their respective systems. Rather than statistics, the systems tend to look at trends in their systems and issues where a serious problem is perceived.

4.4 Chapter Summary

Table 6 summarizes the differing system goals of the MAUDE and ISMP Canada’s Medication Incident Database. This table also describes the authority the operating organizations have with regards to enforcing actions onto the reporters. While these systems are both focused on safety, the goal they use to accomplish this task is very different.

<table>
<thead>
<tr>
<th>Goal of the Reporting System</th>
<th>FDA MAUDE Database</th>
<th>ISMP Canada Medication Incident Database</th>
</tr>
</thead>
<tbody>
<tr>
<td>To provide post-market surveillance for identifying and monitoring significant adverse events involving medical devices. Aim is to detect and correct problems in a timely manner.</td>
<td>To review and analyze medication incident reports and use this information to identify contributing factors and recommend optimal system safeguards.</td>
<td></td>
</tr>
</tbody>
</table>

| Punitive Authority of the Operating Organization | The FDA has the power to enforce reporting through legal sanctions as well as impose punitive actions (e.g. product recalls) onto manufacturers regarding products that pose a threat to public health. | ISMP Canada has no power to enforce reporting or punish reporting individuals or organizations. |

Table 7 summarizes the comparison of the MAUDE and ISMP Canada’s Medication Incident Database with regards to how they structurally implement and portray the various fundamental characteristics identified through the literature search.
Table 7: Summary of the structural differences between the MAUDE and ISMP Canada Medication Incident Database based on the fundamental characteristics

<table>
<thead>
<tr>
<th>Fundamental Characteristics</th>
<th>FDA MAUDE Database</th>
<th>ISMP Canada Medication Incident Database</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reporting Culture</strong></td>
<td><em>Compared in terms of the system’s goals and the punitive authority the organization operating the system has over the reporters (see Table 6). These structural aspects of the systems influence how reporters perceive the culture surrounding the system</em></td>
<td></td>
</tr>
<tr>
<td><strong>Classification of a ‘Reportable Event’:</strong></td>
<td><strong>By Type of Impact</strong>&lt;br&gt;Death &amp; serious injury</td>
<td>Hazardous conditions, near misses, and adverse events</td>
</tr>
<tr>
<td><strong>Classification of a ‘Reportable Event’:</strong></td>
<td><strong>By Type of Event</strong>&lt;br&gt;Medical device related events</td>
<td>Medication related events</td>
</tr>
<tr>
<td><strong>Operational Aspects:</strong></td>
<td><strong>Voluntary vs. Mandatory</strong>&lt;br&gt;Mandatory (primarily), but voluntary reports are welcomed</td>
<td>Voluntary</td>
</tr>
<tr>
<td><strong>Operational Aspects:</strong></td>
<td><strong>Identification of Reporter’s Identity</strong>&lt;br&gt;Identifying information about organizations involved (manufacturer and user facility)</td>
<td>Primarily anonymous, with the option to report confidentially if consent is given by the reporter</td>
</tr>
<tr>
<td><strong>Collection Versus Analyzing Incident Data</strong></td>
<td>Investigation and hazard identification</td>
<td>Analysis and recommendation building</td>
</tr>
<tr>
<td><strong>Description of an Event:</strong></td>
<td><strong>Free-text vs. Structured Classification Information</strong>&lt;br&gt;Information presented via a combination of short-free text information fields, structured option fields (e.g. check boxes or drop down menus), and free-text narrative fields. However, short-free text information fields are used most prominently</td>
<td>Information presented via a combination of short-free text information fields, structured option fields (e.g. check boxes or drop down menus), and free-text narrative fields. However, structure option fields are used most prominently</td>
</tr>
<tr>
<td><strong>Consistency of Language &amp; Standardization</strong></td>
<td>Uses very strict definitions as defined within the policies and regulations governing the FDA, although most of the terms and report fields are specific to the MAUDE</td>
<td>Uses definitions from a variety of sources, but with regards to the database structure and information fields it adapts components from the <em>NCC MERP</em> Taxonomy of Medication Errors</td>
</tr>
<tr>
<td>Fundamental Characteristics</td>
<td>FDA MAUDE Database</td>
<td>ISMP Canada Medication Incident Database</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>--------------------</td>
<td>----------------------------------------</td>
</tr>
<tr>
<td><strong>Accessibility &amp; Ability to Search the System:</strong></td>
<td>Publically accessible</td>
<td>Only accessible by analysts at ISMP Canada</td>
</tr>
<tr>
<td><strong>Access to the Database</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Accessibility &amp; Ability to Search the System:</strong></td>
<td>Online search available, along with the ability to construct a customized database with MAUDE data for complex searches</td>
<td>Capable of complex searches</td>
</tr>
<tr>
<td><strong>Ability to Search the Database</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Timeliness of Reporting</strong></td>
<td>Paper or electronic based report which is estimated to average 66 minutes per response to complete</td>
<td>Online reporting for individual practitioners and computerized reporting for hospitals, with each report appearing to require about 5 minute to complete</td>
</tr>
<tr>
<td><strong>Feedback &amp; Dissemination of Information:</strong></td>
<td>No feedback is given to the user facilities and manufacturers except notices to change or alter manufacturing practices</td>
<td>Feedback is given to reporters who leave their contact information, however only occasionally is this feedback regarding recommendations</td>
</tr>
<tr>
<td><strong>Feedback to Reporters</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Feedback &amp; Dissemination of Information:</strong></td>
<td>May post information on the FDA website or publish public notices, health advisories, or safety alerts</td>
<td>Disseminate recommendations through bi-weekly bulletins and work with partners to try and bring about safety improvements</td>
</tr>
<tr>
<td><strong>Dissemination of Information</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Denominator and Numerator Issues</strong></td>
<td>Acknowledges that data is not reflective of rates and prevalence</td>
<td>Takes a qualitative rather than quantitative approach to discussing data, only using number to provide context</td>
</tr>
</tbody>
</table>

Both the MAUDE and ISMP Canada’s Medication Incident Database are prominent, national reporting systems, despite having differing goals and structures. This comparison is not to show which database is superior or best makes use of the characteristics, but rather to highlight the difference between the two databases in the ways they implemented the characteristics.
5 Investigating Whether Structural Differences Impact the Database Contents

5.1 Objective

The previous chapter aimed to compare the FDA MAUDE database and ISMP Canada’s Medication Incident Database with regards to how they structurally implemented the ten fundamental characteristics. The results of this process noted that both systems were structurally dissimilar with regards to many of the methods used to implement the fundamental characteristics. The objective of the present chapter is to investigate whether the structural differences of the two systems impact the type of incidents (e.g. medication incidents vs. device incidents) and the quality of information (i.e. descriptive information such as the ability to identify the location, impact, and/or cause) contained within the systems. The ability to extract incident type and quality information from database reports is important as it is a prerequisite for meaningful and effective analysis of incidents.8

5.2 Chapter Overview

To achieve the aforementioned objective, the first step is to query the two systems with a case study incident topic that is relevant to both databases. The case study selected must be reflective of the goals of both the MAUDE and ISMP Canada systems, meaning an incident with both device and medication related issues. Incidents surrounding multiple intravenous (IV) infusions were determined to fit these criteria as they may be the result of technology failures, medication issues, or a combination thereof.

Secondly, the results obtained from querying the two systems will be compared to assess whether there are differences between the systems with regards to the type of incidents and quality of information contained within. To compare the type of incidents and quality of information between systems, information fields common to both the systems and relevant to these topics (i.e. type of incidents and quality of information) must first be identified. Both systems were found to contain three descriptive information fields pertaining to where the event occurred (i.e. Location), what was the effect of the event on the patient (i.e. Impact), and what caused the event to occur (i.e. Cause). Identification of Cause and Impact provide details for
comparing the type of incidents contained within the systems, both by the type of events (e.g. medication incidents) and impact of events (e.g. severe harm). Similarly, being able to identify information pertaining to the Location, Impact, and Cause all provide descriptive information detailing what occurred in the incident, thereby reflecting the quality of information. Therefore, comparison of (a) type of incidents and (b) quality of information between the two systems will be assessed with regards to the ability to extract information pertaining to the three fields (i.e. Location, Impact, and Cause).

Extracting Location, Impact, and Cause information from the two systems corresponds to two of the ten fundamental characteristics. Specifically, the relevant fundamental characteristics are: classification of a ‘reportable event’ and description of an event. Table 8 summarizes how extracting information pertaining to the Location, Impact, and Cause corresponds to these two characteristics.

<table>
<thead>
<tr>
<th>Fundamental Characteristic</th>
<th>Relationship Between the Fields (i.e. Location, Impact, and Cause) and the Characteristic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification of a ‘Reportable Event’</td>
<td>The specific information contained within the ‘Impact’ and ‘Cause’ fields of each report can be used to identify each event’s impact (e.g. severe harm) and the general type of event (e.g. device incident). This in turn can be compared against the system’s overall classification of a ‘reportable event’ which defines what type (e.g. medication or surgical error) and impact (e.g. death or no harm) of events the system aims to capture.</td>
</tr>
<tr>
<td>Description of an Event</td>
<td>Information identified within the ‘Location’, ‘Impact’, and ‘Cause’ fields provide information relevant to describing what occurred during an event. The ability to successfully identify these pieces of information can be compared with how the system has structured the fields (e.g. structured taxonomies and free-text narratives) for reporters to describe the event.</td>
</tr>
</tbody>
</table>

In summary, the present chapter will assess whether structural differences between the two databases (based the two fundamental characteristics: classification of a ‘reportable event’ and
description of an event) impacts the types of incidents and quality of information that can be extracted from the systems.

5.3 Case Study: Multiple Intravenous Infusion Incidents

To provide a manageable scope for assessing the two incident reporting databases a case study looking at multiple IV infusion incidents was selected. Multiple IV infusions refer to the administration of several different IV fluids or medications to a single patient simultaneously or in quick succession. Incidents arising from multiple IV infusion scenarios can involve equipment and medication issues along with human or technological errors. Therefore, the scope of the issues of multiple IV infusion errors provides a relevant case study which spans the target goals of both the MAUDE and ISMP Canada Medication Incident Database.

In the Canadian Adverse Event Study, drug and fluid related events were found to contribute to 23.6% of reported adverse events, the second most prevalent category of adverse events after those surgical in nature.\(^3\) This is supported by U.S. and Australian studies which saw adverse drug events contributing to approximately 19.4% and 24% of all adverse events respectively.\(^3,74\) Furthermore, one report suggested that IV medication errors contribute to 55% of all medication errors.\(^120\) A study in two U.K. hospitals found that about one-third of all IV doses administered to patients were associated with a potentially harmful error.\(^121\) The delivery of medication by IV access is a standard practice in medicine, with approximately 90% of hospitalized patients receiving medication through this route.\(^122\) With this frequency of use it is no surprise IV infusions have been identified as frequent contributors to medication errors. Quite often, critical care patients have several medications being given by multiple IV infusion. To assist in the delivery of medication, a common practice is to use infusion pump technology to deliver multiple IV fluids and medications. These infusion strategies provide a convenient method for the unattended administration of multiple therapeutic agents. The most prominent methods of delivering multiple infusions are described below:

1) Secondary “Piggyback” Infusions

- This setup is an infusion in which two drugs are administered sequentially on a single pump channel, shown in Figure 5A. This setup allows for the intermittent administration of therapeutics through a single IV access site. The secondary drug is
hung above the primary infusion and connected to the patient’s IV line using a y-connector check valve. The hydrostatic pressure created by the height difference and the check valve ensure the secondary infusion is administered first and the check valve is closed to prevent the co-administration of the primary solution. Once the secondary infusion has emptied the check valve automatically opens, starting or restarting the primary infusion.

2) Concurrent Infusion
- This setup allows for the delivery of two or more therapeutics through multiple IV lines simultaneously. The IV lines may run through multiple channels of the same pump or through multiple separate pumps, shown in Figure 5B and C respectively.

3) Concurrent and Secondary Infusions
- This setup, shown in Figure 5D, is a combination of therapeutics being delivered as secondary infusions and concurrent infusions.

Figure 5: Multiple infusion setups A) Secondary “piggyback” infusion, B) Multichannel pump concurrent infusion, C) Multi-pump concurrent infusion, and D) Secondary and concurrent infusion

Therefore, the set-up and administration of multiple IV infusions is a topic which easily lends itself to situations in which adverse events are probable. These events in turn can be attributable
to a variety of factors including human interaction with the set-up components, mis-programming of infusion pumps, the wrong medication being delivered or given at a wrong rate, and improper connection of the IV tubing. This creates a topic in which incidents can potentially be attributed to either medication related errors or device and equipment related errors, thereby spanning the goal of both the MAUDE or ISMP Canada Medication Incident Database. Therefore, the question being posed to the databases in this case study is “what types of issues occur during the set-up and delivery of multiple IV infusions.” Questions similar to this could easily be posed by researchers looking for any number of incident topics within incident databases with the goal of exploring the issues and causal factors to assist in the development of targeted safety improvement recommendations.

5.4 Methodology

The methodology was developed and implemented as a joint project carried out with assistance from the Centre for Global eHealth Innovation’s Health Technology Safety Research Team (HTSRT) and ISMP Canada. Over the course of the entire case studies there were six researchers involved in the development and implementation of the methodologies used in this study. The research team consisted of individuals with a variety of backgrounds and experience. The two researchers from ISMP Canada came from backgrounds in nursing and pharmacy. During the development of the methodology there were three HTSRT researchers all from clinical engineering backgrounds, two of which also had human factors experience. During the actual coding process, one of the clinical engineers with human factors experience had to leave the project, but an industrial engineering undergraduate student was added to the team to assist in coding the databases. Therefore at any time during the development and implementation of the methodology there were five researchers involved.

The methodology described in the sections below aims to accomplish three primary tasks. The first task is the querying of the two systems for reports related to multiple IV infusion incidents. The second task involves identifying information fields (e.g. impact of the event on the patient) common to both reporting systems. After identifying these common fields, the task also involves the coding of these fields for each report returned from querying the systems for multiple IV infusion incidents. The final task is analyzing the coding results to determine whether there are statistically significant differences between the two systems in their ability to identify and
classify the information contained within the identified fields (e.g. does the MAUDE system provide more details surrounding the identification of the incident Cause compared to the ISMP Canada system?). All the methods used aim to achieve the end goal of providing data for investigating if the structural differences, arising from how the two systems were designed, impact the type of incident and quality of information contained within the reporting systems.

5.4.1 Querying the Systems

The methods presented in the sections below outline the steps taken to setup the MAUDE and ISMP Canada systems to allow them to be queried for events related to multiple IV infusion incidents.

**Incident Database Setup**

The MAUDE database is searchable online via the FDA website in a limited fashion. However, to perform a complex keyword search of each report’s free-text narratives the database had to be re-constructed in Microsoft Access using the files provided on the FDA’s website. Due to the large file size and number of incident reports submitted to the MAUDE yearly only a single year of reporting data was implemented in the re-constructed database. Reporting data from 2008 was used to rebuild the searchable MAUDE database in Microsoft Access. Data from 2008 was used because at the time of the database re-construction it was the most recent set of data available online that contained a complete years worth of reporting information.

ISMP Canada regularly undertakes projects which involve searching through their database reports. As such, the Medication Incident Database was already setup to perform keyword searching of the various fields and free-text components of the reported incidents. The volume of reports present within the Medication Incident Database is substantially smaller than the MAUDE database. Therefore, a timeframe of approximately 10 years (May 2000 to April 2010) worth of reports were reviewed in order to provide a useful sample size of reports to assess.

**Development of the System Query**

The next step involved developing a query targeted at extracting multiple IV infusion related incident reports from the two systems. To this end, the three clinical engineering researchers
from the HTSRT and the nursing and pharmacy researchers from ISMP Canada jointly brainstormed a list of keywords related to IV infusions which could be implemented into a query. Multiple sessions were held in which the five researchers attended, with the three HTSRT researchers meeting in person and the ISMP researchers attending by teleconference, to discuss the selection of the keywords. At the initial brainstorming session one of the researchers presented a list of keyword terms that reflected those used to describe multiple IV infusion situations. All the researchers reviewed this list and discussed which terms they felt needed to be removed and which terms should be added to the list. Following the discussion, consensus among all the researchers was reached regarding the use of these terms. The terms were developed from clinical knowledge of multiple IV setups and terminology used in the literature. Following the first session the keyword terms were individually entered into the databases to ascertain the number of resulting reports which were returned. This was performed to determine the number of results returned from the search relative to the other terms as well as to examine if terms captured reports applicable to multiple IV infusions. Following this process, the full research team met again to compare the results between the two databases and further refined the keywords through discussion. The team also met to organize all the keywords into three separate categories:

1) IV Therapy Terms – Broad keywords which relate primarily to the administration of IV therapy

2) IV Equipment or Material Terms – Equipment and materials which are commonly utilized during infusion situations

3) Incident Descriptors – Words used to describe processes and errors, or non-specific IV terms, which could be used to refer to infusion situations

The keywords were separated into different categories to allow the team to devise a large Boolean search term which would look for reports containing a combination of three keywords, a single keyword from each of the three categories, rather than searching each keyword individually. The combination of keywords from these three categories helped limit the reports returned from the query to only those detailing specific elements related to multiple IV infusion incidents, as indicated by the category titles. Separate from this Boolean string of terms was a fourth category of primary keywords developed jointly by the research team. Primary keywords
consisted of terms that were unique to the topic of multiple IV infusions, while the keywords in
the other three categories were related to multiple IV infusions, but not unique to them. As such,
the researchers deemed the presence of a single primary keyword in a report important enough to
warrant a review of the incident. The primary keywords were appended to the Boolean string via
OR statements (e.g., [Three part Boolean search] OR primary keyword 1 OR primary keyword 2
etc.). Table 17 in Appendix B displays the keywords in their corresponding category, along with
the format used to search the databases. Based on the list of keywords and the specified format a
large query term was created to search the free-text narratives of the reports in both databases.

The two systems were both queried using this same search term. The query returned a subset of
reports from within the two databases that were thought to be relevant to multiple IV infusion
incidents. The following section describes the methods used to review these returned reports and
extract information for comparing of the two systems with regards to the type of incidents and
quality of information.

5.4.2 Coding the Query Results

The methods presented in the sections below outline the steps taken to identify information fields
common to reports in both databases. After identifying these fields the section discusses the
methods used to identify and code these information fields, thereby allowing comparison
between the two systems.

Identification of Information Fields Common to Both Systems

To compare the contents of the two systems with regards to the type of incidents and quality of
information the researchers first needed to identify the information fields (e.g. Impact of the
event on the patient) that are commonly collected in both systems. The same five researchers
from ISMP Canada and the HTSRT responsible for developing the keyword search methodology
met, again with the three HTSRT researchers meeting in person and the ISMP researchers
attending by teleconference, to discuss what categories were documented and classifiable within
both the MAUDE and Medication Incident Database. The researchers arrived at a consensus that
both systems collected and documented classifiable information regarding where the event
occurred (i.e. Location), what the effect of the event was on the patient (i.e. Impact), and what
caused the event to occur (i.e. Cause). Therefore these three categories (i.e. Location, Impact, and Cause) were selected as the information fields which would be coded and compared between the two systems.

In addition to being identifiable in both systems, these three categories also are reflective of the type of incidents and quality of information. For example, identification of Cause and Impact information will provide details for comparing the type of incidents contained within the systems (e.g. medication incident, severe harm). Similarly, being able to identify information pertaining to the Location, Impact, and Cause all provide descriptive information detailing what occurred in the incident, thereby reflecting the quality of information. Therefore, these three categories are well suited to being used to compare the two systems with regards to the type of incidents and quality of information.

With the three fields (i.e. Location, Impact, and Cause) established, they were then implemented within a coding scheme. A coding scheme provides a consistent structure for classifying detailed information within the fields through the use of predefined coding options. For example, predefined coding options of the Impact field may include options such as no harm, harm, and death. To develop the coding options for the three fields the research team discussed options which were often used to code these fields in developed taxonomies, such as the JCAHO Patient Safety Event Taxonomy\textsuperscript{95}, the WHO’s international classification of patient safety\textsuperscript{96}, and the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) framework\textsuperscript{123}. Based on these discussions the teams were able to arrive at a consensus regarding the predefined coding options contained within each of the three fields. The three fields and their corresponding options used to code the multiple IV infusion incident reports within the MAUDE and ISMP Canada systems are presented below. The definitions detailing each field and coding option are provided in Appendix B.

- **Location**: This field establishes the location in which the incident occurred. The Location coding options included:
  - Hospital
    - Operating Room
    - Intensive Care Unit
    - Transferring Between Units
- Emergency Department
- General Wards
- Pediatric or Neonate
- Palliative
- Obstetrics
- Other
- Unknown
  - Homecare
  - Transport
  - Other
  - Unknown

**Impact**: This field rates the level of harm caused to a patient as a result of the incident. The Impact coding options were devised based on a combination of the conceptual framework for the international classification of patient safety by the WHO\(^6\) and the NCC MERP framework\(^{123}\). The Impact coding options included:
  - Hazardous Condition
  - No Harm
  - No Harm
  - Mild Harm
  - Moderate Harm
  - Severe Harm
  - Death
  - Unknown

**Cause**: This field identifies what factor led to an incident occurring. The Cause field was divided into 6 categories (listed in Table 9) based on general sections of a typical IV administration setup, shown in Figure 6. These 6 categories were further broken down into specific coding options for identifying a specific causal factor of the reported incident. The specific Cause coding options were jointly developed following discussion of the coding teams’ experience in hospital environments and literature findings on IV infusion errors. To simplify the inter-rater reliability process it was necessary to restrict the teams to only selecting one causal factor for each report.
Figure 6: Separation of the incident Cause based on its location within the IV administration setup (example shown for a piggyback infusion set-up)

Table 9: Breakdown of the Cause field into its general categories and specific Cause coding options

<table>
<thead>
<tr>
<th>General Cause Category</th>
<th>Specific Cause Coding Options</th>
</tr>
</thead>
</table>
| IV Bag                 | ▪ Wrong Volume  
                          ▪ Wrong Concentration  
                          ▪ Labeling Issues  
                          ▪ Bag Height is Incorrect  
                          ▪ Wrong Medication  
                          ▪ Manufacturing Issue  
                          ▪ Other |
| IV Tubing              | ▪ Backflow  
                          ▪ Leaks, Breaks, and Disconnections  
                          ▪ Misconnections  
                          ▪ Kinks  
                          ▪ Clamps  
                          ▪ Drug Incompatibility  
                          ▪ Manufacturing Issue  
                          ▪ Other |
### Infusion Pump
- Pump Out of Specification (not validated)
- Pump Reported Out of Specification (validated)
- Misprogramming (validated)
- Reported Misprogramming (suspected)
- Power Failure
- Pump Failure
- Pump/Channel/Bag/Tubing Mismatch
- Misloaded Tubing
- Wrong Drug Order
- Wrong Time or Missed Infusion
- Manufacturing Issue
- Other

### IV Access Site
- Wrong Route
- Wrong Site
- Accidental Leak, Break or Disconnection
- Infected Line
- Manufacturing Issue
- Other

### Other
- Report details an incident not attributable to one of the cause subcategories

### Undetermined
- Report contains insufficient information to determine any cause

---

**Identifying Reports Applicable to Multiple IV Infusion Incidents**

The reports returned from querying the two systems are not necessarily all relevant to multiple IV infusion incidents. It was likely that the query also captured some events not related to multiple IV infusions, but used similar keywords which resulted in the inclusion in the query results. Therefore, before using the coding scheme outlined above, the reports which were applicable to multiple IV infusion incidents needed to be identified and extracted. Identification of the report’s applicability served to denote if a multiple IV infusion contributed to the incident reported. If so, then the report was applicable, otherwise the report was not applicable. In borderline cases, a “suspected” identification option was used. The “suspected” option was created to allow the research teams to examine additional cases if it was deemed necessary after analyzing the applicable reports. Only reports identified as “applicable” underwent coding of the three information fields (i.e. Location, Impact, and Cause).
Applying the Coding Scheme

The coding process was divided into two passes. The first pass was focused on determining the applicability of the reports returned from the keyword search as a multiple IV infusion incident. For reports determined to be applicable the Location and Impact fields were coded. The second coding pass focused on identifying the coding the Cause field.

To code the events, each of the applicable reports was read, including any relevant structured data fields and free-text narratives, for information pertaining to the three information fields (i.e. Location, Impact, and Cause). Within each of the fields the predefined coding option which best matched the incident described in the report was selected. This process allows for the creation of a table in which each report is classified using consistent terminology for easy aggregation and comparison of the data, within and between databases.

Due to the large size of the datasets returned from the keyword search of each database the task of coding the reports was divided up amongst the five researchers. The two researchers from ISMP Canada reviewed the Medication Incident Database and the three researchers from the HTSRT reviewed the FDA MAUDE database. The teams worked independently, reviewing and coding their respective data, but were frequently in contact to discuss issues of inter-rater reliability and the coding definitions.

Inter-rater Reliability

Since the process of coding the databases was divided between several individuals it was necessary to establish inter-rater reliability between members of the research team. High inter-rater reliability between the research team statistically demonstrates that when individually coding, each member of the team is likely to code an incident report in the same way. Establishing inter-rater reliability allows the data sets to be divided amongst the team, while retaining a degree of uniformity between the coding. A Fleiss’ Kappa test was used to establish reliability between multiple raters. The Kappa statistic ranges from 0 to 1 and calculates the degree of agreement in classification against that which would be expected by chance. A Kappa value of 0.6 (a substantial level of agreement\textsuperscript{124}) was used as the minimum value acceptable to establish inter-rater reliability. This Kappa value seemed to be reasonable based on the results of
other incident database studies in which multiple raters coded report categories.\textsuperscript{3,21,42,125} For example, Nuckols \textit{et al.} (2008) reported moderate to substantial inter-rater agreement (Kappa values 0.41 to 0.72) in the classification of contributing factors in their study.\textsuperscript{42} In another study, Baker \textit{et al.} (2004) reported moderate to substantial inter-rater agreement for the determination of whether an injury had occurred (0.47), whether the injury was caused by health care management (0.45), and whether the event was preventable (0.69).\textsuperscript{3}

Prior to coding the actual incident reports used in this study, all the coders underwent training using a subset of roughly 20 trial MAUDE database reports from years other than 2008. The training reports were coded independently by each member of the research team and then the coding results compared as a group. This training process allowed the team to discuss and resolve disagreements and modify the coding definitions to arrive at a uniform agreement on the fields and predefined coding options. If there was substantial disagreement (i.e. Kappa value < 0.6) in the coding the processes repeated using another subset of trial reports. An inter-rater reliability test was used to help assess when the researchers were ready to proceed (i.e. Kappa value > 0.6) to coding the incident reports for the study.

The direction and guidance provided by the common training and strategy development between the teams aimed to establish uniformity between the teams. However, formal inter-rater reliability was established for each team separately on their database rather than between the two teams (i.e., the two coders at ISMP Canada required high inter-rater reliability with each other on their database, but not with members of the HTSRT reviewing the MAUDE database). This was done partially because of the differences between the structures of the MAUDE and ISMP Canada database. It was also necessary as ISMP Canada’s database is not available for public viewing and searching, as such the HTSRT was restricted from viewing the reports from the ISMP Canada database. From this point the ISMP Canada researchers only focused on the Medication Incident Database reports and the HTSRT researchers on the FDA MAUDE reports. The results of the inter-rater reliability testing are presented in Appendix C.

\textit{Inter-rater Reliability of the First Pass Coding Fields (i.e. Impact and Location)}

Since only reports identified as “applicable” underwent coding of the three fields it was necessary to first establish inter-rater reliability on the ability of the researchers to identify the
applicability of the reports. The ISMP Canada and HTSRT researchers identified the applicability of the first 30 cases of real data from their corresponding database. The Kappa value for each coding team was then calculated and if the value was below 0.6 the research team had to discuss any discrepancies in the identification of applicable reports. The team had to reach consensus and re-identify the applicability of any reports where disagreements occurred. An additional 30 reports were then used to repeat this process. This process continued until a Kappa value of 0.6 or greater was reached.

Once a Kappa of at least 0.6 was established for identifying the report’s applicability the individual researchers in each of the teams independently identified the applicability for a larger sample of reports. The goal was to collect 30 reports which all the coders on the team had deemed “applicable”. Upon establishing these 30 applicable reports each coder independently coded the Impact and Location to establish inter-rater reliability for these fields. A Kappa value for each of these fields was determined separately and if the value was less than 0.6 the team had to discuss, reach consensus, and repeat the process for that field.

Upon establishing inter-rater reliability on all first pass coding fields (i.e. Location and Impact) the teams were able to divide the remaining reports returned from the keyword search. Coding of the Location and Impact was then completed independently without requiring verification from other team members.

**Inter-rater Reliability of the Second Pass Coding Field (i.e. Cause)**

The first pass coding narrows down the data set to only those reports deemed as “applicable” multiple IV infusion incidents and codes the Location and Impact fields. In the second pass coding, each researcher coded the Cause field of the first 30 applicable reports in their corresponding database and the Kappa value determined. A single Kappa value was calculated, which accounted for all 35 Cause coding options. If the Kappa value was below 0.6 the team had to discuss, reach consensus, and repeat the process with another set of 30 applicable reports. Once a value of 0.6 or higher was reached the team once again divided up the remaining reports and independently coded the Cause field for each report.
5.4.3 Analysis of the Coding Results

The coding process aimed to extract information common to both the MAUDE and ISMP Canada systems. To this end, coding the three fields (i.e. Location, Impact, and Cause) provides data for comparing differences between the two systems relevant to the type of incidents and quality of information. The differences between the two systems in their ability to identify and code information pertaining to these three fields were analyzed using Microsoft Excel and the Statistical Package for the Social Sciences (SPSS, v18.0). An alpha level of 0.05 was used for the statistical tests performed.

Fisher’s Exact Tests were performed for each of the analyses to determine whether there was a significant difference in the ability to identify information pertaining to the three fields between the two systems. This test was selected as it is appropriate for between-group comparison of nominal data, such as the pass/fail criteria of selecting a single coding option within a field. The results of these analyzes are discussed in the following sections.

5.5 Results

This section presents the analysis results comparing the differences between the two systems in their ability to identify and code information pertaining to the Location, Impact, and Cause fields. However, it is important to note that the coding findings are associated solely with multiple IV infusion incidents and may not necessarily be representative of the entire MAUDE or ISMP Canada database.

5.5.1 Applicability

Prior to comparing the information pertaining to the ability to identify and code information in the Location, Impact, and Cause fields this section presents the results of extracting the applicable reports returned from querying the two systems. For this study, applicable reports are those found to be related to multiple IV infusion incidents.

The keyword search of ISMP Canada’s Medication Incident Database returned 1,320 incident reports, and 3,486 incident reports in the FDA MAUDE database. Figure 7 shows the distribution of these reports in relation to their applicability as a multiple IV infusion incident between the two systems. The results show a significant difference in the number of reports
applicable to multiple IV infusion incidents returned from the search of the two systems (p<0.05; Fisher’s Exact Test). Specifically, the number of applicable reports returned from the search of the MAUDE database (6%) was significantly lower than those returned from the search of the ISMP Canada’s Medication Incident Database (32%). Only the reports which were deemed applicable underwent coding of the Location, Impact, and Cause categories.

![Diagram showing the results of identifying the applicability (i.e. applicability as a multiple IV infusion incident) of the reports returned from the keyword search of the MAUDE and ISMP Canada Medication Incident Database](image)

**Figure 7:** Results of identifying the applicability (i.e. applicability as a multiple IV infusion incident) of the reports returned from the keyword search of the MAUDE and ISMP Canada Medication Incident Database

### 5.5.2 Location

The results of coding the Location field for all the applicable reports within the two systems are shown in Figure 8. In both systems a majority of the incidents were found to have occurred in a hospital setting. For events determined to have occurred within a hospital the ISMP Canada Medication Incident Database was significantly more successful (64%) at identifying a specific hospital location than the MAUDE (42%; p<0.05).
Figure 8: Results of coding the Location of the reports found applicable to multiple IV infusion incidents within the MAUDE and ISMP Canada Medication Incident Database

5.5.3 Impact

Results of coding the Impact of the applicable reports between the two systems are shown in Figure 9. To simplify the task of analyzing this data, the Impact coding options were combined into four levels corresponding to a more general separation of incident impacts (i.e. Hazardous Conditions, No Harm, Mild to Moderate Harm, and Severe Harm & Death). Table 10 shows where the two systems are significantly different with regards to the percentage of reports associated with each of the four levels of Impact.
Figure 9: Results of coding the Impact of the reports found applicable to multiple IV infusion incidents within the MAUDE and ISMP Canada Medication Incident Database.
Table 10: Distribution of event Impact between the MAUDE and ISMP database (unknown harm category excluded)

<table>
<thead>
<tr>
<th>Level of Impact</th>
<th>Impacts from Figure 9 Reflected in This Level of Impact</th>
<th>MAUDE Database</th>
<th>ISMP Database</th>
<th>Significant Difference (*p &lt; 0.05)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazardous Condition</td>
<td>Hazardous</td>
<td>1%</td>
<td>3%</td>
<td></td>
</tr>
<tr>
<td>No Harm</td>
<td>No Harm, Near Miss</td>
<td>33%</td>
<td>80%</td>
<td>*</td>
</tr>
<tr>
<td>Mild to Moderate Harm</td>
<td>Mild Harm, Moderate Harm</td>
<td>35%</td>
<td>8%</td>
<td>*</td>
</tr>
<tr>
<td>Severe Harm &amp; Death**</td>
<td>Severe Harm, Death</td>
<td>9%</td>
<td>3%</td>
<td>*</td>
</tr>
</tbody>
</table>

**This grouping now reflects the MAUDE’s classification of a ‘reportable event’ based on the incident’s impact on the patient.

The distribution of reports resulting in hazardous conditions was not significant (p>0.05) between the two databases. However, the distribution of events resulting in no harm, mild to moderate harm, and severe harm & death between the two databases were all significant (p<0.05).

5.5.4 Cause

Table 11 shows the results from the process of coding the Cause of the multiple IV infusion incidents. The results are expressed in terms of the percentage of reports within each database related to the specific Causes. This table also shows the significance (p<0.05) of each specific Cause between the two systems.
<table>
<thead>
<tr>
<th>Specific Cause</th>
<th>MAUDE Database</th>
<th>ISMP Canada Database</th>
<th>Significant Difference (*p &lt; 0.05)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IV Bag Issues</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wrong Volume</td>
<td>0.00%</td>
<td>0.71%</td>
<td></td>
</tr>
<tr>
<td>Wrong Concentration</td>
<td>0.00%</td>
<td>3.07%</td>
<td>*</td>
</tr>
<tr>
<td>Labeling Issues</td>
<td>0.00%</td>
<td>3.07%</td>
<td>*</td>
</tr>
<tr>
<td>Bag Height is Incorrect</td>
<td>0.00%</td>
<td>0.47%</td>
<td></td>
</tr>
<tr>
<td>Wrong Medication</td>
<td>0.47%</td>
<td>7.78%</td>
<td>*</td>
</tr>
<tr>
<td>Manufacturing Issue</td>
<td>0.00%</td>
<td>0.00%</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>0.95%</td>
<td>6.60%</td>
<td>*</td>
</tr>
<tr>
<td><strong>IV Tubing Issues</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Backflow</td>
<td>11.37%</td>
<td>0.24%</td>
<td>*</td>
</tr>
<tr>
<td>Leaks, Breaks and Disconnections</td>
<td>9.95%</td>
<td>4.25%</td>
<td>*</td>
</tr>
<tr>
<td>Misconnection</td>
<td>0.00%</td>
<td>4.25%</td>
<td>*</td>
</tr>
<tr>
<td>Kinks</td>
<td>0.47%</td>
<td>0.00%</td>
<td></td>
</tr>
<tr>
<td>Clamps</td>
<td>3.79%</td>
<td>13.21%</td>
<td>*</td>
</tr>
<tr>
<td>Drug Incompatibility</td>
<td>0.47%</td>
<td>0.94%</td>
<td></td>
</tr>
<tr>
<td>Manufacturing Issue</td>
<td>0.95%</td>
<td>0.00%</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>8.06%</td>
<td>3.07%</td>
<td>*</td>
</tr>
<tr>
<td><strong>Infusion Pump Issues</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pump Out of Specification (not validated)</td>
<td>10.43%</td>
<td>0.24%</td>
<td>*</td>
</tr>
<tr>
<td>Pump Reported out of Specification (validated)</td>
<td>1.42%</td>
<td>0.00%</td>
<td>*</td>
</tr>
<tr>
<td>Misprogramming (validated)</td>
<td>4.74%</td>
<td>13.44%</td>
<td>*</td>
</tr>
<tr>
<td>Reported Misprogramming (suspected)</td>
<td>1.42%</td>
<td>1.89%</td>
<td></td>
</tr>
<tr>
<td>Power Failure</td>
<td>3.79%</td>
<td>0.47%</td>
<td>*</td>
</tr>
<tr>
<td>Pump Failure</td>
<td>16.59%</td>
<td>2.59%</td>
<td>*</td>
</tr>
<tr>
<td>Pump/Channel/Bag/Tubing Mismatch</td>
<td>1.42%</td>
<td>13.68%</td>
<td>*</td>
</tr>
<tr>
<td>Misloaded Tubing</td>
<td>0.47%</td>
<td>0.00%</td>
<td></td>
</tr>
<tr>
<td>Wrong Drug Order</td>
<td>0.00%</td>
<td>0.71%</td>
<td></td>
</tr>
<tr>
<td>Wrong Time or Missed Infusion</td>
<td>0.47%</td>
<td>5.66%</td>
<td>*</td>
</tr>
<tr>
<td>Manufacturing Issue</td>
<td>0.00%</td>
<td>0.00%</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>8.53%</td>
<td>1.89%</td>
<td>*</td>
</tr>
<tr>
<td><strong>IV Access Issues</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wrong Route</td>
<td>0.00%</td>
<td>4.48%</td>
<td>*</td>
</tr>
<tr>
<td>Wrong Site</td>
<td>0.95%</td>
<td>0.94%</td>
<td></td>
</tr>
<tr>
<td>Accidental Leak, Break or Disconnection</td>
<td>1.42%</td>
<td>0.71%</td>
<td></td>
</tr>
<tr>
<td>Infected Line</td>
<td>0.00%</td>
<td>0.00%</td>
<td></td>
</tr>
<tr>
<td>Manufacturing Issue</td>
<td>0.00%</td>
<td>0.00%</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>0.47%</td>
<td>0.00%</td>
<td></td>
</tr>
</tbody>
</table>
5.5.5  Overall Ability to Identify Information in the Three Fields

Figure 10 shows the results of how often the applicable reports within MAUDE and ISMP Canada systems contained sufficient information to identify information relevant to coding the Location, Impact, and Cause fields. These results are reflective of how often the database coders had to classify the fields as “unknown” or “undetermined”. In the ISMP Canada system, a Location could be determined for all the reports (100%), whereas in the MAUDE system significantly fewer reports contained an identifiable Location (60%; p<0.05). ISMP Canada’s system was also found to contain significantly more reports that identified an Impact (94%) than those in the MAUDE (78%; p<0.05). Finally, ISMP Canada’s system also contained significantly more reports which allowed for the identification of an incident Cause (97%) than the reports in the MAUDE (91%; p<0.05).
5.6 Discussion

Extracting information from incident reports pertaining to the Location, Impact, and Cause provides useful data for exploring how the structural differences of two of the ten fundamental characteristics affect the type of events and quality of information contained within the systems. Specifically, the relevant characteristics are: classification of a ‘reportable event’ and description of an event. Table 8 summarizes the relationship between the three fields (i.e. Location, Impact, and Cause) and these two fundamental characteristics. As highlighted in Chapter 4, the MAUDE and ISMP Canada database have both structurally implemented many of the fundamental characteristics differently. These differences include the ways in which the two systems’ have implemented the classification of a ‘reportable event’ and description of an event. Therefore, the present section aims to discuss how the differences between the two systems, with regards to the structural implementation of these two characteristics, are reflected in the differences of coding result for the Location, Impact, and Cause.

Classification of a ‘Reportable Event’
Classification of a ‘reportable event’ is the fundamental characteristic associated with how the systems’ define the incidents that should be reported to the database. A specific impact (e.g. death or no harm) or event type (e.g. surgical, device, or medication errors) may be used in this definition to focus the system towards collecting particular incidents. Therefore, the focused definition’s influence on the contents of the database should be reflected in the results of coding the Impact and Cause fields.

Firstly, results of coding the Cause field (Table 11) highlight the percentage of reports attributable to specific causes of multiple IV infusion incidents within the two systems. Table 12 extracts from these results the Causes that were significantly more prevalent in one of the databases than the other. Despite using the exact same keywords and coding strategies for both systems there is a significant difference between the Cause results of the two systems. The incident Causes associated with each of the systems (as shown in Table 12) reveals a division in the type of incidents captured by the systems. For example, the ISMP Canada database has significantly more Causes related to medication administration processes and set-up practices of multiple IV infusions. This would suggest that it captures significantly more medication/process related incidents than the MAUDE. In contrast, the MAUDE database has significantly more Causes related to issues with components or devices involved in the delivery of multiple IV infusions. Therefore, this suggests that the MAUDE captures significantly more device related incidents than the ISMP Canada system.
Table 12: Specific causes of multiple IV infusion incidents in which ISMP Canada’s Medication Incident Database and the FDA’s MAUDE database contained a significantly larger percentage of their incidents related to

<table>
<thead>
<tr>
<th>ISMP Canada Medication Incident Database</th>
<th>FDA MAUDE Database</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrong Concentration of Medication</td>
<td>Backflow of Fluid in the Tubing</td>
</tr>
<tr>
<td>IV Bag Labeling Issues</td>
<td>Tubing Leaks, Breaks, &amp; Disconnections</td>
</tr>
<tr>
<td>Wrong Medication Administered</td>
<td>Infusion Pump Out of Specification</td>
</tr>
<tr>
<td>IV Tubing Misconnections</td>
<td>Infusion Pump Power Failure</td>
</tr>
<tr>
<td>IV Tubing Clamp Issues</td>
<td>Infusion Pump Failure</td>
</tr>
<tr>
<td>Mis-programming of the Infusion Pump</td>
<td></td>
</tr>
<tr>
<td>Mismatch of the Infusion Components</td>
<td></td>
</tr>
<tr>
<td>Wrong Time or Missed Infusion</td>
<td></td>
</tr>
<tr>
<td>Wrong Route of Delivery</td>
<td></td>
</tr>
</tbody>
</table>

One of the database coding findings which highlights this division of medication/process versus device related incidents most strikingly is the coding of the Cause field with respect to infusion pump issues, shown in Figure 11. Viewing the percentage of reports from both databases as related to infusion pump associated Causes side by side highlights the prevalence of certain Causes in one database over the other. For example, the validated misprogrammings, pump/channel/bag/tubing mismatches, and wrong time or missed infusions are all much more prominent in ISMP Canada’s database than in the MAUDE. All three of these Causes are related to actions taken by the clinician in administering medications. In contrast, pump failures, power failures, and the pump being out of specification issues are much more prominent in the MAUDE than ISMP Canada’s database. These issues have little to do with infusion delivery practices, but rather are failures on the part of the technology which impacted the safe delivery of medication.
Taking a similar look at the results of coding the Impact field of the two systems (Table 10) also highlights differences between the systems with regards to the percentage of reports associated with certain Impacts. The data reveals that the MAUDE contains a significantly higher percentage of reports associated with mild to moderate harm or severe harm and death related Impacts than the ISMP Canada database. Meanwhile the ISMP Canada database contains a significantly higher percentage of reports associated with no harm coming to the patient.

This division between the systems with regards to the Cause (i.e. medication vs. device related incident) and Impact (i.e. no harm vs. harm (mild, moderate, severe) and death) makes sense when taking into account the differences in how the systems’ have implemented the classification of a ‘reportable incident’ fundamental characteristic. For example, the MAUDE database’s classification of a ‘reportable event’ defines and mandates that reports related to medical devices, resulting in serious injury or death be reported to the system. In contrast, ISMP Canada’s classification of a ‘reportable event’ defines medication related events ranging from those posing hazardous conditions to those resulting in a patient’s death as reportable events.
Therefore, the MAUDE detecting significantly more multiple IV infusion events being attributable to technology or equipment failing and ISMP Canada’s system detecting significantly more attributable to medication administration errors aligns with how the systems classify the event type to be reported. While these findings aren’t shocking, this observation brings up a very interesting finding considering that each database emphasizes a different perspective of the same issue, arrived at using the exact same search strategy. This is very important to note as it highlights the issue that by separating databases into specialty-based systems, there is the chance that one specialty-based system will not give the user a complete picture of the factors surrounding the topic being investigated. Rather a database may highlight a specific issue as a high priority problem based on its classification of a ‘reportable event’. Whether this is fully representative of the topic under investigation may be questionable.

Similarly, the MAUDE detecting significantly more events associated with Impacts ranging from harm to death than the ISMP Canada system aligns with how the MAUDE classifies the event impact to be reported. Meanwhile, the ISMP Canada system, which does not define a specific Impact in its classification of a ‘reportable event’, has a majority of reports associated with no harm (80%). This could be reflective of the greater number of near misses and no harm events which occur in the typical delivery of health care when compared to more severe cases. However, as the ISMP Canada database is voluntary this could also reflect what health care practitioners are willing to share with an external organization. This would aligned with other research findings which suggest that voluntary systems typically collect more near misses than adverse events. In this case it may indicate that the type of events contained within the systems may also be related to differences in the way systems implement the operational aspects characteristics (e.g voluntary vs. mandatory reporting).

Overall, the findings highlight how the different way in which the two systems have implemented the classification of a ‘reportable event’ characteristic has a significant influence on the type of reports contained within the systems, with regards to both their Impact and Cause. Differences in how a system classifies a ‘reportable event’ will influence the focus of the reports contained within a system. For example, specifying device related incidents will result in the system collecting mainly incidents arising from devices related causes (e.g. battery failures), while potentially overlooking the significance of other issues (e.g. user errors). Therefore the
results may only reveal one facet of the incident type being investigated while ignoring other facets which may be equally prevalent and important. It cannot be said with any certainty how the databases’ classify a ‘reportable event’ either with respect to the Cause or Impact is superior to the other; they simply may capture two different aspects of the same topic. However, these results do highlight the importance for users to be aware of what they are trying to determine and how the database’s classification of a ‘reportable event’ will impact the type of events contained within the system, thereby influencing the findings of their investigation.

**Description of an Event**

Description of an event is the fundamental characteristic associated with how the systems’ present information (e.g. free-text narratives, structured classification options) relevant to describing the incident (e.g. Location, Impact, Cause). Both the MAUDE and ISMP Canada systems implemented this characteristic in the same way, using a combination of structured classification options, short free-text fields, and free-text narratives. The Location, Impact, and Cause are all examples of information contained within the system reports providing information for describing an incident. Two of these fields, the Location and Impact, were presented in both reporting systems as structured fields where the reporter had to select one of several predefined options (either via check boxes or drop-down menus). In both systems, the Cause information was provided via the free-text narrative of the report. Therefore, for the purposes of the presented work, the ability to identify information relevant to the Location, Impact, and Cause fields provides common elements of both databases to comparatively assess the ability to identify descriptive information. Figure 10 shows how often the coding team was successful at identifying a Location, Impact, and Cause within the reports returned from the system query.

Identifying the Location where an incident occurred should be a straightforward element to identify as it is does not typically require a subjective assessment on the part of the reporter. Having to identify the Location from a list of potential options would seem to make this task even simpler. However, with regard to this study, identifying the event Location in the MAUDE database was more of a challenge than anticipated. The structured field intended to display the Location was often left blank or was classified as ‘other’ with no specifying information. Occasionally the coders were able to identify a Location by reading and extracting information
from the free-text narrative, but this still resulted in a Location only being identifiable 60% of the time. In contrast, a Location was always identifiable in the ISMP Canada database.

These results are interesting because both databases provided similar methods for the reporter to identify the Location information in the incident report. That is, both systems require the reporter to select a Location from a predefined list. The only difference is the number of options the reporter has to select from, with the MAUDE database containing fewer options. However, both lists of options include common Locations such as hospital, home, and nursing home. Therefore, the reason for this observed difference in the ability to classify a Location must exist beyond solely the structure of this field used to collect the Location information.

Another factor potentially influencing the use of the Location classification field in the MAUDE is that it is one of many fields (approximately 60 fields), while in the ISMP Canada database it is only one of eight mandatory fields. It has been noted that reporters tend to complete only those fields that are required. Therefore, when the instructions for completing the MAUDE reporting form states “complete all sections that apply ... if information is unknown, not available or does not apply, the section should be left blank” despite it being a known element it could be seen by reporters as an unnecessary piece of information. Thus, reporters may leave it blank in consideration of other fields they feel are more relevant and worth their time. Therefore, the characteristic of the timeliness of reporting may result in those reporting to the MAUDE filling in certain fields while leaving others blank to facilitate a quicker completion time. Meanwhile reporters to the ISMP Canada database may find that they can complete all the information fields in a time that they deem worth their effort.

Identifying an incident’s Impact may be more subjective than the Location as classifying harm can often be divided into several levels (e.g. mild, moderate, and severe harm) which aren’t always separated by distinct, visible features. Again, both systems used a structured field with predefined options for classifying the Impact, however the options provided were very different between the two databases. The MAUDE took a very broad approach at identifying the Impact and offered four options: death, serious injury, malfunction, or other. ISMP Canada’s database took a more specific approach and divided the Impact into nine options: no error, 3 levels of no
harm, 4 levels of harm, and death. In both systems, the free-text narrative describing the incident provided further opportunity to try and extract information pertinent to identifying the Impact.

The results demonstrating the percentage of reports where it was possible to identify the incident Impact (Figure 10) highlighted that the ISMP Canada system was significantly more successful at providing information useful in identifying an Impact than the MAUDE. The more specific predefined Impact options of the ISMP Canada database resulted in all but 6% of the reports having an unidentifiable Impact. In contrast, the broad predefined Impact options of the MAUDE, in conjunction with limited contextual information provided in the free-text narrative helpful in determining an Impact, resulted in 22% of the reports not having an identifiable Impact. Therefore, this finding suggests that a detailed set of predefined options for a structured field (e.g. Impact in some databases) may be significantly more likely to provide identifiable descriptive information than a very broad set of options and relying on the free-text to provide information for identifying more specific details. This finding therefore highlights how a slight difference in the implementation of the description of an event characteristic may impact the ability to extract information from the systems.

Regarding the identification of a Cause, neither database contained any predefined fields which would assist in identification of Cause with regard to multiple IV infusion incidents. Therefore, coding had to rely purely on the information contained within the free-text narrative. The implementation of the free-text narrative is the same between both databases except that the MAUDE allows a narrative for both the user facility and the device manufacturer. The result of identifying the Cause was fairly successful for both databases, with over 90% of reports in both containing an identifiable Cause. However, the ISMP Canada system was significantly more successful than the MAUDE in providing useful information for identifying the Cause.

The MAUDE contains information identifying the reporting parties, a free-text narrative from both the user facility and manufacturer, and a “good faith effort” by the manufacturers to request further information from the user facility to understand what occurred in an event. However, despite all this, the MAUDE system was significantly less useful in identifying a Cause than the ISMP Canada system. Part of the issue in trying to extract identifiable information from the free-text narrative of the MAUDE was due to a large number of reports containing statements along
the lines of “though requested, no additional information was provided” or “follow-up report will be filed if any additional information becomes available.” This lack of response for follow-up information misses the opportunity presented in reporting systems, such as the MAUDE, capable of requesting follow-up information to help collect more detailed information. Therefore, any identifiable Cause information was often limited to what the user facility initially reported in their narrative as it appears the manufacturers were often unsuccessful in obtaining additional information on their follow-up.

The information documented in the MAUDE’s free-text narrative was found to be limited in its usefulness to extract information describing the incident, such as the Location, Impact, and Cause. The lack of quality free-text information may be the result of differences between the implementation of several of the fundamental characteristics beyond only the description of an event. This may include the timeliness of reporting which relates to how much time and effort reporters are willing to spend submitting a report. Structural differences in the operational aspects with regards to the voluntary versus mandatory nature of the system could also influence the quality of free-text information. People mandated to report may submit solely because they are forced to and therefore put less effort into providing quality information. Finally, the reporting culture may also play a role if the reporters perceive that submitting a report may result in blame or punishment. This fear, in turn, may result in the reporters providing very broad and non-specific data in an attempt to hide the severity of the incident and their involvement. It is impossible to determine the role all these characteristics may have played in influencing the ability to identify the Location, Impact, and Cause, although it does highlight the potential interaction of the various fundamental characteristics.

Overall, the findings indicate that the ISMP Canada system was significantly more successful at providing information relevant to identifying a Location, Impact, and Cause of the reported events. However, the findings also highlight that it is probably beyond solely the differences in the description of an event characteristic that impacts this ability to extract descriptive information. Both systems use the same general method for providing descriptive information about an event. Therefore, differences in other characteristics such as the timeliness of reporting, operational aspects (e.g. voluntary vs. mandatory reporting), and the reporting culture may have influenced the ability to extract identifiable information from the systems. This demonstrates the
complex interactions potentially involved between the various fundamental characteristics with regards to simply extracting descriptive information from the system.

In conclusion, the structural differences with regards to several characteristics, beyond only the description of an event, probably interact to impact the quality of information (i.e. descriptive information such as the Location, Impact, or Cause) contained within the systems.

5.7 Chapter Summary

This chapter presented a case study investigation of the MAUDE and ISMP Canada Medication Incident Database using multiple IV infusion related incidents. Using this case study, the present chapter aimed to assess if the structural differences between the two databases (based on the classification of a ‘reportable event’ and the description of an event fundamental characteristics) impact the type of incidents and quality of information that can be extracted from the systems. The structural differences, with regards to the two fundamental characteristics, were found to impact the type of events and quality of information. For example, the different classification of a ‘reportable event’, both by event type and event impact, influenced the type of events which were predominantly found within the two systems. The same methodology was used to search both databases, but the most commonly identified type of incidents were very different between the two systems. The most commonly identified type of incidents within each system corresponded to structural differences in the classification of a `reportable event` with regards to how the systems’ defined the event type and impact of a reportable event. However, more important is the fact that this division created systems which focused on different facets of the same topic which went overlooked in the other system.

With regard to the quality of information contained within the systems, this was found to be impacted not only by structural differences in the description of an event characteristic, but potential several other characteristics as well. Despite implementing similar methodology for capturing descriptive information (i.e. Location, Impact, and Cause) about an event, the MAUDE database was significantly less successful at identify a Location, Impact, and Cause. Therefore, it was proposed that structural differences in characteristics beyond just the description of an event, such as the timeliness of reporting, operational aspects, and reporting culture, may interact to influence the overall ability to extract quality information from the system reports.
All these findings serve to demonstrate how the results of using and searching a database can be influenced by differences in the implementation of the various fundamental characteristics. However, the results themselves are not necessarily influenced by only one of the characteristics alone and may be due to the interaction of characteristics. The next chapter aims to provide a framework model for looking at how the fundamental characteristics combine and interact within the incident reporting process. The framework also looks at how these interactions spread across multiple organizational levels within the health care system. Finally, the framework provides a method for observing how the implementation and interactions of the fundamental characteristics work towards promoting the goals for which the systems were implemented.
6 Applying a Framework for Exploring the Incident Reporting Process

6.1 Objective

Holden & Karsh (2007) noted that in the incident reporting literature there has been an absence of theoretically grounded organizing frameworks for aiding in guiding successful reporting system design. The fields of human factors, social and cognitive psychology, and technology change/acceptance provide a variety of theoretical frameworks to select from; however the incident reporting literature for the most part has lacked a theoretical basis. This chapter presents a risk management framework applied to examining the incident reporting process. This includes highlighting how the fundamental characteristics influence the incident reporting process. To this end, the incident reporting process of the two example databases (i.e. the FDA’s MAUDE and ISMP Canada’s Medication Incident Database) will be mapped onto the framework. Using the framework, the objective is to highlight the portrayal of the fundamental characteristics and their influence on the communication of incident information throughout the incident reporting process. The present section also aims to highlight the mechanisms within the two example reporting systems which promote the goals of the reporting system. These goals include those which are specified by the operating organization of the reporting system as well as the general goals/benefits that all incident reporting can offer. The general goals/benefits were presented in Table 1 of Chapter 1.2.

6.2 Rasmussen’s Risk Management Framework

The pressures and constraints that shape work practices are constantly shifting and as a result traditional modeling methods, such as task analysis, which depend on assumptions of stable and tightly constrained environments are often inadequate as references for understanding actual work practices. In addition, modeling of socio-technical system elements are often modeled by decomposition into separately modeled elements or organizational levels which often result into a ‘horizontal’ orientation of research topics which can ignore the interdependencies across levels. Therefore, to map the incident reporting process, which is extremely variable and often involves interaction across multiple individuals, institutions and organizations, a framework must be selected which allows these complex interactions to be accurately portrayed.
Rasmussen’s (1997) risk management framework takes a systems-based perspective of modeling complex socio-technical systems.\textsuperscript{127,129} The framework views a system as being comprised of a hierarchy of individuals and organizations (Figure 12) with the interactions across these hierarchical levels critical to the successful functioning and monitoring of the system as a whole.\textsuperscript{130}

![Hierarchical levels of a complex socio-technical system involved in risk management](image)

**Figure 12: Hierarchical levels of a complex socio-technical system involved in risk management (adapted from Rasmussen (1997))**

Without this interaction across the various levels, known as ‘vertical integration’, the processes which encourage the effective operation of the system can become unstable.\textsuperscript{130} This model notes that each layer of the hierarchy plays a critical, yet different, role in maintaining the system and that issues often arise from a lack of vertical integration, not just deficiencies at any one level alone.\textsuperscript{127,130} Vertical integration requires decisions made at high levels to propagate down the hierarchy and be reflected in the decisions and actions occurring at lower levels of the system.\textsuperscript{130,131} Conversely, information about the system’s current status at the lower levels should
propagate upwards and inform the decisions and actions occurring at the higher levels.\textsuperscript{130,131} These interdependencies across the levels should form a closed loop feedback system.

While this framework has mainly been applied to analyzing specific incidents in a variety of socio-technical systems, such as the \textit{E. coli} outbreak in Walkerton, Ontario\textsuperscript{127} and police firearm mishaps\textsuperscript{132}, it equally lends itself to mapping the hierarchy and processes of incident reporting. The emphasis this framework places on feedback, vertical integration, and interaction between various individuals or organizations mirrors the structures and concerns of incident reporting. In addition, Holden & Karsh (2007) identified the need for research and investigation into this vertical alignment and how variables at the different levels impact the success of the reporting process.\textsuperscript{62} As such, Rasmussen’s (1997) risk management framework provides a good modeling option for mapping the incident reporting process and exploring the decision makers (e.g. front-line staff, risk management personnel, regulatory bodies) and characteristics involved in the operation of the system.

Figure 12 is commonly used to represent the hierarchy of the socio-technical system although the precise number of levels and their labels can vary.\textsuperscript{130,131} Table 13 provides a variation on the label of the six organizational levels and describes what actors and activities are present at each level\textsuperscript{130} as well as how these levels can be applied in the context of health care.

\textbf{Table 13: Typical organizational levels present within Rasmussen’s (1997) framework and examples of how they can be represented within the context of health care}

<table>
<thead>
<tr>
<th>Hierarchy Level \hspace{1cm} (Bottom to Top)</th>
<th>Description of the Level</th>
<th>Examples of Health Care Elements Represented at this Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equipment &amp; Surroundings</td>
<td>The configuration and physical characteristics of the landscape, buildings, equipment, tools, etc., found at the location and involved in the process.</td>
<td>Patient, Medication &amp; Devices, Incident Reporting Database</td>
</tr>
<tr>
<td>Physical Processes &amp; Actor Activities</td>
<td>Activities of the individual front-line staff members that are responsible for interaction directly with the process being controlled.</td>
<td>Front-Line Health Care Staff (Nurses, Doctors, etc.)</td>
</tr>
</tbody>
</table>
With the hierarchy established, the first step in modeling the system is to identify the actors, individuals and organization involved as decision makers within the system. These decision makers form the landscape through which the process propagates and their relationships are mapped by their location within the system. Identifying the action targets or work objectives that each decision maker upholds at their corresponding level is also a critical element to establish at this stage. At higher levels, the objective and values may be formulated rather generally and then as objectives propagate down the hierarchy, the degrees of freedom for action multiply as there are often several methods of implementing the objectives. As such, objectives are interpreted according to the particular local context. Once the process flow has been established an important question becomes whether information about the actual state is available to decision makers. In addition, the information must be compatible or comparable to the objectives of the decision maker.

At this stage one approach proposed by Rasmussen is the Accimap modeling approach. In this approach the decision makers and decisions involved within a system that permits a specific accident to occur are graphically represented with respect to the hierarchy. This method is aimed at the design of improved systems, not an allocation of responsibility, and is used to identify and present the causal flow of events upstream from where they began and identify areas
for system improvement. In the presented work, this method is not done for one specific accident, but rather the general flow of an incident report through the system and how it interacts with the decision makers and system characteristics across the various levels.

In the following sections the MAUDE and ISMP Canada Medication Incident Database are modeled using Rasmussen’s (1997) framework. Drawing upon how each of the databases portray many of the characteristics discussed in the previous chapters the databases’ reporting process can be mapped onto the hierarchy. This process starts by identifying the levels of the hierarchy and the actors involved at each of these levels. With the hierarchy and actors established the general reporting, analysis, and communication processes through which incident reports progresses is mapped onto the hierarchy. This creates a pathway which highlights the communication of incident information which spans across the levels and actors of the hierarchy. Using the outlined pathway, the individual fundamental characteristics are inserted with regard to where in the process they influence the path of the reporting information. The characteristics will form links with one another and at times they may create multiple paths by which reporting information can travel. This progression serves to populate and form linkages within the framework, shaping how the incident information is communicated throughout the entire reporting process. Figure 13 is a legend for the framework describing the fundamental characteristics and some other notable aspects of the system depicted within the framework at the various levels of the hierarchy.
Figure 13: Legend for identifying the fundamental characteristics and other notable aspects in the reporting system frameworks

With the process modeled it will then be discussed with regard to how the characteristics function within the hierarchical system and are aligned to meet the goals for which the database was designed and implemented. The framework will also allow for discussion of how well the system is implemented to promote vertical integration between the hierarchical levels and establish a closed loop feedback system for communication. In addition, as Rasmussen’s framework doesn’t simply try and explain why something occurred but helps suggest how they might be prevented\textsuperscript{127}, the framework offers further opportunities for assessing the system. As
such, the framework will also assist in exploring if the characteristics are implemented in such a way as to set-up the structural mechanisms for promoting the four benefits noted to be associated with incident reporting systems in general, as presented in Table 1.

6.3 Applying the Framework to the Example Databases

Using the theories and concepts outlined above, the FDA’s MAUDE and ISMP Canada’s Medication Incident Database reporting processes were mapped onto the organizational hierarchy of Rasmussen’s (1997) risk management framework. The incident reporting process for the MAUDE and ISMP Canada reporting systems were mapped onto the framework based on information obtained through the FDA’s and ISMP Canada’s websites and their reporting guidelines. As a highly regulated system there are several published guidelines detailing the reporting process for user facilities and manufacturers reporting to the MAUDE.\textsuperscript{116} There is less published information regarding ISMP Canada’s incident reporting process. Therefore, in addition to information obtained through their website, Roger Cheng, a Project Leader at ISMP Canada, was consulted to help highlight ISMP Canada’s reporting process in order to populate the framework.

Figure 14 displays the fully mapped MAUDE reporting process within the framework and is followed by a brief description of the reporting process with respect to each of the levels of the hierarchy. Similarly, Figure 15 displays the ISMP Canada Medication Incident Database reporting process mapped onto the framework and followed by a brief description of the reporting processes at the hierarchy’s levels. The shaded boxes in the left hand column of the models show the specific actors involved in the reporting process at the various hierarchical levels with respect to the modeled system. The framework also makes note of the fundamental characteristics playing a role during certain activities of the incident reporting process. The characteristics are denoted in the model by circles corresponding to the legend shown in Figure 13.

6.3.1 Mapping the MAUDE Reporting Process onto the Framework

Figure 14 shows the FDA’s MAUDE database and its corresponding reporting processes mapped onto Rasmussen’s (1997) hierarchical framework.
Figure 14: The FDA’s MAUDE incident reporting process mapped onto Rasmussen’s (1997) framework
The first item to note in the framework is the level at which the operating organization resides, the FDA in the case of the MAUDE. This piece of information is useful when assessing and determining what power the organization has in terms of enforcing reporting practices and the type of changes it is capable of bringing about, for example changes isolated to a specific organization versus changes on a national scale. In addition, identifying the operating organization of the system also helps to understand how its goals, mandates, and enforcing abilities propagate down the hierarchy which in turn assists in the understanding of the reporting pathways. The FDA fits into two of the hierarchical levels, the Government and Regulatory Bodies & Associations levels. This is because it is an agency of the U.S. Department of Health and Human Services, which gives it government level responsibilities; as well it has the ability through various means to enforce regulations and policies regarding medical devices.

The Equipment & Surroundings Level of the MAUDE

With regards to the MAUDE, the policies and regulations at the highest levels mandate the type of events to be reported (i.e. medical device related events resulting in serious injury or death) as well as the mandatory nature of the reporting system. These elements work to shape the system itself, which resides at the bottom of the hierarchy within the Equipment & Surroundings level. The characteristics which are shaped include the system’s classification of a “reportable event” and how the system handles the operational aspects (i.e. mandatory reporting with identifying information). The characteristic of accessibility & ability to search the system is also noted at this level as it is an attribute of the database itself. Overall, the characteristics and aspects located within the Equipment & Surroundings level set the reporting system up as a physical tool for the activity of collecting incident reports.

The Actor Activities Level of the MAUDE

Knowledge regarding the system’s existence and what to report to it connects the Equipment & Surroundings level to the Actor Activities level. When an incident occurs that aligns with the front-line staff’s knowledge of what the system considers a “reportable event” the reporting process begins. However, at this level the characteristic of the timeliness of reporting may influence the process. Health care staff are often quite busy and taking substantial time out of
their schedule to start the timely process of documenting the incident in detail for the MAUDE report may not be observed as an effective use of their limited time. The information required in a reporting form for the MAUDE is substantial and contains over 30 fields for the user facility to complete. However, as they are mandated to report they cannot simply ignore the event, therefore quickly completing the form is the only way to limit the time spent on reporting. This in turn can impact the level of detail and quality of information passed along in the reporting process.

**The Management Level of the MAUDE**

The staff who were involved in the incident initiate the process and bring the incident to the attention of their supervising body at the Management level of the framework. At this level action may be taken to investigate the event and determine why it occurred. However, an investigation at this level is not mandated so the reporting path splits between those that choose to investigate further and those that do not. Since not all facilities have the same policies and methods of practice, performing an investigation at this level may help uncover contextual and detailed information which only those familiar with the facility can identify. In the multiple IV infusion case study presented in Chapter 5 it was generally observed that sites rarely investigated events beyond hospital medical engineering departments or quality associates confirming that an issue with a device had occurred and the general problem with the device (e.g. pump failed / shut down unexpectedly or tubing leaking).

**The Local Organizations Level of the MAUDE**

Whether an investigation occurs or not, the information gets passed along to the Local Organizations level of the framework and the user facility (e.g. hospital management) submits the reporting information to the manufacturer of the device(s) involved in the incident. The manufacturer then proceeds to review the reports it collects from the user facilities. The manufacturer is mandated to investigate the incident and provide all “reasonably known” information about an event. If all the “reasonably known” information is obtained then the report potentially has more useful information for describing and understanding what issues with the device caused the event. If insufficient information is known about the incident and more information is required manufacturers are mandated to provide at least one documented follow-
up effort to request more information from the user facility to be added to the free-text narrative. However, in the multiple IV infusions case study, many of the reports appeared to be unsuccessful in receiving information from user facilities following the request. It was found that reports often used statements such as “though requested, no additional information was provided” and the information presented was therefore all the manufacturer had to rely on for their investigation. This may leave gaps in the description of the event and thereby potentially less useful in understanding the issues. Regardless of the level of detail within the reports the manufacturer has to submit the report to the FDA.

_The Regulatory Bodies & Associations and Government Levels of the MAUDE_  

As mentioned previously, the FDA maintains a position within both of the Regulatory Body and Government levels of the hierarchy. Upon receiving a report the FDA proceeds to enter the report into the MAUDE database. This formalizes the upward progression through the organizational hierarchy of the incident information, keeping the operating organization aware of what is occurring at the lower levels.  

At this level the FDA may also take action if they perceive a threat to public health based on the report received or when taking the report into context with previously submitted reports. Actions may be to request further information from the manufacturer or in more severe cases the FDA may issue notices, alerts or recalls to the manufacturer. These situations propagate information back down to the Local Organizations level of the hierarchy and require manufactures to take actions to correct the noted problems. This provides some feedback to the manufacturers, but typically only for cases where there is concern about their products. The FDA may also disseminate information via public notices, advisories, or safety alerts regarding devices through mediums such as their website. This information then serves to inform the general public about issues. Also displayed at this level, yet not necessarily connected to the actions of the FDA or the reporting facilities, is the public’s ability to access and search the system, which links the top level with this feature of the database at the lowest level.
6.3.2 Mapping the ISMP Canada Medication Incident Database Reporting Process onto the Framework

Figure 15 shows ISMP Canada’s Medication Incident Database and its corresponding reporting processes mapped onto Rasmussen’s (1997) hierarchical framework.
Figure 15: ISMP Canada’s Medication Incident Database reporting process mapped onto Rasmussen’s (1997) framework
Unlike the FDA, ISMP Canada is not part of the government and has no direct regulatory or policy setting powers, nor is it governed by policies or regulations. Therefore, ISMP Canada is free to set out its own goals and set the types of events they wish to capture. As such, ISMP Canada resides within the middle of the organizational hierarchy at the Local Organizations level, the same level that health care facilities occupy. It best fits within this level as ISMP Canada collects information from a variety of facilities and individuals, just as a hospital looks over a variety of departments. In addition, ISMP Canada plans and sets out recommendations which, while they cannot be enforced like regulations, serve a similar purpose. In essence, ISMP Canada serves as an independent, multidisciplinary, expert body that is able to objectively assess causes of error and proposes recommendations for effective change, but has no punitive power over reporters or abilities to directly enforce change.

**The Equipment & Surroundings Level of the ISMP Canada Medication Incident Database**

Similar to the MAUDE model, the bottom level shows the reporting system itself and includes all the relevant information regarding the classification of a “reportable event” and the operational aspects (i.e. voluntary with the option to submit both anonymously or confidentially). Also, shown at this level of the framework, dealing with the characteristic of accessibility & ability to search the system, is the inability of the public to access the system. Since the system is not publically accessible it does not allow any interaction with the database, outside of ISMP Canada, and thus remains an isolated element in the framework.

**The Actor Activities Level of the ISMP Canada Medication Incident Database**

Also similar to the MAUDE is how the reporting process is triggered when front-line staff recognize an event that meets the system’s definition of a reportable event and submit a report. However, unlike the MAUDE, the ISMP Canada system is voluntary so there is a decision to go along with this level of the hierarchy. Nothing is forcing the reporter to submit a report; the choice is entirely up to the front-line staff. Therefore, the voluntary nature of the database and the choice it introduces into the system may carry with it a higher chance for under-reporting. Also impacting the choice to submit a report may be the timeliness of reporting. The information
required to submit a report to the system is not as extensive as that for the MAUDE, but different reporter will have different perceptions of how much time is worth the effort of reporting.

At this level there are also three pathways that the reporting process may follow. Reporting may be carried out through a hospital-based system or by individual practitioners. Individual practitioners have the option to submit anonymously in which case they cannot be contacted for further information by ISMP Canada. They also have the option to report confidentially which allows the reporter to be contacted following the submission of the report. This contact is also shown at this level, except rather than originating from a lower level of the hierarchy it extends downwards from the Local Organizations level. ISMP Canada uses this communication back to the Actor Activities level as either a way to simply thank the reporter for submitting a report, request further information, or provide some form of feedback regarding published reports related to the one being submitted. Therefore, this communication pathway serves to strengthen the characteristic of feedback and dissemination of information, as well as the description of an event by allowing further information to be obtained and added to the free-text description.

**The Management Level of the ISMP Canada Medication Incident Database**

This level is bypassed by individual practitioners submitting reports on their own, through the online reporting process. Online reporting in this manner isolates the reporters from supervising parties who potentially do have the capability of holding the reporters responsible for their involvement in an incident. However, a reporter going through their hospital’s ISMP Canada reporting interface pass through this level of the hierarchy. In these situations, reports from frontline staff get inputted into the ISMP Canada hospital reporting software which may be viewed by risk managers. Further information may be inputted by the risk managers as well at this level depending on hospital practices. In general ISMP Canada doesn’t follow-up for more information when reports are submitted through a hospital. This is because the reporter and the hospital are not generally identified in the report.

**The Local Organizations Level of the ISMP Canada Medication Incident Database**

At this level ISMP Canada receives the submitted reports and files them into the Medication Incident Database. However, confidentially submitted reports will first be reviewed and the
communication process back to the Actor Activities level previously mentioned will occur. If further information is obtained at this stage via a request for more information there is the potential for strengthening the descriptive quality of information for understanding the event.

At this level ISMP Canada reviews many of the reports to identify issues. Strengthening this process is the team of analysts that ISMP Canada employs to assist in reviewing and analyzing the reports. Stemming from this review and analysis work ISMP Canada may use the reports through a variety of means. One path by which ISMP Canada may utilize their reporting data at this level is to carry out targeted studies through aggregate analysis to investigate specific types of events. ISMP Canada also disseminates bi-weekly Safety Bulletins via their website and email to highlight issues they have noted based on their studies. Specific events based on those submitted to their system may be presented in these bulletins in an effort to raise awareness and present recommendations for mitigating future occurrences.

**The Regulatory Bodies & Associations and Government Levels of the ISMP Canada Medication Incident Database**

ISMP Canada also forms partnerships with a variety of external organizations that span the hierarchical levels including the Government and Regulatory Bodies & Associations levels. At these levels these partnerships may serve to help use ISMP Canada’s experience, knowledge, and database resources to propose recommendations for policies or regulatory guidelines. While alone ISMP Canada doesn’t have power to mandate changes, these partnerships serve to work with organizations which can take actions to effect change at the various levels of the health care system. Partnerships similar to these, but at the Local Organizations level with manufacturers and other safety focused organizations, promote similar methods of bringing about change.

### 6.3.3 Examples of Using the Framework to Explore Aspects of the Fundamental Characteristics

This section aims to present two simple examples where the framework is used to explore elements of the fundamental characteristics and how they are portrayed in the reporting process. Using the framework in this manner may help to highlight areas where the characteristics are not
structured to promote the full benefits which they seek to offer. The two examples presented are topics that deal with aspects of the reporting processes spanning multiple levels of the organizational hierarchy.

**Example 1: Accessibility of the System to the Public**

This first example looks at how each of the example reporting systems treats the accessibility of their incident database. Accessibility for this example is with regards to who, external to the operating organization, has the ability to review reports submitted to the database. The components of the frameworks related to this aspect of accessibility are highlighted in Figure 16 and Figure 17 for the MAUDE and ISMP Canada Medication Incident Database respectively.
Figure 16: MAUDE framework highlighting the components related to the accessibility of the system to the public
Figure 17: ISMP Canada Medication Incident Database framework highlighting the components related to the accessibility of the system to the public
The aspect of accessibility is a part of the database itself and as such it initially resides at the Equipment & Surroundings level of the hierarchy. In the MAUDE database, the system is accessible and searchable by the general public. This links it to the top levels of the hierarchy where the public is represented and spans across all the other actors represented at the levels in between. This offers opportunities for researchers to perform their own investigations and analysis of the MAUDE data which in turn can be used to disseminate findings across the hierarchical levels. Several studies have used the MAUDE in this manner and published findings regarding specific device related issues, such as cochlear implants\textsuperscript{134} and patient-controlled analgesia\textsuperscript{6}. The publically accessible system also offers clinicians considering the use of a new medical device\textsuperscript{119} or investigating a currently owned device the opportunity to explore issues or concerns which have been reported about the device. This opportunity is illustrated at the Actor Activities level of the hierarchy.

In contrast, the ISMP Canada system is not accessible to the public and only ISMP Canada has access to review all the reports contained within the system. As a result the aspect of accessibility in this system remains an isolated element within the framework, with no connections with the other hierarchical levels. This means it doesn’t offer the same opportunities as the MAUDE with regards to allowing external researchers to use the data in their own studies. This is not to say an organization has to choose to make their system publically accessible, some organizations may wish to keep their data private for various reasons. However, they should still be aware of how their choice with regards to accessibility impacts across the entire hierarchy and the opportunities which are potentially missed.

\textit{Example 2: Feedback of Information Regarding the Submitted Event to the Reporter}

This second example looks at the aspect of feedback to the reporters within the two systems. Feedback is often considered an essential action and can help encourage people’s willingness to continue to report incidents.\textsuperscript{2} Figure 18 and Figure 19 highlight components of the framework models which reflect the use of feedback within the MAUDE and ISMP Canada Medication Incident Database respectively.
Figure 18: MAUDE framework highlighting the components related to the feedback of information to the reporter(s)
Figure 19: ISMP Canada’s Medication Incident Database framework highlighting the components related to the feedback of information to the reporter(s)
With regards to the MAUDE’s framework model the only feedback present is between the FDA and manufacturer reporting the event. This feedback however is not with regards to every submitted event and typically only occurs when the FDA notices an issue they are curious about or perceive as a threat to public health. In these situations the feedback therefore is typically either requests for further information or notices for actions required by the manufacturer to correct the issues with their devices. While this is not necessarily feedback reflecting recommendations on how manufacturers can fix problems, it does serve to inform manufactures of areas where they must improve the safety of their products.

However, the manufacturers are just one of the actors responsible for the reporting process in the MAUDE, the user facilities and front-line staff also play a substantial role in initiating the report. Therefore, noticeably absent from the framework is any indication of feedback to these actors (highlighting a lack of vertical integration). Manufacturers may take it upon themselves to provide feedback information regarding the event to the user facility, but this is not a structured part of the MAUDE. Although mandatory reporting forces the user facilities to report, without any sort of feedback regarding how their efforts are being utilized staff may become increasingly less likely to take the time to report incidents. This could mean that staff will spend less time providing detailed information. Therefore, this highlights an area of the MAUDE where there is a potential weakness in the system that could be impacting other elements (i.e. the description of the event which in turn affects the ability to carry out investigations).

Looking at the framework of ISMP Canada Medication Incident Database reporting process shows there is communication between ISMP Canada and individual practitioners who report confidentially. ISMP Canada aims to contact reporters who submit confidentially and provide some sort of feedback (Roger Cheng, Project Leader – ISMP Canada, personal communication, July 19, 2011). For those reporting anonymously or through a hospital there is generally no way to identify the initial reporter and therefore no way to provide any sort of directed feedback. The feedback provided may be a simple thank you for submitting a report, a request for further information or consent to use the submitted incident in a publication, or passing along information to the reporter about similar events to that submitted which ISMP Canada has published details on. Regardless of the type of feedback some effort is expended on letting the reporter know that their effort is appreciated and not necessarily disappearing into an
administrative black hole. This in turn may help ensure the reporter’s continued willingness to report to the system.\textsuperscript{18} Since only reporters at the Actor Activities level of the framework typically play a role in reporting an event, this system provides a feedback mechanism to those responsible for reporting, who submit confidentially.

These two examples serve to illustrate how the framework can help highlight pathways that put mechanisms in place to promote the effective use of specific elements and characteristics of the reporting process. The following section aims to explore how a similar approach can be taken to investigate how the framework can be used to look at the goals of the reporting systems and the components in place to help promote these goals.

6.3.4 Using the Framework to Assess How the Systems Provide the Mechanisms for Promoting Their Goals

Both of the example incident reporting systems have been designed and implemented with regard to meeting a specific goal unique to their system. In addition, incident reporting systems have the potential to achieve goals which are not unique to a single system, but reflect the benefits that effective incident reporting systems can offer with regards to improving patient safety. These general goals reflective of the potential benefits of reporting systems\textsuperscript{17} are given in Table 1 of Chapter 1.2, but for reference are restated below.

1. Allow monitoring of underlying trends and patterns, encouraging early identification of incidents
2. Support timely investigations of incidents
3. Provide feedback to health care staff, patients, and administrative personnel regarding the nature of the incident and considerations underway to prevent future occurrence
4. Promote learning from incidents, including near misses and adverse events

Achieving these general goals may not be a focus of all systems, but effectively achieving these goals can serve to optimize the benefits which incident reporting can provide the health care system. Determining if a system is effectively achieving either their specific system goal or these more general goals requires investigating and measuring outcomes of their implementation, which goes beyond the work proposed in this study. However, the frameworks provide great
resources for looking at how the processes and structures surrounding the operation of the system can create the mechanisms through which the system can promote and attempt to achieve these goals. Mechanisms refer to parts of the system that work together to promote a specific action or goal. The present section aims use the framework models developed for the MAUDE and ISMP Canada Medication Incident Database to explore the mechanisms the systems exhibit for promoting their specific system goals and the general incident reporting goals.

6.3.4.1 FDA’s MAUDE

Specific Goals of the System

Above all else the goal of the FDA is to protect the public health by assuring safety, efficacy, and security of items such as drugs, medical devices, cosmetics, and food. To this end, the MAUDE is tasked with post-market surveillance and monitoring of adverse events involving medical devices. The overarching goal guiding the operation of the MAUDE is providing surveillance for detecting significant medical device incidents, and correcting the identified problems in a timely manner. Therefore, this goal can be summarized as having two aims:

1) Provide surveillance of significant medical device adverse events.
2) Correct identified problems in a timely manner.

Figure 20 highlights the parts of the framework where components are currently in place which reflect the system’s attempt to promote the specific goal for which it was implemented.
Figure 20: MAUDE framework highlighting the mechanisms related to promoting the specific goals of the MAUDE
With regards to the MAUDE’s aim of providing surveillance, Figure 20 highlights the policies and regulations made at the Government and Regulatory Bodies & Associations levels of the hierarchy which clearly define what is to be monitored by the system. In addition, for a system whose aim is to provide surveillance it is important to get a clear picture of all the types and the general prevalence of events which occur. Therefore, under-reporting of the target events can seriously undermine the system’s ability to provide credible surveillance. Therefore the mandatory nature of the system sets out a mechanism for deterring under-reporting. The combination of the clear definition of a ‘reportable event’ and the mandatory nature of the system create a structure that promotes the system’s aim for providing surveillance.

The framework in Figure 20 also highlights the components of the system which target the system’s aim of carrying out the timely correction of identified issues. The FDA mandates a timely reporting process for user facilities and manufacturers (as displayed in Table 5). However, reporting is different from correcting an issue. Manufacturers are also required to investigate incidents; however this also does not necessarily mean correcting the problem. The components of the system that best reflect the FDA’s attempt to correct issues is with regards to their noticing an area of concern and issuing notices or alerts to the manufacturer about these issues that require corrective actions. The issues are not corrected by the FDA itself, but rather passed along to the manufactures.

However, since the FDA exists at the Government and Regulatory Bodies & Associations level of the hierarchy it does have the power to enforce manufacturers to take action towards correcting issues. However, not all reports in the system cause the FDA to issue notices or alerts to the manufacturer and thus don’t undergo this same level of enforced corrective action. Overall, mechanisms within the MAUDE process are more aptly structured to provide timely investigation of issues and correction of only a portion of the issues.

**General Goals of Incident Reporting Systems**

Figure 21 highlights the components within the MAUDE framework which reflect the mechanisms for potentially achieving the four goals of incident reporting systems.
Figure 21: MAUDE framework highlighting the mechanisms related to promoting the general four goals of incident reporting systems
The first general goal of incident reporting systems is allowing monitoring and identification of incidents. This goal actually aligns itself perfectly with the MAUDE’s aim of providing surveillance of medical device adverse events, as described previously. The mechanisms and structures for promoting this goal are well established within the MAUDE.

The next general goal of incident reporting systems is promoting the timely investigation of incidents. The MAUDE’s system goal of promoting the timely correction of problems is similar but different from this goal. However, as highlighted previously, the MAUDE has strict timelines for user facilities and manufacturers to report incidents, a process which also involves investigation. As highlighted in the framework in Figure 21, the components related to this goal of promoting investigation include a substantial number of the activities of the overall reporting process. Manufacturers are mandated to investigate reported events, and non-mandated investigations at the user facility level also offer the opportunity for addition work feeding the investigation process.

The last two general goals of providing feedback and learning from incidents are both goals dealing with aspects of using and communicating the results of the reporting process. How the MAUDE database uses feedback was presented as an example in Chapter 6.3.3. The example noted how feedback to the manufacturer was present to a degree, but the system lacked mechanisms for providing any feedback to the front-line staff and user facilities, which serve as the base for the entire reporting process.

As a system which collects identifying information about the reporting parties (e.g. front-line staff and user facilities) feedback is particularly important. Information that identifies the reporters links them to the incident, which may carry with it some fear of being blamed or punished for their involvement. Therefore, the system must demonstrate there is a benefit to this risk of reporting. Such a benefit can be as simple as providing constructive feedback to the reporters to demonstrate that their effort in reporting is being used for positive change, rather than disappearing into an administrative black hole. The view of the system should not be that it is all risk and no real benefit in reporting to it.23

Overall, the incomplete feedback mechanisms indicate a lack of vertical integration within the system itself. Information propagates up the system to the FDA for monitoring medical device
usage. However, the downward propagation of information stops at the level of the manufacturer and never completes the loop of communication. This indicates an area of the MAUDE where the mechanisms aren’t in place for promoting one of the general goals.

The final general goal of incident reporting systems is with regards to promoting learning from incidents. The mechanisms which promote learning are those that use the information obtained through reporting and share it with those capable of using it to prevent future reoccurrences of events. To promote this goal, the FDA published and posts information to their website as a mechanism to inform the general public and device users of potential medical device issues and concerns. The other mechanisms that promote learning are the opportunities presented by the system being accessible by the public. Allowing the public access to the system allows learning to occur at various hierarchical levels. Where the feedback mechanisms failed to achieve vertical integration of the system, these learning and dissemination mechanisms provide the potential for the downwards propagation of information learnt from the reporting system.

### 6.3.4.2 ISMP Canada’s Medication Incident Database

**Specific Goals of the System**

ISMP Canada is an agency committed to the advancement of medication safety in all health care settings. ISMP Canada has set out a number of goals for itself, but the most pertinent goals regarding their incident reporting practices can be summarized as having two main aims:

1) To review and analyze medication incident and near miss reports, identifying contributing factors and causes.

2) Make recommendations for the prevention of harmful medication incidents and to disseminate this information.

Similar to the MAUDE, the framework model of this system can help explore what mechanisms and structures are in place to promote these goals. Figure 22 highlights the components of the framework which best reflect the system’s attempt to achieve these two aims.
Figure 22: ISMP Canada Medication Incident Database framework highlighting the mechanisms related to promoting the specific goals of the ISMP Canada system.
ISMP Canada’s goal to review and analyze medication incidents makes no mention of a need to capture all events or wanting to review incidents for the purpose of surveillance. Therefore, the voluntary nature of the system doesn’t really impact this goal. ISMP Canada reviews many of the reports submitted to it in order to help identify issues, causes, and contributing factors. Feeding into and supporting this are the dedicated analysts which ISMP employs for the purpose of reviewing and analyzing the reports it collects. This combination provides a good mechanism for promoting incident analysis by expert individuals with clinically significant knowledge useful for understanding the factors and causes of the incident. Further strengthening the goal of analysis are the studies ISMP Canada undertakes using their reporting data to carry out aggregate analysis of certain event types, looking for common trends and issues beyond analysis on a case by case basis. Overall, the system appears to have a number of components in place to provide mechanisms by which to promote the review and analysis of reports.

With regard to the goal of making recommendations for the prevention of harmful medication incidents, this goal builds from the mechanisms in place for reviewing and analyzing the report data. These components may assist in building the recommendations, but there are further components that ISMP Canada has in place for disseminating these recommendations. ISMP Canada’s partnerships with other organizations at various other hierarchical levels serve to help build these recommendations as well. These partnerships also provide mechanisms by which ISMP Canada may translate their recommendations into implemented safety improvement strategies through policies, regulations, or changes to medication products (e.g. labeling practices). These types of actions based on ISMP Canada’s recommendation serve to provide widespread dissemination of their work.

Another way ISMP Canada disseminates their recommendations is through publication and distribution of bi-weekly Safety Bulletins. These provide insights into a variety of issues ISMP Canada is aware of and wishes to share with the public, including recommendations for safer medication practices. Therefore, ISMP Canada has implemented several mechanisms within its reporting process by which it can make recommendations and disseminate information.
General Goals of Incident Reporting Systems

Figure 23 highlights the components within the ISMP Canada Medication Incident Database framework which reflect the mechanisms for potentially achieving the four general goals of incident reporting systems.
Figure 23: ISMP Canada Medication Incident Database framework highlighting the mechanisms related to promoting the four general goals of incident reporting systems.
The actions of ISMP Canada are not governed by any government policies or regulations, therefore it serves as an independent organization that if free to dictate its own goals. However, as a result it doesn’t have any power to enforce mandatory reporting to the system. Therefore, the system is a voluntary reporting system, which introduces the issue of under-reporting. With regards to the general goal of promoting the monitoring and identification of incidents the issue of under-reporting does impact the ability to achieve surveillance level monitoring. However it still allows the identification of incidents to look for common issues and patterns.

Using the ISMP Canada framework model to explore what components of the reporting process are in place for supporting timely investigation reveals there are very few mechanisms promoting it. ISMP Canada may review reports and analyze them, but that is typically done at their own pace and does not really serve to investigate incidents as they occur. Therefore, the only component within the entire process where there is the potential for timely investigation is with regard to reports submitted through hospitals. Even at this stage an investigation is not required and is more reflective of hospital reporting activities than those associated with reporting to ISMP Canada. Therefore, the system doesn’t appear to have any dedicated focus with regard to promoting timely investigation of incidents.

The mechanism of providing feedback in the ISMP Canada Medication Incident Database was presented as an example in Chapter 6.3.3. In this example it was noted that there is a process in place for promoting feedback to reporters that submit reports confidentially. Reports which are submitted anonymously or through a hospital system don’t receive any feedback because there is typically no reporter identified to provide feedback to. For a voluntary system it is particularly important to have in place a good feedback process as staff are only likely to continue reporting events they are not mandated to if they believe it is being used to improve health care outcomes. Unlike mandatory systems which force reporters to continue reporting, reporters to voluntary systems can simply choose to stop reporting altogether if they see no benefit. Overall, the feedback utilized in this system provides propagation of information back down the hierarchy to achieve vertical integration within the actors of the system.

The ISMP Canada system appears to have many components in place for promoting learning from incidents. The specific goal of the system itself is reflective of this more general goal. The
process in place for reviewing and analyzing reports by expert analysts combine as one mechanism for promoting this goal. ISMP Canada’s aggregate analysis studies provide another mechanism for learning from the reporting system. A third mechanism for learning is evident in the partnerships ISMP Canada forms with other organizations. These partnerships allow access to additional resources with which to make recommendations and disseminate findings across hierarchical levels, including those levels above ISMP Canada. The final mechanism in place to promote learning is ISMP Canada’s bi-weekly Safety Bulletin publications. These serve to publically disseminate findings and recommendations across all levels of the hierarchy and further enhance the vertical integration of the system.

6.4 Chapter Summary

This chapter presented the use of Rasmussen’s (1997) risk management framework as a tool for exploring the interactions and influences of the fundamental characteristics of incident reporting systems across the various actors and organization involved in the reporting process. Rasmussen’s framework models complex socio-technical systems as a hierarchy of individuals and organizations, and promotes the need for vertical integration within systems. The reporting processes of the FDA’s MAUDE and ISMP Canada’s Medication Incident Database were mapped onto this framework to examine how the fundamental characteristics interact and form the structure of the reporting processes. The modeling process highlighted that the fundamental characteristics are not always represented a single time throughout the process. Rather, they may be represented with respect to multiple activities and components spread across multiple levels of the hierarchy.

The models also illustrate how the framework can be used to explore and examine specific aspects of the system (e.g. accessibility or feedback). Building upon this, the models provide a method for discussing how the components and activities combine to create mechanisms and structures for promoting the system to meet goals. These goals may be specific to the system and reflect the reason it was implemented or they could be the goals that reflect the benefits of incident reporting in general. This work highlights how the mechanisms promoting the goals were often spread across the various levels of the hierarchy. As such, this provides valuable insight into exploring the connections and interactions required between the various actors and organization to promote the system to achieve its goals. Overall Rasmussen’s framework
provides a very useful tool for graphically exploring the complex interactions of the incident reporting process. Where the literature search explores and highlights the fundamental characteristics as individual components the framework provides a model which demonstrates the complex interaction that actually exists between these characteristics.
7 Discussion and Limitations of the Study

7.1 Discussion

The IOM’s 1999 To Err is Human report\(^5\) was one of the first major publications to bring the high number of incidents that occur in health care to the attention of the general public.\(^9\) Around the same time several other publications also began to highlight similarly shocking statistics about health care incidents\(^3,10-12\) demonstrating that this issue is not limited to a single country, but rather poses a worldwide concern. One effort stemming from these publications was recommendations to expand the use of incident reporting systems in health care to improve patient safety. However, even now most health care reporting systems are in their infancy\(^18\) and progress building from the recommendations made in the various publications has been slow.\(^9\) In addition, most of the literature on reporting systems has primarily been concerned with the act of collecting reports\(^4\), rather than the activities of analyzing the data and communicating the findings and recommendations. However, it is the actions of analysis and communication that turn an incident report into a lesson to improve patient safety.\(^8,20,22\) The simple counting of the collected reports serves relatively little purpose in the aim to improve patient safety.\(^20,21\) Therefore, the work presented in this study was targeted at building a better understanding of the fundamental characteristics of incident reporting systems that impact the ability to analyze incident data and communicate information to the larger health care community.

The work presented here first developed a list of the fundamental characteristics considered to be essential elements for making incident reporting systems effective tools for incident analysis and communication. These characteristics, listed in Table 14, are based on commonly identified elements and considerations found through a systematic review of the literature on incident reporting in health care and high-risk industries.
The systematic exploration of these characteristics revealed that for a number of these characteristics there are often multiple methods by which they can be implemented or portrayed within a system (e.g. voluntary versus mandatory reporting, publically accessible systems versus systems only available to a single organization). In addition, the search revealed a lack of consensus in the literature regarding the most effective method of implementing many of these characteristics. For example, there are debates over the use of mandatory versus voluntary reporting systems and free-text narratives versus structured taxonomies for describing events. Both approaches offer benefits and limitations for their methods of implementing the fundamental characteristics (i.e. operational aspects and description of an event) and different publications support different viewpoints.

The list of fundamental characteristics developed and the discussions surrounding them presented in this research provide a detailed exploration of essential reporting system elements for analysis and communication activities. Most of the literature to date has either focused on evaluating specific systems, discussing one or two characteristics of reporting systems, or highlighting limitations and weaknesses in reporting systems. As such, the research undertaken
in this study presents a systematic and comprehensive source of information for exploring incident reporting system characteristics which has been lacking in the published literature.

Developing the list of fundamental characteristics and building an understanding of how they affect the incident reporting activities provided the basis for the rest of the work in this research. Having established the ten characteristics and identifying that many of them can be implemented through different methods, the focus of the research progressed to exploring how the characteristics have been structurally implemented in current reporting systems. This refers to the way in which the characteristic has been defined within the system as an invariable component of the reporting database or the reporting process. Policies, regulations, reporting and process guidelines, or the physical layout of the database itself, are aspects of the reporting system which define how certain characteristics are structurally implemented. Two national reporting systems, the FDA’s MAUDE and ISMP Canada’s Medication Incident Database, were presented in the research as case studies for comparing how the structural implementation of the ten characteristics can vary between systems.

The MAUDE and ISMP Canada systems were established to pursue different goals. The MAUDE is aimed at providing post-market surveillance of adverse events involving medical devices, while ISMP Canada’s Medication Incident Database aims to review and analyze medication incidents and develop recommendations for preventing further incidents. This difference in their goals was also reflected in the way that many of the ten fundamental characteristics were structurally implemented, differently, between the systems. For example, the MAUDE utilized mandatory reporting while ISMP Canada was voluntary, the MAUDE made their system accessible to the public while ISMP Canada’s was not publically assessable, and the MAUDE contained information identifying the reporting organizations while ISMP Canada’s system was anonymous or confidential. While there were differences like these, the systems did share some common elements such as acknowledging the denominator and numerator issue in calculating rates and using a combination of free-text and structured options to provide descriptive information. However, overall there were more differences in the systems than similarities. The comparison made here did not aim to reveal which system was superior or which made better use of the characteristics, but rather to highlight the differences in the way that reporting systems may structurally implement various aspects of the fundamental
characteristics. Regardless of how they implemented the characteristics, the systems both exhibited all ten of the fundamental characteristics proposed.

Having identified the differences in the two example databases with regard to their structural implementation of the ten characteristics, the next portion of the research aimed to look at how this can impact the content of the systems, including the type of events and quality of information. To explore this, a formal search and coding process was used to query the MAUDE and ISMP Canada Medication Incident Database for reports related to multiple IV infusion incidents. The case study of multiple IV infusion incidents was selected as a topic that deals both with medication and technology related issues, thereby spanning both systems’ classification of a ‘reportable event’. The same search strategies were applied to both databases and a series of results were developed with which to compare the two systems. The structural differences between the two systems were looked at with regard to two of the ten fundamental characteristics: the classification of a ‘reportable event’ and the description of an event.

The type of events contained within the system was found to be impacted by how the system structurally implemented the classification of a ‘reportable event’. Despite using the same methodology to search the systems, the most commonly identified type of incidents within each of the systems was very different. Therefore, one of the findings building from this is the need to be aware of how structural differences influence the type of reports contained within different reporting systems. Different systems may capture incidents related to different facets of the same overall topic while neglecting or overlooking others. This in turn can result in an incomplete picture or understanding of an incident topic when relying solely on a single database with a specific classification of a ‘reportable event’. Therefore, a vital message is for users to be aware of how the system’s structure may influence the reports it contains and how this in turn will influence the question they are investigating.

With regard to the quality of information, despite implementing the description of an event characteristic in the same way, one system was significantly more successful at providing information describing the incident (i.e. the incident location, patient impact, and cause of the incident). This revealed that other characteristics, which were structured differently between the systems, must also impact the descriptive contents of the database. One such characteristic may be the timeliness of reporting. Studies have found that in general reporters only complete fields
that are mandatory, ignoring the others. Therefore, when presented with a long list of fields, reporters may provide incomplete or low quality information in order to facilitate a shorter time to complete a report. Another characteristic which may similarly influence the quality of descriptive information is the difference between mandatory and voluntary systems. In a voluntary system, people tend to report what they want to report with the aim of sharing information to allow others to learn from the event. However, in a mandatory system, a number of people only report because they are forced to. If they see no other benefit to reporting they may not put the effort into providing quality information. Similarly, if the culture is perceived as one of blame, reporters may try to hide the nature of the incident and not provide very detailed information in order to hide the severity and their role in it. From the presented work, it was not possible to determine which of these characteristics played a role in the different rate of success in extracting information from the system reports. However, it does demonstrate that the fundamental characteristic may be intertwined and interact to influence the usefulness of the system.

The systematic literature search and the comparison of the two example databases explored the ten fundamental characteristics as individual elements of the system. However, the multiple IV infusions case study highlighted that it is unlikely that the characteristics themselves serve as isolated elements in the reporting system. Therefore, the final process used to investigate the ten fundamental characteristics was an exploration of how the characteristics interact within the incident reporting process and impact the goals of the reporting system. Rasmussen’s (1997) risk management framework was presented as a tool for exploring this interaction of the fundamental characteristics.

Rasmussen’s framework uses an organizational hierarchy to model complex socio-technical systems and emphasizes the need for vertical integration within a system. The organizational hierarchy is particularly useful in health care, which tends to be comprised of no single, centralized oversight body, but rather a mix of monitoring agencies, accreditation bodies, government licensing bodies, and a wide variety of specialized professional associations responsible for setting standards. While these organizations populate the upper levels of the hierarchy, at the bottom levels there are a variety of medical specialties and subspecialties interacting with each other and an equally large array of allied health professionals. All these actors and organizations combine within this hierarchy to form a system more complex than any
other industry in terms of relationships and interactions.\textsuperscript{9} These same complex relationships across the various hierarchy levels also make the concept of vertical integration particularly important in health care. Vertical integration refers to the communication of information up the hierarchy to inform those at the top levels of the system’s current status combined with communication back down the hierarchy to inform those at the lower levels of decisions and actions of the organizations directing the system at the upper hierarchy levels. Vicente (2006) puts forth that each level of the hierarchy plays a critical, yet different, role in maintaining the stability of the system and that system issues often arise from a lack of vertical integration.\textsuperscript{130} This is particularly noteworthy in health care where feedback, a downward communication pathway, is regarded as essential to the success of incident reporting.\textsuperscript{8} However, lack of feedback and limited management response from reporting has been noted as a common barrier to reporting incidents.\textsuperscript{4,26,53-55} This barrier causes reporters to become increasingly less likely to report incidents\textsuperscript{25}, thereby destabilizing the reporting process due to poor vertical integration. As such, it has been stated that it is more important to develop a response system for communicating findings from the reports than a reporting system for merely collecting data which contribute little to patient safety advancement.\textsuperscript{23} Because of the complexity of the organizational structure in health care and the known issues with communication, the organizational hierarchy and the emphasis on vertical integration provided through Rasmussen’s framework is a particularly useful model for exploring the issues of health care incident reporting.

For the purposes of the study, Rasmussen’s framework was used to map the incident reporting processes of the MAUDE and ISMP Canada Medication Incident Database. This was done to examine how the fundamental characteristics interact across the various levels of the organizational hierarchy as well as create the mechanisms for promoting system goals. Mapping the reporting process of these two systems onto the framework demonstrated that many of the characteristics are represented multiple times throughout the process. Rather the characteristics are often represented with respect to multiple activities and components, spread across multiple levels of the hierarchy. The framework also was demonstrated to be useful for exploring specific aspects of the systems (e.g. accessibility and feedback) and suggesting where potential limitations in the process exist or where implementing an aspect in a different way may open up different opportunities. Finally, the framework was also used to investigate the mechanisms within the structures and processes of the system for it to promote its goals. The mechanisms for
achieving the specific system goals of the MAUDE and ISMP Canada Medication Incident Database, for which they were designed and implemented, were one set of goals explored. The other set of goals explored were those reflecting the benefits of incident reporting in general (as listed in Table 1). This work helped to illustrate how the mechanisms promoting these goals were often spread across the various levels of the hierarchy, drawing upon the various fundamental characteristics, and often required interactions between various actors and organizations within the system. This process also served to highlight where there were weaknesses in achieving the goals.

Overall the work undertaken in this study serves to provide an exploratory investigation of a topic which has been under-explored with respect to incident reporting systems. Little comprehensive work has been presented to date looking at the fundamental characteristics for promoting the vital analysis and communication activities of incident reporting. As such the work presented here addresses this oversight by providing a comprehensive literature review of the fundamental characteristics, and an exploration of these characteristics. The characteristics were explored and discussed based on differences in their structural implementation within current systems, their impact on the contents of the databases, and finally their interaction with one another and the overall incident reporting process. Incident reporting systems do offer great potential for improving patient safety, but there needs to be more work performed like that presented in this research to build a better understanding of the important components of incident reporting systems in order to design and implement them effectively.

7.2 Limitations

The following sections highlight the limitations of the approaches taken in the presented work to explore the fundamental characteristics influencing the analysis and communication activities of incident reporting systems.

7.2.1 Development of the Ten Fundamental Characteristics

The ten fundamental characteristics were developed through a systematic review of the literature, followed by a thematic analysis of the publications returned from the review. One limitation inherent in literature reviews is the potential to not capture all relevant publications due to the applied search strategy. To help mitigate this limitation multiple literature databases were chosen...
in this study with the intent of capturing as many published articles relevant to the topic as possible. However, despite this it is possible that several relevant publications may have been overlooked. With regards to the thematic analysis, a limitation in this study was that the ten characteristics were developed by a single researcher. Future work will require a second researcher to perform a similar review and thematic analysis to validate the selection of these ten characteristics.

### 7.2.2 Comparison of the Two Existing Databases

The primary limitation surrounding the comparison of how the FDA’s MAUDE and ISMP Canada’s Medication Incident Database implemented the ten fundamental characteristics was that it was performed by a single researcher. The comparison was not based on opinion, but rather on components of the reporting systems as defined by facts presented within the policies, regulations, guidelines, and physical layout of the systems. However, there is still a potential for the researcher’s biases or perceptions regarding the systems to influence the comparison findings. Therefore, validation of the comparison findings would benefit from a second researcher assessing the two systems based on the ten characteristics and comparing their findings with those documented in the present work.

### 7.2.3 Investigating the Contents of the Two Example Systems

The comparison of the contents of the MAUDE and ISMP Canada reporting systems documented in the present work looked at a single case study. As a result, the findings presented with regards to this section are only applicable to reports regarding multiple IV infusion incidents. Further work is required to assess if the results are reflective of the entire reporting system. In addition, since the reporting systems are substantially different with regards to their implementation of many of the fundamental characteristics it is difficult to highlight the impact a single one of these characteristics may have on the contents of the overall system. With regards to the coding process itself, since ISMP Canada’s incident reports could only be viewed by ISMP Canada staff this limited the ability of the HTSRT researchers to view reports from the Medication Incident Database. This resulted in all the training on how to code the reports of the two systems being performed using only reports obtained from the MAUDE. This in turn is not necessarily representative of the reports contained within the ISMP Canada Medication Incident Database, therefore limiting the utility of the training. In addition, since ISMP Canada reports
could not be viewed by all the researchers, inter-rater reliability could only be established between the researchers responsible for coding a single database (i.e. between the two researchers coding he ISMP Canada database and between the three researchers coding the MAUDE database) and not across all five researchers for both databases. While this ensures uniformity in the coding between the researchers coding the same systems it does not ensure uniformity in the coding between the two systems.

7.2.4 Applying the Framework for Exploring the Incident Reporting Process

Similar to the development of the ten fundamental characteristics and the comparison of the two example reporting systems, a limitation of the framework section is that the mapping of the reporting process was carried out by a single researcher. To validate the mapping of the MAUDE and ISMP Canada reporting processes an additional researcher is required to perform the same task. Another limitation is the information used to map the reporting process. The MAUDE reporting process was mapped using information obtained from the FDA’s manufacturer and user facility reporting guidelines. However, while these guidelines describe the reporting process intended to be followed it may not necessarily reflect the actual practice of how all incident reports are communicated and analyzed. Therefore, someone with first-hand knowledge of how reports are processed in the MAUDE database should be consulted to verify that the process mapped onto the framework using the reporting guidelines is representative of the actual reporting process. This strategy was used in mapping the reporting process of the ISMP Canada Medication Incident Database. Due to a lack of publically accessible documents detailing the complete ISMP Canada reporting process an individual knowledgeable in how reports are processed in the ISMP Canada system was consulted.
8 Future Directions

This chapter discusses several areas where future work building upon the findings and observation presented in this study would serve to benefit the field of incident reporting in health care.

The first proposed area for future work is the need for validation of the ten fundamental characteristics developed in the presented work. The ten fundamental characteristics were developed from a thematic analysis of the results of a comprehensive literature review carried out by a single researcher. Having only a single researcher involved in the process of extracting the fundamental characteristics influencing analysis and communication activities in health care incident reporting systems is one of the limitations of this study. In order to validate the characteristics extracted, at least one additional researcher should perform a similar literature review and see if there is agreement with the present research regarding the characteristics. Upon validation of the ten fundamental characteristics extracted there is potential for their use as a form of “checklist” to help in assessing and understanding reporting systems. The ten characteristics can serve as a set of defined elements for designers and users of incident reporting systems alike to ensure they are aware of important considerations surrounding a reporting system. The established characteristics can also provide a set of specific elements that are helpful when comparing different reporting systems with one another, similar to the work presented in Chapter 4.

A second area where future work would be beneficial is expanding the processes used in the present work to assess a range of existing reporting systems with different variations in the way they have structurally implemented the fundamental characteristics. The MAUDE and ISMP Canada systems served as appropriate systems to demonstrate how different the system structures can be from one another, but to expand on this work, systems need to be explored with less variable structures as well. By investigating and mapping the characteristics and goals of more systems there is the potential for patterns to be found in how systems choose to combine certain characteristics to meet specific goals. The work would also benefit from exploring additional factors surrounding the systems such as the operating organization’s regulatory power and its ability to enforce change, the purpose of the system from the perspective of the operating organization, the resources available, and the scope of who is reporting to the system. This
process may be the first step in identifying the optimal implementation strategies for promoting the system goals in a very effective manner, although additional work would also be required to validate the strategies. It is probable that different goals require the use of different methods, but this approach would start the process of creating valid guidelines and roadmaps for creating systems with the proper characteristics and components needed to meet specific goals more effectively.

One of the limitations of the assessment of the contents of the MAUDE database and ISMP Canada Medication Incident Database presented in this work was that the results were only reflective of multiple IV infusion related reports. While this case study provides a preliminary basis for investigating the two databases, further work would be required to determine if the observations and finding are reflective of the entire database. This process may require a more extensive study to determine the overall quality of information and type of reports contained within these two systems.

The use of Rasmussen’s framework provided insights into a number of areas of potentially useful future research. One of these future areas of work is looking at the roles and interactions of the organizations and individuals across the hierarchy more closely. The work presented within the current study using, the framework, illustrated the level of necessary connectivity and vertical integration between the organizational levels. However, the study of incident reporting systems could benefit from a more detailed evaluation of this connectivity (its presence, absence and utility) in current systems. Lack of feedback is a known limitation to incident reporting and this has an impact on reporting practices. By investigating where within the organizational hierarchy of a system vertical integration is weak or fails completely may provide insight into suggestions for building a more stable and effective communication system. Investigating this could entail a very detailed study that interviews staff at each level of the hierarchy to determine how they interact in the reporting process, their perceptions of how their work is utilized by the levels above them, and how they are kept informed regarding their efforts from the levels above. This study would greatly add to the study of reporting systems to highlight the issues involved in the activities of communication.

Expanding the use of the framework to also look at additional organizational and contextual factors (e.g. financial resources, education and training, political climate) influencing the
reporting process is another area where future work could focus. Organizational management theories and concepts exist which are used to explore systems in business that could be applied to investigating and developing a better understanding of the organizational nature of incident reporting systems. While the theories may not be completely applicable to incident reporting itself, some of the themes and concepts presented may be very relevant to the operation and use of incident reporting systems. Two examples of such concepts are clinical microsystem\textsuperscript{135} and innovative diffusion theory\textsuperscript{136}. Including organizational management concepts alongside the framework may serve to better understand the nature of the weaknesses in reporting systems as well as potentially assist in recommending solutions.

Another area where future efforts can potentially assist in the study of incident reporting is in providing better guidance for conducting searches of incident reporting systems. The multiple IV infusion case study presented in this work and used to compare the contents of the two databases highlighted the importance of knowing how the database influences the type of information you find in it and how when posing a query to the database the user should be aware of this influence. This is a feature that is extremely important for system users to understand. However, knowledge about where researchers, risk managers, and front-line staff can go to access reporting information is another factor to take into account. If users are only aware of a single database they have access to then even acknowledging how the database influences their search results does not preclude that they may be obtaining an incomplete picture of the topic. Therefore, future work could be directed at identifying the incident reporting systems that the public have access to and creating a repository linking to them. This repository could then be used by those looking for specific types of incident or those trying to perform a detailed research study. In addition, once all the systems available have been identified, work could be done to determine how the contents of the database are affected by the system to help guide casual users of the systems to perform a more effective search for topics and be aware of the implications the systems have on their contents. Having such a repository available serves to promote dissemination of information as well and offers the potential to maximize the use of the collected reports.

The work presented in the study looking at the interactions of the fundamental characteristics and the ability to achieve system goals is just one area where Rasmussen’s framework presents an important new tool for investigating health care incident reporting systems and the reporting
process. There is potential that with further exploration of the applicability of the framework, it could become a valuable tool, assisting in the design and optimization of incident reporting systems. Using it to plan and design a system is a logical application of the framework. Starting with the goal(s) of the system, the designer can use the hierarchical framework to start to map the system and identify the characteristics, aspects, and components that interact to promote the goals. At the same time it allows the identification of the various actors and organizations which need to be involved in the process at and across the various hierarchy levels. The framework also emphasizes the pathway needed to communicate information via vertical integration. To do this, the system must include a pathway by which reporting information is translated up the hierarchy from the reporters at the bottom to the operating organization at the top, as well as providing a pathway back down the hierarchy to provide feedback and disseminate findings. Exploring this topic further could add a very useful tool to the study, implementation, and use of incident reporting systems.

In a similar fashion, Rasmussen’s framework can also serve as a way to graphically inform all the actors and organizations involved in the incident reporting process how they fit into the overall process and how their role impacts upon other actors. The framework provides a simple method of outlining the reporting process and the general roles of those involved in a way that can be understood by individuals from any educational background (e.g. policy management, nursing). By clearly showing how the activities at one level of the hierarchy impact the activities of the actors in the levels above and below could be very beneficial for ensuring actors are aware of what occurs beyond their role in the reporting process. This, in turn, may help strengthen the vertical integration of the systems by demonstrating to the actors the purpose their involvement in the overall process and that their actions are actually being used to promote change.

A final recommendation for future work is evaluating the extent to which incident reporting systems have clear and measurable goals. The goals of incident reporting systems may be based on high-level statements regarding what people perceive incident reporting as providing (e.g. improving patient safety). However, these statements are very general and don’t necessarily provide guidance on how to determine if a system is actually meeting these goals. The work presented surrounding the use of Rasmussen’s framework for modeling incident reporting processes may offer an opportunity to carry out a more detailed and careful analysis of incident reporting goals. This in turn could lead to the creation of system goals with specific regard to the
design and implementation of system components, thereby proving functional support to promote the goals. This in turn may offer metrics that would be helpful in gauging the system’s success, as measured against its stated goals.
9 Conclusions

The implementation of health care incident reporting systems has received serious effort within the past couple of decades to target the high number of incidents known to occur in health care. However, many systems are still in their infancy and progress stemming from their implementation has been slow. In addition, even though it has been highlighted that the collection of incident reports alone serves relatively little purpose in improving patient safety, a majority of the research into incident reporting has primarily been on the act of collecting reports. As a result, the more important activities of analyzing incidents and communicating findings and recommendations have been relatively neglected in the research and literature. The primary objective of the present work was to explore the fundamental characteristics of incident reporting systems which promote the activities of analysis and communication.

This was done by performing a comprehensive literature search of the literature on incident reporting systems in health care and high risk industries to develop a list of fundamental characteristics commonly identified as essential for effective incident analysis and communication. Ten characteristics were identified in the literature search and the remaining work explored these ten characteristics through several approaches. The FDA’s MAUDE and ISMP Canada’s Medication Incident Database were used as example incident reporting systems for exploring the fundamental characteristics and their influence on the incident reporting process.

The literature review revealed that there is a general lack of consensus with regard to the best methods for implementing the characteristics within reporting systems. This was strongly highlighted in comparing the two example systems based on how they structurally implemented the characteristics. However, while the systems did vary drastically with regard to how they implemented many of the characteristics, they also were both shown to still exhibit all ten of the characteristics regardless of their differences.

The characteristics were next explored with regard to how the structural differences of the two systems impacted the contents of the systems. To this end, both systems were queried using a common incident topic, multiple IV infusion incidents, to compare the differences in the search results. The way in which the characteristics are structured was shown to impact the contents of
the system, including the type of events and the ability to identify information in the system’s reports useful for analysis activities. The process also highlighted the need for system users to be aware of what they wish to achieve by querying the system and how the structure of the system itself may impact what they find. The work also suggested that the differences between the contents of the two systems are most likely due to the interaction and combination of the various characteristics rather than a single characteristic alone.

Rasmussen’s (1997) framework was presented in the final chapter as a method to highlight the portrayal of the fundamental characteristics within the incident reporting process in its entirety. Mapping the incident reporting process of the two example systems onto the framework provided a visual way of identifying the complex interactions of the characteristics, actors, and organizations involved in the reporting process. This also served to show how the characteristics are often reflected in multiple activities of the reporting process and combine to form mechanisms for promoting the system’s goals. The framework also highlighted the pathways for communicating incident information to the various actors and organizations involved in health care.

There is still much more work required to make incident reporting systems more effective. However, the presented work provides a comprehensive look at the fundamental characteristics of analysis and communication-related activities in incident reporting systems. These characteristics are key considerations in how systems carry out these activities, which are essential for useful and effective incident reporting systems. The work also presents Rasmussen’s framework as a tool for helping to investigate incident reporting systems, a tool that the literature has reported as being needed. Overall, the work presented serves as an exploratory foundation for helping to propel the understanding of incident reporting systems further towards the goal of creating systems that are effective at improving patient safety.
Bibliography


13. Gong, Y. Data consistency in a voluntary medical incident reporting system. Journal of Medical Systems , Published Online; 2009.


41. Johnson, C. How will we get the data and what will we do with it then? issues in the reporting of adverse healthcare events. Quality and Safety in Health Care. 2003; 12(Suppl II): ii64-ii67.


### Appendix A: Literature Search Methodology

The bracketed numbers refers to the final number of relevant articles after reading the articles fully and applying the inclusion and exclusion criteria and removing those duplicated in the databases searched previously.

Table 15: Incident reporting systems in health care literature review summary

<table>
<thead>
<tr>
<th>Databases</th>
<th>Search Terms</th>
<th>Number Returned</th>
<th>Number Relevant</th>
</tr>
</thead>
<tbody>
<tr>
<td>OVID MEDLINE</td>
<td>incident(s) OR error(s) OR adverse events(s) OR near miss(es) AND incident reporting OR incident report OR incident database(s) AND hospital(s) OR healthcare OR medicine AND risk management OR patient safety OR incident analysis AND</td>
<td>103</td>
<td>26 (25)</td>
</tr>
<tr>
<td>EMBASE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OVID Healthstar</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>International Pharmaceutical Abstracts</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PsycINFO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PubMed</td>
<td>“incident reporting” AND database(s) OR system(s)</td>
<td>196</td>
<td>33 (10)</td>
</tr>
<tr>
<td>Web of Science</td>
<td></td>
<td>72</td>
<td>15 (10)</td>
</tr>
<tr>
<td>Google Scholar</td>
<td>“incident reporting” AND “incident analysis” AND medical OR hospital*</td>
<td>105</td>
<td>8 (6)</td>
</tr>
</tbody>
</table>

Total Relevant and Unique Articles: 51

Table 16: Incident reporting systems in industry literature review summary

<table>
<thead>
<tr>
<th>Databases</th>
<th>Search Terms</th>
<th>Number Returned</th>
<th>Number Relevant</th>
</tr>
</thead>
<tbody>
<tr>
<td>COMPENDEX &amp; Inspec</td>
<td>incident(s) OR error(s) OR adverse event(s) AND industry OR aviation OR nuclear OR chemical AND reporting system</td>
<td>72</td>
<td>20 (15)</td>
</tr>
<tr>
<td>Web of Science</td>
<td></td>
<td>62</td>
<td>20 (5)</td>
</tr>
<tr>
<td>Scholars Portal</td>
<td></td>
<td>178</td>
<td>20 (5)</td>
</tr>
<tr>
<td>Scopus</td>
<td></td>
<td>97</td>
<td>9 (1)</td>
</tr>
<tr>
<td>Google Scholar</td>
<td>“incident reporting” AND “reporting system” AND “industry” AND “incident analysis” AND aviation OR chemical OR nuclear</td>
<td>132</td>
<td>5 (5)</td>
</tr>
</tbody>
</table>

Total Relevant and Unique Articles: 31
Figure 24: Literature search strategy applied to the search for publications related to incident reporting in health care

Figure 25: Literature search strategy applied to the search for publications related to incident reporting in industry

An additional 32 publications were added after reviewing the bibliographic references of the articles returned from the detailed search. This brought the total publications used for the systematic literature review up to 114.
Appendix B: Incident Database Assessment Methodology

Table 17 below displays the keywords used to perform the search of the MAUDE and ISMP Canada databases for multiple IV infusion related incidents.

Searching the free-text fields of the incident databases does not occur by looking for single words or phrases, but rather looks for them in the context of the entire free-text message. For example, simply searching for the word “infusion” would not return a report stating “The infusion failed”. Therefore, to search for words imbedded in the free-text care had to be taken to ensure the proper format was used for each keyword. The format makes use of the wildcard character (*) and spaces to search for specific words within the free-text fields of the incident reports. The wildcard character denotes any single character (spaces, numbers, or letters) or groups of characters. The wildcard character allows the search query to flexibly search for the terms within a larger section of text as either the word itself or as part of a longer word. For example, the search term “*report*” will look for reports which use the terms report, reports, reportable, or reporting. In addition, the use of spaces around the terms should be noted in relation to the wildcard character as it dictates the desired segregation of the term from characters located in the text around it. For example, simply searching for “*IV*” would return words that contain “IV”, such as “live”, “lived”, “give”, “liver” etc. The use of a space around the word (e.g., “* IV *”) prevents this occurrence. Therefore, to return the report with the phrase “The infusion failed” when searching for the word infusion the search term would need to be “* infusion *”.

The keywords were separated into the four categories for incorporation into a large Boolean search term. The groups of terms from the IV Therapy Terms, IV Equipment or Material Terms, and Incident Descriptor categories were connected using an AND logic operator. This ensured the search found any report within the dataset with included at least a single term from each of these three categories. For example, using the first term in each of these categories, a report had to contain the words IV, label, and dose. The Primary Keyword category was linked to this three part search phrasing using an OR logic operator. The use of any one of these primary keywords in a report was considered to have a high probability of being related to a multiple IV infusion incident. Therefore a report had to contain either one term from each of the first three categories or any one term from the primary keyword list to be returned from the database search.
### Table 17: Multiple IV infusion incident keywords with Microsoft Access query formatting

<table>
<thead>
<tr>
<th>IV Therapy Terms</th>
<th>IV Equipment or Material Terms</th>
<th>Incident Descriptors</th>
<th>Primary Keywords</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;# IV*&quot;</td>
<td>&quot;#LABEL*&quot;</td>
<td>&quot;* DOSE*&quot;</td>
<td>&quot;#PERIPHERAL*&quot;</td>
</tr>
<tr>
<td>&quot;#I.V*&quot;</td>
<td>&quot;#BAG*&quot;</td>
<td>&quot;* ERROR*&quot;</td>
<td>&quot;#CALCULAT*&quot;</td>
</tr>
<tr>
<td>&quot;#INFUS*&quot;</td>
<td>&quot;# PORT*&quot;</td>
<td>&quot;* ENTER*&quot;</td>
<td>&quot;#DRIP*&quot;</td>
</tr>
<tr>
<td>&quot;#PIV*&quot;</td>
<td>&quot;# PUMP *&quot;</td>
<td>&quot;* LABEL*&quot;</td>
<td>&quot;#SUBCUT*&quot;</td>
</tr>
<tr>
<td>&quot;#PCA*&quot;</td>
<td>&quot;# SET*&quot;</td>
<td>&quot;* RATE*&quot;</td>
<td>&quot;#EPIDURAL*&quot;</td>
</tr>
<tr>
<td>&quot;#VTBI*&quot;</td>
<td>&quot;#CATHETER*&quot;</td>
<td>&quot;* SET*&quot;</td>
<td>&quot;#COMPAT*&quot;</td>
</tr>
<tr>
<td>&quot;#PCEA*&quot;</td>
<td>&quot;#CONNECT*&quot;</td>
<td>&quot;* INJ*&quot;</td>
<td>&quot;#TITRAT*&quot;</td>
</tr>
<tr>
<td></td>
<td>&quot;# TUBING *&quot;</td>
<td>&quot;* INCIDENT*&quot;</td>
<td>&quot;#GT*&quot;</td>
</tr>
<tr>
<td></td>
<td>&quot;# LINE *&quot;</td>
<td>&quot;* FLOW*&quot;</td>
<td>&quot;#CONFUS*&quot;</td>
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<td>&quot;# FLUID*&quot;</td>
<td>&quot;* FLOW*&quot;</td>
<td>&quot;#GRAVITY*&quot;</td>
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<td></td>
<td>&quot;# CHANNEL*&quot;</td>
<td>&quot;* INCIDENT*&quot;</td>
<td>&quot;#Y'D*&quot;</td>
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<td></td>
<td>&quot;# BOTTLE*&quot;</td>
<td>&quot;* FLOW*&quot;</td>
<td>&quot;#SWITCH*&quot;</td>
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<tr>
<td></td>
<td>&quot;# PICC*&quot;</td>
<td>&quot;* FLOW*&quot;</td>
<td>&quot;#LOAD*&quot;</td>
</tr>
<tr>
<td></td>
<td>&quot;# CLAMP*&quot;</td>
<td>&quot;* FLOW*&quot;</td>
<td>&quot;#MIS*&quot;</td>
</tr>
<tr>
<td></td>
<td>&quot;# POLE*&quot;</td>
<td>&quot;* FLOW*&quot;</td>
<td>&quot;# MIXED*&quot;</td>
</tr>
<tr>
<td></td>
<td>&quot;# CVAD*&quot;</td>
<td>&quot;* FLOW*&quot;</td>
<td>&quot;# INSTEAD OF*&quot;</td>
</tr>
<tr>
<td></td>
<td>&quot;# CVL*&quot;</td>
<td>&quot;* FLOW*&quot;</td>
<td>&quot;# WRONG*&quot;</td>
</tr>
<tr>
<td></td>
<td>&quot;* MODULE*&quot;</td>
<td>&quot;* FLOW*&quot;</td>
<td>&quot;#OPEN*&quot;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&quot;* FLOW*&quot;</td>
<td>&quot;# CLOSE*&quot;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&quot;* FLOW*&quot;</td>
<td>&quot;# HIGHER*&quot;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&quot;* FLOW*&quot;</td>
<td>&quot;# LOWER*&quot;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&quot;* FLOW*&quot;</td>
<td>&quot;# DIFFERENT*&quot;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&quot;* FLOW*&quot;</td>
<td>&quot;# MANY*&quot;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&quot;* FLOW*&quot;</td>
<td>&quot;# ALSO*&quot;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&quot;* FLOW*&quot;</td>
<td>&quot;# Duration*&quot;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&quot;* FLOW*&quot;</td>
<td></td>
</tr>
</tbody>
</table>

Table 18 below shows the definitions used for the first pass coding categories and any notes used by the researchers to help ensure uniformity between their coding.
Table 18: Definitions and notes used in the identification of applicable reports and the first pass coding of the Impact and Location fields

<table>
<thead>
<tr>
<th>Applicability</th>
<th>Definition</th>
<th>Additional Notes or Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applicable</td>
<td>Report must <strong>explicitly</strong> mention the presence of a piggyback infusion AND/OR multiple infusions occurring on the patient. If however, it is clear that the only multiple infusions in the report are initiated as a response to patient harm, the report is not applicable or suspected (depending on the rest of the report). It is recognized that this may include some cases that may not be relevant, but this will be addressed in the second coding pass.</td>
<td>The term &quot;secondary infusion&quot; or &quot;piggyback&quot; infusion is explicitly mentioned. The mention of a single drug does NOT make the report applicable, multiple drugs or infusions must be explicitly stated. The only exception to this rule of a single drug not being applicable is the delivery of TPN (i.e. parenteral infusions) as these typically feature the concurrent infusion of amino acids and lipids.</td>
</tr>
<tr>
<td>Not Applicable</td>
<td>Report does not describe an incident related to piggyback infusions or multiple concurrent infusions.</td>
<td>As a simple rule of thumb, if the report does not fit into the other two categories, it must be not applicable by default.</td>
</tr>
</tbody>
</table>
| Suspected      | Report **does not explicitly** describe the involvement of piggyback or multiple concurrent infusions, but because certain keywords or situations are present (see the "Suspected" worksheet in this file), the presence of multiple infusions are suspected to play a role. | }
<table>
<thead>
<tr>
<th>Impact</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazardous</td>
<td>No error, no harm</td>
</tr>
<tr>
<td>Near Miss</td>
<td>Error does not reach patient, no harm</td>
</tr>
<tr>
<td>No Harm</td>
<td>Error reaches patient, no harm</td>
</tr>
<tr>
<td>Harm: Mild</td>
<td>WHO Defn: Patient outcome is <strong>symptomatic</strong>: loss of function or harm is minimal or intermediate but short term, and no or minimal intervention (e.g. extra observation, investigation, review or minor treatment) is required.</td>
</tr>
<tr>
<td>Harm: Moderate</td>
<td>WHO Defn: Patient outcome is symptomatic; requiring intervention (e.g., additional operative procedure; additional therapeutic treatment), an increased length of stay, or causing permanent or long term harm or loss of function</td>
</tr>
<tr>
<td>Harm: Severe</td>
<td>WHO Defn: Patient outcome is symptomatic, requiring life-saving intervention or major surgical/medical intervention, shortening life expectancy or causing major permanent or long term harm or loss of function</td>
</tr>
<tr>
<td>Harm: Undetermined</td>
<td>Harm occured - raters will consult clinical experts to determine if a rating can be determined</td>
</tr>
<tr>
<td>Death</td>
<td>WHO Defn: On balance of probabilities, death was caused or brought forward in the short term y the incident</td>
</tr>
<tr>
<td>Unknown</td>
<td>There is insufficient information in the report to determine whether or not harm occurred.</td>
</tr>
<tr>
<td>Comments (if necessary; describe the importance of the infusions to the outcome)</td>
<td>If the case is particularly complex, comments may be necessary. Also, specifically for cases coded &quot;Death&quot; or &quot;unknown&quot;, it is helpful to have comments to ascertain the importance of the IV infusions to the eventual outcome.</td>
</tr>
</tbody>
</table>

**Note:** If any interventions are described or stated, harm occurred and one of these definitions must be selected. For example, if the report describes an additional drug used to counteract the effects of an overinfusion, but states there was no harm to the patient, we will actually select that harm did occur given the fact that an intervention was administered.
Since not all reports directly used the words secondary, concurrent, or piggyback infusion despite there being some potential for being a multiple IV infusion issue the coding team developed a “Suspected” applicability coding option. This “Suspected” category was created in case at the end of the coding process only a handful of applicable multiple IV infusion incidents were found. If this were to happen the coding teams would investigate the suspected cases further for issues related to multiple IV infusions. Based on the clinical experience of the two researchers from ISMP Canada with a nursing and pharmacy background and literature information it was determined that multiple IV medications are commonly delivered in critical care settings. Therefore a list of terms often associated with critical care settings and drugs often administered in critical care settings was developed based on the literature and clinical experience. If a report returned for the keyword search contained one of these terms the coding team was instructed to classify the applicability of the event “Suspected”. Table 19 and Table 20 below shows the list of terms used for this process and the rules in place surrounding their use.
Table 19: Terms used to denote if a report is suspected to be related to a multiple IV infusion issue, but does not explicitly mention multiple medications being delivered

Note that these keywords should apply ONLY to the "Applicability code". For example, while anaesthesia often occurs in the OR and requires multiple concurrent piggybacks, it is not appropriate to code the location to "Hospital: OR" and the Issue to "Both piggyback and sequential" unless they are explicitly described in the report. If a specific drug name is mentioned it is enough to lead us to code it as "suspected" since drugs are delivered piggyback. Note that basic IV fluids do not count (Dextrose/D5W, normal saline, lactated ringers or mixes of them).

<table>
<thead>
<tr>
<th>Common words associated with critical care</th>
<th>Drug names and class of IV drugs that would only be used in a critical care setting (ICU, PACU, OR, ER, NICU, PICU)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ventilated</td>
<td>Adenosine</td>
</tr>
<tr>
<td>Respirator</td>
<td>Adrenalin</td>
</tr>
<tr>
<td>Intubated</td>
<td>Amiodarone</td>
</tr>
<tr>
<td>Cardiac monitor</td>
<td>Amrinon</td>
</tr>
<tr>
<td>Monitor</td>
<td>Atropine</td>
</tr>
<tr>
<td>Arterial line</td>
<td>Bretyllium</td>
</tr>
<tr>
<td>Art line</td>
<td>Dobutamine</td>
</tr>
<tr>
<td>P.A. catheter</td>
<td>Dopamine</td>
</tr>
<tr>
<td>Swan-Ganz catheter</td>
<td>Ephedrine</td>
</tr>
<tr>
<td>Swan</td>
<td>Epinephrine</td>
</tr>
<tr>
<td>Shock, shocky</td>
<td>Fentanyl – Sublimaze</td>
</tr>
<tr>
<td>Sepsis</td>
<td>Furosemide – Lasix</td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>Heparin (not exclusive to critical care areas but frequently seen there)</td>
</tr>
<tr>
<td>Cardiac</td>
<td>Ibutilide</td>
</tr>
<tr>
<td>Anaesthesia</td>
<td>Insulin</td>
</tr>
<tr>
<td></td>
<td>Isoprenalin</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 20: Further rules used to instruct the coding teams when to code a reports as "Suspfiged" applicability

<table>
<thead>
<tr>
<th>Situations that would lead to &quot;suspected&quot;</th>
</tr>
</thead>
<tbody>
<tr>
<td>The use of antibiotics implies a piggyback is in use. In fact, any drug with the exception of potassium chloride is implied to be given piggyback as the maintenance fluid is used to ensure the patency of the IV access.</td>
</tr>
<tr>
<td>Epidurals are typically given with an IV</td>
</tr>
<tr>
<td>Y sites or Y'd tubing implies multiple connectors and is therefore a reason to place a report under the &quot;Suspfiged&quot; category</td>
</tr>
<tr>
<td>Any reference to a specific pump or channel implies that the reporter is distinguishing the problem infusion from other infusions at the bedside.</td>
</tr>
</tbody>
</table>

Table 21 below shows the second pass coding options for the Cause field. For coding options denoted with an asterisk next to their name please refer to the legend below the table which explains the rules used by the coding teams in coding that category.

Table 21: Second pass coding options for the Cause field and rules used by the coding teams for the coding processes

<table>
<thead>
<tr>
<th>The Cause can be attributed to one of the following categories</th>
<th>For each category, there are more detailed coding options that can be coded</th>
<th>Category Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IV Bags</strong></td>
<td>Wrong Volume in IV Bag</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Wrong Concentration in IV Bag</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Labeling Issues</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bag Height is Incorrect</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Wrong Medication</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Manufacturing Issue*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other (use only when absolutely necessary)*</td>
<td></td>
</tr>
</tbody>
</table>
| **IV Tubing** | Backflow  
Leaks, Breaks and Disconnections  
(if not specific to access site, code it here)  
Misconnections  
Kinks  
Clamps  
Drug Incompatibility  
Manufacturing Issue (product came defective)*  
Other (use only when absolutely necessary)* |
|---|---|
| **Pump** | Pump out of specification (proven by biomed testing)  
Pump reported out of specification (reported, not validated)  
Misprogramming (validated that user misprogrammed)  
Reported Misprogramming (suspected only)  
Power Failure  
Pump Failure  
Pump/channel/bag/tubing Mismatch  
Misloaded Tubing  
Wrong drug order (but programmed correctly)  
Wrong Time or Missed Infusion  
Manufacturing Issue (product came defective)*  
Other (use only when absolutely necessary)* |
| **Pump failure vs Pump out of Spec** | A pump failure results in the pump not pumping. This in turn results in the infusion either not running or freeflowing. In contrast, a pump out of spec results in the pump pumping the infusion, but not within the technical specifications (i.e., too fast or too slow). |
| **IV access site** | Wrong route (epidural, intrathecal, sub Q)  
Wrong site (wrong IV site used)  
Accidental leak, break or disconnection  
Infected line  
Manufacturing Issue (product came defective)*  
Other (use only when absolutely necessary)* |
| **Other** |  |
| **Undetermined** | Reports with conflicting information or minimal information |
**General Notes**

**"Other"**
Only use "Other" when the incident cause doesn't fit into any of the other coding options (i.e., err on the side of force fitting into a category). However, this coding option may be required when:

a) the incident cause is not listed in a category
b) an incident cause cannot be determined because of insufficient information (i.e., undetermined). Note: state "undetermined" in comments

c) the incident has multiple contributing causes without a dominant cause (i.e., cannot force fit into one category)

**"Manufacturing Issue"**
When coding an incident as a Manufacturing Issue, make sure it is clear that the product came like that. That is, it is not possible that the nurse or support staff damaged the pump and/or tubing. If the incident meets this definition, then this subcategory prevails over other subcategories (e.g., if the tubing leaks as a result of a manufacturing issue, then the subcategory is "Manufacturing Issue" and not "Leaks, Breaks and Disconnections"). However, if it is not 100% clear the tubing was manufactured with a leak, then code it as "Leaks, Breaks and Disconnections")

**Communication Issue**
Incidents with communication issues should be directed to "Wrong Drug Order" or "Wrong Time or Missed Infusion" under Pump

**Comments**
Comments only when issue is not clear
Appendix C: Database Coding Inter-rater Reliability Results

The kappa value results of the first and second pass inter-rater reliability testing are shown in Table 22.

Table 22: Fleiss’ Kappa results for establishing inter-rater reliability

<table>
<thead>
<tr>
<th>Inter-rater Category</th>
<th>ISMP Fleiss’ Kappa</th>
<th>HTSRT Fleiss’ Kappa</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Pass Coding</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Applicability – First Set</td>
<td>0.63</td>
<td>0.50</td>
</tr>
<tr>
<td>Applicability – Second Set</td>
<td></td>
<td>0.78</td>
</tr>
<tr>
<td>Impact</td>
<td>0.81</td>
<td>0.63</td>
</tr>
<tr>
<td>Location</td>
<td>0.75</td>
<td>0.80</td>
</tr>
<tr>
<td>2nd Pass Coding</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cause – First Set</td>
<td>0.58</td>
<td>0.65</td>
</tr>
<tr>
<td>Cause – Second Set</td>
<td>0.57</td>
<td></td>
</tr>
<tr>
<td>Cause – Third Set</td>
<td>0.69</td>
<td></td>
</tr>
</tbody>
</table>

Using the first 30 reports in the incident databases the inter-rater reliability for the coding of the applicability was determined. ISMP Canada scored a Kappa value of 0.63, thus establishing inter-rater reliability for their team. Initially two raters from the HTSRT coded the first 30 reports from the MAUDE and scored a Kappa value of 0.5. This value was deemed too low for establishing inter-rater reliability and the HTSRT had to code a second set of 30 reports. At this point another researcher became available and joined the HTSRT for the remainder of the project. Upon coding the second set of 30 reports the Kappa value was calculated to be 0.78, regarded as a high level of agreement.

Using the first 30 reports deemed as “applicable” by the members of each database team the inter-rater reliability for the Impact and Location fields was determined. ISMP Canada established Kappa values of 0.81 and 0.75 respectively. The HTSRT established values of 0.63 and 0.80 respectively. As all Kappa values were above the 0.60 value for denoting a substantial level of agreement there was no need for a second attempt at establishing inter-rater reliability.

Using another set of 30 “applicable” reports the inter-rater reliability was established for the Cause field. The HTSRT established inter-rater reliability on their first set of 30 reports with a Kappa value of 0.63. ISMP Canada required three sets of 30 reports, scoring Kappa values of 0.58 and 0.57 on the first two sets before establishing inter-rater reliability on the third set with a Kappa value of 0.69. As the single Kappa value accounted for all 35 Causal coding options,
reflecting agreement between researchers in coding a report in 1 out of 35 possible Cause options, the inter-rater reliability should be considered relatively high.