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LEARNING FROM PATIENT INJURY CLAIMS

An assessment of the potential contribution of
patient injury claims to a safety information
system in healthcare

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To my parents, Leelo and Priidu

ABSTRACT

Background: The Institute of Medicine report, *To err is human*, heightened attention to safety and quality performance in healthcare. This has led to demands on healthcare systems to collect data on safety and quality performance. Patient safety improvement requires learning at many levels in the system leading to changes in organizational structure and processes along many dimensions. Safety information systems support learning about the performance of a system by collecting, analyzing, and providing feedback of data.

Other industries have come further than healthcare in measuring safety performance as well as in identifying industry specific knowledge about sources of vulnerabilities and hazards. In healthcare, evidence based measures are being developed such as incident reporting systems, medical chart reviews, patient safety indicators and malpractice claims data. The Swedish patient insurance claims database is a source of data on safety performance that has not yet been systematically studied.

The aim of this thesis is to assess the potential contribution of patient injury claims have in supporting organizational learning in improving patient safety and to present a framework for the management of patient safety information in healthcare.

Principal findings: Patient injury claims are, by themselves, not sufficient to serve as a sensor for vulnerabilities in healthcare. They do, however, provide a broad national source of patient generated information on negative outcomes of care which complements other healthcare generated reporting systems (Study I-II). Swedish healthcare leaders have a relatively high awareness of patient safety and give it high priority. However, few healthcare organizations actively involve patients in improving safety (Study III). Based on the assumption that analogies to known phenomena promote learning, the preservation of genomic integrity was presented as a model to describe different sources of variability, applicable also to patient safety (Study IV).

Conclusions: Patient injury claims are less subject to bias than other sources of patient generated safety data (especially litigated malpractice claims), inexpensive, national, and allow for aggregation of data across many providers to identify rare complications. Analysis of the data can be done on both high level and granular levels of the system, which allows for organization specific feedback. From an organizational learning perspective, patient injury claims have both limitations and potential contributions. While there are limitations regarding timeliness, coverage and validity if they are used to provide an estimate of the rate of preventable adverse events, patient injury claims data contain useful information regarding adverse events and could act as a starting point for identifying areas in health care for further analysis in order to find vulnerabilities. Healthcare needs to develop comprehensive safety information systems that combine different sources of data to detect and learn from vulnerabilities.

LIST OF PUBLICATIONS

- I. **Pukk K**, Lundberg J, Penaloza-Pesantes R, Brommels M, Gaffney FA. Do women simply complain more? National patient claims data show gender and age differences. *Quality Management in Healthcare*. 2003; 12 (4): 225-231.
- II. **Pukk K**, Ask J, Brommels M, Thor J, Penaloza-Pesantes R, Gaffney FA. Analysis of 23,364 patient-generated, physician reviewed patient injury claims from a non-tort, blame-free, national patient insurance system: Lessons learned from Sweden. Submitted to *Quality and Safety in Healthcare*.
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1 PROLOGUE

In 1999, the Institute of Medicine released their first report on safety in healthcare, *To Err is Human* [2]. This became a wake-up call for the medical establishment with the revelation that the number of patients who were injured by the very healthcare system designed to help cure them was equivalent to 3 jumbo jets crashing every other day.

As a medical student, and later as a physician, I have been witness to this first hand. However, there has been little in my education that has prepared me for understanding and coping with this, let alone being aware of the problem. Accidents, when they occur, are often isolated incidents, usually affecting only one patient and caregiver at a time. It was the Institute of Medicine, by aggregating all of these isolated events, which first showed how large the iceberg really could be and brought this grave problem to the attention of professionals and the public.

Medical education has a tendency to focus on learning how to diagnose and treat diseases. It is the competency and responsibility of the individual physician that determines the quality of care that a patient receives. When something goes wrong, the explanation reads that it is because the physician lacks knowledge or experience or because of the complicated nature of the patient's illness. Even though we learn about the body as a system and how the different parts of the body interrelate and cooperate, we do not apply these insights to how we structure our healthcare system and how we can work with others to improve the care of our patients.

I began this project as a biological scientist, confident in our ability to find a concrete and objective measurement tool that could be used to assess and improve patient safety. In my journey as a doctoral student, I have come to see healthcare organizations as complex systems. The outputs of these systems are dependent on so many variables and it is because of this that it is so hard to find that one specific sensor.

During my doctoral studies, I have found myself questioning many of the attitudes and beliefs I adopted in medical school. I have begun to nuance the mechanical and scientific paradigms from my medical training and learned to see complex interrelationships. Things are not all that simple, indeed it is the very complexity of these organizations that makes trying to understand these systems such an interesting and rewarding challenge. Through collaborating with scientists from other disciplines and other countries I have learned how different scientific models and methods can help us understand safety and care in new ways. In the following pages, I present the results of this journey.

I have hopefully become a better doctor, revised my understanding of how we can provide quality healthcare and broadened my understanding of what science really is.

2 HOW SAFE IS HEALTHCARE?

Until recently, we have not been aware of how safe or perhaps we should say, dangerous, healthcare has been for our patients. Retrospective chart reviews, conducted in several countries, estimate that one to four percent of hospitalized patients are injured as a result of *adverse events* (i.e. complications due to examination, treatment or care which can cause harm to patients) [3-9]. An overview of these studies points to the fact that preventable medical errors are a major cause of morbidity and mortality in hospitalized patients (Table 1).

Adverse drug events are the most well studied type of adverse events, because of existing documentation systems. One US review study found that medication errors occur in 2% to 27% of patients admitted, increasing length of stay by 2.8-4.5 days. Notwithstanding the cost in human suffering, the economic costs are consequential. One US hospital has estimated their costs for adverse drug events and medical negligence claims to be \$5.6 million per hospital per year. Of that figure, \$2.8 million was thought to be preventable. [10]

Table 1: An overview of collected studies of adverse events

Study	Method	Year	Patients	Adverse Events (%)	Preventable AE's (%)
Harvard	Chart reviews	1991 (1984)	31,429 2,671,863	3.7	1.0
Utah/ Colorado	Chart reviews	1992 2000	14,700 charts	4.0	0.9
England	Chart reviews	2001	1000	11.7	-
Australia	Chart reviews T-1, T0, T+1	1995	14,179 470,000	16.6	8.3
Denmark	Chart reviews T-1, T0, T+1	2001	1,079 charts	9.0	3.6
Canada	Chart reviews	2004	3,745 charts from 5 regions	7.5	2.8
LÖF Sweden	Claims made	1997- 2004	23,364 claims per 11,514,798 patients	0.20	0.11

Based on [4-9, Study II]

The reported rates of adverse events vary remarkably because of differences in detection methods, definitions of adverse events, and healthcare settings. However, it is thought that the actual incidence rate is higher due to under-reporting. The Canadian study [7] found that about 185,000 of the 2.5 million patients receiving care experienced an injury not caused by the underlying disease. Almost 70,000 of these cases were judged to be avoidable.

Based on the different studies on adverse events in the United States, medical error has been identified as the eighth most common cause of death. It has been estimated that between 44,000-98,000 people die each year [2].

In Denmark, around 5,000 people die each year from medical error. Moreover, the average length of hospital stay for patients in the study who experienced an adverse event was lengthened by 7 days. Another Danish report estimated that the cost for compensating and treating iatrogenic injuries was estimated to be between 17 and 29 million Danish crowns per year. This is approximately 10% of the economic resources of healthcare [11].

There is no Swedish study comparable to those above. However, the Swedish National Board of Health and Welfare performs audits and collects patient discharge data. In 2003, about 23,000 care-related injuries or complications were registered. This gives us a first indication of the situation in Sweden.

Sweden has three national reporting systems that collect information about medical errors that cause injury to a patient. In all three, the patient, a relative or the provider can take the initiative to file a claim or make a complaint. Two of the systems are part of the government licensing and negligence monitoring of healthcare professionals: HSAN and *Lex Maria*. The third system is unique to the Scandinavian countries (Norway, Denmark, Finland) – a national, no-blame, patient insurance system. This system compensates patients for self-reported injuries received due to medical error after review by medical experts. The Swedish Mutual Insurance Company of the County Councils (LÖF) receives around 9,000 claims every year.

Lex Maria generates about 1000 error reports each year. In a study of 3,000 reports filed to HSAN (Malpractice Inspectorate) during 2000, it was found that 1,500 cases included data showing a patient safety error [12]. Of these 1,500 patients, 250 suffered permanent loss of function, 500 had functional losses that disappeared with time, 150 suffered no consequences, and at least 150 deaths were due to adverse events. As the figure only contains malpractice reports, collected as part of a punitive system, it probably underestimates the true error rates.

Due to the findings above, patient safety has become one of the most important health policy issues during the last decade. Governments as well as individual clinicians and researchers are trying to identify the risks present in healthcare and how to develop methods for systematic evaluation and effective safety management. This has led to an increased demand for data on the quality and safety performance of individual practitioners and provider organizations.

Today, there are but few measures available to evaluate progress in patient safety for decision makers [13, 14]. However, other industries have developed and validated indicators for monitoring and improving performance. While healthcare is still behind these industries, evidence based measures are being developed and improved [15-17].

3 LEARNING FROM ACCIDENTS – A THEORETICAL FRAMEWORK

In order to improve safety in healthcare, it is important to understand how other industries have understood and learned from the mechanisms behind accidents. What follows is a review of the field that summarizes different schools of thought on how and why accidents happen and how this understanding can determine how we define safety. I expand this review in chapter four by looking at different existing safety management strategies. In chapter five, I briefly summarize the current safety trends in healthcare. By summarizing the field and my own understanding of it, I hope to provide a context for the studies and the subsequent discussion in the thesis.

3.1 WHY DO ACCIDENTS HAPPEN?

Most of our understanding of risk and safety has developed through the study of socio-technical systems. A system can be defined as “a network of interdependent components that work together to accomplish the aim of the system” [18]. Non-technical systems are comprised of human activities. Technical systems are made up of the components, machines, computers, and controlling devices that perform activities. Socio-technical systems are combinations of people and machines that are needed to carry out a given task or provide a specific function [19]. Healthcare is an example of the latter.

In trying to understand the accidents that have occurred in these systems, different accident models have been developed [19, 20]. These different models help us understand past events by creating a mental model of how and why accidents happen. Mental models are representations of reality that people use to understand specific phenomena.

“In interacting with the environment, with others, and with the artifacts of technology, people form internal, mental models of themselves and of the things with which they are interacting. These models provide predictive and explanatory power for understanding the interaction” [21].

The accident models used influence safety management practice both consciously and unconsciously. They guide investigators in their questions, delineation of the data to be collected, analysis and presentation of information, as well as defining the “stop rules” for when to terminate the search for causes. Accident models also support the identification of remedial actions as well as the communication and learning that arises between people by providing a common frame of reference [22].

3.1.1 Accident models

Several different accident models have been developed over time. Old accident models still exist in parallel with many of our modern models. For instance, *fate* is still a dominating explanatory factor for many people. It follows from the fatalistic view that not much can be done to prevent accidents. Fortunately, more modern accident models have been developed. Hollnagel has classified these into different groups: single-factor, simple linear, complex linear, energy, process, and systemic models [20].

3.1.1.1 Single-factor models

Single-factor models describe the “accident proneness” of individual workers [23]. Accident proneness states that certain individuals, due to personality traits, are more susceptible to accidents than others. This theory implies that removing “accident prone” individuals, the “bad apples”, from hazardous situations, can reduce the risk for accidents. Today, “accident proneness” is considered to represent only a small fraction of accidents. Accident models focusing solely on personal factors are no longer used in industry.

However, another single-factor accident model that is still in use in safety management is the “human factor” explanation. Studies have shown that 88% of accidents were caused primarily by negligent or dangerous acts of individual workers [24, 25].

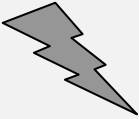
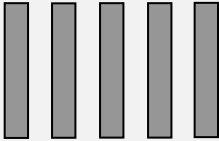

3.1.1.2 Simple linear accident models

Simple linear accident models are another group of accident models. Early linear causation models, like Heinrich’s “domino model”, describe accidents as the last step in a chain of linked events. Therefore, the cause of error can be found by simply following the line of events upstream through the chain that led to the accident. The safety management models that were inspired by this model imply that breaking the chain of events, through “spacing the dominos” or “removing a domino” can prevent accidents (Heinrich as quoted in [20]). This model has influenced the development of the accident classification schemes used to collect and analyze data in many countries. However, the weakness of linear causation models is that they do not take into account the possibility of multiple causes. Complex linear accident models were developed to meet this condition (see section 3.1.1.5).

3.1.1.3 Energy accident models

Energy accident models stem from epidemiological studies and are based on the observation that a transfer of energy above the tolerance level of a body causes injury to a person [20]. Inspired by this model, Haddon systematized and prioritized the established accident prevention principles into 10 generic strategies [22] (Table 2).

Table 2: Ten strategies for accident prevention

Hazard (Energy source)	Barriers	Victim (Vulnerable target)
		
Strategies related to the energy source	Strategies related to barriers	Strategies related to the vulnerable target
<ol style="list-style-type: none"> 1. Prevent buildup of energy 2. Modify the qualities of the energy 3. Limit the amount of energy 4. Prevent uncontrolled release of energy 5. Modify rate and distribution of energy 	<ol style="list-style-type: none"> 6. Separate, in time and space, the energy from the vulnerable target 7. Separate the energy and the vulnerable target with physical barriers 	<ol style="list-style-type: none"> 8. Make the vulnerable target more resistant to energy flow 9. Limit the development of loss (injury or damage) 10. Stabilize, repair and rehabilitate the object of the damage

(Adapted from Haddon)

Based on the energy accident model, Haddon grouped these safety management strategies into three approaches and then ranked them in order of priority. Primary

strategies focus on eliminating or reducing the hazard or energy source. If that is not possible, then defenses or barriers are introduced. Personal protective equipment or strategies are the last resort. Different industries are associated with a specific risk or type of energy. The energy can be, for instance, mechanical, chemical, thermal, or electrical. Consequently, context specific strategies need to be developed for each situation and environment based on these principles.

3.1.1.4 *Process accident models*

Process accident models describe how a system deteriorates through a sequence of events over time from a state of normalcy into a state where an accident occurs. Process accident models make a clear distinction between the accident sequence and the underlying causes or contributing factors and also distinguish between four different phases of the accident sequence. In the first phase of the process accident model, the system shifts from normal operation to a state characterized by lack of control and an increasing deviation frequency. These deviations are called *critical incidents* or *unsafe acts*. In the second phase the situation moves from a lack of control to loss of control. In the third, or injury phase, the target starts absorbing energy that ceases in the fourth phase. The significance of deviations as risk factors for accidents is supported by empirical evidence. When a production system is in a state of lack-of-control, characterized by production disturbances, defective equipment, and non-ordinary staff, the accident risk increases [22].

A number of process and energy-based accident models exist. Haddon developed another process accident model for the study of traffic accidents [26]. In that model, the phases are called pre-crash, crash and post crash. In the initial phases of the accident, the system goes from a normal state to one characterized by lack of control due to an increasing frequency of deviations.

3.1.1.5 *Combined complex linear and energy accident models*

Reason's model of organizational accidents is a combination of features from both *complex linear accident models* and *energy accident models*. That part of the organization which is near the hazardous process is called the *sharp end* whereas those parts that are further away, but which still influence the work conditions are called the *blunt end*. An accident is therefore defined as the result of a complex sequential interaction of *unsafe acts* made by sharp end agents and *latent conditions* represented by weaknesses in barriers and defenses. These latent conditions are potential accidents "waiting to happen" – built into the system as it evolved. These accidents are usually hidden at the blunt end of the organization but become visible at the sharp end of the organization.

In the Reason model [27], different classes of human failure are described, based on the following:

1. Unsafe acts are specific failures made by individual operators at the sharp end – the hazardous process.
2. Failure types are general classes of organizational and/or management failures:
 - a. *Function failure types* are latent failures, resulting from decisions made by line managers, designers and planners
 - b. *Source failure types* are also latent failures resulting from top management decisions at the strategic level.

Organizations can cope with the risk of adverse events by creating defensive barriers. These layers act to prevent latent or active failures from causing harm. The barriers may be at the individual, team, or institutional level or technical or organizational in nature. Techniques may involve variability detection and feedback mechanisms, protective barriers that prevent errors from causing injuries, or other mechanisms. A metaphor that has been used to describe the model is that of several slices of Swiss cheese. Because of the multiple layers of defense (slices of cheese), multiple weaknesses (holes in the cheese) are required in several layers an adverse event to occur.

3.1.1.6 *Systemic accident models*

An underlying difference between the linear and systemic accident models is related to how they describe the system. In the linear model the system is seen as being genuinely stable until disturbed by an accident. According to the systemic models, system performance is a dynamic process influenced by both exogenous and endogenous variability. Accidents are seen as the flip side of a system's usual ability to cope with variability.

The purpose of a *systemic accident model* is to describe the whole system, not just the separate mechanisms which lead to an accident. In the systemic model, accidents are viewed as a normal occurrence within systems. They are caused by stochastic combinations or aggregations of conditions and events occurring at the same time within the system – a phenomenon called *concurrency* [28].

More recently developed systemic accident models view accidents, as well as normal performance, as non-linear, emergent phenomena within complex adaptive systems. These systems can change from being dynamically stable to being dynamically unstable. The change can occur slowly, as in the gradual migration towards safety margins, or suddenly, as in an accident. [20]

3.2 WHAT IS SAFETY?

Depending on the accident model we subscribe to, we can define safety in different ways. Seen from the vantage of simple linear causation models, safety means the ability to resist specific causes by breaking the chain of events. Complex causation models view safety as the ability to uphold the barriers and defenses in the system.

In systemic models, safety is defined as the degree of robustness of all processes that protect the system from disturbances and threats. It is the system's ability to uphold dynamic control of variability that makes it safe – this is a reflection of the system's resilience.

Resilience can be seen as the “ability to recognize, adapt to, and handle unanticipated perturbations that call into question the model of competence of the system and demand a shift of process, strategies and coordination” [20]. Both resilience and its opposite, brittleness, are properties of the system as a whole as well as of the individual actors and their behavior [29].

Resilience at the sharp end is affected by how the organization creates pressures and goals and how conflicts between competing goals are handled. Poor application of safety solutions like automations and standardizations can influence the work of frontline staff negatively.

Resilience at the blunt end is conversely the result of how sharp end staff adapt to the combined pressure from strategic goals in the form of workarounds or innovative tactics. Workarounds are adaptations made by front line operators to cope with simultaneous demands or workload bottlenecks. They counteract attempts to standardize work processes that are all too often designed to meet the need of just one task at a time.

Given the many different accident models (of which I have only presented a selection) and the different ways in which it is possible to define what safety is, the question becomes how it can be managed.

4 SAFETY MANAGEMENT STRATEGIES

Safety management strategies are actions aimed at managing risks and the prevention of accidents. All of the accident models, described above, have contributed to our understanding of safety as a phenomenon. In some cases, however, they have also caused confusion when safety management strategies based on the models have been applied too liberally and out of context. In this chapter, I present a number of different strategies that can be of use when we turn our attention to monitoring safety in healthcare in chapter five.

Inspired by Taylor's theories about scientific management, safety management began by focusing on simplifying, standardizing, and centrally monitoring operational tasks. However, this is hard to do with tasks that are complex and unpredictable and where frontline operators know more about the nature of the work than their managers do. In modern safety management the focus has shifted to supporting the individuals in the organization.

Amalberti has categorized organizations based on accident prevalence [30]. Different safety management methods dominate depending on the phase of safety development. *Amateur systems*, i.e. dangerous systems, are systems where the risk of accidents is greater than one accident per 1,000 events (e.g. bungee jumping or mountain climbing). These are non-professional systems where the safety measures regulating the systems are highly individual and focus on the technical equipment used. Safe systems or *regulated systems* have an accident risk between one accident per 1,000 events and one per 100,000 events. Automobile use, chemical industries or chartered flights are examples of regulated systems. Safety in these systems is dependent on professionals. There are four typical safety strategies:

- Regulations and procedures
- Anticipation of accidents or near accidents based on experiences from past accidents
- Error resistant design and a reporting policy
- Feedback and credit to staff for improvements realized. This helps reinforce the importance of a safety system.

Paradoxically, strategies developed to create safety can become hazardous to their organizations. For instance, *ultra safe systems*, where the risk of accidents is below one per 100,000 or even one per million (e.g. regularly scheduled civilian flights, railroads in Europe and the nuclear industry), tend to be ageing, over-regulated, and rigid. Since accidents so rarely occur in these systems, they differ in nature from those occurring in the safe systems. In ultra safe systems, accidents can result from rare combinations of factors, making incident reporting and traditional safety analyses ineffective in averting major disasters. The safety of ultra-safe systems therefore tends to become a political rather than a scientific subject, favoring short-term measures with high visibility. In ultra safe organizations, the focus of safety strategies needs to shift back to the individual worker and support their ability to compensate and sometimes violate the existing rules and regulations in order to maintain safe performance.

4.1 ACCIDENT REPORTING SYSTEMS

Detection of adverse events is an important part of organizational resilience [31, 32]. Reporting systems evolved as a means to provide feedback about deviances from normal production. When it works well, the reporting process should be straightforward and the reports handled with confidentiality. The agency or department that collects and analyzes the data should be independent of a sanctioning body. Feedback should be rapid, useful, intelligible, accessible and easy to disseminate to the reporting community. [27, 31]

Accident investigations begin by backtracking from the incident to find failures and weakness in the organization that contributed to the accident. Many accident investigation frameworks attempt to identify and analyze barriers that have failed as well as other general failure types. General failure types are then monitored and used for improving training and situational awareness of risks involved for workers near the hazardous process.

Different frameworks also exist for predicting possible errors. One commonly used approach is failure mode and effect analysis (FMEA), in which the likelihood of a particular process failure is combined with an estimate of the relative impact of that error to produce a *criticality index*. By combining the probability of failure with the consequences of failure, this index allows for the prioritization of specific processes as quality improvement targets. For instance, a FMEA analysis of the medication dispensing process on a general hospital ward might break down all the steps from receipt of orders in the central pharmacy to filling automated dispensing machines by pharmacy technicians. Each step in this process is assigned a probability of failure and an impact score, so that all steps could be ranked according to the product of these two numbers. Steps ranked at the top (i.e., those with the highest criticality indices) would be prioritized for error proofing [27, 33].

An organization needs administrative procedures and routines for accident reporting, investigation and distribution of information. It also needs instruments and tools as well as principles in place to guide the collection, processing, storing, and distribution of information on accident risks. An effective safety information system should be based on what we have learned from performance measurement systems.

4.2 PERFORMANCE MEASUREMENT SYSTEMS

While feedback and learning from past accident experiences has been a central strategy in safety management, it is not a unique to the field. Performance feedback is a management strategy with a long history independent from safety management. The concept of performance feedback was first introduced in cybernetics [34]. Cybernetics is defined as control and communication in animal and machine. Feedback in cybernetics is viewed as integral to action.

The simplest feedback control models consist of a goal, a sensor, a comparator and an output function. Action is initiated when the comparator registers that the output perceived by the sensor differs from the goal. Control by negative feedback is a common regulatory mechanism in management systems.

The purpose of a performance measurement system is to collect, compute and present quantified constructs for managerial purposes to follow up, monitor and improve or-

ganizational performance [35]. These systems are used for a wide variety of purposes in organizations. The output of the organization is monitored and the difference between results and norms is used as an input for action.

A key idea behind performance measurement systems, in general, is that they facilitate the efforts of high-level management to hierarchically coordinate the activities of units. Performance measurement systems should serve as a link between the various units of an organization and facilitate higher management's dissemination of plans and goals (which are linked to the overall strategy) throughout the organization. Furthermore, the system enables control through a bottom-up procedure of updating management about the performance of their sub-units [36].

From an informational point of view, the legitimacy and acceptance of performance measurement is dependent upon the quality of output information [37]. A low level of quality means that people within organizations are unwilling to learn from and use the information system. In situations where low quality information is used, the problem is even worse: decisions might be made on false grounds. Some studies indicate that many performance measurement systems suffer from various kinds of data quality problems. Examples of such problems are vague definitions of performance measures, lack of validation strategies, software constraints, mismatched syntax, complexity as system integration interfaces increase, data conversion errors, visualization errors and individual registration and computation failures. The ideal – high quality performance measurement systems – requires that users can rely upon the information.

The desirable characteristics of the outputs of a performance measurement system are the following [38]:

- Performance measures should enable or facilitate benchmarking
- Ratio-based performance measures are preferable to absolute numbers
- Performance measures should be directly under the control of the evaluated organization
- No financial measures should be adopted
- Performance measures should be simple and easy to use and provide fast feedback
- Performance measures should stimulate improvement rather than only monitoring.

Based on these principles, a system can be built that provides information to decision makers and managers to improve safety. Such an information providing system is an essential part of an organization's safety management system.

4.2.1 Safety information systems

A safety information system provides data that can be used to make management decisions. Monitoring and managing resilience, or its absence, called brittleness, is about gathering information about how the system adapts to disturbances in the environment. Several factors can be studied, including:

- Buffering capacity – the size or type of disruption the system can absorb or adapt to without fundamental changes to its structure,
- Flexibility versus stiffness – the system's ability to restructure itself in response to external changes or pressures,
- Margin – how closely to a performance boundary the system operates, and

- Tolerance – whether the system degrades slowly or collapses when pressure exceeds adaptive capacity.

Data on accident experiences are usually collected by reporting accidents and near accidents, unsafe conditions, and through workplace inspections, risk analyses and safety audits. The reports are analyzed and solutions developed. These are then disseminated throughout the line organization and to safety representatives and staff. A memory bank is continuously updated with summaries of accident and incident reports, risk analysis reports, solutions to safety problems as well as standards, rules and regulations. [22]

Three requirements for an effective safety information system:

- Data collection should be reliable, valid and provide adequate coverage.
- The distribution and presentation of the information should have relevance, be comprehensive yet easy to grasp, be timely and available when it is needed.
- The safety information system as a whole should use methods that are easily understood and accepted, promote and encourage involvement, and be cost efficient.

Safety information systems use performance measures to help organizations understand safety. But to do this, it is helpful to know what a good performance indicator is [22].

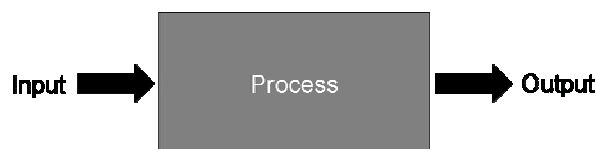
- The performance indicator should be *observable and quantifiable*, i.e. it must be possible to observe and measure performance by applying a recognized data collection method and scale of measurement
- The indicator should be a *valid measure* of the risk of loss
- It should be *sensitive to change* and give early warnings by capturing signals about significant risks for losses through accidents
- It should be *compatible* to other measures and not give decision-makers contradictory signals.

Two additional requirements are derived from theories on human information processing and organizational learning.

- The indicators should be *transparent and easily understood*, i.e. their meaning is apparent and in line with the understanding and mental models of the user.
- The measure should also be *robust against manipulation* and prevent organizations from cosmetic action and avoid making the necessary risk-reducing changes.

4.2.2 Safety performance measures

Figure 1: Diagram of a simple system



Different approaches to evaluate the safety levels of a system, many of them based on selected indicators or have been developed. A basic model of a system is based on an *input* that

undergoes a *process* that yields an *output* or *outcome*. A common way to measure safety is to follow negative outcomes, such as the occurrence of adverse events.

These can be fatalities or how measures, much work time has been lost due to injuries (lost time injuries). However, the number of negative outcomes as an indicator is only useful when the accident rates are high enough. Most industries today, thanks to

many-layered defenses, experience few serious accidents. Consequently, the information retrieved from analyzing serious accidents is of limited value. Furthermore, these data are often collected too late to guide improvement efforts. In systems where adverse outcomes are rare, outcome measures are an unreliable indicator of the safety performance of the system. [30]

The elements of complex socio-technological systems such as healthcare can be people, hardware, software, facilities, policies and documents, all of which are required to produce system level results. The results of socio-technological systems include such things as properties, characteristics, functions, behavior and performance that emerge on a system level. The results produced by the system are beyond that contributed independently by the parts. Another weakness with outcome measures is that they do not yield information about the mechanisms that impact safety. For this reason, many organizations try to follow the mechanisms that influence processes in addition to outcomes. Reason has identified several different mechanisms that influence processes [27, 39]. These can be grouped into five measurable clusters:

- *Safety specific factors*: incident and accident reporting, safety policy, emergency resources and procedures
- *Management factors*: management of change, leadership, administration, and communication
- *Technical factors*: levels of automation, human-system interfaces, engineering controls, and design
- *Procedural factors*: standards, rules, administrative controls, operating procedures
- *Training*: formal and informal, skills and competencies required to perform tasks

4.3 FEEDBACK FOR ORGANIZATIONAL LEARNING AND ADAPTATION

Measuring performance, processes and output provides information about how safe an organization is. This alone does not lead to an improvement in safety because there is no guarantee that an organization will learn. The existence of a safety information system *per se* does little to improve safety if the information is not used. How well an organization can learn from its mistakes depends, not only on the knowledge and skills of its members, but also on the attitudes, sense of responsibility and the amount of authority members have. Safety improvement is dependent on well functioning feedback loops as well as a climate that supports organizational learning and adaptation.

4.3.1 Learning from accidents

There a number of ways decision-makers can learn from the feedback provided by safety information systems. One of the most commonly referenced approaches is that of experiential learning [39]. According to the model, adults learn from interacting with their environment through concrete experiences, by reflective observations, by actively experimenting and by applying theories or abstract concepts. Experience won can be transformed into actions or conceptualized into new mental models of the environment. The individual will gradually improve her understanding of the real-world phenomena (know-why) and her ability to act effectively (know-how).

Hale describes a rational problem solving cycle where the current situation is compared to the desired situation (as defined by standards). The problem is recognized, defined and analyzed with respect to causes. A technical, organizational or societal solution is generated which is implemented and the effects are monitored and evaluated. One example of a rational problem solving cycle is continuous quality improvement [40]. In this approach to learning, groups of professionals go through a shared learning experience, fed by output data from their own system. They reflect on the current system and its behavior in order to gain understanding. Based on their understandings, the team redesigns its work processes and the plans, tests and studies the outcomes of small-scale interventions. The experiences can then guide other improvement projects conducted around a similar type of problem.

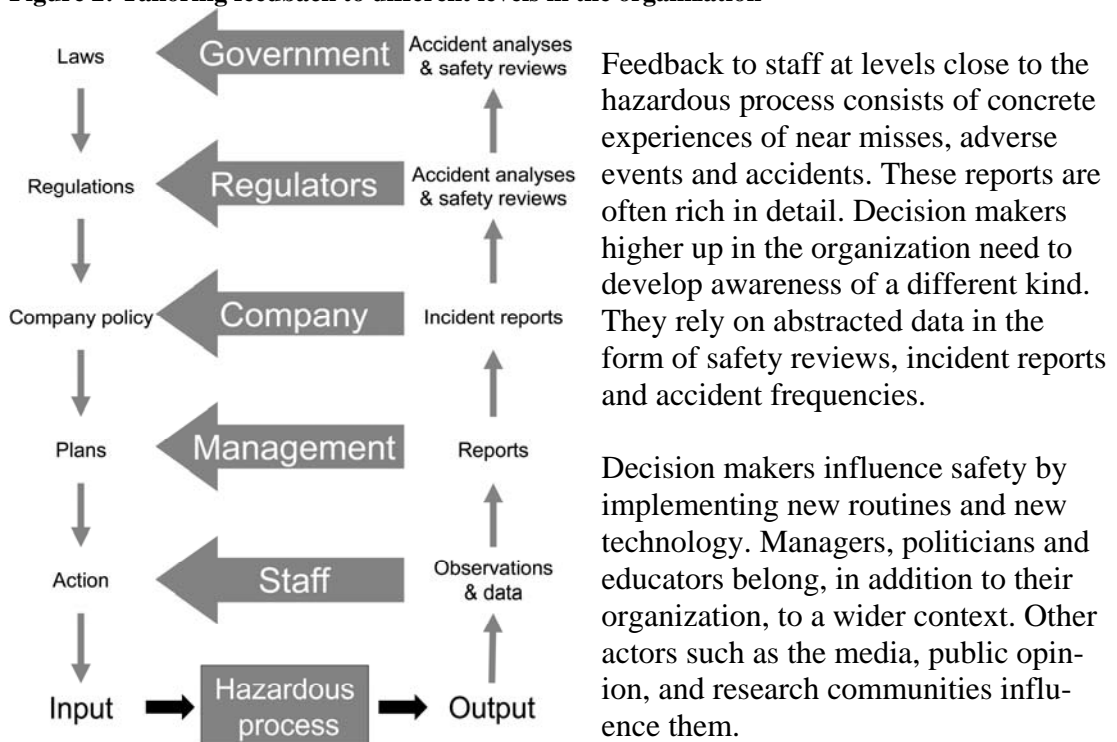
Both the experiential learning model and rational problem solving cycles are dependent upon feedback.

4.3.2 Levels of feedback

All decision makers need feedback on safety performance. To enable successful risk and safety management, decision-makers need to become aware of the boundaries that delineate safe performance, the efforts needed to make visible these boundaries, and the pressures that drive the system towards the edge.

To make the most of the information that is fed back, it is important to pay attention to the context of the receiver. Since improving the safety performance of an organization depends on the co-ordination of decision-making at several levels [1] it is reasonable to expect that the type of feedback should be tailored to the type of decision made (Figure 2).

Figure 2: Tailoring feedback to different levels in the organization



(Adapted from Rasmussen [1])

Safety management systems can also use feed forward mechanisms which use anticipated risks rather than accidents that already have occurred as a source of information

to influence actions. Regardless of the method for obtaining the feedback, it is important that it ends up in an organization that can learn.

4.3.3 The role of context

The context of an organization determines how information is gathered and entered into a safety information system, how the information is analyzed, processed and presented, and what is learned. For instance, decision makers can be under pressure to choose throughput (production) over thoroughness (quality). The context also influences the existing view on why accidents happen as well as the reporting culture of the organization. This means that the quality of the lessons learned from a safety management system is dependent on the safety climate of the organization.

Since the mid 1980s, much attention has been on how culture influences the reliability of organizations managing high-risk systems [41]. The concept of a safety culture emerged from investigations into the nuclear meltdown at Chernobyl [42]. Many industries have also been interested in measuring the level of safety culture [43].

The concept of *safety climate* is derived from organizational climate theory and was first developed by social psychologists like Lewin and McGregor [44, 45]. Lewin used the concept of climate to describe attitudes, emotions, social processes, and their interactions. McGregor focused on the impact of leadership on employees' perceptions of the organizational climate.

One field in modern safety research uses safety climate survey instruments to explore perceptions of risk and safety, as well as values and attitudes. By analyzing theories of safety culture, and empirical studies of safe and unsafe organizations, several safety climate factors have been identified [46].

One such factor is that of management's commitment to safety [47-49]. Seo et al. [50] include this factor in their suggested five constructs based on safety climate studies: managers' commitment to safety, supervisor safety support, co-worker safety support, employee participation in safety related decision-making and activities, and the competence level of employees in terms of safety.

Reason also emphasizes the important role top management plays as a driving force for safe performance [27]. Important factors are commitment, competence and cognizance. Commitment requires motivation – does the organization strive to be a model for good safety practices or just placate regulators? Commitment also requires that adequate monetary and staff resources be allocated to safety improvement. Competence is the ability to realize this motivation in concrete organizational structures, strategies and routines that support safe work practice. But neither commitment nor competence is sufficient if the organization does not have an awareness or understanding (cognizance) of the risks that are present in the system and the ongoing nature of safety management.

While the attention of safety climate research has mainly been focused on management and/or the macro organizational level, there are other approaches to safety management research. In contrast to a focus on the impact of top management and organizational structures, another school of research proposes that safety can only be understood at the sharp end of the organization [20, 51, 52]. One example of this type of

organization are “high reliability organizations” that have been very successful at creating a culture of incident reporting as well as learning from these reports.

It is the culture that rewards reliability that helps coordinate the individual actions of workers in the system to improve safety. This idea has been developed further into the concept of *mindfulness* [32]. Mindfulness is characterized by five attitudes: a pre-occupation with failure, reluctance to simplify interpretations, sensitivity to operations, a commitment to resilience, and deference to expertise.

In his study of operators in nuclear power plants, Gauthereau writes that mindfulness is not only an attitude which guides the actions of individual operators, but is also built into the physical design of the workplace, the organization of the work, and the individuals’ identity as practitioners. “This culture of reliability is recreated everyday through competent practice through participation in the communities in the organization” [29].

4.3.4 Organizational learning

The level of learning from adverse events can be analyzed based on the depth of learning from a past experience. In single-loop learning [53], only immediate corrective actions are taken and the same type of incident or accident may happen again. Single-loop learning is often seen on the frontlines, where individuals and groups temporarily change routines to solve problems. Those solutions may uphold a certain degree of safety, but they may also create workarounds that mask underlying safety problems [1, 54, 55]

Reliable changes to improve safety often involve learning across groups and divisions in the organization. In double-loop learning, the organization not only solves the problem at hand; it also reflects on the underlying procedures, policies and goals. This enables an evolution of the organizational structure itself [53]. Preventive actions can be taken, such as changing the rules, routines or the design of the task, so that the risk of an accident reoccurring is mitigated.

Unfortunately, individuals and organizations have barriers that can obstruct organizational learning. There are cognitive barriers as to how much information humans can perceive and process that hinder organizational learning. There are also defenses to avoid embarrassment and threats. These defenses impede learning from accidents and incidents. When mismatches occur between intention and result, self-protective actions are often taken to control damage and avoid compromising inquiries. This is one reason for why an organization might try to link an accident to unique and situational causes rather than system failures [53].

Dörner has found four causes for the mistakes humans make in dealing with complex systems:

“The slowness of our thinking and the small amount of information we can process at any one time, our tendency to protect our sense of competence, the limited inflow capacity of our memory, and our tendency to focus only on immediately pressing problems.” [56]

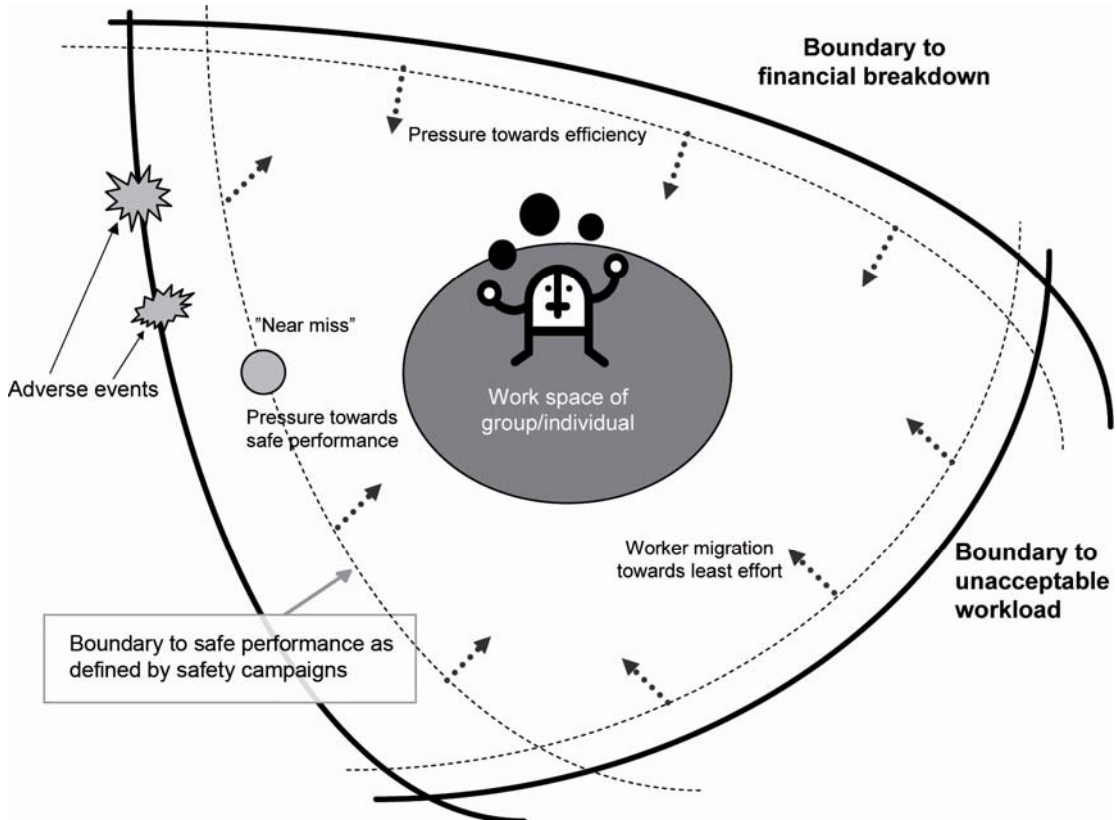
4.3.5 Adaptation of work practice

Organizational learning is manifested in new, or modified, organizational routines, processes or behavior [57]. One way to see that an organization has learned from the feedback it received from its safety information systems is to look for evidence of adaptations in work practices.

Work practice can be defined as the repeated performance of a professional activity [29]. Socio-technological systems consist of individuals and groups interacting with technology, routines, and policies to achieve the goals of the organization. Everyday work in an organization involves individuals and groups of individuals who are continuously confronted with situations in which choices have to be made. Most of those choices are made unconsciously or routinely, as work practice adapts to changes in the task or in the environment. Since tasks are repeatedly subjected to local adjustments, work practice will vary over time. Furthermore, the activities performed become part of the experience of the workers and will influence the context and thereby future performance. What constitutes “good work” is based on experiences from the successful performance of tasks [58].

An organization has several and sometimes conflicting goals. The objective is to achieve those goals while avoiding financial breakdown, unacceptable workload levels and accidents. Work systems such as healthcare organizations are bounded both by goals and resource constraints. It is therefore possible to describe a potential workspace in which the actors perform their tasks (Figure 3) that is formed by boundaries that delineate failure in these areas (thick lines).

Figure 3: A model of the bounded workspace in an adaptive system



(Adapted from Rasmussen [58])

An organization or individual will set up its own marginal boundaries (dashed lines) to lessen the risk of crossing the boundaries that lead to failure. These create buffer zones. An example would be a safety campaign that set boundaries for what is considered safe work practice. While crossing such a boundary does not lead to accidents per se, it would break the cultural norms of the organization.

In a normal work situation, workers are immersed in the context of the workspace and know the flow of activity and relevant action alternatives by rote. The worker chooses how to complete his/her task by choosing between several possible work strategies based on his/her perceptions of the organization's goals, and the financial, time and safety constraints. The work practice will therefore show great variability due to local situational pressures as workers change and modify their strategies. This variation in work practice contributes to the organization's capacity to manage and learn from variability [54, 59].

In a complex working environment, such as a clinic, several actors migrate independently within a space of acceptable performance. This behavior is similar to that of gas molecules in a constrained space, something referred to as Brownian movements, where molecules are constantly "bumping" into each other and the boundaries of the container. From time to time, actors may migrate towards one of the boundaries of the workspace, even crossing it. If the boundary is reversible the actor can recover and compensate for the event, if, however, an irreversible boundary is crossed, an accident occurs.

The actors in socio-technological systems such as healthcare need to manage cognitive workload, complex technological systems as well as failures or surprising side effects of actions. The variability of the system is further increased in healthcare since the workspace involves interaction with a sick individual. To avoid accidents, organizations try to stay clear of crossing the boundaries to unacceptable performance or behavior (thick line). Over time, this produces a marginal boundary that marks the acceptable limit of operations (dashed line). The socio-technical processes, workplace design and the mental models of risk and safety that operators share influence the marginal boundary. Deliberately crossing that boundary breaks the social norms of the organization. Uncertainty about the location of the marginal boundary can lead to unintended crossing of the margin, but when the organization recognizes that, immediate recovery actions can be taken to bring operations back within the limits. These episodes are referred to as near misses. In practice the exact location of the safety boundary is uncertain and can often be determined only retrospectively through investigation of accidents.

The publicity generated from serious adverse events usually lead to the organization's safety marginal boundary moving inwards. Long periods without adverse events of reported near misses may lead to more "experimentation" and the workspace will drift closer towards a boundary of unacceptable performance – a phenomenon called *normalization of deviance* or *marginal creep* [60, 61].

Stable, low risk systems have a workspace that moves in a small stable arena well away from the marginal and accident boundaries. Stable high-risk systems operate nearer the margin and thus nearer accidents. In these systems, safety comes from minimizing workspace drift through standardization of work practice. Unstable, high-risk systems have, in contrast, large workspace shifts that can take them from low to high risk. These organizations often have inaccurate, imprecise, and divergent under-

standings of the current workspace, which factors are influential, and their degree of impact. [54]

Safety is the ability of an organization to maximize the safety buffer zone (the space between the boundary and the marginal boundary), while still achieving organizational goals. However, systems such as hospitals often work close to the safety margin in order to reduce workload and cost. Individuals at the sharp end of the system can create safe work practice by constantly adapting to changes as well as anticipating possible risks that have not yet emerged. This mindfulness is an important form of self-organizing behavior that keeps the system within the boundaries of safe performance [32, 52].

4.3.6 High reliability organizations

High reliability organizations (HROs) have been able to develop an accurate, precise and shared understanding of the location of their workspace in relation to the boundaries that delineate safe practice. Moreover, they are successful at generating and making use of strategies that influence workspace movement towards safer practice.

HROs are characterized by the presence of highly predictable and effective operations in the face of hazards that can potentially harm hundreds of thousands of people at a time. HROs, have three traits in common [29, 41]. First, failure for these organizations leads to consequences that are not acceptable. They operate not only under a demand for effectiveness but also for unmitigated success. Second, they typically have systems in which the technology, the organization, and the social setting are woven together inseparably. Failure for an HRO is not only defined as failure in meeting safety demands, but also as a failure to deliver the expected service. Third, the success of HROs is not only defined by internal criteria; they also need to meet the criteria set by external regulatory agencies and the public. [52]

Leadership in HROs demonstrates a willingness to shift decision-making power to knowledgeable experts and frontline employees who are familiar with the immediate situation and can respond promptly. Leadership also avoids simplifying or explaining away problems, is sensitive to operational personnel, and has a willingness to strengthen the ability of employees to improvise and learn from experience. HROs often have several methods for learning: a good reporting culture (features that promote incident reporting and feedback to the reporting community), simulations of the system's abilities to cope with stress, and training teams to support each others' situational awareness and thus helping the organization to adapt to new demands [52, 59]. Methods like these have been adapted to and applied in healthcare safety management [62-64].

HROs are also exemplified by a constant heedfulness among employees at every level. *Heedfulness* is the reluctance to simplify and use of experiential learning [52, 59]. Ryle wrote in 1949,

“Heedful performance is not the same as habitual performance. In habitual performance each performance is a replica of its predecessor, whereas in heedful performance, each action is modified by its predecessor” (As quoted in Weick and Suthcliffe [52]).

Gauthereau makes the case that the heedfulness of work practice at both the sharp and the blunt end should be based on double-loop learning. Not only should actors reflect on how to create safety, they also should reflect on what safety is [29].

The members of the HRO need to have clearly stated goals to be able to prioritize between different pressures. This helps the individual become aware of a drift in the system towards unacceptable performance, and enables them to act on those signals.

After this review of different strategies for monitoring and learning from error that exist in other industries, and how they can be applied as in HROs, the next chapter presents approaches to safety management that have been applied to healthcare.

5 SAFETY MANAGEMENT IN HEALTHCARE

When the Institute of Medicine report, *To Err is Human*, was released in 1999, patient safety became a major health policy issue worldwide. Since then, different strategies have been proposed to improve safety in healthcare. These strategies can be divided into three broad categories [65]:

- Reducing errors made by healthcare professionals
- Reducing patient injuries, and
- Improving the use of evidence based medicine.

Reducing errors made by healthcare professionals is a challenging strategy. Healthcare professionals often do not want to acknowledge or discuss adverse events in order to avoid embarrassment, blame or sanctions. A professional culture of perfection and the persisting norm of “blaming and shaming” help reinforce this attitude [64, 66, 67].

The strategy to improve safety by reducing patient injuries is hampered by common, but outdated accident models which hold the individual professional responsible for patient safety [64]. This mental model has unfortunately led safety management to focus on the competence and performance of individual clinicians. Regulatory agencies thus focus primarily on identifying and removing the individual “bad apples” to reduce patient injuries. Once an error has been explained by negligence or by individual incompetence, further investigations or searches for alternative causes have traditionally ceased [68, 69].

This view on errors has been supported by litigating bodies, according to whom an individual has to be held responsible [70]. New perspectives from reliability analysis and safety management in other industries, as well as from psychology fields such as cognition research and human factors research, have provided new insights. Failures in communication have been found to be a leading contributing factor in all types of adverse events [71, 72]. These failures can occur between practitioners of different professions, most commonly physicians and nurses, as well as between healthcare providers and patients. There are also many external and internal factors that influence a person in his/her work setting. Environmental changes need to be made to that setting to prevent an adverse event [70].

The third approach of improving the use of evidence based medicine is another area where a lot of work has been and still needs to be done. Healthcare has been poor in applying the results of research to patient care [73]. The same applies to the use of research in safety. However, large campaigns such as the Institute for Healthcare Improvement’s “100 K lives” and that of the Leapfrog group are examples of how to successfully improve the implementation of research findings [74, 75].

Safety and quality in healthcare are now prioritized areas for systematic evaluation as well as have caught the public interest. This has led to an increased demand for data on the quality and safety performance of individual practitioners and provider organization. Other industries have already developed and validated indicators and measures for monitoring and improving performance. These measures have been used to create low cost indicators for routine use by decision makers. A few measures have been designed for evaluating patient safety [13, 14].

5.1 SOURCES OF SAFETY INFORMATION IN HEALTHCARE

While healthcare is still behind other industries in its ability to measure safety evidence based measures are presently being developed and improved [17, 76]. Potential sources of patient safety information that have been assessed are the reporting of errors, near misses and adverse events, administrative data (e.g. patient safety indicators), medical chart studies, direct observation, safety climate, and patient generated information (e.g. patient complaints, malpractice claims, patient injury claims).

5.1.1.1 *Reporting of errors, near misses and adverse events*

This strategy has been proposed as an important method for healthcare organizations to learn about safety [27, 77-79]. The value of using adverse events depends on how well they mark the boundaries of the workspace. They also show how the system in question can stretch when disrupted (buffer capacity) [20]. Professional prestige, as well as a fear of litigation, creates barriers to reporting near misses and adverse events. This hinders hospitals from developing into safety-focused learning organizations [80, 81].

5.1.1.2 *Administrative data*

Administrative data are routinely collected, of low cost, and are generally thorough despite eventual inaccuracies due to variability in coding practices [16, 82]. Administrative data cover more episodes of care and thereby are a bigger net for capturing adverse events than reporting systems.

Patient safety indicators have been developed as a tool for tracking and improving patient safety performance when analyzing administrative data. They are typically derived from administrative data like hospital discharge registers. The International Classification of Diseases (ICD-10) and other diagnosis and procedure codes are used to medically identify in-hospital patient safety events. The patient safety indicators are expressed as rates, the numerator being the number of occurrences of a specific outcome and the denominator the total population at risk. Studies report that tracking risk adjusted patient safety indicators over time is useful [76].

Indicators can track, for instance, possible surgical complications and other nosocomial events and screen for potential problems that patients experience as a result of their care. The rationale is to find errors and injuries that are preventable by system changes. In order to be valid, the numerator (the event or harm) and the denominator (the population at risk) have to be clearly defined and measured with a minimal of bias. Many current publicly reported performance measures are likely to be incomplete according to this criterion, and therefore insufficient for assessing safety [83]. Patient safety indicators are not detailed and timely enough to be used alone as an indicator of safety, but are reliable and simple enough to serve as a higher level safety performance measure [76, 84, 85].

Establishing safety indicators that can provide valid measurements is a first important step towards monitoring and improving safety and reliability [86]. By developing international patient safety indicators, it is possible to make comparisons across healthcare systems which support mutual learning and quality improvement [87]. The first set of indicators was published in the US by the Agency for Healthcare Research and Quality [17]. Safety indicators have been developed as part of the National

Health Services performance measurement system in Great Britain [88]. The OECD has defined a set of safety indicators as part of its health statistics service [87]. Patient safety indicators are now used for hospital performance monitoring in a number of other countries [76, 86].

5.1.1.3 *Medical chart studies*

Tracking adverse events through medical records may be more sensitive than through reporting systems [89-91]. Large population based reviews of medical records have been the norm in research into errors and adverse events [3-9]. They have been the golden standard for assessing the prevalence of adverse events and preventable adverse events in healthcare [90]. The downside is that such studies are resource intensive and time consuming.

The increasing use of electronic medical records opens up for computerized screening using *trigger tools* which look for specific terms, diagnostic codes or laboratory values [92].

5.1.1.4 *Direct observation*

Another source of safety information can be generated through direct observation of clinical practice [93, 94]. Tests can be designed to study how the system responds to stress and changes. Crews in aviation and now also in healthcare are continuously tested in *simulators* to evaluate their capability to cope with a large variety of unexpected events and crisis situations. The modeling of systems behavior using real input data could provide other possibilities to run different scenarios and test administrative systems [95, 96]. Direct observation can be costly, but it provides rich and valid information on the processes of care [95, 97].

Another observational tool is *audits*. Healthcare organizations should scrutinize work practice and the routines and procedures that are in place to detect, evaluate, and map organizational misalignments and drift due to self-organized stress reduction and/or coping strategies. An independent body could make these audits, or departments could peer review each other's routines and work processes. An audit could also be performed by reciprocal peer reviews performed by individual clinicians and teams. Observation and audits require an organizational culture that facilitates and values critical questions that challenge that which is often taken for granted [95].

5.1.1.5 *Measures of safety climate*

Safety culture assessment has been proposed as a tool for improving patient safety in healthcare organizations [98]. The influence of organizational climate on patient safety has been studied and several safety climate survey instruments have been developed during the last five years [48, 49, 71, 99, 100]. Valid measures of safety climate have been made by systematically assessing frontline caregivers' perceptions of the organization's commitment to safety [101]. Some evidence suggests that interventions can influence the safety climate [102, 103]. Recently, healthcare safety culture or climate questionnaires have been reviewed for their psychometric properties [104]. Out of the 29 studies identified, 12 were deemed suitable for assessment. The review concluded that only a few met the psychometric criteria the authors listed as a standard and that more considerations should be given to psychometric factors in the design of safety culture instruments, especially if they are used in large scale surveys across healthcare organizations. Studies on the views of healthcare leaders, either

focusing on one group of employees or on single subjects, do not attempt to measure attitudes or composite phenomena like climate.

5.1.1.6 Patient generated information

Patients are able to make trustworthy reports of undesirable events that occur during hospital care and are less subject to cultural barriers than staff when they report adverse events [105].

Unsolicited patient complaints have been found to cover all aspects of patient encounters with the healthcare system (e.g. rudeness, food, parking, access, communication, timeliness, etc.). A correlation with malpractice claims has been found [106]. A subsequent study from the same group showed that surgical patients who had made any type of formal complaint about their hospitalization were more likely to have suffered a complication [107]. Patient complaints can thus serve as a potential marker for adverse events.

Several formal systems exist that offer patients and their relatives the possibility to express and record their views on their care and the performance of practitioners and provider organizations. Many provider organizations regularly survey their patients and many countries have complaint procedures (complaint boards or ombudsmen). Complaints can also be made to public regulating bodies and inspectorates.

Malpractice claims are one set of data that is increasingly being used for analysis. Malpractice claims can offer rich data, but are subject to *hindsight bias* and selection factors in what is reported. Hindsight bias is the tendency to confuse correlation with causality, in other words to assume that acts preceding an adverse outcome were unsafe acts [108]. In a recently published review article of studies on closed malpractice claims from anesthesiology, surgery, primary care, obstetrics and mental health, Vincent et al emphasize the limitations of using claims data as a proxy for injury occurrence [109]. One concern with using claims data is the occasional time delay between the occurrence of the adverse event and subsequent claim filing. Claims can reflect out-of-date practices because of this delay. Another weakness is the lack of denominator data and selection bias due to different compensation schemes. Some of these concerns have also been addressed in studies of no-fault malpractice schemes [110-113].

It should be recognized that most claims studies are derived from litigated files, as legal issues make it virtually impossible to access material prior to settlement. Litigated claims are, however, highly selective, representing only those claims which have been settled publicly and for which a record exists. The full record is almost never available. These cases represent situations in which the causality or the value of the injury were highly contested and ultimately settled by judges and juries in the presence of highly conflicting medical opinion. However, despite the concerns raised, the authors propose that injury claims can be useful to identify rare events where other sources of data are not readily available [109].

Several requirements for an adequate collection and review of claims have been proposed [109]. Relevant questions and variables should be identified prospectively, adequacy and completeness of data sets verified, and claims reviews performed in a timely and standardized fashion by expert reviewers.

Malpractice claims represent one possible source of information about adverse events. The advantage of a malpractice claims review is that the method has the potential to detect rare events and latent errors, such as faulty design, bad maintenance or lack of staffing. However, the results from an analysis of malpractice claims should be treated as a working hypothesis, be subject to further investigation, and used only as part of a *general* quality and safety improvement strategy. In addition, an effort should be made to understand the patient's perspective. [109]

5.2 LEARNING FROM PATIENT SAFETY DATA

A few frameworks for evaluating different sources of patient safety information have been published. These are presented in the following section.

5.2.1 Context and incident rate

Thomas and Petersen have classified and reviewed eight different methods of studying errors and adverse events in healthcare and categorized them into two groups [90]. The first group includes methods that yield information about the complex context surrounding adverse events and give information about underlying latent errors. These methods are malpractice claims analysis, incident report analysis, morbidity and mortality conferences, and autopsies. However, they are not a good measure of the true incidence of errors since they all suffer from time delay and under-reporting. This makes them unfit as measures when evaluating interventions.

The second group of methods provides estimates about the incidence of adverse events and near misses in everyday clinical work. These are prospective follow-up studies of treatments, complication rates, direct clinical observation, and medical record reviews. These methods are more suitable for evaluating improvement interventions; they can be employed in prospective and randomized studies. The drawback with these methods is that they are weak on detecting latent system errors because of the local nature of the observed data.

Thomas and Peterson [90] conclude that estimations of true error rates are impossible and that different datasets all give a partial and skewed picture. To gain a more accurate estimate of the number and nature of adverse events, they propose a multifactor approach where data from different sources are combined.

5.2.2 Input/structure-process-outcome

5.2.2.1 Measures of quality

Another approach to assess quality in healthcare is structured around the input-process-outcome model [114]. The input to a system is both what goes into the system and the structure that receives what comes in. Structure is of particular relevance to organizational learning since it describes, not only the stable characteristics of a system of care delivery like staffing, equipment and facilities, but also how these elements are organized to deliver care through formalized routines. System improvement requires a change in structure which is why structural data is important for organizational learning [115].

Research from quality improvement also suggests that process measures are more sensitive than outcome measures to differences in quality across providers and time.

They are also easier to interpret and act upon, partly because they have clearer accountability. [115-117]

5.2.2.2 *Measures of safety*

The performance of a system is dependent on how resources are transformed through actions or processes to produce an output. Inputs to a system interact and influence the quality of the processes and thereby also the transformation of inputs to outputs. In the model, structure (how care is organized) and process (how care is given) influence patient outcomes (the results achieved).

Donabedian's model for measuring quality in healthcare [114] has also been proposed as a framework for measuring safety [65]. A system has a number of preconditions or inputs. For example, there are a number of distinguishable elements, people, leadership, technology, departments and organizational levels in the county, as well as in and out patient care facilities. The healthcare processes consist of integrated subsystems of independent clinicians who cooperatively interact to fulfill the objectives of providing healthcare to patients. Most current measures of safety performance focus on process or outcome elements, but some have been developed that involve the structural elements of care. Another study [83] based on Donabedian's model designed measurements that addressed two categories: outcome and process measures and structural and context measurements. The first category addressed questions of a) how often do we harm patients? and b) how often do we use evidence based medicine? The second category captured indicators that are essential to patient safety but not measurable as valid rates. This category assessed structural and context measures, addressing the questions a) how do we know we learned from mistakes? and b) how well have we created a culture of safety (measured with a safety climate questionnaire)? Structural, input measures include institutional variables such as how involved leaders are in patient safety efforts, the existence of safety management systems for learning from error, credentialing mechanisms to ensure staff competence, and team variables (e.g. do staff lower in the hierarchy feel comfortable voicing concerns to team members higher up in the organization?).

It has been argued that outcome measures have more face validity than process measures and are therefore more meaningful for public discussions of patient safety [103, 117, 118]. However, a weakness to using outcome measures is that they draw attention to safety problems only after things have already gone wrong [108].

5.2.2.3 *Reactive and proactive indicators*

Safety information can be classified as being reactive or proactive [22]. *Reactive indicators* can only be applied after the event; *proactive indicators* can be used before an event to assess the safety performance of the system as a whole.

Reactive measures collect information on accidents or incidents that have already occurred. They give an insight into system vulnerabilities as well as a partial or complete picture of which defenses did not hold. Analyses can be made of several incidents to reveal recurrent patterns of cause and effect.

Proactive measures can identify latent errors such as local and organizational conditions that need correction to strengthen the resilience of the organization. They can also provide information on the current weaknesses of safety barriers and where bar-

riers might fail. Examples of proactive measures are simulations, audits, and risk analyses.

5.3 SUMMARY

Systematic efforts are needed to improve patient safety, requiring information collected from many sources. Presently, information has in many cases to be collected manually, and there is a lack of a coherent framework to guide the information gathering [119]. Most studies so far have investigated the information value of only one source of information on safety incidents. Most of the measures that are used either lack validity or target specific populations. They do not allow for generalizing results to the entire organization [120, 121]. What is needed is a model for structured information about current healthcare processes, a model that can inform about what is actually being done and how and why things go wrong. Ideally, this information and incident management system should be based on a universal patient safety classification. Such a system should preferably be designed by utilizing experience from other high risk industries. Its base could be an information model broadly applicable with respect to use, users and scope. The system should interface with and complement existing systems as well as allow for cross-mapping to other classification schemes [119, 122].

Experiences from other industries emphasize the importance of having a safety information system. A number of sources of information on adverse events in healthcare have been assessed, but only a few comprehensive information management models have been presented. Those that have been developed still need to be evaluated and tested in practice. Current publicly reported measures are insufficient for assessing safety. Most of the measures that are used either lack validity or target specific populations, making the results difficult to generalize to the entire organization. No uniform safety management theory has yet been developed for healthcare. Many safety practices are improvement strategies that are applied to healthcare organizations and they could benefit from a comprehensive framework for handling patient safety information.

6 BACKGROUND, AIM AND STUDY APPROACH

6.1 BACKGROUND

The Swedish patient insurance is non-punitive, confidential, independent from sanctioning authorities, uses expert analysis, provides regular feedback of claims data to the hospitals, and has recently created financial incentives for hospitals to perform systems oriented root-cause analysis based on patient injury claims. The material in the patient insurance claims database has been used in reports and regular reviews in the Swedish Medical Journal and has been proposed as one yet unexplored source of information on adverse events [123].

The Swedish patient insurance was founded in 1975. A single insurance carrier, the Mutual Insurance Company of the County Councils (LÖF), owned by the county governments, is responsible for providing healthcare to their inhabitants. It insures all patients against injury resulting from medical errors. Patients have a right to file a claim if they think that they have been injured as a result of faulty equipment, medical treatment or the care process. The premium is set to mirror the number of inhabitants rather than previous claims experience and costs around SEK 45 per inhabitant per year [124]. It is the patient who is insured, rather than the provider.

Patient injury claims can also be filed for injuries caused by an accident during care, and/or if the patient has contracted an infection during treatment. Patients file a claim by completing a simple form, available from the treatment facility or the Internet. There is no fee for filing and providers are encouraged to assist patients whenever an error might have caused a patient injury. Upon receipt of a claim, the patient insurance obtains and reviews complete medical records, initially by claims adjusters, and later by medical specialists with expertise in the patient's type of treatment and injury. Compensation is granted if the injury is assessed as avoidable and covers additional treatment costs and income loss caused by the injury.

The system is not a "no-fault" system. Compensation is provided only for injuries due to an incorrect diagnosis or injuries that could have been avoided by another intervention or if the intervention had been performed in another manner. The standard for comparison is the practice of an experienced specialist. However, the system is "blame-free" and the company maintains no record of individual provider identity.

Part of the value of the Swedish model is that it does not matter by whom an error was made. Compensation is paid if the injury fulfils the criteria according to the law and the medical assessment. Information is not shared outside the company, especially not with regulatory or sanctioning bodies. The patient will not be reimbursed if the treatment did not give desired results or if a known unavoidable complication occurred. If, however, the patient suffers an injury due to a side effect of a drug that has been prescribed correctly, the patient can be entitled to reimbursement from a separate insurance scheme.

A collaboration was established between the Swedish patient insurance (Mutual Insurance Company of the County Councils) and the Medical Management Centre at the Karolinska Institutet in 2002. Its purpose was to combine the patient injury claims data with the national patient registry, enabling analyses of patient claims rates. The

intention was to explore if the information could be used to guide patient safety and quality improvement efforts. One offspring of the collaboration is the comprehensive package of comparative claims reports that is delivered annually to hospital managers and clinical department heads, another is this thesis.

6.2 AIMS AND OBJECTIVES

The aim of this thesis is

- To assess the potential contribution of patient injury claims in supporting organizational learning for patient safety improvement, and
- To present a framework for the management of patient safety information in healthcare.

The specific objectives for the four studies are

- To explore the value, feasibility, and usefulness of the Swedish patient insurance database as a source of information for patient safety information systems (Studies I and II)
- To explore the views on patient safety of those who are the receivers of feedback from safety information systems (Study III)
- To discuss how a biological model known to healthcare professionals can be used to demonstrate mechanisms central to safety (Study IV).

6.3 STUDY APPROACH

I was a member of a team that developed a database that combined the Swedish patient insurance claims register with data from the national patient register, covering the years 1997-2004. The database enables statistical analyses of claims and the calculation of claims rates for in-patient activities in Swedish public hospitals. Claims have been analyzed per hospital, clinical specialty and procedure. In order to test the feasibility of the database we calculated and displayed the annual numbers of claims and claims rates for all 76 Swedish hospitals, the number of claims and claims rates per specialty in all hospitals, the annual claims expenditures by specialty and the top procedures by claims and claims rates during the period of study. We explored the possibility of analytical studies by calculating and comparing claims and claims rates by gender and age groups.

The underlying assumption was that patient generated injury claims, collected nationally in an administrative, non-tort system, physician validated, and rate-adjusted for clinical volumes, are a useful but currently unexploited source of information on patient safety and medical errors.

In parallel with the empirical studies I have done a conceptual analysis of models and theories from safety management and performance measurement. I have used the perspectives of performance measurement, safety theory and systems theory to reflect on the potential use of patient insurance data and other indicators of quality and safety. In the final part of the thesis I present a framework for a patient safety information system, based on the theoretical models, the experience developed in other industries, empirical studies of patient injury claims and managers' perceptions of patient safety.

7 SUBSTUDIES

I have chosen to present here the rationale behind the studies as they relate to my thesis as well as reflections about materials and methods and design that are not mentioned in the articles themselves. The main findings from the studies are summarized in brief. The graphs and detailed findings can be found in the appended papers.

7.1 STUDY I & II

7.1.1 Rationale

Studies I and II were performed on the Swedish Patient Insurance data that we compiled, combined with National Patient Registry data on discharges, and checked for quality. Analyses on possible gender and age patterns of patient injuries as well as number of claims, claims rates and proportions of claims compensated by hospital, specialty and surgical procedure were performed in order to explore the value, feasibility, and usefulness of that source of information for patient safety information systems.

7.1.2 Materials and methods

Through collaboration with the Swedish Patient Insurance, we got access to claims registered between the years 1996-2004. Denominator data for determining the rates of claims filed were obtained from the National Board of Health and Welfare Patient Registry. It contains information on all discharges from Swedish hospitals. A new database was created by linking patient injury claims with discharges by hospital, department, specialty, surgical procedure, patient age, gender, injury type and consequences of injury. Injury type and consequences were identified using a classification from the Mutual Insurance Company of the County Councils, based on the injury criteria defined by the Patient Injury Law.

The opening of new hospitals and mergers of existing hospitals as well as changes in services provided complicated the linking procedure. Record mismatches were dealt with either by including a new hospital in the data for part of the study period or by combining data from merged hospitals and presenting them as one single entity for the whole period. Hospitals that closed completely during the study period and hospitals with fewer than two claims per year were excluded from the analyses.

Due to problems with coding, two specialties were omitted from Study I, anesthesia and oral surgery. A great majority of the claims in those specialties had been registered differently in the discharge database.

The patient injury claims, comprised of all the material from the study period (with the exceptions mentioned above), were classified and analyzed with respect to the numbers of claims and claims rates by county, hospital, hospital department, surgical procedure, patient age, sex and by injury type and consequences.

Seventy-four hospitals were included in Study I and 76 hospitals in Study II. Descriptive statistics, time series analysis and comparisons across sites and procedures were produced using SAS, Inc., and Excel software. This approach yields a log over all the mapping strategies, data clean up, and analyses that improves reproducibility.

7.1.3 Main findings

As shown in Study II, from 1997 to 2004, a total of 23,364 in-patient injury claims were filed from hospitals that had 11,514,798 discharges during the same period. The overall claims rate was 0.20% (range 0.14-0.23%). The proportion of claims compensated was 49.5% (range 47.0-52.6%). In almost half of the cases, the specialists reviewing the claim found that the injury was an avoidable consequence of the treatment or care process. Of all injuries compensated in 1997-2004, 2.2% were deaths, 28.3% major disabilities, and 69.5% minor disabilities. The overall claims rate in the Swedish system was less than one tenth of adverse event rates, reported from other information sources, and similar to that found in large, US academic medical centers. The compensation rate was substantially lower than that of the US malpractice insurance system.

Study I revealed that, although people over sixty years of age consume more health-care than younger age groups, they do not file injury claims as frequently. Middle aged (aged 40-59 years) patients filed injury claims almost twice the national rate, whereas patients younger than 19 years and older than 80 years of age filed significantly below the average rate. Study I also showed a gender difference in both claims and compensation rates. Women have higher claims rates than men, but their claims are judged eligible for compensation more often than those of men.

Study II exhibited examples of reports that can be produced from national injury claims and hospital discharge data. Injury claims rates add more than the information provided by looking at the absolute number of claims filed. There were considerable differences in claims rates across hospitals, specialties and surgical procedures in this material from Sweden.

7.1.4 Discussion and methodological considerations

Studies from other countries show quite consistently that patient injury or malpractice claims rates are only a fraction of the rates of adverse events calculated based on an analysis of patient records. Presently, the knowledge about patients' inclination to file claims is limited. An awareness of these observations and limitations are crucial for the first of the two overall aims of this thesis – to assess the potential contribution of patient injury claims in supporting organizational learning for patient safety improvement. I have therefore chosen to discuss the insights provided by Studies I and II and their methodological strengths and weaknesses in more depth in chapter 8.

7.2 STUDY III

7.2.1 Rationale

Previous research has shown the importance of involving leadership in promoting safety, both in healthcare and other industries. Therefore, we set out to survey Swedish healthcare leaders about their awareness of and knowledge on patient safety, the priority they give to patient safety issues, and their views on the cause of errors and suitable safety management strategies. The hope was that the survey findings would serve as a basis for clarifying what information would be important to leaders promoting patient safety improvement.

7.2.2 Materials and methods

Study III reports findings from a survey of 1,129 Swedish healthcare leaders. The questionnaire was designed by translating a survey questionnaire used in the UK [125] with questions grouped into six areas; general assessment of the health care system, awareness of patient safety performance, current safety management strategies, views on benefits of safety management approaches, transparency regarding reporting of patient safety data and patient involvement in improving safety. The survey was sent out as a mail questionnaire with 623 responding, giving a response rate of 55%. Descriptive statistics of the responses was displayed as frequency distributions across subgroups of respondents. Subgroup means were tested for similarity by a repetitive one-way ANOVA procedure. Homogenous groups of responses were sought by hierarchical cluster analysis.

7.2.3 Main findings

The results show a relatively high awareness of patient safety among healthcare leaders, who also give patient safety high priority. There was a marked polarity between those leaders who thought that the healthcare system worked reasonably well and those who thought that major system changes were needed, as well as between those who were of the opinion that funding was sufficient to maintain and improve patient safety and those who found funding inadequate. There was also a polarization between leaders that related vulnerabilities in patient safety to system failures and those who saw them as human errors. There were also two groups of leaders differing from each other, those who were willing to publish safety information and those who did not think that safety information should be publicly disclosed. A surprising finding was that only 10% of the leaders said that their organizations actively involved patients in improving safety, even though a majority said that patients were knowledgeable enough about their condition to contribute. Over half of the respondents reported that their organizations did not involve patients in patient safety issues at all.

7.2.4 Discussion and methodological considerations

This was the first systematic survey on Swedish healthcare leaders' awareness, priorities and strategies as to patient safety. We found only one survey internationally with the same approach and decided to use the survey instrument of that UK study [125]. When comparing the two surveys, UK leaders had a higher awareness, were more concerned with the level of resources and their impact on patient safety improvement. They also assessed that their organizations prioritized patient safety slightly lower than in Sweden. The UK healthcare leaders were more willing to publicly disclose safety performance information on hospitals and clinical departments.

The weakness of the selected instrument is that it has only shown content validity. In this respect, though, its strength is that the content was assessed by groups of experts in two different countries (Sweden and the UK), and for three of the questions in three countries (Sweden, the UK and the US). Awareness surveys generally have not met the psychometric criteria applied to instruments used when measuring patient safety climate. Without a rigorously assessed instrument there is the risk that different respondents have understood the questions differently and we consequently interpret our findings with caution.

The survey was sent to a sample of Swedish healthcare leaders, based on a mailing list covering all public healthcare organizations. The list was updated by approaching

healthcare institutions to crosscheck for missing managerial positions common to healthcare and identifying their holders. There is a risk that some managers were not reached that way, but the total size of the final list (over 2,000) indicates that their number is small. Among the respondents there was a slight over-representation of district general hospital managers compared to managers of other institutions and a minor under-representation of Western, Southern and Stockholm regions compared to South-Eastern, Central and Northern regions. Although the overall response rate was satisfactory (55%), a generalization of the findings to all the Swedish healthcare managers has to be made with these limitations in mind.

7.3 STUDY IV

7.3.1 Rationale

The overarching theme of this thesis is learning. I have reflected during my medical studies and later during my internship that patient safety has not been included in medical training in Sweden. My review of the safety literature in other industries shows that the mental models we hold impact our understanding about how accidents occur, the causes we identify, and the solutions we design to make organizations safer. The use of other mental models or metaphors can help our understanding of mechanisms that can increase the risks of accidents or make organizations safer and facilitate organizational learning. In this fourth study, we set out to look for a biological model familiar to healthcare professionals that could be used to demonstrate central mechanisms of safety.

7.3.2 Materials and methods

Study IV is a conceptual paper using the analogy of the principles and mechanisms of the DNA damage response as a metaphor for describing central concepts of safety science. Biological systems are remarkable for their high robustness, flexibility, and efficiency. The paper discusses similarities and differences between the systems of DNA repair and organizational approaches to safety management in healthcare.

7.3.3 Main findings

Just as with the preservation of genomic integrity, safety in healthcare organizations depends on successful management of variability. Multiple safety strategies have to work together to create a dynamic equilibrium where the effects of errors are constantly coped with. A conceptual model is introduced for describing different sources of variability in healthcare. Safety management strategies must manage different sources of variability in the inputs, processes and outputs of care.

7.3.4 Discussion and methodological considerations

To understand complex systems it is necessary to use both abstraction and decomposition. Decomposition means that the system is divided into elements small enough to understand those elements. However the function of the whole system cannot be understood by the study of the elements alone. It is also necessary to study their interrelationships [18]. Many theories of organization and management use abstractions based on implicit images or metaphors that lead us to see, understand, and manage organizations in distinctive yet partial ways. Metaphors help us understand one element of experience in terms of another, but in highlighting certain interpretations they

also tends to force other explanations into the background, creating distortions. While helping highlight certain aspects of a phenomenon, they blind us to others [126].

Clearly there are differences between healthcare organizations and cells. As has been stated in chapter 3 of this thesis, the mental models of how and why errors and accidents occur drive our understanding of how safety can be managed in healthcare. Patient safety management and systems thinking is currently not taught in most medical schools. Our hypothesis in study IV was that demonstrating the parallels between the DNA damage response and patient safety could be one way of engaging the preclinical faculty at the medical schools and facilitate the inclusion of patient safety management into the curriculum. Insights about the complex mechanisms that govern organisms possessed by biomedical scientists may inform the design of safer healthcare systems.

8 DISCUSSION

8.1 PATIENT INJURY CLAIMS AS A SAFETY INDICATOR

There is no direct measurement for determining the safety of patient care. There are, however, a number of indirect indicators. The question, therefore, is what can patient injury claims add to our understanding about how patient safety can be improved?

The starting point for our studies was the assumption that patient injury claims provide unique and complimentary information compared to other performance measures available in health care. The fact that the system collects over 9,000 claims per year makes it potentially one of the largest sources of information on adverse events in Sweden. The studies presented show that the Swedish patient injury insurance system, based on patient-generated claims, and physician reviews of the alleged medical error and resulting injury, does have the potential to provide information on medical malpractice and allow comparisons to be made between regions, hospitals, specialties, procedures, and patient groups.

Elg et al [37] state, that from an information point of view, the legitimacy and acceptance of performance measurement is dependent upon the quality of output information. Before it can be used to guide hospital managers, clinical leaders, and policy makers about improvements needs about patient satisfaction, quality and patient safety, several questions regarding the reliability, validity, feasibility and usefulness of the information need to be discussed. These criteria will therefore be used to assess patient insurance claims as a source for information in the following sections.

8.1.1 Reliability

Combining the patient insurance claims data with the national patient register made it possible to calculate claims rates. Records were linked using the unique personal identification number, given to all residents in Sweden.

Denominator data were collected from the patient register, managed by the Swedish National Board of Health and Welfare. The database includes key variables regarding all patient discharges from all Swedish hospitals. Hospital data was extracted from the database for all hospitals with three or more malpractice claims annually during the period of study. Since 1966, the personal identification number has been used as an identifier of each hospital stay. This allows for an evaluation of the completeness of the filing of reported variables as well as their coding. The missing data on the personal identification number for the whole registry in the year 2001 was 0.4 %. Missing data on hospital, gender, and age of the patients have been negligible.

Numerator data was collected from the patient insurance claims database. In 1992, a study of the reliability of the database was conducted [127]. A randomized sample of 10% of the surgical injury claims in the years 1987-1989 was drawn in order to evaluate the reliability of the database. Administrative as well as medical variables were reviewed and the authors concluded that there were relatively few errors.

The patient insurance claims database is evaluated annually, with a focus on filing routines, classification of data, and the accuracy of the reporting of hospitals. This

assessment is an intraorganizational administrative procedure. No scientific evaluations have been performed lately. There are certain quality checks, such as that the computer system requires surgical and diagnostic codes to be entered in a three-letter plus two-digit format. While this is one way to prevent mistakes, it is still possible to enter the letters or digits in an incorrect order. Recently, the Mutual Insurance Company of the County Councils has worked to improve the quality of data registration by hiring a qualified medical secretary to code incoming injury claims.

Several potential risks of inaccuracy were addressed in Studies I and II. During the study period (1997-2004) a total of 23,364 claims were filed from 76 hospitals with a total of 11,514,708 discharges. An observation period of 6 and 8 years respectively was chosen to minimize the effect of annual variation. The analyses of specific surgical procedures were limited to the 500 most common to avoid skewing the data distribution by including infrequently performed procedures. All procedures were included when the data were analyzed by clinical department and by specialty.

Age and gender checks were made where possible and showed negligible error rates. Examples include gender of patients undergoing obstetrical or gynecological procedures, sex-specific urological procedures, and age of pediatric patients, newborns, etc. The accuracy of the data was also assessed by reviewing specific surgical procedures and clinical diagnoses regarding their appropriateness to the departments to which they were assigned. Data trends were reviewed annually and large variations in hospital data were checked, first internally, and if necessary, with external data sources. Hospitals mergers, closures, and internal changes in departmental structure were the most commonly encountered reasons for the observed variations in what was overall a very stable dataset.

Some of the surgical claims did not include the corresponding operation code. This was limited only to claims denied compensation. Claims can be denied for many different reasons; for some of the categories, the operation code had simply not been compulsory to fill in. An estimate (based on a crude model) is that the overall claims rate for surgical procedures in the register is about 10-15% higher than the claims rate reported. During the study period attempts were made to improve injury coding by adding ICD-10 complication diagnosis codes.

Finally, a number of additional verification steps were taken. All data, including both patient injury claims and hospital discharge data for each hospital have been returned to the respective hospitals on an annual basis. Occasional differences in departmental assignments of clinical volume were adjudicated and corrected where appropriate.

8.1.2 Validity

One commonly used definition of adverse events is “undesired events, causing patients harm, not by the underlying disease, but as a consequence of examination, treatment or care”. To detect all these undesired events would require a constantly ongoing prospective observation of all care processes with a registration of all events meeting the above definition. However, such a system does not exist. The realization of such a system would require a number of external patient safety experts as observers, far exceeding available resources. Using healthcare staff, or patients, as observers would introduce a number of potential biases. The approaches presently used, retrospective chart studies, incident reporting, administrative data, patient complaints, and malpractice claims data are all surrogates to the ideal observational procedure be-

cause they present only a partial picture of the true incident rates of adverse events. [90]

Our studies have looked at the use of patient injury claims as a complementary source of information. In this case, the patient is the source for the information about adverse events. The patient injury insurance compensates only avoidable injuries caused by healthcare interventions. Minor injuries or expected complications are excluded.

The patients generate claims. This requires that the patient is both aware of the injury and decides to file a claim. There is a risk both for false negatives because of under-reporting and false positives if the patient reports an injury not eligible for compensation. The claims that do come in to the Swedish patient insurance can therefore include both false positives and true positives.

The claims are assessed in a two-stage process. In the first, a claims adjuster makes a first cull, eliminating only those claims that are not caused by healthcare or too minor to receive compensation. The next step is a review by professional clinicians who use a list of criteria to determine which of the claims concern avoidable injuries. These claims are compensated. After review by specialists, around half of all claims in Sweden were awarded compensation. The professional review eliminates the false positives. A weakness of the process is that there might be systematic differences in the way in which these experts apply the criteria.

Current data do not show why patients choose to file a claim or who assisted them. However, even in the absence of this type of data some assumptions can be made. Professional prestige as well as fear of litigation creates barriers to disclosure and open discussion of medical errors [128]. No-fault systems, by contrast, do not place the responsibility of a medical error on an individual provider and may both reduce barriers to file for compensation and increase the possibility that an error is disclosed. The current data from Study II show that even in a system with a very low threshold for filing and a high compensation rate, the number of patients seeking compensation is still quite low, when compared with the number hospitalized. This echoes the findings from New Zealand [112].

The likelihood with which Swedish patients make claims may depend on how openly information is shared with them, how readily available claim forms are, and how much support the hospital staff give patients in filing their claims. Such differences between hospitals might increase the number of claims filed, but a lower threshold for filing claims would be expected to reduce the proportion of claims judged eligible. The result would be a negative correlation between the overall claims rate and the rate of paid claims. However, no such correlation for hospitals ($R=0.14$, $P = 0.218$) was found, although a trend toward a positive correlation was noted at the departmental level ($R=0.34$, $p = 0.052$) [Study II]. In the light of this finding, it is unlikely that differences in how staff help patients file claims influence differences in claims rates.

There have been several studies on the causes of under-reporting. Heinrich, quoted in [22], showed that, in general, the less severe the resulting injury, the less likely it is reported. Davies et al. [112, 129-131] analyzed hospital records and compensation claims for medical injury for the same year and region in New Zealand. Slightly more than 2% of hospital admissions were associated with an adverse event that would potentially be compensated under their review criteria. Although the claims process was well targeted, few claims were filed and even fewer were actually compensated.

The ratio of successful claims to events potentially eligible for compensation was estimated to approximately 1:30. In a more recent study, 1 in 25 patients who experienced injuries that were both serious and preventable according to New Zealand's "no blame" system filed a complaint [132].

The relatively high claims and compensation rates for surgical compared to non-surgical specialties raises several important questions, especially given the approximately equal proportion of medical and surgical errors in numerous chart review studies. It is not known whether patients are more likely to detect surgical than medical errors, or whether they are more forgiving of errors in medical units. The same discrepancy is also found in other systems. It is possible that surgical errors are simply more obvious than those associated with medical errors, both to the patient and the provider. Gawande et al. suggest a number of other possible explanatory factors, like invasiveness, a culture of "surgical cure" that leads to higher patient expectations, a poorer doctor-patient relationship, and treatment complexity [3].

Our analysis of the data showed a variation in rates of compensation between specialties. Vaughan has discussed how common errors can be seen as a normal occurrence, a concept known as the *normalization of deviance* [133]. It is reasonable to assume that this phenomenon could affect the definition of what is considered to be an avoidable injury. Thus, there could exist differences in how claims are judged based on which complications are seen as normal occurrences and thus rarely compensated.

Lee and Domino list a number of limitations of claims analysis based on the American Society of Anesthesiologists Closed Claims Project [134]. Claims are a subset of adverse events, there is a bias towards more serious injury, a lack of denominator data, a geographical imbalance in reporting, changes in practice patterns, a partial reliance on direct participants, data is transcribed retrospectively, there are no comparison groups, and the appropriateness of care is based on judgment with low reliability.

Compared to these concerns, Swedish patient injury claims have the following advantages: Qualified medical experts using consistent, well-defined criteria with access to full clinical documentation assess injury claims. The injury claims database covers all hospitals with more than three or more malpractice claims annually throughout the entire country, thereby avoiding sampling and geographical biases. By combining the claims database with the national patient register, we had access to denominator data and were able to calculate rates, thus eliminating the effect of variation in caseload.

In that respect it is interesting to make a comparison between Swedish claims and with US malpractice data. Published national data are not available from the US, but the University Health System Consortium's annual claims survey of its member academic medical centers reported a median claims rate (per discharge) of 0.23% \pm 0.016 for a comparable period, 1995-2004. Participation in this internal member survey varied from year to year, but typically included 26-30 institutions with a total of 700,000-1,100,000 annual discharges. The compensation rate of claims and lawsuits was approximately 26% over that period of time, compared with approximately 50% in the Swedish system. The claims rate in Sweden is also similar to what has been reported in previous studies on malpractice. This is less than one-tenth of the error rate found in retrospective chart reviews [3-9]. Indeed, very few adverse events result in a malpractice claim. Considering the intuitively appealing assumption of fewer

hurdles to error reporting in a no-blame system, it is thought provoking to note that our study of the Swedish system claims rates seem to be “equal” to similar data from a litigation system. In addition, both systems underreport as compared to chart reviews.

The difference in nature between no-blame and litigation systems might lead to systematic differences in claims rates when comparing providers, specialties, procedures, and patient groups within each system. Consequently, comparisons across these differing systems must be made with caution.

8.1.3 Feasibility and usefulness

Safety outcome measures such as accidents and, in particular, those accidents that result in fatalities or injuries are commonly used as safety performance indicators in other industries. Injuries are measurable events, rather than abstract concepts and therefore injury rates have face validity as performance indicators. Although safety has as its primary aim the prevention of accidents, it is also concerned with the minimization of any likely adverse consequences. But accidents are a sensitive performance indicator only when there is a reasonable frequency of accidents.

Accidents are multi-causal in nature. From a prevention viewpoint, safety is concerned with eliminating these causal factors or interfering with the relationships between them. As performance indicators, accidents are post hoc measures; they measure the failure of accident prevention activities, but not which of these prevention activities failed. Consequently, measuring safety in terms of patient injuries does not give a complete picture of how the safety management system is functioning in a hospital or clinic.

As criteria for assessing the usefulness of patient injury claims, the desirable characteristics of performance measures proposed by Neely [38, 135] will be used:

- Performance measures should enable or facilitate benchmarking
- Ratio based performance measures are preferable to absolute numbers
- Performance measures should be directly under the control of the evaluated organization
- No financial measures should be adopted
- Performance measures should be simple and easy to use and provide fast feedback
- Performance measures should stimulate improvement rather than just monitor.

8.1.3.1 Benchmarking

The content and full coverage of the patient injury claims database makes it possible to produce descriptive reports of the claims rates in different geographical regions, hospitals, specialties, groups of procedures and single surgical procedures. For example, a comparison of hospitals in Study II shows striking differences in the injury claims rates. There is a six-fold difference between the lowest and highest hospital.

However, to use this data for benchmarking purposes should be done with great caution. Variation in injury claims rates and compensation could result from factors connected to the quality of care, hospital size, and production volume. The variations seen could also be due to the mix of specialties, as claims rates vary considerably across hospital departments (specialties). Claims are filed more frequently by surgical

specialties, which is similar to what was reported in a previously published US study [3]. Furthermore, patient related factors such as age, sex, co-morbidities, BMI, socio-economic status, etc could influence patients' propensity to file a claim.

8.1.3.2 Ratio based performance

In Sweden, it is possible to cross reference information from the injury claims database with the hospital discharge register, and thus present data as rates rather than absolute numbers. In Study II, we show examples of ratio based performance comparisons.

8.1.3.3 Controlled by the evaluated organization

The data is continuously collected by the patient insurance and fed back to the organization on a regular basis thereby providing an easily accessible information source regarding adverse events external to the hospitals' own information systems.

8.1.3.4 Avoid adopting financial measures

This is still an open question. Today, insurance premiums are not related to the risk for injury as estimated by injury claims experience. It is caseload and population, not prior claims experience, which determine the insurance cost for the counties.

8.1.3.5 Simple, timely, and easy to use

Data collection costs are low because the Mutual Insurance Company of the County Councils is already collecting the information for administrative purposes. However, the data has not been presented from a safety management perspective. But during the last several years, the database has been made available to hospitals and researchers. After receiving feedback from these groups, the mutual insurance company of the county has improved the quality of the data analyses and the presentation of the data. This has made the data easier to understand and use.

Regarding the timeliness of the data, feedback of claims is provided monthly, but to be able to make decisions around safety on hospital or department level or to be able to detect early warning signals requires faster sources for information feedback.

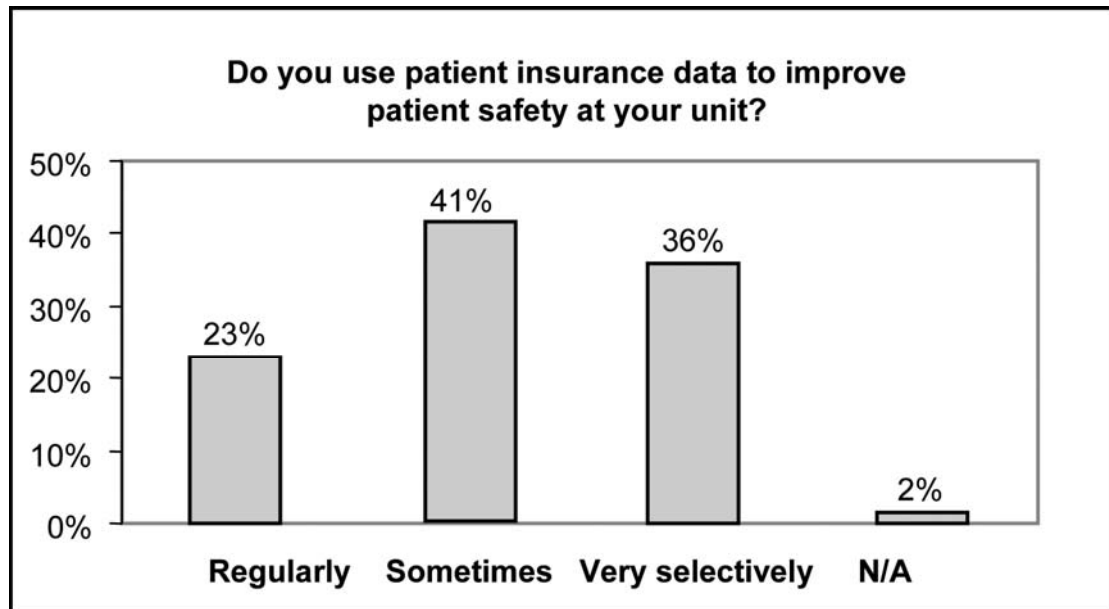
An important function of a safety information system is to feedback data on injury causes or compounding factors to the proper locations in the hospital. The injury claims database contains this information. In addition, the Swedish personal id-number allows for cross-referencing to other databases and to hospital medical charts, making it easier to perform more in depth analyses. The classifications and categories of the database have also been improved to support such in depth analyses that relate causes with diagnoses.

8.1.3.6 Stimulate improvement

The strengths of patient injury claims are that they value consumers and generate resonance among practitioners. Patient injuries are easy to relate to because they represent a breach in the core values of healthcare, "*primum non nocere*," making them a motivator for improvement. The Mutual Insurance Company of the County Councils also encourages hospitals with an economic incentive of 10,000 SEK to perform root cause analyses of injury claims cases.

However, more needs to be done if patient injury claims are to stimulate improvement. The patient insurance database is so far the only national data on injured patients that has been distributed to decision makers in healthcare. In a previous study [136], few departments reported that patient safety was a driver for quality improvement projects. An unpublished survey study from 2003 [137], found that only a 23% of managers regularly use patient injury claims as a source of information in their work with patient safety.

Figure 4: Frequency of use of patient injury claims data



Survey conducted in Dec 2003
N=133, Response rate 38.7%

Study III showed that a majority of leaders thought that at least some patients have enough knowledge about their own condition to play an active role in improving the safety of their care. But when asked about whether their organization actively involved patients in activities to improve safety and reduce risks, only 10% reported that all or most patients were involved. Forty-three percent reported that some patients were involved and 51% reported that their organizations did not actively involve patients. These findings suggest that patient generated information is not an information source that is currently used in Swedish healthcare to inform safety management decisions.

Another way of using safety information data is to evaluate improvement efforts. Changes in claims rate should ideally lend themselves to statistical analysis, time series charts or control charts. However, the sensitivity of injury rates in detecting changes in the level of performance over time has not been explored. There are also a number of methodological weaknesses. Accidents are multi-causal events. They do not always happen, they do not always happen the same way, and they do not always result in injury. If a change occurs in the number of reported injuries this may be due to:

- An actual change in the number of accidents which are occurring
- A random change in the number of accidents which resulted in injury
- A random increase in the severity of the injuries, resulting in an increase in reporting

- A change in incentives for filing a claim for patients.

Consequently, in a “steady-state” organization, with no change in its “safety”, there will be considerable variation in the number of injuries that occur. This variability affects the sensitivity of injuries as performance indicators. It makes detecting “real” changes in performance difficult. In smaller hospitals, or clinical departments, with few patient injury claims, the difference between stochastic variation and changes due to safety improvement efforts becomes even harder to detect. Nevertheless, patient generated, physician reviewed patient injury claims represent the largest single source of data and have shown remarkable overall stability in over a decade of follow-up.

8.1.4 Conclusions

Patient injury claims rates are a consumer generated ratio based indicator, less subject to bias than other sources of patient generated safety data, inexpensive, national, and allow for the aggregation of data across many providers to identify rare complications. Because the data have high granularity it is possible to produce reports of claims both on national, regional, and local levels or to present data on claims from specialties or procedures. The fact that specialists also review the injury claims makes it possible to provide feedback of the consequences of adverse events that is relevant to practitioners and organizations.

The claims provide a broad national source of information which complements other healthcare generated reporting systems or data from closed malpractice claims in tort systems.

Table 3: Strengths and weaknesses of using patient injury claims

Strengths	Weaknesses
Values consumers	Relevance
Practical	Validity
Broad scope	Not comprehensive - underreporting - not risk adjusted
Generates resonance	Timeliness
Systematically reviewed	Normalization of deviance

Regarding the validity of patient injury claims rate as an indicator of safety performance, several considerations must be raised. Patient injury claims, regardless of their source, clearly do not represent a complete picture of the epidemiology of medical errors or causes for patient safety concerns. At a minimum, patient injury claims data reflect patient dissatisfaction with their care and physician reviewer validated reports of medical injury from medical error. The reliability and the validity of the data need to be strengthened before patient injury claims rates can become widely accepted and usable.

Studies that compare the information content of the patient insurance database with other reporting systems such as Lex Maria and HSAN for adverse events in Swedish health care are yet to be directly compared, but the consistently greater volume of claims compared to these other systems shows that patients injury claims are identifying substandard care not found by the other systems. This is to be expected in that the overwhelming majority of patient injury claims are not related to physician im-

pairment nor willful or criminal acts. The methodological limitations discussed above highlight the difficulties in using the data for making comparisons between injury rates or risks across organizations or in using injury claims rates to evaluate interventions aiming at improving patient safety. Accidents are multi-causal events. Injury claims do not provide information about how and why they happened. If a change occurs in the number of reported injuries this may be due to many underlying factors.

8.2 A SAFETY INFORMATION SYSTEM FOR SWEDISH HEALTHCARE

Existing studies have investigated the value of one single source of information on adverse events. The most commonly used approaches are fragmented and the majority of healthcare organizations lack comprehensive sources of information on failures in patient safety. The existing sources of information are not effectively used to provide structured information about what is being done, what is going wrong, and why [119].

In this last part of the thesis I describe a framework for collecting, categorizing, analyzing, and feeding safety information back to decision makers to support learning and safety management (at different levels of the healthcare system).

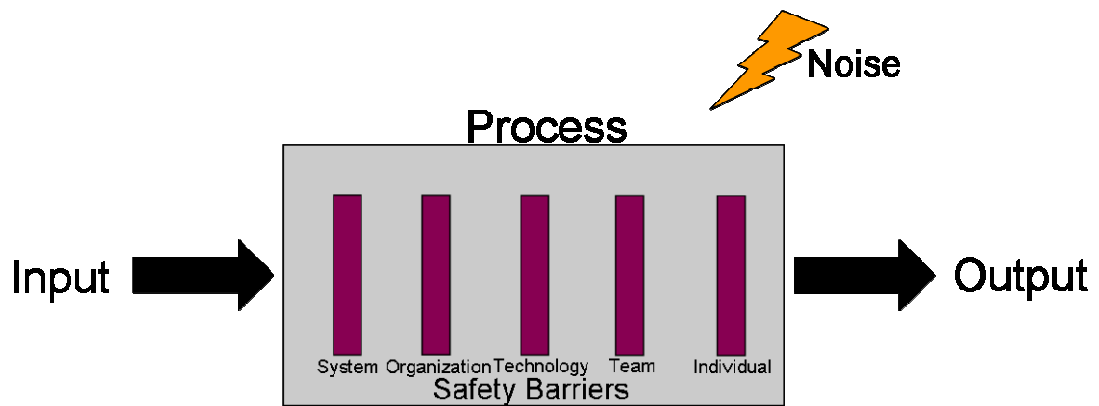
The framework includes the underlying accident meta-model or risk management framework presented in Study IV, an example of sensors that produce safety information, and the potential measures available today in Swedish healthcare. Patient injury claims will be readdressed as one of many potential sources of information on safety performance.

8.2.1 Risk management framework

As in the preservation of genomic integrity, safety in healthcare organizations can be described as a dynamic equilibrium where multiple safety strategies work together to mitigate the effects of errors. All of this is done in an environment filled with extensive distractions, i.e. “noise”. Picture an intensive care unit. Errors can occur due to people, environment, the technologies used, and the organization itself (e.g., policies, culture, and structure). Almost always, they occur as a result of the *interactions* between these components of the system. Noise can be figurative (e.g. variability in the workload, use of complicated error-prone devices, and information overload) or literal (auditory alarms on ICU equipment, phones, beepers, lack of suitable workspace, etc.). All of these factors lead to vulnerabilities in the system.

These vulnerabilities arise at many different levels in the organization [41, 138]. In Study IV, we describe different sources of variability in healthcare. These can be found in Table 4.

Table 4: Sources of vulnerabilities in healthcare as described in study IV



Input Variability	Process Variability	Output Variability	Noise
Patient case mix	Work practice	Negative (injuries & medical errors)	Stress
Nature & number of diseases	Existence of clinical guidelines	Positive (No injury, but near miss/adverse event is hidden in the system)	Distractions
Variations in clinical manifestation	Adherence to clinical guidelines		Cognitive limitations
Variability in training of medical staff	Lack of communication		Individual & organizational defense mechanisms (Deny, distance & dispute)
Design & function of technology	Lack of routines		
	Quality & existence of safety barriers		

(Developed from Gauthereau)

Variability can be found in the input, processes and the outputs of a system. In terms of input and structure, there is internal variability in the training and experience of healthcare staff, the effects of drugs, the design and function of technology and in the way healthcare processes are organized. There is external variability in changes in patient flow. This variability, or stochastic fluctuation, is inherent in healthcare organizations and make them susceptible to errors, especially as volume changes lead to mismatches in staffing and with other resources.

Internal variability can be found in processes in the form of, for example, variations in the existence, quality and adherence to clinical guidelines and the quality, existence, and effectiveness of safety barriers. The processes can also be poorly designed which leads to variability in the work practice of clinicians. Output variability is often the result of variations in input/structure and process.

Safety is created by monitoring and managing different sources of variability in the inputs, processes and outputs of patient care. An organization needs to learn to manage variability because it can cause losses in production and adverse events. This can be done through features that identify and learn from the variability in the inputs and processes, barriers enabling the system to be resilient against residual variability and finally, features that enable the system to learn from the variability of the output.

While healthcare organizations already have a number of processes to manage disruptions or variability, they are not enough, as evidenced by the large number of negative outcomes. It is the dedication of healthcare staff to their patients that leads to many cases of averted adverse events. However, this occurs mostly at the sharp-end around the patient and consists mostly of ad-hoc interventions or workarounds that add to rather than reduce variability. Information from these events is seldom spread to others. The learning that occurs is most often single-loop and concentrated around the patient care process. Patient safety improvement requires changes in organizational routines and work practice. The changes need to cut across a number of divisions, levels of hierarchy and professions.

High reliability organizations have been able to create a culture where learning that occurs in the proximity of the hazardous process is disseminated throughout the entire organization. They also have a culture of mindfulness that permeates the entire organization and guides decision-making while high degrees of standardization simultaneously reduce variability and increase the safety margins for those at the sharp end. Essential to this process is an effective safety information system, which provides decision makers at all levels with relevant information by monitoring, analyzing, and identifying different sources of variability.

8.2.2 A framework for patient safety information

I see healthcare as a complex adaptive socio-technological system in which decision makers at different levels create safety by managing variability in their workspace. Organizational climate and awareness campaigns delineate the marginal boundaries of that workspace. The heedfulness of each individual worker is dependent on situational awareness. As Ashby states, “*the variety of the outcomes of the system can only be decreased by increasing the variety in the controller of that system*” (Ashby 1970 quoted in [22]). This situational awareness and the methods with which a worker or decision maker can vary his/her response are based on feedback about how individual work practice affects a patient’s outcome. It is therefore of great importance that the feedback provided by a safety information system is tailored to the appropriate level.

Effective organizational learning requires data that covers several dimensions such as input-process-output as well as allows for different levels of analysis so that patterns can be detected at the different levels in the system (high and low levels of granularity). This means that healthcare organizations, just like cells, need many sensors for safety information, working in networked arrays to manage safety as well as strategies to improve accuracy, processing, and integration from various sensors.

In the section below, I have integrated the different approaches to evaluating safety in healthcare described in the beginning of the thesis into a framework presented in Table 5.

Table 5: Data sources and potential performance measures in a safety information system for Swedish healthcare

Input/structure		Process		Output	
Sensor	Monitored performance measure	Sensor	Monitored performance measure	Sensor	Monitored performance measure
Patient safety surveys	Awareness & knowledge about safety interventions & risks Learning climate	Quality registers	Adherence to guidelines	Patient injury claims	Patient injury claims rate Rate of paid claims Claims rate per department Costs
Audits	Existence & quality of safety information system	Reports of risks & unsafe conditions	No. & nature of risks identified	Lex Maria & HSAN	No. of cases No. & nature of injuries & adverse events
Training of clinical staff	Medical competence Communication skills Patient safety management	Observations of clinical practice & workplace inspections	% correct behavior Patient safety risks in current work practice	Medical chart reviews	No. & nature of adverse events No. & nature of complications Prolonged stay Costs
Risk analysis/ Healthcare failure mode & effect analysis	Description of failures in organizational structure, technology & process	Incident reporting systems, patient complaints	Frequency of adverse events No. of high potential adverse events No. of adverse events per patient per year	Patient safety indicators	Rates of monitor outcomes or complications
		Simulation	Limitations & safety breaches in current system Communication during stress No. & nature of adverse events Ability of teams to cope with pressure & learn from mistakes	Quality registers	No. & nature of complications

(Adapted from Kjellén [22])

Audits, patient safety surveys, and assessment and training of the competence of clinical staff are all potential sensors monitoring the variability in input and structure. The variability in the processes of care can be monitored by using quality registers, observations of clinical practice, incident reports, simulations, and reports of unsafe conditions from staff working in the frontlines. Monitoring of patient safety indicators and complications in administrative data and in quality registers, medical chart reviews, filed complaints and claims to regulating organizations (Lex Maria and HSAN) give information about variability in the outcomes of care.

Safety analysis of adverse events whether they have been found through medical chart reviews, patient injury claims, Lex Maria and HSAN cases or by local incident reporting systems provide additional information about vulnerabilities in both input, safety management structures (barriers) and in the processes of care. Risk analyses are proactive sensors that give information about potential variability in the structure and processes of care.

Feedback of safety information needs to be tailored to different decision makers in the system [1, 64]. Different actors in the system have different roles in creating safe structures, processes, and outcomes of care and therefore need different safety information.

While the complexity of a healthcare system far exceeds a list of terms in a table, the sensors presented above provide data that yields a high granularity as well as information sources that are of a more holistic nature. Analysis of adverse events can provide rich and detailed information about the structure and processes of care needed for system improvement. Aggregated indicators have a potential for reliability and statistical significance guiding decisions on a higher level in the system.

Senior leadership and governmental organizations are likely to experience accountability for high-visibility aspects of safety that are easily understood by media and the public such as serious adverse events, patient injuries and mortality rates.

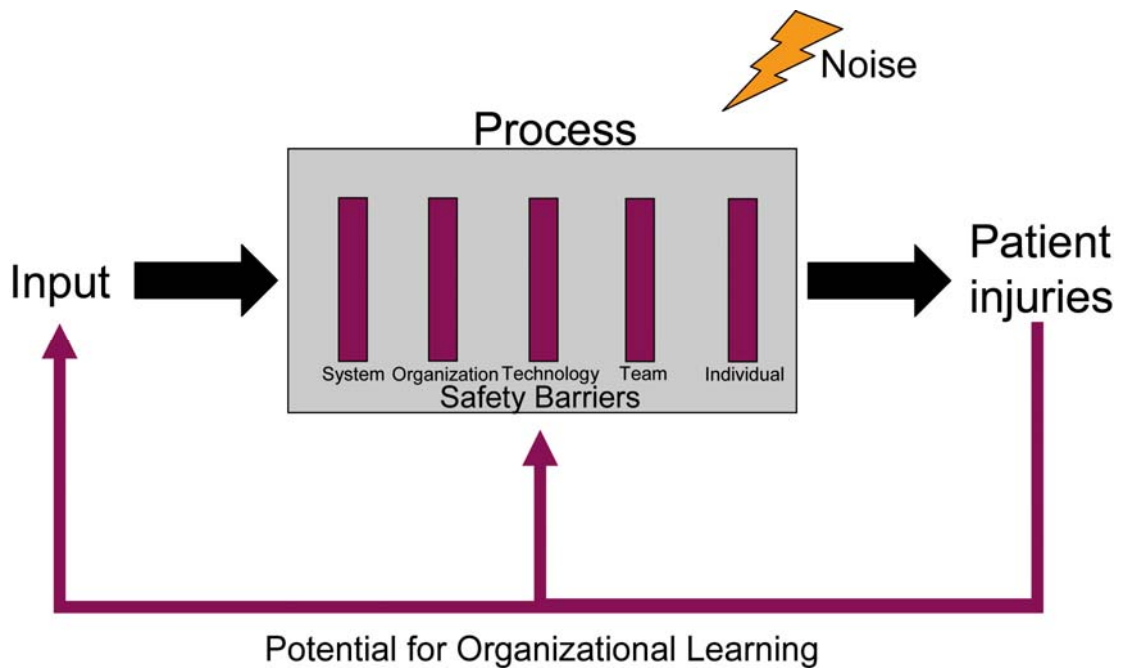
Middle managers have a production line quality aspect on safety in that they look at adherence to guidelines, incident reports, medical complication rates, and patient injury claims rates.

Individual clinicians are interested in safety data that affects their work practice and livelihood such as information from safety analyses, information on look-alike drugs, and risk analyses of new routines.

Measures that are relevant at senior management level may not seem relevant to clinicians and vice versa. Some system level outcome data are meaningful to members of different professions, such as mortality rates or injury rates. These can support communication up and down the hierarchy of decision makers, between units and across specialties.

The studies of the patient insurance database reported in this thesis have explored patient injury claims as one potential sensor for safety information in healthcare.

Figure 5: Learning from patient injury claims



(Adapted from Gauthereau)

As I have described earlier there are still many concerns about using patient injury claims rates as a sensor. Patient injury claims are *outcome* measures and therefore subject to the limitations inherent to outcome measures. Claims rates give no information on causes, nor can they be used as an estimate of true injury and error frequency due to under reporting. While there are limitations regarding timeliness, coverage, and validity when patient injury claims rates alone are used to provide an estimate of the rate of preventable adverse events, the data does contain useful information regarding adverse events that could and should inform decisions on areas of focus and prioritization of analyses and improvement interventions.

Monitoring of injury claims frequencies could identify what are thought to be rare events and can be used as a sensor to identify “black spots” or certain procedures where more comprehensive safety analysis is needed. The results from these analyses could be used to identify general types of failure or point to recurring underlying causes in the organization.

Patient injury claims have a potential role to play in an integrated approach to patient safety information. Although they are at a relatively high level of abstraction compared to sources of information such as medical chart reviews and incident reports, they can be presented as system-wide rates or rates for certain specialties. They can thus serve as an additional source of information to politicians and senior decision makers about system outcomes. Information about variability in claims rates across geographical regions or hospital organizations for the same surgical procedure can help start a discussion and query about what the underlying causes of the differences. These discussions can deepen understandings of the safety levels of current work practice.

As for learning locally at hospitals, feedback of patient injury claims comes often too late to make them useful for following up changes in the organization since they oftentimes reflect outdated practices. However, since it is possible to aggregate data from a multitude of hospitals at a macro level, patient injury claims can help identify latent safety issues that would otherwise remain undetected. This information can then be fed back to individual hospitals to enable local learning and improvements in work practice. In addition, the Swedish personal identification number and the fact that the medical records of each case are collected and kept by the Swedish patient insurance allows for easy access to perform safety analyses when needed. This adds to the value and the richness of the data in supporting learning about how processes of care affect patient safety.

Once identified and reported, lessons can be drawn from vulnerabilities found in the structure and processes of care and combined with advances in science, serve as a starting point for continuous improvement, either in the form of formalized organizational change, or as more informal adaptation through change in work routines, i.e., evolution. One possibility could be that senior leaders review the patient injury claims reports; middle managers perform safety analyses based on the injury claims, and with leadership support, learn and implement solutions to reduce variability and improve safety.

8.3 FURTHER RESEARCH

There is a need for further studies both of the quality improvement of performance measures like patient injury claims as well as case studies of how safety related information is perceived, learned from and acted upon by decision makers at different levels in the health care system. Studies are also needed of how safety information can be integrated into other systems for quality assessment and performance measurement in healthcare.

9 CONCLUSIONS AND POLICY IMPLICATIONS

The aims of this doctoral thesis were twofold:

- To assess the potential contribution of patient injury claims in supporting organizational learning for patient safety improvement, and
- To present a framework for the management of patient safety information in healthcare.

What we found was, in brief, the following:

- Patient injury claims are, by themselves, not sufficient to serve as a lone sensor for vulnerabilities in healthcare. They do, however, provide a broad national source of patient generated information on negative outcomes of care which complements other healthcare generated reporting systems.
- Swedish healthcare leaders have both a relatively high awareness of patient safety and give it high priority. However, few healthcare organizations actively involved patients in improving safety.
- Even though we do not teach much about safety management in healthcare education today, models that are familiar to medical professionals exist that can be used to demonstrate mechanisms central to safety.

The complex phenomena that lie behind safe care and adverse events can only, I believe, be captured through a combination of several sources of data. This is the rationale behind the framework over how such an information system can be organized.

By placing several existing data sources into a context, it is easier to understand the type of information that can be generated. My hope is that it will become easier to reflect on where in an organizational structure learning needs to take place so that the feedback can best be tailored to the appropriate decision maker to more effectively improve safety.

There are several factors that determine the usefulness of a patient safety information system, such as the context of the system and the mental models of the decision makers that dictate how such an information system can be used. Further studies are needed to identify the type of information most suitable for decision makers and how the different sources of information can best support policy decisions. The fact that so few patients are involved in improving safety is a finding that I feel represents an area with a considerable potential for improvement.

10 EPILOGUE

A patient turns to a healthcare provider to find a cure. It is not always that we can oblige, though we always can find ways to comfort and alleviate. However, it is unconscionable that a system designed to help can harm and kill. This disturbing fact has been a driving force behind my desire to learn more about safety and to help improve healthcare.

When I started this project, we had the somewhat ambitious goal of creating a unifying safety management theory for healthcare based upon general safety theory and our knowledge of healthcare systems. As so often happens in science, our ambitious aims were humbled over time.

During my time as a doctoral student, I have explored a, for me, entirely new field of knowledge. My aim with this thesis was to try to capture this journey. I redefined my ambitious aim of generating new knowledge and instead tried to apply existing knowledge from the field of safety science to deal with the issue of safety in healthcare.

While healthcare has indeed a lot to learn from other industries, there is also much that is unique and specific to healthcare. We deal not only with the complexities of socio-technical systems, but also the interaction of that system with the complex system that is a patient. The nature and number of diseases and the unique ways in which they manifest themselves in our patients presents a complex challenge to which a healthcare system must adapt.

It has been a rewarding challenge to be part of a new scientific field. One of the toughest challenges has been to set limits for my studies as I constantly am tempted by new things to study. The Medical Management Centre was founded shortly before I registered as a PhD student. Parallel to my studies, I have had the privilege to witness and partake in its development. I have learned much about the nature of health services research and the unique relationship that a researcher has to the collaborative organizations that they study.

The work on this thesis has given me new knowledge as well as new perspectives on my role as a doctor and as a researcher. I hope that in the near future, healthcare will make it a habit to learn from its errors and above all, do no more harm.

11 SVENSK SAMMANFATTNING

Under de senaste 10 åren har studier visat att antalet patienter som skadas i samband med vård och behandling är omfattande. I USA beräknas mellan 44.000 och 98.000 patienter dö till följd av vårdskador varje år. Studier har dessutom visat att över hälften av dessa skador hade kunnat undvikas med rådande medicinsk kunskap. Vårdskador orsakar lidande och död hos patienter samt kostnader för samhället i form av förlängda vårdtider, kostnader för behandling av komplikationer och infektioner.

Hälso- och sjukvården är en komplex verksamhet. Forskning har visat att det uppstår risker eller sårbarheter spontant i komplexa system – detta fenomen förklaras av ”Normal accident theory”. Modern säkerhetsforskning definierar säkerhet i ett system inte som avsaknad av risker eller misstag utan i termer av systemets förmåga att kunna hantera sårbarheter eller risker så att dessa inte leder till skada för personal, utrustning eller patienter. Vi vet från studier att skador och tillbud är vanliga i sjukvården. Även de fall där en negativ händelse inträffat utan att patienten har kommit till skada rymmer mycket information om risker som finns i systemet.

I sjukvården kan risker uppkomma i olika delar av organisationen. Variabilitet i vårdens inflöde (patient mix, stort antal olika sjukdomar som varierar i symtomatologi, varierande kompetens och erfarenhet hos personal, design och funktion av teknisk utrustning) och processer (lokala arbetssätt, förekomst och följsamhet till rutiner och säkerhetsbarriärer, kommunikation) bidrar till risker. Stress, distraktioner, kognitiva begränsningar i att hantera information kan ses som ett störande brus i arbetet med patienter som kan skapa risker.

Patientsäkerhet har fått ökad uppmärksamhet sedan studierna publicerades vilket fört med sig krav på data samt metoder för att kunna bedöma hur säker vården är. Andra branscher såsom flyget och kärnkraftsindustrin har kommit längre i att utveckla system för att följa upp och förbättra säkerheten. Erfarenheter därifrån pekar på att organisationer behöver informationssystem för att samla in, analysera och återföra information om såväl tillbud, olyckor och risker i verksamheten och lära av dessa för att förbättra säkerheten. Sjukvården använder sedan många år olika indikatorer och mått för verksamhetsuppföljning. Donabedians modell av organisationer med input (struktur, resurser, inflöde), processer (processmått) och output (utfallsmått) ligger till grund för många sätt att mäta och följa upp sjukvårdens kvalitet och resultat.

Olika källor till information om hur säker vården är håller på att utvärderas runt om i världen. Patientsäkerhetsindikatorer, journalstudier och fall från rättsliga tvister i amerikanska domstolar är några exempel på datakällor som har undersökts som möjliga källor till information.

Proaktiva källor till information försöker fånga in risker som finns in systemet innan en olycka skett. Metoder för riskanalyser, rapporter från personal och patienter om upplevda risker, inspektioner av följsamhet till rutiner och vårdprogram, säkerhetsinspektioner och simulering är exempel på metoder att samla in riskinformation i förebyggande syfte. I detta fall samlas information om hur vårdens processer fungerar in som stöd i säkerhetsarbetet. Det finns även proaktiva mått som följer sjukvårdens inflöde samt förekomsten av brus- eller störningar i arbetet. Regelbundna uppföljningar av personalens kompetens, simuleringar för att testa färdigheter samt teknisk utrustning är några exempel. Säkerhetsenkäter kan ge insyn i kunskaper och attityder

hos vårdens medarbetare och chefer. Arbetsplats inspektioner ger inblick i hur arbetsmiljö och stress påverkar det dagliga arbetet kring patienten.

Man kan också dela upp metoder utifrån vilken slags säkerhets information de ger.

Metoder som fångar den komplexa verklighet/kontext som omger tillbud eller felhandlingar

T.ex. morbiditets och mortalitets konferenser, analys av stämningar för felbehandlingar, avvikelserapporter och obduktioner. Dessa metoder kan avslöja vilka latent fel i systemet som kan ligga bakom tillbud och har lett till förbättringar av rutiner och vårdprogram t.ex inom anestesi där analys av malpractice fall lett till att pulsoximetrar nu används som rutin. Metoderna har dock svagheter eftersom de inte kan användas till att uppskatta hur ofta fel eller tillbud händer. Dessa system lider alla av underrapportering, ett flertal faktorer påverkar om ett tillbud leder till en avvikelserapport, obduktion eller om patienten väljer att stämna sjukhuset för felbehandling. Metoder som dessa ska därför användas sparsamt för att utvärdera förbättringsarbete eller interventioner i syfte att förbättra patientsäkerheten och behöver kompletteras med mer precisa mätmetoder.

Metoder som möjliggör uppskattning av sann fel/tillbuds frekvens i löpande kliniskt arbete

T.ex. prospektiv klinisk uppföljning av behandlingar, komplikationer, direkt klinisk observation och journalstudier. Dessa metoder är mer passande för att utvärdera effekten av interventioner eller förbättringsarbete. De möjliggör även randomiserade studier av interventioner så att kriterier för evidensbaserad medicin kan uppfyllas även för interventioner riktade mot att förbättra patient säkerheten. De är däremot sämre för att upptäcka latent fel eftersom de kan ha uppstått vid ett annat tillfälle eller en annan plats än den som observerats.

Många uppföljningssystem i sjukvården idag bygger på att medarbetare i vården anmäler eller dokumenterar tillbud som skett. Det finns dock några system som samlar in rapporter även från patienter. Patientskaderegleringen är ett rikstäckande rapporteringssystem dit patienter som upplevt att de skadats i samband med vård eller behandling kan anmäla och söka ersättning. Information om anmälningarna samlas i Patientskaderegistret, som upprättades 1975.

Genom att kombinera data om skadeanmälningar från slutenvården med socialstyrelsens data över sjukvårdsproduktion kunde vi åskådligt göra anmälningsfrekvenser för landsting, sjukhus, kliniker samt enskilda diagnoser eller ingrepp. Dessa frekvenser kan inte ensamma användas för att uppskatta hur ofta skador uppkommer i vården eftersom det finns en grav underrapportering. I *Studie I* och *II* har vi studerat skillnader i anmälningsfrekvenser mellan kön, åldersgrupper samt tittat på fördelningar av anmälningar mellan olika specialiteter och typer av ingrepp. Databasen innehåller en hel del intressant information men för att kunna förstå varför skadorna uppkommer behövs fördjupade analyser (orsaksanalyser).

Patientskadeanmälningar innehåller viktig information om var i sjukvården skador sker samt vilken typ av skador som uppkommer i olika verksamheter. Vissa verksamheter är överrepresenterade i registret. Registret innehåller mer information om kirurgiska specialiteter än om medicinska trots att journalstudier inte kunnat påvisa att det skulle föreligga en högre risk för att råka ut för tillbud i en kirurgisk verksamhet.

Patientskaderegistret är rikstäckande och genom att titta på data från många sjukhus samtidigt kan även ovanliga skador upptäckas. De förklarar dock inte varför skador har skett. Det finns också en lång eftersläpning mellan det att skadan skett till den anmäls vilket gör att det kan vara svårt att ta till sig och använda informationen.

Som mått på hur säker vården är eller hur ofta tillbud som leder till skada i vården sker räcker dock inte frekvensen patientskadeanmälningar ensamt. Studier har visat att det finns en betydande underrapportering – långt ifrån alla skador upptäcks och även av dem som upptäcks anmäls enbart ett fåtal. Rädsla för rättsliga påföljder liksom en kultur inom sjukvården där ”professionella ej gör fel” bidrar till att tillbud inte anmäls eller diskuteras öppet varför kanske inte alla patienter får information om vart man kan vända sig.

En ökning i antalet anmälningar för en verksamhet kan bero på ökad anmälningsbenägenhet, slumpen eller på att det uppkommit fler skador. Dessa problem gör att data i nuläget inte kan användas för att bedöma hur säkert ett sjukhus är eller för att jämföra olika sjukhus eller verksamheter med varandra. För att kunna avgöra hur vanliga skador som orsakats av vården är behöver sannolikt data från flera olika rapporteringssystem analyseras.

Sjukvårdens förutsättningar att göra rätt och att lära av negativa händelser påverkas av vilken säkerhets och lärande kultur som finns i organisationen. Chefer inom vården spelar en viktig roll, både i att skapa system för lärande kring tillbud och skador, men också vad gäller att stötta ett säkerhetsarbete där rapportering och analys av avvikelser görs för att lära istället för att döma enskilda individer.

I en tidigare studie från 2003 rapporterade endast ett fåtal chefer att patientsäkerhet varit en drivkraft i klinikens förbättringsarbete. Under de senaste åren har dock många insatser gjorts i Sverige för att lyfta patientsäkerhet till en strategisk fråga. Därför gjordes en studie av svenska sjukvårdschefer kunskaper och attityder kring säkerhetsarbete. *Studie III* visar att chefer inom svensk sjukvård prioriterar säkerhet som en viktig fråga men att de jämfört med deras brittiska motsvarigheter ej i samma utsträckning välkomnar öppna jämförelser av avvikelser. Få chefer låter patienter bidra till klinikens säkerhetsarbete.

Förutsättningarna för att lära av medicinska tillbud och skador påverkas också av vilka mentala modeller av säkerhet och säkerhetsarbete som vårdens medarbetare har. De flesta chefer liksom andra som jobbar inom vården har gått medicinska utbildningar. Dessa innehåller inte undervisning om system, säkerhet eller hur organisationer kan arbeta med att förbättra säkerheten. Medicinska utbildningar förmedlar dock mentala modeller som skulle kunna stödja förståelsen kring säkerhetsarbete enligt Ashby. I *Studie IV* dras paralleller mellan något som de flesta läkare känner till – hur celler skyddar sig mot DNA skador och systematiskt säkerhetsarbete i vården. Målet med analogin är att visa på hur de kunskaper vi har om celler som system kan hjälpa oss i att förstå hur vården kan bli säkrare för patienterna.

Ashby skrev i sin ”law of requisite variety” att om man vill styra eller kontrollera ett system så bör kontrollsystemets komplexitet spegla systemets. I säkerhetsarbete innebär det, att om sårbarheter kan uppstå på många olika nivåer i en organisation, så behöver säkerhetsarbete ske på många parallella sätt och på olika nivåer i organisationen för att systemet ska kunna hantera och lära sig av de risker som uppstår.

Ett informationssystem i vården som stöttar säkerhetsarbete behöver kunna fånga upp riskinformation i såväl inflöde, processer och utfall. Retroaktiva källor till information om risker utgår ifrån redan inträffade händelser där patienter skadats eller nästan kommit till skada. Sådana utfallsdata kan hittas i sjukhusens administrativa system, patientjournaler, rättsfall, patientskadeanmälningar, HSAN anmälningar och i olika avvikelserapporteringsystem inklusive Lex Maria.

Sjukvårdens system för patientsäkerhet skulle kunna inkludera en kombination av olika informationskällor och olika strategier för att hantera risker. Patientskaderegistret skulle tillsammans med andra data från avvikelserapporteringsystem, uppföljning av patientsäkerhetsindikatorer, HSAN och riskanalyser skapa ett informationssystem som vården skulle kunna lära av för att identifiera risker och brister i systemet och undvika framtida skador.

Pågående avvikelserapportering, obduktioner, morbiditets och mortalitets konferenser och analys av patientskadeanmälningar kan ge uppslag till mer riktade studier av journaler, prospektiva kliniska uppföljnings studier, riskanalyser och observation av patientvård.

Ännu finns inget utvecklat system för att mäta och följa upp säkerhet i vården. Olika nivåer i sjukvården behöver olika data för att kunna förstå och förbättra säkerheten. I avhandlingen presenteras ett ramverk för hur olika källor till information om avvikelser i svensk sjukvård kan bidra till lärande. Mer forskning behövs kring vilka mål som ska ställas upp för säkerhetsarbetet, vilka datakällor som bäst stödjer beslutsfattare och hur data ska analyseras och återföras för att bäst stödja det säkerhetsarbete som pågår i sjukvården.

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13 GLOSSARY OF TERMS

N.B. Since the terms used in the field of patient safety have yet to be defined internationally, I have chosen to include references or defined them according to how they are used in this dissertation.

Accident	An unplanned event that has the potential to cause adverse consequences (Kjellén).
Accident risk	A condition in the workplace or in the management system that increases the risk for accidents. It can be a vulnerability, deviation, contributing factor or root cause (Kjellén).
Active error	Occurs at the point of contact between a human and some aspect of a larger system, e.g., a human-machine interface. Usually readily apparent (e.g., pushing an incorrect button, ignoring a warning light) and almost always involve someone at the frontline (AHRQ Patient safety glossary http://www.psnet.ahrq.gov/glossary.aspx).
Adverse drug event	An injury resulting from medical intervention relating to a drug (USA Veterans Health Administration glossary, at http://www.va.gov/ncps/glossary.html).
Adverse event	There are many definitions of the term. Basically, an adverse event “is an event which definitely should not have happened” (Runciman Med J Australia 2006 184(10 suppl)s41-3). “Undesired events, causing patients harm, not by the underlying disease, but as a consequence of examination, treatment or care”, or “an unintended injury or complication which results in disability, death or prolonged hospital stay and is caused by healthcare management (rather than a patient’s disease)” (Wilson et al (1995). An incident that harmed a patient (Runciman Med J Australia 2006 184(10 suppl)S41-3). Serious adverse events cause death or disability lasting more than three months or prolonging hospital stay more than a week.
Barriers	Organizations can cope with the risk of adverse events by creating defensive barriers. These act to prevent hazards such as latent or active failures from causing harm (Reason).
Blunt end	The “blunt end” refers to the many layers of the health care system not in direct contact with patients, but which influence the personnel and equipment at the “sharp end” that do contact patients. The blunt end thus consists of those who set policy, manage health care institutions, design medical devices, and the other people and forces, which, though removed in time and space from direct patient care, nonetheless affect how care is delivered. Thus, an error programming an intravenous pump would represent a problem at the sharp end, while the institution’s decision to use multiple different types of infusion pumps, making programming errors more likely, would represent a problem at the blunt end. (AHRQ Patient safety glossary http://www.psnet.ahrq.gov/glossary.aspx)
Concurrence	Accidents become inevitable in complex, tightly coupled systems regardless of steps taken to increase safety. In fact, these steps sometimes increase the risk for future accidents through unintended collateral effects and general increases in system complexity. The phenomenon is called concurrence. (AHRQ Patient safety glossary http://www.psnet.ahrq.gov/glossary.aspx)
Critical incidents	“Occurrences that are “significant or pivotal, in either a desirable or an undesirable way”. “Significant or pivotal” means that there was significant potential for harm (or actual harm), but also that the event has the potential to reveal important hazards in the organization (AHRQ Patient safety glossary

<http://www.psnet.ahrq.gov/glossary.aspx>).

Deviations	A divergence or departure from the expected or normal behavior, act, or course of events.
Double loop-learning	<i>Double-loop</i> learning occurs when an error is detected and corrected in ways that involve the modification of an organization's underlying norms, policies and objectives (Argyris & Schön).
Error	An act of commission (doing something wrong) or omission (failing to do the right thing) that leads to an undesirable outcome or significant potential for such an outcome. For instance, ordering a medication for a patient with a documented allergy to that medication would be an act of commission. Failing to prescribe a proven medication with major benefits for an eligible patient (e.g., low-dose unfractionated heparin as venous thromboembolism prophylaxis for a patient after hip replacement surgery) would represent an error of omission (AHRQ Patient safety glossary http://www.psnet.ahrq.gov/glossary.aspx).
Failure mode and effects analysis	(FMEA) A qualitative risk management method for reliability analysis, which involves the study of the fault modes that can exist in different sub-systems as well as their effects on the function of that subsystem (International Electrotechnical vocabulary IECV, Online database http://std.iec.ch).
Harm	Physical injury or damage to health, property or environment.
Hazards	Source of potential harm or a situation with a potential for harm.
Heedfulness	"In heedful performance each action is modified by its predecessor" (Ryle).
Hindsight bias	"The tendency to confuse correlation with causality, in other words to assume that acts that preceded an adverse outcome were unsafe acts" (Henriksen and Kaplan). "In the context of safety analysis, hindsight bias refers to the tendency to judge the events leading up to an accident as errors because the bad outcome is known. The more severe the outcome, the more likely that decisions leading up to this outcome will be judged as errors. Judging the antecedent decisions as errors implies that the outcome was preventable. Those reviewing events after the fact see the outcome as more foreseeable and therefore more preventable than they would have appreciated in real time". (AHRQ Patient safety glossary http://www.psnet.ahrq.gov/glossary.aspx)
HSAN	<i>Hälso- och sjukvårdens ansvarsnämnd</i> – The Swedish Medical Responsibility Board
Incident	"Any event or circumstance that could have or did harm anyone or which resulted in a complaint, loss or damage" (Runciman Med J Australia 2006 184(10 suppl) 41-3).
Input	The input to a system is both what goes into the system and the structure that receives what comes in.
Latent conditions (or error)	"James Reason coined the terms "active" and "latent" as applied to errors. Latent errors (or latent conditions) refer to less apparent failures of organization or design that contributed to the occurrence of errors or allowed them to cause harm to patients. For instance, whereas the active failure in a particular adverse event may have been a mistake in programming an intravenous pump, a latent error might be that the institution uses multiple different types of infusion pumps, making programming errors more likely. Thus, latent errors are quite literally "accidents waiting to happen." Latent errors are sometimes referred to as errors at the "blunt end," referring to the many layers of the health care system that affect the person "holding" the scalpel.

Active failures, in contrast, are sometimes referred to as errors at the “sharp end,” or the personnel and parts of the health care system in direct contact with patients.” (AHRQ Patient safety glossary <http://www.psnet.ahrq.gov/glossary.aspx>)

Lex Maria	The statutory requirement in Sweden for healthcare providers to report all severe mishaps, complications or errors to the National Board of Health and Welfare.
LÖF	<i>Landstingens ömsesidiga försäkringsbolag</i> – The Mutual Insurance Company of the County Councils
Lost time injuries	How much work time has been lost due to injuries (Kjellén).
Malpractice claims	Litigation claims filed within a tort-system by patients.
Medication error	A mistake in writing prescriptions, dispensing or administering drugs (one type of “ADE”) (USA Veterans Health Administration glossary, at http://www.va.gov/ncps/glossary.html).
Mental models	“Mental models are psychological representations of real, hypothetical, or imaginary situations. Scottish psychologist Kenneth Craik (1943) first proposed mental models as the basis for anticipating events and explaining events (ie, for reasoning). Though easiest to conceptualize in terms of mental pictures of objects (eg, a DNA double helix or the inside of an internal combustion engine) mental models can also include "scripts" or processes and other properties beyond images. Mental models create differing expectations, which suggest different courses of action. For instance, when you walk into a fast-food restaurant, you are invoking a different mental model than when in a fancy restaurant. Based on this model, you automatically go to place your order at the counter, rather than sitting at a booth and expecting a waiter to take your order.” (AHRQ Patient safety glossary http://www.psnet.ahrq.gov/glossary.aspx)
Mindfulness	“Mindfulness is a technique in which a person becomes intentionally aware of his or her thoughts and actions in the present moment, non-judgmentally” (http://en.wikipedia.org). In HROs mindfulness is used to describe a culture of learning characterized by five attitudes: a preoccupation with failure, reluctance to simplify interpretations, sensitivity to operations, a commitment to resilience, and deference to expertise (Weick and Suthcliffe).
Near miss	An occasion where an error was narrowly avoided. Or “an event where the error was detected and intercepted before harm was done” (Orser et al., 2000).
Normalization of deviance	Long periods without adverse events of reported near misses may lead to more “experimentation” and the workspace will drift closer towards a boundary of unacceptable performance- a phenomenon called normalization of deviance (Vaughan).
Output	The results produced by a system.
Patient injury claim	A claim filed by a patient in a non-tort insurance scheme
Patient safety indicator	Consists of a numerator that is made up of the number of patients suffering from a certain complication and a denominator that is the population at risk.
Proactive indicators	Indicators that can be used to predict vulnerabilities or risks i.e. indicators that can be used before an event to assess the safety performance of the sys-

tem as a whole.

Process	A repetitive flow of activities transforming inputs of the system to outputs.
Reactive indicators	Indicators that can be applied only after an adverse event has occurred.
Reliability	<p>The ability of an item or system to perform a required function under given conditions for a given time interval (International Electrotechnical vocabulary IEV, Online database http://std.iec.ch).</p> <p>Defect rate per opportunity for that defect. (In healthcare often translated to the population of patients at risk for the medical error or adverse drug event, presented as units of 10) (Provonost et al Creating high reliability In healthcare organizations HSR: Health Services research 41:4; Part II (August 2006)).</p>
Resilience	“The ability to recognize, adapt to, and handle unanticipated perturbations that call into question the model of competence of the system and demand a shift of process, strategies and coordination” (Hollnagel). “Successful management of variability” (Gauthereau).
Risk	The probability of an adverse outcome and the severity of the resultant harm to health of individuals in a defined population, associated with the use of healthcare technology applied for a given condition under specific conditions of use.
Risk analysis	A systematic identification and categorization of risk to personnel, the environment material assets (Kjellen). Note – in this thesis the concept of risk is widened to involve risk to patients as well.
Root cause	Most basic cause of an accident or adverse event, i.e. lack of adequate management control resulting in deviations and contributing factors.
Safety	A judgment of the acceptability of risk in a specific situation (Office of technology assessment, SBU Sweden). Safety is concerned with the prevention of accidents. But it is also concerned with the prevention of injury, property damage and anything else that may adversely effect either the organization or its employees (Kjellén). Safety is the ability to maximize the safety buffer zone while still achieving the organizational goals (Rasmussen).
Safety climate	The perceptions and attitudes of an organization towards safety, often measured with psychometric testing (Rollenhagen).
Safety culture	“An assembly of characteristics and attitudes in organizations and individuals. It is the compound of two general components, a framework within an organization and the attitude of staff in responding to, and benefiting from, this framework” (IAEA, 1991).
Safety information system	A type of performance measurement system, safety information systems provide support for decisions and signaling regarding safety issues to decision makers by collecting, analyzing and feeding back safety related information.
Safety intervention, method or strategy	“Any action taken to prevent or minimize harm to a patient. The term is used generically to describe actions taken at the clinical, organizational and national level by different actors. In this review “safety method” rather than “intervention” is more often used to describe methods for collecting, analyzing and acting on safety data, and risk assessment. “Strategy” is more often used to describe a collection of activities or interventions carried out by an organization or a national body” (USA Veterans Health Administration glossary, at http://www.va.gov/ncps/glossary.html).

Safety management	Safety management is a systematic process that organizations deploy to improve safety and reduce the number and severity injuries and adverse events.
Sentinel event	<p>“Sentinel events are a type of adverse event. Sentinel events, are unexpected occurrences involving death or serious physical or psychological injury, or risk thereof. Serious injury specifically includes loss of limb or function. Major permanent loss of function means sensory, motor, physiologic, or intellectual impairment not previously present that requires continued treatment or life-style change. The phrase <i>risk thereof</i> includes any process variation for which a recurrence would carry a significant chance of serious adverse outcomes. Sentinel events signal the need for immediate investigation and response.</p> <p>Some examples of sentinel events include:</p> <ul style="list-style-type: none"> • death resulting from a medication error or other treatment related error • suicide of a patient in a setting where they receive around-the-clock care • surgery on the wrong patient or body part regardless of the magnitude of the operation • and hemolytic transfusion reaction involving the administration of blood or blood products having major blood group incompatibilities” <p>(USA Veterans Health Administration glossary, available at http://www.va.gov/ncps/glossary.html).</p>
Sharp end	“Refers to the personnel or parts of the health care system in direct contact with patients. Personnel operating at the sharp end may literally be holding a scalpel (e.g., an orthopedist who operates on the wrong leg) or figuratively be administering any kind of therapy (eg, a nurse programming an intravenous pump) or performing any aspect of care” (AHRQ Patient safety glossary http://www.psnet.ahrq.gov/glossary.aspx).
Single-loop learning	When the error detected and corrected permits the organization to carry on its present policies or achieve its present objectives, then that error-and-correction process is referred to as <i>single-loop</i> learning (Argyris & Schön).
Situational awareness	“The degree to which one’s perception of a situation matches reality” (AHRQ Patient safety glossary http://www.psnet.ahrq.gov/glossary.aspx).
System	“A network of interdependent components that are working together to accomplish the aim of the system” (Deming WE, 1993).
Tolerance	How the system responds when pressure exceeds adaptive capacity.
Unsafe acts	See active errors.
Variability	The capacity of something of being subject to variations or changes (Gauthereau 2001).
Work practice	The repeated performance of a professional activity (Gauthereau 2001).
Workarounds	“From the perspective of frontline personnel trying to accomplish their work, the design of equipment or the policies governing works tasks can seem counterproductive. When frontline personnel adopt consistent patterns of work or ways of bypassing safety features of medical equipment, these patterns and actions are referred to as “workarounds.” Although workarounds “fix the problem,” the system remains unaltered and thus continues to present potential safety hazards for future patients” (AHRQ Patient safety glossary http://www.psnet.ahrq.gov/glossary.aspx).

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