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# **Measures of Patient Safety**

## **- Studies of Swedish Reporting Systems and Evaluation of an Intervention Aimed at Improved Patient Safety Culture**

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“Medicine used to be simple, ineffective and relatively safe.

Now it is complex, effective and potentially dangerous”

(Professor Sir Chyrl Chantler)

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# ABSTRACT

Unsafe health care delivery results in millions of patients suffering from injuries or death worldwide. A Swedish study estimated the prevalence of preventable adverse events as high as 8.6% in hospital care, which demonstrates that patient safety is no less a problem in Sweden than elsewhere. Reporting of adverse events has become an integral part of patient safety work. The aim of reporting is to identify patient safety problems and provide background data and information for efforts to improve patient safety. However, adverse events in health care can be captured and measured using different methods and stored in disparate systems that are not fully integrated. This makes it difficult to obtain a complete coherent picture of the frequency and nature of various types of adverse events. Another difficulty is to distinguish between adverse events and accepted complications of medical care.

The overall aim of this thesis is to generate knowledge for improved understanding of how patient safety can be measured in terms of reporting adverse events and improved by targeting patient safety culture with an intervention implemented in a Swedish county council. Three research questions have been derived from the aim: (1) To what extent can analysis of patient claims contribute to an understanding of the magnitude of the patient safety problem? (2) To what extent do data captured from different reporting systems in Sweden differ? (3) To what extent can a structured intervention that fosters learning on patient safety issues and encourages leadership commitment improve the patient safety culture in a Swedish county council from a five-year perspective?

The research is based on studies of three national reporting systems: Lex Maria to the National Board of Health and Welfare; patient claims to the County Councils' Mutual Insurance Company; and medical data reported to the National Swedish Spine Register (Swespine). Data have also been assembled as part of an evaluation within the Patient Safety Dialogue intervention.

This thesis indicates that different Swedish reporting systems provide disparate views and have many discrepancies regarding data quality and coverage of adverse events. Patient claims seem to be an important source of information that can complement information from incident reporting systems and quality registries in health care to provide an understanding of the magnitude of the patient safety problem.

The research also shows that a structured intervention that fosters learning on patient safety issues and encourages leadership commitment can improve the culture of patient safety. However, a longer period of time and focused efforts might be required to achieve improvements across all departments within a Swedish county council.

# LIST OF PAPERS

This thesis is based on four papers referred to in the text as paper A, B, C and D. The published papers have been reprinted with the permission of the copyright holders.

- A            Reporting of sentinel events in Swedish hospitals: comparison of severe adverse events reported by patients and providers.  
Öhrn, A., Elfström, J., Liedgren, C., Rutberg, H.  
*Joint Commission Journal on Quality and Patient Safety*, 2011. 37: 495–501
- B            What can we learn from patient claims? - analysing of patient injuries following orthopaedic surgery.  
Öhrn, A., Elfström, J., Tropp, H., Rutberg, H.  
Submitted to *Patient Safety in Surgery* November 2011
- C            Adverse events in spine surgery in Sweden: a comparison of patient claims data and national quality register (Swespine) data.  
Öhrn, A., Rutberg, H., Nilsen, P., Olai, A., Tropp, H.  
*Acta Orthopaedica*, 2011. 82 (6): 727–731
- D            Patient Safety Dialogue: evaluation of an intervention aimed at achieving an improved patient safety culture.  
Öhrn, A., Rutberg, H., Nilsen, P.  
*Journal of Patient Safety*, 2011. 7(4): 185-192

# PREFACE

My interest in patient safety issues began in 2000 when I was recruited as a project leader to handle incident reporting at the County Council of Östergötland, Sweden. It soon became obvious that incident reporting was just one small element of patient safety. The ensuing years were eventful for me, as I was very involved in developing the County Council's work on patient safety. We established a programme consisting of several components that is still in use and is continuously being developed and improved.

Two personal meetings were crucial in providing me with a better insight into the complexities of patient safety. In 2001, Synnöve Ödegård PhD introduced me to the concept of high-risk industries and she explained how health care could be considered such an industry. Synnöve also introduced me to the concept of thinking and acting proactively when she stated, *"If you want to understand the risks involved in health care - ask the employees, they know."* Another important meeting was with Professor Eric Hollnagel in 2002, at that time employed at the Linköping University. He introduced me to the system approach to safety, as opposed to an individual approach. During our first one-hour meeting he explained concepts such as underlying causes, latent failure conditions and why we should be cautious about blaming individuals. He said, *"You know, the off-piste skier and the avalanche? ... that part [the avalanche] of the system has become unstable so that only a minor active failure [the skier going off-piste] is needed to unleash the latent condition. That's what it's like in health care too!"*

These enlightening meetings and my own work at the County Council were useful when I became a PhD student and embarked on patient safety research in 2003. The research has been conducted in parallel with my practical work, a combination that has often been demanding, not only in terms of finding sufficient time for both agendas but also the need to scrutinize the patient safety work I was involved in from an external viewpoint. However, it

has also been very stimulating and rewarding, and I feel that research and practice have both benefitted from it.

Hence, this thesis has emerged from my own practical experiences and research interests in patient safety. It examines various patient safety-related reporting systems and evaluates an intervention aimed to foster an improved patient safety culture in the County Council of Östergötland, Sweden.

# 1. INTRODUCTION

Adverse events in connection with medical care are common. Unsafe health care delivery results in millions of patients suffering from injuries or death worldwide [1–5]. Errors are acts of commission (doing something wrong) or omission (failing to do the right thing) that lead to an undesirable outcome or significant potential for such an outcome [6]. It is only during the last two decades that safety in health care has emerged as a distinct health care discipline supported by an expanding scientific knowledge base. Patient safety is now widely recognized as an integral component and cornerstone of high-quality health care. Patient harm and medical errors are now acknowledged and discussed with great interest by health care professionals as well as politicians and the general public.

Even if Hippocrates stated “first, do no harm” over 2000 years ago, it was not until the late 1980s that medical errors and the problem of patient injury in health care began to be discussed more openly. The Harvard Medical Practice Study was published in 1990 and concluded that almost 4% of all patients admitted to hospital care suffered an adverse event, i.e. an injury or harm resulting from medical care. Most adverse events resulted in minimal or transient disability but 14% caused or were implicated in the patient’s death [7,8]. The study was replicated in Australia in 1995 [5], Denmark in 2001 [3], United Kingdom in 2001 [9], New Zealand in 2002 [2], Canada in 2004 [1], Sweden in 2008 [4], and in Germany in 2009 [10] and the studies showed similar results.

The Institute of Medicine in the United States provided a crucial impetus for the development of patient safety with its publication of *To Err Is Human. Building a Safer Health System* [11] in 1999. This report identified medical errors as one of the five most common causes of death [11].

A Swedish study [4] was also conducted based on the Harvard Medical Practice Study protocol [7,8]. This study estimated the prevalence of preventable adverse events as high as 8.6% in hospital care, with an incidence of 5.0% for the index episode of care. An index episode is defined as that period/hospital stay when the adverse event occurred. Twelve percent of these adverse events were serious, causing death or permanent disability of the patient. When extrapolated to the 1.2 million index admissions during the study period, the results of this study indicated that approximately 10,000 patients per year may suffer permanent disability due to preventable adverse events. In 3,000 cases, preventable adverse events may contribute to a fatal outcome. In accordance with earlier definitions [2-3, 5], an adverse event in the Swedish national study was defined as an unintended injury or complication resulting in disability at discharge, death or prolongation of hospital stay, caused by health care management (including omissions) rather than the patient's disease. Two-fifths of the adverse events were related to organ injury, followed by infections. The most common cause of adverse events was invasive procedures, e.g. endoscopies and other surgical operations. Preventable events were more common among patients over 65 years of age.

In conclusion, the Swedish study demonstrated that patient safety is no less a problem in Sweden than elsewhere. The study results underscored the importance of conducting research for improved understanding of how patient safety can be improved.

## **2. THEORETICAL FRAMEWORK**

This chapter provides an overview of several important concepts concerning patient safety problems and solutions. The first part discusses approaches to understand and explain why errors occur and how errors can be captured and measured. The last section of the chapter deals with patient safety culture issues.

### **2.1. How does an error occur?**

A number of models have been developed with the aim of understanding and explaining why and how errors occur [12-15]. These models, often referred to as “accident models”, help to create a picture of an accident’s course of events, from the start to the result/outcome. The models also provide a better understanding of the underlying causes of accidents.

#### **2.1.1. A typology of errors**

Error is “a preventable event leading to an adverse outcome being either an act of commission (doing something wrong) or omission (failing to do the right thing) that leads to an undesirable outcome or having significant potential for such an outcome” [6].

Errors can be classified as slips or mistakes/lapses. Slips are errors that occur as part of the daily routine, e.g. when we perform a task on autopilot and may be distracted or have a heavy work load. Mistakes/lapses results from incorrect choices, usually due to insufficient knowledge, lack of experience or training, inadequate information or applying the wrong set of rules to a decision [14, 16].

Some errors can result in adverse events. An adverse event is defined as “an incident that results in harm to a patient” [17]. An adverse event can also be preventable or non-preventable (Figure 1). Some preventable adverse events can be characterized as negligent; these events fall below a professional level of care. Errors can also result in near misses [16]. A near miss is “an incident which did not reach the patient” [17].

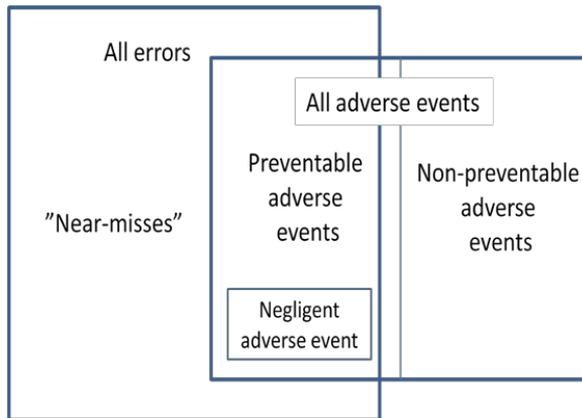


Figure 1: Patient safety terminology. Adapted from Wachter [16].

### 2.1.2. Preventable versus non-preventable adverse events

Patients may experience harm from their medical care in the absence of any errors, for example, from the side effects of medication or complications of surgery. The patient safety literature distinguishes between preventable adverse events and non-preventable events; the latter are referred to as complications. A preventable adverse event is defined as an adverse event that would not have occurred if the patient had received ordinary standards of care appropriate for the time. A non-preventable adverse event is an adverse event resulting from a complication that cannot be prevented given the current state of knowledge [17]. An example of a non-preventable event is when appropriate doses of antibiotics for a bacterial infection are administered and an allergic reaction occurs; this is a well-known adverse effect of antibiotics.

It is often difficult to distinguish between a preventable and a non-preventable adverse event. If the circumstances of the event are not systematically documented, disagreement can arise on whether the event was preventable or not. When a patient experiences a poor outcome, it is often assumed that the outcome was caused by the underlying disease, which is often the case. However, a thorough review of the episode may reveal that medical care was at least partially responsible. Time factors can also contribute to the difficulty in distinguishing between preventable and non-preventable adverse events. Due to the fast developments in medicine an adverse event previously considered non-preventable (complication) is today seen as preventable [16].

Correct assessment to distinguish a preventable adverse event from a non-preventable requires an explicit review process. Brennan and colleagues [18] used such a process in the so-called Harvard Medical Practice Study, which has been adopted by other investigators [1-2, 4-5, 8-10, 19]. The method involves a two-stage sampling process whereby medical records are first screened by nurses using 18 screening criteria. Those records that meet any of the criteria are then reviewed independently by physicians to identify adverse events and cases of negligence (e.g. inattention).

The numbers of adverse events assessed retrospectively as preventable using the Harvard model varies in different studies, from 37% in one study [1] to 51% [5] in another. This variation illustrates the considerable difficulties of assessment. The Swedish study of nearly 2000 medical records [4] estimated that 70% of the adverse events identified were preventable, which is a higher figure than reported in other studies. The Swedish reviewers were mostly employed and thoroughly trained in patient safety perspectives by the National Board of Health and Welfare, in contrast to previous studies in which the reviewers were recruited from hospitals. The authors of the Swedish study offered this as a potential explanation for the differences in numbers of preventable adverse events detected.

### **2.1.3. Individual and system approaches**

Errors can be viewed from two different perspectives: the individual (or personal) approach and the system approach. The individual approach assumes that an individual person is responsible for a medical error that has occurred. Hence, the individual approach is often referred to as “naming, blaming, and shaming”. Health care has traditionally focused on the “sharp end” of the system, i.e. the frontline staff who interact with the hazardous process in their roles as physicians, nurses, pharmacists, and the like. The historical view of error at the sharp end arose primarily from deviant behaviours such as forgetfulness, inattention, poor motivation, carelessness, negligence, and recklessness. The opposite, “the blunt end” of the system, affects safety through the effect of constraints and resources for frontline workers at the sharp end [15, 20].

The system approach posits that humans are fallible and errors are to be *expected*, even in the best organizations. Errors are seen as consequences rather than causes. In a system approach, errors have their origins in upstream systemic factors, not in the malice of human nature. The systemic factors include recurrent error traps in the workplace and various organizational processes. Solutions are based on the assumption that we cannot change human nature but we can modify the conditions under which humans work. When an adverse event occurs, the important issue is not who did something wrong, but *how* and *why* the defences failed [15, 20].

### **2.1.4. The Swiss cheese model**

The Swiss cheese model was developed by Reason [15]. The name of the model is derived from comparing safety systems in different organizations to a stack of slices of Swiss cheese. The model demonstrates that a single sharp-end error is rarely sufficient to cause harm in complex organizations (Figure 2). Instead, such errors must penetrate multiple incomplete layers of defences or barriers to cause a devastating result.

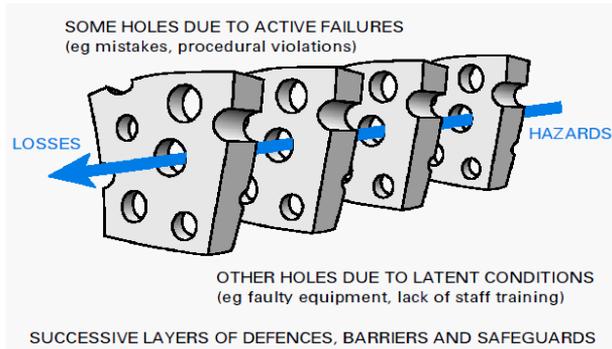


Figure 2: The Swiss cheese model of accident causation  
(adapted from the work of James Reason) [20].

Reason uses the terms active failures and latent conditions to describe different types of errors. Active failures occur in most cases at the sharp end and the error immediately affects the patient. Latent conditions arise from decisions made by designers, builders, legislators, and top-level management. These decisions, if they are erroneous or defective, can later lead to active failures depending on the conditions of the system. Latent conditions may lead to deficiencies due to time pressure, understaffing, inadequate equipment, unworkable procedures, and design and construction deficiencies. Latent conditions can be dormant within the system for a long time before they combine with local triggers such as heavy work load and overcrowded hospitals to create an accident [15]. Active failures and latent conditions are influenced by the underlying safety culture of the organization [21].

Reason described that every step in a process has the potential for failure to varying degrees. Hence, defences, barriers, and safeguards occupy a key position in the system approach and function to protect potential victims from hazards. Examples of barriers are alarms, physical barriers, automatic shutdown, procedures and administrative controls but can also include people such as physicians and nurses. The defences can be considered as slices of a Swiss cheese. They are usually functional but there are always weaknesses (i.e. holes in the cheese). These holes are continually opening, shutting, and shifting location. An accident occurs when the holes in many layers momentarily line up to permit a trajectory of accident opportunity, thus bringing hazards into damaging contact with victims.

### **2.1.5. The ETTO principle**

Individuals and organizations need to be both efficient and thorough. Efficiency is necessary because resources and time are always limited, yet we must be sufficiently thorough to ensure that we do things in the right way. The sustained existence of a system depends on a trade-off between efficiency, i.e. carrying out actions promptly, and thoroughness, i.e. making sure that the situation is correctly understood and that the actions are appropriate for the purpose. This balance is called the ETTO principle, where ETTO stands for Efficiency Thoroughness Trade-Off [22]. The ETTO principle is applicable to individual and organizational performance and at both the sharp end and the blunt end. In all cases, a shortage of time is clearly an important factor.

ETTO can be illustrated by a pair of scales, with one side representing efficiency and the other thoroughness. The scales must be in balance (Figure 3). The ETTO principle provides an explanation why errors occur and characterizes organizations as socio-technical systems, which means that they depend on effective interaction and collaboration between humans, technologies and organizations. People, in contrast to programmed machines, can take shortcuts and sometime even break rules when efficiency is prioritized at the expense of thoroughness.

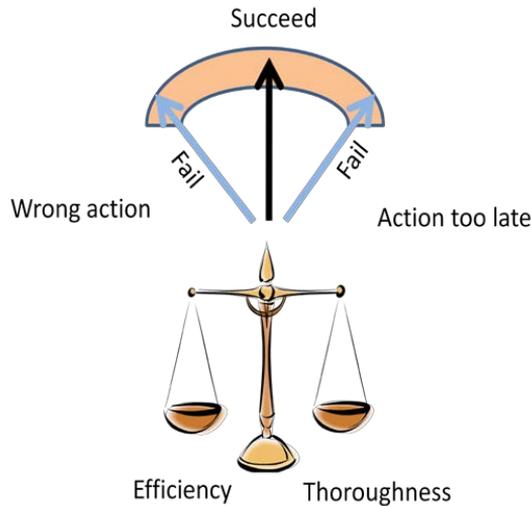


Figure 3: The ETTO principle (adapted from the work of Erik Hollnagel) [22]

### 2.1.6. Linking causes and consequences

Several approaches (methods and techniques) have been developed for use in health care to analyse why and how accidents occur. Analysis techniques widely used both internationally and in Sweden include Root Cause Analysis (RCA) and Healthcare Failure Mode Effect Analysis (HFMEA). RCA is used when serious adverse events have occurred; HFMEA is a method used for risk analysis and is usually initiated when organizational changes may have an effect on patient safety or when many similar serious adverse events have occurred. HFMEA is also used when serious risks are identified in a working process, e.g. administration of medication or diagnostic procedures. Descriptions of the two techniques were translated into Swedish in 2005 and have been published in a nationally distributed handbook [23].

New techniques have been developed in the last decade, including the Cognitive Reliability and Error Analysis Method (CREAM) and Resilience Engineering. These techniques have been developed against the background of development in socio-technical systems in the last 20

years, i.e. more adapted to the complexities of health care organizations of today. CREAM is a technique used to evaluate the probability that a human error might occur in the completion of a specific task [12]. The aim of Resilience Engineering [13, 24] is to understand the normal function of complex socio-technical systems and draw conclusions as to how they fail. Safety in Resilience Engineering is defined as the ability to succeed under varying conditions. A premise is that it is easier and more effective to increase safety by studying things that go right than things that go wrong. Knowledge on how and if these modern techniques will be applicable in health care organizations is still limited.

## **2.2. Capturing and measuring adverse events**

Adverse events in health care can be captured and measured using different methods and systems. However, data about adverse events are stored in disparate, not fully integrated, systems, which make it difficult to obtain a complete coherent picture of the frequency and nature of various types of adverse events. Another difficulty is to distinguish between adverse events and accepted complications of medical care. The following section describes three types of reporting:

- incident reporting in health care;
- reporting of claims for compensation by patients; and
- reporting to quality registries.

### **2.2.1. Incident reporting**

Incident reporting of adverse events, near misses and risks has become an integral part of today's patient safety work. The aim of incident reporting is to identify patient safety problems and provide background data and information for efforts to improve patient safety. In high-risk industries such as aviation, nuclear power, and petrochemical processing, incident reporting has been used as a tool for error prevention for decades [25]. It is only

more recently that this tool has become widely used in health care. In 1995, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) in the United States mandated hospital-based surveillance of adverse events because of the perception that incidents resulting in harm were occurring frequently [26]. In Sweden, the first regulation for mandatory incident reporting by providers was launched in 1996 [27]; it was revised in 2005 [28] and once again in 2011 [29].

A serious event involving death or serious physical or psychological injury, or the risk thereof, should immediately be investigated to find out the underlying factors [30]. In several countries, serious events must be reported to an authority by law. In Sweden, this legislative requirement to report all severe mishaps, complications or adverse events is called *lex Maria*. According to *lex Maria*, all serious adverse events should be reported to the National Board of Health and Welfare, a government agency under the Ministry of Health [31]. During the last decade, investigations in connection with *lex Maria* have become more oriented towards system failures than individual errors.

The number of *lex Maria* reports from hospitals and general practitioners to the National Board of Health and Welfare has increased steadily during 2005–2010, from 1050 to 2124 reports (Table 1). Since 2006, *lex Maria* also covers suicide in relation to care, which could be one reason for the increased numbers of reports. Another reason might be the increased attention being paid to patient safety issues in general in Sweden during the last decade. An increase in the number of reports should not be taken as an indication of deterioration in patient safety but rather as an indication of increased openness and willingness to report, i.e. improved safety culture [32].

**Table 1: Number of lex Maria reports to the National Board of Health and Welfare in Sweden and the County Council of Östergötland, Sweden during 2005–2010**

<i>Year</i>	<i>Number of lex Maria reports in Sweden</i>	<i>Number of lex Maria reports in County Council of Östergötland, Sweden</i>	<i>Number (%) of RCA analyses of lex Maria reports (in County Council of Östergötland, Sweden)</i>
<b>2005</b>	1050	55	36 (65)
<b>2006</b>	1440	80	49 (61)
<b>2007</b>	1509	89	60 (67)
<b>2008</b>	1621	81	57 (70)
<b>2009</b>	1931	110	51 (46)
<b>2010</b>	2124	118	46 (39)

Research has documented that incident reporting is associated with a number of limitations and challenges, making these data unreliable as a measure of patient safety [33]. In general, underreporting is a major weakness of the method [34-38]. This problem applies to both voluntary and mandatory reporting systems. Kingston et al [39] and other studies [40-41] have identified poor and slow feedback as an important reason for underreporting. Other studies have referred to lack of confidence in reporting incidents that have a negative impact [42-43]. It has also been claimed that a poor patient safety culture is associated with underreporting [44-46]. A further difficulty is that definitions of events vary widely and the classification of events is not systematic because of lack of standardization [33].

### **2.2.2. Patient reporting**

Another source of information concerning adverse events is data from patients and their relatives. Patients in Sweden can report to the National Board of Health and Welfare and to the County Councils' Mutual Insurance Company.

A patient complaint to the National Board may initiate supervision in the same way as if a hospital or general practitioner had reported a *lex Maria*. The National Board can recommend and decide actions for the organization under scrutiny, e.g. changes in routines. If necessary, they will follow up the recommended actions by inspections.

A patient claim to the County Councils' Mutual Insurance Company is a request for compensation for an unanticipated medical outcome initiated by a patient (or a family member or attorney). Patient compensation provides financial compensation for pain and suffering, loss of income, disability and/or inconvenience. If the patient died as a consequence of care, the insurance pays adequate compensation for funeral expenses and in some cases also for loss of maintenance [47].

Compensation is paid only for injuries deemed avoidable by medical experts at the insurance company. All Swedish county councils and regions participate in mutual insurance and contribute economically to the insurance. The insurance system in Sweden (and the other Nordic countries) is non-punitive, confidential, and independent from sanctioning authorities. The handling of patient claims differs between countries. In some countries, it is common with legal proceedings. In these countries, the claim enables litigation managers, lawyers and others to determine legal liability. Legal proceedings are rare in the Nordic countries.

Research from other countries has shown a number of limitations in the use of claims data as a measure of patient safety levels and developments. These limitations include lack of denominator data, bias towards more severe injuries, problems in the reliability of judgements and unrepresentative nature of claims. Some other concerns involving claims data are the occasional time delay between the occurrence of the adverse event and subsequent claim filing and the problem with availability to the full medical records [48-52]. Furthermore, claims data are subjected to hindsight bias. Only a small proportion of injured patients are ever compensated, the time to obtain compensation is usually long, and there are considerable administrative costs involved in investigations and decision making [53]. However, despite these limitations, claims data may potentially play an important role in estimating the extent and severity of serious adverse events [54-56]. Claims data collected in a more structured and standardized format than is normally the case could potentially yield important benefits for patient safety [48].

### **2.2.3. Reporting to quality registers**

Several national quality registers have been established in Sweden in the last decades. There are almost 90 registers covering several acute and chronic diseases, including diabetes mellitus, heart disease and stroke as well as areas such as intensive care and maternity care. The registers contain individual data dealing with patient problems, medical interventions, quality of life and outcome after treatment. The data are stored in central databases and are continuously submitted by units and departments. The registries are focused on quality improvement and health care planning. The data can be used at different levels, e.g. departments, specialist societies (in Swedish: Specialistföreningar), through benchmarking of clinical outcomes and stimulating competition in achieving best practice. The data are also used by politicians, the Swedish Association of Local Authorities, regions and the National Board for comparisons within Swedish healthcare (in Swedish: Öppna Jämförelser). The main funding for the registers is provided by the Swedish Association of Local Authorities and Regions [57].

International research indicates some limitations with quality registries as a measure of patient safety levels and developments. A review of 53 studies investigating how 47 medical registries provided feedback to health care professionals by identifying barriers and success factors [58]. One limitation identified was accessibility. Data were captured and stored in databases that were not online. Feedback was given quarterly or yearly by different reports. The registries were not easily used as data sources because of the limited possibilities to deliver timely feedback. Another limitation was the quality of the data, which makes it difficult to use the register for health care planning. Factors mentioned frequently for improvement of a quality register are the (trust in) quality of the data, feedback, motivation of the recipients to report, organizational factors (e.g. the availability of the infrastructure to implement quality improvements) and outcome expectancy of the recipients of the feedback [58]. Many of these problems have been addressed in the Swedish registers in the last decade.

When data reported to the Swedish Hernia Register were compared with adverse events reported by patients, only 22% of the adverse events reported by patients were recorded in the register [59]. Many adverse events that occurred during patients' hospital stay and after discharge were not recorded in the register. One reason might be disagreement between what the patient and the health care provider perceive as an adverse event [60].

## **2.3. Patient safety culture**

The groundbreaking 1999 report *"To Err is Human. Building a safer health system"* by the Institute of Medicine [11] stressed the need to move away from a culture of blame that punishes people for making mistakes towards a positive patient safety culture that acknowledge error and provides the opportunity to learn from occurrences of error. Since this report was published, the concept of a patient safety culture has attracted a great deal

of attention. Influencing patient safety culture is widely regarded as an important way to improve patient safety. This section defines patient safety culture and discusses various issues related to this concept.

### **2.3.1. The concept of patient safety culture**

The concept of safety culture emanates from organizational culture, a concept developed during the 1970s and 1980s [61, 62]. There has been considerable debate about the definition and differentiation of the terms safety culture and safety climate [63]. Despite distinct etymologies, the terms safety culture and safety climate are often used interchangeably [64]. Some authors [61, 63] have argued that the safety climate is related to individuals' attitudes towards safety, whereas safety culture can be seen as the shared beliefs and convictions underpinning individual attitudes. In the organizational literature, the concept of culture generally implies something less tractable and more complex than climate. An important distinction comes from Schein [65] who proposed that climate, as determined by attitudes and comprising values and beliefs, is only a surface manifestation of culture and that culture manifests itself in deeper levels of unconscious assumptions. Denison [66] has argued that the methods used by researchers could aid in distinguishing between studies that measured culture from those that measured climate. Denison stated that culture must be measured by qualitative methods, whereas climate can be measured by quantitative methods because techniques such as questionnaire surveys cannot fully represent the underlying safety culture. Similarly, Mearns et al. [67] proposed that safety climate is a more appropriate term for questionnaire-based surveys, as these are only capable of a superficial evaluation of the workforces' attitudes towards safety at a given point in time, i.e. a snapshot of the prevailing safety culture.

A positive safety culture requires involvement and commitment of leadership, a focus on systems, systematic data collection and reporting, identification of potential hazards and a

blame-free environment [68]. Organizations with a positive safety culture are characterized by a communication based on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measures.

Organizations with a high positive safety culture are also referred to as high-risk organizations (HRO). An HRO is an organization that has succeeded in avoiding severe accidents in an environment where accidents can normally be expected due to risk factors and complexity. HRO is associated with high-risk industries such as nuclear power, aircraft carriers and aircraft controls, and HROs have been rigorously examined by a combination of observations, interviews, questionnaires and archival analysis [69, 70]. Reliability is considered “a dynamic non-event.” It is dynamic because safety is preserved by timely human adjustments; it is a non-event because successful outcomes rarely call attention to themselves [71]. HROs were first described by Perrow [72] in his work on the Three Miles Island nuclear incident in 1979.

HROs perform demanding tasks under considerable time pressure and they carry out demanding activities with low incident rates and almost without catastrophic failures over several years. In HROs, it is recognized that human variability in the shape of compensation and adaptation to changing events represents one of the system's most important safeguards [71]. For these organizations, the pursuit of safety is not so much about preventing isolated failures, either human or technical, as about making the system as robust as possible in the face of its human and operational hazards. HROs are not immune to adverse events, but they have learnt to convert occasional setbacks into enhanced resilience of the system [20].

Despite a growing interest in safety culture in health care, much remains to be revealed concerning how culture data in combination with other sources of information can be utilized to obtain patient safety improvement. Although the importance of establishing a positive patient safety culture to achieve a favourable safety performance is widely

acknowledged, causal culture-performance links have predominantly been demonstrated in industries outside health care [73]. In contrast, health care researchers have only recently begun to investigate the extent to which the patient safety culture affects safety performance. There is some research evidence to suggest that a positive culture is associated with better performance as measured by needle stick risk, infections, treatment errors, readmission rates and patient satisfaction [74-78] but there is also research [79] that does not support such conclusions. Many researchers [77-82] have called for more research into patient safety culture as a determinant of various safety procedures and outcomes, for improved understanding of the nature of patient safety culture.

### **2.3.2. A model of cultural maturity**

Several patient safety researchers have elaborated on the concept of patient safety culture. The concept of cultural maturity was introduced by Westrum [83] in 2004. He described three different levels of organizational culture based on how mature or evolved the culture is: pathologic, bureaucratic and generative levels. A pathologic culture is power-oriented, which means low cooperation with shirked responsibility, hidden information, personal power and failure/mistakes are suppressed and lead to “scapegoating” and new ideas are actively crushed. A bureaucratic culture has modest cooperation and preoccupation with rules, positions, and departmental turf and narrow responsibility. Data and information are collected but tend to be ignored. Failure/mistake in this culture leads to justice and new ideas are seen to create problems. A generative culture represents the most advanced state of cultural maturity and is characterized by a high degree of cooperation. Risks are shared and failures and mistakes lead to inquiry and new thinking.

Parker and Hudson [84] extended Westrum's typology to a five-level model and adapted the model for use in the gas and oil industries [85]. The levels in the five-level model were described as pathologic, reactive, calculative, proactive and generative (Table 2). The

generative level has also been named HRO. Each step is described in terms of concrete (e.g. management systems in place), abstract (e.g. attitudes and behaviours), and organizational aspects. This model enables organizations to determine their current level of maturity, identify areas of strengths and weaknesses, and suggest actions needed in order to reach the next level. The model has been in use with self-reporting instruments such as the Manchester Patient Safety Framework [86-88] and the Patient Safety Culture Improvement tool [89].

Table 2: Levels of organizational safety culture [86]

<i>Level</i>	<i>Description</i>
Pathologic	Who cares about safety as long as we are not caught?
Reactive	Safety is important: we do a lot every time we have an accident
Calculative	We have systems in place to manage all hazards
Proactive	We try to anticipate safety problems before they arise
Generative	HSE (Health, Safety, Environment) is how we do business round here

A number of self-reporting instruments have been developed for measuring patient safety culture [80, 90-92]. The Manchester Patient Safety Framework is a tool aimed at stimulating discussions about patient safety in teams, between staff groups and in organizations [86-87, 93].

### **2.3.3. Influencing patient safety culture through WalkRounds interventions**

Interventions that specifically target patient safety culture have been developed in response to the call for improved patient safety culture in health care. One of the most widely

documented efforts is the Patient Safety Leadership WalkRounds, which was developed by Frankel and colleagues [94]. Frankel has described WalkRounds as a “management tool designed to help organizations decrease adverse events and improve employee attitudes” [95]. Since Frankel introduced WalkRounds in 1999 similar walkround-style interventions have been developed and implemented in Canada and the United States [96-100], and elsewhere, including some Swedish county councils.

WalkRounds encompasses the seven steps described in Table 3 [101].

<i>Steps</i>	<i>Description</i>
Preparation	Ensure commitment and regular participation by leadership, secure dedicated resources from the quality and safety department, and clear communicate processes, scheduling and feedback mechanisms for the rest of the organization
Scheduling	Set time for WalkRounds months in advance and accommodate schedules of executive team members, supporting patient safety staff, and other participants
Conducting walkrounds	Decide where to conduct the sessions; sessions should include opening and closing statement and a series of questions
Tracking	Set up a robust process for tracking and ranking collected data
Reporting	Share WalkRounds data with a multidisciplinary committee so that action items may be assigned to management personnel
Feedback	Establish a clearly delineated and formal structure for feedback to frontline providers who participate in WalkRounds and to executive boards about findings and actions taken to address them
Measurement	Evaluate whether WalkRounds are effective in improving the organization’s culture

A WalkRounds is led by a core group of people, which includes the senior leaders (executives and/or vice presidents) and is conducted in the patient area for approximately one hour. The group, joined by one or two nurses in the patient area and other available staff, asks specific questions about possible adverse events or near misses and about the factors or systems

issues that might have led to these events. The questions are pre-circulated to the department's staff. At the end of the WalkRounds, brief information about the concepts of patient safety, such as the importance of reporting near misses and human factors, is provided. After the WalkRounds, the participants are given a transcript of the discussion including a list of the safety issues raised. They are then asked to select three issues they feel have most impact to provide increased patient safety. The issues selected are then sent to the senior leader who conducted the WalkRounds and she/he is responsible for taking actions to resolve the issues. Events that are captured in the discussion are entered in a database and classified [102].

### 3. AIMS

The overall aim of this thesis is to improve understanding of how patient safety can be measured in terms of reporting adverse events and improved by targeting patient safety culture with an intervention implemented in a Swedish county council.

The research questions for this thesis are:

- To what extent can analysis of patient claims contribute to an understanding of the magnitude of the patient safety problem?
- To what extent do data captured from different incident reporting systems in Sweden differ?
- To what extent can a structured intervention that fosters learning on patient safety issues and encourages leadership commitment, improve the patient safety culture in a Swedish county council from a five-year perspective?

Table 4 lists the specific aims for the four papers in this thesis.

Table 4: The specific objectives for the four papers

<i>Paper</i>	<i>Title of the paper</i>	<i>Aim of the paper</i>
<b>A</b>	Reporting of sentinel events in Swedish hospitals: comparison of severe adverse events reported by patients and providers	To determine the extent and pattern of reporting of serious adverse events in a mandatory national reporting system compared to the reporting of adverse events by patients
<b>B</b>	What can we learn from patient claims? - analysing of patient injuries following orthopaedic surgery.	To describe and analyse the nature of patient injuries following orthopaedic treatment in hospitals using the national database for patient claims in Sweden
<b>C</b>	Adverse events in spine surgery in Sweden: a comparison of patient claims data and national quality register (Swespine) data	To describe and analyse the outcome after spine surgery by comparing claims data from the County Councils' Mutual Insurance Company with data from a national register and medical records
<b>D</b>	Patient Safety Dialogue: Evaluation of an intervention aimed at achieving an improved patient safety culture	To evaluate the effectiveness of an intervention, the Patient Safety Dialogue, implemented at 50 departments in 3 hospitals in a Swedish county council, in terms of results and changes concerning the maturity of the patient safety culture

## **4. MATERIALS AND METHODS**

This chapter describes the materials and methods used in the four papers in this thesis. An overview of the study context in the different papers is presented, followed by a presentation of the data sources and the methodology used in the four papers.

Papers A, B and C analyse and compare different reporting systems concerning adverse events, whereas paper D reports on an intervention aimed to follow up patient safety work, including reporting of adverse events.

### **4.1. Study context**

This section provides a description of the overall study context of the four papers in this thesis. A brief description of Swedish health care is given, followed by data about the County Council of Östergötland, and a description of the patient safety programme established in this county council.

#### **4.1.1. Swedish health care**

The four papers were conducted in the context of Swedish health care. In Sweden, responsibility for providing health care is decentralized to the county councils and municipal governments. County councils are political entities whose representatives are elected by the electorate every four years on the same day as the national general elections. Every county council must provide residents with good quality medical care, and promote good health for the entire population. County councils are also responsible for dental care for local residents up to the age of 20 years. Sweden has 20 county councils (two of which are referred to as

regions) and 290 municipalities. One municipality, the island of Gotland, has the same responsibilities for health care as the county councils [103].

#### **4.1.2. The County Council of Östergötland**

Papers A and D deal with the situation in the County Council of Östergötland, which is the fourth largest county council in Sweden. It has nearly 420,000 inhabitants. There are three hospitals, one of which is a university hospital, and 41 primary health care centres. More than 11,000 people are employed by the county council. Patient safety is a priority issue in the county council and the patient safety unit is integrated with the county council's executive board.

The County Council of Östergötland has had a patient safety unit since 2005, with chief medical officers and facilitators with expertise in patient safety work. The patient safety unit is in charge of research and development, education, and assessments concerning patient safety issues.

#### **4.1.3. The patient safety programme in the County Council of Östergötland**

A comprehensive patient safety programme was initiated in the County Council of Östergötland in 2000. The programme can be described in terms of Donabedian's model [104] of structure, process and outcome, and an additional component, context. Donabedian's model does not specify context as a specific dimension, but it is clear that the outcomes are not only the result of specific processes (activities) and the structure (organization of the work, resources, etc.). The same structure and processes can yield different results in different environments.

The intention of the programme was to improve patient safety by implementing structural components, techniques, methods and tools to build trust and understanding, encourage leadership commitment, and foster learning of patient safety issues. The patient safety programme consists of several components (Figure 4).

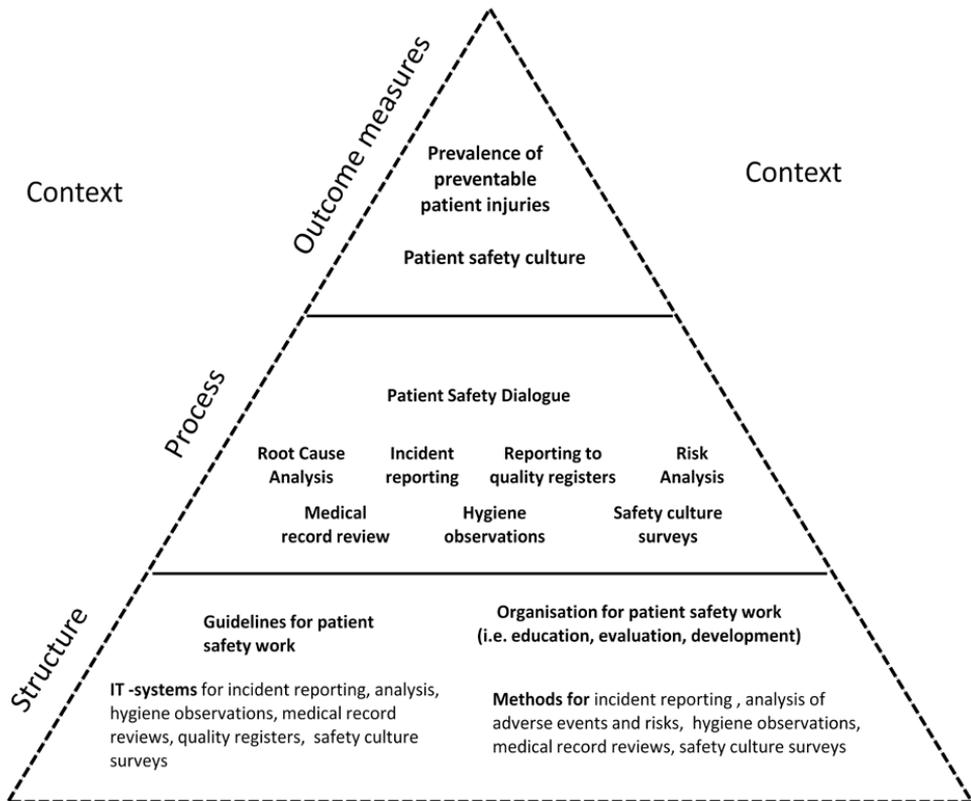


Figure 4: The conceptual model of the patient safety programme implemented in the County Council of Östergötland, Sweden.

The structure dimension in Donabedian’s model consists of the environment, national directives, and various resources such as staff, buildings, equipment and budgets. The county council programme includes several structural components, including guidelines for patient safety work (decided by the board of the county council), a patient safety

organization (the patient safety unit) and the provision of IT systems and methods for undertaking various analyses, including incident reporting, RCA, risk analyses, hygiene observations, reviewing medical records and measuring patient safety culture.

The process dimension in Donabedian's model includes management/organizational and clinical/front-end processes, e.g. human resource policy, training, communication, evidence-based practices. The county council patient safety programme involves a number of activities, including incident reporting, conducting RCA and risk analyses, measuring various patient safety-related outcomes, reviewing medical records, observing adherence to hygiene and dress code, conducting patient safety culture surveys and the Patient Safety Dialogue. The aim of the Patient Safety Dialogue is to follow up the implementation of the patient safety programme by a cycle of five phases. The Patient Safety Dialogue is described in further detail in section 4.2.5.

## **4.2. Data sources**

Five data sources were used in the four papers in this thesis:

- Patient claims reported to the County Councils' Mutual Insurance Company
- Lex Maria reported to the National Board of Health and Welfare
- Medical data reported to the National Swedish Spine Register (Swespine)
- Medical records
- Data assembled as part of the evaluation embedded in the Patient Safety Dialogue

Table 5 presents an overview of the data sources. The five sources are described in more detail in the subsequent subsections.

Table 5: The data sources and how these have been used in the papers included in this thesis

<i>Data source</i>	<i>Type of data</i>	<i>Data reported by</i>	<i>Period for data collection</i>	<i>Level of data</i>	<i>Used in paper</i>
The County Councils' Mutual Insurance Company (LÖF)	Patient claims including hospital discharge data, medical specialty, diagnostic codes, surgical procedure codes, patient age, sex, decision on compensation, injury type, degree of disability/consequences	Patient and/or relatives	1996-2005	Regional National	A B,C
The National Board of Health and Welfare	The register of lex Maria reports	Health care staff	1996-2003	Regional	A
National Swedish Spine Register (Swespine)	Medical data on sex, age, date of admission, surgical procedure and discharge. The surgeon's report on the procedure and any perioperative complications and adverse events identified during the hospital stay. Follow-up assessment 1, 2 and 5 years including validated outcome instruments (global assessment, Oswestry Disability Index, pain (Visual Analog Scale) and SF-36)	Health care staff	2003-2005	National	C
Medical records	Medical data on hospital stay and outpatient visits	Health care staff	1996-2005	Regional National	A C
Data collected as part of the Patient Safety Dialogues	Evaluation form in three areas: hospital-acquired infections, outcome measurements, general patient safety	Health care staff	2005-2010	Regional	D

### **4.2.1. County Councils' Mutual Insurance Company**

Data from the County Councils' Mutual Insurance Company were used in papers A, B and C in this thesis. In 1975, a voluntary collective insurance solution was introduced in Sweden and in 1996 the Patient Injury Act [47] was implemented. The Mutual Insurance Company [105] is a national no-fault insurance system governed by the Swedish Patient Injury Act. Through the insurance, providers voluntarily contribute economically to compensate patients subjected to preventable adverse events in Swedish health care. Patients, or their relatives, who believe they have experienced a medical injury, may file a claim free of charge within three years after the injury became noticeable by the patient or by a health care provider. On receiving a claim, the insurance company investigates the case and, with the help of medical experts, decides whether compensation should be paid or not. The experts apply specific criteria to review the patient's records as well as reports from the medical staff involved for evidence of negligence.

The system has several characteristics associated with successful reporting; it is non-punitive, confidential, and independent from sanctioning authorities, and uses expert analysis and provides feedback to hospitals on claims data. Other Nordic countries have also implemented patient insurance (Finland 1987, Norway 1988 and Denmark 1992). Information in the system is not shared with regulatory agencies or professional sanctioning bodies. Compared with other countries, e.g. the United States, public prosecution is rare in Sweden.

The insurance company database contains information on injury claims and data such as hospital discharge, medical specialty, surgical procedure, patient age, and sex. Injury types and consequences are classified by the insurance company based on injury criteria defined by the Patient Injury Act [47].

Compensation paid by the insurance company covers additional treatment costs and loss of income caused by the injury. The criteria for compensation are based on the assumption that the injury could have been avoided if an experienced specialist had treated the patient.

Compensation is not paid for well-known and common complications. The economic compensation from the insurance company is calculated in accordance with the general principles of Swedish tort law, but awards are generally lower than in the United States due to the comprehensive social security system in Sweden, which includes many other types of insurance (health/sickness, traffic injuries, pharmaceutical benefits, work-related, etc.). The insurance company receives about 9000 claims every year, half of which are accepted for compensation. Injuries associated with orthopaedic treatment resulted in the highest proportion of patient claims sustained (28%), followed by general surgery (20%), obstetrics and gynaecology (11%), anaesthesiology (6%) and internal medicine (5%) [105].

#### **4.2.2. Lex Maria**

Paper A of this thesis used data from lex Maria reports. Lex Maria [31] regulates that Swedish health care providers must report all serious adverse events. It is operated by the National Board of Health and Welfare, a government agency under the Ministry of Health. Lex Maria is named after a Swedish hospital where a catastrophic accident occurred in 1936 leading to the death of four persons. This mandatory system is part of the government licensing and negligence monitoring of health care professionals.

Severe adverse events leading to a patient injury, which is not a consequence of the patient's condition, should be reported according to lex Maria. When a serious adverse event occurs, the head of the department has to report it to the chief medical officer of the health care organization. The chief medical officer then decides whether the event should be reported to the National Board of Health and Welfare. The health care organization investigates the event and performs an event analysis. The National Board of Health and Welfare investigates the case and reviews medical records, statements from the personnel involved, as well as the event analysis. After the investigation, the National Board of Health and Welfare can recommend and decide actions for the organization under review, i.e.

changes in routines. If necessary, they will follow up the recommended actions by inspections.

### **4.2.3. National Swedish Spine Register (Swespine)**

Paper C in this thesis used data from the National Swedish Spine Register (Swespine). This is a national quality register, set up in 1992, to which complications and outcomes of treatment related to spine surgery in Sweden are reported [106].

Swespine contains pre- and perioperative baseline data on complications, as well as several validated outcome measures based on patient answers preoperatively and after 1, 2, and 5 years [107-108]. More than 75% of all departments performing spine surgery in Sweden report to the register [109]. The Swespine database includes basic hospital data on sex, age, date of admission, surgical procedure and discharge. The surgeon's report on the procedure and any perioperative complications and adverse events identified during the hospital stay are also included. Follow-up assessment is using several validated outcome instruments:

- Oswestry Disability Index, which measures the patient's permanent functional disability
- Visual Analog Scale (VAS), which measures a patient's pain
- SF-36, which measures functional health and well-being as well as psychometrically-based physical and mental health

Surgical success is defined by a report from the patient that they are totally pain free or have experienced a major improvement. Questions about complications, reoperations and patient satisfaction are included in the follow-up assessment.

#### **4.2.4. Medical records**

Papers A and C in this thesis used data from medical records. The providers of health care and medical services have a responsibility to keep documentation from hospital stay and outpatient visits according to the legislation [110]. All registered staff, i.e. physicians, nurses, dentists, are held accountable for the documentation in the patient's medical record. The documentation must contain information about the patient's identity, the background for the patient's care and diagnosis and planned actions.

#### **4.2.5. Patient Safety Dialogue**

Paper D in this thesis used data assembled as part of the Patient Safety Dialogue intervention, which is an integral component of the County Council of Östergötland's patient safety programme (described above). The intervention was developed in 2005, inspired by WalkRounds interventions developed by Frankel [94]. The Patient Safety Dialogue is conducted by a team from the patient safety unit and consists of five phases: (1) preparation; (2) meeting; (3) assessment; (4) reporting; and (5) improvement (Figure 5). Meetings are repeated every 18 months, which is called the cycle time. Three rounds of Patient Safety Dialogue have been conducted and are included in paper D. A fourth round is currently in progress.

The Patient Safety Dialogue emphasizes dialogue between representatives from the departments and an administrative patient safety unit integrated with the county council's executive board. The clinical leaders and staff members with special patient safety assignments from the department participate. The chief medical officer and other members of the patient safety unit are the other discussion partners.



Figure 5: The different phases of the Patient Safety Dialogue intervention over a cycle

The preparation phase begins when representatives from the patient safety unit contact the department where the meeting is going to be held to request patient safety-related data. Before the meeting, the department receives a list of structured questions involving three areas of patient safety:

- hospital-acquired infections
- outcome measurements and
- general patient safety

The area of hospital-acquired infections focuses on various aspects of the department’s registration of infections, employees’ compliance with hygiene rules, and implementation of hygiene control actions. Outcome measurement involves the department’s use of national evidence-based guidelines and treatment results measured in local, regional, and national quality registers. The area of general patient safety deals with the department’s incident reporting and the use of different methods for analysing incidents.

A team from the county council’s patient safety unit (chief medical officer, a facilitator, and an infection control nurse) and representatives from the department (the head of the department, the nurse manager, the physician leaders, the hygiene coordinator and the patient safety coordinator) participate in the meeting.

The meeting is held in the form of a discussion based on a structured list of questions covering the three areas (Appendix 1). Immediately after the meeting, the patient safety team who participated in the meeting gather to assess the department's level of safety culture maturity in the three areas.

The assessment is based on a consensus discussion among the patient safety team. Each of the three areas is scored. The assessment instrument, developed by the patient safety unit, is adapted from the Manchester Patient Safety Assessment Framework instrument [86, 93], which describes five stages of safety culture evolution, from pathologic and reactive via calculative to proactive and generative (Table 2).

After the meeting, representatives from the patient safety team compile a feedback report based on all the relevant data from the different sources and the discussion at the meeting. The report includes suggested actions to be taken to improve patient safety culture and the safety area scores along with a brief written commentary. The report is sent to the department head for verification of the accuracy of the content and the report is then submitted to the county council's executive board for information purposes.

The time between two Patient Safety Dialogues is the period of improvement; the department is now expected to undertake the actions that have been proposed by the patient safety team.

### **4.3. Methodology**

This section describes the methodology used in the four papers: medical record review (papers A and C), analysis of registry data (papers A, B and C), and analysis of an assessment that was part of the Patient Safety Dialogue (paper D).

### **4.3.1. Paper A. Reporting of sentinel events in Swedish hospitals: comparison of severe adverse events reported by patients and providers**

In paper A, a study group ( $n=113$ ) consisting of patients with serious consequences from injury, death or disability of more than 16% was selected from the County Councils' Mutual Insurance Company's database. First, it was checked if these cases already had been reported as lex Maria. The 113 medical records were then reviewed by three chief medical officers in two steps, first individually and then in a consensus discussion. The three chief medical officers had long experience as physicians and 3–12 years' experience of examining and reporting lex Maria as chief medical officers.

The aim of the review was to establish if a patient injury that resulted in compensation from the County Councils' Mutual Insurance Company should or should not have been reported as a lex Maria to the National Board of Health and Welfare.

A structured questionnaire was used in the individual medical record review (Appendix 2). The questionnaire was compiled by one of the reviewers and then discussed, tested and agreed by all three reviewers. The questionnaire contained questions with "Yes", "No" or "Unclear" as alternative answers. If "No" was chosen for all questions, the injury was assessed as "should not be reported as a lex Maria according to regulations". If "Yes" was chosen for one or more question, the injury was assessed as "should be reported as a lex Maria according to the regulation". If the reviewer not was able to chose between "Yes" and "No" the review was classified as "Unclear – cannot decide". The three chief medical officers compiled individual assessments for each patient ( $n=113$ ).

As preparation for step 2, the consensus discussion, the assessments were grouped into two categories: agreement and disagreement. Consensus was categorized as agreement between all three reviewers or agreement by two with the third reviewer undetermined. When two reviewers voted for either "should be reported" or "should not be reported" and

the third reviewer had the opposite opinion, the result of the review was classified as “disagreement.”

Cases that were classified as “disagreement” ( $n=25$ ) were further analysed during the consensus discussion. The three reviewers collectively discussed cases they did not agree upon to determine how each of them had finally interpreted and classified the case. After the consensus discussion, agreement was reached in a further 19 cases.

The inter-observer variation among the three reviewers was determined by the kappa statistic.

#### **4.3.2. Paper B. What can we learn from patient claims? - analysing of patient injuries following orthopaedic surgery**

In paper B, data from the County Councils’ Mutual Insurance Company and the National Patient Register at the National Board of Health and Welfare were analysed in order to study and describe the nature of patient injuries following orthopaedic treatment in hospitals.

All patient claims reported to the County Councils’ Mutual Insurance Company after a hospital stay in Sweden for orthopaedic treatment during 1998–2001 were included ( $n=6029$ ). A file was obtained from the National Patient Register of the National Board of Health and Welfare with all discharges after orthopaedic treatment included in the same period ( $n=391\ 579$ ).

Data from patient claims (e.g. age, hospital, department, date of admission and discharge, diagnosis and surgical procedures) were analysed and a descriptive compilation was made. The number of patient claims in every age category and diagnosis of surgical procedure (three-character codes from ICD-10) were compared with the discharge data from the National Patient Register. The patient injury rate of compensation was calculated.

### **4.3.3. Paper C. Adverse events in spine surgery in Sweden: analysis of patient claims data and national quality register data**

The National Swedish Spine Register (Swespine) and patient claims from the County Councils' Mutual Insurance Company were analysed and compared in paper C. The paper also used medical record review. The registers were compared with respect to the number of:

- complications
- degree of disability
- clinical outcome

The study also investigated Swespine's coverage concerning injured patients and complications.

The County Councils' Mutual Insurance Company provided a file listing all patients who claimed compensation after spine surgery during 2003–2005 ( $n=208$ ). Of the 208 patient claims, 26 claims were excluded because the injury was not related to the surgical procedure (e.g. teeth injuries during anaesthesia). Thus, 182 claims were analysed in this study.

From Swespine, a file of all registered surgical procedures in spine surgery during 2003–2005 was obtained ( $n=7819$ ). Both registries have a field with patients' unique personal identification number and this allows for comparison between the two registries to investigate to what extent patients with compensated injuries were registered in Swespine. Thus, the two registries were compiled into a new file.

A medical record review of the 182 patient claims was performed to compare the documented data in the medical record with the registered data in Swespine. A structured protocol was used for the medical record review (Appendix 3). The protocol included items such as diagnosis, surgical procedures, equipment used during the procedures and

complications and their causes during and after the surgical procedures. The protocol was compiled by two orthopaedic surgeons and then tested on a number of medical records.

The results from the medical review were included in the above-mentioned file. Thus, the file contained data pertaining to 182 patients from three sources: the insurance company (patient claims concerning the degree of disability and decision about compensation), Swespine (pre-, peri-, and postoperative data) and from the medical record review (data about admission and surgical procedure, complications during and after the surgical procedure).

#### **4.3.4. Paper D. Patient Safety Dialogue: evaluation of an intervention aimed at achieving an improved patient safety culture**

Paper D evaluated the Patient Safety Dialogue conducted at 50 departments (37 medical and 13 psychiatric) in three hospitals in the County Council of Östergötland, Sweden. The medical departments encompassed surgical specialties (e.g. general surgery, neurosurgery, and orthopaedics) and internal medicine specialties (e.g. paediatrics, cardiology, and haematology). The psychiatric departments included adult, adolescent, and child psychiatry services.

All these departments had participated in the Patient Safety Dialogue in three rounds from 2005 to 2010 and after each round an assessment was made of the department's level of safety culture maturity in 3 areas: hospital-acquired infections; outcome measurements and general patient safety.

After the meeting with the department, the patient safety team gathers in order to assess the department's level of safety culture maturity in the three areas. Each team member makes their own individual assessment for each of the three areas mentioned above. The assessment is based on the results of the discussion and several other sources, e.g. incident

reporting, outcomes from national quality registries. Following the individual assessments, all team members' show their results and the team agree on a score in a consensus discussion.

The assessment instrument, developed by the patient safety unit, was an adaptation of the Manchester Patient Safety Assessment Framework instrument [87-88,94], which describes five stages of safety culture evolution (see section 2.3.2 Model of cultural maturity).

The results from the three rounds were compiled in a file and the average assessment scores were computed for the three areas. Confidence intervals were computed for the discrepancy between the round 1 and the round 3 scores. The departments were classified into three types of trajectories on the basis of the development of their scores over time:

- Continuously improving departments that improved their score in each round, i.e. the score for round 2 was higher than for round 1 and the round 3 score was higher than the round 2 score
- Developing departments increased the score in either round 2 or round 3, but not in both, and scored higher in round 3 than in round 1
- Non-improving departments had the same score in all three rounds or scored lower in round 3 than in round 1 but did not decrease with each round

## **4.4. Ethical considerations**

Approval for ethical considerations was required from the Regional Ethical Review Board in Linköping, Sweden, for papers A, B and C of this thesis, according to Swedish regulations. For paper C, the director of the County Councils' Mutual Insurance Company and the board of Swespine also approved the registry data study. Paper D did not require ethical approval because the Patient Safety Dialogue is considered a component of the wider quality improvement project work in the County Council of Östergötland.

## 5. RESULTS

In this chapter, the results and the conclusions of the four studies in the thesis are presented. The complete results of all studies can be found in the papers appended in the second part of the thesis.

### 5.1. Paper A. Reporting of sentinel events in Swedish hospitals: comparison of severe adverse events reported by patients and providers

The first paper presented data on sentinel events (lex Maria) reported from one region, the County Council of Östergötland, Sweden, to the Swedish National Board of Health and Welfare from 1996 to 2003 ( $n=320$ ) and patient claims ( $n=1578$ ) reported to the County Councils' Mutual Insurance Company during the same period. The objective was to determine the extent and pattern of reporting of serious adverse events in a mandatory national reporting system and compare this with the reporting of adverse events by patients.

A group of patients ( $n=113$ ) who sustained serious consequences from adverse events (death or disability of more than 16%) was selected from the group with patient claims. These claims were analysed and compared with lex Maria reports ( $n=320$ ). Three reviewers (chief medical officers) reviewed the medical records of the study group and assessed whether the claim should have been reported as a lex Maria or not.

Of the 113 patient claims with serious consequences, it was found that 23 (20%) were reported as lex Maria to the National Board of Health and Welfare. Patient injuries that resulted in death or more than 30% disability were reported as lex Maria to a greater extent. The main reasons for injuries in the study group were delayed diagnosis and/or treatment

(28%) and hospital-acquired infections and sepsis (17%). None of the patients with infections were reported as lex Maria. Orthopaedic surgery had the largest number of reported injuries with the most serious consequences. Individual errors were more frequent in cases reported as lex Maria. Two-thirds of adverse events reported were attributed to individual errors compared with one-third of unreported cases.

There was agreement in 26% of the cases ( $n=29$ ) that the injury should have been reported as a lex Maria. There was moderate pair-wise agreement between the three reviewers ( $\kappa=0.42, 0.43, 0.44$ ) concerning their assessments of which cases should have been reported as a lex Maria or not.

One out of five patient claims with serious consequences, assessed as avoidable by medical experts at the insurance company, was reported as a lex Maria to the National Board of Health and Welfare in accordance with regulations. It can be concluded that adverse events causing severe harm were underreported to a great extent.

## **5.2. Paper B. What can we learn from patient claims? - analysing of patient injuries following orthopaedic surgery**

Paper B collected data from two sources: the National Patient Register at the National Board of Health and Welfare and the County Councils' Mutual Insurance Company.

The aim was to describe and analyse the nature of patient injuries following orthopaedic treatment in hospitals using the national database for patient claims in Sweden. During the study period, 1998–2001, 6029 patient claims were filed with the insurance company as a result of orthopaedic surgery. Of these patient claims, 56% were assessed as avoidable adverse events and were compensated accordingly. The injuries most frequently

compensated were hospital-acquired infections and sepsis (22%), followed by delayed diagnosis and/or treatment (17%) (Table 6).

Table 6: Type of injury and the proportion of expense for patient injury in orthopaedics in Sweden during the period 1998–2001

<i>Type of injury</i>	<i>Number of compensated claims (%)</i>	<i>Proportion of expense (%)</i>
Hospital-acquired infections and sepsis	741 (22)	25.5
Delayed diagnosis and/or treatment	577 (17)	23.5
Other injuries	358 (10)	8.5
Fracture/dislocation	291 (9)	5.5
Severance (e.g. nerve)	271 (8)	13.2
Pain	181 (5)	2.7
Compression injury (e.g. cast, table)	178 (5)	2.5
Bleeding	40 (1)	2.1
Thrombosis, embolism	36 (1)	0.3
Unspecified other local injury	688 (20)	16.2
<b>Total</b>	<b>3361</b>	<b>100</b>

In relation to the large number of hospital admissions at orthopaedic departments during the study period, patient injury led to compensation in 0.9% of all admissions. The surgical procedure that caused the highest rate of compensated adverse events was “decompression

of spinal cord and nerve roots". These injuries also resulted in a higher degree of disability. One out of five of these injured patients were seriously disabled (>16%) or died.

Patients undergoing spinal surgery and hip/knee replacement run the highest risk of being severely injured during orthopaedic surgery.

### **5.3. Paper C. Adverse events in spine surgery in Sweden: analysis of patient claims data and national quality register data**

Paper C investigated adverse events in spine surgery in Sweden by comparing patient claims data from the County Councils' Mutual Insurance Company register with data from the National Swedish Spine Register (Swespine).

The aim was to describe and analyse the outcome after spine surgery by comparing claims data from the County Councils' Mutual Insurance Company with data from a national register and medical records. A further aim was to investigate the coverage of injured patients and the data captured on complications in Swespine. The medical records of the patients filing claims ( $n=182$ ) were reviewed and compared with Swespine data. The study period was from 2003 to 2005.

Of the 182 claims, 139 (76%) were approved and the patients received compensation, i.e. the injury was considered avoidable by the medical experts at the insurance company. Less than two-thirds ( $n=119$ ) of the 182 patients who claimed economic compensation from the County Councils' Mutual Insurance Company were registered in Swespine. Of the 210 complications associated with these 182 claims, only 74 were listed in Swespine. Dural lesion was the most frequent complication, with 56 cases found (51 were detected during the

surgical procedure and five were detected postoperatively). Of the 56 cases with an identified dural lesion, 40 patients received compensation from the insurance company for an avoidable adverse event. Of the 56 cases, 38 were reported in Swespine but only 27 had a dural lesion registered as a complication to the spine surgery. Wound infections were also a common reason for compensation ( $n=30$ ) (Table 7).

Table 7: The distribution of complications found in the medical record review of patient claims to the County Councils' Mutual Insurance Company and complications reported to Swespine from 2003 to 2005 (a patient can have more than one complication)

<i>Type of complication</i>	<i>Number of complications found in the review of claims to the County Councils' Mutual Insurance Company</i>	<i>Number of complications registered in the Swespine national quality register</i>
Dural lesion	56	27
Infection	34	1
Implant problem	18	9
Hematoma	16	7
Wrong level	8	0
Nerve tear	31	8
Other	47	22
<b>Total</b>	<b>210</b>	<b>74</b>

Dural lesions and infections are common complications in spine surgery, but they are not well recorded in the national Swespine quality register despite being an important reason for postoperative disability.

## **5.4. Paper D. Patient Safety Dialogue: evaluation of an intervention aimed at achieving an improved patient safety culture**

This paper evaluated the effectiveness of an intervention, the Patient Safety Dialogue, implemented at 50 departments in three hospitals in a Swedish county council, in terms of results and changes concerning the maturity of the patient safety culture.

The average assessment score for the somatic departments increased for every cycle with the exception of the hospital-acquired infection domain in round 3, which was identical to round 2. The psychiatric care departments improved in every round with one exception; the score for the round 2 outcome measurements was lower than the round 1 score for this safety domain. The average scores for the somatic departments were higher than for the psychiatric departments in all rounds.

Fifty percent of the departments in the hospital-acquired infections domain, 68% in outcome measurements, and 78% in general patient safety improved their score with each round, and were thus categorized as “continuously improving” departments or “developing” departments, which meant that they scored higher in round 3 than in round 1, but did not improve between rounds 1 and 2.

The results from three rounds of the Patient Safety Dialogue conducted over five years showed that most of the 50 departments that were evaluated improved their patient safety culture maturity in the areas of hospital-acquired infections, outcome measurements, and general patient safety. The intervention thus appears to be effective in supporting an improved patient safety culture. However, one-third of the departments did not improve during the five-year study period.

## **6. DISCUSSION**

This chapter discusses the main findings and methodological considerations from the four studies in this thesis, followed by a more general discussion. Conclusions are stated and future research work is suggested for further improvements in this area.

### **6.1. Discussion of findings from papers A, B and C**

The first three papers in this thesis focused on incident reporting from two different perspectives: the patient and the health care provider. Papers A and C analysed the extent of overlap between these two different methods of reporting. The general findings showed that there was considerable discrepancy between what is reported by patients and what is reported by health care providers. These findings are supported by other studies [35-37, 111]. Although reporting systems are considered to be of key importance for improving safety in health care, several studies have documented underreporting of serious adverse events [35-38].

Injuries that resulted in serious consequences (death or very serious disability) were reported as patient claims but were reported to a smaller extent by the providers. This occurred despite a regulation that gives clear instructions on how, what and why providers must report serious events [31]. Research has documented that underreporting is common and barriers to functional incident reporting have been described in several studies. These obstacles include the following: fear of reprisal; concerns about litigation; confusion over what constitutes an adverse event; lack of feedback; lack of support from colleagues and only little immediate effect on improving quality of patient care [39, 112-114].

Paper A indicates that only a small number of patient claims with serious consequences were reported as *lex Maria*. The three chief medical officers taking part in this investigation differed in their opinions about which cases should be reported according to *lex Maria*. It is likely that many adverse events leading to injuries are not reported because they are considered complications by physicians. This might be explained by the fact that it is difficult to determine whether an adverse event is caused by health care or should be considered as a complication inherent to treatment [37].

Paper A also suggests that the decision on whether an adverse event should be reported according to *lex Maria* may also depend on the background of the chief medical officer regarding the specific adverse event. The three chief medical officers in paper A had long experience as physicians in different specialities before they became chief medical officers. Becoming a chief medical officer in Sweden does not require any formal education or specific training. The recruitment of chief medical officers in Sweden is primarily based on expressed interest in patient safety issues and experience as a physician. Patient safety training is not obligatory in medical training or in the nursing profession. Several international studies have described comprehensive patient safety programmes where training is an important integral component [102, 115-118].

A formal education and training as a prerequisite to becoming a chief medical officer might increase the probability of a more equal assessment of adverse events. It might also increase the level of understanding and knowledge about patient safety issues and facilitate the journey for health care to become a high-reliability organization. Education designed for future chief medical officers could include a formal component on rules and regulations, legislations, methods and tools within the patient safety field. Training and assessment of adverse events could be another part of the education. The assessment of adverse events should be made by studying real cases both individually and together with colleagues because our result from the consensus discussion indicates that this is a learning opportunity.

Papers A and C showed that few patients with infections causing disability were reported from the providers as *lex Maria* or as complications in the quality register. One explanation for this might be that a postoperative infection sometimes occurs after the patient has been discharged from hospital. The patient might not consider that the infection is associated with the hospital stay and therefore refrain from reporting to the hospital. Other explanations might be underestimation of the seriousness of the consequences of hospital-acquired infections or simply a belief that infections are normal complications of prolonged hospitalization [119]. Our finding that hospital-acquired infections are not reported to the National Board of Health and Welfare despite the fact that the regulation requires that they should be reported suggests that there might be a need for the National Board to demand more compliance with the regulation.

Hospital-acquired infections have received increased attention in recent years. The Swedish Association of Local Authorities and Regions have been a driving force in their efforts to prevent these infections in Sweden. They have launched an action programme and organized point prevalence measurements every year [120].

In paper A, orthopaedic surgery was found to have a high number of reported claims to the County Councils' Mutual Insurance Company. This finding was analysed in more detail in papers B and C. The large number of orthopaedic claims might be explained by high patient expectations for a positive outcome [121].

Paper C compared claims for economic compensation after orthopaedic treatment from the County Councils' Mutual Insurance Company with complications listed in the Swespine quality register. There was considerable underreporting of surgical complications to Swespine. This finding is consistent with the results of a study of another national Swedish quality register, the Swedish Hernia Register [59].

Another finding in paper C was that dural lesions and infections were the most common complications. In most cases, the injury was documented in the patient's file but more commonly not included in the Swespine report. Dural lesions and infections were poorly recorded in Swespine although they were important causes of problems that contributed to high levels of disability. Despite the high incidence, it is most likely that surgeons sometimes do not consider a dural lesion to be an important complication. These findings are in line with other results showing lack of documentation of complications [37].

The overall purpose of the Swedish quality registers is to provide data that can be used to increase our knowledge on the frequency, costs and effects of various treatments in order to facilitate improvements in the quality of health care [108]. However, our findings suggest that there might be considerable quality problems with these registries that must be accounted for when interpreting the data. Quality register data are useful tools for measuring improvements but the quality of the data needs to be improved to make them more useful. Moreover, investments in technical solutions for better collection of data would be appreciated [59, 122-123].

Inconsistency was found when patient claims were analysed and compared with lex Maria and data from Swespine. A full understanding of the pattern of adverse events and outcomes after spine surgery thus requires analysis of data from many sources. Medical record review and patient claims analysis are two important sources of information that may provide a more accurate picture of adverse events and their outcome.

Patient claims seem to be an important complement to other sources of patient safety data. The literature shows that patients' experiences and observations of health care are an important source of information [124-125]. However, patient claims as a measure of patient safety have been criticized in international studies [48, 51]. According to these studies, claims data have some weaknesses. First, data are collected for insurance purposes, not initially for the purpose of improving patient safety. Second, claims represents only a very

small proportion of instances in which care has been sub-standard or patients have been harmed. Third, there are no denominator data.

These weaknesses also apply to the database of the County Councils' Mutual Insurance Company but to a lesser extent. First, data are collected for insurance purposes but the insurance company has been an open and an important actor in the development of the national patient safety strategy in Sweden and they have tried to build a structured database in order to help researchers to use the data. Second, this Swedish database collects some 10,000 claims yearly and is therefore one of the largest sources of data and information on adverse events in Sweden. About 45% of the reported injuries are compensated. In 2009, the number of claims compensated by the County Council of Östergötland ( $n=225$ ) greatly exceeded the number of reports according to lex Maria ( $n=110$ ). This trend can also be seen nationally with a yearly average (2006–2011) of about 4500 compensated patient claims and about 1800 lex Maria reports. Third, Sweden has denominator data unlike many other countries. By using the unique personal identification number, it is possible to calculate the rate of claims by combining the patient claims data with the National Patient Register and/or other sources such as quality registers. Consequently, patient claims in the Swedish database seem to be more reliable as a patient safety indicator compared with claims data from other countries.

## **6.2. Discussion of findings from paper D**

Paper D describes and evaluates the locally developed Patient Safety Dialogue, which intends to build trust and understanding, encourage leadership commitment, and foster learning on patient safety issues.

The intervention was inspired by WalkRounds interventions [94-95], but it differs in many ways. The Patient Safety Dialogue intervention does not focus on interaction with the frontline staff at the sharp end of care. Instead, the intervention emphasizes dialogue

between clinical leaders and staff members with special patient safety assignments at the department level and a chief medical officer and other representatives from an administrative patient safety unit integrated with the county council's executive board. The face-to-face communication between clinical leaders and staff members with special patient safety assignments at the department level and the representatives from the patient safety unit is intended to foster leadership commitment and broader awareness concerning patient safety issues. Clinical leadership involvement facilitates decision making to achieve desired system improvements. However, this focus on leadership means that the Patient Safety Dialogue largely fails to account for the frontline personnel's perspective on patient safety issues, in contrast to WalkRounds interventions [96-100] as already stated above. The County Council of Östergötland intends to develop and evaluate an intervention that combines aspects of the leadership-oriented Patient Safety Dialogue with the bottom-up-oriented WalkRounds approach, which has a strong focus on interaction with frontline health care providers.

The main finding in paper D on the Patient Safety Dialogue was that more than two-thirds of the departments evaluated attained higher scores in round 3 than in round 1, and thus were categorized as either "continuously improving" or "developing departments". Still, the performance of the departments varied a great deal as many departments did not improve at all during the 5-year study period. The impression after more than 5 years of the Patient Safety Dialogue is that the departments that showed the greatest improvements have committed leaders who actively support patient safety issues by asking for results and also allocate resources for patient safety work. This interpretation is supported by other research that has emphasized the importance of having a champion who is committed to patient safety, e.g. a patient safety coordinator [126].

Although it may seem impressive that two-thirds of the departments were continuously improving or developing departments, this result means that approximately one-third of the departments did not improve their patient safety culture during the 5-year study period. The reason for this lack of improvement is not clear and requires further investigation. It

suggests that work towards a mature patient safety culture must be conducted with a long-term perspective; this is also emphasized in the literature [33].

To gain a comprehensive picture of patient safety, health care organizations should use a variety of tools. Comprehensive safety programs containing different components have been implemented successfully in health care organizations worldwide in order to increase the safety culture [102, 115-118]. Implementing a comprehensive patient safety strategy in a large health care system requires the simultaneous use of different tools to achieve significant change, like the patient safety programme implemented in the County Council of Östergötland. Adverse event reporting, root cause analysis, risk analysis, trigger tool detection, measurement of compliance to hygiene rules, registration of hospital-acquired infections and complications are some other examples of methods successfully used. A systematic and comprehensive strategy with follow-up is required in order to build a better safety culture [33, 45, 127]. However, despite studies that show a better safety culture after comprehensive patient safety programmes, relatively few studies show a decrease in the number of injured patients as a consequence of an improved safety culture.

### **6.3. Methodological considerations**

A major concern when conducting research in an area that is also one's own professional working field is the potential conflict of the dual roles of being a researcher and a practitioner. The studies in this thesis have been conducted parallel with my work to develop and implement the patient safety strategy in the county council. This has likely influenced some of the interpretations of the research findings. However, the combination of practice-based knowledge and research gives a multi-perspective approach, which sometimes can be an advantage.

A vital role in this research is the use of multiple methods for data collection. Data were used from three sources of reporting of incidents and complications and from an evaluation form

on patient safety culture. The studies were conducted at regional (papers A and D) and national level (papers B and C), which might strengthen the validity of our findings.

Paper A was a review of 113 medical records performed by three chief medical officers with the aim of deciding whether claims should be reported as *lex Maria* or not. All three medical officers were active within the County Council of Östergötland and two of them had a position as chief medical officer during the study period (one throughout the study period and the other for part of the period). All three chief medical officers reviewed all the medical records, therefore at some occasions a chief medical officer had to review his own previous decisions. This was discussed initially but the reviewers decided not to exclude such cases as they were also independently reviewed by the other two medical officers. However, it cannot be excluded that some bias occurred that might have influenced the results.

In papers A and C the reviews of the medical records were conducted according to protocols specially developed for this purpose by the research team. This might have influenced the validity. It would have been an advantage to use a research tool previously tested for reliability and validity. However, no such tool corresponding to our requirements for reviewing the medical records was identified.

A methodological obstacle with patient claims is the long period of time for processing a claim. A patient who believes he/she suffered an injury during treatment must apply for compensation within three years of becoming fully aware of the injury.

The database at the County Councils' Mutual Insurance Company has nationwide coverage and by compiling data from all Swedish hospitals, even rare injuries and their consequences can be detected. However, the database does not include any deeper analyses of the causes of the injury and therefore a medical record review is sometimes necessary to get a better understanding of the injury.

Patient claims addressed to the insurance company are probably underreported for different reasons: (1) some patients do not feel that they are injured because they assess the actual injury as an unpreventable complication; (2) some patients do not know that they can be economically compensated by the insurance company; (3) some patients are not able to claim because they have a serious harm or another serious disease.

The evaluation of the Patient Safety Dialogue described in paper D has some limitations that must be considered when interpreting the results. It would have been desirable to have control departments to compare with the departments that participated in the intervention. However, a case–control or experimental design was not feasible as a result of a decision by the county council that all hospital departments were required to participate in the Patient Safety Dialogue as part of a comprehensive quality improvement program. Hence, the study’s observational design is an obvious shortcoming.

We relied on assessments of the maturity of the patient safety culture that are part of the Patient Safety Dialogue instead of conducting evaluations exclusively for research purposes. Nevertheless, the assessments were performed with strict adherence to rigorous protocols established by the patient safety unit. The assessment instrument used was inspired by the Manchester Patient Safety Assessment Framework, which has been applied for several years in English health care organizations by the National Patient Safety Agency under the National Health Services [88]. The instrument’s classification of organizations provides a robust framework for the questions and assessments in the Patient Safety Dialogue. The assessments are intended to be as objective as possible with individual assessment and a consensus discussion. The purpose of the consensus discussion was to reduce the risk for subjective assessments based on individual opinions. Still, subjectivity cannot be completely ruled out, as there are many open-ended questions that give room for different interpretations. Although many of the assessments are made on the basis of factual reporting and objective data supplied by the departments, there are also aspects of the assessments that entirely rely on the discussion with the department representatives in the meeting. This could lead to social desirability bias, that is, the tendency to reply in a manner

that will be viewed favourably by others. This effect is well known within research fields such as medicine, psychology, and the social sciences [128].

## **6.4. General discussion**

Errors have always occurred in health care. However, before the publication of the Institute of Medicine's report in 1999 [11], patient safety issues were not highly prioritized by health care practitioners, policy makers or the general public because the full magnitude of the problem was not known. The report provided a much-needed measure to understand the problem of unsafe care.

This thesis focuses on measures of various aspects of patient safety. Papers A, B and C analysed different aspects of adverse events, with the aim of investigating how these can be captured using different national incident reporting systems and quality registers. Measurement was also an important aspect of paper D, as various dimensions of the patient safety culture are scored in an assessment that is an integral part of the Patient Safety Dialogue intervention.

There are three general reasons for measuring patient safety: to understand what is happening as measurement can make things transparent; to control aspects of what is happening; and to improve processes and products. Papers A, B and C aimed to provide an understanding of the magnitude of the patient safety problem, whereas paper D was more oriented towards measuring for problem control and potential improvements, with results of the assessment being fed back to the departments' management team and the patient safety unit to provide the basis for taking appropriate actions for improved patient safety.

In areas involving road traffic, offshore and aviation, safety problems are assessed by the number of fatal or non-fatal accidents. The experience from these high-risk industries and environments [14, 129] demonstrates the importance of measuring safety problems to

develop new improved solutions. Some of these high-risk industries have a zero vision with no deaths or serious injuries. In Swedish health care, a zero vision for preventable adverse events leading to harm has been discussed. Zero vision in health care as it is defined today aims to eliminate all preventable adverse events, e.g. Swedish health care should eliminate more than 100 000 adverse events yearly. In other areas such as road traffic, the focus of the zero vision is on serious adverse events leading to death, not on all injuries. The new Patient Safety Act [130] defines “serious health care injury” as a health care injury that is permanent and not minor, or has resulted in the patient having a significantly increased need of care or that the patient has died. One could argue that redefining the zero vision with a focus on serious health care injuries would not only make the measurement easier but also the vision more trustworthy. A zero vision in Swedish health care calls for a strong culture, requiring measurement systems based on designing, collecting, analysing and presenting data.

Since the Institute of Medicine’s report, many researchers have emphasized the importance of reliable measurements to achieve improved patient safety in health care organizations [33, 131-133]. However, measuring patient safety is associated with considerable difficulties. These problems can be summarized in the following three categories:

- Definitions and classifications of adverse events
- Reporting and accessibility
- Coverage

An important prerequisite for obtaining valid and reliable data on adverse events is the use of standardized definitions and classifications within the patient safety field.

To some extent, the three reporting systems described in papers A, B and C used different classifications of causes of adverse event. However, the definition of an adverse event is similar concerning the cases that should be reported according to lex Maria and a patient claim assessed by the insurance company. Despite this, the handling of the reports differs substantially in the two reporting systems, which may lead to differences in the assessments

of adverse events. Hence, this leaves room for different interpretations and speculations. The need to be clear and distinct in the classification of reports has been emphasized in the literature [134-135].

The identification of an adverse event and its preventability is typically made by a chief medical officer in a hospital, a specialist at the National Board of Health and Welfare or experts at the insurance company. However, the rigour by which the reviews are undertaken might vary, from a review based on a single professional assessment of the circumstances to reviews that use multiple professional assessments and explicit criteria. These differences in the review processes are likely to affect the reliability and validity of assessments of whether adverse events are preventable or not.

Another important aspect of patient safety measures is how data about adverse events are captured (by an incident reporting system or by review of medical records) and how these data are classified. A considerable amount of safety and quality data are collected but these data tend to be widely scattered in different reporting systems and may be relatively inaccessible to health care managers and clinical teams.

The most common method for capturing patient safety data is self-reports of adverse events. However, self-reporting has some limitations. One is the motivation to report within health care. It is well known that nurses tend to report near misses and adverse events to a greater extent than physicians [119]. This might give an incorrect picture and imbalance between adverse events that occurred in diagnostic and treatment processes and nursing processes. The frequency of reporting can also change over time. For example, implementation of interventions with a focus on reporting a specific type of adverse event and the introduction of new and easier ways to report incidents may affect reporting of adverse events. Other circumstances may also influence the safety culture and thus the motivation to report adverse events.

Incident reporting is associated with several future challenges. One is to reduce underreporting and a key element will be to demonstrate how improvements can be based on incident reporting and analysis [136]. Another challenge is the opportunity to explore the role of patients and their relatives in reporting incidents. It is known that many events identified by patients are not captured by hospital incident reporting systems or included in the medical records [124]. Incident reporting should be seen in a broader context; on its own it will never provide a complete picture of what might have gone wrong [136-137].

Adverse events can also be measured by so-called trigger tools [138]. This is a systematic screening method that involves a retrospective review of medical records using triggers to identify possible adverse events. The method presupposes knowledge and education of the reviewer. If relevant education, training and assessments are at hand, the trigger tool method seems to be more valid and reliable for the measuring of patient safety compared with incident reporting [139]. Thus, even if the global trigger tool seems to be more effective and successful than incident reporting, this method is more resource intensive. However, if the method can be integrated and automated within a commercial electronic health record system, then it is believed that the method can be more generally available and useful. A Swedish project has recently accomplished such automation of this tool [140]. A multi-faceted approach including data mining of administrative and clinical data sets, regular reviews of medical records and different surveys of patients and staff might complement the incident reporting [141-144].

The results from papers A, B and C showed that different incident reporting systems provide disparate pictures of patient safety and indicated an underreporting of adverse events. Different studies have shown that reporting systems fail to detect many adverse events and only a small, non-random fraction of incidents are submitted to reporting systems [11, 19, 34, 36].

For all types of adverse events there is an initial lack of baseline data that cannot be accounted for. There is a lack of denominators, i.e. the populations at risk are unknown, which make it impossible to make comparisons over time. The outcome might be that we do not know if a decrease in reports demonstrates that health care has become safer or if the willingness to report got worse [132].

Assuming that reliable and valid data can be obtained, the next question is how these data can be transformed into information and knowledge that provides a basis for prioritizing, planning and undertaking various actions to improve patient safety. Information is defined as data that are endowed with meaning and purpose, whereas knowledge is often seen as information that has been processed, organized or structured in some way. Knowledge needs to be disseminated in organizations to achieve organizational learning, i.e. yielding changed norms, routines, rules and regulations that affect the behaviour of the organization's members. The ambition of the Patient Safety Dialogue described in paper D is to achieve this transformation of patient safety data into organizational learning in terms of an improved patient safety culture. However, the study demonstrated the difficulty of the data learning process as one-third of the departments had not improved in three cycles (5 years) of the intervention.

Even though the value of different reporting systems seems to be limited, it is believed that the willingness to report incidents and their investigation, combined with analysis of aggregated incident data, might generate useful information to address weaknesses in work systems and processes. As Reason describes [14], if even near misses tend to be reported and analysed, the large volumes of incidents and near misses can provide greater opportunities to identify patterns of causes, which can provide valuable knowledge on the weaknesses within processes.

The patient safety feedback loop, i.e. the process from reporting to learning and improving the frontline clinical work system, must go round in circles and it has to operate continuously rather than only temporary or as a process on the periphery of other activities [32, 145]. To

make a sustained and long-term commitment to patient safety improvements, health care must focus more on organizational learning. Organizational learning is a process of detecting and correcting errors. This learning can be made by single loop learning and/or double loop learning [146]. Single loop learning means that an organization can learn from errors by modifying or correcting activities and/or complementing with new activities. The single loop repeats different attempts to solve the same problem. Double loop learning means to modify or correct the process and the activities but also that the organizations conditions and requirements should be transformed. This transformation might make the processes more adapted and improve outcomes. Thus, both single loop and double loop learning must exist but more and better activities do not lead to a long-term improvement unless favourable conditions prevail.

To some extent, Swedish health care is still at the stage of collecting data and providing information on patient safety, perhaps viewing this as a safety management system. However, it should be noted that organizations that collect a great deal of data and produce mostly descriptive statistics belong to the calculative level in the model of organizational safety culture (Table 2) [85]. It is hoped that Swedish health care organizations will move from the calculative to the proactive level and start to predict what the next incident might be. After this level, organizations must be ready to climb and reach the generative level (high-reliability organization) with mindful people who operate with openness and trust and where learning from error might be a natural process. But a prerequisite to this journey is a long-term commitment to patient safety improvement and an encouraging leadership at all levels.

## **6.5. Conclusions**

The conclusions of the four papers of this thesis can be summarized as follows:

- Patient claims seem to be an important source of information that can complement information from incident reporting systems and quality registries in health care in order to provide an understanding of the magnitude of the patient safety problem.
- Different Swedish reporting systems provide disparate views and have many discrepancies regarding data quality and coverage of adverse events.
- A structured intervention fostering learning on patient safety issues and encouraging leadership commitment can improve patient safety culture from a five-year perspective. However, it might require a longer period of time and focused efforts to achieve improvements across all departments in a Swedish county council.

## **6.6. Future research**

This thesis has contributed to the knowledge on the different content within incident reporting systems and how they differ regarding coverage and quality of information. However, further research is needed on several aspects.

The studies in papers A, B and C were conducted with data from the beginning of this century. Efforts to improve patient safety have increased markedly in the last five years. It would therefore be of great value to collect new data to investigate changes over time and potential improvements.

Study D found that the Patient Safety Dialogue intervention seems to be effective in supporting an improved patient safety culture. Two-thirds of the departments improved during the 5-year study period. It would be interesting to analyse in more detail the factors that characterize the departments that had a continuous improvement in patient safety maturity.

Another field for further research is the relationship between performance and safety culture. Health care researchers have only recently begun to investigate the extent to which the patient safety culture affects safety performance.

# SVENSK SAMMANFATTNING

Ett stort antal internationella studier har försökt identifiera och kvantifiera frekvensen av vårdskador i sjukvården. Den svenska vårdskadestudien från 2008 visade att 8,6 % av de patienter som vårdats inom somatisk slutenvård drabbades av en vårdskada. Tolv procent av vårdskadorna bedömdes vara allvarliga och innebar permanent invaliditet eller bidrog till patientens död. Omräknat till antal patienter och i relation till antalet vårdtillfällen i Sverige drabbas årligen 10 000 patienter av vårdskador med allvarlig konsekvens och i 3000 fall kan vårdskadan ha bidragit till att patienten avlidit.

Inträffade vårdskador rapporteras i olika typer av fristående system och av såväl medarbetare inom hälso- och sjukvård som patienter och närstående. Exempel på system för rapportering av vårdskador är lokala avvikelshanteringssystem, vårdgivarens lex Maria-anmälningar till Socialstyrelsen, sjukvårdens komplikationsregistreringar i nationella kvalitetsregister samt patienternas begäran om ekonomisk kompensation för inträffad vårdskada från patientförsäkringen. Även om de olika rapporteringssystemens syften är likartade, det vill säga, att identifiera och analysera inträffade vårdskador och komplikationer för ett lärande, så finns ett förmodat mörkertal och diskrepans mellan de olika registren.

Syftet med denna avhandling är att bidra med ökad kunskap dels genom analys och jämförelser av innehåll i och mellan olika rapporteringssystem, dels genom att beskriva och mäta en intervention ämnad att förbättra patientsäkerhetskulturen i ett svenskt landsting. Följande tre forskningsfrågor har avhandlingen försökt besvara: (1) I vilken omfattning kan patienternas rapportering bidra till ökad förståelse och kunskap om patientsäkerhetsområdet? (2) I vilken omfattning skiljer sig data i olika svenska rapporteringssystem? (3) I vilken omfattning leder en strukturerad intervention som är ämnad att främja lärande från patientsäkerhetsarbete till förbättrad säkerhetskultur inom ett landsting under en femårsperiod?

I avhandlingen ingår fyra studier varav tre (studie A, B och C) har baserats på data från tre olika nationella rapporteringssystem: lex Maria-anmälningar till Socialstyrelsen, patientanmälningar till patientförsäkringen (Landstingets Ömsesidiga Försäkringsbolag) samt medicinska data inrapporterade till Svenska Ryggregistret (Swespine). I studie D har data från utvärderingar av Patientsäkerhetsdialoger analyserats.

I studie A analyserades 113 patientfall som fått ekonomisk ersättning för en inträffad allvarlig vårdskada från patientförsäkringen. Resultatet visade att endast 20 % var lex Maria-anmälda. Patientfallen bedömdes retrospektivt i två steg, individuellt och i konsensusdiskussion, för att avgöra om vårdskadan borde ha anmälts som en lex Maria eller ej. I 15 % av fallen var bedömarna samstämmiga om en anmälan. Samstämmigheten ökade efter konsensusdiskussion till 26 %. Resultatet visar att sjukvården underrapporterar till lex Maria samt att bedömning av vårdskador kan förbättras med hjälp av konsensusdiskussioner.

I studie B analyserades 6029 patientanmälningar till patientförsäkringen. Resultatet visade att ortopedi stod för den största andelen vårdskador (28 %). De vanligaste orsakerna till vårdskador var infektioner (22 %). Ryggoperationer orsakade mest allvarliga bestående skador och invaliditet i jämförelse med andra ortopediska operationer.

Studie C analyserade 182 patientfall som anmälts till patientförsäkringen efter att skada uppkommit efter ryggoperationer. Data jämfördes på personnivå med registrerad data i kvalitetsregistret Swespine i syfte att jämföra täckningsgrad, kvalitet på data samt utfall för patienten. Resultatet visade att mindre än två tredjedelar av patienterna var registrerade i Swespine. Vid journalgranskning identifierades 210 olika komplikationer/patientskador och av dessa var 74 registrerade i Swespine. De vanligaste orsakerna till skada och invaliditet var durarift och infektion. Ingen av infektionerna var registrerade i Swespine. Studien visar en underrapportering av komplikationer/patientskador i Swespine.

I studie D beskrivs och analyseras en intervention, Patientsäkerhetsdialoger, som syftar till att förbättra patientsäkerhetskulturen i ett landsting. Resultatet visar att två tredjedelar av enheterna under fem år har förbättrat sin patientsäkerhetskultur mätt på en femgradig skala. Somatiska enheter förbättrades i större utsträckning än psykiatriska enheter. Studien påvisar att utveckling av patientsäkerhetskultur kräver systematisk uppföljning, tid och uthållighet.

Avhandlingen visar att det finns ett betydande mörkertal och kvalitetsbrister i sjukvårdens rapporteringssystem. Patienternas rapportering av inträffade händelser är en viktig del och utgör ett komplement för ökad förståelse och kunskap av patientsäkerhetsområdet.

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## Appendix 1: Questions asked in the Patient Safety Dialogue in paper D

Patient safety culture dimension	Patient safety area	Questions asked in the meeting
Leadership commitment	All areas	How and to what extent is the leadership committed to the department's quality and patient safety work? How and to what extent are employees, including physicians, involved in the department's quality and patient safety activities?
Structure/organization	GPS	How do you document procedures and routines for patient safety work? Do you have a specific employee assigned to work with patient safety (e.g. a patient safety coordinator)?
Systematic identification and registration	HAI	How do you systematically identify hospital-acquired infections? How do you measure adherence to hygiene rules?
	OM	How do you identify main processes of care, both within your department and processes in common with other departments? Do you take part in relevant national quality registers? Do you use national guidelines for developing local routines and procedures?
	GPS	How do you involve staff in identifying and reporting adverse events and risks? Have you identified the three most important risks in your department? How do you work with root cause analysis and risk analysis? Do you regularly have "Morbidity and Mortality" conferences?
Analysis and activities of improvement	HAI	How do you systematically analyse hospital-acquired infections? How do you follow up measurements of adherence to hygiene rules? How do you measure the effectiveness of implemented actions?
	OM	Describe your outcome measurements in comparison with other organizations How can you improve your results? What kind of actions have you implemented to improve your results?
	GPS	How do you measure adherence to adverse event reporting routines? What actions have you implemented based on your root cause analysis and risk analysis? How do you measure the effectiveness of implemented actions based on root cause analysis and risk analysis?
Overall patient safety culture	GPS	Are physicians committed to work with patient safety? Can you openly discuss adverse events at your department? How do you involve patients in the patient safety work? How do you take care of patients and relatives after a serious adverse event? How do you take care of the employees involved after a serious adverse event?

*Abbreviations:* GPS, general patient safety; HAI, hospital-acquired infections; OM, outcome measurements.

## Appendix 2: The questionnaire used for individual review in paper A

1) Was the injury a well known complication arising from another disease and/or health care intervention?

No

Yes

2) Was it suicide?

No

Yes

2a) If yes, did it happen on the ward or on the day of discharge?

Yes

No

3) Was it a consequence of a fall?

No

Yes

4) Has the injury been reported as a lex Maria?

No

Yes

5) Should the event have been reported as a lex Maria?

No

Yes

Unclear

*Should not be reported as a lex Maria*

Comments:

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## Appendix 3: The structured protocol used for medical review in paper C

Code: \_\_\_\_\_ Personal number: \_\_\_\_\_ Gender:  Male  Female  
 Hospital: \_\_\_\_\_ Department: \_\_\_\_\_  
 Time in hospital (index date): \_\_\_\_\_ - \_\_\_\_\_

Cause for complaint:  Remaining back pain  Remaining leg pain  
 Injury during surgical procedure  
 Additional problems  
 Back pain  Leg pain  Infection  Paresis  
 Other neurological symptoms  Other symptoms

Codes for diagnosis (ICD10) and surgical procedures (ICD10) at the time of injury (if further injury occurs during reoperation after index injury- please use a new form)

Main diagnosis: \_\_\_\_\_ Other diagnosis \_\_\_\_\_  
 Surgical procedures: \_\_\_\_\_ Other surgical procedures \_\_\_\_\_

Date for surgical procedure  
 Index procedure is a reoperation  No  Yes  < 6 wk  > 6 wk  
 from previous procedure

If reoperation, same level/side?  No  Yes  
 If reoperation, was it an injury at previous procedure?  No  Yes

Main surgeon (name): \_\_\_\_\_ Title: \_\_\_\_\_  
 Assistant (name): \_\_\_\_\_ Title: \_\_\_\_\_

Medical equipment during the surgical procedure  
 Magnifying glass  Microscope  Not documented  
 not documented if X-ray was used during the surgical procedure  X-ray was used during the surgical procedure (in documentation)

Periop. problems  
 No  Dural lesion  Bleeding  Technical equipment  
 Implant  Nerve root damage  Other  X-ray

Causes for injury  
 Dural lesion  Wrong level/side  Hematoma  Infection  
 Implant  Nerve root damage  Other

Has the injury led to new surgical procedure/s?  No  Yes  
 If yes – how many?  
 Has new injury occurred following reoperation/s  No  Yes