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Analytical Methods to Support Risk Identification and Analysis in Healthcare Systems

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by

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Dedication

To Ehsan, who supported me in every way that one can be supported. To my mom, who always called to make sure I eat well. To my dad, who believes in me from the distance. To my family and to all my friends. To Andrea, tia Ruby, Paola, Dayna, Adalgiza, Gina, Andres, Erika, Alejandro, Nadia, Claudia Avendaño, Juancho, Johanna, tia Yamila, Lissette, Marelbis, tia Linda, Shary Rose, Monica, Laura and Sandra, who gave me "animo" when I needed it. To Tuly Andrea, who sent me inspiring music when i most needed it. To God, who never left me alone.

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Abstract

Healthcare systems require continuous monitoring of risk to prevent adverse events. Risk analysis is a time consuming activity that depends on the background of analysts and available data. Patient safety data is often incomplete and biased. This research proposes systematic approaches to monitor risk in healthcare using available patient safety data. The methodologies combine traditional healthcare risk analysis methods with safety theory concepts, in an innovative manner, to allocate available evidence to potential risk sources throughout the system. We propose the use of data mining to analyze near-miss reports and guide the identification of risk sources. In addition, we propose a Maximum-Entropy based approach to monitor risk sources and prioritize investigation efforts accordingly. The products of this research are intended to facilitate risk analysis and allow for timely identification of risks to prevent harm to patients.

Chapter 1: Introduction

In 1999, the Institute of Medicine (IOM) reported that errors in healthcare are a "leading cause of death and injury" in the United States. The IOM estimated that up to 98,000 people die annually in hospitals in the U.S., due to preventable adverse events. The total cost of these errors was estimated to be between $ 17 and $ 29 billion, with direct health care cost representing about 50 %. In 2010, HealthGrades reported that one million patient-safety incidents occurred from 2006 to 2008 among Medicare patients. One in ten patients that experienced a patient-safety incident subsequently died. Costs related were estimated to be $8.9 billion [1]. The report notes that there are 40,000 harm-related events daily [2].

According to IOM, all health care settings should implement patient safety programs that continuously seek to identify system failures and analyze their contributing factors, to design safer systems. IOM recommends that patient safety programs focus on: the identification, analysis and classification of patient safety events, the enhancement of surveillance strategies, and the design of systems that prevent errors [3]. In Florida, it is mandatory that healthcare organizations have a risk management program that includes formal incident reporting and analysis. Although reports of less severe incidents, and their management, are internal to each organization, reporting and analysis of adverse events is required by the Agency for Health Care Administration (AHCA) (Florida Statute, Chapter 395.0197) and other (accrediting) agencies. The management of incident reports includes

the identification of related risks and analysis of causes to develop solutions that prevent similar situations from taking place in the future.

To identify risks, healthcare organizations have a risk domain that they use to characterize and classify incidents, and other types of data available, i.e. patient safety data (malpractice claims, patient complaints, quality indicators, rounds, and administrative information, among others). This domain allows for the analysis of data by areas of interest. A healthcare risk manager or a patient safety officer collects and combines patient safety data to identify potentially relevant trends and patterns. Tools recommended for the analysis of such statistics include Run Charts, Pareto Charts and Histograms [4].

Once risks are identified, possible causes should be tracked to determine appropriate solutions. In human-driven systems, human error is generally pointed as the major cause of adverse events [5, 6]. Identification of causes has been traditionally followed by blame and litigation, changes in procedures, and training of individuals involved. It has been argued that methodologies for identification and classification of causes of adverse events are influenced by hindsight [7] and background bias, which suggest that different investigators will come up with different explanations [8], limiting the consistency of conclusions and efficacy of solutions derived. Fortunately, healthcare organizations are recognizing the benefits of having a a systems view of their processes. A systems approach recognizes that healthcare workers are part of a bigger system that is faulty as a whole. Therefore, systems should be designed taking into consideration potentially dangerous interactions among people, facilities and equipment, and ensuring that these are constrained from situations that may lead to adverse outcomes.

The most commonly used risk identification methods are Failure Modes and Effects Analysis (FMEA) and Root Cause Analysis (RCA). FMEA is a prospective method that uses brainstorming to combine experts' opinions to measure and rank risks. RCA is a retrospective methodology based on investigation procedures. These methods provide tools to organize current information and data about risk, but data processing and anal-

ysis depends mostly on the investigator. Therefore, these risk analysis methods are time consuming, infrequent, and exhibit some bias. The main reason for the popularity of these types of analysis lies on the availability and format of available data.

A major concern for the IOM, and a challenge for healthcare organizations, has been the lack and limitations of patient safety data to allow for analysis using traditional, statistics based risk analysis techniques. Patient safety data consist of facts, observations, or measurements that lead to the identification of failures that harmed (or could have harmed) patients. Adverse events are the most common form of patient safety data because they presumably evidence failure. However, not all adverse events are caused by failures in the system, and not all failures in the system result in adverse events. Alternative forms of patient safety data include near-miss reports, compliance, and assessment of safety culture [9–12]. This challenge opens up an area of research that rises from the need to develop methodologies that systematically process patient safety data in a timely and unbiased manner.

The need for the development of formal tools to systematically organize, process and analyze patient safety data is important to provide direction for risk analysis, and to help analysts in their efforts to make sense of risk. Centralized and automated data analysis helps "overcome limitations of the human mind" [13]. Such analysis also allows for the identification of interactions or potential risk sources that the naked eye is likely to miss, and improves the timeliness of feedback. Risk managers could then focus on understanding the system, identifying sources of risk and developing strategies to prevent or solve patient safety problems.

Healthcare risk analysis should accommodate inputs from expertise and keep track of the learning that takes place over time. The development of healthcare risk analysis support tools requires the use of models that capture existing risk knowledge and relate it to upcoming patient safety data. The fields of general safety and reliability provide models that could potentially be adapted to the healthcare environment. For example, several

authors [14–17] propose to view risk and accidents in terms of ineffective safety constraints and controls. These models provide insight into what can be defined as sources of risk, and thus monitored over time to track and prevent potential failures. In addition, there are modeling techniques intended to cope with limitations and uncertainty of data. For instance, the principle of maximum entropy is often used to estimate a probability distribution when available data is incomplete [18].

Most of these models have been successfully applied to in different contexts. Nevertheless their application to risks in healthcare systems has not been extensive due to the nature of these kinds of systems. Different approaches will pose different challenges when applied to healthcare environments. For example, in human-driven systems, such as healthcare, each component of the system, as well as all possible interactions, can be regarded as a potential source of risk. There are infinitely many interaction possibilities, so analysis including all of them would be impractical. Thus, there is need to develop models of risk in healthcare systems that explicitly define and characterize potential risk sources.

This research explores the use of analytical tools to support the systematic analysis of patient safety data to monitor risk and its sources. The next chapter introduces the state of the art of risk analysis in healthcare systems, and presents a framework for the development of models intended to support patient safety management. This chapter corresponds to a paper that is currently submitted for publication. Chapter 3 presents the development and implementation of a near-miss reporting and analysis system to guide the identification of sources of risk. This chapter corresponds to a paper accepted for publication in the Journal of Biomedical Informatics [19]. Chapter 4 introduces the concept of patient safety interventions and illustrates their use in characterizing potential sources of risk to facilitate risk analysis using traditional methods. Chapter 5 proposes a model based on the principle of maximum entropy to assess the performance of patient

safety interventions in terms of available data. Finally, chapter 6 presents a summary of this dissertation and comments on future research directions.

Chapter 2: The Challenge and Opportunity of Modeling Risk in the Delivery of Healthcare

2.1 Introduction

In 1999, the Institute of Medicine (IOM) reported that errors in healthcare are a "leading cause of death and injury" in the United States exceeding motor vehicle accidents, breast cancer and AIDS [20]. The IOM estimated that up to 98,000 people die annually in hospitals in the U.S. due to preventable adverse events. The total cost of these errors was estimated to be between $17 and $29 billion with direct healthcare cost representing over 50%. Following this report, in 2005 the IOM reported that "at least 1.5 million Americans are sickened, injured or killed each year by errors in prescribing, dispensing and taking medication", with extra medical costs conservatively estimated to be $3.5 billion a year [21, 22]. In 2008, a study from AHRQ (Agency for Healthcare Research and Quality) estimated the costs of surgical errors to be nearly $1.5 billion per year for employers and insurance companies [23]. In 2010, HealthGrades reported that one million patient-safety incidents occurred from 2006 to 2008 among Medicare patients. One in ten patients that experienced a patient-safety incident subsequently died. Costs related were estimated to be $8.9 billion [1]. The report notes that there are 40,000 harm-related events daily [2]. Furthermore, there are indirect costs of errors that affect patients (opportunity costs, loss of trust in the system, diminished satisfaction, time lost from work, and physical discomfort), healthcare professionals (diminished satisfaction, loss of morale and frustration), society (lost worker productivity, reduced school attendance, lower levels

of population health), and the healthcare system (cost of error mitigation, and litigation) [24].

Healthcare demands the effective monitoring and control of systems, so that they actually contribute to improve the health of the community and consequently maximize the value of health expenditures [25]. Many health care institutes and associations have called for the development and implementation of tools to assist in the reduction of preventable adverse outcomes in the delivery of care. These efforts fall under the umbrella of patient safety which basically implies the prevention of harm to patients as a consequence of the delivery of care [26].

Healthcare managers and other stakeholders should be provided with effective tools to understand the system and monitor risks that compromise patient safety to define priorities, allocate resources and evaluate potential solutions, This article presents an overview of common methods used to assess and monitor risks in healthcare, as well as in other industries, and explores alternative model-based methods proposed by several authors to identify opportunities for modeling risk in the delivery of healthcare.

Over the years, several methodologies for the identification, evaluation and management of risks in healthcare have been proposed by safety, health, and engineering investigators [27, 28]. These methods are focused mostly on analyzing adverse events and identifying the source of human error. It has been argued that hindsight and background bias may limit the consistency of conclusions drawn from such methods, and therefore the efficiency of derived solutions [7, 8]. The effective identification of actual errors and their differentiation from system failures will lead to increased opportunities in improving outcomes in healthcare delivery.

This paper focuses on exploring the state of the art of the identification, assessment and control of risks that compromise patient safety to develop a framework to support model-based risk management. The aims of this article are: (1) to explore the existing patient safety knowledge base, (2) to review analytical tools currently used in healthcare

organizations to manage patient safety and (3) model-based methodologies, proposed or applied in patient safety efforts; and (4) to identify opportunities to enhance the analysis of risks in the delivery of care to support patient safety management through modeling. We review the safety and patient safety literature with emphasis in risk assessment and monitoring, as they relate to the study and prevention of adverse events.

The article is organized as follows. Section 2.2 addresses aim (1) by introducing concepts related to patient safety, including quality of care and human error. Section 2.3 addresses aim (2) by presenting an overview of safety and concepts related, emphasizing the case of aviation. Section 2.4 describes healthcare risk management through patient safety programs and introduces models found in the literature, thus addressing aim (3). Section 2.5 addresses aim (4) by discussing the desirable characteristics of models intended to monitor risk in healthcare processes. Concluding remarks are summarized in section 2.6.

2.2 Healthcare Delivery: Quality, Patient Safety and Human Error

The products of healthcare processes are mainly services intended to improve quality of life, generally in the presence of an illness or an undesirable condition. These services are expected to diminish or (hopefully) eliminate such conditions. Yet, current evidence suggests that healthcare delivery adds risk to the condition of the patient [29].

Healthcare delivery systems are socio-technical structures that encompass different levels of influence, e.g. operations, management, and regulators [17, 30–32]. The interactions of components within and across different levels are ultimately driven by patient needs. As a result, healthcare delivery is a dynamic, human-oriented system whose components are connected by education, laws, policies, protocols, and procedures [14].

At the operational level, the human oriented nature of healthcare systems implies that provider knowledge, skills, and even mood, may influence performance [33], as in the case of diagnosis [34]. This effect is compounded by patient differences. Although some

decision support tools such as evidence-based care are available, they do not guarantee homogeneity in outcomes. Therefore, healthcare outcomes exhibit high variability, which affects the quality of care [35].

The IOM defines quality as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" [36]. Safety is the first of six aims of the IOM for a quality healthcare system, together with effectiveness, patient centeredness, timeliness, efficiency and equitability. Safety is an "important subset of quality" that depends on the interaction of the components in the healthcare system [37]. In contrast to other sectors, quality and safety are directly intermingled in healthcare [5]; failures that jeopardize patient safety negatively impact quality [38]. Conversely, quality improvement programs can enhance patient safety [35].

According to the National Patient Safety Foundation (NPSF), patient safety refers to "avoidance, prevention and amelioration of adverse outcomes or injuries stemming from failures in the processes of healthcare itself" [37]. In human-driven systems, such as healthcare, human error is the most accounted cause of failure [5]. It has been estimated that 70-80% of the investigations of accidents conclude that human error is the main cause [6, 17]. A reason for this is the significantly improved reliability of the technology used in high risk industries, such as chemical and nuclear power plants [39]. Although there are several methodologies that claim to offer a systematic approach to determine causes of events, most of them are influenced by hindsight [7] and background bias, which suggests that different investigators will arrive at different explanations [8].

In reality, not all adverse events are caused by errors. System failures may be hidden (in the blunt-end) and cause harm when aggravated by human performance (sharp-end). On the other hand, not all errors result in adverse events [40]. Error outcomes range from those that occur without injury to those that cause preventable death. In general, we refer to two possible error outcomes: near-misses and adverse events.

Adverse events are preventable outcomes that develop into temporary or permanent disability, or death. In healthcare, not all fatal outcomes are caused by errors since they can be a natural consequence of the disease, and may not be preventable. Yet, adverse events are the most known types of outcomes of medical errors, since they are the focus of classic patient safety reports. On the other hand, near-misses (a term borrowed from aviation) denote adverse events that did not occur because of the intervention of an individual or by a "fortunate" natural evolution of the circumstances [41]. Near-miss in a clinical context refers to incidents that produce no harm.

Dillon and Tinsley [42] suggest that, while adverse events are considered evidence of failure, near-misses are often perceived as successful outcomes rather than potential failures. Still, near-misses are believed to share most of the characteristics of adverse events, including their causes [43]. Furthermore, they may evidence the potential for adverse events [12, 32]. Even so, most efforts to improve patient safety focus on studying observed adverse events. Patient safety has traditionally relied upon error identification, blame allocation, and litigation. However, the literature shows a trend to encourage a system approach to safety [44]. A system approach consists of designing systems that, while considering the vulnerability of the human condition, identify sources of error, help prevent them, and avoid harm to patients [45, 46].

A systems approach to safety is supported by Reason's studies of human error and system disaster in which harm is defined as the consequence of a series of components failing to protect against error [47]. In this context, the cause of errors is not careless workers, but defective systems which, once improved, can significantly reduce preventable harm [46]. According to Cook and Woods [48] people should be considered as the "primary source of resilience in creating safety" and they must be provided with the tools to understand the systems and their gaps so they can be proactive under any circumstance.

The IOM urged healthcare organizations to prioritize patient safety through the creation of patient safety programs that aim to prevent harm to individuals [20]. Currently,

these programs are a requirement for the accreditation of hospitals by the Joint Commission (JC). Therefore, most organizations have established patient safety committees [46, 49, 50]. Patient safety programs focus on the identification, analysis and classification of error-triggering events and the design of systems that prevent errors [26]. Some argue that the rate of development of such programs needs to increase [3] and most organizations still appear to lack in the implementation of fundamental quality and safety standards [45, 51, 52].

2.3 Risk Assessment and Hazard Identification

Safety is a condition that denotes freedom from harm [49]. It is a "dynamic property of systems" [53] that is directly related with the effective management of errors under the presence of situations that have the potential to damage or deteriorate the quality of life of individuals or communities [54, 55]. As a science, safety uses theories of accident causation and systems' models to identify root causes of failures. It aims to keep individuals from harm by identifying hazards and providing guidelines to prevent failures or protect from the effects of possible adverse outcomes. The identification of hazards and quantification of potential harm have been challenging topics for safety experts in all fields. One way to measure potential harm is to assess the probability and severity of potential adverse events.

The combination of the probability of adverse events and the severity of their potential harm under dangerous conditions is called risk. The lower the risk is, the safer the system appears to operate. Every process has some risk. Risks can be tangible, such as exposure to gas, and intangible, such as the potential for terrorist attacks. Tangible risks are easier to study because they involve a physical and measurable feature, while intangible risks have to be assessed through other, observable characteristics of the system that appear to be correlated.

Risk management focuses on identifying, modeling, monitoring, and analyzing hazards to determine how safe systems are. As the system grows in complexity or delicacy, the risk management function becomes more critical and difficult since models are harder to develop and validate [56].

Traditionally, adverse events are investigated to identify their sources (or hazards) and prevent their recurrence. Yet, some of the most devastating failures are rare events and their probability of recurrence is very low. Frequently, accident investigations tend to focus on human factors as the cause and solutions generally consist of system redesign, making it more complex and introducing new, unrecognized hazards [56, 57]. These new latent failures will become a concern when their undesirable consequences are observed.

The availability of reliable data on the frequency and the nature of failures allows for the development of models that provide a practical way to understand risk and enhance safety by giving insight into the causes of failure and their possible consequences [58]. Lack of data implies that models may not represent reality and strategies to prevent adverse events may not match what is needed [54, 59].

Gathering data is more difficult when dealing with intangible risks. For example, preventing gas poisoning in the workplace can be achieved by measuring and monitoring gas concentration with a sensor and activating an alarm when current concentrations go above safe levels. However, defining and monitoring an indicator for the probability of the occurrence, and expected consequences, of errors in medical decision making is not straightforward. In this case, more expertise and deeper analysis is required [60]. Healthcare delivery is an example of a system were intangible risks prevail. In such cases, properly designed reporting systems could provide relevant information on hazards, failures and potential consequences.

Systematic reporting helps to identify the weaknesses of the system before an accident occurs. For example, effective near-miss reporting allows proactive learning and efficient management of risk, therefore improving safety [61]. Schemes for reporting near misses

have been institutionalized in aviation, nuclear power environments, petrochemical processing, steel production and military operations. Near-miss reporting in aviation and the nuclear power industry is non-punitive. The aviation sector gathers information on near-misses that are investigated by the National Transportation Safety Board. These data come from incident reporting systems and have been used to redesign aircraft, improve air traffic control systems, and enhance pilot training [11]. However, data by itself is not enough to enhance safety. Data must be analyzed in an unbiased manner to develop models that lead to valid conclusions about the system's operation. Below are some of the most commonly used risk analysis methodologies.

2.3.1 Risk Analysis

Risk analysis is a set of systematic activities that lead to the identification and evaluation of potential failures and their consequences. There are different phases in the risk analysis process, such as risk identification, risk modeling, failure assessment, measurement of potential consequences, and development and evaluation of preventive or mitigating actions. There are a number of techniques to support these activities, and their choice depends on the objectives of the analysis, and the characteristics of the system. Risk analysis techniques can be broadly classified as qualitative and quantitative. A complete risk analysis uses a mix of methodologies to address different phases of the process.

Qualitative methods for risk analysis are popular when it is difficult to determine the probability of events. This is the case for events that are highly influenced by human factors, and whose associated data is limited. Besides, these approaches are relatively easy to understand and implement, though time consuming. Qualitative methods broadly consist of the systematic investigation and team analysis of (past or potential) events to determine corrective actions, process redesign, and policy changes. Essentially, they consist of methodical ways to organize available data and draw conclusions from it. Most

of the time, data consist of descriptions of witnesses and experts, and resulting models are verbal and symbolic representations of the system and proposed solutions. Some of the most used qualitative methods are presented in table 2.1. Among these, there are methodologies that guide the investigation of causes such as the traditional Root Cause Analysis (RCA), and Critical Incident Technique (CIT). There are also the tools that aid in the understanding and analysis of the causes and their relations, such as Event and Fault Tree Analysis. Some qualitative tools aid in the (prospective) analysis of potential risks, such as Hazard and Operability Studies (HAZOP). Frequently, qualitative risk analysis is used to identify the likely failures without necessarily measuring their probabilities. In this case, the objective is to introduce defenses that eliminate the occurrence of such failures [62].

Although the immediate benefits of qualitative methodologies have made them popular in most systems, particularly in healthcare, the ability to quantify outcomes from descriptive data is advantageous, especially in evaluating solutions, justifying resources, and monitoring long term effectiveness.

Quantitative methods are mostly used at the technical level where risks are tangible and associated with the reliability of processes, equipment and parts. These methods provide measures of risk and uncertainty allowing for ranking of accident scenarios, prioritization of solutions, allocation of resources, and translation of results into explicit costs and benefits [69].

The lack of structured and consistent data is the prominent issue in modeling and quantifying human-behavior-related risk. Therefore most quantitative approaches base their measures in expert opinions. Lyons et al. [70] present a summary of some popular Human Reliability Analysis (HRA) techniques that have been used, or have potential to be applied, in healthcare systems. Table 2.2 presents some methodologies and tools that have been used in quantitatively assessing risk of systems. The most commonly used is FMEA, which was initially introduced into healthcare in the area of medical devices, but

Table 2.1: Qualitative methods for risk analysis

Root cause analysis **RCA**	Retrospective methodology that addresses the root causes of observed incidents. Seeks answers about the problem, its consequences, and causal relationships. Used to analyze adverse events, near-misses and other important events [60]
Hazard and Operability Studies **HAZOP**	Prospective methodology founded in the principle that hazards are due to deviations from normal operation. Seeks to identify the possible deviations by analyzing the design and operations [63]. Frequently applied in petroleum, petrochemical and chemical industries [64]. Seeks to define detection methods and corrective actions for the most critical failure modes.
Critical Incident Analysis or Technique **CIT**	Retrospective methodology used to collect and analyze reports of behaviors. Determines that an incident is likely to occur with minimum evidence of agreement of independent observers, and provides practical and quick solutions. Applied in business, organizational psychology, education, and industry [65].
Event tree analysis	Visual tool to represent scenarios when specific initiating events occur, and depict the relations between associated events.
First order reliability methods **FORM**	Iteratively calculates a reliability index for limit-state functions of specified input variables such as stress [66]. Used in decision making processes with parameter uncertainty (e.g. analysis of structures dealing with earthquakes)
Fault Tree Analysis **FTA**	Identifies an undesired event, and explores and represents possible causes and their relations by logical connectors “AND” and “OR”. Assesses and measures the availability, maintainability, and reliability of the system, relative to failures [67, 68].

has been recommended by the JC for proactive risk management [44, 46, 71]. Others like PRA have been successfully used in various industrial sectors and have been evolving to be usable in human driven systems (ST-PRA) [28, 50]. However, some believe that their success in such systems has limited potential [14].

The success of risk analysis lies in choosing the right approach to develop risk models that allow learning about how the system performs under different conditions, and assess the effects of proposed changes to make risk informed decisions [62]. Other important success factors include: follow-up to implementation, feedback to decision makers, and monitoring for necessary adjustments or corrections to the initial assumptions, especially when models are adapted from other types of systems or industries.

Healthcare processes are generally compared to aviation processes. Some resemblance can be found in that both sectors have human-technology interactions and involve critical decision-making [72]. Yet there are differences such as the physics/mechanics of the processes that dictate the availability and suitability of predictive models, and how the consequences of a single failure will impact a community. Nevertheless, it is believed that the success in aviation safety enhancement can be translated to healthcare [73].

2.3.2 The Case of Aviation: Near-Miss Analysis

Traditionally, risk analysis is motivated by the occurrence of an accident after which an exhaustive investigation of causes is performed with the purpose of learning from the relations between the 'remembered' inputs and the observed outputs and preventing reoccurrence. Such an approach has limited value in processes like aviation operations where accidents are sporadic but remarkably noticeable [72]. Hence, aviation shifted to an enhanced safety culture that allows proactive risk management by promoting prevention of future (unseen) adverse events.

Table 2.2: Quantitative/semi-quantitative methods for risk analysis

Failure Mode and Effect Analysis **FMEA**	Prospective methodology to identify potential failure modes of activities or systems, assign probabilities and identify causes and effects. Seeks to define detection methods and corrective actions for more likely failure modes.
Failure Mode Effects and Criticality Analysis **FMECA**	New version of FMEA that includes criticality: a relative measure of the consequences of a failure mode and its frequency. Ranks potential failure modes according to criticality. Seeks to define detection methods and corrective actions for the most critical failure modes.
Probabilistic Risk Assessment **PRA**	Organizes the sequence of events through an event tree with probabilities assigned to each branch of the tree. Uses Bayesian analysis to calculate the overall risk. The Nuclear Regulatory Commission requires that nuclear power plants in the United States use PRA to identify and quantify vulnerabilities to failure. PRA has limited use in complex, human-driven systems.
Socio-Technical Probabilistic Risk Assessment **ST-PRA**	Emerged from PRA to include human factors in identifying high priority safety needs.
First order reliability methods **FORM**	Iteratively calculates a reliability index for limit-state functions of specified input variables such as stress [66]. Used in decision making processes with parameter uncertainty (e.g. analysis of structures dealing with earthquakes)
Markov Method	Analyzes systems with constant failure and repair rates. It is based on certain assumptions regarding the transition between states and their probabilities. Used for reliability and human error analysis.
Bayesian Analysis	Estimates the probability of expected events given the occurrence of some other observable and related events.
Simulation	Uses a physical or a mathematical model of the system to observe failure modes, or outcomes from different scenarios. Used in industrial systems, and in training.

Aviation safety-committed culture is rooted in the following principles: (1) there is no such thing as an error-free environment, (2) errors are mostly due to faulty systems and system design, (3) reporting must stimulate error information sharing, (4) adverse events are the "tip of the iceberg", and (5) failure prevention must be a continuous effort [73]. Aviation risk management strategy includes: continuous teamwork training (crew resource management, CRM); standardizing error investigation, documentation and feedback; promoting the participation of all personnel in safety related endeavors; and using data to guide changes and improvement initiatives.

There are several complementary sources of data related to aviation safety. Some examples are observation of normal flights, crew surveys and incident reporting. Non-punitive incident reporting allows the identification of error inducing conditions [72]. In aviation, incident reporting has been broadened to include near-misses in an effort to identify latent failures and prevent their realization.

Gathering and analyzing reported near-misses focuses on learning from accidents or events that did not happen, providing information on both the factors that triggered such events and those that prevented them. Besides aviation, near-miss reporting and analysis has been adopted by chemical and nuclear power plants. The Wharton School of Management [74] illustrates how accidents can be reduced with systematic near-miss analysis. Near-misses are much more common than actual accidents, but are not easily observable, so a well designed infrastructure for identifying and reporting near-misses, analyzing them, and disseminating feedback is required. Such a structure must be confidential and non-punitive.

Aviation incident reporting is based on guidelines established by NASA's Aviation Safety Reporting System and the UK Confidential Human Factors Incident Reporting scheme (CHIRP). In this system, pilots and other crew members describe how adverse event precursors are detected and mitigated. This information is then published in newsletters and websites to inform staff of potential hazards [75]. Incident reports have led to

improved maintenance and flight operations as well as equipment redesign. Nevertheless, since the nature of this reporting system is voluntary, there is not sufficient information to confidently determine error rates [72].

The US Aviation Safety Reporting System consists of teams of trained coders who analyze each reported incident. The analysis of approximately 30,000 reported incidents is estimated to cost about $3 million annually (about $100 per case) [75]. Unfortunately, the frequency of incidents in healthcare is expected to significantly exceed aviation's. Estimates suggest that around one million serious errors occur each year [76]. This potential massive amount of data collection makes the development and implementation of a national reporting/analysis system costly and logistically difficult to implement [75].

These observations tend to discourage development and implementation of similar approaches in healthcare. Nevertheless, near-miss analysis is recommended by the IOM to understand, monitor, and enhance mindfulness of the risks in the system. Near-miss reporting has been introduced in some patient safety programs in hospitals, although implementation has been slow and analysis has been limited. In general, healthcare risks share many characteristics with other high risk industries but require consideration of the particular attributes before attempting to implement seemingly successful models.

2.4 Risk Management in the Delivery of Healthcare

2.4.1 Risk and Patient Safety

Patients are exposed to two types of risks. The first is the risk inherent to their medical condition, i.e. the clinical risk. This risk encompasses the risk brought by the patient (risk of the disease itself as well as co-morbid conditions) and the risk brought by the intervention or treatment. Observing an actual adverse event related to this risk depends on the development of the disease and on the appropriateness and effectiveness of treatments.

The second is the risk of experiencing an adverse event due to unintended performance of the healthcare delivery system, i.e. healthcare delivery risk, regardless of the medical condition. This risk compromises patient safety and is the focus of this section.

Traditionally, patient safety has been conceived as a quality matter. The concept of risk has been used in a delivery context to measure quality of care. For example, in acute care hospitals, morbidity and mortality outcomes are studied by statistically removing the effects of the patients' clinical risk factors on the rates. In these so called risk-adjusted outcome measures, the healthcare delivery process is a "black box". Its quality is measured as the variation of the risk-adjusted outcomes [77–79].

Today, patient safety efforts are focusing more on understanding the "black box", and identifying sources of healthcare delivery risks. According to the JC [80], healthcare delivery risks stem from failures in communication among patients, practitioners, and staff; substandard patient management; and faulty performance before, during and after a clinical intervention. Causes include organizational failures in areas such as management, organizational culture, and protocols/processes (latent failures); technical failure, and human error (active failures) [81]. Efforts to reduce risk should use some of the principles of high reliability organizations (HRO's) such as focus on identifying, understanding and preventing failures and (or) their consequences on the system. HRO's build and adapt their processes based on "risk awareness and acknowledgement" [82]. Understanding the system is fundamental to controlling risks. In the case of dynamic systems such as healthcare, continuous monitoring of system behavior is vital to detect potentially induced risks.

The 1999 IOM report presents several recommendations to enhance patient safety. The establishment of safety programs in hospitals is one of them. As a result, some risk analysis tools such as FMEA and RCA have gained popularity in the evaluation of risk in healthcare systems and outcomes. Similarly, PRA and variations have been proposed in patient safety research initiatives as an appropriate tool for the prospective analysis of risk

in healthcare delivery systems [28, 83]. However, the benefits offered by these tools in dynamic, complex, human-driven systems are not consistent over time so, an innovative theoretical platform is needed [14].

A major concern of the IOM is the lack of safety data to use conventional analysis techniques. Therefore, in 2004, an IOM committee presented a plan to develop patient safety data standards [26]. The report describes the IOM's vision of a national health information infrastructure that integrates clinical information with patient safety data to support decisions of providers and patients. The efforts of the federal government to establish a system that guarantees continuity of healthcare data for military personnel transitioning to the veteran's affairs system are steps toward building that infrastructure [84].

2.4.2 Patient Safety Data

Patient safety data include any piece of information that leads to the identification and measurement of failures in the healthcare delivery system that have the potential to harm patients. Adverse events are the usual form of patient safety data because they presumably evidence failure. However, as previously stated, patient safety data should not necessarily be restricted to adverse events, since not all adverse events are caused by failures in the system and not all failures in the system result in adverse events. Alternative forms of patient safety data include near-misses, compliance with safe practices, and assessment of safety culture [9–12]. Preferred choice of data depends on the problem or the intervention being evaluated [85] and on the "information infrastructure" of the institution.

Current sources of patient safety data include: mandatory and voluntary incident reports, RCA reports, morbidity and mortality cases, malpractice claims [86], chart reviews, case reviews, direct observation, and patient administration system (PAS) surveillance

[27]. Each source of patient safety data has its strengths and weaknesses. For example, compared to other sources, chart review may identify a larger number of incidents [87]. On the other hand, direct observation helps identify errors (commission/omission) directly related to human performance [88]. However, these methodologies are costly and time consuming. For this reason, chart review and direct observation are mostly used in time-limited or problem-specific studies [89]. It has been argued that different approaches lead to the identification of different types of incidents. It is recommended that several sources of safety data are used [87]. Currently, incident reporting and retrospective identification of causes have become the typical approach to manage patient safety [7, 46].

The IOM emphasized the use and standardization of incident reports to assess and improve safety [20, 26]. Most proposals of reporting systems found in the literature focus on actual errors [7, 90, 91] and only recent ones include near-miss reporting [9]. By 2008, twenty seven states had established mandatory reporting of adverse events [92, 93]. Florida [94] and New York [95] have used voluntary near-miss reporting systems to provide some feedback in the form of advisories. Some institutions have implemented internal, voluntary near-miss reporting systems [96]. Nevertheless, data structure, reliability and analysis vary among states and institutions; the validity and sharing of information remain a challenge.

The IOM stresses the relevance of reporting and analysis of near-misses for: modeling, to understand how failures become near-misses or adverse events; trending, to study/monitor the distribution of failure; and enhancing alertness when clear adverse events have low frequency. However, most analyses focus on trending. There is the need to develop models to support the analysis of near-misses, as well as other types of patient safety data.

Since most reports consist of free text, their analysis is done by experts who review, classify and code each report according to a taxonomy that allows for context-specific interpretation [97–99]. Trend analysis of aggregate classified reports helps determine

areas that require deeper investigation [87] and establish priorities through Pareto charts [26]. Some authors have proposed enriching incident reports by linking them to electronic medical records so that the analysis includes patient risk factors [100]. Bilimoria et al. [101] propose an application that tracks previous occurrences of electronic reports, so that the analysis pinpoints potential system problems.

Incident reports are also analyzed individually to identify root causes, similar to the Aviation Safety Reporting System [102]. In the case of near-misses, RCA is believed to lead to the identification of potential adverse events and their causes [29, 73]. In general, the identification of causes leads to interventions, or system changes, aiming to improve future outcomes. Additionally, individual near-miss analysis allows for the identification and understanding of effective recovery procedures. These (recovery strategies) help strengthen general procedures, and develop tools to prevent/protect against failure [103]. However incident reporting alone does not suffice to identify and prevent adverse events [87, 89, 98] because of biases in the data, such as incompleteness and lack of timeliness, embedded in reports [104].

The IOM patient safety research agenda includes the development of error/recovery models and the integration of retrospective and prospective risk analysis techniques [26]. They recommend the use of visual models (cause-effect/Ishikawa) diagrams and process flow diagrams) to create a shared understanding of the system, enhance incident analysis, and validate proposed solution approaches. Such models should allow for the use of available data to evaluate system performance and provide necessary information to providers to deliver appropriate and safe services [105].

So far, we have presented the state of the art of current practices in healthcare risk management as they relate to patient safety. In the process, we have identified several opportunities for improvement in the way risks are currently identified, assessed and monitored. These opportunities include the need for the identification of system failures versus human error, the lack structured and consistent data and/or analysis methods that

are appropriate for the data that is available, the need for guidelines to select or develop appropriate risk analysis models and methods that will lead to better understanding the system and support decision making, and the need for a theoretical platform for continuous monitoring to detect potentially induced risks over time. In what follows, we present the results of our review of the literature on model-based approaches in healthcare systems to understand and control risks that compromise patient safety.

2.4.3 Models for Risk in the Delivery of Healthcare

Valid visual models provide the basis for the development of back-end analyses that are able to represent the behavior of the system in terms of its critical variables. The most commonly used model in patient safety is the Swiss cheese model proposed by Reason (1990). This model provides a basic representation of the behavior of system failures, and has become the foundation of most risk analysis approaches [44]. There are several models that have been proposed to characterize safety in all types of industries, and have become the foundation of safety theory [14, 106]. Still, the use of such models in healthcare initiatives has been limited. There is the need to advance healthcare beyond other industrial settings that are concerned with the development and application of formal models to understand, monitor and make decisions related to safety.

Models are relevant in the implementation and evaluation of proposed solutions or interventions. Nevertheless, the actual use of models for systematic analysis in patient safety management is scarce. The literature presents some isolated instances of proposals and/or applications of models that address risk, or safety, in the delivery of healthcare. The models are rooted in theories of system dynamics, reliability, (occupational) safety, and quality control.

Carayon et al. [71] proposes a model of the healthcare delivery system that includes patient safety. The Systems Engineering Initiative for Patient Safety (SEIPS) model char-

acterizes system components and their interactions to identify their potential effects on patients, healthcare workers and the healthcare organization. The model is built upon concepts from human factors, systems engineering and well-known healthcare quality models to facilitate the understanding of the system and risks that compromise patient safety.

Cook and Rasmussen [107] present a system dynamics model that illustrates how congestion in a surgical intensive care unit (ICU) causes other hospital units to alter their operations by delaying transfers and changing operational plans, thus jeopardizing patient safety. Lee et al. [108] proposes the use of causal loop diagrams from system dynamics as an alternative to flowcharts to represent and analyze adverse events. Similarly, Cooke and Rohleder [32] use system dynamics to illustrate their proposed learning approach to enhance safety in organizations. The author models risk as a hidden system that is parallel to the service system, and has its own outcomes. System dynamics has been used in healthcare systems analysis to identify bottlenecks and improve flow [109] since some believe that it provides sound methods to address the "dynamic complexity of health systems" [108]. Nevertheless, system dynamics based models have had limited application in patient safety.

Effken et al. [110, 111] propose the use of simulation to model the performance of a healthcare service delivery unit, and evaluate strategies to improve outcomes (quality and safety). The authors build a causal model of the impact of patient, unit and organization's characteristics in outcomes (medication errors and falls). Then, they develop the simulation model using a tool (OrgAhead) that was originally created to analyze organizational behavior, and that considers decision making and learning. Currently the model is undergoing additional revisions. Systems simulation applications in healthcare delivery have mainly focused on patient flow and capacity analyses. Applications in patient safety are scarce because of the difficulty in modeling and validating variables related to human behavior.

Dhillon [112] proposes to apply traditional reliability models to healthcare systems, defining failures as errors. He defines the "reliability" of a healthcare professional as his/her probability of not committing an error. A known statistical distribution for the time-to-err is assumed, to conventionally estimate the reliability. The author also illustrates the potential use of Markov models to estimate this reliability, as well as the reliability of the delivery system. Likewise, Pate-Cornell et al. [113, 114] use a Markov process for the analysis of risks in an anesthesia delivery system. The states of the process are determined by the states of the anesthesia system (resources, providers) and the patient responses. The measure of interest is the limiting probability of reaching one of the limiting states: brain-damage/death or recovered-patient. The model is used to evaluate the effect of organizational factors on the state transition rates and hence on the limiting probabilities. The results of the corresponding analysis are used to support the evaluation and prioritization of strategies to prevent anesthesia adverse events.

Pradhan et al. [115] show how to use sequence diagrams to model information flow in healthcare processes and identify potentially risky activities or interactions. The authors then estimate the probability of failure in patient care episodes assuming that processes within are independent of each other and using reliability of serial systems models. They also use utility theory to estimate an expected value for the effects of failures in patient care episodes.

Ekaette et al. [116] proposes the use of probabilistic trees to analyze a radiation treatment delivery system. After careful study and analysis of the system, the authors identified potential accident scenarios, and determined causal relations. Probabilities were assigned using expert knowledge. The authors show that probabilistic tree analysis is as useful as incident reporting to identify system vulnerabilities.

Cooper and Lipsitch [117] proposes to analyze hospital infection data through Hidden Markov Models (HMM). The author proposes a model of the "mechanistic" dynamics of the transmission process as the hidden process and to use available infection data as ob-

served outcomes needed to estimate the model parameters. In this case, the model is easy to understand and interpret given knowledge about the infection transmission process. On the other hand, Benneyan et al. [118] propose the use of statistical process control (SPC) to monitor the occurrence of infections and other rare incidents. The authors propose a new type of SPC chart that better fits this purpose. SPC tools have been used in healthcare delivery to monitor outcomes such as infections, surgical complications, and patient falls. SPC tools are useful to monitor "sporadic" (random) outcomes that are measurable and provide complete data [99]. For the case of "systematic" outcomes, models that account for the dynamics of the system are needed.

Some authors have developed conceptual models to understand the dynamics of the delivery system of their interest. For example, Veazie [119] proposes a model for the individual decision making process of a healthcare professional under constraints of information (availability) and uncertainty of patient responses. The author defines four components in the decision making process: decision environment, problem space, action space, and goal space. Healthcare professionals relate the needs of the patient with each one of the model components. He assumes the existence of "appropriate" criteria for matching patient needs and defines an error as the non-correspondence of identified vs. appropriate criteria. The main purpose of this model is to provide a framework for intervening decision making behavior that leads to adverse outcomes. Chuang et al. [120] present a conceptual model for learning from adverse events, based on theories of organizational learning. The authors divide learning into: individual (perceived characteristics of the failure), group (experiences and leadership), and institutional learning (safety management). They identify specific factors that hinder or facilitate learning at each of these levels. The model provides a framework to identify strategies to improve learning and prevent reoccurrence of failures.

Quantitative modeling is scarce in patient safety because traditional tools assume the existence of data needed to estimate model parameters, such as the case of the models

proposed by Dhillon [112]. Actually implementing these types of models requires exploration of all possible sources of data, including the assessment of experts [113, 114]. Nevertheless, experts' assessment is believed to underestimate actual risks [116]. In general, conceptual models seem to be the most common approach to understanding systems and their risks.

So far, we have reviewed how safety is addressed in healthcare, and in other industries that have been compared to healthcare such as aviation. We have also explored the literature to find alternative model-based approaches to (patient) safety-related problems. In the next section, we present a summary of the specific characteristics that we identified are needed in models of risk in healthcare delivery systems, and that define a research area within healthcare systems engineering.

2.5 Discussion

Many organizations have recognized the importance of understanding their systems before improving them [115]. For example, aviation implemented CRM as a result of finding that teamwork skills and the capacity of managing unknown situations are critical to prevent catastrophic consequences of accidents. In the case of healthcare, processes, operational risks and their sources must be understood and monitored to enhance patient safety. Moreover there is a need to comprehend the impact that changes may have on both, the performance of the healthcare delivery system and its risks to support decision making. This objective can be achieved through the development of models [121] that explicitly consider risk sources, are kept up to date, and are developed in collaboration with managers, providers, patients and researchers.

Developing a model challenges our knowledge about the system and boosts our understanding of it [122] which in turn, strengthens the validity and robustness of the models developed (see figure 2.1). However, modeling healthcare delivery is complex due to

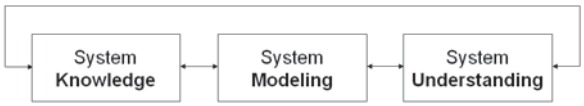

Figure 2.1: The modeling cycle

the presence of human behavior, organizational structures, hierarchy among providers, limited communication protocols, resistance to change, and the unavailability of data. Nevertheless, modeling tools such as statistical process control, queuing theory and simulation have been adapted and used in the improvement of healthcare operations [118, 123]. Still, models of risk actually used to support patient safety enhancement efforts are scarce.

Traditionally, patient safety initiatives are the result of post-incident investigations and focus on localized areas, although a systems approach has been strongly encouraged [26, 123]. System models provide an overall perspective that helps visualize and communicate how different sub-systems interact and impact each other, as well as the system itself [107]. These models can assist in the selection of proposed solutions by explicitly determining safety needs and identifying characteristics that may facilitate or hinder the success of patient safety interventions. For example, while human behavior introduces variability and makes the system vulnerable to failure, it also brings flexibility and learning capacity that allows the system to be proactive in the presence of unexpected situations. Models can also aid in monitoring deviations from expected performance of implemented solutions. Rasmussen's dynamic safety model locates systems performance in a space delimited by boundaries of unacceptable performance i.e. feasible operating space [107]. There is the opportunity to mathematically define this space to monitor the performance of a system in terms of its location within the space relative to such boundaries. Depending on the objective and level of specificity required, modeling tools range from diagrammatic system descriptions [121] to complex mathematical models. Regardless of the tool chosen, a model for risk in the delivery of care must represent the

Table 2.3: Considerations for risk models to enhance patient safety

Models to support patient safety should:
• Characterize potential risk sources • Be dynamic • Allow for proactive identification and assessment of risks • Include quantitative risks measures that are relevant to the system and understandable to users • Use different sources of patient safety data available • Identify and assess biases in patient safety data • Support the enhancement of risk awareness • Be scalable

system and its risks to the extent that is deemed adequate by stakeholders [124]. Models should be simple and intuitive such that they are understood, accepted and used as tools in managing patient safety [125]. Box 1 presents a summary of challenging considerations for models that support patient safety to be useful in improving care.

As proposed by Cooke and Rohleder [32], and supported in different ways by safety theorists [14, 47, 106], incidents are due to the substandard performance, or failure, of specific system components, or their interactions. The explicit characterization of potential sources of risk facilitates the analysis of patient safety data. In addition, this characterization allows for the development of formal models that represent the behavior of such sources and their effect on risk. For example, Leveson proposes to use safety constraints and system controls as sources of risk. In healthcare systems, patient safety interventions play a similar role to safety constraints since they are implemented to reduce the probability of specific adverse events [126]. To some extent the literature discusses the suitability of evidence of the effectiveness of patient safety interventions [127, 128].

We argue that models need to be developed models to evaluate the performance of patient safety interventions within specific systems. These models will help answer the question of effectiveness by identifying both, generalizable factors to define implementation guidelines, and factors specific to each particular organization that should be studied to ensure success. System dynamics and stochastic models of the possible states of each intervention could provide insight into the potential realization of undesirable scenarios. Still, these types of models should be adapted to consider characteristics that are particular to healthcare.

Healthcare systems are dynamic in nature due to the constant evolution of diseases, medical knowledge, technology, and human factors [97]. Thus modeling, monitoring, evaluating and improving the system should be dynamic as well. Otherwise, the emergence of new risks will soon render models and their solutions obsolete and inefficient. For example, adverse drug events related to illegible prescriptions are expected to be abolished with the implementation of computerized physician order entry (CPOE). Although this solution will likely eliminate errors due to illegibility, new hazards related to the new technology may arise. Such is the case of users forgetting to save data, ignoring reminders, and duplication of information, among others [129]. Hence, it is necessary that risks are identified and evaluated over time and that the possibility for new risks be made explicit in the corresponding models. For example, a particular state of a risk source may be defined as "undefined state" and patient safety data that are not clearly linked to known states may be assigned to this state to reflect lack of knowledge about the corresponding source and the need for further assessment.

The dynamic nature of healthcare delivery also demands proactive identification and assessment of its risks. Although the evaluation of past incidents may help understand the possible consequences of specific hazards, the prevention of future incidents is better approached by "foreseeing" potential failures. The timely identification and intervention of processes in need of improvement, or susceptible to serious consequences, will reduce the

probability of failure [115]. For example, the reporting and analysis of near-misses offers the opportunity to identify potential failures before suffering adverse consequences [26]. Such is the case of the "no-fault medical-event reporting system for transfusion medicine" (MERS-TM) in a Toronto, Canada teaching hospital, which helped identify different risks through near-misses reported and their analysis resulted in a dramatic reduction of the frequency and severity of reported events [10]. This type of system also allows for dynamic risk monitoring because the evidence of new risks will surface as related near-misses are reported.

The identification of potential risk sources should include a quantitative measure [130]. Qualitative analysis is still necessary because available patient safety data consist mainly of medical charts and narrative reports. However, systematic, quantitative risk assessment allows for prioritization of strategies and solutions, aids in the definition of target performance, and guides the monitoring of improvement over time [82, 131]. Additionally, defined risk measure(s) must be relevant to the system and meaningful to users [132] and should also permit prospective risk analysis. For example, an updated probability of an adverse event can be interpreted by users and could be estimated prior to the occurrence of accidents, using information from near-misses [43]. Also this measure could be translated into potential accidents during the next period or into potential litigation costs. Still, patient safety data has some limitations that hinder its use to statistically assess probability distributions. So we should use the subjective interpretation of probability [133] as a measure of the uncertainty about risk that is determined by the state of knowledge about the performance of risk sources.

It is important to keep in mind that different sources of patient safety data provide valuable information about risks in the system [87]. Studies on patient safety data sources suggest that there is potential value in assessing risk, although their use will require meticulous preprocessing [89, 134]. Some of these data have biases since they are generated by people and may be incomplete, inaccurate or untimely. Risk models should use available

data sources, recognizing their biases, to update knowledge about the system and flag potential breakdowns. For example, Pate-Cornell et al. [114] considers biases in incident reports by applying an "underreporting factor" to estimate the probability of anesthesia adverse events obtained from the Australian Incident Monitoring System (AIMS). On the other hand, Cooper and Lipsitch's model for the analysis of hospital acquired infections provides insight into the transmission process, while using common hospital administrative data to update parameter values that can signal elevated risk of infection [117]. Traditional analysis methods such as FMEA and RCA may be used to pre-process patient safety data before using it in actual models. For example, RCA may be used to identify actual links between observed outcomes and risk sources. The use of existing qualitative risk analysis methodologies facilitates the understanding of procedures to build, implement and update models.

One of the main objectives of patient safety initiatives should be to enhance risk awareness to reinforce proactive decision making, which in turn should minimize errors and their adverse consequences [26]. In most healthcare settings, the low frequency of adverse events requires that providers be informed or reminded of the risks in the system and their mitigating strategies [32]. The Florida Patient Safety Corporation [94] used public advisories to enhance awareness on significant risks identified through their state near-miss and adverse event reporting systems. Timely feedback on the performance of risk sources, such as potentially faulty patient safety interventions, will provide healthcare workers with information to appropriately react to otherwise unexpected failures.

Finally, models developed as a tool to manage and improve patient safety should be scalable. As a system grows or our understating of it expands, the model should be able to grow as well. For example, graph-based models that represent the links among risk sources, potential adverse events, and types of patient safety data can grow -by adding nodes and edges– as new components are identified with experience. Similarly, simula-

tion models also exemplify possible scalable models, since they can be adapted to include new subsystems or new interactions between existing systems.

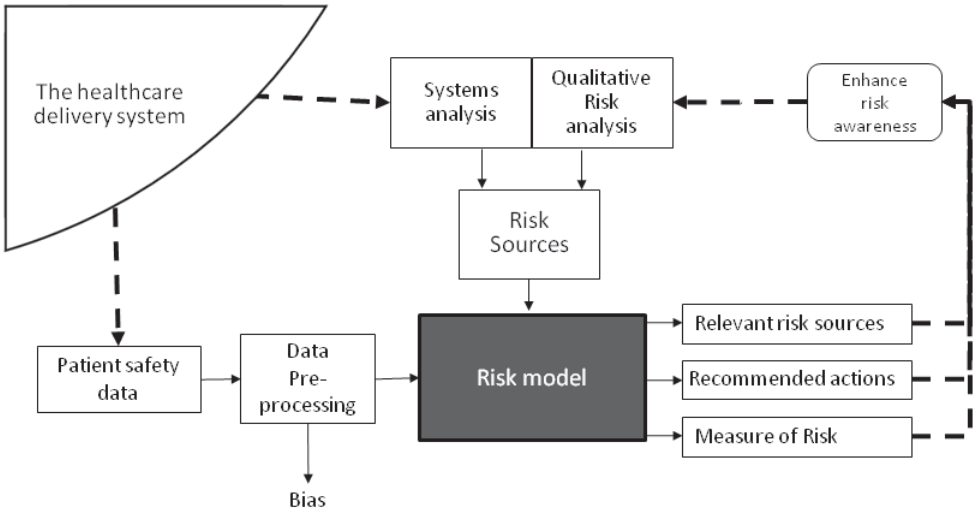

Figure 2.2: Risk model building blocks

Patient safety management should be equipped with an analytic framework to support the analysis of performance of healthcare systems [123], using available sources of data, to identify and track risks [26]. Figure 2.2 depicts the desirable components of the healthcare risk model outlined in this section. Dotted lines represent the dynamic interaction between components. We highlight that systems and risk analysis should be designed and carried out with the aim that their conclusions can be used to develop models that support risk management and decision making, rather than to make a single decision and be filed. Therefore, new models should be developed that are capable of capturing the outputs of existing risk analysis methods, such as FMEA and RCA. Alternatively, these qualitative methodologies may be adapted, or new ones developed, so that their outputs can be useful in engineering modeling endeavors. Similarly, there is the need to define appropriate methods to process patient safety data to be usable in the desired model. Information from patient safety data can be actively used to update measures of risk, or to identify the need to reassess parameters obtained from qualitative risk analysis.

In addition, mapping an abstract concept, such as risk, to real system components or interactions requires the identification of such components whose behavior affect outcomes that are directly related to risk, i.e., risk sources. There is the need for research on the identification of such components, or their classes. Then, there is the need to determine which observable outcomes could be used as markers of their performance, and what is the relation among these components, the corresponding outcomes, and uncommon, but potentially undesirable, events that should be avoided. These types of models can also incorporate broader recommendations specific to each risk source, such as "investigation needed" or "further data of a particular type should be collected".

Working with concepts commonly used in healthcare risk analysis will guarantee that the resulting model will have a user-friendly front-end that is understandable to users and stakeholders, while serving as the core of a decision support model to evaluate and prioritize potential solutions.

2.6 Conclusions

Current estimates of adverse events suggest that healthcare services add some risk to the already vulnerable condition of patients. Consequently, hospital accreditation requirements now include the establishment of institutional patient safety programs. These programs address patient safety mainly through qualitative analysis of available patient safety data, and the implementation of interventions. In this paper we provided an overview of patient safety, common methodologies used by healthcare organizations, and alternative approaches proposed by researchers in the area. In addition, we identified challenges and opportunities to enhance patient safety management efforts through modeling.

Particular characteristics of healthcare systems, and patient safety data, make traditional statistical methods unsuitable to assess risk, determine lasting solutions, and monitor system performance in terms of safety. In addition, the development of models

to support patient safety management has been hindered by the lack of understanding of risk in healthcare delivery systems. The literature presents some applications that address different patient safety-related situations through modeling and analysis. Although limited in number, they follow the recommendations of the IOM and NAE to use engineering based tools to understand and improve care delivery. Still, there is the need for modeling to understand risks in the delivery of care and how it is affected by interactions and performance of subsystems.

Modeling risk in the healthcare delivery can shed light on aspects in need of immediate attention and assist in the evaluation and selection of potential solutions. These models should explicitly characterize sources of risk, to facilitate analysis and feedback, be dynamic to reflect the changing nature of the service, have a prospective component to prevent adverse outcomes and support proactive decision making, have a quantitative component to allow monitoring and evaluation, and use available patient safety data to continuously update our knowledge about the system. To achieve a model with these characteristics, concepts and tools from different disciplines must be combined and adapted.

For example, the definition of sources of risk requires understanding of the performance of these system components and their impact on the performance of the healthcare system as a whole. In the example of patient safety interventions as sources of risk, the literature focuses mostly on establishing evidence of their global effectiveness [127, 128]. Still, the performance of interventions will depend on the system in which they are implemented. Therefore, there is the need to define guidelines to evaluate and monitor the performance of risk sources in particular settings.

These considerations confirm the need for formal research in modeling risk in healthcare delivery and its potential value to patient safety and quality of care.

Chapter 3: Clustering-Based Methodology for Analyzing Near-Miss Reports and Identifying Risks in Healthcare Delivery

3.1 Introduction

According to the HealthGrades Seventh Annual Patient Safety in American Hospitals Study, one million patient-safety incidents occurred from 2006 to 2008 among Medicare patients. One in ten patients that experienced a patient-safety incident subsequently died. Costs related were estimated to be $8.9 billion [1]. The report notes that according to the Institute for Healthcare Improvement, there are 40,000 harm-related events daily [2].

Most hospitals have some mechanism for reporting incidents to identify related risks and prevent their reoccurrence. Incident reports mostly consist of free text or narrative. These reports are analyzed by being classified into a pre-specified classification system that allows tabulating and aggregating events according to the predefined attributes. This type of analysis leads to prioritization of safety initiatives, and allocation of interventions to sources of risk related to the most frequent attributes. Classifying is a limited approach since some of the most devastating accidents have been the result of risks identified only in hindsight. Attributes that characterize different components of an incident generally point to well-known (potential) risk areas, so analysts can identify only obvious relations among incidents.

The Institute of Medicine strongly encourages reporting and analysis of near-misses since they can point out risk without patients being harmed. Near-misses are incidents that could have caused harm but did not [41]. They are believed to be indicators of areas

of increased risk. They are also much more frequent than adverse events, offering advantages for risk identification and analysis [26].

This research is focused on developing a methodology to support the gathering and analysis of near-miss reports. It proposes a taxonomy to code near-misses and an unsupervised clustering methodology to process such reports and guide further risk analysis. The outcome of this methodology is a rank of groups of reports that may lead to the identification of obvious, as well as potentially hidden, sources of risk. The proposed methodology is applicable to different (preferred) classification systems and can be automated into a risk management information system.

The next section introduces concepts related to near-misses and their analysis, including existing taxonomies for their classification. Section 3.3 introduces the proposed methodology to analyze near-miss reports and the proposed taxonomy for near-misses. Section 3.4 explains clustering of near-miss reports. Section 3.5 presents suggestions for risk analysis using near-miss clusters and illustrates the output of the clustering methodology using simulated data. Section 3.6 presents some comments on the validity of our approach, and conclusions and future work are discussed in Section 3.7

3.2 Near-Miss Analysis

"Near-miss" is a term borrowed from aviation that denotes an adverse event that did not occur because of the intervention of an individual or by a fortunate evolution of the circumstances. It refers to incidents that did not result in harm. They are believed to be precursors of adverse events [60] and thus share the same causal continuum [43] as documented in chemical [12] and transportation safety research [26, 60, 80]. They allow for analysis of risks before consequences are observed and are more frequent than adverse events (7-100 times more frequent [26]).

The use of near-miss reports has disadvantages typical of incident reporting systems [98, 135–138]. Therefore, it requires a reporting infrastructure that is simple, confidential and non-punitive. The Patient Safety and Quality Improvement Act of 2005 (Public Law 109-41), was enacted to address reporting barriers [98]. Still, incident reports constitute a non-random sample of an unknown population at risk; therefore, simple rates of reported incidents are not proper metrics to monitor safety. There is a need for the development of more suitable methods to analyze incident reports [75].

3.2.1 Incident Reporting and Analysis

Incident reporting is relevant to health care delivery because risks related to human behavior are intangible. In such situations, systematic reporting and analysis helps to identify weaknesses in the system before accidents occur. However, expertise and thorough analysis are required to identify system risk [60].

Most incident reporting systems consist of free text. Therefore, their analysis is generally done by experts who review, classify and code each report according to a taxonomy that allows for context-specific interpretation [97–99]. Analysis of aggregate classified reports helps determine areas that require deeper investigation [87] and establish priorities. Some authors have proposed enriching incident reports by linking them to electronic medical records so the analysis includes patient risk factors [100, 101]. Incident reports are also analyzed individually to identify root causes, similar to the Aviation Safety Reporting System [102]. In the case of near-misses, root cause analysis (RCA) is believed to lead to the identification of potential adverse events and their causes [29, 73], although their generalization requires consistency of risk throughout the different processes within and around the delivery system [139].

Health care is attempting to replicate the incident reporting and analysis model of aviation. The US Aviation Safety Reporting System consists of teams of trained coders

who analyze each reported incident. Unfortunately, estimates suggest that around one million serious errors occur each year in healthcare delivery systems [76], which significantly exceeds the frequency of incidents in aviation and makes the development and implementation of a national reporting/analysis system costly and logistically difficult to implement [75]. Nevertheless, near-miss reporting has been introduced in some patient safety programs in hospitals [95, 96]. Still, implementation has been rather slow because of reporting barriers and limited analyses [9, 92, 93, 95].

3.2.2 Incident Classification Systems

An effective classification is needed to systematically detect and analyze patient safety events. Classification systems for errors and near-misses can be found addressing specific areas of health care [140]. Most taxonomies deal with hospital based incidents, but there are a number of studies that propose classification systems for primary care [141].

The following is a summary of classification systems found in the literature. The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) published a taxonomy of medication errors in 1998 [140]. Wilson et al. [142] developed a generic taxonomy in 1999, from an analysis of the adverse events presented in a study of the quality of Australian health care published in 1995. Dovey et al. [143] proposed a preliminary taxonomy for error in family medicine in 2002. Rubin et al. presented their classification of errors in health care in 2003 [144] which was used in 2006 by Steele [145] in primary optometric care with satisfying results. In 2004, Zhang et al. [146] proposed and evaluated a cognitive taxonomy of medical errors to understand and potentially predict them. In 2005, Woods et al. [147] presented a system to classify patient safety events. In 2002, Makeham et al. described the international taxonomy developed by the Primary Care International Study of Medical Errors (PCISME), and intended to describe errors reported in Australia, Canada, the Netherlands, New Zealand,

the United Kingdom and the United States. This taxonomy was re-evaluated by Jacobs et al. in 2007 [148], who concluded that it is not suitable for Canadian data, and proposed a new classification system for errors in family medicine.

In 2003, The World Health Organization (WHO) set out to develop the International Patient Safety Event Taxonomy, intended to be adaptable and consistent across the continuum of health care and around the world. This taxonomy is being empirically validated [149]. In 2005, the Joint Commission (JC, formerly known as JCAHO) published a taxonomy for near misses and adverse events based upon previous studies available in the literature [80]. The whole taxonomy has over 200 subcategories and is endorsed by the National Quality Forum as a standard for safety data sharing and analysis across health care [81, 150]. In 2010, the Agency for Healthcare Research and Quality (AHRQ) released common formats for reporting patient safety data [151, 152]. These formats consist of requirements and specifications to facilitate the collection, aggregation and analysis of incident reports. The main goal is that such incidents be submitted to Patient Safety Organizations (PSOs) and shared through a network of patient safety databases (NPSD). Although analysis methodologies and their outputs are yet to be defined, the agency expects that establishing a common language and definitions for safety events will lead to better analysis of patient safety events.

In the United States, the JC patient safety event taxonomy is considered an important guideline for safety analysts and researchers; however, there is no official taxonomy. Institutions classify and analyze incidents following general recommendations, or state regulations, but still according to their own preferences. Our research focuses on supporting risk analysts in their quest to find sources of risk. Information technology and data mining techniques are used to systematically organize current knowledge about system risk and analyze near-miss reports using the preferred taxonomy.

3.3 Methodology to Analyze Near-Miss Reports

We propose the use of unsupervised clustering techniques to analyze near-miss reports and facilitate subsequent risk analysis. Our proposed methodology is supported by a risk database that stores previous knowledge about risks in the system. The methodology consists of:

1. Systematic reporting of near-misses based on a taxonomy that facilitates both reporting and initial processing of reports.

2. Identification of clusters of near-miss reports to be considered together in risk analysis.

3. Determination of the validity of clusters as indicators of system risk. Valid clusters will be preserved in the database for analysis of future incidents, so new near-misses can be assigned to existing "valid" clusters or form new clusters.

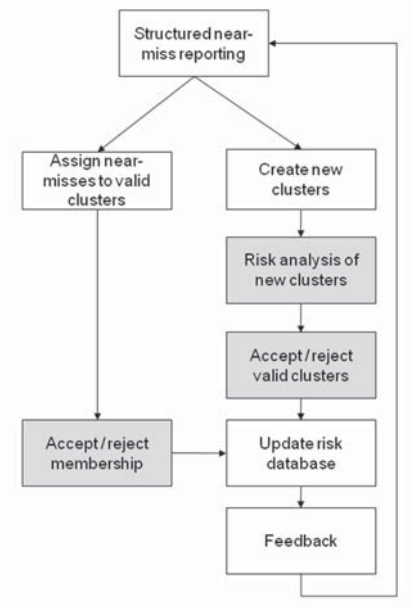

Figure 3.1: Methodology to analyze near-miss reports

The methodology is illustrated in Figure 3.1. Shaded blocks represent steps in the analysis that require human input, such as risk analysis and accepting or rejecting the va-

lidity of clusters found by the system. The proposed methodology supports risk analysis by organizing and allocating previous knowledge about system risk. Basically, new near-misses reported will be assigned to both a code defined by the preferred taxonomy and a cluster defined by patterns within reports in a period of interest. Since it is important to identify all potentially risky interactions in the system, it is not required that resulting clusters of near-misses identified be mutually exclusive. Near-misses assigned to previously existing valid clusters can also be assigned to new clusters to find new potential risks.

We assume that there is no initial information about risk in the system. However, if there are areas of interest represented by a combination of codes in the taxonomy, i.e., a particular activity such as patient discharge, clusters formed by near-misses related to patient discharge activities can be initially determined as valid. The proposed methodology is intended to find (and rank) risk sources. We characterize risk sources as combinations of categorical values of the different attributes of the near-miss that co-occur frequently.

In order to develop and implement this analysis methodology, a coding scheme for near-misses is needed. We propose a taxonomy structure based on subsets of the JC patient safety event taxonomy, but simpler since it will be adapted to the specific setting where it will be used. This structure is recommended for institutions that do not currently have a coding scheme for reporting and plan to develop their own. The overall analysis methodology can be implemented using any taxonomy for reporting, as long as one is used.

3.3.1 Proposed Taxonomy for Near-Misses in Outpatient Settings

Since a taxonomy is required for a real-time near-miss reporting system, it should be as simple as possible while as comprehensive as possible. We conducted brainstorming sessions with nurses, AHP (Allied Health Practitioners), LIP (Licensed Independent Prac-

titioner), physicians and other medical staff, from 13 outpatient clinics at the University of South Florida, including ambulatory surgery, dermatology, family medicine, geriatrics, gynecology, internal medicine and gastroenterology, obstetrics, ophthalmology, pediatrics, psychiatry, surgery, radiology and chemotherapy. During these sessions, we obtained a total of 667 near-misses. First, we analyzed these near-misses to find duplicates, and identified 386 unique event types. These unique near-misses were analyzed by a multidisciplinary team, who identified 4 dimensions that could be used to describe them. These dimensions were mainly derived from the JC patient safety event taxonomy [80].

Each classified near-miss report is intended to provide standard characteristics of the encounter and of the attributes perceived by the reporter to have had the most significant influence on the corresponding near-miss. If an event is identified as the result of a sequence or the combination of several significant failures, we recommend that multiple near-miss reports be submitted, so that their attributes can be included in further analysis. This specific taxonomy was developed for near-misses in outpatient clinics; so, the lowest level categories are specific to outpatient settings. Nevertheless, the overall structure is adaptable to any setting.

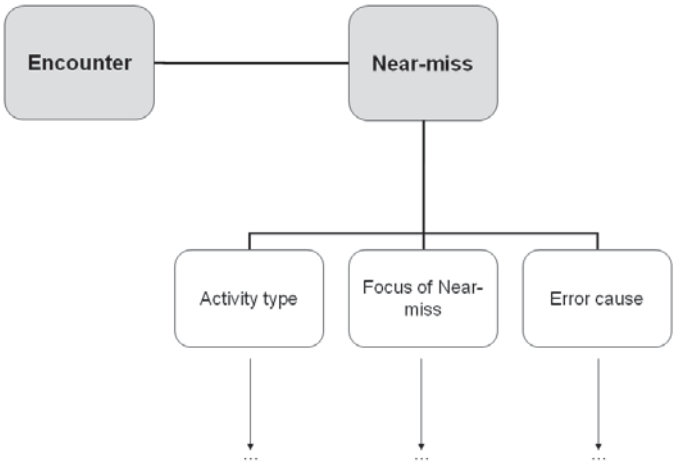

Figure 3.2: Dimensions of the taxonomy

Information about the characteristics of the encounter is intended to be pulled directly from the electronic health record system of the institution. Therefore, it is as comprehensive as the information system of the institution allows. For the case of the outpatient clinics, we propose to include: the clinic or location, the service or procedure according to the codification available, the staff member involved, and demographic information about the patient (age, gender, coexisting conditions, race/ethnicity and socio-economic status). Actual categories and subcategories depend on the setting and its information infrastructure.

Information about the characteristics of the near-miss is intended to be reported by the staff member who experienced and/or noticed the event. We propose that the near-miss is characterized by three main dimensions, each one corresponding to an attribute of the event. These are: activity type, focus of near-miss and error cause.

The *activity type* corresponds to the activity that was in process when the event occurred. In our taxonomy for near-misses in outpatient settings, the main categories for activity type are: information management, patient management, medical test/procedure and resource management. Each one of these categories has sub-categories that can be further subdivided as needed (Figure 3.3).

The *focus* of the near-miss is the defining characteristic of the near-miss. It is related to the incident and the potential consequences that were not actually experienced. The categories of this attribute include: equipment/supplies, medication use, patient specific, safety in the workplace, socio-economic based and test/procedure related. Subcategories and detail are shown in Figure 3.4.

The *error cause* attempts to identify what type of breakdown caused the error. In our taxonomy, categories include: human factor, organizational factor and technical mechanical factor. Subcategories and detail are shown in Figure 3.5.

As previously mentioned, the proposed taxonomy structure is applicable to any setting. In fact, the research team has started to adapt this taxonomy to an inpatient setting.

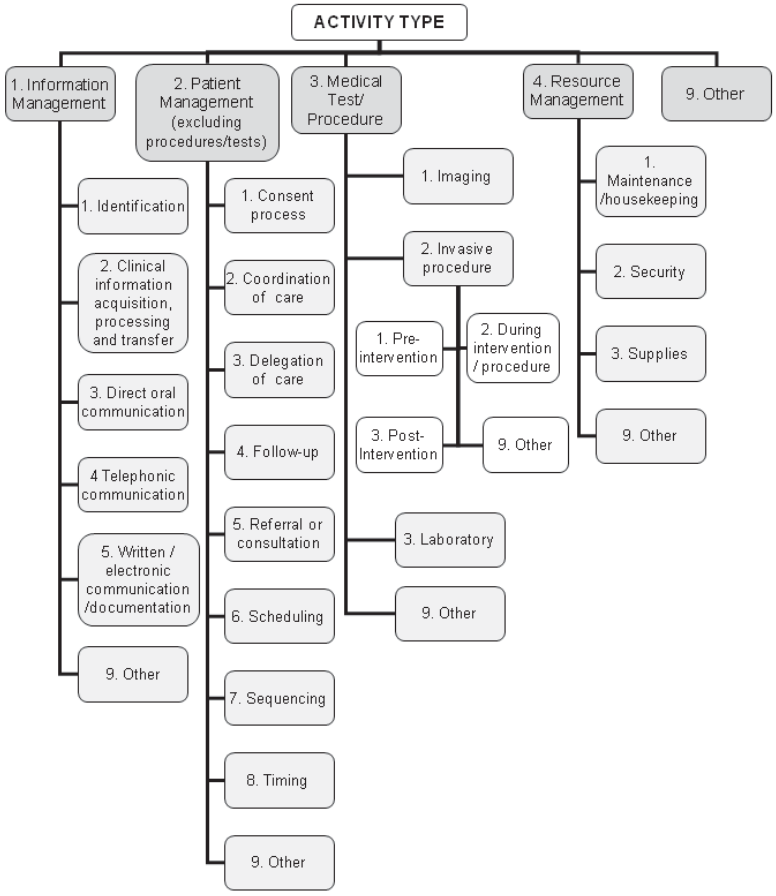

Figure 3.3: Categories and subcategories for “Activity Type”

Some categories, sub-categories and detail had to be added to each of the dimensions and some terms had to be revised. Nevertheless, the structure of the taxonomy remained as having three dimensions to describe the near-miss.

3.3.1.1 Developing a Taxonomy for Near-Misses in a Particular Setting

The proposed taxonomy structure has four dimensions intended to be preserved regardless of the setting where it will be utilized, while categories and subcategories should arise from the specific characteristics of the setting. Brainstorming was used to form the taxonomy and to assign initial values of severity to each dimension of the taxonomy. The steps follow:

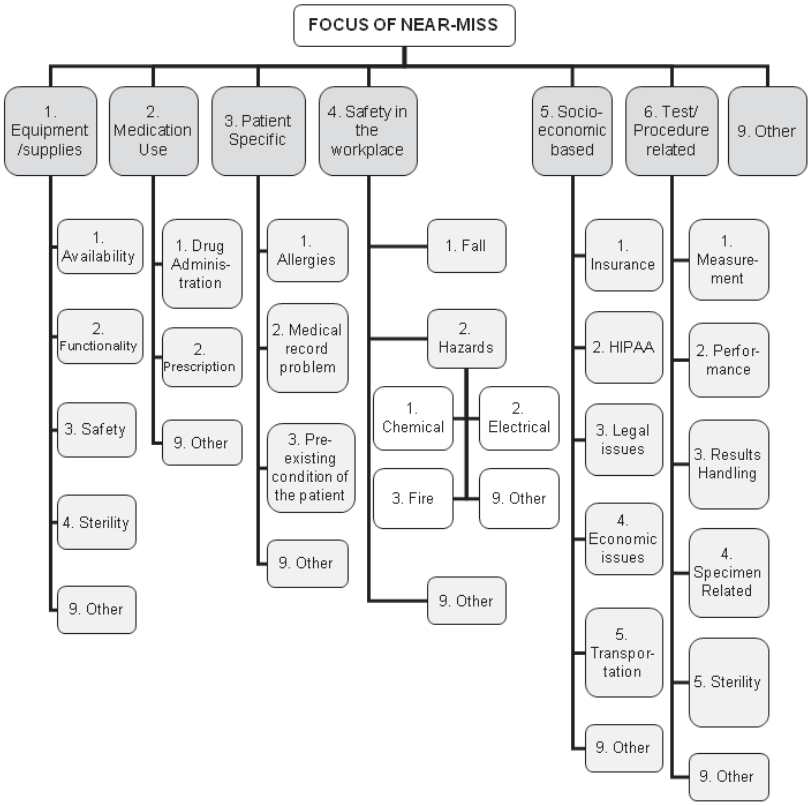

Figure 3.4: Categories and subcategories for “Focus of Near-Miss”

1. Initialize each dimension of the taxonomy with basic categories from the JC Patient Safety Event Taxonomy that are deemed applicable to the setting. This will form the initial near-miss taxonomy.

2. Carry out a brainstorming session about near-misses with the participation of several types of health care workers. The nominal group process is used to elicit spontaneous reporting of near-miss events experienced or witnessed by the individual participants. The resulting list of near-misses will be called “potential near-misses”.

3. Record the severity of the potential near-misses following an agreed upon scale. We used a Failure Modes and Effects Analysis (FMEA) scale.

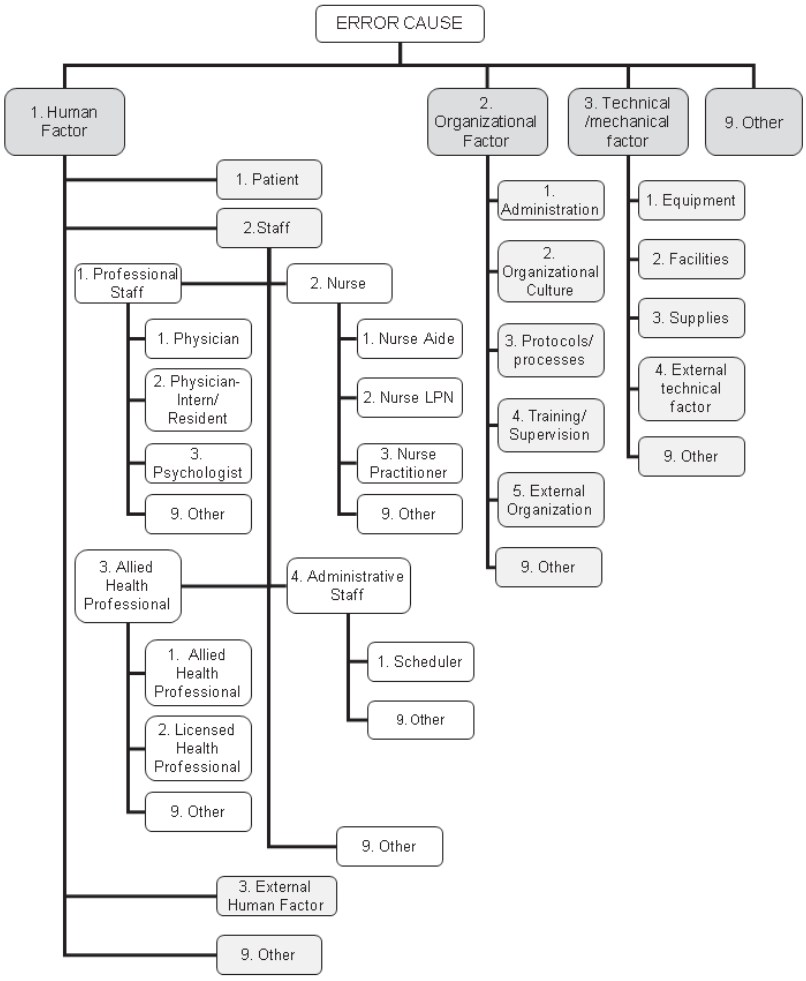

Figure 3.5: Categories and subcategories for “Error Cause”

4. Classify potential near-misses using the initial near-miss taxonomy (from step 1). Iterate until all potential near-misses are assigned to a combination of categories and subcategories in each dimension, as follows:

   (a) Create a new category or subcategory for potential near-misses classified as “other” in any dimension.

   (b) Re-evaluate potential near-misses to check if they correspond to a newly created category.

   (c) Re-evaluate categories in each dimension to merge similar categories.

5. For each code in the taxonomy, calculate the following severity indicators based on the scores of the potential near-misses assigned to the code:

   Most likely Severity: severity that repeats the most among the corresponding near-misses [153].

   Severity of worst case scenario: worst severity score of the corresponding near-misses (corresponds to the minimum value in our scoring system).

The severity indicators will be stored in a risk database (see Figure 3.6) and used later when analyzing near-misses reported into a system based on this taxonomy. They will also be updated as new near-miss data arise and are analyzed.

3.3.2 Risk Database

A simple risk database should be kept, so new near-misses can be related to prior occurrences or current risk information. This database can also be used to manage risk and their corresponding recommended actions. See Figure 3.6.

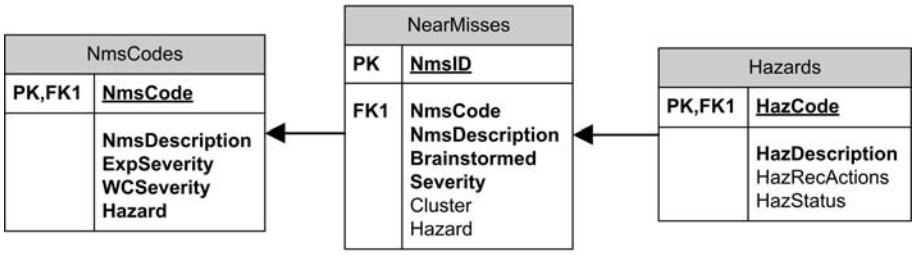

Figure 3.6: Simple risk database

For the purpose of the Hazard analysis, the near-miss table is filtered by cluster according to the ranking, and near-misses are sorted according to their codes considering item-sets first.

3.4 Clustering Near-Miss Reports

Clustering is a data mining methodology that consists of grouping similar data into "clusters". In our application, a cluster is defined as a set of near-misses that are closely related to each other, and less related to near-misses outside the cluster. Near-miss clusters should also have a set of categorical values that will characterize the source of risk related to the cluster. We are interested in finding at least one significant cluster according to some risk defining criteria.

Our proposed methodology consists of clustering near-miss data, characterizing the resulting clusters and ranking them according to some risk defining criteria. This methodology will be explained in detail in section 3.4.3. We will first describe the data and introduce concepts from data mining relevant to this application.

3.4.1 Near-Miss Data

The first part of the research consisted of defining an appropriate structure for the reporting of near-misses that allows timely analysis of data. The proposed taxonomy for near-misses defines the shape of incident reports. Reports are characterized by all components in the taxonomy; for each dimension we will include the category, sub-category and detail. Therefore, we have more attributes in the data set than the actual dimensions of the taxonomy. This will facilitate further analysis of similarities between near-miss reports.

As seen in table 3.1, the near-miss reports dataset is formed by objects characterized by 18 attributes. Most of these attributes are categorical-nominal, but there are still numerical attributes such as age of the patient or date and time of the event, which make the dataset mixed. The reporting system is in principle voluntary; therefore, observations are not a random sample of events that actually take place in the institution. Hence, inference

Table 3.1: Near-miss report structure

Column Number	Column Name	Original Attribute	Description	Attribute Type	Bounds / No of categories
0	EIN	EIN	Encounter Identification Number	Key	
1	Date	Date	Number of days since Jan 00-00	Numerical	[0, inf]
2	time	Time	% of day	Numerical	[0,1]
3	Set1	Setting	Setting Category	Categorical	3
4	Set2		Setting Detail	Categorical	13
5	Serv	Service	Service Category Code	Categorical	3
6	Comp	Complexity	Service Complexity Code	Categorical	15
7	Age	Age	Patient Age	Numerical	[0, 100]
8	Gend	Gender	Patient Gender	Categorical	2
9	Acat	Activity	Activity Category	Categorical	4
10	Asub		Activity Subcategory	Categorical	19
11	Adet		Activity Detail	Categorical	21
12	ECca	Error Cause	Error Cause Category	Categorical	3
13	ECsu		Error Cause Subcategory	Categorical	12
14	ECde1		Error Cause Detail1	Categorical	15
15	ECde2		Error Cause Detail2	Categorical	20
16	FOca	Focus	Focus Category	Categorical	6
17	FOsu		Focus Subcategory	Categorical	12
18	FOde		Focus Detail	Categorical	23

from frequency analysis and other descriptive statistical analyses may provide biased results.

The second step in this research is to develop a methodology to evaluate near-miss reports and extract groups of such reports that may present hidden relations. In this process, there is not a predetermined classification of causes. The objective in this step is to provide the risk analyst with groups of reports characterized by specific combinations of attribute values that should be analyzed together to discover common causes. We use clustering for this purpose.

3.4.2 Clustering Categorical and Mixed Data

Selecting the most appropriate clustering algorithm depends on the specific characteristics of the data and the objective of the analysis. Our work focuses on clustering near-miss reports, which consist of both qualitative and quantitative attributes. However, there is no universally valid pre-determined taxonomy of sources of risk to classify reports. Therefore, data must be clustered without information about which categories are available to assign them to; thus unsupervised clustering will be used. Unsupervised clustering consists of finding natural clusters in the dataset without a pre-determined number of clusters or specific cluster-defining characteristics. In unsupervised learning, the validity of models and conclusions drawn from the analysis are subjective, since there are no expectations or reference for results [154]. Additionally, the meaning of each cluster should be guided by the data and validated by further subject matter expert analysis.

In this application, each near-miss report is a data point or observation. There are a total of N observations in the database. Each observation, x_i, $i = 1,...,N$ is characterized by a pattern of m different attributes. Each attribute can be categorical or numerical depending on its domain, A_j, $j = 1,...,m$. Then, each observation x_i is formed by the array $(x_{a1}, x_{a2}, ..., x_{am})$. Categorical attributes are nominal, i.e., the order of the coding does not have an informative meaning. For example, the "factor" of the near-miss is arbitrarily coded as: 1: human, 2: technical or 3: organizational.

The mixed nature of the near-miss data set allows for the use of methodologies to cluster both categorical and mixed data. If a categorical-only data-clustering algorithm is chosen, one can "discretize" numerical attributes into categorical by creating meaningful categories within the numerical values that the attribute can take. In this paper, we propose to use the K-prototypes algorithm, presented by Huang [155], because it does not require transforming numerical attributes into categorical; it is designed for datasets with mixed attributes. The k-prototypes algorithm seeks to minimize the cost of a cluster,

which is the sum of distances of each element of the cluster to its corresponding prototype. The distance between elements is a combination of "mismatching" and Euclidean distance for categorical and numerical attributes respectively. Mismatching determines the number of attributes in which two categorical observations differ.

Any unsupervised clustering algorithm applicable to the data defined by the preferred taxonomy is applicable to the proposed methodology.

3.4.3 Methodology to Cluster Near-Misses

A near-miss cluster is defined as a group of the near- miss reports with more than 1 element (it can be generalized to more than n_0 elements). Near-miss clusters should also have an item-set with a support higher than a specified threshold. The item-set will represent the risk-source related to the cluster. The objective is to find at least one low-cost cluster that has item-sets with maximum support. The steps of the methodology are outlined below:

1. Define parameters:

   T: Threshold for item-sets. The threshold is defined as the minimum support that an item-set should have to be considered significant.

   ε: Positive number that represents insignificant change in the cost of the cluster ensemble.

2. Evaluate the whole data set as a cluster using cluster indicators from table 3.2.

3. Cluster the dataset. See the proposed Unsupervised Bisecting K-Prototypes algorithm presented later in this section.

4. For each resulting cluster, label it and record its elements and cluster indicators table 3.2.

5. Characterize the resulting clusters using item-sets.

6. Rank all resulting clusters (including the cluster formed by the whole dataset) according to the preferred indicators.

It is assumed that cluster priority is based on identifying risk source characteristics related to:

- Unknown or unexplored events, i.e., events with a lot of uncertainty associated because there is not a clear idea of their probability or impact.
- Low probability, but high impact (severity) events.
- High probability, low impact events, i.e., events that occur frequently.

Indicators are defined to represent each one of these characteristics. Table 3.2 presents each indicator and how to obtain it. We propose to use these indicators to prioritize cluster analysis. The arrangement shown in table 3.3 (in section 3.5) illustrates clusters ranked by cost-density criteria.

In what follows, we define specific concepts related to the proposed methodology to cluster near-misses to be used in step III of the methodology, illustrate the clustering algorithm used and illustrate the outcomes of the methodology.

Let S be the data-set formed by N near-miss reports. Each report is characterized by m attributes, out of which, m_n are numerical and m_c are categorical. Each categorical attribute, $j = 1,...,m_c$, has a set of possible values A_j that come from the taxonomy. Numerical attributes, $j = m_c + 1,...,m$ should be standardized to a number between 0 and 1. We will refer to the similarity of observations as d. Similarity between observations is defined in this paper as in [155].

Table 3.2: Cluster indicators to be used in ranking of near-miss groups

Cluster Indicator	**Description**
Cost, $E(k)$	Clustering indicator that measures the quality of the cluster in terms of its scatter. It is an output of the clustering algorithm. See section 4.3.2.
% Novel reports	Number of near-miss reports in the cluster whose code does not have severity indicators assigned yet.
Most likely severity	Severity score that repeats the most within the cluster. It is initially calculated automatically from information in the risk database related to the codes of the near-misses included in the cluster.
Worst case scenario	Worst severity found among the corresponding codes of near-miss reports. Corresponds to the minimum value in our scoring system. It is initially calculated automatically from information in the risk database.
Density	Number of near-miss reports in the cluster.
Cost/Density	Cluster cost as determined by clustering methodology over number of near-misses in the cluster.
Item-sets (support)	Joint values of different attributes that occur more frequently than the specified support. Item-sets are found using the Apriori algorithm.

3.4.4 Data Setup

1. Rearrange the columns of the dataset so categorical attributes are together, preferably, but not necessarily, at the beginning.

2. Standardize numerical attributes to a $[0,1]$ scale where $\min(A_j) = 0$ and

   $\max(A_j) = 1,\ j = m_c + 1, ..., m$

3. Set $K = 1$, i.e. the current number of clusters equal to 1. Assign the whole data set to this cluster.

4. Set $t = 0$ (iteration $t = 0$).

5. Let the current cluster of interest $k^* = 1$ and evaluate the maximum similarity between elements within the cluster, $dmax(1)$.

3.4.5 Iteration t

1. *Step 1.* Record the furthest elements of cluster k^*, f_1^* and f_2^*. Assign these elements to the set of initial prototypes, P_0 so that: $P_0^1 = f_1^*$ and $P_0^2 = f_1^*$.

2. *Step 2.* Partition cluster k^* into two sub-clusters by following the k-prototypes algorithm described in Huang [155]. The output of this step consists of: the new sub-clusters k_1^* and k_2^*, the set of updated prototypes P_f , the maximum similarity within each sub-cluster, $dmax(k_1^*)$ and $dmax(k_2^*)$, the cost of each cluster, $E_{k_1^*}$ and $E_{k_2^*}$ and the total cost of the clustering scheme of iteration t, $E(t)$ as defined in [155].

3. *Step 3.* Update the current clustering ensemble for the iteration:

   If 2 sub-clusters were produced (this can be observed by checking that the set of updated prototypes has two elements) then:

(a) Increase the number of clusters of the iteration:

$$K \leftarrow K + 1$$

(b) Replace the cluster of interest with the first sub-cluster:

$$k^* \leftarrow k_1^*$$

(c) Put the second sub-cluster in the last position of the list of clusters:

$$k \leftarrow K, \text{ and } k \leftarrow k_2^*$$

(d) Record the number of clusters of the current iteration.

$$n_c(t) \leftarrow K$$

Otherwise, leave the cluster ensemble as it currently is and set $n_c(t) = K$.

4. *Step 4.* Verify stopping conditions:

   If the total cost $E(t)$ does not change significantly, i.e. $|E(t) - E(t-1)| < \varepsilon$, then go to Step 6.

   Otherwise, let $t \leftarrow t + 1$.

5. *Step 5.* Choose the cluster with the highest *dmax* as the current cluster of interest, k^*:

$$k^* = \text{argmax}_{k=1,\ldots,K}\{dmax(k)\}$$

   Go to Step 1.

6. *Step 6.* Verify that all prototypes are different, and run a final iteration with the final distinct prototypes.

7. *Step 7.* For each cluster, calculate its density, n_k, cost, $E(k)$, and the ratio, $\frac{E_k}{n_k}$.

The output of the algorithm is a table with the information obtained in Step 7. Further analysis allows ranking of clusters by the indicators from table 3.2, to obtain a summary similar to the one illustrated in table 3.3.

The unsupervised version of the k-prototypes algorithm is applicable to other algorithms that use a spatial reference to define cluster centers such as k-means and k-medoids, when there is no prior information that should help determine the initial centers. The speed of the methodology depends on the speed of the clustering algorithm used; therefore, simpler clustering algorithms are preferred. The convergence of the algorithm is guaranteed if additional stopping conditions are considered (for example, maximum number of clusters allowed, minimum number of elements in each cluster, desired cluster ensemble cost reduction).

As mentioned in section 3.4.2, the validity of clusters from unsupervised learning will depend on the analysis of clusters by experts, since there are no expectations or reference for the corresponding results [154]. Since structured near-miss reports reflect the perceptions of reporters, the resulting clusters are expected to reflect areas that healthcare workers consistently relate to near-miss events experienced by them. We use clustering to organize these data and help analysts in further investigation efforts. The proposed clustering methodology ensures that obviously similar reports are grouped together, while allowing for groups of "non-obviously" similar reports to be formed as well. The next step in the proposed methodology is to characterize each cluster in terms of its components.

The proposed clustering algorithm can be replaced within the overall methodology, described in section 3.4.3, by other clustering techniques deemed applicable to the dataset of interest.

3.4.6 Cluster Characterization

Each cluster will be characterized by the significant attribute values in their elements, which are found in the corresponding item-sets. For categorical attributes, attribute values present in the cluster in a proportion higher than a specified threshold (support) will be used to characterize the cluster as the corresponding source of risk. The Apriori algorithm [154] is proposed to find item-sets for categorical attributes. Additionally, we propose that significant numerical attributes be determined by their coefficient of variation, so numerical values with small coefficient of variation are included in the item-set.

3.5 Analysis of Near-Miss Clusters

While the taxonomy for near-misses is intended to characterize events (or potential events), the distinct combinations of attribute values of coded reports is intended to guide the identification of sources of risk. Clustering coded near-misses provides the means to find subsets of near-misses likely to identify potential risk areas in the system, when analyzed together.

The near-miss reporting and analysis system is being implemented at the University of South Florida (USF) Health Clinics. Table 3.3 shows the output of our clustering methodology to a sample of 33 near-misses reported by USF personnel.

The table shows a list clusters ranked by values for cost-density ratio. Columns 5 to 15 show the corresponding attribute values of the cluster item-set. We omitted all the date fields in this table. Column 4 (Support) shows the "support" of the item-set, which can be interpreted as the proportion of reports within the cluster that have that particular combination of attribute values in their individual code.

For example, the first cluster in the rank, cluster No 3, has the majority of reports ($n = 21$). This cluster is characterized 100% (Support = 1) by having taken place on

Table 3.3: Summary of near-miss clusters

					Item-set								
					Activity	Error Cause			Focus				
No	**n**	**Cost/n**	**Support**	**Site**	**Category**	**Category**	**Sub-category**	**Detail**	**Detail**	**Category**	**Sub-category**	**Gender**	**Race**	**Age**
3	21	25.24	1	1		Human Factors	Staff	Professional Staff	Physician	Patient Specific	Medical Record Problem			
1	7	34.53	1	1		Human Factors								
4	3	38.26	1										WHT	
2	1	67.42	1		Medical Test/ Procedure					Test / Procedure Related	Results Handling	F		49.5

site 1, being related to patient-specific issues within the medical records, and being attributed to physicians' human factors. Events within this cluster can be further studied to find related potential sources of risk. In particular, when reviewing the comments of the reports within the cluster, we found a consistent situation where critical documentation for surgical procedures, such as orders and consent, is missing from the medical record. Similar documentation problems were identified during the taxonomy brainstorming sessions as a common threat to patient safety in the outpatient environment. Analysis by the corresponding risk manager (or quality manager) should be done to identify actual risks related to the documentation procedures and develop solutions to prevent potential adverse events.

The second cluster in the rank, cluster number 1, is formed by reports that seem different. Moreover, this cluster has only one attribute in its item-set, which means that the only common characteristic of these reports is that they are due to human factors. This information may be insufficient for further analysis of this particular cluster as an indicator of a potential source of risk, and may be dismissed as a valid cluster.

Using this cluster structure in conjunction with a formal risk analysis technique will allow for the identification and validation of risk sources related to each cluster. Table 3.4

Table 3.4: Modified "Systems Hazards Analysis"

Modified System Hazards Analysis						
Cluster No:		**Item-sets:**				
Valid cluster?		**Risk sources identified:**				
No	**Near-miss code**	**Near-miss description**	**Severity (IMRI)**	**Hazards/risks?**	**Recommended Actions**	**RA Status**
	From reporting system. Ordered according to Item-sets	From reporting system	From risk database: expected severity of near misses with similar code.	Automatic/overwrite.	Automatic/add.	Automatic, tied to hazard risks

illustrates a modified System Hazard Analysis (SHA) for near-misses in each cluster. The structure of SHA facilitates the use of information technology to automatically allocate previous information to newly reported near-misses.

We modified the original System Hazard Analysis found in [156] by adding a header of cluster characteristics, so that it can be used as a form to input risk analysis data in the risk database. The header includes the cluster identifier, item-set, check-box to validate (or reject) the cluster after risk analysis and a field to register actual system risks (hazards) identified. Fields were added to characterize each near-miss within the cluster. A column for near-miss code was included. We suggest automating an initial assignment of severity score, hazards/risks and recommended actions from the database. The analyst will confirm or overwrite such assignments as a result of his/her analysis. For more information about risk identification and assessment techniques, refer to [156].

3.6 Validity

The main goal of our methodology is to find clusters of near-misses that inform formal risk analysis. Accordingly, the taxonomy was designed to be mutually exclusive and

exhaustive. Therefore, the main attributes of a near-miss should be identified to make the corresponding report using this taxonomy. We used brainstorming to identify as many of the potential near-misses proper of outpatient settings as possible.

To ensure face validity, the taxonomy was mostly derived from the JC patient safety event taxonomy, which is endorsed by the National Quality Forum [81]. Categories within the "Activity" dimension in our taxonomy were obtained from some of the categories of the "Type" dimension of the JC's taxonomy. Similarly, the main categories in our "Error Cause" dimension were derived from categories found in the JC's "Cause" dimension. Both of these were expanded to cover more explicitly the situations that may arise in the USF outpatient clinic. Finally, our "Focus" dimension is a logical extension of information required to characterize near-misses.

Additionally, the application of our methodology to the preliminary set of near-misses resulted in tight clusters of obviously related reports (construct validity), as well as not-so-obvious groups of events that share some characteristics, but that would probably have been missed by individual analysis (concept validity). In our preliminary results, the most consistent risk was related to documentation in the medical record, which also came up during our brainstorming sessions as a common threat to patient safety. Refer to section 3.4.6 for details of the preliminary characterization and analysis of clusters.

3.7 Conclusions and Future Work

Near-miss reports, and the knowledge derived from their analysis, can be accumulated over time to enhance the analysis and interpretation of reports. Availability of current risk-information will strengthen risk identification and effectively guide risk management efforts. This article presented a methodology to systematically handle near-miss reports and support their analysis.

We described the main components of the methodology, beginning with a suggested taxonomy structure to report near-misses and facilitate their processing. The taxonomy is based on the JC patient safety event taxonomy, but less complex because it focuses on the system where it will be used. Then, we used an unsupervised bisecting k-prototypes algorithm to cluster near-misses. Unsupervised clustering yields groups of near-misses that should be analyzed together for risk identification. Finally, we suggest a modified system hazard analysis, supported by a risk database, to aid analysts in the identification of system risks.

The overall methodology can be applied to all types of incidents and is not restricted to near-misses. A different taxonomy for near-misses or incidents can be used if preferred. Additionally, a different clustering methodology can be used for clustering near-miss reports. Finally, a preferred risk analysis methodology such as FMEA, or other, can be implemented.

As mentioned in section 3.5, the near-miss reporting system has been partially implemented at the University of South Florida Clinics. So far, the taxonomy has been developed (see section 3.2.2) and staff has been trained in its use. The reporting system is available in all the computers within the facilities. The clustering methodology has been manually applied to the reports available. Clusters have been prioritized using the cost-density criteria, and risks related to documentation protocols have identified.

The next stages of development and implementation include automation, evaluation and enhancement. The methodology will be automated into a risk database to accumulate information about risk over time, and severity and novelty criteria will be included. The overall methodology will be revisited to address specific situations that arise from day-to-day use. Specifically, the cluster (risk) validation and learning portion of the methodology will be evaluated and enhanced to appropriately manage information about invalid and valid clusters, and the corresponding sources of risk that are identified over time.

Chapter 4: Using Patient Safety Interventions to Monitor Risk in Healthcare Delivery Systems

4.1 Introduction

In healthcare processes, failure is not always evident because it does not necessarily result in adverse events. Therefore, one of the objectives of healthcare risk management is to gather and analyze patient safety data to proactively identify potential failures that may contribute to future adverse events. Common forms of patient safety data include voluntary incident reports, patient complaints, and malpractice claims, among others. The sources of occurrence of these outcomes are often indentified through qualitative approaches that tend to be time consuming, and therefore infrequent.

This chapter focuses on developing a framework for risk analysis in healthcare delivery systems that includes a formal characterization of potential risk sources. The aim is that such sources can be analyzed in terms of observable data, so that their performance can be monitored on a more frequent basis. This framework is intended to become the foundation for the design of an information and decision support system that stores and processes both, patient safety data and the results of risk analysis, to provide healthcare risk managers, and other stakeholders, with the appropriate, relevant, information at the right time, to ensure safe care.

Ideally, patient safety data should be used to assess the likelihood of potential adverse events and associated impact (or costs), and allocate preventive or corrective efforts (figure 4.1).

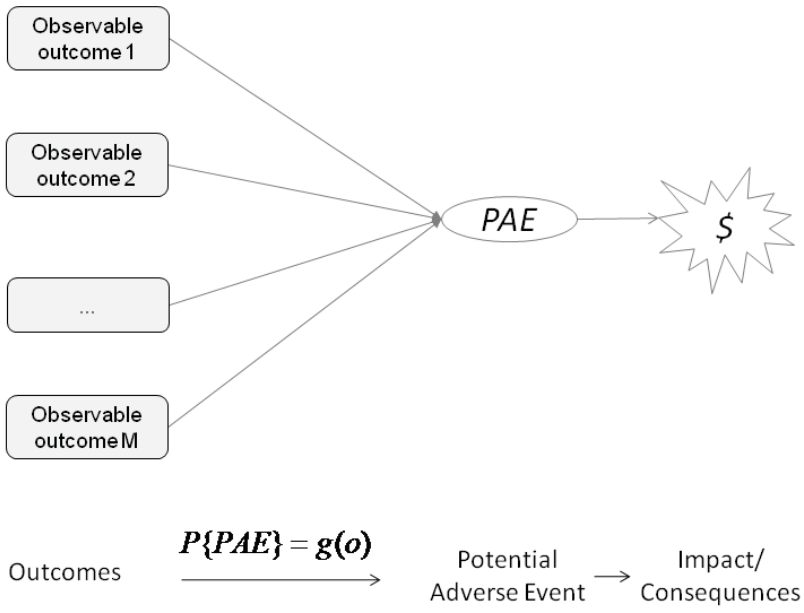

Figure 4.1: Traditional risk analysis model

In healthcare, a popular source of data about potential adverse events, is incident reporting. Traditionally, reports of adverse events are analyzed to understand their causes, assess their likelihood and prevent their recurrence. However, incident reporting systems are believed to capture only a small and biased portion of actual incidents that take place in the system and therefore, it is not recommended that their rates of occurrences be solely used to assess risk [87].

Other forms of patient safety data can provide with relevant information to create a better picture about risk. Each form has its strengths and weaknesses. For example, compared to other sources, chart review identifies a larger number of failures [87], while direct observation helps identify errors (commission/omission), or failures directly related to human performance [88]. These methodologies are costly and time consuming. For this reason, chart review and direct observation are mostly used in time-limited or problem-specific studies [89]. It has been argued that different approaches lead to the identification of different types of failure. Thus, it is recommended that several sources

of safety data are concurrently used to create risk analysis models that support decisions to enhance patient safety.

The use of disparate, perhaps incommesurable, sources of data to identify potential sources of risk presents a challenge to healthcare risk managers. Even though several information systems exist that process and present this data in a more understandable fashion (histograms, runs charts), it is up to the analyst to discover connections and to identify causes or sources. The causes of events of interest are mainly identified through investigative and qualitative methods, and therefore conclusions are subject to circumstancial, hindsight and background bias, which limits the consistency of results and efficiency of derived solutions [7]. Frequently, these investigations tend to focus on human factors as the cause [8].

The IOM patient safety research agenda emphasizes the importance of the development of healthcare risk models, and the integration of retrospective and prospective risk analysis techniques [26]. Risk modeling is useful to understand the mechanics of risk in the system, unify knowledge, and explore and evaluate risk management options [157]. Such models should allow for the use of available data to assess risk and provide the necessary information to help providers deliver appropriate and safe services [105].

The next section briefly describes commonly used techniques for risk analysis in healthcare. In addition, it introduces relevant concepts from general safety theories that will be used to propose an explicit characterization of risk sources. This characterization will become the foundation of our proposed modeling framework for risk in healthcare systems.

4.2 Risk Identification and Analysis

Traditionally, risk and safety have been concerned with identifying root causes of observed adverse events and preventing their re-occurrence. The most commonly used

tool for this purpose is RCA, which is used to investigate accident causes and determine the necessary corrective actions [46]. However, RCA has disadvantages due to its qualitative and retrospective nature; it is time consuming, results are strongly influenced by the background of the investigators, and it takes place when something has happened and most likely somebody has been harmed. In addition, some suggest that RCA may be biased toward the identification of superficial causes, since system causes are often related to organizational issues that are easier to identify than to solve, such as inadequate staffing ratios or poor IT infrastructure [126].

There are several other techniques intended to analyze specific hazards or risks, determine their causes, and define and manage the corresponding recommended actions [156]. Safety researchers have been active in adapting existing methods, or proposing new methodologies and models to analyze and understand the risk of adverse events and their causes.

Basic theorists of safety and accident causation seem to agree that the the path to adverse events is associated to the performance of safety constraints. Safety constraints are functions, devices or procedures intended to prevent specific events. According to Reason, adverse events are the product of safety constraints aligning their weaknesses to allow for the occurrence of undesired events and their consequences [33]. This follows Rasmussen's thinking that the performance of systems should be analyzed "in terms of system constraints, acceptable performance, and adaptation to change" [17].

Along these lines, several researchers have proposed risk models based on the analysis of the performance of safety constraints. Leveson proposed to view adverse events as the result of inefficient controls on the interactions of system components. Their methodology STAMP (Systems-Theoretic Accident Model and Processes) provides the means to investigate and analyze adverse events in terms of ineffective system controls as risk sources [14]. However, this is mainly a static, retrospective, qualitative methodology.

Similarly, Aven et al. proposed a method to estimate risk of hydrocarbon release in offshore platforms in terms of safety constraints. Their methodology combines traditional risk analysis techniques, available industry data on probability and frequency of adverse events, and assessment of risk influencing factors within the particular organization. The outcomes of the methodology are a measure of risk and an analysis of the performance of safety barriers that facilitates decision making to enhance system safety [15]. This method also uses the concept of constraints to analyze risk and identify its sources. It is prospective (rather than retrospective) since it uses event trees and fault trees to analyze potential adverse events before they take place. It can be applied to different types of adverse events. Nevertheless, it is a static analysis methodology that has to be carried out every time the analysis is needed, since some input data and parameters may change.

Rognin et al. [158] suggest that global reliability of socio-technical systems relies on regulation. Regulation is a systematic behavior in one part of the system that constraints some behavior in other part of the system. The authors develop a model of information cooperation and regulation to analyze its impact in system reliability.

Chuang [16] proposed a retrospective methodology to analyze patient safety events as part of a control problem. The methodology is called SOEA (system oriented event analysis). The authors use patient safety and quality indicators to determine which patient safety events and related system components will be analyzed. Selected system components related to the events are classified according to their attributes (flow components, structural components, and operating components) and hazard evaluation is performed to discover other system components that affect performance. Then, new controls are imposed to the system to enhance its performance. The advantage of this methodology is that it provides a framework to define the system to be analyzed, including interactions with other systems, so that risk analysis identifies sources that are not necessarily contained in the system of interest.

This research proposes to use the concept of safety constraints for prospective risk identification and analysis in healthcare delivery systems. Sources of risk are characterized with the safety constraints available in the system, so that risk analysis focuses on finding relations between these sources and potential adverse events through observable data. In the context of healthcare, patient safety interventions can be regarded as safety constraints.

4.3 Patient Safety Interventions

When risks are identified, then they should be controlled by means of the appropriate treatment [159]. In healthcare, risk control is generally achieved through the implementation of patient safety interventions (PSIs), e.g. technology, improved procedures, or new policies intended to improve care by minimizing harm to patients, and thus risk [160]. PSIs are analogous to safety constraints in other industries. A PSI becomes a "safety constraint" once it is implemented. We will use the word "intervention" to refer to both, interventions and constraints.

The main objective of PSIs is to guide processes along a safe path, to reduce incidents and adverse events [126]. Nevertheless, because of the socio-technical nature of healthcare delivery systems, some interventions may not always perform as intended. Once implemented, different factors may affect their functioning. For example, in a bar-code medication administration system, technical factors, such as damaged bar codes [161], will counteract the initial purpose of ensuring the administration of the right medication to patients. Also, human factors, such as human errors, will prevent staff from correctly using the bar code reader. Additionally, organizational factors, such as insufficient training, will have a similar effect on the process. Therefore, and following the general safety literature trend (previous section), we propose to use patient safety interventions to

characterize potential risk sources, whose performance should be monitored over time to detect potentially dangerous deviations that may result in adverse events.

This research proposes to use patient safety interventions to characterize sources of risk, and to assess the likelihood of adverse events (PAEs), as shown in figure 4.2.

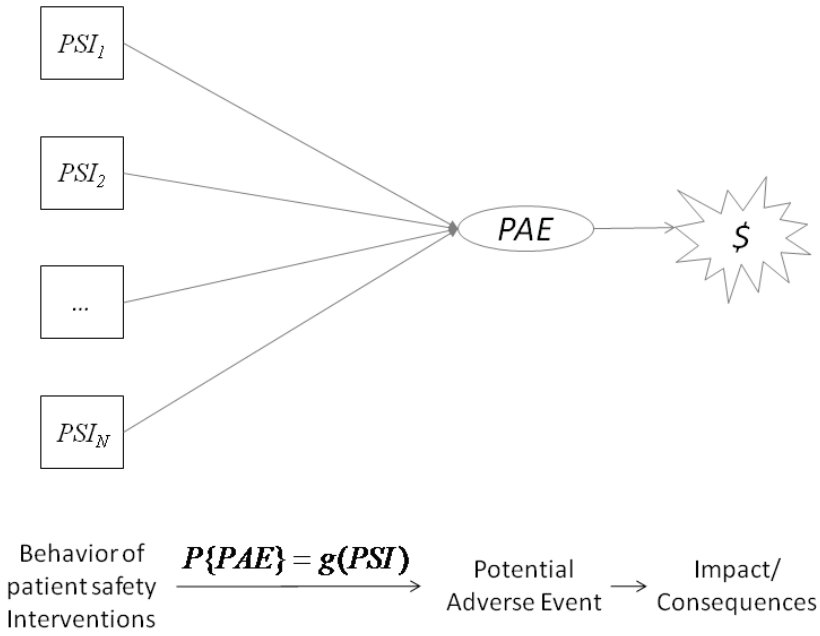

Figure 4.2: Risk analysis model using patient safety interventions

However, the performance of patient safety interventions is not a readily observable quantity and it should be defined and measured, or assessed. Since patient safety data provides insight into risks, then available patient safety data should be used to assess the performance of patient safety interventions, so that risks can be assessed, while potentially relevant risk-sources are identified (see figure 4.3).

The implications of using patient safety data to assess the performance of interventions rather than to directly identify errors, or assess the likelihood of potential adverse events, include:

- The explicit definition of risk sources to guide analysis (such as RCA) and focus on practical problems and realistic solutions.

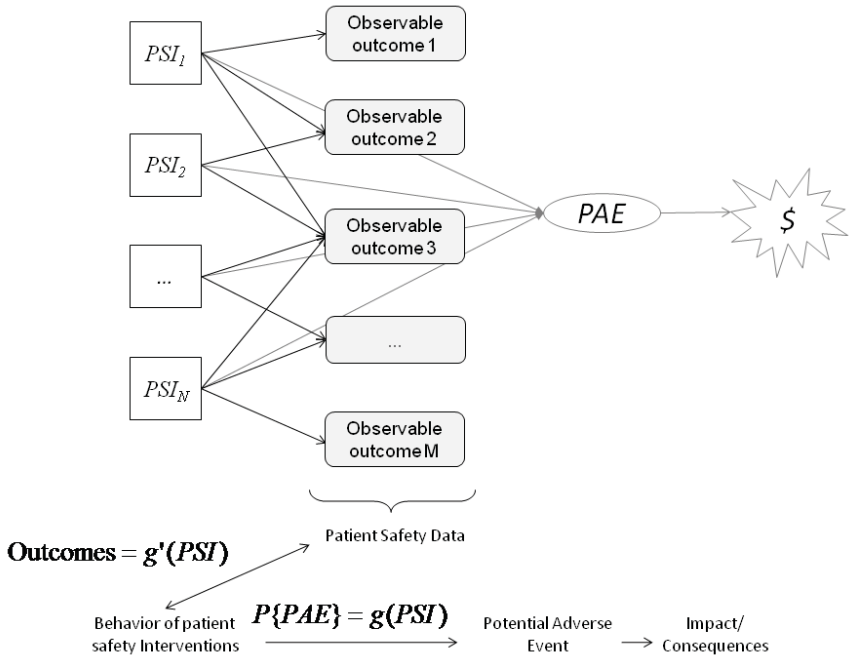

Figure 4.3: Proposed risk analysis model

- The opportunity to redefine the "risk domain" of an organization to include PSIs as potential "areas" or points of interest.

- The increased motivation to understand the performance of patient safety interventions and their relation to different sources of patient safety data, which can be used to develop decision support models.

- The ability to justify the gathering of additional types of data, such as chart reviews, when there is suspicion about the latency of specific risk sources.

- The need for information systems to manage patient safety data by assigning occurrences to the corresponding interventions, so that analysis can be automated and feedback expedited.

- The reduction in time required to analyze patient safety data and identify sources of risk.

- The expected improvement in the reliability of some patient safety data sources, such as incident reporting, since people would report to point the substandard performance of a system component, the PSI, rather than to expose an error or admit blame.

However, the format and nature of patient safety data hinders the use of traditional (statistical) modeling tools to assess the performance of patient safety interventions. Patient safety data, such as incident reports and patient complaints, are often incomplete. In addition, these data do not constitute a random sample of the incidents that take place in the system. Furthermore, most patient safety interventions consist of procedures (such as handwashing, or barrier precautions) for which a frequency of use cannot be easily assessed to determine outcome rates. Therefore, there is the need to develop an understanding of the actual relation between observable patient safety data and the performance of patient safety interventions. Even the ability to link observable outcomes to the performance of specific PSIs provides relevant information about risk in the system to guide further investigation or risk analysis efforts.

In the remainder of this chapter we present suggestions for developing a formal characterization of healthcare delivery systems that includes risk, and facilitates risk analysis using traditional methods and information technology. Such characterization will be used in the next chapter in an analytical model that uses available data to model the performance of patient safety interventions.

4.4 Developing a Healthcare Risk Model

According to Kessels-Habraken et al., incident reporting and analysis is strengthened by (a prior) prospective risk analysis of the system [162]. In agreement with this result, we propose to use prospective risk analysis to identify potential adverse events and then merge this knowledge with forthcoming patient safety data, for example incident reports,

to monitor risk. Most of the existing (traditional and novel) risk analysis methodologies are mostly qualitative and static. Thus, the analysis depends greatly on the background and experience of the investigator [8], feedback takes long periods of time, and conclusions may become obsolete as the system changes. Our proposed framework addresses these gaps by providing for a platform to centralize knowledge in an modeling framework that accommodates the outputs of traditional risk analysis and available patient safety data.

4.4.1 Modeling Approach

Table 4.1: Modeling assumptions

Assumptions
• The healthcare delivery system is formed by 2 parallel subsystems, i.e., the service and risk systems, as proposed by [32]. • The service system is formed by resources, activities and services provided within the system. • The risk system is formed by patient safety interventions in the system. • Risks will be mapped to the performance of patient safety interventions.

We propose to view the healthcare system as two parallel subsystems, namely the service system and the risk system, as suggested by Cooke [32].

The *service system* is formed by the resources available within the delivery system. These resources can be divided into classes or types, for example: medical providers, supporting staff, patient information system, equipment, facilities, supplies, and procedures [71]. The performance of the risk system is evaluated through quality and cost indicators.

The *risk system* is characterized by the set of PSIs. PSIs are safety constraints designed and put in place to prevent (specific) potential adverse events (PAEs). Although some PSIs may come from outside the system (e.g. government regulation) [17], focus

may be initially placed on those that are under the control of the system. Interventions originally designed and implemented to control patient safety outcomes, and subsequently improve quality outcomes, should be considered as system constraints. A checklist before surgery is an example of a PSI.

The performance of the risk system should be evaluated and monitored using *patient safety data*. Examples of patient safety data are near-misses, mandatory and voluntary incident reports, morbidity and mortality cases, malpractice claims, and triggers [34], among others. Each type of patient safety data, as defined by the organization's risk domain or by a standard classification system [80, 81, 151] constitutes an outcome; e.g., a blood-product near-miss report following the AHRQ common formats event description.

Interactions among system components (resources and PSIs) will be determined by the activities and services. Given the service and risk systems, there is a number of *activities* (or classes of tasks) that can be performed within the boundaries of the system e.g. injecting a patient, rehabilitative therapy, and others. They are characterized by system components that they require to be carried out, such as resources required for the activity, level of participation of the patient (active, passive, not present), formal procedures, and PSIs related.

Activities form sequences, or sets, that define *services*. Note that an activity could be be carried out several times within a particular service.

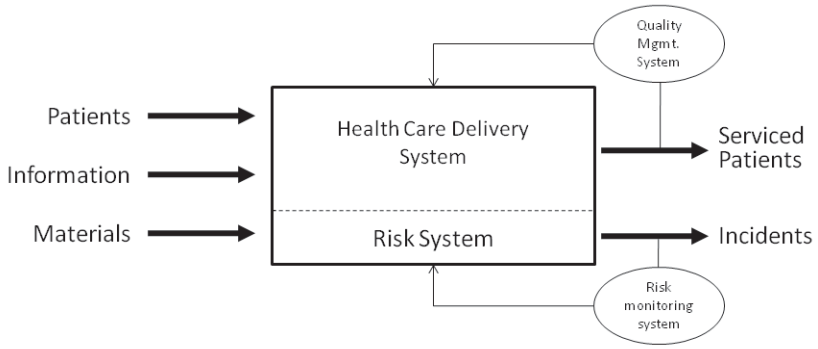

Figure 4.4: The service and risk systems (from Cooke and Rohleder, 2006)

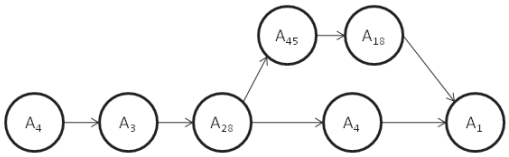

Figure 4.5: An example of a service

Every service can be associated with particular patient safety outcomes, and *potential adverse event(s)* (PAEs). PAEs are events of concern due to past experience within the system or in other (similar) systems. PAEs are not frequently observed in normal operation, however their severity demands that controls are in place to avoid them. Some PAEs can be identified through specific patient safety data sources, such as mandatory adverse event reporting. PAEs should be carefully defined since they pose the highest severity among all possible patient safety outcomes, and should be avoided.

Other patient safety outcomes, such as near-misses, are more common in daily operations and are believed to suggest the extent of the risk of PAEs [43]. Therefore, it is strongly recommended that these outcomes are monitored and prospectively analyzed to assess and prevent PAEs [26]. Different services may be related to one or more patient safety outcomes and PAEs. Each PAE related to each service can be subsequently related to specific activities, and thus to particular system components (resources and PSIs).

Systems analysis and prospective risk analysis methods can be used to characterize the system for the first time, and to update it when necessary. The proposed characterization is intended to help organize current knowledge about the system and its (expected) performance. Once the system is characterized by its resources, PSIs, data sources, services, PAEs and patient safety outcomes, their relations can be established using traditional risk assessment methods, and be used to develop models that facilitate the analysis of upcoming patient safety data. The result of this stage can be incorporated into a database that can be used in future risk analysis efforts. Such database would act as a

central of risk-knowledge, where new relations are incorporated as they are discovered and old relations may be removed as they are proved invalid.

4.4.2 Risk Analysis Database

Although gathering initial data for the model might seem time consuming, the process is not significantly different from risk analysis efforts common in most healthcare settings. The proposed characterization allows for the use of database structures to track events of interest, such as what PSIs and resources are related to observed outcomes or PAEs (figure 4.6). Besides, it will be possible to update the database and interactions as new components are added to the system, such as new interventions implemented. Results of risk analysis, such as FMEA and RCA, can also be included in the database to relate activities and interventions to patient safety outcomes and PAEs. Figure 4.9 illustrate an example of the relations in a characterization-database.

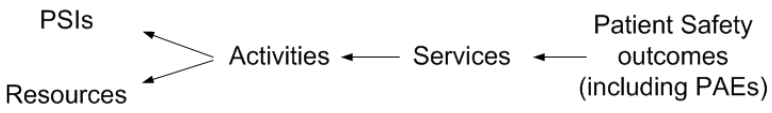

Figure 4.6: Backtracking from observable data

From this characterization, risks related to a particular PAE can be analyzed in terms of their associated services or activities. In addition, when particular outcomes are observed, then priority can be given to study components and interactions shared by these outcomes.

4.4.3 System Visualization

So far we have defined sets of components and their interactions. Visualizing the model helps sharing it with other stakeholders and validating it. It also facilitates risk analysis by showing relations that may otherwise be overlooked. A natural way to visualize our system characterization is using graph models [163], since they allow for the representation of relations between different types of entities, or system components.

Figure 4.7 shows a graph where nodes represent resources, PSIs, activities, services and outcomes (we included patient safety outcomes, PAEs and quality outcomes). For simplicity, we have clustered the nodes according to their type. We have added a node named "patient" to denote the patient being present, or not, in an activity (whenever there is an edge from the patient node to such activity). Nodes with the legend "q_n" represent quality data sources, which may be included in the system characterization if desired.

Whenever an outcome takes place, the related resources and interventions can be identified, as shown in figure 4.8. PAEs related to the outcome, its resources or PSIs can also be identified.

4.5 Risk Analysis

The proposed system representation facilitates the organization of data and information about the system, allowing for risk analysis to be performed at each node. This graph representation can be used to support probabilistic risk assessment (PRA) [28], in which edges that connect outcomes to services, activities or any other entity can be given a weight equal to the perceived likelihood of such entity causing the outcome. Similarly, the severity can be allocated to each outcome node. If there is information about the expected frequency of services, then a likelihood of such outcomes could be estimated using

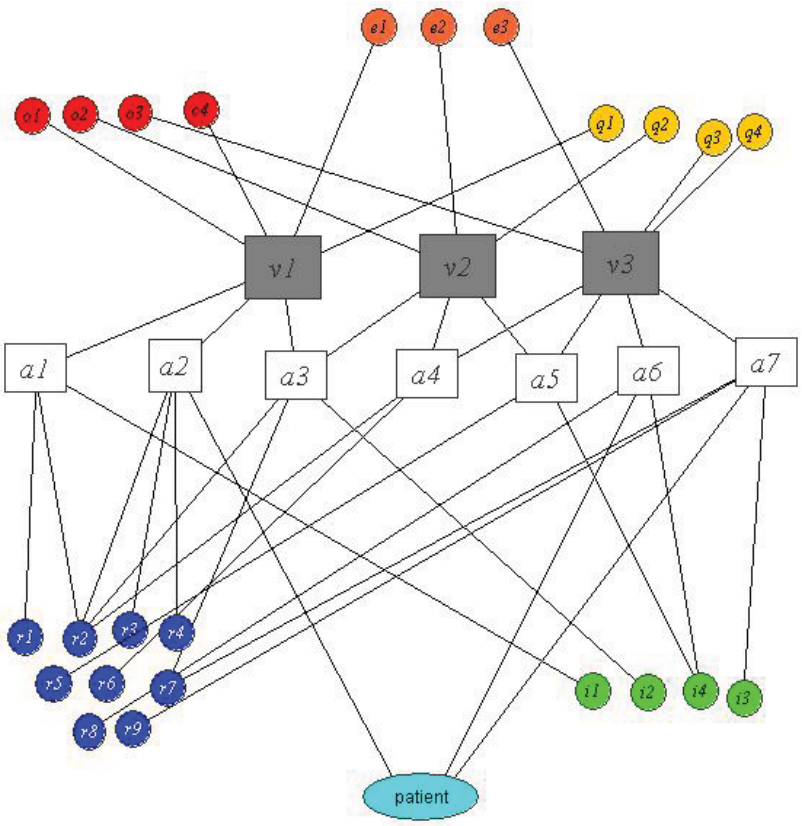

Figure 4.7: Example of graph representation

PRA calculations and such nodes could then be ranked in terms of their corresponding risk scores.

In what follows, we elaborate in the use of commonly known risk analysis techniques using the proposed system characterization.

4.5.1 Failure Modes and Effects Analysis

FMEA is a prospective risk analysis methodology that involves quantification of beliefs related to risk and outcomes. We suggest the use of FMEA every time the system changes or grows to reflect such changes in the model. In this section, we illustrate the use of FMEA to build and update a model in terms of patient safety interventions and available patient safety data. We propose to use the structure of a traditional FMEA [156,

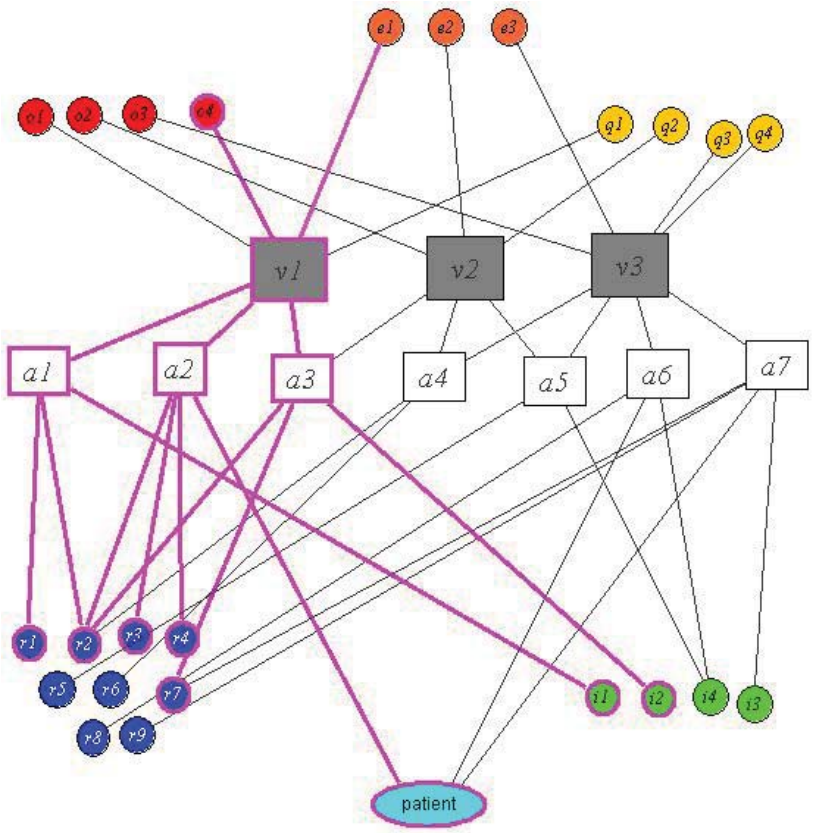

Figure 4.8: Tracking outcome 4 in the graph representation

164] to assess the possible states of PSIs, but incorporating information about observable outcomes that are believed to be related to each intervention and corresponding failure modes.

We propose to perform an expanded version of the Failure Modes and Effects Analysis (eFMEA). The objective of the eFMEA is to facilitate the organization of existing knowledge about the risk system. The information obtained from the eFMEA can be incorporated into the risk database to be consulted in future risk identification efforts, and updated as new patient safety interventions are added to the risk system or new links between PSIs, potential adverse events, and observable data are identified (figure 4.9). The goal of the eFMEA is to match services with patient safety interventions, PAEs and outcomes. Therefore, the FMEA is setup following a list of services and PAE's identified previously. If new PAEs arise, they must be appended to the list and related to the cor-

responding service. When PAE's are related to specific services, they are automatically linked to specific activities (and their activity sets), facilitating the identification of risk in interactions of specific system components (resources and constraints).

The expanded FMEA is illustrated in table 5.1.The logic of the table follows. After selecting a service for analysis, the potential adverse events (PAEs) that can be related to that service are listed (column 1). PAEs can be thought of as failure modes of the corresponding service; each service can have more than one PAE assigned to them, and PAEs can be assigned to more than one service. The potential undesirable effects of the PAE are also recorded (column 2). Each adverse event is assigned scores for likelihood of occurrence, likelihood of detection and severity, according to a traditional FMEA or some agreed-upon scale (columns 3-5). Up to this point, the analysis is similar to a traditional FMEA, and thus a risk priority number (RPN) can be calculated (column 6). In addition, participants are asked to identify the patient safety interventions (PSIs) (or lack of) (column 7) that attempt to prevent the occurrence of the adverse event in question and the possible states of the PSI that are expected to contribute mostly to the occurrence of this PAE (analogous to failure modes of interventions) (column 8). Depending on the latency of the PAE and the state of the intervention, different outcomes in patient safety data sources might be observed (column 9). The likelihood of observing one of those outcomes given the latency of the PAE in question and the state of the intervention is recorded (column 10). Finally, participants are asked to assess what is the likelihood of observing the corresponding PAE if the PSI is in the respective state (column 11).

The main difference from traditional versions of FMEA can be seen in the last five columns of table 5.1. It consists of identifying and assessing the likelihood of possible observable outcomes that depend on the state of patient safety interventions. This assessments will allow to link observable outcomes to states of patient safety interventions and potential adverse events to be used in models of risk. Likelihood and rate (or frequency) estimates can be assessed according to a scale that is familiar to those performing the

analysis. Units of reference may include percentage of patients experiencing such outcomes in a specific period, total number of outcomes in a period, number of outcomes per number of patient-bed days, outcomes per patient days at risk, and number of outcomes per times the intervention was used in the period of interest. It is important that the period of this frequency, or a denominator for a rate, can be assessed using the administrative information system of the organization, so that these can be used in modeling efforts using actual rates of observed data. The literature has some standard scores that may be used for this purpose [156, 165].

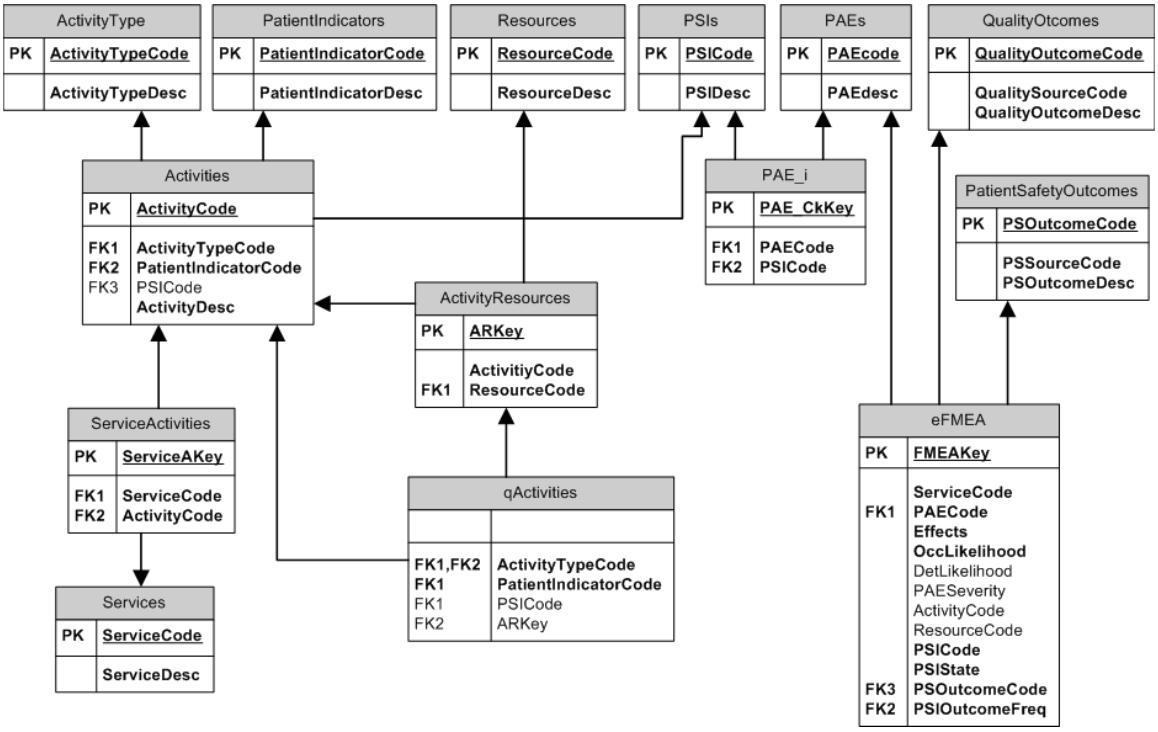

Figure 4.9: Example of characterization database

4.5.2 Root Cause Analysis

Whenever an outcome of interest takes place, an RCA can be guided by inspection of the graph representation of the system (section 4.4.3). When the system size does not allow for visual inspection, a query in the risk database (section 4.4.2) will ease the pro-

cess of linking outcomes to potential sources during the course of an RCA. Findings from the RCA can be used to validate and update the risk model by adding or removing entities and (or) interactions. In such a case, the poposed model serves as a central location for knowledge obtained from data, and from risk analysis.

4.5.3 Risk Mapping

If the frequency of each service can be forecasted, then figure 4.8 can be used to guide the assessment of the probability of adverse events. The assessment team can focus on assessing the probability weights of the links between services, outcomes and adverse events. The information from the eFMEA can be used to obtain this assessments. Therefore, once information about risks are included in the risk database through an eFMEA, then risk maps can be created by combining the relevant information, avoiding duplicate assessments that may be inconsistent. Furthermore, analysis of the resulting risk map can be used to confirm or question the validity of the knowledge about risk that is currently stored in the database.

4.6 Conclusions

This chapter justified the use of patient safety interventions as sources of risk, as it is supported by the general safety literature. In addition, it proposed a plan to gather, organize and use data commonly available in healthcare. Furthermore, we illustrated how this characterization can be used to facilitate risk analysis through traditional methods.

Structuring information about the system and available data in the proposed manner, allows for the development of models of the performance of risk sources in terms of observable outcomes, and potentially facilitates risk analysis, enhancing its benefits. Still, operational data in healthcare tends to be incomplete and biased. In addition, most

information about risk comes from experts' assessments and the analysis of faulty data. Therefore, models that aim to address risk identification and analysis should account for these limitations in data and information.

Chapter 5: Maximum-Entropy Based Model to Monitor Risk in Healthcare Delivery Systems

5.1 Introduction

Some say that healthcare itself is one of the main causes of death in the world [162]. Healthcare delivery systems are human driven, and as such, care processes are subject to variability and change over time. Variability in human behavior can not only bring resilience to the system [57, 166], but can also lead to behaviors that cause unintended outcomes, thus increasing the risk of harm to patients beyond acceptable thresholds [47]. In addition, the increased use of technology has introduced new risks related to the use of medical devices and equipment. Risks related to substandard human-technology interactions are difficult to identify and assess due to their ubiquity and inconspicuousness. In healthcare settings, risks are visible when it is too late, which means that somebody has been harmed. Therefore, there is the need for the systematic identification of risks in order to prevent harm to patients.

Healthcare organizations usually identify risks using mostly qualitative risk analysis methodologies, such as Root Cause Analysis (RCA), Failure Modes and Effects Analysis (FMEA), and Risk Mapping. These tools focus mostly on determining scores for the likelihood and severity of identified risks. Scores are generally obtained from experts' assessments, ideally based on historical data about previously identified risks. These analyses are designed so that they must be conducted each time that there is a concern

regarding safety, and their outcomes are generally a set of failure modes or causes that should be addressed to reduce the latency of the corresponding risk.

The main reason for the popularity of qualitative risk analysis methodologies lies on the availability and shape of related data. A major concern for the Institute of Medicine (IOM), and a challenge for risk managers, has been the lack and limitations of operational data to allow for continuous analysis and monitoring using traditional or statistics-based techniques. Patient safety data consist of facts, observations, and/or measurements that lead to the identification of failures that harmed (or could have harmed) patients. They are often incomplete and subject to bias, since they are usually obtained from healthcare workers in the form of free text or narrative [151], even though they may be classified according to a taxonomy or event classification for analysis [19, 80].

The need for the development of tools that systematically organize, process and analyze patient safety data is important to help healthcare risk managers overcome the limitations of their human condition and enhance their efforts to make sense of risk in a consistent manner. We formulated an analytical model that integrates experts' risk assessments (similar to those of an FMEA) and available patient safety data to identify potentially relevant sources of risk. The proposed model is intended to support an automated risk analysis engine for decision making in healthcare risk management. The underlying risk model allows for the identification of potential risk sources by finding connections among outcomes and system components that the naked eye is likely to miss because they seem irrelevant, or because the corresponding assessments may have been forgotten over time. Risk managers could then focus on understanding the system, identifying sources of risk, updating their assessments and the model, and developing strategies to prevent or solve patient safety problems.

To build the desired risk analysis model, potential sources of risk were explicitly characterized in terms of system components whose performance should be monitored over time. Then, FMEA assessments were adapted to link commonly available and observable

data to the performance of such risk-sources. The Principle of Maximum Entropy (Maxent) was used to assess probability-based scores for each risk-source, given the limitations of available patient safety data. Using the output of the proposed Maxent formulation, the risk analyst can use RCA to confirm the validity of risk flags and determine the need for intervention. Our proposed model is based on FMEA and RCA because these are the most common risk analysis techniques in healthcare, and their use will facilitate understanding and implementation.

This research has several contributions. (i) It provides new insights on the analysis of risks by revisiting the focus of risk assessment efforts and introducing a well defined set of risk sources that should be monitored to guide analysis and support decision making. (ii) It introduces the states of these risk sources as an intermediate measure of risk that can be used for the assessment of the likelihood of adverse events, while providing for explicit criteria to identify potentially relevant sources. (iii) It contributes to the risk analysis literature by formulating a model that is built using information and methods that are commonly available in healthcare systems (e.g. FMEA), and available patient safety data (e.g. incident reports). In general, the proposed approach advances healthcare risk analysis by providing a structure for the many available sources of information about risk, and combining them in a model. This approach will facilitate and expedite risk analysis by directly pinpointing potentially relevant risk sources, and will help diagnose the need for new or updated assessments given observed data.

The next section provides some detail on healthcare risk identification and analysis, introduces the concept of patient safety interventions as risk sources, illustrates the use of an expanded version of an FMEA that incorporates observable data, and formulates the underlying risk model. Section 5.3 presents the Maxent formulation to assess probability-based scores, while section 5.4 illustrates how identification and monitoring of risks is facilitated using the proposed formulation. Section 5.5 contains remarks and comments about future research directions.

5.2 Modeling Risk in Healthcare Delivery Systems

In healthcare, as in other sectors, risk management aims to systematically identify all risks within the organization. These include risks that compromise patient safety which are the focus of this paper. Risks in healthcare are understood and characterized in many ways, even within a single institution; and are generally perceived as the exposure to circumstances that may lead to adverse (undesirable, preventable) events. Examples of risks could be: the potential for a patient fall, the potential for acquiring an infection during a hospital stay, or the potential of an employee getting a needlestick injury.

According to Rasmussen [17], socio-technical systems such as healthcare delivery systems lack some structure that would allow them to use traditional predictive risk analysis tools. For example, organizations such as power plants have technology that allows them to track system performance and determine potentially dangerous trends. However, healthcare services are human driven and many healthcare processes cannot be automated for data collection. Therefore, patient safety data tends to be incomplete and biased.

Healthcare organizations collect a wide range of data that are utilized for risk identification and analysis, including: mandatory and voluntary incident reports, malpractice claims information, patient complaints, quality indicators, rounds, chart reviews (i.e. occurrence screening) and administrative information, among others. There is no formal mechanism to use these data in the identification of risks. These data are generally classified into the organization's risk domain or classification system and analyzed by areas of interest. Tools recommended for the analysis of such data include run charts, Pareto charts and histograms [4].

After risks are identified, they should be analyzed to assess the likelihood of related adverse events and their severity or potential for loss. Risk analysis looks deeper into the data to identify underlying system issues that contribute to adverse events, to prioritize and plan for resources, and to define appropriate treatments or solutions. Formal risk

analysis is also triggered by the occurrence of an unexpected adverse event (e.g. a patient fall)[167], or by the implementation of a new or changed process (e.g design of a new operating room). Likelihood and severity are generally assigned in the form of scores that are obtained from the assessments of experts who are familiar with the process.

The most common methods for risk analysis are FMEA and RCA. FMEA is a structured proactive method to identify the ways in which a process may fail —failure modes— in order to assess their likelihood of occurrence, likelihood of detection, and potential for harm [164]. Assessments are given in the form of standard scales or rates that make sense to the analysts. There are standard fields in an FMEA, but some variations are found in the literature [156, 164, 165, 168]. RCA is a method to identify causes of events such as near-misses, adverse events and other important events. When conducted on adverse events, it is a mainly retrospective methodology that addresses the root causes of observed incidents by asking questions about the incident, its consequences and potential sources [60].

Although some methods have been proposed to utilize the results of these types of risk analysis over time [169], it is common that assessments are used for a one-time decision making. New assessments are obtained by conducting a new analysis when deemed necessary [164]. We propose that the results of risk analysis be used over time to facilitate risk monitoring and to detect changes in the performance of the system, reflecting the need for new assessments.

We propose an explicit characterization of risk sources, so that risk analysis activities and models focus on their performance and incorporate their effects on observable data. We explored the broader safety literature to define this characterization in terms of system components whose performance should be monitored over time. The next section presents the concept of patient safety interventions and proposes their use as sources of risk.

5.2.1 Sources of Risk: Patient Safety Interventions

Analysis of patient safety data should lead to the identification of current risks, to the foreseeing of possible critical adverse events, and ultimately, to the development of strategies aimed at preventing or mitigating circumstances that challenge the safety of patients [4]. These strategies generally consist of the selection and implementation of patient safety interventions. These interventions can be technology, improved procedures, or new policies to improve care processes. They are analogous to the concept of *safety constraint* in other industries, and their main objective is to guide processes in order to reduce patient safety incidents and adverse events [126].

According to the safety literature, safety constraints play an important role in the occurrence of accidents [8, 17, 33]. Some authors have proposed models based on the performance of safety constraints to identify and assess risk [14, 15]. However, these models have similar disadvantages to RCA and FMEA, in that they are also mainly qualitative, and thus time consuming. Generally, the results of theses analyses are static, which means that they have to be conducted every time the analysis is needed.

In this work, we propose to use the concept of safety constraints in healthcare systems, i.e. patient safety interventions (PSIs), to characterize the set of potential sources of risk. We use PSIs to facilitate the analysis of patient safety data. We refer to the set of the sources of risk, or PSIs, as *the risk system* [32]. We define the state of the risk system as a vector of the states of all PSIs. The goal is to determine the most likely state of the risk system in the least biased manner, given the available data and the current knowledge about risks. The state of each PSI is assumed to be binary, and defined as *normal operation* and *failed state*. These states correspond to the intervention, either working as intended upon implementation, or not, respectively. In the next section we illustrate an analysis similar to an FMEA but based on patient safety interventions and observable outcomes, which can be used to build a model to monitor risk in healthcare systems.

5.2.2 Using Failure Modes and Effects Analysis to Monitor Risk

To assess the possible states of PSIs, we propose an expanded FMEA (eFMEA) incorporating information about observable outcomes that are related to each intervention and their corresponding states. Ideally, the eFMEA facilitates the organization of knowledge about the risk system in order to model its performance using observable data. The information obtained from the eFMEA exercise can be stored, updated, and utilized subsequently in identifying risks.

As in the traditional FMEA, the analysis should be conducted by a team. The eFMEA is set up following a list of services offered by the unit of analysis, e.g. clinic, department, or other. We refer to this unit of analysis as *the system*. We interpret the different kinds of potential adverse events (PAEs) as failure modes of the healthcare system. When PAEs are identified for a particular service, and such a PAE has no related intervention in place, then the traditional FMEA should follow. In this case, the corresponding corrective action could be considered as a new intervention in the system. In addition, the eFMEA encourages risk analysts to take a step further and to define what observable outcomes are expected given an intervention state.

Table 5.1 shows an example of a form that can be used to conduct this expanded FMEA.

Table 5.1: Expanded FMEA form for a particular service

PAE (Failure Mode)	**PAE Effects**	**Occurrence** Likelihood	**Detection** Likelihood	**Severity**	**RPN**	**PSI**	**PSI State**	**Outcome** (Observable)	**PSI-State Outcome Rate**	**Likelihood of PAE in PSI-state**
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)

The logic of table 5.1 follows. After selecting a service for analysis, the PAEs that can be related to that service are listed (column 1). PAEs can be thought of as failure modes of the corresponding service; each service can have more than one PAE associated with them, and PAEs can be assigned to more than one service. The potential undesirable

effects of the PAE are also recorded (column 2). Each adverse event is assigned scores for the likelihood of occurrence, the likelihood of detection, and the severity, according to a traditional FMEA or some agreed-upon scale (columns 3-5). Up to this point, the analysis is similar to a traditional FMEA, and thus a risk priority number (RPN) can be calculated (column 6). In addition, participants are asked to identify the PSIs (or lack of) (column 7) that attempt to prevent the occurrence of the adverse event in question and the possible states of the PSI that are expected to contribute mostly to the occurrence of this PAE (analogous to failure modes of interventions) (column 8). Depending on the latency of the PAE and the state of the intervention, different outcomes in patient safety data sources may be observed (column 9). The expected frequency of observing one of those outcomes, given the latency of the PAE in question and the state of the intervention, is recorded as the state dependent outcome frequency (column 10). Finally, participants are asked to assess what is the likelihood of observing the corresponding PAE if the PSI is in the respective state (column 11).

The main difference from traditional versions of the FMEA can be seen in the last five columns of table 5.1. It consists of identifying and assessing the expected frequency, or rate, of possible observable outcomes that depend on the state of PSIs. These assessments allow to link observable outcomes to states of PSIs and PAEs to be used in models of risk. The estimates of likelihood and frequency, or rate, can be assessed according to a scale that is familiar to those performing the analysis. The corresponding units of reference may include percentage of patients experiencing such outcomes in a specific period, total number of outcomes in a period, number of outcomes per number of patient-bed days, outcomes per patient days at risk, and number of outcomes per times the intervention was used in the period of interest. It is important that the period of this frequency, or a denominator for a rate, can be assessed using the administrative information system of the organization. The literature has some standard scores that may be used for this

purpose [156, 165]. Table 5.9 shows an example of a scale that may be used to obtain these assessments.

The next section presents the formulation of the model built from the information obtained from the eFMEA and explains the objectives of the corresponding analysis.

5.2.3 Problem Formulation

This research focuses on a healthcare delivery system. A system can be a single unit or department of an organization, for example the emergency department at the local hospital. The system has several resources that determine the activities or tasks that can be performed. Among these resources, there is the set of potential risk sources, i.e. the risk system, $\mathscr{I}$. These risk-sources are related to both, the set of PAEs known to the system, $\mathscr{E}$, and the set of patient safety outcomes, $\mathscr{O}$. The set of PAEs is formed by the elements in column 1 of the eFMEA, and the set of outcomes is defined by the available patient safety data sources, such as particular types of incident reports, or categories of patient complaints, among others. We assume that patient safety outcomes are categorical-nominal, and that they may be incomplete and biased.

For every period of interest (e.g. a shift or a week), the frequency or rate of the different patient safety outcomes can be obtained. These outcomes include events that are less severe than adverse events. For risk identification, we assume that an assessment of the probability of PAEs, $\mathrm{P}\{e\}, e \in \mathscr{E}$, is desired. We will use the information obtained from an eFMEA to build a model that allows for the assessment of such a probability. However, it is expected that the assessments obtained from an eFMEA are strongly biased by the background of the experts involved. Therefore, these assessments, as well as the probability scores obtained from our proposed formulation, are interpreted as the representation of the existing knowledge about the risk system [133].

To assess P$\{e\}$, we use the state of PSIs, $y_i \in \mathscr{S}_i$, as an intermediate variable; there are N interventions in the system. $\mathscr{S}_i$ represents the set of possible states of intervention i. This state represents the behavior of the particular patient safety intervention, compared to what it was expected from it upon implementation. Using this intermediate quantity has the advantage of obtaining a measure of the relevance of potential risk sources, allowing for their prioritization in subsequent analysis and improvement efforts.

However, often the state of the risk system is not obvious. Determining the state of the risk system requires an analysis that includes human, organizational and technical factors. Since these types of analyses are costly and time consuming, their use in healthcare is infrequent. Still, monitoring the behavior of the risk system should be done periodically to account for adaptations and changes in the system (turnover, new laws, learning curves, among others) [17].

Since PSIs are intended to prevent specific adverse events and patient safety outcomes are forms of failure, which may reflect the latency of such adverse events, we propose to use patient safety outcomes to assess the possible states of patient safety interventions. We denote the observed frequency of outcome o_j as $f(o_j)$.

If we let $y = (y_1, y_2, ..., y_N)$ be the state of the risk system (a vector of the states of each intervention), $\mathscr{S} = (\mathscr{S}_1 \times \mathscr{S}_2 \times ... \times \mathscr{S}_N)$ be the set of size $n = 2^N$ that represents the cartesian product of the sets of state of all interventions in the system, and $f = (f(o_1), f(o_2), ..., f(o_M))$ be the actual frequency of occurrence of outcomes $o_1, o_2, ..., o_M$ in a period, then the problem can be expressed as finding the value y that produced f in the period of interest. For this purpose, we need g, so that:

$$g(y) = f \tag{5.1}$$

The function g is the risk model and it represents the existing knowledge about the behavior of the risk system. This knowledge attempts to describe the performance of PSIs and their relation to observable outcomes. This representation is easier to interpret and assess by system experts, since it attempts to represent a cause-effect relation between states of the risk system and observed outcomes, respectively.

If knowledge about the risk system is represented by the eFMEA presented in section 5.2.2, then g could be defined as the system of linear equations formed by:

$$\sum_{s \in \mathscr{S}} a_{js} \cdot \mathrm{P}\{y = s\} \approx f(o_j) \qquad \forall j = 1, ..., M \tag{5.2}$$

$$\sum_{s \in \mathscr{S}} \mathrm{P}\{y = s\} = 1$$

$$\mathrm{P}\{y = s\} \geq 0 \qquad \forall s \in \mathscr{S}$$

Where a_{js} is the frequency of occurrence of outcome j when the risk system is in state s. This risk system outcome frequency (RS-outcome frequency) is estimated using the assessments of experts in the eFMEA (column 10 of table 5.1). Let $\lambda_{y_i}(o_j)$ be the eFMEA PSI-state outcome frequency (for outcome type o_j when intervention i is in state y_i). If a model is created for each individual intervention, then we would have $a_{jy_i} = \lambda_{y_i}(o_j)$ for each intervention i, and for each outcome type o_j. However, when we want to track more than one intervention at once, $N > 1$, these assessments should be combined for each state of the risk system, as follows.

$$a_{js} = \sum_{\substack{i=1 \\ (y_i \in s)}}^{N} \lambda_{y_i}(o_j) \qquad \forall j = 1, ..., M \tag{5.3}$$

$$\forall s \in \mathscr{S}$$

Where $s = (y_1, y_2, y_3, ..., y_N)$ is a state of the risk system.

$f(o_j)$ is obtained by finding the frequency of outcome type j in the same units of $\lambda_{y_i}(o_j)$.

The objective of the formulation defined in (5.2) is to find the probability distribution of the possible states of the risk system that is consistent with the current knowledge about the risk system, represented by the coefficients a_{js}, and some function of the observed outcomes, represented by $f(o_j)$. The first equation in (5.2) is analogous to the first moment or the expected value of $a_j s$ with respect to the probability distribution of y as it relates to a predetermined function of the observable data. In this research, we use the linear risk model to monitor the performance of patient safety interventions. We use the interpretation of probabilities as a measure of the uncertainty about risk, which is determined by the state of knowledge about the performance of the delivery system [133].

The simplest case is when the risk system has only one intervention ($N = 1$) and when there is only one type of outcome ($M = 1$). This is illustrated in the following system of equations:

$$a_0 \cdot \mathrm{P}\{y = 0\} + a_1 \cdot \mathrm{P}\{y = 1\} \approx f(o) \tag{5.4}$$

$$\mathrm{P}\{y = 0\} + \mathrm{P}\{y = 1\} = 1$$

$$\mathrm{P}\{y = 0\}, \mathrm{P}\{y = 1\} \geq 0$$

In this case, only one equation is needed to estimate the probability distribution, since the risk system has only two states $\{0, 1\}$.

However, in most healthcare institutions, there are many interventions to be monitored, along with several patient safety data sources. Each intervention may be linked to more than one outcome type, and conversely, some outcome types may be potentially affected by more than one intervention. An example for the latter is the *identification of*

use of Vitamin K through a trigger tool that suggests the presence of over-anticoagulation with Warfarin [170]. This outcome may be evidence of irregularities in an intervention that attempts to prevent adverse drug events, such as *a guided prescription program within in the computerized physician order entry system* or in a *management protocol to correct over-anticoagulation with oral vitamin K* [171].

In addition, according to the definition of the risk system and its corresponding state vector y, the possible number of states of the system grows exponentially with the number of patient safety interventions. So, the model will most likely be a linear system of $M+1$ equalities with n unknowns, where $M > 2$ and $n > M$.

This problem will most likely have infinitely many solutions. Thus, there is the need for a criterion to select among these solutions without adding bias or omitting any relevant information. We use *the principle of maximum entropy* as the criterion to select the most unbiased probability distribution among those feasible. In the following section, we introduce the concept of entropy and the *principle of maximum entropy* (Maxent)[18] and formulate the model as it corresponds to the proposed application.

5.3 Maximum Entropy Model to Identify Risk Sources

We propose to use the principle of maximum entropy (Maxent) [18] to estimate the probability mass function of the states of the risk system based on the most recent eFMEA and observed patient safety data. Entropy is a measure of information and uncertainty of a random variable [172, 173]. Maxent is generally used to make inferences about probability distributions of variables, so that the probability distributions are consistent with available, but incomplete, data [174]. Probability distributions with higher entropy are preferred [175].

Applications of Maxent include language processing [176], text classification [177], economy [178], aggregation of experts' predictions [179], production analysis [180], and ecology [181, 182], among many others.

We are interested in estimating a probability distribution for y, which is consistent with the current system risk model parameters, a_{js}, and available data, f. Shannon's entropy function of y, $H(y)$, is a function that maps the probability mass function (pmf) of y into a real number defined by:

$$H(y) = -\sum_{s \in \mathscr{S}} \mathrm{P}\{y = s\} \cdot \ln\left(\mathrm{P}\{y = s\}\right) \tag{5.5}$$

The Maxent model is a nonlinear programming model whose objective is to maximize Shannon's entropy of the variable of interest [183], while meeting some constraints determined by knowledge about the the variable or its pmf. The decision variables are the probabilities of each state of the variable of interest. In our case, the constraints are obtained from equations (5.2).

In summary, the formulation of the Maxent model follows:

Objective

$$\max H(y)$$

Subject to:

$$\sum_{s \in \mathscr{S}} a_{js} \cdot \mathrm{P}\{y = s\} \approx f(o_j) \qquad \forall j = 1, ..., M \tag{5.6}$$

$$\sum_{s \in \mathscr{S}} \mathrm{P}\{y = s\} = 1$$

$$\mathrm{P}\{y = s\} \geq 0 \qquad \forall s \in \mathscr{S}$$

To avoid overfitting, the expected value under the probability distribution should be close to the observed frequency, rather than equal to it [182]. We used a small value, ε_j, so that equations (5.6) become:

$$f(X_j) - \varepsilon_j \leq \sum_{i=1}^{n} a_{ji} \cdot p_i \leq f(X_j) + \varepsilon_j \qquad \forall j = 1, ..., m$$

It can be verified that, in the absence of constraint (5.6), the program yields the discrete uniform probability mass function, where:

$$\mathrm{P}\{y = s_1\} = ... = \mathrm{P}\{y = s_n\} = \frac{1}{2^n} \qquad \forall s_1, s_2 \in \mathscr{S}$$

The discrete uniform distribution is the distribution with maximum uncertainty, and it means that we have no information about y. Thus, there is no reason to believe that one state of the risk system is more (or less) likely than others. The literature presents efficient solution algorithms that can solve this problem [176, 184].

5.3.1 Practical Considerations

In a practical setting, there are many PSIs and many outcomes that can be potentially considered to build the desired model. However, it is important that PSIs and outcomes, included in the model, have certain characteristics so that the resulting model is sound for risk identification. In particular, this section addresses how to decide what PSIs and outcomes to include and provides suggestions to guide experts' assessments so that the left hand side of the final linear system of equations is consistent, and the model can be potentially useful. In addition, some comments about the solution of the model are presented at the end.

We first outline the conditions, and then interpret these as instructions to guide the assessment of PSI-state outcome frequencies. The conditions follow:

1. Each outcome type included in the model should be associated with at least one intervention.

   If a particular outcome o_j is not related to any PSI, then $\lambda_{y_i}(o_j) = 0 \; \forall y_i \in \mathscr{S}_i, i = 1,...,N$, and therefore, the corresponding coefficients in the linear system (obtained through equation (5.3)) would all be 0. If a positive frequency is observed for that particular outcome in a period, then the linear system will have an equation with a zero left hand side and a positive right hand side, and therefore, the system would be inconsistent.

2. Each PSI included in the formulation should be linked to at least one outcome type.

   If an intervention is not related to any observable outcomes included in the model, then there will not be enough information to distinguish the various states of the risk system that differ only on the state of that particular intervention. For example, if $s_{(1)}$ and $s_{(2)} \in \mathscr{S}$ are two different states of the risk system that differ only in the state of intervention $l \in \mathscr{I}$:

$$\forall i \in \mathscr{I}, \exists o_j \in \mathscr{O}, y_i \in \mathscr{S}_i : \lambda_{y_i}(o_j) > 0 \tag{5.7}$$

$$\begin{aligned} s_{(1)} &= (y_{1(1)}, y_{2(1)}, ..., y_{l(1)}, ..., y_{N(1)}) \\ s_{(2)} &= (y_{1(2)}, y_{2(2)}, ..., y_{l(2)}, ..., y_{N(2)}) \\ y_{i(1)} &= y_{i(2)} \qquad\qquad \forall i \neq l \end{aligned}$$

   Then, if $\lambda_{y_l}(o_j) = 0, \forall o_j \in \mathscr{O}$, it can be shown that $a_{j1} = a_{j2}, \forall j = 1,...,M$

The resulting Maxent probability distribution would have equal probabilities for these two particular states. In practice, interventions without observable outcomes associated with them should be removed from the model.

3. The state frequency of an outcome should be different for at least one of the states of the corresponding PSI(s).

   This condition ensures that the observed frequency of the outcome is allocated in different proportions to the different states of the risk system, which differ only in the state of the particular intervention. In this way, the model can help distinguish among PSI states through the observed outcomes, by assigning different probabilities to different states.

4. If an intervention is related to more than one outcome, then at least one of these outcomes should have a different PSI-state frequency from the others.

   Furthermore, the difference between the frequencies of an outcome in the different states ($\lambda_{y_i=1}(o_j) - \lambda_{y_i=0}(o_j)$) should be different for at least one of these outcomes.

   These conditions allow each outcome to represent the performance of a particular intervention at different levels of accuracy.

5. If an outcome is related to more than one intervention, then the corresponding outcome frequencies for different interventions should be different.

6. Each PSI should be related to the least number of outcomes possible.

   If the goal is to ensure that the right hand side of the proposed model is consistent, then ideally each intervention should be associated to only one outcome. In such a case, keeping track of each outcome separately would be sufficient to track the performance of the PSIs. However, this one-to-one relationship may not be realistic in most settings. Therefore, the model we propose is useful for the cases when PSIs

are related to more than one outcome, and when outcomes may be shared by more than one PSI. Still, the more overlap between PSIs and outcomes makes it more likely that the resulting coefficients form an inconsistent model.

When many PSIs and outcomes overlap, the possibilities for an inconsistent model increase. It can be proved that the above conditions guarantee consistency in the left hand side of a system in which each intervention is related to up to two of the outcomes. The case where each intervention is related to up to 3 or more outcomes is more difficult to verify analytically, due to the number of possible combinations of values and relations to be considered. However, all experiments in this work were done with PSIs related to up to three outcomes that meet the specified conditions, helping verify that the conditions help ensure the consistency of the model.

The conditions above can be translated into directions to guide assessments during an eFMEA. The following type(s) of outcome(s) should be identified for each PSI of interest: one highly sensitive outcome, and a few outcomes (the minimum possible, but necessary) that are moderately and remotely sensitive to the performance of such a PSI.

An outcome is highly sensitive to a state of an intervention when the occurrence of a few of these outcomes represents high evidence of the intervention's being in such a state. There may be a particular outcome whose occurrence strongly indicates that an intervention is in a particular state. For example, if a few patients actually fall, then we may say that there is strong evidence that the Fall Prevention and Management aid [185] is in a faulty state. Highly sensitive outcomes can also be thought of as those that are undesirable, such as adverse events, and that should be acted upon as soon as possible. These outcomes should be identified upon implementation of the intervention as the specific outcomes that such a PSI is intended to prevent. Highly sensitive outcomes probably have the smallest PSI state frequency among all the outcomes related to the corresponding state(s) of the intervention(s).

Each intervention may have other outcome types that depend on its states, but these may be less sensitive, i.e. moderately or remotely sensitive. These outcomes may represent some evidence of the PSI's being in a particular state, but more evidence would be needed to make a conclusion. These outcomes are not critical, and the occurrence of a few of them may even imply that the intervention is working as intended. For example, a few near-misses about the lack of patient knowledge regarding discharge instructions may imply that an intervention aimed at confirming discharge information directly with the patient is working as intended, since it is detecting patients that are misinformed before they leave the hospital. These outcomes may also be related to other interventions. In the example, the near-miss described may also mean that the intervention to educate the patient (if any) is not working as intended.

Once assessments are obtained, and model parameters are calculated using equation (5.3) to form the system of equations, then the actual frequency of outcomes observed in a period of interest is obtained. If particular outcomes are not observed in a period, then their corresponding equations can be omitted from the Maxent model. Since patient safety data is often incomplete, lack of data *does not* necessarily imply the no-occurrence of the corresponding outcomes. For example, the lack of near-misses of a particular type does not mean that the corresponding incident did not occur. The omission of the corresponding equation is interpreted as having no evidence regarding the corresponding outcome. On the other hand, including such an equation in the model implies that there *is* evidence that the corresponding outcome had a frequency of 0 in the period of interest. This equation will cause the probability of the states, corresponding to such an intervention, to be smaller, implying that it *is* working as intended.

Regarding solution, most software packages can solve the Maxent formulation. However, there may be computational limitations related to combinatorial explosion, since the states of the risk system grow exponentially with the number of PSIs. One way to approach this situation is to use additional information about the risk system to select a

subset of $\mathscr{S}$ to be included in the model, and thus reduce the computational burden. The analyst may be interested in states that have up to a certain number of interventions in the failed state at the same time (represented by a 1 in the position of the corresponding intervention). For example, we may be interested in finding the probability of risk system states that have up to 3 interventions in the failed state at the same time (states with up to three 1's). The Maxent formulation will produce a pmf over the states included in the model. In our simulation of a risk system with 8 PSIs, we only included states that have up to 3 PSIs in the failed state, which reduced the number of variables from 256 to 93 without compromising the quality of the resulting pmf. In a practical context, whenever there are computational limitations that hinder the solution of the larger formulation, we suggest to solve the model with the least number of states that make sense to the analyst, and to increase the number of states sequentially until the probability distribution does not show significant changes.

The next section presents the simulation used to validate our methodology and evaluate its performance under different scenarios.

5.3.2 Experimental Results

We developed a simulation to evaluate the validity of our proposed model by verifying that the probability distribution obtained from the Maxent model is an accurate representation of the real probability distribution in a decision making context. We evaluated *pmf accuracy*, i.e., measure of how consistent the Maxent pmf is, to be used as a marker of the "real" pmf, and *ranking accuracy*, i.e., measure of how accurate the ranking of the states of the risk system is. We verified the accuracy of the ranking of the top 1, 3, and 5 states.

In the first stage of validation, we assumed that the parameters provided by experts are consistent with the simulated "reality". We also used the simulation to illustrate the

usability of the method, and to identify potential shortcomings of our methodology in a practical environment, where experts' assessments deviate from this "reality".

5.3.2.1 Simulation

For each experiment, the risk system was simulated as follows. The system has N PSIs, each of which can be in one of two states, namely: *normal operation*, represented by a value of 0, and *failed state*, represented by a value of 1. There are M categorical outcome types that can be observed in the form of frequencies in a period. PSI-state outcomes frequencies were specified for each intervention and each outcome.

The state of the risk system was defined as a vector whose elements represent the state of each PSI. There are $n = 2^N$ states of the risk system. PSI-state outcome frequencies were defined according to the considerations outlined in section 5.3.1, and outcome frequencies for each state of the risk system (RS-state outcome frequencies) were obtained using equation (5.3). States of the risk system were generated according to a pre-specified probability mass function (the true pmf), and the "actual" outcomes were simulated using M Poisson distributions, whose means are the corresponding RS-state outcome frequencies.

The proposed approach combines available data with experts' assessments to find an estimate for the pmf of the states of the risk system. Experts' knowledge is represented by the estimates $\lambda_{y_i}(o_j)$ that form the corresponding coefficients, a_{js}, in the linear system. However, there is no guarantee that these assessments will match the ideal parameters that the model should have to be a valid representation of reality.

Let $\lambda^*_{y_i}(o_j)$ be the ideal PSI-state outcome frequency for outcome type o_j when intervention i is in state y_i. We specified $\lambda^*_{y_i}(o_j)$ to simulate the risk system, and defined some modifications to these parameters, in order to simulate scenarios of experts' knowledge that would form the corresponding Maxent formulation. In general, there are two

scenarios that represent the possible characteristics of $\lambda_{y_i}(o_j)$ with respect to $\lambda^*_{y_i}(o_j)$. The first scenario refers to the case where the model parameters are consistent with the behavior of the real system, namely *consistent model*. The second scenario refers to the case where the model parameters are biased with respect to the behavior of the system, namely, *biased model*. The model is consistent whenever:

$$\lambda_{y_i}(o) \approx \lambda^*_{y_i}(o_j) \qquad\qquad \forall y_i \in \mathscr{S}_i,\ \forall o_j \in \mathscr{O}$$

The model is biased when experts are biased, which means that their assessments may deviate from "reality". Two types of biases were defined. The first type results in an *overestimated* model, in which PSI-state outcome frequencies provided by experts are higher than the true frequencies for the undesirable states (i.e. state 1) and lower than the true frequencies, perhaps zero, for desirable states (i.e. state 0). Overestimated parameters were simulated using $\lambda^*_{y_i}(o_j)$ and a scaling factor, δ, so that:

$$\lambda_{y_i}(o) = \begin{cases} \delta \cdot \lambda^*_{y_i}(o_j) & \text{for } y_i = 1, \\ 0 & \text{for } y_i = 0 \end{cases} \tag{5.8}$$

The second type of bias does not have a particular structure; therefore we called the corresponding model the *general bias* model. There may be PSI-state outcome frequencies that are either lower or higher for any of the states. Still, it was assumed that the experts know which observable data is linked to each intervention. In our simulation, we randomly changed the non-zero frequencies. To simulate this scenario, we multiplied the true PSI-state outcome frequencies of undesirable states by a random number and rounded the result to the closest integer. We made sure that the outcome frequency was

higher for undesirable than desirable states by adding them and using this result as the state outcome frequency for undesirable states.

For each scenario, we implemented the Maxent formulation specified in section 5.3 to obtain the Maxent pmf, and to determine the pmf accuracy and the ranking accuracy. Each scenario was simulated up to 100 times. We experimented with instances with 2, 3, 4, 6, 8 and 10 PSIs. Each one of these instances was designed with $M = N$, and PSI-outcome frequencies were assigned as recommended in section 5.3.1, using values from table 5.9. In addition, we simulated cases where $M < N$, using subsets of the outcomes originally defined, and where recommended considerations to build the model are not necessarily followed. These cases were intended to illustrate the corresponding output of the model.

The results showed no significant difference in the performance of our approach relative to the size of the risk system; therefore, we present most of our illustrations based on a risk system with four PSIs ($N = 4$).

5.3.2.2 Results for the Consistent Model

Table 5.2: Experimental results for consistent model

Number of Interventions (N)	**Number of Outcomes (M)**	**pmf Accuracy** (Correlation)	**State Ranking Accuracy (%)**		
			Top 1	**Top 3**	**Top 5**
2	2	0.82	37	82	100
3	3	0.87	46	82	88
4	4	0.86	38	76	85
6	6	0.97	85	84	86
8	8	0.92	64	84	82
10	10	0.93	92	92	86

Initially, the performance of the model was evaluated assuming that the experts' assessments of the model parameters correspond to the simulated reality. Table 5.2 shows the summary results for each one of the system configurations evaluated. We also simu-

lated a consistent model for configurations with less outcomes than PSIs. In the case of a system with 4 PSIs, we simulated different instances with 1, 2, 3 and 4 outcome types that do not necessarily follow the recommendations outlined in section 5.3.1. The results are shown in figure 5.1 and summarized in table 5.3.

To simulate the risk system with one outcome type, we ran the simulation and formulated the model using each outcome separately. Similarly, the system with $M < N$ outcomes was simulated by using a subset of the outcomes in the Maxent formulation at a time. Figure 5.1 shows the results of the simulation of one random iteration. The figure presents up to two of the instances considered for each number of outcome types modeled.

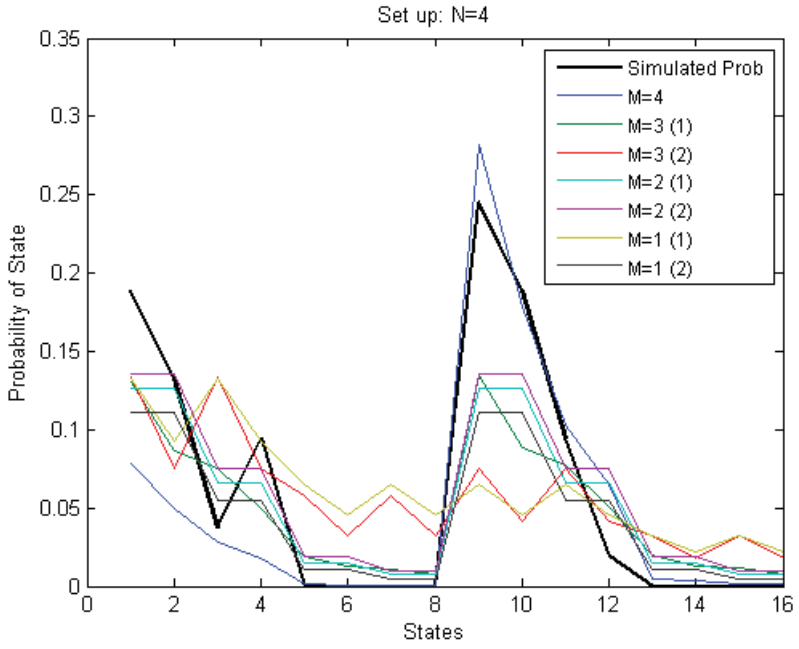

Figure 5.1: Results for consistent model (4 PSIs)

It is desired that states with higher simulated probability are assigned a higher probability by the model so that we can use this probability measure to prioritize states of the risk system. As can be seen in the figure, the probability distribution obtained from the Maxent model behaves in a similar fashion as the simulated one, except for the cases in

Table 5.3: Experimental results for consistent model $(N = 4)$

Number of Outcome Types (M)	**Instance**	**pmf Accuracy** (Correlation)	**State Ranking Accuracy (%)**		
			Top 1	**Top 3**	**Top 5**
4	1	0.86	38	76	85
3	1	0.86	32	75	86
3	2	0.63	30	51	65
3	3	0.84	24	72	82
3	4	0.84	40	77	84
2	1	0.79	11	66	79
2	2	0.85	39	74	85
2	3	0.52	26	43	60
2	4	0.42	19	45	55
1	1	0.51	22	42	59
1	2	0.83	23	70	83
1	3	0.38	23	49	58
1	4	0.22	18	25	37

which the number of outcome types was lower than the number of interventions, limiting the amount of information available for each intervention.

Table 5.3 shows, for each instance, the correlation between the simulated vs. the modeled probability, and the accuracy for the top 1, 3 and 5 states ranked according to the output of the model. The ranking accuracy for the top l states is defined as the percentage of states ranked in the first l places, when they should have been ranked in these places according to the true pmf. The instance with 4 outcome types was very similar to the simulated probability, since most of the considerations specified in section 5.3.1 were incorporated in the model parameters. This similarity can be confirmed in table 5.3, where the correlation is 0.86. The ranking accuracy can be interpreted as 38% of the iterations identified the most relevant state (top 1). Similarly, 76% of the iterations correctly identified the top 3 states, and 85% of them correctly identified the top 5.

The first, third and fourth instances of the model with 3 outcomes had parameters in which all PSIs were associated with the outcomes considered. The pmf correlation and the quality of the ranking were maintained. The second instance with 3 outcomes used

parameters in which one of the PSIs was not related to any of the outcomes; therefore the indicators showed less accuracy, both for pmf and ranking.

In the examples where 2 outcome types were used, pmf and ranking accuracy decreased, since it was more difficult to cover all PSIs with such few outcomes. In the first instance, outcome 1 was related to PSIs 1, 3 and 4, and outcome 2 was related to PSIs 2 and 3, thus covering all PSIs. In the second, third and fourth instances, outcomes were associated with 2 and 3 PSIs each, but there was no information about one of the PSIs.

Finally, the instances where only one of the outcomes was considered at a time had parameters that related the outcome to 2, 3 and 1 interventions respectively, but where up to 2 PSIs were not represented by these outcomes.

Figure 5.1 shows that given the limited information about the risk system, the resulting pmf ranges from being very similar to the simulated pmf, to being almost flat, as expected.

These preliminary results confirm that the more data about interventions available, the better the assessment is, since each data type contributes to better differentiating among the possible states of the risk system. The results obtained from the experiments helped validate the model for the case when the parameters are consistent with the "parameters" of the real system. In general, the model helps distinguish between likely and unlikely states. However, it was noted that in some instances, the model cannot distinguish among likely states (states with non-zero probability), due to the quality of the particular data used in terms of how it relates to the different states of the risk system. Still, we emphasize that even in the case where the model cannot distinguish among likely states, it helps reduce the number of candidate risk sources to prioritize for further investigation efforts in the light of the observed patient safety data.

5.3.2.3 Results for Biased Model

Overestimated parameters were simulated using equation (5.8) to modify the parameters from the consistent model. We varied the scaling factor, δ, over the values of 2, 3, 5 and 8. Results for examples with 4 PSIs and 4 outcomes are illustrated in figure 5.2.

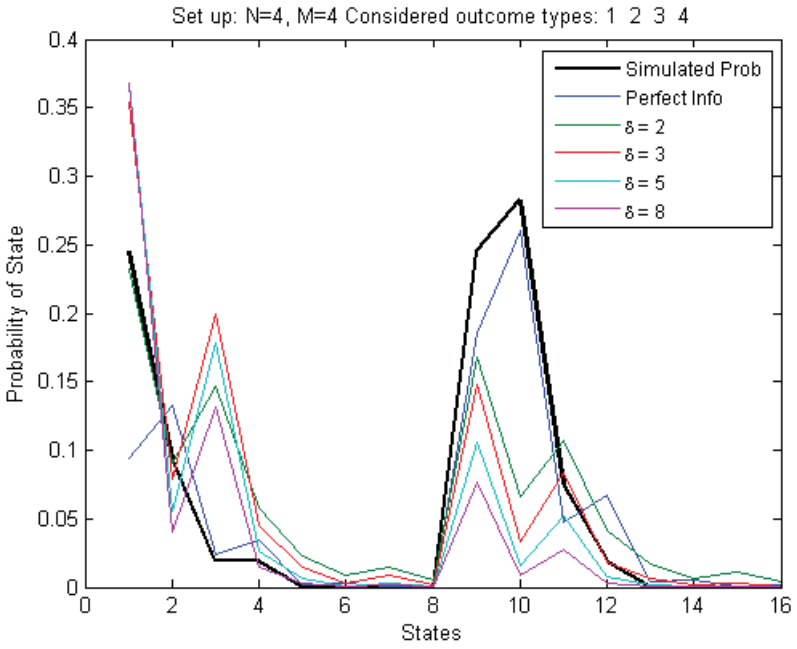

Figure 5.2: Results for overestimated parameters

Table 5.4: Experimental results for overestimated parameters ($N = 4$)

Scaling Factor (δ)	**Correlation**	State Ranking Accuracy (%)		
		Top 1	**Top 3**	**Top 5**
1	0.860	38	76	85
2	0.795	53	68	77
3	0.731	53	68	76
5	0.697	53	68	76
8	0.678	53	68	76

The general behavior of the Maxent pmf agrees with that of the true probability distribution, even though the correlation decreased slightly as δ increased. Table 5.4 also

shows that the ranking accuracy of the model was maintained. Additionally, there were no infeasible iterations in these scenarios.

In the case of general bias, the RS-state outcome frequencies deviated significantly and randomly from the true parameters. For the analysis of this scenario, we used the parameters from the consistent model, and modified it according to section 5.3.2.1. A significant amount of instances yielded no feasible solution (64% - 88% of the instances evaluated). Therefore, infeasibility can be used as a marker of bias in the model and of the need for reassessment of the corresponding parameters.

There were mixed results for instances with a feasible solution, as shown in table 5.5. The correlation and ranking accuracy suggest that most of these resulted in a pmf that could be useful for decision making. However, there may be instances where the resulting probability distribution deviates significantly from the real one.

Table 5.5: Experimental results for feasible, biased instances

No. of Interventions (N)	**Feasible Instances (%)**	**Correlation**	Ranking Accuracy (%)			
			Top 1	**Top 3**	**Top 5**	**Top 10**
2	66	0.651	59	76	-	-
3	85	0.777	68	75	85	-
4	19	0.592	32	56	65	82
6	3	0.891	33	67	67	83
8	29	0.500	51	41	33	42
10	7	0.317	14	29	31	29

Feasible instances that resulted from biased models were further analyzed in terms of a probability score calculated for each individual intervention. This probability score was obtained by adding the probabilities of the states where the corresponding intervention is not working as intended (states where the value of y_i for the corresponding intervention is 1).

In the case of 4 interventions, 71% of the 28 feasible instances ranked the top 1 intervention within the top 2 of the priority list. In the case of 8 PSIs, 60% of the 29 feasi-

ble instances ranked the top 1 intervention within the top 2 of the priority list, and 74% ranked it within the top 3.

In general, we conclude that the output of the Maxent model can be used to guide investigation efforts or to diagnose the need for reassessment of model parameters. RCA can be used to analyze the output of the Maxent model.

The above experimental results helped verify that a model that combines data and knowledge about the system in a non-biased manner can provide accurate assessments useful for decision making (construct validity). In addition, experimentation helped identify the strengths and weaknesses of the proposed formulation in the presence of bias. In the next section we illustrate risk identification and monitoring using the proposed Maxent formulation.

5.4 Risk Identification and Monitoring

Healthcare systems use patient safety data to guide risk management efforts in the identification of risks and their causes or sources. The proposed approach is intended to support this analysis by using qualitative risk assessment to create links between data and risk sources, and then using these links to systematically "translate" observed data into likely sources. Therefore, our approach helps determine the appropriate investigative, preventive or corrective actions needed to enhance patient safety on a more frequent basis. This information can even guide strategies that require less resources, such as determining the focus for weekly awareness campaigns to keep healthcare workers attentive of potential failures with specific PSIs.

The resulting pmf of the states of the risk system, and additional information from the eFMEA, can be used to estimate an updated likelihood of each PAE. If the likelihood of some PAE is above a pre-specified threshold, then the source can be tracked by identifying the states of the risk system and the corresponding patient safety interventions, which

likely contributed to the observed outcomes. PSIs with high probabilities of being in the undesirable states can be regarded as potentially relevant sources.

For each analysis period, patient safety data should be gathered and transformed into frequencies $f(o_j), \forall o_j : f(o_j) > 0$. The corresponding Maxent model can be formulated and solved to obtain an assessment of $P\{y = s\}, \forall s \in \mathscr{S}$. Each analysis period can be a specific month, week, or day; periods may also overlap (i.e. the last 2 weeks).

Table 5.6 illustrates an example of the direct output of the model, using the results from the simulation experiments of a risk system with 4 interventions and 4 outcomes. The example shows that the most likely state of the risk system is where all interventions are working as intended (state $(0,0,0,0)$). However, there is a relatively high probability (0.28) for the state in which intervention 1 alone is not performing as intended, represented with the vector $(1,0,0,0)$. Other states may be considered by the analyst to have an acceptable or low probability, and thus the focus would remain on investigating intervention 1 first. If, for example, intervention 1 corresponds to the use of a bar code medication administration system, then the hospital staff can be warned to be aware of problems in the use of such a system. Furthermore, users can be encouraged to report issues in using such an intervention during the administration of medication to patients.

Using the states of the risk system, as opposed to individual interventions, will help identify potentially relevant interactions among several interventions at the same time. Nevertheless, a likelihood score for the failed state of each PSI can be calculated using the probability assessments of all RS-states. This score is obtained by adding the probabilities of the states where the corresponding intervention is not working as intended (states where the value of y_i for the corresponding intervention is 1). Illustrative results are shown in table 5.7. This likelihood can also be used for analysis over longer periods, for example, using run charts to detect when the performance of the intervention changes dangerously. Information about potentially dangerous performance trends helps identify the interventions that require close monitoring of their processes and equipment at some

Table 5.6: Maxent model output

State of the Risk System (s) (y_1, y_2, y_3, y_4)	**Probability**	**Rank**
$(0,0,0,0)$	0.4819	1
$(1,0,0,0)$	0.2800	2
$(0,0,0,1)$	0.0677	3
$(1,0,0,1)$	0.0393	4
$(0,0,1,0)$	0.0366	5
$(0,1,0,0)$	0.0336	6
$(1,0,1,0)$	0.0212	7
$(1,1,0,0)$	0.0195	8
$(0,0,1,1)$	0.0051	9
$(0,1,0,1)$	0.0047	10
$(1,0,1,1)$	0.0030	11
$(1,1,0,1)$	0.0027	12
$(0,1,1,0)$	0.0025	13
$(1,1,1,0)$	0.0015	14
$(0,1,1,1)$	0.0004	15
$(1,1,1,1)$	0.0002	16

Table 5.7: Likelihood scores for the failed state of each PSI

PSI	**Score**
1	0.3674
2	0.0651
3	0.0705
4	0.1231

point in time, even if their likelihood of being in an undesired state appears to be low. One of the advantages of our approach is that these types of analysis can be automated using information technology to trigger alarms when necessary.

The likelihood score can also be used to find a weighted likelihood of each type of potential adverse event (PAE) analyzed in the eFMEA:

$$\text{Likelihood}(e) = \sum_{s \in \mathscr{S}_i} \text{Likelihood}(e|y_i = s) P\{y_i = s\} \tag{5.9}$$

The value for Likelihood$(e|y_i = s)$ can be obtained from the eFMEA (column 11 in table 5.1). This likelihood can be kept up to date and compared to experts' assessments used to create risk maps [4]. These updated assessments can be used to represent likelihood using intervals, rather than single points in the risk map. Having intervals in a risk map introduces information about uncertainty about PAEs into the analysis, and helps identify specific areas where information beyond experts' knowledge and available patient safety data is needed to reduce such uncertainty.

If some PAE has a likelihood that is greater than a threshold, or that has significantly shifted from the original assessment, then further analysis can be guided by the Maxent output table 5.6, as shown above. Traditional investigative and risk analysis techniques, such as RCA, can be used to check the validity of flags derived from the model.

Our experimentation showed that if the model is consistent with reality, then the resulting probability distribution can be used to guide decisions regarding which PSIs to focus on first. In addition, the model shows robustness when the true parameters are overestimated according to the expression (5.8). In instances with random bias where a feasible solution existed, results are not as accurate, but they are still useful to guide risk analysis if the top 3 PSIs (according to the failed likelihood score) are considered for analysis. Therefore, the we conclude that the model has utility for guiding risk identification and analysis.

Additionally, we observed that most biased instances were infeasible. Being able to identify that the model is biased is important, since it helps avoiding the allocation of resources to PSIs that may be working as intended or ignoring PSIs that may require immediate attention. A biased model may also reflect the need for new assessments to update the knowledge about the performance of the system, and the corresponding model parameters. The next section specifies how to identify bias in the model using feasibility,

and how to use the corresponding information to guide the updating of experts' assessments.

5.4.1 Identifying Bias

The most effective way to determine if there is bias in the model is to use the resulting pmf to guide an RCA of the most salient outcomes and risk system states. The RCA should aim to confirm that the observed outcomes were actually the result of the (failed) performance of the specific PSI that the model points to. Failure to confirm such a cause and effect relation would indicate the need for new assessments, as described in section 5.2.2 above.

Experimental analysis of the performance of the Maxent model under bias suggests that infeasible instances likely reflect that the model is not consistent with reality, since these instances were commonly observed when simulating scenarios where the model parameters were biased. The possible reasons for the occurrence of an infeasible instance include the lack of consistency between assessments for different outcome types and bias of assessments with respect to reality. However, there may be a natural variability in the system that may cause the formulation to be inconsistent, and minimal corrections may be needed to obtain a feasible, usable solution.

In our simulation, we used a Poisson distribution to generate RS-state outcome frequencies. Very few instances of the consistent model resulted infeasible due to this natural variability of outcomes. Whenever an instance yielded no feasible solution, we evaluated changes needed in the right hand side of equation (5.2), i.e., the frequencies of each outcome type, to make it feasible. Required changes or adjustments were obtained using the phase I of the 2-phase simplex method for linear programming [184, 186]. The resulting (positive) artificial variables were added (or subtracted) to the corresponding value of $f(o_j)$ and the Maxent model was formulated using the new right hand side, and

solved. If the model parameters were consistent, adjustments needed were very small, and the resulting pmf was very close to the simulated pmf.

On the other hand, instances with randomly biased parameters showed that high adjustments were needed to obtain a feasible solution (see table 5.8). In our model, the parameters come from the experts' assessment and represent their beliefs or knowledge about the performance of the risk system with respect to observable outcomes. Therefore, we assume that lack of consistency of an instance of our proposed model reflects inaccurate knowledge about the risk system with respect to observable outcomes in patient safety data sources. Adjusting the outcome data (right hand side) to fit the model will likely provide a biased solution that may be inaccurate in a decision making environment.

Table 5.8: Adjustments needed on the right hand side

RHS	**% of Original Value**
$f(o_1)$	7.35
$f(o_2)$	3.25
$f(o_3)$	35.99
$f(o_4)$	48.53
Overall Change	23.78

Adjustments needed in infeasible instances ranged from 0% to 198% of the original value of the right hand side. In the illustrative example of table 5.8, the observed frequency of outcome types 3 and 4 required the highest adjustments, suggesting that the relation of these outcomes with the corresponding PSIs needs to be reassessed. Future risk assessment activities can then focus on revising the relation between the data types 3 and 4, and the corresponding PSIs.

In summary, an infeasible instance of the Maxent model is the first indicator of bias in the model. If high adjustments to the observed frequencies of outcomes are needed to obtain a feasible solution, then the model is very likely biased. Information about PSIs whose assessments are not consistent with actual occurrences can help guide the focus of future risk assessments, or can help determine the need for formal measurement. Out-

come types that required the highest adjustment represent data sources whose relation to the risk system is inconsistent.

5.5 Discussion

This research developed a risk modeling framework based on using the state of patient safety interventions (i.e. safety constraints in healthcare systems) as sources of risk, as supported by the general safety literature. This chapter focused on illustrating how this framework can be used to formulate a specific model that unifies risk assessment and data analysis efforts, given the limitations of patient safety data. The model described allows for the identification of potentially relevant risk sources, by estimating a probability of such risk sources being in an undesirable state. The proposed model can be used by healthcare risk managers or patient safety officers to determine the focus of periodic awareness campaigns, and to provide direction for investigation efforts.

To smooth changes and capitalize on existing efforts, we based the proposed model on an analysis similar to a FMEA, which is a widely accepted risk analysis method in healthcare systems. We expanded the focus of the FMEA to include PSIs and their expected performance in terms of common sources of patient safety data. The assessments obtained from the expanded FMEA were used as parameters of a model that supports the analysis of less-severe outcomes. Such a model strictly reflects the shared knowledge about risk the system, and can be used to guide future risk analysis efforts, and to validate or challenge such knowledge in the light of actual outcomes.

In this work, we focused on evaluating the anticipated use of the proposed model in the analysis of upcoming patient safety data. The challenges in such an analysis include incompleteness of data and bias in its interpretation. Therefore we used the principle of maximum entropy to reduce the effect of bias, and to account for incompleteness. Experimental results using simulation showed that the model is useful to effectively guide

risk identification and analysis efforts when the model parameters are consistent with reality. In addition, experimentation showed that the model is robust when experts' assessments overestimate outcomes, and that general bias can be identified through infeasibility. Furthermore, analysis of such infeasibility can be used to explicitly determine where assessments need to be revisited.

The proposed approach uses modeling to complement traditional risk analysis methods, such as FMEA, so that the knowledge gained from these analyses is used frequently, and in a consistent manner, before new assessments are obtained. In addition, other tools, such as RCA, can be used to validate the causes of less severe outcomes to make sure that the system is performing safely, rather than to find the causes of adverse events after they take place. Basically, we are converting a retrospective risk analysis method, such as RCA, into a prospective one by using it to analyze minor, non-consequential events, identify latent causes, and develop investigation and solution strategies before actual harm takes place.

The proposed model advances healthcare risk analysis by providing a structure for the many available sources of information about risk, and combining them in a model that will both: facilitate and expedite risk analysis by directly pinpointing potentially relevant risk sources, and help diagnose the need for new or updated assessments given observed data. This research supports the healthcare risk management process in several of its stages [4]. It facilitates the analysis of patient safety data for *risk identification*. It provides guidance into potential risk-sources, and defines a measure of the contribution of each source to identified risks, for *risk analysis*. It helps translate data into internal measures of the performance of solutions implemented, and allows for analysis to be done on a frequent basis for *monitoring and control*.

The success of the proposed approach will translate into improved understanding of risk in the system, prompt risk analysis and timely feedback to stakeholders. The model will motivate the gathering of specific information about risk, since this information can

be readily available for analysis as it is incorporated to the model. In addition, every PSI that is considered for implementation would be evaluated considering their possible failure modes, or states, and the availability and quality of patient safety outcomes that can be used to monitor their performance over time.

This type of model could potentially be used in sectors other than healthcare, since the concept of *safety constraint* comes from the general safety literature. In general, the approach is intended to facilitate the systematic analysis and interpretation of data that comes from disparate data sources. Examples of these types of processes can be found in most socio-technical systems, such as nuclear power plants, chemical plants and power grids [163]. The risk system, i.e. the set of safety constraints, should be defined within the scope of the particular organization. Then, risk assessment methods should be adapted to include observable and related data.

There are several opportunities for the improvement of the proposed formulation. For example, the state of each PSI was defined as a binary variable that represents the intervention either working as intended or not. The definition of states of PSIs can be expanded to include different forms of failure that may cause the intervention not to work as intended. It may be useful to distinguish among forms of failure determined by human factors, organizational factors and technical/mechanical factors.

In addition, the model considers a static picture of the performance of the system, and therefore decisions related to its assessments are not guaranteed to be effective in the long term. However, the proposed approach has an advantage in that analysis can be expedited using information systems, and therefore, such an analysis can be done periodically to account for system changes.

Furthermore, alternative underlying risk models that include the dynamics of the performance of risk sources can be formulated. These models, represented by g in (5.1), may be non-linear, and may not be general for the different types of PSIs.

In future research, alternative characterizations of sources of risk can be incorporated in the model. For example, specific activities, processes, or general services could be used as sources of risk. Regardless of the characterization of risk sources, their states should be defined in a manner that facilitates assessment and interpretation of results for decision making.

Finally, the proposed model is still limited by the knowledge of the analysts and experts who determine the parameters [187]. At this stage of the research, the aim is to enhance the consistency of how risk assessments are used to assist risk managers and patient safety officers in their thinking. Still, there is the need to define formal methods for the assessment of parameters that include experimentation and measurement in the actual system.

The formulation of a Maxent model to support the identification and analysis of risks in healthcare systems confirmed that there is the need for research to explore the use of formal, systematic risk analysis models in this area. Such models should be able to capture the outputs of qualitative methods and consider available data to expedite risk identification and analysis, and to facilitate the prevention of harm to patients.

Table 5.9: Example of a PSI-state outcome frequency scale

Units: expected number of outcomes per week.

Score	**Description**	$\lambda_{y_i}(o_j)$	**Description**
1	Highly sensitive	[3,5]	The particular outcome type represents high evidence of the intervention being in the particular state. Attention is required.
2	Moderately Sensitive	[6, 10]	The particular outcome type represents some evidence of the intervention being in the particular state, but It may be evidence of the performance of other interventions as well. More evidence is needed.
3	Remotely Sensitive	[11,∞]	The particular outcome type may be evidence of the intervention being in the particular state, but is also a very common outcome for other states. It may be evidence of the performance of other interventions as well. More evidence is needed.
4	Not Related	0	The particular outcome type is not related to the performance of the intervention.

Chapter 6: Summary and Future Work

The delivery of healthcare has been described as a high risk process given the alarming estimates of preventable adverse outcomes [20, 46]. Healthcare delivery systems are dynamic, socio-technical complex systems, for which risk monitoring and control remain a challenge for practitioners and researchers. The aim of this research was to develop systematic approaches to monitor risk in healthcare systems, and guide allocation of efforts to enhance patient safety. The main objective was to develop methodologies based on commonly available patient safety data, widely-used risk analysis techniques, and information systems to facilitate and guide risk identification.

A critical factor at the core of healthcare service quality and cost is patient safety, which is defined as the prevention of harm to patients caused from failures in the healthcare system itself. Since the late nineties, preventable medical injuries have been recognized as a major cause of death and disability in the U.S. Today, most healthcare institutions have patient safety programs that manage risks mainly through the analysis of incident reports and the implementation of interventions. However, their effectiveness has been debated [45, 52].

This research first explored the field of healthcare risk management and the literature related to modeling risk in healthcare systems. Gaps and opportunities for formal modeling and analysis of risks were identified. In particular, it was found that the characteristics of healthcare systems and patient safety data make traditional statistical methods unsuitable to assess risk or to monitor the performance of the system in terms of safety. Furthermore, the development of models to support patient safety management has been

hindered by a lack of understanding of risk in healthcare systems. We concluded that effective methods for risk identification in healthcare systems should explicitly characterize sources of risk to facilitate analysis and feedback, be dynamic to reflect the changing nature of the service, have a prospective component to prevent adverse outcomes and support proactive decision making, have a quantitative component to allow monitoring and evaluation, and use available patient safety data to continuously update our knowledge about the system (chapter 2).

In the evaluation of risk analysis methods actually used in healthcare systems, it was identified that some data sources, such as near-miss reports, are underutilized by solely considering their frequency as a marker of risk. Near-miss reports are descriptions of events that could have harmed patients but did not due to a timely intervention or a convenient evolution of the circumstances. They provide some evidence of risk in the system before patients suffer adverse consequences. In addition, we found that existing risk assessment methods do not explicitly support the monitoring of the performance of risk sources over time, because risk analysis methods are time consuming.

Initially, the research focused on the analysis of one type of patient safety data, i.e. near-misses. A taxonomy for near-miss reports was developed to facilitate reporting, data storing, and systematic preprocessing. The proposed taxonomy structure has three basic dimensions that attempt to describe a near-miss. These dimensions include information about the activity that was taking place while the incident occurred, the immediate cause of the breakdown, and the defining characteristics of the near-miss. Each dimension can be further subdivided in specific categories that depend on the organization for which the analysis is intended. The taxonomy allows for coded near-miss reports to be accumulated over time, and analyzed using clustering-based methods.

Clustering was used to find combinations of near-miss attributes which may lead to the identification of risk sources when analyzed, and which may not be obvious to the naked eye. Sources of risk were characterized by each cluster, and the attribute values

of the elements within the cluster. An adapted, unsupervised version of the k-prototypes algorithm was used to allow for the actual data to dictate the number and characteristics of resulting clusters, and thus the identification of unforeseen risk sources. Clusters were characterized using high-support item-sets for categorical attributes, and low coefficient-of-variation numerical attributes. The output of this analysis is a list of potential risk sources (clusters), ranked according to a measure that combines the number of reports in the cluster and the closeness of its elements. Each cluster can be analyzed to confirm or reject its validity as a source of risk using traditional risk identification methods such as root cause analysis (RCA) or system hazard analysis (SHA). Near-misses and valid clusters can be accumulated over time to be used in the analysis of future near-misses (chapter 3). This research was accepted for publication in the Journal of Biomedical Informatics [19].

The possibility of defining an explicit characterization of risk sources in terms of components that should be monitored over time was explored. For this purpose, the literature of safety theory was reviewed, where the concept of safety constraints as sources of risk was found. The general concept of safety constraints was mapped to the concept of patient safety interventions in healthcare systems. Patient safety interventions consist of technology, improved procedures, or new policies intended to improve care by minimizing harm to patients, and thus risk [160]. Examples of these include a bar-code medication administration system, a checklist before surgery, and the use of gloves and gown while in contact with infection-risk patients. The use of patient safety interventions to facilitate the risk identification with the support of information systems was illustrated in chapter 4.

In addition, an alternative modeling technique was proposed to systematically monitor the performance of patient safety interventions using available data. The risk system was defined as the set of patient safety interventions within the system, and the state of the risk system was defined as the combination of the states of the interventions. The principle

of maximum entropy was proposed to obtain a probability distribution of the possible states of the risk system that is consistent with observed data in a period of interest. This probability distribution is the least biased one, and uses only the information available. The model can be built from experts' assessments similar to those of a failure modes and effects analysis. The output of this analysis approach is a list of states of the risk system that can be ranked according to their probability. States of the risk system with higher probability can be analyzed first to identify which interventions, or groups of them, may be not working as intended. This information is useful to guide subsequent risk analysis, such as RCA. In addition, a probability-based score can be calculated for each intervention individually. This risk score can be tracked over time to monitor the performance of each intervention, make decisions related to enhancing awareness about potentially relevant risk sources, identify and remedy weaknesses in safety programs or activities, determine the focus of investigation efforts, and improve the quality of data.

Although the proposed approaches are limited by the quality of experts' assessments, they support the use of such assessments in a consistent manner. In addition, they stimulate a better understanding of the healthcare delivery system, its patient safety interventions and their relation to different sources of more frequently observable data. They reduce the time required to analyze data and identify sources of risk by using information systems to automate some part of the analysis. They encourage the enhancement of patient safety data sources, such as incident reporting, since people would report in order to identify substandard performance of a system component rather than to expose an error. Finally, they potentially allow for explicitly defining requirements and criteria to select among potential solutions.

Findings in this research helped confirm the need for the formal definition of sources of risk and models that relate the performance of those sources to observable patient safety data. Such approach can be used in industries other than healthcare, since the concept of safety constraints comes from the general safety literature.

Future research efforts along this line of research should focus on:

- Formal methods could be defined for the assessment of parameters that include experimentation and measuring in the actual system to complement experts' assessments.
- States of patient safety interventions could be further defined using forms of failure that may cause the interventions not to work as intended. For example, we may want to distinguish among forms of failure determined by human factors, organizational factors and technical/mechanical factors, among others.
- Alternative models of the performance of patient safety interventions could be developed that better reflect the dynamics of these systems. These models may be non-linear, and may not be general for the different types of patient safety interventions.
- Alternative characterizations of sources of risk could be explored and used as it is practical to organizations.

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