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Wrigstad, Jonas

2018

Document Version:
Publisher's PDF, also known as Version of record

[Link to publication](#)

Citation for published version (APA):
Wrigstad, J. (2018). *The inside of a paradigm. An expedition through an incident reporting system.* [Doctoral Thesis (compilation), Department of Clinical Sciences, Lund]. Lund University: Faculty of Medicine.

Total number of authors:
1

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The inside of a paradigm

The inside of a paradigm

An expedition through an incident reporting system

Jonas Wrigstad



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DOCTORAL DISSERTATION

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To be defended at Aula Nedre, LUX Building C, Helgonavägen 3, Lund on the 2nd
of February 2018 at 1.00 pm.

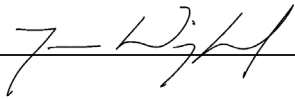
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Organization Department of Clinical Sciences Lund Faculty of Medicine LUND UNIVERSITY SWEDEN	Document name Doctoral dissertation	
	Date of issue February 2nd 2018	
	Sponsoring organization	
Author(s) Jonas Wrigstad, MD		
Title and subtitle The inside of a paradigm. An expedition through an incident reporting system		
Abstract <p>Background: Since 1937, specific legislation has been in use in the Swedish healthcare system, mandating investigation of severe adverse events by authorities. Despite changing political governance and system modifications, the model with healthcare provider organisations reporting adverse events to an authority, has stayed virtually intact. The aim of this thesis is to understand how the incident reporting system in Swedish healthcare is functioning.</p> <p>Methods: The method used to understand the Swedish incident reporting system is a case-study approach in which analyses from multiple cases combine into a rich picture of the system's functioning. The case studies chosen give several perspectives for analyses; one local, one over time, one in depth and one nationwide cross-section. Both quantitative and qualitative methods are used in content analyses of investigations and interviews with key actors of the system. The use of different data sources makes it possible to extrapolate various analytical generalisations from the combined cases.</p> <p>Results: Both healthcare provider organisations and the supervisory authority construct causal factors and subsequent targets for intervention in immediate spatial and temporal proximity of an adverse event. The studied parts of the incident reporting system are highly dependent on individual memory for the implementation process, follow-up procedures and acknowledging previous lessons. Providing an epistemology of the event and suggesting preventive actions is essential to the investigation. Deviations from norm are dealt with through more governing and control. The system's efficiency and closure of cases is a way forward after adverse events.</p> <p>Conclusions: The incident reporting system operates within a paradigm that perseveres as long as no doubt of its superiority is conceptualised by stakeholders within the system. First, there is a micro-organisational understanding of how adverse events occur, and consequently, where targets for intervention are aimed at. Second, there is a system that has a weak organisational memory, involving all levels of the incident reporting system, and that keeps micro-organisational level interventions regenerating. Third, there is the process of conducting investigations, which maintains and reproduces bureaucracy and hence fulfils important psychological purposes to stakeholders within the system.</p>		
Key words Patient safety, Adverse event, Incident investigation, Incident reporting system, Healthcare provider organisation, Supervisory authority, Ontology, Paradigm		
Classification system and/or index terms (if any)		
Supplementary bibliographical information		Language English
ISSN and key title 1652-8220		ISBN 978-91-7619-578-9
Recipient's notes	Number of pages 127	Price
	Security classification	

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The inside of a paradigm

An expedition through an incident reporting system

Jonas Wrigstad



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Lund University
Faculty of Medicine
Doctoral Dissertation Series 2018:11
Department of Clinical Sciences Lund

ISBN 978-91-7619-578-9

ISSN 1652-8220

Printed in Sweden by Media-Tryck, Lund University
Lund 2017



“And I don’t know a soul who’s not been battered
I don’t have a friend who feels at ease
I don’t know a dream that’s not been shattered or driven to its knees
But it’s all right, it’s all right
For we’ve lived so well so long
Still, when I think of the road we’re traveling on
I wonder what’s gone wrong
I can’t help it, I wonder what’s gone wrong”

(Lyrics from *American Tune* by Paul Simon, 1973)

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List of publications

This thesis is based on a synthesis of four papers, referred to as Papers I-IV:

- I. Wrigstad J, Bergström J, Gustafson P. Mind the gap between recommendation and implementation – principles and lessons in the aftermath of incident investigations: a semi-quantitative and qualitative study of factors leading to the successful implementation of recommendations. *BMJ Open* 2014;4:e005326. doi:10.1136/bmjopen-2014-005326.
- II. Wrigstad J, Bergström J, Gustafson P. Incident investigations by the regulatory authority of Swedish healthcare – a 20-year perspective. *Journal of Hospital Administration* 2015;4(6):68-76. doi:10.5430/jha.v4n6p68.
- III. Wrigstad J, Bergström J, Gustafson P. One event, three investigations: The reproduction of a safety norm. *Safety Science* 2017;96: 75-83. doi:10.1016/j.ssci.2017.03.009.
- IV. Wrigstad J, Bergström J, Gustafson P. On safety ontology: a cross-section analysis of incident investigations in a public healthcare system. *Safety in Health* 2017;3:13. doi:10.1186/s40886-017-0064-7.

No formal permission is required from the respective journals, to reuse and embed Papers I-IV in this thesis, because of the papers' Open Access status.

Thesis at a glance

	Question	Method	Results	Conclusions
I	What are the mechanisms behind implementation of targets for intervention from internal incident investigations within a healthcare provider organisation?	A case study with a combined content analysis of 55 internal incident investigations from one Swedish healthcare provider organisation and interviews with 22 commissioning bodies within the same organisation. Semi-quantitative and qualitative.	Only 45% of targets for intervention were implemented. When action was taken on targets for intervention, 73% of these were at a micro-organisational level. Changes in management position as regards the commissioning body meant that no further action was taken. The investigation worked as an incentive for action on the initiative of management rather than the investigation team.	Continuity in management is essential as are targets for intervention at the micro-organisational level. Independent of the formal investigation, the adverse event triggers organisational action and change.
II	How has legislative and organisational change over a 20-year period influenced the incident reporting system and its main actors?	A case study with a combined content analysis of 87 external incident investigations from one regional supervisory authority office in Sweden and interviews with 11 investigators from different supervisory authority offices. Semi-quantitative and qualitative.	In the few investigations where the authority required further demands than presented by the healthcare provider organisation, the targets for intervention were at the micro-organisational level in 65% of cases. The pattern remained unchanged during the entire period. All investigators had a background from the healthcare system and no functioning organisational memory could be found.	The micro-organisational level focus of the incident investigation system reflects an established structure within the authority that remains unchanged over time.
III	How do three different public investigatory bodies respectively construct and understand the causal factors leading up to the same adverse event?	A case study with content analysis of three incident investigations all focused on the same adverse event at a Swedish university hospital. Semi-quantitative and qualitative.	All investigatory bodies construct the causal factors in the immediate temporal and spatial proximity of the adverse event and understand the event as a deviation from norm. Three alternative pathways were identified.	The findings represent a strong discourse on the community analysing adverse events and seem to fulfil certain psychological purposes
IV	With what underlying safety ontology are adverse events in Swedish healthcare investigated?	A case study with content analysis of the 90 most recent internal and external incident investigations from all 6 regional supervisory authority offices in Sweden. Semi-quantitative and qualitative.	84% of targets for intervention were at the micro-organisational level. In 70 of 90 investigations the authority closed the case without further intentions after reviewing the internal incident investigation from the healthcare provider organisation. The picture is similar nationwide.	Obvious signs of traditional linear causality construction with a focus on the immediate spatial proximity of the adverse event were found together with efficiency and closure of cases being essential parts of the incident reporting system. The main actors' performance brings societal closure of harm.

Summary

The research field of safety science is both broad and interdisciplinary. The topic chosen for this thesis is the area of patient safety concerning adverse events in the healthcare system. The overall ambition is to understand how the Swedish public healthcare system uses adverse events, or identified weaknesses in patient safety, for improvement interventions. Since 1937, Swedish healthcare has had an operating mandatory incident reporting system dealing with adverse events. Through the years this incident reporting system has undergone modifications because of changing political governance, but with the model of a healthcare provider organisation reporting adverse events to an authority staying virtually intact. The focus for this thesis is to explore how this incident reporting system functions; how the system investigates adverse events, how the system learns from the investigations of adverse events, and how this learning eventually generates and spreads implementation of patient safety interventions due to adverse events.

The thesis is based on four separate studies, conducted from 2013 to 2017. Using a number of de-identified and completed incident investigations, data is analysed with both quantitative and qualitative methods through content analysis of written reports, and semi-structured interviews with key actors of the system. The first study has a local focus, analysing one healthcare provider organisation's internal incident investigations, with the aim of identifying which mechanisms that contribute to the implementation of targets for intervention after incident investigations. The second study has a focus over time, analysing the healthcare system's supervisory authority and its external incident investigations over a 20-year period, with the aim of identifying how legislative and organisational change has influenced the incident reporting system and its main actors. The third study focuses in depth on one adverse event and the three incident investigations that followed, with the aim of identifying how three different public investigatory bodies, with different purposes of analysis and different resources available, construct and understand causal factors leading up to the same adverse event. The fourth study focuses on analysing a cross-section sample of incident investigations from all regional supervisory authority offices in the country, conducted approximately in the same time-period, with the aim of identifying with what underlying safety ontology adverse events are investigated.

Analysis of data from the separate studies has given a handful of results for further interpretation. Healthcare provider organisations both construct causal factors and implement targets for intervention that are in immediate spatial and temporal proximity to an adverse event. The same traditional linear causality procedure is seen at the supervisory authority when further demands for action are required. This pattern remains unchanged over time, and regardless of societal investigatory body conducting the incident investigation. Both the healthcare provider organisation and the supervisory authority are dependent on individual memory for the implementation process of interventions, follow-up of decisions taken and when using lessons from previous cases. Nowhere can a functioning case management system be found that provides valuable support to the healthcare provider organisations' learning or the supervisory authority's spreading of lessons made. In the aftermath of adverse events, the incident reporting system finds it essential to identify what happened and how to prevent it from happening again, since the event is recognised as a deviation from norm. This deviation is most often seen as human behaviour that requires more governing, more control and tighter safety standards as regards the individual healthcare professional. Equally essential for main stakeholders of the system is efficiency of the process and closure of cases as a way forward after suffering from the harm the adverse event has caused.

The following major conclusions are made. First, that the incident reporting system has a micro-organisational understanding of how adverse events occur and thereby construct the targets for intervention at the same level. Second, that the weak organisational memory involving all levels of the incident reporting system is seen as an explanatory mechanism of the regenerating micro-organisational level interventions. Third, that the investigations maintain and reproduce a bureaucracy, and meet psychological purposes important to different stakeholders within the system. This gives the healthcare system legitimacy, even when learning is weak and repairing seems insufficient. Together, these findings give reason to believe that the entire incident reporting system operates within a paradigm where detected historical events act as explanatory mechanisms to support the claim of such a statement and why the paradigm perseveres.

Introduction

The initial thoughts of writing this thesis go back a few years to two separate and highly personal experiences of dealing with adverse events in clinical practice. First, while collecting data and gradually understanding, through discussions with senior incident investigators, that an interesting account from a healthcare professional did not fit in the format for analysis. Second, the disappointing conclusion while investigating an incident, from a professional position in close connection to the previous adverse event, that organisational change could not be traced at any level at any time upon completion of the incident investigation.

This thesis has the character of building relationships and thereby shifting the point of epistemology during the process, however not in a traditional quantitative cumulative manner. Figuratively speaking, results from the first study formed a base camp for the second study, which in turn acted as ignition to conduct the third study that eventually evoked curiosity to explore and interpret the fourth study. Therefore, the whole research process can be regarded as an expedition cruising between the different shores of an archipelago-like incident reporting system. The ambition has been that the exploration of this archipelago will create a picture of the constituent parts, the junctions between them and the terrain in which the incident reporting system is configured and operates. Here follows a presentation of the emergence of this terrain.

Background

A quote from the classic Oath by Hippocrates, dating back to the dawn of medicine, "...abstain from harming or wronging any man..." brings awareness to potential medical harm being an inherent risk closely linked to its benefits [1]. Despite centuries of scientific evolution, hardly any public, healthcare professional or research attention was brought to reducing medical harm, perhaps because medical therapeutics underwent hardly any change until the beginning of the nineteenth century [2]. In reviewing the history of the medical field about iatrogenic medical harm in *Medical Harm: Historical, Conceptual and Ethical*

Dimensions of Iatrogenic Illness, Sharpe and Faden in 1998 outline historical, yet isolated key events where attention is paid to different kinds of medical harm. Examples of such events are Semmelweis's studies on puerperal fever from 1857, Codman's systematic attempt to assess surgical outcome around 1916 and Schimmel's systematic studies of complications during hospitalisation in 1964 [3].

The first estimate on the incidence of iatrogenic medical harm in a large randomly selected sample of hospital records was presented in 1977 by the California Medical Association [4]. In the beginning of the 1980's, the Royal British Society of Medicine and the American Society of Anaesthesiologists respectively brought attention to anaesthesia-related incidents as a certain professional setting for medical harm. This eventually, in the US, led to the creation of the Anaesthesia Patient Safety Foundation as the pioneer professional organisation dedicated to assuring "patient safety" within its field. At the same time, a publication in 1983 made extensive arguments on the medical profession's need to learn from its errors made in medical practice by advocating professional tolerance and admitting personal fallibility without the use of condemnation [5].

Acknowledging the results from the California Medical Association report, but seeking current and more reliable data on "malpractice", the Harvard Medical Practice Study was published in 1991, and received widespread attention on the matter of medical harm with the report *Incidence of adverse events and negligence in hospitalized patients* [6]. Despite the considerable weight of its findings, the full impact of the Harvard Medical Practice Study was not seen until the release of the Institute of Medicine report in 2000 [7]. The Harvard Medical Practice Study became a cornerstone in the publication of *To Err Is Human: Building a Safer Health System* by the Institute of Medicine which estimated that between 44 000 and 98 000 hospitalised patients in the US die each year because of "medical errors" [8]. The essence in the second of four recommendations in the report is "...identifying and learning from errors through immediate and strong mandatory reporting efforts..." by means of nationwide mandatory reporting systems that provide information about adverse events that result in death or serious harm [8]. The report also states that patient safety, referred to as "freedom from accidental injury", is a critical component of quality improvement that requires regulation and supervisory authority. This statement was soon to be further catalysed by a second report from the Institute of Medicine entitled *Crossing the Quality Chasm: A New Health System for the 21st Century* that in detail describes the difference in what is meant by good healthcare, and the healthcare that is delivered to patients [9]. Not reaching the same global attention, a report from the British Department of Health *An Organisation with a Memory: Learning from Adverse Events in the NHS* (2000) promotes a strategy for patient safety culture within the National Health Service, where learning is seen as the essence of preventing medical harm [10].

Shortly after the publication of the first Institute of Medicine report there was a substantial increase in “patient safety” related research and publications on “patient safety” topics [11]. This included political action with several legislative and regulatory initiatives designed to document errors, and begin searching for solutions on a national level in the United States [12]. Furthermore, these reports together inspired a huge patient safety and quality improvement movement, bringing public attention to “error prevention” [13]. In 2004, the World Health Organization launched the programme World Alliance for Patient Safety [14] where one of six major recommendations, directed towards all member states, is the implementation of incident reporting systems to facilitate learning.

The Swedish public healthcare system has been regulated by legislation for decades, albeit the legislation has changed. Even if new regulations in 1996 from the National Board of Health and Welfare [15] stated the demand for incident reporting systems, a review by the authority in 2002 showed that not much action seemed to have been taken at the time [16]. However, in the years following the reports from the Institute of Medicine and the National Health Service, the Swedish healthcare system became more and more influenced by, and adapted to, the global patient safety and quality improvement movement. This could be seen in various ways; through national programmes, preparatory legislative investigations, different synchronised interventions and local initiatives [17], presumably with the overall intention of reducing medical harm as well as learning from error. Also, legislation followed and changed with increasing attention to incident reporting systems and their structure [18, 19, 20]. As a joint mission, key stakeholders in the Swedish healthcare system – the National Board of Health and Welfare, the Swedish Association of Local Authorities and Regions and the National Patient Insurance Company – brought about an assignment to create a methodological tool for internal incident investigations in the Swedish healthcare system, to be used nationwide by the healthcare provider organisations. Even if the assignment most certainly was both formalised and comprehensible, questions can be raised on what influenced the design process of the methodological support. In the first edition of the manual on methodological support from 2005 [21] it is clearly stated that “The manual has largely been inspired by a methodology called Root Cause Analysis that was developed by the Joint Commission on Accreditation of Healthcare Organisations [22] and amongst others is used at the Department of Veteran Affairs in the USA...” [23]. The Root Cause Analysis manual, named *Root Cause Analysis Tools*, is in turn composed with a variety of approaches and tools from different fields of research. The overall goal is identifying adverse event causation and preventing similar events [24]. According to the Root Cause Analysis manual, the goal of any analysis is to find out:

What happened?

Why did it happen?

How to prevent it from happening again?

An observation regarding influential factors is that the only reference to research when dealing with the first question “What happened?” is to the “Swiss Cheese Model”, introduced by Reason in *Human error* in 1990 [25]. The model suggests that, although many layers of safety lay between an adverse event and an incident, there can be flaws in each layer which, when aligned by circumstances, can allow the incident to occur. Such a model indirectly implies that fixing the flaws will make the system safer.

In 2009, Soop et al estimated through a medical record review study, that the magnitude of medical related adverse events in Swedish healthcare was even greater than shown in the Harvard Medical Practice Study in 1991 [26]. After revisions both in 2009 and 2015 of the Swedish manual on methodological support, the same reference is still made to the original model for internal incident investigation from the Department of Veteran Affairs in the USA [27].

Current regulations and obligations

Sweden, despite changing political governance, has predominantly had a public healthcare system for the last 100 years. Since 1913, surveillance of the healthcare system has been a part of the Swedish society. From 1937 and onward, due to a serious incident in 1936 in a Stockholm hospital, specific legislation has been in use, mandating external investigation by the authorities of severe incidents [28]. The foundation of this legislation states that, if an adverse event has resulted or could have resulted in a severe injury, this should be reported to the authority for an external incident investigation. This model, with a healthcare provider organisation reporting an incident to an authority, has since then remained virtually intact, even though legislative and organisational modifications, including name changes, have been made over the years. In 1968, the National Board of Health and Welfare became the regulatory and supervisory authority of the Swedish healthcare system.

The current and fundamental demands on the healthcare system are regulated in the Health and Welfare Act from 1982 [29], the Patient Safety Act of 2011 [30]

and the Patient Act of 2014 [31]. These regulations state, in brief, that care should be of good quality and fulfil the patients' need for safety in healthcare.

The National Board of Health and Welfare has in recent years issued specific regulations governing the responsibilities of the healthcare provider organisations; for example, using an incident reporting system and carrying out internal incident investigations. In 2011, a legislative change, the Swedish Patient Safety Act, pinpointed the specific responsibility of the healthcare provider organisations for patient safety improvement within their respective organisations [30]. These regulations state that the National Board of Health and Welfare "...ensures that reported adverse events have been investigated to a necessary extent, and that appropriate actions have been taken by the healthcare provider organisations to reach a high level of patient safety".

In June 2013, a new authority, the Health and Social Care Inspectorate, was created [32]. With its creation came the commission to take over the supervisory role of the healthcare system from the National Board of Health and Welfare, both acting under the Ministry of Health and Social Affairs. The Health and Social Care Inspectorate has 6 regional authority offices respectively covering certain geographical regions of the country.

In general, the chief medical officer of a healthcare provider organisation determines when and what to report to the Health and Social Care Inspectorate by using data from the incident reporting system. Upon decision to report, a commissioning body within the healthcare provider organisation is assigned to conduct an internal incident investigation. The commissioning body is most often the chief medical officer or the clinical head of department where the adverse event occurred. An analysis team is set up to perform an internal incident investigation and thereafter present a report, with causal factors and recommendations on actions, to the commissioning body.

The internal incident investigation, with or without comments from the chief medical officer, is thereafter sent to the Health and Social Care Inspectorate. The external incident investigation by the Health and Social Care Inspectorate is always preceded by the healthcare provider organisation's internal incident investigation. At the Health and Social Care Inspectorate, an inspector is assigned to perform the external incident investigation, but since the latest change in legislation, an auditing of the healthcare provider organisation's own internal incident investigation is the actual assignment. The report from the external incident investigation is presented to the head of unit at the Health and Social Care Inspectorate, and after a decision addressing the fulfilment (or not) of the healthcare provider organisation's legislated obligations, the report is sent back to the healthcare provider organisation.

Nomenclature

When embracing a field of literature that by nature is highly interdisciplinary, some definitions and meaning of words may seem confusing, and can at the worst create contextual problems. In the following section a list of expressions used for this thesis is presented with their related synonyms, sometimes used in Papers I-IV. Expressions in the left column are the ones found, for sakes of argument, in the thesis text.

Action taken	Implemented recommendation
Adverse event	Sentinel event, Hazard
Adverse event causation	Accident causation
Incident	Accident
Incident investigation	Root Cause Analysis, Accident investigation
Safety-critical	High-risk, High-reliability
Supervisory authority	Regulatory authority
Target for intervention	Recommendation

Aims of the thesis

The overall aim of this thesis is to understand how the incident reporting system used in the Swedish healthcare system is functioning. This is done by searching both quantitative and qualitative mechanisms that can interpret the nature of its major constituent parts, the junctions (or relationships) between these parts, and the context (or terrain) in which the system operates.

Specific aims have been to identify:

1. which mechanisms that contribute to the implementation of targets for intervention after incident investigations.
2. how legislative and organisational changes have influenced the incident reporting system and its main actors' over a 20-year period.
3. how different public investigatory bodies with different purposes of analysis and available resources construct and understand causal factors leading up to adverse events.
4. with what underlying safety ontology adverse events are investigated.

Methods

The methods in the thesis have been chosen to investigate the Swedish incident reporting system from several perspectives, including the inside perspective as a healthcare professional. Both quantitative and qualitative research approaches have been used.

The overall ambition has been to study the system, both in a broader perspective and in a deeper one, with the use of multiple sources. One approach has been to gain increased knowledge of the whole incident reporting system by in-person exploring the terrain to collect raw information in a seemingly naturalistic manner, as the underlying ambition of the thesis has been to answer the question: *What is going on here?*

When collecting data and analysing cases for the first study, searching for explanatory mechanisms and themes, the strategy that arose, as in comparison, being the most realistic for its purpose was *a case study* as described by Creswell [33]. This methodology was thereafter adopted for the upcoming studies as well. By no means can it be said that the picture in the thesis represents a full and complete view of the incident reporting system. Still, the approaches used, with pre-existing theoretical ideas and multiple data sources, often with limited control over the investigated events, have made it possible to draw a mosaic of perspectives by extrapolating various analytical generalisations from the examined data, thus creating a valuable base for the thesis [34, 35]. Papers I-IV are in nature mainly interpretive, and present an enhanced understanding about the functioning of the incident reporting system, but nevertheless also with aspects of normative conclusions presenting suggestions for alternative directions. Potential pathways for further exploration of the system are discussed in the chapter Future directions. In the following sections, a general description of methods used, and in brief the specific methods, for Papers I-IV is given.

Ethical considerations

Policy activities that constitute research at the institution need to be congruent with both the Regional Ethical Review Board, and the national *Act concerning the ethical review of research involving humans 2003:460*. The study protocols for Papers I-II involved data regarding recorded interviews with respondents working at different organisational levels in the Swedish healthcare system. Both studies were approved by the Regional Ethical Review Board in Lund, Sweden (ref 2013/623 and 2014/468). The study protocols for Papers III-IV involved de-identified and on request publicly available data compiled by the supervisory authority of the Swedish healthcare system. These studies therefore met the criteria for exemption from ethics review.

Case study

A case study is a research method that analyses and describes a real, often contemporary, matter in focus and the context in which it exists [34, 36]. Both qualitative and quantitative data can be collected, analysed and presented in the same study. The case study may not answer the research question completely, but is useful for testing scientific theory and guide further research. In Papers I-IV data from case studies was collected through content analysis and interviews.

Content analysis

Content analysis is a method to systematically reduce large volumes of data into manageable smaller portions of coded or categorised data for further analysis and inference [37, 38]. In Papers I-IV all reports from both internal and external incident investigations have undergone content analysis with a systematic approach on numbering, categorising and coding the content in focus. Occasionally, short excerpts from the reports have been quoted for reasons of clarification and objectivity to the approach used. Using an inside perspective, a coding scheme was used for Papers I-IV, focusing on identifying the hierarchical organisational level of causal factors, targets for intervention or actions taken after incident investigations, and is as follows:

- Micro = a causal factor, target for intervention or action taken within the department/unit where the adverse event occurred; for example, a local procedure, technical skills or staff issues.
- Meso = a causal factor, target for intervention or action taken that involves actors outside the department/unit where the adverse event occurred; for example, the need for collaboration with another department/unit or management at the healthcare provider organisation.
- Macro = a causal factor, target for intervention or action taken that involves actors outside the healthcare provider organisation; for example, collaboration with another healthcare provider organisation, authorities, politics or pharmaceutical companies.

Interviews

An interview provides an opportunity to gain a deeper understanding of the phenomena in focus if allowance is made for elaboration, improvisation and follow-up questions to the respondent [39, 40]. Attention needs, however, to be drawn to the issue of plausible and intelligible data, or not, given the context of the interview situation [41]. In Papers I-II, semi-structured interviews were conducted, meaning that specific questions were planned and responded to during the interview but without further framing of order, time or process [39]. All respondents had provided written consent, had suggested the place for the interview, were able to approve or not to audio recording and were informed of the main research questions in advance. All respondents were de-identified and given a random number, as essential parts of the interviews were transcribed and analysed. Presented quotations in Papers I-IV have been translated from Swedish into English by the first author in each paper.

Statistical analysis

No further statistical analysis than simple arithmetic has been performed in any of the Papers I-IV or in the thesis. Therefore, all calculations presented are described as semi-quantitative.

Literature review

All studies in this thesis were preceded by literature review in relevant fields of research. The literature review, with an interdisciplinary focus, was aimed at constructing a base of knowledge, or epistemology, for further analysis of acquired data. By pursuing this approach, an interdisciplinary analytical framework appeared, thus making it possible to draw conclusions from the different studies.

Paper I

A case study with a combined content analysis of 55 internal incident investigations from one Swedish healthcare provider organisation, and interviews with 22 commissioning bodies within the same organisation. A semi-quantitative and qualitative approach was used.

Paper II

A case study with a combined content analysis of 87 external incident investigations over a 20-year period from one regional supervisory authority office in Sweden, and interviews with 11 investigators from different supervisory authority offices. A semi-quantitative and qualitative approach was used.

Paper III

A case study with content analysis of three incident investigations, all concerning the same serious adverse event at a Swedish university hospital. A semi-quantitative and qualitative approach was used.

Paper IV

A case study with content analysis of the 90 most recent internal and external incident investigations from all 6 regional supervisory authority offices in Sweden. A semi-quantitative and qualitative approach was used.

Results

Each study conducted for this thesis had a different focus and aim, and as such contributed with specific results for further analysis. In the following sections, the main results from the appended Papers I-IV are presented separately and have been linguistically adjusted in accordance with the stated nomenclature in the Introduction chapter.

Paper I

Paper I addresses the first aim of the thesis. The study sought to identify the mechanisms that led to the implementation of targets for intervention presented in internal incident investigations at a Swedish university hospital. A sample of 55 completed incident investigations from the healthcare provider organisation's incident reporting system was compiled by staff at the office of the chief medical officer. Interviews with 22 commissioning bodies at the same organisation were conducted.

Content analysis of internal incident investigations

Thirty-nine of the 55 adverse events were subject to both an internal incident investigation by the healthcare provider organisation and an external incident investigation by the supervisory authority, suggesting that the severity of the adverse event in most of cases had exceeded a legislated threshold as described in the Introduction chapter. Implementations of targets for interventions from the external incident investigations were not analysed in this study.

The commissioning bodies of the 55 incident investigations were similarly distributed between the chief medical officers (n=29) and the clinical heads of departments (n=26).

The average number of team members per investigation was 2.7, and the duration of an investigation varied from 12 to 150 man-hours.

Among the 55 internal incident investigations, a total of 289 separate targets for intervention were identified, of which five targets could not be coded due to uncertainty concerning the meaning of the investigators' findings. Thus, 284 coded targets were included, and questions about 254 of them were asked during the interviews. The distribution of targets for intervention in the organisational hierarchy were as follows:

- Micro-organisational level n=175 (69%)
- Meso-organisational level n=72 (28%)
- Macro-organisational level n=7 (3%)

In the following, data divided into categories from the content analysis, together with data from interviews including some quotations by commissioning bodies, are presented to identify mechanisms important (or not) for the implementation of targets for intervention.

Organisational memory

The interviews revealed that the healthcare provider organisation, after commissioning the investigations, had replaced one chief medical officer. This chief medical officer was involved in 29 internal incident investigations, where one investigation could involve a number of clinical heads of department, all interviewed as well. The interviews also revealed that in 41 cases, regardless of the position of the commissioning body, the clinical heads of department had also been replaced. When asked: "Were you aware of this internal incident investigation with attention to the targets for intervention before this study?", the new chief medical officer was aware of 3/29 and the new clinical heads of department 6/41.

"One could have a system where the chief medical officer is a bit more meticulous and carries out a follow-up of the incident investigations to see what happened. It could be more of supervising position than it is today, but there is no time for that. That would probably be a part time job in itself or a substantially increased workload."

Overall, the respondents were concerned about the lack of knowledge regarding incident investigation reports completed before they assumed their current management position.

"I have not informed myself about past events, but this illustrates two important things, according to myself, that we use the results from the incident investigations too scantily and there is not enough follow-up. (...) But I think the most important matter is – these are historical cases and if one hasn't been clinically involved it's a

problem with commitment – that there is a follow-up on the targets for intervention so that something does happen...”

Nowhere at the healthcare provider organisation did we find a proper system for recording what actions had been taken following targets for intervention from the internal incident investigations. To varying degrees, the respondents had been able to find information on what actions had been taken. Actions had been taken for 45% of targets for intervention, actions had not been taken for 33% of targets for intervention, and the respondents were unable to tell whether or not actions had been taken for 22% of the targets for intervention.

“No, note that there isn’t a single one of these incident investigations I’ve known about. (...) I’ve talked to my assistant director, Dr (...), and to the member of staff responsible for the department’s incident reporting, nurse (...), to collect some information.”

The position of the commissioning body

Whether the commissioning body was a chief medical officer or clinical head of department did not seem to influence the process of implementation. When it was a chief medical officer, actions had been taken in 55/128 (43%) of completed internal incident investigations, and when it was a clinical head of department in 58/126 (46%) investigations.

“... and when many departments are involved in the adverse event it doesn’t work with just one clinical head of department being the commissioning body.. . But it’s also complicated to hand this over to the chief medical officer because it often tends to come to nothing when many actors are involved. Who takes the responsibility?”

Organisational level

In the cases where actions have been taken on targets for intervention (45 %), the interviews showed that a clear majority of these (73%), were at a micro-organisational level.

“Yes, actions have been taken. We’ve written a new document about this procedure, that I have right in front of me, so that I can remember everything that has been done... and regarding that matter we’ve put it on the checklist and the surgeon must ask before surgery whether procedures have been followed. (...) This was a very easy and straightforward thing to solve, one could say. There was one thing that had gone wrong and we tried to fix it... and others weren’t involved.”

The adverse event itself as a trigger for change

In 19 of 50 cases, the interviews showed that the adverse event had initiated organisational actions that were not presented as targets for intervention in the internal incident investigations. It seemed that the investigations in these cases worked more as an incentive for change, but on the initiative of management rather than the investigation team.

“So, you see, despite numerous meetings and brain storming back and forth I still believe that all of this was completely off target. (...) So, in this case we did this formalistic play, which was good, but then we resigned a bit. Thereafter, among the senior colleagues, we drew a pragmatic conclusion and went on. There was someone who quoted Shakespeare at the time; ‘Much ado about nothing’ or something like that...”

“... then some of us decided, within the department, to start a minor recurring training course. (...) You see, it often comes down to quite strange results if we aren’t part of the changing process. (...) And when the colleagues ‘over there’ gained some knowledge about this matter, things definitely got better, at least from my point of view. (...) Today, this way of working is almost self-driven, and I see it as a result completely independent of the investigation.”

Time spent by the investigation team

In 7 of 50 internal incident investigations it was not possible to determine the amount of time spent by the investigating team conducting the investigation. In 43 of 50 investigations, which had 217 targets for intervention, duration ranged from 12 to 150 man-hours. We grouped the different investigations by time spent on the investigation to examine if duration was a factor in implementation and at what level.

The investigations were of short duration (<40 h) (n=14), medium duration (41-80 h) (n=21) and long duration (>81 h) (n=8). We found that in the group with a short duration, actions had been taken on 25/55 targets for intervention, with 21/25 actions at the micro-organisational level. In the group with a medium duration, actions had been taken on 43/116 targets for intervention with 28/43 actions at the micro-organisational level, and in the long-duration group, actions had been taken on 24/46 targets for intervention with 20/24 actions at the micro-organisational level. The duration of the investigations differed by more than a factor 10, without time consumption seeming to influence the actions that were taken on presented targets for intervention, or at what level.

Paper II

Paper II addresses the second aim of the thesis. The study sought to understand how legislative and organisational change over a 20-year period had influenced the incident reporting system and its main actors. A sample of 87 external incident investigations from a regional supervisory authority office in Sweden was compiled by the Health and Social Care Inspectorate. Interviews with 11 investigators from different supervisory authority offices were conducted.

Content analysis of external incident investigations

In 26 of the 87 external incident investigations, the supervisory authority required that the healthcare provider organisation took further action for a total count of 34 more targets for intervention. Twenty-two of 34 actions were targeted at the micro-organisational level, 10 at the meso-organisational level, and 2 at the macro-organisational level. The relative pattern remained unchanged throughout all time-periods over the 20-year period studied. A specific follow-up plan was expressed in 9 of the 87 investigations. Also this pattern was virtually unchanged over the time periods.

In 5 of the 87 external incident investigations, the supervisory authority in their decision referred to previous investigations. In 4 of these 5 investigations, the investigating individual was the same individual in the present and previous investigation.

In the following, data from 11 interviews including some quotations from individual investigators are presented to identify factors important (or not) in the construction of patient safety as identified in the external incident investigations. This section is divided into themes of analysis in accordance with the questions asked in the semi-structured interviews.

When analysing expressions in decisions and possible changes over time the following observations were made. In the first period, the most common expression (12 of 23) in the closing comments of the report was: *“The National Board of Health and Welfare assumes that actions are taken...”*. In the second period, the most common expression (22 of 35) was, even when no further action was taken by the authority: *“A report on actions taken shall be sent to the National Board of Health and Welfare...”* with a time frame of approximately 4 to 6 weeks. After 2010, the most common expression (21 of 29) was *“The National Board of Health and Welfare (note: from June 2013 Health and Social Care Inspectorate) makes the assessment that the healthcare provider organisation has investigated the adverse event to a required extent”*.

Professional background

Nine of 10 respondents considered it advantageous that staff at the regional supervisory authority office had a professional background in healthcare because of their expertise in the field. One respondent saw this as a disadvantage because of the lack of judicial training. The remaining 11th respondent had predominantly done administrative work in different organisations, and saw this as an advantage.

“It requires quite a lot of competence to look into an investigation done by the healthcare provider organisation and it requires knowledge of the actual work (...) When I decide which one in my staff that will perform the investigation focus turns to whom has the best knowhow in this case... for example an orthopaedic case will be given to one of our investigators with a background in orthopaedics and so forth.”

The supervisory authority also seemed to promote a way of working in which investigators were even more specialised in terms of the fields that they work with.

“... and then one of the inspectors says, ‘That case is mine because I’ve recently had a couple of cases at that department!’ (...) This is quite a natural allocation of work depending on our backgrounds.”

Data suggested that the supervisory authority actively had recruited staff based on a principle that it should be able to assign investigators with actual experience of the field being investigated.

“... and when it comes to the need of employment we look closely to see what we lack in terms of competence. (...) Yes, almost only from the healthcare system...mostly nurses.”

Furthermore, data suggested that the combination of a background from the healthcare field and personal experience of performing investigations at the supervisory authority was needed.

“... I mean that it requires plenty of skill to analyse what the healthcare provider organisation presents... and this competence is something one has to gain by working, along with a knowledge of how things look out there. (...) This is something that we talk a lot about here at the office. Inside your head you make a judgement call... and to get there you need experience.”

Methodological support

The emphasis on micro-level actions observed in the content analysis made questions regarding the methodological support for investigation analysis

apparent. All 11 respondents claimed that the main knowledge of how the work gets done is merely by doing it without any certain methodology.

“No, this is something that one learns gradually while getting exposed to it... and, of course, discussing certain issues with senior colleagues occasionally.”

In 2010–11, the supervisory authority occasionally held internal mini-courses on supervision. A checklist has been introduced as an assessment tool to identify if all parts of the investigation process have been covered as stated by the supervisory authority. All newly employed investigators have a tutor during their first year. Two of the 11 respondents pointed out that they had taken academic courses in supervision. Still, there is an expressed lack of methodological support among all respondents.

“No, when I began there was nothing... there were a lot of ideas and I’ve seen documents from 1990 with visions for the authority and these documents could have been written today. (...) Sometimes one wonders why there hasn’t been any progress. It seems like many of these ideas and visions haven’t had an impact.”

“There is a lot to do here! We’ve done as we’ve always done it and nothing else has happened... and there is quite a need for developing methods of investigation and supervision... so, yes, there is a need for tools.”

Organisational memory

The content analysis showed that only 5 of 87 analyses referred to previous investigations, and that 4 of these 5 were written by the same investigator that had written the current investigations. This made it apparent for questions regarding the perceived need (or not) for an organisational memory of past cases. All 11 respondents reported that the case management system in use for the recognition of similar adverse events was working poorly.

“Oh, this system could be so much better... and then when it comes to trying to find specific previous investigations – it’s almost impossible! We can’t use all the archived investigations that actually exist because it’s so difficult to find them. And nothing is indexed in a way that is useful to me.”

One authority office was so dissatisfied working with a suboptimal case management system that they had improvised a new system.

“No, the authority doesn’t have a functioning case management system... We’ve built a minor homemade system here at the office just to keep some kind of track of what we are doing and perhaps give some support to the healthcare providers, but it’s very unprofessional and without any real structure.”

Several respondents referred to their own individual memory and experience of previous cases as their only tool to refer to previous cases:

“The most important thing is that I as an investigator remember the cases because we have a case management system that, to say the least, isn’t at its optimum when it comes to identifying similar adverse events.”

The respondents with the longest employee time expressed concerns of this sole tool and the future for the supervisory authority.

“In my own case there has, of course, been quite a few investigations that have passed by my desk through the years... and therefore, I personally know what has happened and have knowledge about different healthcare provider organisations’ history and things like that... If I would quit my successor would not know any of this!”

Changes in investigation process

All the respondents had been involved in at least one legislative change that supposedly could have had an impact on the investigation process. Given the question “Regarding incident investigations, how has the investigation process changed during your time at the authority?”, they were able to reflect freely, and subsequent questions were asked for confirmation. All in all, the 11 respondents identified a total of 25 changes in the investigation process. The identified changes were divided into groups of answers as follows:

- Less inspections/less field work/less contact with staff in the field – 7 of 11
- More office work – 5 of 11
- Standardised expressions/uniformity in language – 5 of 11
- Reduction in man-hours spent per investigation – 3 of 11
- More team-work/more contact with other inspectors – 2 of 11
- Increase in man-hours spent per investigation – 1 of 11
- A more confusing assignment – 1 of 11
- Increased waiting time for documents – 1 of 11

Follow-up and implementation

All respondents stated that the system for follow-up was insufficient. Nine of 11 described an absence of an established follow-up-system regarding decisions made.

“No, unfortunately not yet... but listen to this. There is one healthcare provider organisation in our region that recently has employed a nurse where their ambition is that she will look into all the specific decisions from our investigations. What she actually will do thereafter is to focus on if the healthcare provider organisation has yet implemented what has been decided... Do you see? They really want to do a follow-up of their own! This is beyond all quality improvement or patient safety culture improvement that anyone else has done before, as far as I know.”

Two of 11 respondents described that they do random follow-up when there is time, but that it ends with a personal visit to the healthcare provider organisation and nothing further.

“No, we don't have a system for this. We do follow-ups far too rarely. This is something that I personally hope we will do more of in the future...however, I've twice during the last six months done two un-notified inspections at departments and asked a couple of questions to staff regarding things that the healthcare provider organisation has stated as implemented and wondered if they can see that there has been a change. And then it shows that many things haven't changed. They might have heard about plans and visions. (...) Yes, I've talked with clinical heads of departments as well... the same problems exist year after year without any change.”

The role of the authority

Even if the judicial framing of an assigned task for investigators at the supervisory authority is regulated and explicit, the legislative changes over the years have not changed the officially stated role of being both “auditing” and “supportive”. Bearing this in mind, we asked the respondents to reflect on their personal view of the assigned task. The question was openly asked; hence we got a diverse set of answers. We grouped the answers as belonging to an “auditing perspective”, a “supportive perspective” or a “system perspective”.

Five of 11 respondents expressed what we labelled as an “auditing perspective”, i.e. a perspective where the investigator emphasises his or her role as an external, and clearly separated from the healthcare provider organisation, auditing body assigned the task to improve the system by an unbiased expert judgement:

“This is what: to put forward decisions that are understandable, standing on a solid medical and judicial basis without the involvement of any personal opinion... that

we can make the healthcare system safer because we create the lessons, not only lecturing. That's how I look upon my assigned role!"

Three respondents expressed their role to be more of a support function than an auditor in their relation to the healthcare provider organisation. This "supportive perspective" is one in which the inspector emphasises the dialogue between authority and healthcare provider organisation as a mean to contribute to patient safety initiatives:

"It's in the personal meeting with the healthcare provider organisation, the clinical heads of department and politicians that I can change things... and then contribute to the improvement of healthcare."

Three respondents discussed their own role in terms of reflections focused on how to make the system as a whole function in the most progressive way. Since this perspective is one focusing on the interactions and relations within the system rather than any specific role, we have labelled this perspective the "system perspective":

"Yes, here I feel a divided loyalty both as it is and what I would like it to be, so to speak... and I would like to work more with the overall development of the meaning of uniformity, quality improvement... and things like that... one could say development of the methodology... but the days are just filled with being a decision-maker. (...) To me it's not just reaching uniformity. The decision should end up at the right level."

Paper III

Paper III addresses the third aim of the thesis. The study explored how three different public investigatory bodies respectively, with different purposes of analysis and different resources available, constructed and understood the causal factors leading up to the same adverse event at a Swedish university hospital. The adverse event in focus was at the time the only adverse event in Swedish healthcare that had been investigated by three different investigatory bodies at approximately the same time.

The adverse event

A severely ill patient with cardiac valve disease was admitted to the Department of Thoracic Surgery at a Swedish university hospital. The patient was scheduled for surgery to receive a mechanical valve-prosthesis. During the valve-replacement

procedure on 12 October 2010, an external pacemaker was placed to be able to stimulate the heart postoperatively, if necessary. After surgery, the patient was cared for in the Thoracic Intensive Care Unit. On the first post-operative day, the patient had an episode with grave cardiac arrhythmia and underwent successful cardiopulmonary resuscitation, otherwise the condition of the patient improved as expected. The stay in the Thoracic Intensive Care Unit lasted in total 4 days, and plans were made to transfer the patient to a regular ward on the 17 October. In the evening of the 16th, a shortage of beds was upcoming at the unit. A decision was made by the doctors on call on the Thoracic Intensive Care Unit and the Cardiology Intensive Care Unit to transfer the patient to the Cardiology Intensive Care Unit as a so-called satellite patient. This meant that care was given by staff at the Cardiology Intensive Care Unit, but the patient was formally still under medical supervision by the Thoracic Intensive Care Unit. On arrival at the Cardiology Intensive Care Unit, a monitoring device for detection of arrhythmia was connected to the patient. At a routine check by a nurse during the night shift the patient was found lifeless in bed. Resuscitation was attempted without any result, and the patient was declared dead. An autopsy was performed a couple of days later.

Based on a content analysis of the three different incident investigations of this adverse event, the study defined three main themes of adverse event construction and three alternative pathways that could have better aligned the investigations with contemporary safety science. In the following, themes supported by using some significant statements from the investigations, and a presentation of the alternative pathways, are presented.

Theme one: Immediate temporal proximity

The first theme is the construction(s) of the adverse event as one that occurred in the adverse event's immediate temporal proximity.

The graphic layout from the healthcare provider organisation's investigation defines the time span investigated as from the day of surgery until the adverse event; in total 6 days. The most extensive part of the investigation, where broken barriers and causal factors are identified, is from the transfer from the Thoracic Intensive Care Unit to the Cardiology Intensive Care Unit until the adverse event, with 9 of 13 boxes in the graphic layout covering this 6-hour period. This converts to 2½ of the 3 pages in the report where the event is described, and where all 4 causal factors are identified, thus in the immediate temporal proximity of the event.

The legislated role of the National Board of Health and Welfare is not to conduct its own investigation, as much as it is to review and comment on the investigation

process of the healthcare provider organisation. Consequently, the causal map of the National Board of Health and Welfare regarding the timeline is identical to the causal map of the healthcare provider organisation.

The Swedish Accident Investigation Authority's description of the adverse event is a time line that starts on the day the patient is admitted to the hospital and ends at the autopsy, thus approximately 10 days. When describing and framing the adverse event, 3½ of 4½ pages in the report comment on the time-period of approximately 6 hours from the transfer from the Thoracic Intensive Care Unit until the adverse event in the Cardiology Intensive Care Unit. This is equivalent to the time-period where all 4 causal factors are identified, thus in the event's immediate proximity.

Theme two: Immediate spatial proximity

The second theme relates to how all three investigations locate the causal factors as occurring in the patient's immediate spatial proximity.

Of the presented causal factors in the different investigations, the first one presented in the healthcare provider organisation's report and the Swedish Accident Investigation Authority's report are identical: failure of hand-over between staff (and departments). We coded this as a causal factor at a meso-organisational level.

“Nurse 2 on the night shift received the handwritten piece of paper with information of the Thoracic Intensive Care Unit patient from nurse 1 on the evening shift. Since nurse 2 on the night shift was unable to take immediate care of the patient, she handed over the responsibility for this patient, and all her patients, including the handwritten notes to nurse 3 on the night shift. Nurse 3 on the night shift knew nothing about the patient apart from the handwritten notes she had received.”

A system with so called satellite patients is an informal, but well-known, routine in the Swedish healthcare system to cope with recurring shortages of beds in different departments, intensive care units and wards. The core message of the second presented causal factor is also identical in the healthcare provider organisation's investigation and the Swedish Accident Investigation Authority's: the absence of a formal routine and distinct responsibilities within the satellite system. We coded this as a causal factor at a meso-organisational level.

“When there was a shortage of beds at the Thoracic Intensive Care Unit during the evening on the fourth postoperative day, it was decided to transfer the patient temporarily over night to the Cardiology Intensive Care Unit for cardiac monitoring, before moving to a ward at the thoracic department the following day.

A shortage of beds is unfortunately a recurring phenomenon in most organisations that involve thoracic surgery because of sudden emergency cases.”

Shortage of staff is a reappearing and well-known problem in Swedish healthcare. In the healthcare provider organisation’s investigation, this problem is identified and presented as the third causal factor: not sufficiently enough nurses on the night shift. The causal factor is also supported, yet not stated, in the reports of the other investigations. There is no discussion in any of the investigations regarding shortage of staff being a problem in general and thus, this was coded as a causal factor at a micro-organisational level. It should be noted that the staff level on the ward was normal during the night when the adverse event took place.

“When assistant nurse 1 on the evening shift was about to connect the patient to the cardiac monitoring device she was suddenly interrupted by the janitor who asked for help to transfer another patient going for an examination at the department of neuroradiology.”

Training and competence of staff is crucial for any healthcare provider organisation with the ambition of maintaining safe healthcare. The fourth presented causal factor by the healthcare provider organisation is merely identical to the third causal factor presented by the Swedish Accident Investigation Authority, the core message being: routines for staff regarding the cardiac monitoring system and its interpretation. This was coded as a causal factor at a micro-organisational level.

“There is a lack of knowledge within staff regarding how the cardiac monitoring functions and interpretation of monitoring data including how a temporary pacemaker is used for treatment. Training of newly employed nurses and assistant nurses is continuously ongoing within the department, but there is no follow-up with repetition and testing over time.”

An intensive care unit can be a stressful workplace, a dynamic workload constantly changing, different alarms from different devices and sudden interruptions of work because of unforeseen events. Therefore, the physical premises where the work is done and the location of control centres is of importance to maintain standard of care and staff’s ability to work. The fourth presented causal factor by the Swedish Accident Investigation Authority identifies this: the staff’s feasibility of giving surveillance to the patient. This was coded as a causal factor at a micro-organisational level.

“When the Swedish Accident Investigation Authority performed individual interviews approximately half a year after the adverse event, staff said that no alarms had been detected from the patient. However, from the manufacturer’s files one can find that four ‘red alarms’ actively have been silenced from the control centre...”

Theme three: The event as a deviation from norm

The third theme focuses on the underlying conviction that the adverse event represents a deviation from a safety norm.

A number of statements, with the core message that the adverse event represents a deviation from a safety norm were identified. The system could and should adhere to this safety norm through means of management structure and staff compliance. All three investigations shared the same conception of an underlying model as to why adverse events occur; a linear chain of events from a human root cause.

For all three investigations, analysis shows that work performance variability, i.e. degrees of freedom in how to conduct work at the staff level, is constructed as a threat to patient safety. Inherent in this idea is that there is one best practice for each task, and that any deviation from such best practice represents a violation and calls for increased formal structuring of work.

“We look upon the event seriously and claim that the patient in this case has not been treated according to standard procedures during transfer to the Cardiology Intensive Care Unit and during the stay at the Cardiology Intensive Care Unit.”

Inherent in the idea of the incident representing a deviation in an inherently safe (if only complying with the norm) system, is also the dualistic search for causal factors at either the level of unsafe human behaviour or malfunctioning technology. Consequently, the potentially complex interaction between humans and technology is not discussed at all in any of the three reports. The Swedish Accident Investigation Authority’s investigation identifies that during the period 2006 to 2012, there has been 17 reported adverse events into the hospital’s incident reporting system related to “cardiac monitoring” in this Cardiology Intensive Care Unit. Instead of constructing this as a problem of human-machine configuration and interaction, the investigations are satisfied with concluding that no defects have been found in the monitoring system after examination by the manufacturer. The Swedish Accident Investigation Authority investigation notes that the full Swedish instruction manual comprises 366 written pages.

“No faults have been recognised in the technical equipment according to the manufacturer, meaning it has worked as intended.”

The reports acknowledge how staff was coping with time pressure, a perceived shortage of staff and an increased workload during the work-shift. However, rather than analysing staff behaviour as a product of this environment, all three reports make the analytical choice to fundamentally attribute the unfolding of events to staff behaviour rather than the work environment. Again, the idea is that staff

members could, and should, work according to a safety norm that would not have allowed the adverse event to take place.

“In this case the impression is that formal handover was done too quickly. There was not even time to give the compulsory oral report and instead a handwritten piece of paper with notes on a new patient was handed over.”

Alternative pathway one: Addressing the macro-organisational level

The focus of the first alternative pathway is the possibility for an investigation to address the macro level of the Swedish healthcare system.

The two identified causal factors at the meso-organisational level are identical, as regards the core of interest. First, there was a failure in communication between staff and the intensive care units when the patient was transferred. Second, there were insufficient guidelines when transferring a patient between the two current intensive care units. An adverse event like this gives opportunity to formulate more systemic explanations of adverse events, where one of many additional questions (see Paper III), targeted at the macro-organisational level, includes:

What makes an informal routine with satellite patients a reasonable solution?

Alternative pathway two: The possibility to study normal work

The second alternative pathway relates to the possibility of studying normal work.

In a seemingly dualistic manner none of the investigations found any defects of the matter (the monitoring system), and hence looked for the defects of the mind (human behaviour). Both the healthcare provider organisation and the National Board of Health and Welfare present a similar scenario at the micro-organisational level, with inadequate technical skill of staff in cardiac monitoring and non-adherence to procedures in surveillance of the monitoring system. The Swedish Accident Investigation Authority, with vastly more resources put into their investigation, presents a similar causal construction. The authority recognises numerous reported adverse events from the past that focus on human-machine interaction. Still, their report focuses mainly on insufficient management and controlling of staff. We see this as a lost opportunity to analyse how human and machine actors are configured in their working environment. An analysis of the implementation of, and relation to, technological devices, interfaces and functions could reveal sources of brittleness and/or resilience not only in this hospital, but perhaps the healthcare system as a whole. The second alternative pathway includes, as one of many (see Paper III), the following question:

How can cognitive work analysis become a part of the process to implement new technology to healthcare working environments?

Alternative pathway three: The possibility to acknowledge and appreciate human adaptive capacity

The third alternative pathway deals with the possibility of an investigation to acknowledge and appreciate human adaptive capacity.

In all three investigations, the individuals fail to adhere to safety standards and norms. In none of the investigations, adaptive human behaviour is regarded as a valuable resource with the ability to adjust and adapt to risky, messy and complex situations. Instead, humans are constructed as a problem to manage and control. Encouragement should be made to an analytical shift of focus into one that acknowledges how human action and agency is a vital resource to harness in complex and variable working environments, and how human adaptive capacity sometimes (perhaps in this case?) can work to “hide” system brittleness. Thereby, this event offers the possibility to ask multiple questions (see Paper III), one being the following:

Do staff members at the involved units believe that organisational levels higher in the hierarchy understand the difference between work-as-imagined and work-as-done?

Paper IV

Paper IV addresses the fourth aim of the thesis. The study sought to understand with what underlying safety ontology adverse events in Swedish healthcare are investigated. A sample of 90 recently conducted internal and external incident investigations, all performed in approximately the same time-period and covering all 6 regional supervisory authority offices in Sweden, was compiled by the Health and Social Care Inspectorate.

Internal incident investigations

In the 90 investigations analysed, a total of 313 targets for intervention were identified. The total distribution (%) of these targets was as follows:

- Micro-organisational level n=263 (84%)
- Meso-organisational level n=48 (15.3%)
- Macro-organisational level n=2 (0.7%)

On examining the nature of investigations, 43 of 90 had the character of a “short internal report”, compared to the more traditional “internal incident investigation” done by an analysis team. The number of targets for intervention was higher in the group of internal incident investigations, but the relative distribution of targets for intervention was similar in the two groups:

Short internal report:

- Micro-organisational level n=86 (86%)
- Meso-organisational level n=13 (13%)
- Macro-organisational level n=1 (1%)

Internal incident investigation:

- Micro-organisational level n=177 (83.1%)
- Meso-organisational level n=35 (16.4%)
- Macro-organisational level n=1 (0.5%)

In 5 of 90 investigations, no targets for intervention were presented by the healthcare provider organisation. In these 5 investigations, the supervisory authority closed the case with no further intention.

In 16 of 90 investigations, the chief medical officer recognised that “similar events” had occurred within the healthcare provider organisation. In 1 of these 16 investigations, there was a follow-up plan by the supervisory authority. In the remaining 15 investigations, the supervisory authority closed the case.

In 8 of 90 investigations, the healthcare provider organisation, on its own initiative, tried to improve standards of patient safety through system intervention, either using lateral distribution of knowledge at a meso- and macro-organisational level, or by performing a risk analysis because of acquired knowledge from the investigation. In none of the 8 investigations did the supervisory authority do anything further.

External incident investigations

In 70 of 90 investigations, the supervisory authority closed the case without further action after reviewing the internal incident investigation. In the following investigations, one or more action(s) were taken by the supervisory authority:

- In 15 of 90 the supervisory authority called for a completion of the investigation, and thereafter closed the case in 13 of them. The 2 remaining were planned for follow-up or a site visit.
- In 3 of 90 there was a plan for follow-up
- In 3 of 90 a “new supervisory case” was opened for a separate investigation
- In 2 of 90 a site visit took place before decision

In one regional supervisory authority office, examination revealed the following from one individual (=one head of unit):

- 5 of 15 calls for completion came from this individual
- 2 of 3 plans for follow-up came from this individual
- 1 of 3 “new supervisory case” was created by this individual
- 2 of 2 site visits before decision were called upon by this individual

In the following two sections, a sample of quotations from the investigations is presented for clarification of the results.

Examples of targets for intervention

The micro-organisational level:

“A review at the department regarding what kind of straps that are in use to secure patients on an operating table will be performed.”

The meso-organisational level:

“Develop a routine within the organisation to ensure which department or unit that is responsible for the follow-up of newly diagnosed prostate cancer.”

The macro-organisational level:

“A regional programme for all healthcare provider organisations will be produced during 2016 for this group of diagnoses with the aim of shortening the delay for a group of patients.”

Examples of decisions from the Health and Social Care Inspectorate

“The Health and Social Care Inspectorate finds that the healthcare provider organisation has fulfilled its demands of reporting and investigating. The Health and Social Care Inspectorate closes the case.”

“The Health and Social Care Inspectorate closes the case and will not take any further action.”

“The Health and Social Care Inspectorate finds that the healthcare provider organisation has not fulfilled its demands of investigating since remains of flaws are noticed and actions have not been taken. The Health and Social Care Inspectorate closes this case and opens a ‘new supervisory case’ to audit the healthcare provider organisation’s patient safety work.”

Discussion

“How do we cultivate the art of finding what we’re not seeking?”

Quote from Pagan Kennedy, New York Times, 2 January, 2016

Given the aims of this thesis and its interdisciplinary nature, this chapter presents a synthesis of the analysis made in each of the studies conducted, and thereby an attempt to contribute to an understanding of how the Swedish incident reporting system is functioning. The chapter is divided into four separate sections.

The adverse event causation model

In principle, an incident investigation necessitates an adverse event causation model to be able to pursue a structured investigatory process regarding analysis, thereby identifying targets for intervention. Below follows a brief presentation of the major historical cornerstones, partly using a categorisation from Lundberg et al, on adverse event causation with models used [42] and thereafter how these can be applied to the findings in Papers I-IV.

The earliest modern school of thought in adverse event causation belongs to Heinrich in the 1930’s and his ideas from industrial accidents as a simple linear model with a chain of events [43]. These ideas evolved from Newton’s reductionist theory from the 17th century on cause and effect; that incidents were always triggered by root causes in direct relationship. This assumes that the functioning of a system depends on its constituent parts. Therefore, finding the root cause and fixing it meant that the likelihood of future similar incidents would diminish. With these ideas came also the notion of root causes being one of two, either mechanical or human.

In the late 1940’s, Gordon introduced the epidemiological model, also categorised as a complex linear model, with ideas from incidents in medicine and the military [44]. His theory was that incidents occur because of interactions between certain factors; humans, technology and environment. The theory does not present a root

cause, but instead the interactions that occur give reason to believe that an incident will emerge. A few decades later, in the late 1970's, Turner incorporated the ideas of Gordon and Heinrich into how adverse event causation needs to be constructed through observation of communication and culture over longer periods of time, where work done to its nature is harmless under normal circumstances, but suddenly becomes hazardous under other circumstances [45]. This was a model that considered the causes behind large-scale industrial disasters, and involved the interaction of technology and a vulnerable organisational structure. This school of thought created a platform for Reason's model in 1990, where he presented ideas of barriers, or layers of defence, as key elements in adverse event causation and prevention [25]. The model was a result of a strong collaboration between research (Reason, psychologist) and industry (Wreathall, engineer), and the simple graphical design could be an explanation to its global success in various types of organisations [46]. All barriers carry dynamic holes or flaws that represent an organisational weakness. When circumstances coincide, and such holes are aligned in a way that organisational weakness is exposed, an adverse event occurs. The concept, mainly from Turner, that organisational learning and cultural environment are at the heart of adverse event causation was further developed by Vaughan in 1996 when introducing "normalisation of deviance" as being an organisation's gradual acceptance of risk over time if deviation from standard routine becomes a "normalised" pattern in work performance [47]. Vaughan's theories from investigating NASA's (National Aeronautics and Space Administration) loss of space shuttle Challenger would soon be followed by Snook's analysis of a shoot-down incident over northern Iraq that describes the slow "practical drift" of an organisation that uncouples practice from formal routine [48].

Alongside these mentioned models, reactions to reductionist assumptions of explaining system function and their flaws by examining the constituent components, slowly grew stronger first in the fields of mathematics and meteorology, and later in biology and physics, from the late 19th century and forward [49]. The reactions had in common that system behaviour is not always predictable, as for example in thermodynamics, and introduced the notion of "open systems", where events unfold in a non-linear way as a distinction from descriptions of "closed systems" with linear events. In 1969, Rasmussen made the distinction between routine and non-routine operations as an important mechanism in adverse event causation [50]. He presented the idea of failure as a consequence of human operators' need to adjust procedures, taking many parameters into consideration in a non-routine situation. Such reactions and ideas turned into a scientific movement and were eventually defined through a number of principles that together were described as "complexity theory". Even if Rasmussen had argued in terms of complexity, and Turner earlier had touched on the notion,

Perrow in 1984 introduced the pioneering ideas of complexity in an adverse event causation model where coupled components in a system always hold a catastrophic potential [51]. The structural components in a system influence adverse event causation by gradually increasing the risk of incidents when the number of components grows, including the non-linear interactions between them in the coupled system. This was, again, a model that came from studying large-scale industrial disasters and brought to attention the multitude of interactions as being complex and the unavoidable incident that eventually would occur. In the 1990's, Rasmussen, with a global conceptualisation on cognition, introduced the ideas of dynamics and hierarchies as essential factors when theorising on adverse events from a wider socio-technical perspective [52, 53]. The theory presented a model of an organisation that constantly fluctuates in a non-linear way to obtain equilibrium within the outer boundaries of acceptable work load, acceptable efficiency and acceptable safety, but where pressures and goal conflicts make crossings of boundaries possible, and as a result adverse events occur. Followers of Rasmussen later introduced the notion of resilience, where adaption and variability of components are crucial factors for sustaining operations when the organisation is put under unexpected stress or threat [54]. When adverse events occur, the organisation should not propagate more control or managerial governance, but convert focus to the creation of increased adaptive capacity, and seek sources of enhanced variability to cope with the complex environment in which it exists [55, 56, 57].

Added together, the findings in Papers I-IV give reason to assume that the incident reporting system, as judged by its function, is equipped with a micro-organisational level understanding of adverse events that rarely goes further than the earliest schools of thought on adverse event causation.

Firstly, the organisational level: at which level are the causal factors constructed?; to where are the targets for intervention aimed?; and which actions are eventually taken? In Paper III much attention was brought to "where are" causal factors identified using three different investigations of the same adverse event as a model. All investigations constructed the underlying causal factors in both close temporal and close spatial proximity to the adverse event, and several times the causal factors were identical and related to human behaviour. In Papers I, II and IV, parts of content analyses involved the construction of targets for intervention, both by the healthcare provider organisation and the supervisory authority. Studying this construction both locally, over time and nationwide ended up with the same interpretation; the targets for interventions were most predominantly aimed toward the micro-organisational level of the organisation. In Paper I, adding results from the content analysis and the interview study gave a picture of which actions that had been taken. This showed that a clear majority of actions taken were at the micro-organisational level.

Secondly, the resources spent on the investigatory process. At a local level in Paper I, only a limited difference in organisational level could be noticed on actions taken, even when time spent by the investigatory team increased more than tenfold. In Paper III, studying the same adverse event from the perspective of three different investigations, little difference in organisational level could be noticed in the construction of underlying causal factors. The resource span differed from 4 months and a 14-page report to 33 months and an 81-page report, leaving financial issues aside.

Thirdly, the professional background of the investigator. From the interview study in Paper II, it is clear that frontline investigators and the decision-making heads of unit at the supervisory authority are recruited from the healthcare field, equivalent to the recruitment process noticed in other organisations [58]. They rely on their former professional training from that time-period, and this experience is viewed upon as advantageous in authority work performance. From the content analysis in Paper III, the major difference was the constellation of teams, comparing the Swedish Accident Investigation Authority with the other two teams. The Swedish Accident Investigation Authority team had the widest academic background, with team members from outside the medical field. Still, being the first and only case in medicine ever investigated by this authority, the explicit questions eventually asked during the investigation were identical to the questions raised by the other investigatory teams.

Fourthly, the methodological support introduced in 2005 and spread nationwide to healthcare provider organisations within the public healthcare system. In the manual, reference on methodological support is made to Reason and his ideas of adverse event causation, known as the “Swiss Cheese Model” [25]. However, using the support in the simplest of ways, without identifying e.g. organisational barriers with flaws, the model becomes a simple linear model. In Paper IV, the investigators at the healthcare provider organisations seem to have started performing more condensed and shorter investigations, but still with causal factors and targets for interventions found at the same micro-organisational level, and thereby implying an understanding of the essence in adverse event causation.

The organisational memory

Learning can be described as a phenomenon of discovery, retention and exploitation of stored knowledge [59]. In safety improvement work, learning from past events, minor adverse events or large-scale disasters, has for decades been an essential component. Such learning can be dealt with in numerous ways. Different organisations approach learning through different methods; analysis and

categorisation of statistics on adverse events, environmental studies of others' adverse events, or performing incident investigations after one's own adverse events. In all these cases, the overall goal with the learning process is the creation of an organisational memory that uses the acquired learning as a basis for present work procedures, and as a tool for change and improvement.

What is organisational memory? For this discussion, the focus of interest is only what can be described as the long-term (or sustainable) memory of an organisation, thus what is remembered over a longer a period. It can be said that science has widely accepted a taxonomy that makes a distinction between two main classes of long-term memory [60, 61, 62, 63]; a procedural memory (or implicit, or unconscious) that has to do with skills and routines, and a declarative (or explicit, or conscious) memory that has to do with facts or conceptualising something. The declarative memory can be divided further into a semantic memory that includes general knowledge, as opposed to the episodic memory that is distinctly personal and has to do with subjective recollection of personal knowledge. The last of the mentioned main classes implies that subjective forgetting is also an aspect of memory. Cilliers argues that information that is not used "fades away", but the more the information is used, the stronger the memory will become [64].

Understanding the concept "organisational memory", as introduced in the 1970–80s, is however more diverged, since different schools of thought argue in different ways, from Argyris and Schon [65] who question the actual existence of the expression saying that organisations are not capable of "remembering" and claim that organisations work with continuous re-evaluation of behaviours and routines [66], to Sandelands and Stablein [67] who argue more in favour of its existence by saying that "organisations are mental entities capable of thought", or Weick and Gilfillan [68] who state "an organisation may preserve knowledge of the past even when key organisational members leave", based on their laboratory studies. In 1994, also after conducting laboratory studies, Cohen and Bacdayan claim that the procedural memory is where organisational routines are actually stored [69]. Models have been presented that grasp the concept of organisational memory; for example, the ideas of Walsh and Ungson [70] with retention of knowledge in a number of "stored bins", including for example the individuals' bin, the culture bin and the structure bin. Moorman and Miner [59] described the expressions "procedural" and "declarative" for an organisational memory when discussing the template from where organisations improvise on actions taken. Furthermore Mahler, after analysis of NASA's two major space shuttle accidents in 1986 and 2003, looks upon organisational memory as a collection of processes used by the organisation to improve its structure in which individuals learn [71]. Whatever model preferred, a combination of both individual memory and

corporate memory, within a defined entity or organisation, are characteristic features of organisational memory.

Aspects of an organisation's learning are key elements in the previously described adverse event causation models, from the earliest simple linear systems [43] to the more recent model of resilience [72]. Furthermore, the recommendations in the report *To Err is Human: Building a Safer Health System* stated the importance of "learning from errors" by using incident reporting systems [8], and the report in 2000 from the British Department of Health *An organisation with a memory: learning from adverse events in the NHS* [10] had a strong focus on learning from systems thinking. The Swedish legislative changes in 2011 [30] and 2013 [32] both emphasised the responsibility of the healthcare provider organisation "to learn" from adverse events. The aim of this thesis does not include having an academic standpoint on taxonomy in the field of research regarding learning, here described as organisational memory, nor does it include a discussion on preferred model. Therefore, the analytical starting point for this thesis was to understand if and how signs of an organisational memory, more than the subjective human component, could be identified somewhere among the main actors in the Swedish incident reporting system.

Added together, the findings in Papers I-IV give reason to believe that an organisational memory regarding learning from adverse events in the incident reporting system technically exists. However, this learning is local, dissemination is very weak, and aspects of forgetting are substantial.

Firstly, the strong dependency of the system on individual memory. Both the healthcare provider organisation and the supervisory authority showed obvious signs of vulnerability regarding memory, as shown in Papers I and II. When management individuals changed, both at the healthcare provider organisation and the supervisory authority, the stored knowledge also disappeared. Case managements systems functioned so poorly that examples of improvised local systems felt superior. Even with time to prepare and check documents, many investigations were unheard of, and many suggested targets for interventions from investigations that were unknown to the main actors.

Secondly, using files and archives as an essential component of organisational memory. The interviews in Paper I showed only weak signs of disseminated learning when using files and archives to show which actions had been taken or not. In Paper III, the investigators studying files from previous adverse events at the department in focus, noticed a large volume of closely related adverse events and used this information for arguments of more governance and control, not as a problem with absence of disseminated learning.

Thirdly, the missed opportunity to use established routes for communication to construct organisational memory. In Paper IV, recurrent signs of poor communication are seen when main actors occasionally signal awareness of system weakness, but notice is neither taken nor acted upon, and the case is closed.

The purpose of investigation

The most obvious purpose for performing incident investigations is the act of repairing and learning. Both these acts are of solid value, and mostly unquestioned, to stakeholders within the system. Their implications have been discussed in the previous sections, however the act of learning seems very weak in the studies presented and the act of repairing seems to nearly bypass two of three organisational levels. Therefore, other purposes need to be identified, that bring about an understanding of why the continuity of the investigation process is sustained. These purposes are to their nature relatively more abstract, and the interpretations made from Papers I-IV are from actions taken (or not taken) by the main actors.

Since legislation should reflect society it can be argued, that incident investigations should be performed when legislation demand this, whatever society's reasons may be for such a demand. Thus, from a political and judicial perspective, it appears to make sense to investigate a matter when something *has gone wrong*, and thereby comply with societal demands. Perrow and Sagan argue that such political sense-making is an aspect of investigating adverse events [51, 73]. Hence, lawmakers have framed the investigation process, as well as the main actors' role in the system, including the obligations concerning it. The message sent, is that actions should be taken when messy situations occur, and learning should take place to prevent something similar happening again once things have been repaired. But again, are there other understandable purposes that explain *why* the processes of investigation continue and as such, seemingly unquestioned, when learning remains weak and repeated repairing seldom takes place at more than one organisational level?

Concerns about the purposes of incident investigations have been raised in the past. Fischhoff argues that, in retrospect, we attempt to make sense of what we know about the adverse event, but are unaware of the effect that "outcome knowledge" has on our perceptions [74]. The investigation aims at reconstructing what happened and why it happened, in search for explanations that make sense and present preventive actions to a commissioning body and other stakeholders, but does this with hindsight perceptions and are therefore of questionable value. Healy argues in favour of increased "epistemological pluralism" with multiple

voices heard to guide a choice between different pathways as opposed to a traditional solitary way [75]. Also, Sharpe emphasises the need for incident investigations to seek alternate directions forward, not having a backward-looking approach, through more interdisciplinary work and ethical considerations to broaden the perspectives [76].

However, the studies conducted for this thesis, have identified two separate purposes that present explanatory mechanisms to *why* the investigation processes continue regardless of learnings done (or not done) or repairs made (or not made). Both purposes can be regarded as aspects of human rationality and humans in organisations. A need for rational understanding of circumstances seems deep-rooted in human behaviour, especially when things *have gone wrong*. This understanding, or sense-making, needs a plausible structure that subsequently becomes part of the healing process. The two purposes can be summarised as a) maintaining a bureaucratic investigation procedure and b) fulfilment of societal psychological purposes, where Dekker argues in favour of both [77, 78, 79]. First, he argues that bureaucratic infrastructure has increased “at a distance from the operation”, driven by factors such as changes in legislation and changes in liability [77]. Furthermore, the internal safety bureaucracies drive the activities and relationships among safety professionals including a reinforcement of personal beliefs concerning safety management [78]. Second, he suggests that the entire process is an exercise that fulfils four psychological purposes: the epistemological purpose that establishes what happened through an adverse event causation model, the preventive purpose that identifies targets for intervention, the moral purpose that draws the boundaries of safety standards and norms for a profession or a healthcare system, and the existential purpose that helps a healthcare system and those suffering to cope with suffering after harm from an adverse event [79]. Using such a model of purposes, the processes can remain unquestioned while different stakeholders in the system are embraced; those seeking accountability and those seeking credibility.

Added together, the findings in Papers I-IV give reason to believe that the incident reporting system continuously legitimises its bureaucratic and psychological status.

Firstly, the strong signs of explaining what happened and identifying future prevention. All of Papers I-IV identify descriptions of how events have unfolded and ways to prevent similar events from happening again. These signs are interpreted as a fulfilment of both the epistemological and preventive purposes.

Secondly, the strong signs of “closure of cases”. In Papers II and IV, the authority closes a substantial amount of cases without further interaction, which seems to be guided by the need to legitimise its bureaucratic functioning (and production) by closing its opened cases. In Paper II, follow-up by the authority is identified as a

very rare procedure. In Paper IV, closure takes place even when no causal factors have been found or when signals of system weakness are presented. In Paper II, a trend is identified in the authority work process with less inspection and more office work over time. In Paper IV, there are signs of shorter reports and fewer investigators at the different healthcare provider organisations when conducting investigations. All these signs are interpreted as the process being substantially more important than the investigation outcome and a fulfilment of the existential purpose for investigation.

Thirdly, the linguistic expressions used. In Papers II, III and IV, examples are shown of widely used expressions that send messages from the reports of completed investigations that certain boundaries regarding safety standards and norms have been violated. These signs are interpreted as an act of drawing moral boundaries around professions; thus fulfilment of the moral purpose.

Fourthly, the trend over time in authority work performance. In Paper II, legislation and obligations change during a 20-year period and, along with it, how work is done. During this time the working process gradually changes to more uniformity of language, more office work, less field-work and less contact with staff at the healthcare provider organisation. Also, “auditing” is the most common expression used by investigators describing their personal role on duty. These are signs interpreted as an increase in the bureaucratic infrastructure “at a distance from the operation”.

A paradigm

Using the term *paradigm* as an analytical standpoint might seem pretentious when Thomas Kuhn with his publication of *The Structure of Scientific Revolutions* in 1962 [80] labelled a paradigm as, in summary and in other words, being an evolutionary developed pattern of scientific problem-solving that has accumulated through “normal science”, and therefore exists as a norm with consensus in the scientific community regarding relevant questions asked, relevant methods used, and relevant interpretations made. Such a system of norms can shift over time when the relevance in argumentation and conclusions reach a shifting point that sparks an upheaval, sometimes a crisis and even revolutions. It could partly be argued that other terms can describe the findings in this thesis accurately, for example, discourse or ontology, which have been used in Papers I-IV. Nevertheless, from a perspective *inside* the healthcare system, paradigm still seems more appropriate to use when summarising the analyses from *all* the studies presented and put in relation to the context from which they have arisen; a movement set in motion by alarming historical facts, a methodology with the

relevant questions presented through implementation of a manual for causation analysis, and a national consensus by key stakeholders of the healthcare system to focus and attend to the issue of investigation for improvement of patient safety and quality of care. Even if Kuhn's ideas were strictly based on scientific evolution, and the findings in this thesis are more socio-technical in nature, the studies presented suggest that there is a similar cognitive framework of questions, methods and interpretations made, based on certain norms accepted by the patient safety community, keeping the paradigm intact. In the following, a discussion that elaborates on the claim of such a paradigm is presented.

The 1991 publication of the *Harvard Medical Practice Study* was a serious awakening call on the magnitude of adverse events in the healthcare field [6]. Using the Harvard Medical Practice Study report as a cornerstone for argumentation, the Institute of Medicine launched the report *To Err is Human: Building a Safer Health System* with clear recommendations addressing the importance of incident reporting systems in healthcare [8]. American institutions were soon to embrace and present a methodology on adverse event causation for investigatory support, with the implication that it could be used as a methodological backbone regardless of adverse event. The alarming findings from 1991, and the impact these had on major American institutions in the healthcare system, highly influenced the Swedish patient safety community and lawmakers to act as well. New legislation, ministerial construction and regulations followed during the decade after the Institute of Medicine report. A number of changes were made, focusing on the incident reporting system and obligations of the main actors [18, 19, 20, 30, 32]. In 2005, the methodological support for conducting incident investigations was nationally distributed to the healthcare provider organisations. At this time, research in safety science had since long introduced at least a handful of alternative adverse event causation models [47, 51, 52]. Yet, no traces of more than a single model could be found in the methodology presented. Through the selected adoption of a specific methodology by key stakeholders in the Swedish healthcare system, came also an institutionalisation of the investigatory approach; this is how we investigate it, this is how we fix it and this is how we prevent it from happening again. Any model constructed is based on assumptions, scientific or other, and in the case of models for incident investigation the causal factors *found* reflect the assumptions of the model. This is summarised in the principle WYLFIWYF (What-You-Look-For-Is-What-You-Find) [81]. Taking it one step further, the causal factors *found* are also what eventually will be fixed when repairing what is broken, and is summarised in a second principle WYFIWYF (What-You-Find-Is-What-You-Fix) [42]. Since the methodology used in the Swedish incident reporting system was actively selected by those with the power to select, the causal factors are more *constructed* than found by the methodology.

This implies an obvious risk of guiding an investigatory process in a certain direction. Even if unintentional, it should be regarded as a natural consequence.

Paper II showed that the main actors of the incident reporting system have adapted their work to legislative change, and to the introduction of the manual for methodological support. From the time when the supervisory authority, in principle, acted as the sole investigator of adverse events, there was a period with a mixture of both the healthcare provider organisation and the authority performing investigations, to an on-going period in which the healthcare provider organisation by practical means is the sole investigator and the authority has an auditing role over the process. This gradual shift, that has taken place during nearly two decades, is a shift towards a system that emphasises the healthcare provider organisation's obligations to investigate and to learn after adverse events, and thereby also a shift towards healthcare professionals themselves investigating events in the healthcare field. Despite two major revisions of the manual for methodological support, in 2009 and 2015, the same linear adverse event causation model remains with the same reference made to American institutions. Furthermore, Paper II showed that healthcare professionals are recruited for careers at the supervisory authority without signs of further methodological or theoretical training, suggesting a situation of unchanged and persisting safety paradigm over time. In Paper III, all three investigations, with immense resources altogether, focus in detail on the immediate temporal and spatial proximity of the adverse event, where isolated human or mechanical failure is scrutinised. These signs are interpreted as an investigatory understanding of a system with an underlying safety norm. Both Papers III and IV showed, that only limited further interpretations were made in the external incident investigations on adverse event causation or targets for intervention, and therefore denying the possibility of epistemological pluralism.

With the claim of a paradigm comes the responsibility to recognise if anomalies exist, and how they are dealt with when discovered. Kuhn argues that anomalies will lead to further "invention" or "novelties" of the underlying theory. Various "elaboration", or modifications, will take place for the "assimilation", or implementation, of new ideas into the paradigm to eliminate any "puzzles", or conflicts. In the revisions from 2009 and 2015 of the manual for methodological support that was introduced in 2005, modifications of rhetoric were made, but the underlying model of adverse event causation was left intact. In brief, the modifications made were statements about more "prevention of risk", acknowledging "interactions of processes" and adhering to "a system perspective" (instead of systematic) in the 2009 revision. The 2015 revision introduced the notion of "resilience" and made elaborating statements on the importance of the interview situation.

Anomalies noticed and discussed in the studies were the following: First, in Paper I, signs of adverse events occasionally acting as triggers for organisational change, regardless of the formal investigation process, were present. This was mainly interpreted as a lowering of the investigation mandate, and also complicated the investigation because of the parallel qualitative organisational changes that had taken place during the process. Interviews with commissioning bodies identified the expressions “formalistic play” when referring to incident investigation and “strange results” when referring to targets for intervention. Second, in Paper II, only a minority of the investigators at the supervisory authority looked upon their role as having a “system perspective”. This was interpreted as individual professionals at the authority with a focus on interactions, relations and seeking progress of the whole healthcare system. One respondent revealed the frustration of a work situation “...filled with being a decision-maker...”, but at the same time strived at “...the decision should end up at the right level.” Third, in Paper IV, one sole investigator showed obvious signs of variability in investigation behaviour by identifying the necessity of more accounts from the adverse event, more site visits by the authority and more follow-up on decisions taken. The interpretation of this behaviour is the actual existence of various ways to conduct authority work, regardless of stated obligations.

Going one step further, a discussion on paradigm raises the question if there is anything on the outside of the paradigm. Kuhn argues that no paradigm exists that resolves all its problems. He describes “counter-instances” as a natural evolutionary consequence of almost any paradigm, but with no sharp dividing line when this transforms into “crisis” and allows a new paradigm to ultimately emerge. As a recent example in 2013, a series of articles in one of Sweden’s most influential newspapers, later published in book format, raised concerns on the governance of the Swedish public healthcare system, and displayed signs of the financial market being highly involved at different organisational levels of the system [82]. The publications brought huge public and healthcare professional attention to the issue of Swedish healthcare being a market equipped with price tags on patients, and different healthcare units being regarded as commercial merchandise [83, 84, 85]. Another example is from 2012, with a nationwide uprising among newly graduated nurses [86]. With the uprising came a demand on a non-negotiable lower limit of the starting salary. Media’s attention and the public understanding was massive and gave the demand informal legitimacy, while politicians were put under huge pressure with subsequent staff vacancies in numerous wards and emergency departments all over the nation [87, 88].

In the ensuing years after *To Err is Human: Building a Safer Health System*, many academic studies focused on various aspects of incident reporting systems, including system design [89], effects of reporting [90, 91], learning from events [92, 93] the willingness to report [94, 95, 96] and even failures of understanding

the magnitude of reported events from one healthcare provider organisation [97], thereby giving academic legitimacy to the system. However, in recent years, numerous studies have been published that address the overall problems with incident reporting systems in the healthcare field, key elements of patient safety and quality improvement that remain a challenge [24, 98, 99, 100]. This vast amount of studies gives reason to raise the question of why the paradigm prevails. Tracing back to the Institute of Medicine reports from 2000 and 2001, statements were made on patient safety being “a component” of quality improvement. Other components, emphasised in the reports, were aspects of efficiency, recognising patient-centred care, care given timely and being equitable [8, 9]. The Swedish Agency for Public Management officially argues that the healthcare system’s incident reporting system and the latest ministerial construction Health and Social Care Inspectorate should seek to align with a more systematic approach and efficiency on legislated obligations, since this way of work has been acknowledged and appreciated in other authorities [101]. Hence, a route of uniformity and effectiveness in conducting incident investigations seems to previously have been chosen and recently exhorted to continue by important stakeholders in the public Swedish healthcare system. This implies that quality improvement is the essential aim that may overshadow the individual components, such as patient safety, and thereby suggesting that the prevailing paradigm in reality is about *quality*.

The bottom line of the discussion on paradigm, with or without a quality label, and which includes the specific aims of the thesis, therefore becomes that the Swedish incident reporting system for the last 20-year period continuously operates with an inherent micro-organisational level understanding of adverse event causation, where construction takes place in the immediate temporal and spatial proximity of the adverse event, and where implementation of targets for intervention necessitates management continuity and micro-organisational level intervention, or else, only limited action is taken.

Conclusions

With the methods used, and discussion on results presented in this thesis, a schematic picture can be drawn that sheds some light over the archipelago-like construction site where the constituent parts, some of the junctions between them and the context in which the Swedish healthcare system's incident reporting system presently exists. This is the monochromatic picture that arises and the conclusions that can be made.

The studied incident reporting system operates on a daily basis with the ambition to enhance patient safety and quality of care in the Swedish healthcare system. The existing paradigm in which it operates is a consequence of the global quality movement that evolved after the publication of the report *To Err Is Human: Building a Safer Health System* in 2000. After its release, a variety of ways to increase patient safety and improve quality of care were introduced and received international attention. A key element was the use of incident investigations, which became a widespread safety improvement strategy. With only minor modifications, an institutionalised American manual on methodological support was adopted by the Swedish patient safety community, and was rapidly implemented as a tool-kit in the Swedish incident reporting system. Its use, indirectly supported through legislation, led to stating obligations for the main actors to perform incident investigations. The structure of the incident reporting system has through the years thereafter stayed nearly intact, despite new legislation and ministerial construction. Also, the fundamentals of the tool-kit in use, with its adverse event causation model, have since its introduction in 2005 remained virtually the same, despite intermittent extensive revisions of other parts of the manual. The main actors of the incident reporting system have remained in their same hierarchical positions, adapted to legislative change, but with the essence of work unchanged regardless of adverse event investigated. It can therefore be argued that how the healthcare system understands how adverse events occur and how to deal with them, has remained very close to stable. It seems reasonable to believe that this paradigm will prevail for as long as doubt of its superiority is not conceptualised by important stakeholders within the system.

The substantial, and connected, findings from conducted studies for this thesis that support the idea of a paradigm are the following: Firstly, the micro-organisational level understanding of adverse event causation, and the targets for intervention

that follow. These seem to embrace the entire incident reporting system without noted change over time, across organisational levels of the healthcare system or through in-depth analysis of cases. Legislation presents, and from time to time changes, details in obligations concerning the main actors. At the same time, the main actors continue to fulfil the stated obligations and find adapted ways of work performance to cope with change, even though the tool-kit remains unchanged. The individuals in the incident reporting system are parts of a recycling system, where positions in organisational level can change upwards in hierarchy from one main actor to another, but without further education, training or enhanced methodological support on adverse event causation. Therefore, patient safety ontology within the system becomes unchallenged, epistemological pluralism virtually non-existent, and similar micro-organisational level interventions keep on regenerating.

Secondly, there is a lack of a sustainable organisational memory that involves the entire incident reporting system. Only minor traces of such a memory can be found at the unit where the adverse event previously occurred, with the healthcare provider organisation or at the supervisory authority. The only substantial memory identified is at the individual level, and as such a factor that may vanish upon individual career change or shifts in management positions. Indirectly, this absence of a sustainable organisational memory, using historical events for disseminated learning and structural support, is regarded as another explanatory mechanism of the regenerating micro-organisational level interventions that may seem reasonable at the time when they are presented, but probably fails to increase patient safety or improve quality of care over time.

Thirdly, the process of conducting incident investigations fulfils purposes other than political or judicial. The process of investigation maintains and reproduces a bureaucracy, and also meets psychological purposes important to different stakeholders within the system. This gives the system legitimacy and perseverance, even when learning is weak and repairing seems insufficient. Strong signs were found of an incident reporting system adhering to an efficient investigation process and where “closure of cases” was important, even when the adverse event causation model had failed, or signs of system weakness occurred. The chosen linguistic expressions and the lack of constructive dialogue between main actors, are partly seen as moral confessions, and partly as ways for the entire community to move forward, regardless of the adverse event investigated and with a perceived sense of increased patient safety and improved quality of care.

Future directions

Arguments made in this thesis rely on a synthesis of separate studies. In the following section a handful of ideas and perspectives are presented, that may contribute to an enhanced sense of knowledge of the question *What is going on here?*, and could guide future research projects to confirm, or deny, the presented findings. All ideas have slowly grown to become tempting fields for further analysis, as this thesis has found its texture and structure.

Daily, all over the healthcare system “normal work” is carried out without much attention. Routines are followed and care is given, even if every day and every patient is unique, something which necessitates aspects of human variability. How does staff at the sharp end recognise an adverse event in comparison to an event regarded as “normal work”?

Statistics show that the number of adverse events reported in the Swedish incident reporting systems is far higher than the internal incident investigations, and far, far higher than the number of external incident investigations performed. Perhaps many of the reported adverse events should not be investigated for various rational reasons, but on the other hand, perhaps some of the events should have been dealt with? How is this filter of the incident reporting system constructed – only human, somewhat technical, or other mechanisms – for sorting out which adverse event that deserves incident investigation, and which event that does not?

Culture, hierarchies, organisational structure and politics all act as components in defining norm within an organisation and thereby defines *how work is done*. Can patterns be found in filed (and forgotten?) documents of previous adverse events, never acted upon, that help explain even further the underlying organisational adverse event causation model?

Given the nationwide spread of the incident reporting system in the public healthcare system, and the mandatory use of it for many years, large volumes of filed incident investigations can be found at every single healthcare provider organisation. How is this stored learning, or organisational memory, used on a local and national level in the continuous safety improvement work?

One of the studies gave hints of “organisational change” triggered by the adverse events that had occurred, but change unrelated to the actual formal internal incident investigations. What mechanisms induce such triggering and can themes

of “organisational change” be detected that guide the understanding of system adaption to adverse events?

The functioning of the present incident reporting system has here been described in detail. Despite a huge difference in resources, little difference is noticed in the final results from investigations. Could adjustments be made to its structure, for example lateral distribution of learnings or increased follow-up, so that the system operates more appropriately and functions more in accordance with the findings and suggestions in this thesis? Or is a completely different approach, with a variety of methodologies available and an enhanced level of investigatory knowledge about safety-critical organisations, needed for such an aim?

Signs of learning are weak and the micro-organisational level of understanding adverse event causation seems to proceed and stay unchanged. Should reporting of adverse events cease entirely and resources instead be transferred to the investigation of “close calls” in search for an understanding of mechanisms behind system vulnerability and human adaption when preventing adverse events?

Populärvetenskaplig sammanfattning

Denna avhandling återspeglar det som slutligen sker med de rapporterade brister i svensk hälso- och sjukvårds säkerhet, som drabbar patienter i form av allvarliga skador, så kallade *vårdskador*.

I Sverige har säkerhet för patienter varit aktuellt sedan 1936 då 4 dödsfall inträffade på Maria Sjukhus i Stockholm efter en förväxling av lokalbedövning och rengöringsmedel. Som en direkt konsekvens av dödsfallen antogs den lag som än idag styr hur allvarliga vårdskador utreds; lex Maria. Svensk hälso- och sjukvård har sedan dess haft ett lagstadgat avvikelserapporteringsystem för att handlägga och utreda rapporterade vårdskador. Tillsynsmyndighet över hälso- och sjukvården har sedan flera årtionden varit Socialstyrelsen och är sedan 2013 Inspektionen för Vård och Omsorg. Även om vissa anpassningar har skett genom åren av myndighetens arbetssätt och justeringar till ändrad lagstiftning, finns själva grundfundamentet kvar; hälso- och sjukvården ska anmäla allvarliga vårdskador, eller risker för allvarliga vårdskador, till en tillsynsmyndighet, vilken ska genomföra en oberoende utredning där målsättningen är att öka säkerheten för patienter.

Det övergripande målet med avhandlingsarbetet är att förstå hur svensk hälso- och sjukvård utreder och använder rapporterade vårdskador till förbättringsåtgärder. Avhandlingens huvudsakliga fokus är att undersöka hur avvikelserapporterings-systemet fungerar; hur vårdskador utreds, hur hälso- och sjukvårdssystemet lär sig av utredningarna samt hur lärandet och de vidtagna åtgärderna sprids inom hälso- och sjukvård.

Forskning om säkerhet i olika delar av samhället har pågått i närmare ett sekel. Det finns idag en bred kunskapsbas om säkerhet med förgreningar in i en rad olika vetenskapliga discipliner. Trots omfattande säkerhetsforskning inom olika delar av samhället fanns för 25 – 30 år sedan knappast någon forskning om säkerhet inom hälso- och sjukvård, det vi idag kallar *patientsäkerhet*. Svensk hälso- och sjukvårds användande av begreppet patientsäkerhet har dock under de senaste 15 – 20 åren blivit alltmer vanligt förekommande. Den bakomliggande förklaringen till detta går att spåra till en global rörelse, vilken startade efter publiceringen av en mycket inflytelserik amerikansk rapport år 2000. Rapporten både synliggjorde den stora omfattningen av vårdskador inom hälso- och sjukvård, samt påpekade tydligt behovet av att höja vårdkvaliteten, och där stärkandet av patientsäkerhet ansågs

vara en av hörnstenarna. En av åtgärderna som lyftes fram var obligatoriska avvikelserapporteringsystem. Dessa bedömdes kunna identifiera orsaker till vårdskador, och även skapa ett lärande för att undvika att en liknande händelse inträffar igen. Svensk hälso- och sjukvårds engagemang i patientsäkerhetsrelaterade frågor influerades tydligt av den globala rörelsen. Inom några år lanserades bland annat en metodhandbok för utredning av vårdskador. Handboken, som har använts landsomfattande sedan år 2005 och har reviderats vid två tillfällen, förklarar i detalj hur en utredning går till, samt vilka frågor som ska vara besvarade när den presenteras för uppdragsgivaren.

För att undersöka de fokusfrågor denna avhandling ställer har ett antal avidentifierade och avslutade utredningar analyserats med ett tillvägagångssätt, som kallas *fallstudie*. Såväl innehållsanalyser av de olika utredningarna, som intervjuer med en rad nyckelpersoner, har gjorts. De fyra fallstudier som har genomförts har bidragit till att förstå avvikelserapporteringsystemet ur flera olika perspektiv; lokalt, över tid, på djupet och på bredden. Analyserna har gett en mångfacetterad bild av hur systemet fungerar. Ur resultaten har ett antal slutsatser kunnat dras.

Den första studien undersöker de lokala utredningar, som hälso- och sjukvård genomför internt före anmälan till tillsynsmyndighet. Resultaten visar att utredningarna har en tydlig tendens att både föreslå och genomföra åtgärdsförslag, som är riktade direkt mot den snäva geografiska plats där vårdskadan inträffade. Vidare visar resultaten att när byten sker på chefspositioner medför detta att lärdomar från, och därmed minnet av, tidigare utredningar försvinner. Studien visar dessutom att den plats inom hälso- och sjukvård där vårdskadan inträffade genomgår en förändring, som kan vara ett lokalt lärande, men som inte går att återfinna i den genomförda utredningen.

Den andra studien undersöker över en längre tidsperiod de utredningar, som tillsynsmyndigheten genomför efter anmälan från hälso- och sjukvård. Resultaten visar att tillsynsmyndighetens utredning i ett stort antal fall inte tillför något ytterligare. I de fall där utredningen tillför något är åtgärderna, på samma sätt som i den interna utredningen, riktade mot den snäva geografiska plats där vårdskadan inträffade. Detta mönster förblir oförändrat över tid, trots ändrad lagstiftning och anpassningar av myndighetens arbetssätt. Vidare visar resultaten att merparten av utredare och beslutsfattare på myndigheten har sin professionella bakgrund i hälso- och sjukvård. De ser detta som en fördel i sin uppdragsutövning och de flesta av dem ser dessutom sin roll på myndigheten som granskare av den interna utredning gjord inom hälso- och sjukvård.

Den tredje studien undersöker i detalj tre utredningar av samma allvarliga händelse, vilken fram till idag är det enda tillfälle där två olika myndigheter gör varsin oberoende utredning, och där dessutom Statens Haverikommission gör sin

första utredning någonsin av en händelse inom hälso- och sjukvård. Resultaten visar att trots mycket stora skillnader i tids- och resursåtgång presenterar samtliga utredningar att bakomliggande orsaker till händelsen finns i en nära anslutning till där händelsen inträffade, både i rum och i tid. Några alternativa förklaringar förs i princip inte fram. Vidare ser samtliga utredningar hela händelsen som ett avvikande från ett i övrigt säkert system, där säkerheten kan återställas med hjälp av mer styrning och reglering.

Den fjärde studien undersöker ett tvärsnitt av utredningar från hela landet, där samtliga har genomförts i närtid och under samma tidsperiod. Resultaten visar att det föreligger en stor likhet avseende hur avvikelser utreds, såväl inom hälso- och sjukvård som hos myndigheten. Vidare visar resultaten att det finns påtagliga brister i spridandet och lärandet efter avvikelser. Dessutom noteras att viktiga inslag i avvikelserapporteringssystemets handläggning är effektivitet och ett avslutande av ärenden.

Den övergripande slutsats, som kan dras från denna avhandling är att hela avvikelserapporteringssystemets sätt att fungera är en del av ett paradigm med en historisk förankring där genomförande av utredning blir viktigare än utredningsresultat. Ett sådant paradigm kommer att fortsätta råda, så länge det inte utmanas av något som är en del av systemet. Tre större enskilda slutsatser underbygger detta påstående. Den första är att avvikelserapporteringssystemet har en inbyggd förståelse för hur vårdskador uppstår och att bakomliggande orsaker återfinns, i allt väsentligt, i nära anslutning till där vårdskadan inträffade. Därför presenterar utredningar åtgärdsförslag som riktar in sig snävt i tid och rum i förhållande till vårdskadan. Den andra slutsatsen är att minnet inom både hälso- och sjukvård och tillsynsmyndighet är påtagligt svagt, vilket är en anledning till att utredningar fortsätter att presentera åtgärdsförslag, vilka riktar in sig på samma ställen som i tidigare utredningar. Den tredje slutsatsen är att utredningar är en del av en självgående byråkratisk process, som samtidigt uppfyller viktiga samhälleliga psykologiska syften för både de som är drabbade, och de som är involverade i utredning av skadan.

Acknowledgements

The work behind this thesis has been conceivable only because of the many efforts, sincere contributions and highly inspiring thoughts and comments from a large number of people. With endless support from my family, supervisors, colleagues and friends the research process has gradually come close to a natural source of joy during the years. In the following are some people that deserve a special mention. I thank you all, for making this expedition a truly memorable adventure:

Pelle Gustafson, my supervisor; for all your absolutely amazing knowledge about the mysteries of the research process, guiding me kindly and gently through the “ups and downs”, and thereby gradually shaping the scientist. Without your expertise and sincere willingness to jointly enter this field of research, I would still be standing there, without an academic platform or financial support.

Johan Bergström, my co-supervisor; for years of invaluable and outstanding theoretical support. Without your guidance, from the first days as a novice at the faculty, on everything from ideas on research design to literature in patient safety science and transforming premature drafts to readable manuscripts, it would not have happened.

Eva Linell, former patient safety coordinator; for your enthusiasm, encouragement and solid down-to-earth-pragmatism on dealing with adverse events, that overwhelmed me, and made it almost inevitable to commence exploring this field.

Sidney Dekker, professor at Griffith University in Brisbane, Australia; for our brief encounter when career pathways happened to cross many years ago. I’m deeply grateful to the tremendous impact our enlightening chats had back then on my desire of exploring the field of safety science.

Elisabeth Olhager, clinical head at the Department of Paediatric Surgery and Neonatal Care; for making statements on the importance to continue and prioritise the project together with leadership support and personal trust.

Katarina Hanséus, former clinical head at the Department of Paediatric Surgery and Neonatal Care; for leadership support and personal trust early in the process when times were rough.

Per Westrin, head of unit at the Department of Paediatric Anaesthesia and Paediatric Intensive Care; for years of patience and understanding, allowing the research process to take time and resources from clinical practice.

David Grubb, closest colleague and friend; for innumerable, vivid and sometimes almost preposterous analyses of the world around us, including a fascination with incomprehensible organisational structure and human behaviour as a part of it, during long working days when “normal work” is the last thing on your mind.

Ann-Kristin Olsson, former and senior colleague; for all the cases with unhurried bedside teaching about the essence of paediatric anaesthesia and intensive care medicine under highly stressful critical conditions, making me realise that “good” is clearly separated from “fast” when it comes to manual skills and safe procedures.

Colleagues at the Department of Paediatric Anaesthesia and Paediatric Intensive Care; for years of good, solid and professional collegiality, support in clinical practice around-the-clock and for hard work when I have been absent, but now and then also presenting remarkably naturalistic (sorry, guys and girls!), yet lost (please, breathe again!), opportunities for qualitative studies on aspects of human behaviour during pressure and fatigue.

Karin Pappila and Linda Hansson, ICU nurses at the Paediatric Intensive Care Unit; for the remarkable implementation and continuous follow-up of the “Formula 1” transition-of-care-concept at the unit, now acting as a standard for patient safety improvement work, both at the department and at the hospital.

Co-workers and staff at the Paediatric Operating Theatre and the Paediatric Intensive Care Unit; for all the work accomplished throughout the years, day and night. Many moments together, have acted as inspiration for ideas in this thesis regarding the width of human adaptive capacity.

Friends, near and far away; for all the memorable and amusing contributions to a regular life beyond a computer screen.

The floorball gang in southern Lund; for immense opportunities of Monday night pressure relief when a momentary lapse of reason creates the illusion of every single game played being a World Cup final.

Psychotherapist nr 1, my running shoes; for miles and miles of support, often night time, while structuring and cleansing messy mindsets.

Psychotherapist nr 2, the sports in TV-channel Viasat®; for numerous occasions of much needed distraction when intellectual capacity has reached a deadlock.

My father; for passing on, through yourself, many of my ancestors' unspoken insight that writing is both a gift and a pleasure for life. And for all the moments of you just being there, wise and listening.

My parents, sisters with their families, stepmother, mother-in-law and brother-in-law with family; for all the love, interest, and understanding during my days of living a life less ordinary. I'm probably still the same, just slightly older with a whiter shade of pale.

Ellen and Beata, my daughters; on my journey through life, adding all the small footsteps and giant leaps taken, you are the summit of all creations ever made. The love and pride I feel being with you, looking at you, thinking about you, is infinite and eternal.

Lena, my wife; my dearest love and best friend from the day we met. For always, no matter what circumstance, being incredibly present, honest, supportive and empathetic in all aspects of sharing a life and building a family together – in sickness and in health to love and to cherish. No one has taught me, like you, so much about the core of life itself - I'm your greatest admirer!

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BMJ Open Mind the gap between recommendation and implementation – principles and lessons in the aftermath of incident investigations: a semi-quantitative and qualitative study of factors leading to the successful implementation of recommendations

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To cite: Wrigstad J, Bergström J, Gustafson P. Mind the gap between recommendation and implementation—principles and lessons in the aftermath of incident investigations: a semi-quantitative and qualitative study of factors leading to the successful implementation of recommendations. *BMJ Open* 2014;**4**:e005326. doi:10.1136/bmjopen-2014-005326

► Prepublication history for this paper is available online. To view these files please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2014-005326>).

Received 23 March 2014
Revised 2 May 2014
Accepted 6 May 2014



CrossMark

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ABSTRACT

Objectives: Using the findings of incident investigations to improve patient safety management is well-established and mandatory under Swedish law. This study seeks to identify the mechanisms behind successful implementation of the recommendations of incident investigations.

Setting: This study was based in a university hospital in southern Sweden.

Participants: A sample of 55 incident investigations from 2008 to 2010 were selected from the hospital's incident reporting system by staff in the office of the chief medical officer. These investigations were initiated by 23 different commissioning bodies and contained 289 separate recommendations. We used a three-stage method: content analysis to code the recommendations, semi-structured interviews with the commissioning bodies focusing on which recommendations had been implemented and why, and data analysis of the coded recommendations together with data from the interviews.

Results: We found that a clear majority (70%) of the recommendations presented to the commissioning bodies were targeted at the micro-level of the organisation. In nearly half (45%) of all recommendations, actions had been taken and a clear majority (73%) of these were at the micro-level. Changes in the management positions of the commissioning bodies meant that very little further action was taken. Other actions, independent of incident investigations, were often taken within the organisation.

Conclusions: We conclude that two principles ('close in space' and 'close in time') seem to be important for bridging the gap between recommendation and implementation. The micro-level focus was expected because of the method of investigation used. Adverse events trigger organisational action independently of incident investigations.

Strengths and limitations of this study

- The results presented in this study show the strength of using a design that combines content analysis with interviews to thereby provide deeper understanding of the different aspects of the data.
- The semi-structured nature of the interviews seemed to make the respondents willing to elaborate and reflect freely on both questions and follow-up questions, which resulted in a substantial amount of qualitative data.
- The coding scheme used in the content analysis and the categories used in the data analysis could have possibly resulted in a limited perspective of a more complex reality.

INTRODUCTION

When adverse events (AEs) occur in complex socio-technical healthcare systems, it is difficult—if not impossible—to identify the underlying causal factors. The importance of using past events to promote organisational learning is obvious but hard to institutionalise in practice.¹ Nevertheless, incident investigations have for decades been routine and regarded as important tools in safety management, primarily to prevent similar events occurring again by promoting recommendations for ensuring continuous improvement.

Different organisations use different methods to conduct incident investigations, with the majority, including healthcare, having adopted an underlying accident model in which recommendations made assume the system has a stable causal

structure.^{2,3} This stable causal structure implies that the recommendations are derived by identifying the root cause with no need to relate the specific recommendations to the damaged system as a whole.² Johnson argues that understanding of how certain recommendations are formulated is generally weak.⁴ It has been shown that investigators spend a surprisingly short amount of time providing recommendations in comparison to other parts of the process.⁵ Furthermore, the factors governing successful implementation of recommendations have so far received limited attention in the literature.^{6,7}

The aim of this study was to start filling this knowledge gap by analysing the mechanisms behind the successful implementation of recommendations formulated in investigations of incidents in Swedish healthcare. The approach follows Hollnagel's advice to search for the positive rather than the negative aspects of safety.⁸

BACKGROUND

The Swedish healthcare system's regulatory authority at the time of the study, the National Board of Health and Welfare (NBoHaW), has issued regulations governing the responsibilities of the different healthcare providers, for example, when using an incident reporting system and carrying out incident investigations. Swedish law states that the responsibility for patient safety improvement lies with the separate healthcare providers.^{9,10} The law also states that if an AE has resulted, or could have resulted, in a serious incident, this should be reported to the regulatory authority for separate investigation. This investigation, the so-called Lex Maria (LM) investigation, is independent of the incident investigation conducted by the healthcare provider. The chief medical officer (CMO) of an organisation generally decides whether or not to report an AE to the NBoHaW, although the CMO has neither formal legal authority nor responsibility for the safety level of the organisation.

A commissioning body (CB) initiates and sets the terms of reference for the incident investigation, and is ultimately responsible for follow-up of the report recommendations.

The analysis team, set up by the CB, consists of at least one healthcare professional trained in investigating AEs in the Swedish healthcare system. Since 2005, methodological support for conducting investigations has been provided by the Swedish Association of Local Authorities and Regions (SALAR) and supported by the NBoHaW.⁵ In Swedish healthcare, completed incident investigation reports are, after de-identification, made publicly available, as are LM investigations conducted by the NBoHaW.

METHODS

We used a three-stage method. First, we carried out content analysis to code the recommendations in a sample of 55 incident investigations of AEs in a Swedish university hospital. We then conducted semi-structured

interviews with CBs focusing on which recommendations had been implemented and why. Finally, we performed data analysis using the coded recommendations together with the interview data, to identify specific mechanisms contributing to successful implementation of recommendations. Due to the semi-quantitative nature of the study, we carried out no further statistical analyses.

Content analysis

The first step was to sample a limited number of completed incident investigations. In collaboration with the CMO at a Swedish university hospital, data on registered AEs which resulted in incident investigations were collected from the hospital incident reporting system. The CMO was asked to determine for which years after 2005 (when the methodological support manual by SALAR was published) the hospital had sufficient qualified incident investigator staff working within the organisation and familiar with the methodology. Second, at least 1 year should have elapsed after completion of the incident investigation to allow for the implementation of recommendations. Third, the selection of investigations should be linked to incidents in which the department of anaesthesia and intensive care was involved as the main author is an anaesthesiologist, ensuring (1) a comprehensive data set through contacts with important actors, as well as (2) full understanding of the cases and investigations, regardless of complexity. This resulted in the selection of 55 separate incident investigations from January 2008 to December 2010, initiated by 23 different CBs. We also identified the staff position initiating the incident investigation, as this was the same position to which the recommendations would be presented upon completion. Thus, continuity in management was of interest, not individuals.

The completed incident investigations were linked to existing additional investigations, for example, LM investigations, using the hospital incident reporting system.

All incident investigation reports and recommendations were numbered as they were received from the office of the CMO. Data from the reports were coded according to the CB at the time of investigation, the ward from which the analysis was commissioned, the time spent by the team conducting the investigation, the number of team members, the number of suggested recommendations, and whether or not the findings of the investigation were reported by the hospital to the NBoHaW (as an LM investigation).

Rasmussen and Svending¹¹ have shifted the focus to include 'what' causal factors are identified in the aftermath of AEs, and 'where' in the organisational hierarchy the identified causal factors are. We therefore coded the reports according to the hierarchical level of the target of the recommendations using a micro-meso-macro perspective.¹² This was done in order to identify potential correlations between hierarchical level and the likelihood of the recommendation being implemented. A micro-level recommendation could be implemented by



the CB entirely within the same department without major constraints, for example, as regards local procedures, technical skills or staff issues. With a meso-level recommendation, the CB had to collaborate with a stakeholder outside the department but within the hospital, for example, another department or the hospital management. With a macro-level recommendation, the boundaries of the hospital had to be crossed, for example, authorities, politicians or pharmaceutical companies had to be contacted.

From the written reports it was not possible to determine to what extent the different recommendations had been implemented or not. These data were added to the coding scheme following the interviews.

Semi-structured interviews

The second part of this study consisted of interviews with the different CBs at the hospital, to gain deeper insight into which recommendations had been implemented and why. The interviews were semi-structured as they focused on specific reports, but with the possibility for the respondents to reflect freely on the questions asked.

All of the CBs received written information before the interview about the background and aims of the project, as well as the main questions forming the basis of the interview. All respondents were de-identified and given a random number. Twenty-two of 23 CBs (or their successors) provided written consent to being interviewed. This made it possible to ask questions of interest about 50 of 55 incident investigation reports, with a total of 254 coded recommendations. Four of the 22 CBs delegated the interview to either an assistant director (2/4) or the head advisor in patient safety (2/4). The interviews were all carried out between April and September 2012 by the first author (JW) at a place suggested by the respondent. Twenty of the interviews were audio recorded. In two of the interviews the respondents did not agree to audio recording and so extensive notes were taken instead. All quotations presented here have been translated from Swedish to English by the first author and are all tagged with the number of the coded respondent.

All interviews included a minimum of three questions (see below). Subsequent questions were asked depending on the answers given by the respondents.

1. Have you taken part in this incident investigation report and given attention to the recommendations *before* this study?
2. Which recommendations from the incident report have been *implemented* in the organisation?
3. Have, to your knowledge, any *alternative* actions been taken within the organisation because of the incident investigation report that were not presented as recommendations?

During the period studied, the hospital had a system where in one part of the hospital the CB was nearly always the CMO, while in the other part the CB was the

clinical head of department. In addition, a CMO in a Swedish hospital cannot also be clinical head of a department at the same time. Therefore, for investigation reports where the CB was the CMO, interviews were also conducted with the clinical heads of the departments involved in order to gain deeper knowledge of how far the implementation of recommendations to the different departments had progressed.

Data analysis

The analysis used the interview data to seek naturalistically generalised factors explaining the results of the content analysis.^{13 14}

Before naturalistic generalisation, the coding scheme was extended to include the different answers as to whether action had been taken or not on specific recommendations. We used three categories in this study:

1. Actions have been taken and initiated/completed regarding the recommendation
2. Actions have not been taken regarding the recommendation
3. No knowledge if actions have been taken.

As many clinical heads of department would be interviewed about the same specific incident investigation, some of their answers might be assigned to conflicting categories. It was therefore important to follow up answers to category A with questions about how and when the particular recommendation had resulted in actions.

We analysed interview data in a search for generalised patterns: Why did the distribution between micro-level, meso-level and macro-level recommendations look the way it did? What was the connection with successful implementation, and why? What aspects of successful recommendation implementation were not captured in the content analysis, and why? Did, or did not, factors such as the position of the CB or the time spent by the analysis team, influence the likelihood of the suggested recommendations being implemented?

RESULTS

Content analysis of incident investigation reports

Thirty-nine of the 55 AEs were subject to both an incident investigation by the hospital and to an LM investigation by the authorities, suggesting that the severity of the AE in most events had exceeded an official threshold. Implementations of recommendations from LM investigations were not analysed in this study.

The CBs of the 55 incident investigations were similarly distributed between CMO (n=29) and heads of department (n=26).

The average number of team members per investigation was 2.7, and the duration of an investigation varied from 12 to 150 man-hours, similar to the findings by Rollenhagen for typical investigations in patient safety.⁵

A total of 289 separate recommendations were identified in the 55 incident investigations, with five

Table 1 Distribution of the recommendations according to the three hierarchical levels and whether they were reported as having resulted in actions

Hierarchical level	No. of recommendations for which actions have been taken	No. of recommendations for which actions have not been taken	No. of recommendations for which it is not known if actions have been taken	Total number
Macro	1	6	0	7
Meso	30	26	16	72
Micro	82	53	40	175
Total number	113	85	56	

recommendations not coded due to uncertainty concerning the meaning of the investigators' findings. Thus 284 coded recommendations were included and questions about 254 of them were asked during the interviews. The distribution of these recommendations in the organisational hierarchy is shown in [table 1](#).

In the following sections semi-quantitative and qualitative data, including the categories from the content analysis and quotations from interviews with CBs, will be presented in order to identify mechanisms important (or not) for the successful implementation of recommendations.

Management continuity

The interviews revealed that the hospital, after commissioning the investigations, had replaced one CMO. This CMO was involved in 29 incident investigations, where one incident investigation could involve a number of department directors. The interviews also revealed that in 41 cases, regardless of the position of the CB, the clinical heads of department also had been replaced. When the question 'Have you taken part in this incident investigation report and given attention to the recommendations before this study?' was asked, the new CMO had taken part in 3/29 investigations, as did 6/41 of the new clinical heads of department. As one of the CBs noted:

One could have a system where the CMO is a bit more meticulous and does a follow-up of the incident investigations to see what happened. It could be more of a supervising position than it is today, but there is no time for that. That would probably be a part time job in itself or a substantially increased workload. (11)

Overall, the respondents were concerned about lack of knowledge regarding incident investigation reports completed before they assumed their current management position:

I have not informed myself about past events, but that illustrates two important things, according to myself, that we use the results from the incident investigations too scantily and there is not enough follow-up ... But I think the most important matter is – these are historical cases and if one hasn't been clinically involved it's a problem with commitment – that there is a follow-up on the recommendations so that something does happen. (2)

No, note that there isn't a single one of these incident investigations I've known about [...] I've talked to my assistant director [a doctor] and to the member of staff responsible for the departments incident reporting [a nurse] to collect some information. (22)

Nowhere in the organisation did we find a proper system for recording what actions had been taken following the recommendations of the incident investigations. To varying degrees, the respondents had been able to find information on what actions had been taken. As shown in [table 1](#), actions had been taken for 45% of recommendations, actions had not been taken for 33% of recommendations, and our respondents were unable to tell us whether or not actions had been taken for 22% of recommendations.

The position of the CB

Whether the CB was a CMO or head of department did not seem to influence the process of implementation. When it was a CMO, actions had been taken in 55/128 (43%) of completed investigations, and when it was a head of department in 58/126 (46%):

...and when many departments are involved in the adverse event it doesn't work with just one director of department being the commissioning body ... But it's also complicated to hand this over to the chief medical officer because it often has a tendency to come to nothing when many actors are involved. Who takes the responsibility? (11)

Micro, meso or macro

As seen in [table 1](#), in the cases where actions had been taken, the interviews showed that a majority were at the micro-level:

Yes, actions have been taken. We've written a new document about this procedure, that I have right in front of me, so that I can remember everything that has been done ... and regarding *that* matter, we've put it on the checklist and the surgeon must ask before surgery whether procedures have been followed ... This was a very easy and straightforward thing to solve, one could say. There was one thing that had gone wrong and we tried to fix it ... and others weren't involved. (4)



The event itself as a trigger for change

In 19 of 50 cases, the interviews showed that the AE had initiated organisational actions that were not presented as recommendations in the reports. It seemed that the incident investigations in these cases worked more as an incentive for change, but on the initiative of management rather than the analysis team:

So you see, despite numerous meetings and brain storming back and forth, I still believe that all of this was completely off target ... So in this case we did this formalistic play, which was good, but then we relaxed a bit. Thereafter, among the senior colleagues, we drew a pragmatic conclusion and went on. There was someone who quoted Shakespeare at the time: 'Much ado about nothing' or something like that ... (10)

...then some of us decided, within the department, to start a minor recurring training course ... You see, it often comes down to quite strange results if we aren't part of the changing process ... And when the colleagues 'over there' gained some knowledge about this matter, things definitely got better, at least from my point of view ... Today this way of working is almost self-driven and I see it as a result completely independent of the investigation. (16)

Time spent by the investigation team

In seven of 50 incident investigations, it was not possible to determine the amount of time spent by the team conducting the investigation. In 43 of 50 investigations, which had 217 recommendations, duration ranged from 12 to 150 man-hours. We grouped the different investigations by time spent on the investigation in order to examine if duration was a factor in implementation and at what level.

The investigations were of short duration (<40 h) (n=14), medium duration (41–80 h) (n=21) and long duration (>81 h) (n=8). We found that in the group with a short duration, actions had been taken on 25/55 recommendations, with 21/25 actions at the micro-level. In the group with a medium duration, actions had been taken on 43/116 recommendations with 28/43 actions at the micro-level, and in the long duration group, actions had been taken on 24/46 recommendations with 20/24 actions at the micro-level. The duration of the investigations differed by more than a factor 10 but this did not seem to influence actions taken to meet the recommendations, or at what level.

DISCUSSION

This study has several strengths and limitations. The results presented show the advantages of using a design that combines content analysis with interviews to thereby achieve deeper understanding of the different aspects of the data. The semi-structured nature of the interviews seemed to encourage the respondents to elaborate and reflect freely on both questions and follow-up questions, which resulted in a substantial amount of qualitative data.

The coding scheme in the content analysis and the categories used in the data analysis could possibly result in a limited perspective of a more complex reality. It could be argued that an investigation is not complete before formal post-implementation follow-up has been carried out. However, we have not studied the effect of the implemented recommendations, since the focus of study was the gap between recommendation and implementation.

We do not draw general conclusions from this study. However, we expect our findings are not unique to the speciality (anaesthesiology) or type of hospital studied (university hospital), and thus believe that our findings may be valid for other Swedish hospitals, and possibly hospitals in countries with similar systems for investigating AEs.

This study shows that a clear majority of the recommendations presented to the CB were targeted at the micro-level of the organisation, even when the investigating team spent a considerable amount of time on their work. We suggest this finding reflects not that the micro-level is necessarily the most meaningful target of intervention but rather the investigating teams' understanding of how incidents happen. This is summarised in Hollnagel's two principles: WYLFYWF ('What You Look For Is What You Find') and WYFIWF ('What You Find Is What You Fix').^{2 7 15} In this study, the causes the investigators sought are intimately linked to the linear causation model provided by the method available to them. The linear incident model inherent in the method provided by SALAR⁵ and used in the investigations studied, identifies certain problems as relevant targets of intervention. This is not the first study to suggest that linear incident investigation methods tend to locate causes at the micro-level of the organisational hierarchy,¹⁶ although we also see that what is found is not always fixed and it is not always the recommendations written in the reports that decide what will be fixed.

In the literature on healthcare system safety, much focus has been directed towards the sharp end, such as transition in care: change of shifts, change of ward and change in level of care.^{17–19} Based on the findings from this study, we argue that in order to understand the successful implementation of recommendations following analyses of AEs, important factors found at the blunt end of the organisation should also be considered, such as changes in management positions or management continuity. Our results show that if the individual in a management position was the successor to the original CB, that individual had very little knowledge of an existing completed investigation, and understandably, took very little further action in addition to that taken by their predecessor.

Consequently, two principles—'close in space' and 'close in time'—seem to be important factors for closing the gap between recommendation and implementation when a model such as that employed in this university hospital, is used.

The finding that the event itself triggers organisational interventions regardless of the incident investigation recommendations requires further elaboration. This finding could be interpreted as lowering the organisational mandate of the analysis process, but it also complicates the process of conducting the analysis, especially if a model assuming a stable causal structure is employed. If organisational interventions are initiated simply as a result of the event, then the organisation essentially goes through a qualitative process of change as a result of that event. Consequently, this implies that the organisation is qualitatively different after the event than it was before.

Since the organisation did not record which recommendations had been implemented, our findings rely almost entirely on interviewee responses. This may introduce uncertainty about the reliability of the analysis results, but may also raise concern about how incident investigations are used by the organisation to improve patient safety. Based on the interviews, nearly half of all the recommendations had been implemented, regardless of how severe the organisation perceived the AE to be. A clear majority of these recommendations were at the micro-level, with the management position of the CB having very little effect.

The focus on success mechanisms also becomes a focus on system vulnerabilities and potential improvement. The finding suggesting that 'close in time' and 'close in space' actions are more likely to be implemented can indeed guide future work to improve the method of learning from AEs in the Swedish healthcare system. We suggest that future research and projects aimed at improving the quality of the system, focus on four aims. (1) Ways should be developed to institutionalise an organisational memory of AEs and the analyses following them so that the system becomes less sensitive to management continuity. (2) The target of analysis following AEs should be changed so as to spread suggested actions more evenly between the micro-, meso- and macro-levels of the organisation. This requires analysis focussing on interactions and relationships at higher organisational levels, and also investigation teams with basic competence in safety science and the interpretation of complex systems. (3) The gap between the investigation team and the investigated organisation should be closed. Based on the finding that other actions are taken in addition to those suggested by the incident investigation teams, we suggest future work is required on enhancing dialogue between analysis team and the organisation analysed. (4) Lessons should be learnt from incidents outside the formalised system. We suggest future research is conducted on the possible storytelling of past incidents in healthcare organisations. There may be many lessons that are never mentioned in formal investigations which can nevertheless be incorporated as part of organisational memory and everyday behaviour.

CONCLUSIONS

This study seeks to understand the factors that lead to the successful implementation of recommendations suggested in incident investigations following AEs in a Swedish university hospital. Based on the findings, we conclude that continuity in management is an important factor for successful implementation of recommendations ('close in time'), as is a clear majority of the recommendations presented in the investigations being targeted at the micro-level of the organisation where the same applies to the recommendations that are actually implemented ('close in space'). The micro-level focus of the investigations is expected given the linear causal model underlying the method of analysis. For recommendations to be targeted towards the meso- and macro-levels of the organisation, the model used for investigation needs to seek causes at the level of organisational interactions and relationships. Furthermore, the AE itself triggers organisational interventions regardless of the recommendations made in the incident investigations. In addition, neither the time spent by the investigation team nor the position of the CB seems to contribute to the successful implementation of recommendations.

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Acknowledgements The authors would like to thank the staff at the office of the chief medical officer of the hospital for their contribution by providing all the necessary incident investigation reports.

Contributors JW developed the study, collected, analysed and interpreted the data, and wrote the manuscript. JB and PG contributed to study design, analysis of the data and revision of the manuscript.

Funding The project was partially funded by a grant from The Swedish National Patient Insurance Company.

Competing interests None.

Ethics approval The study was approved by the Regional Ethical Review Board in Lund, Sweden.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement No additional data are available.

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Paper II



ORIGINAL ARTICLE

Incident investigations by the regulatory authority of Swedish healthcare – a 20-year perspective

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Received: June 22, 2015

Accepted: August 30, 2015

Online Published: September 7, 2015

DOI: 10.5430/jha.v4n6p68

URL: <http://dx.doi.org/10.5430/jha.v4n6p68>

ABSTRACT

Objective: The purpose of this study was to describe procedural changes in hospital incident investigations and show the consequences of these changes over time.

Methods: A two-stage method was used. First component of the study was a content analysis of 87 incident investigations conducted 1995-2014 by the regulatory authority after adverse events in a Swedish university hospital. Second component was conducting semi-structured interviews with 11 investigators from all regulatory authority regional offices in Sweden.

Results: In a minority of incident investigations, where further demands for action were required by the regulatory authority, a major portion of these were aimed at the micro-level. A plan for follow-up was expressed in only one tenth of the investigations. All investigators had a background from the healthcare system and saw this as advantageous. Their personal memory was claimed to be the only tool when referring to previous cases. Less fieldwork, more office work and more uniformity of language were recognised changes in comparison over time. The role of doing “auditing” was the most common description by the investigators themselves.

Conclusions: The micro-level focus of the investigations reflected an organisational structure within the regulatory authority. We saw signs of parallel system weaknesses within the Swedish healthcare system with a clear absence of formalised organisational memory and a malfunctioning follow-up system of incident investigations. This can be seen both regarding the healthcare providers and the regulatory authority. The reports from the qualitative interviews data indicated that “auditing at the office” was considered the main occupation in incident investigations conducted by the regulatory authority.

Key Words: Incident investigation, Regulatory authority, Organisational change, Role, Surveillance, Organisational memory, Follow-up

1. INTRODUCTION

Since the publication of the seminal report *To Err is Human*,^[1] patient safety has experienced a rise on the healthcare policy agenda worldwide. The report emphasised the need for systems to report and analyse adverse events and incidents as a key in safety improvement efforts and inter-

vention. Consequently, healthcare organisations worldwide have invested great resources in systems aiming at estimating the numbers of adverse events, categorising them, and using them as arguments for the economical advantages of safety improvement.^[2-4] The vast amount of academic studies of incident reporting systems in healthcare have mainly focused

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on matters of system design,^[5] effects,^[6] or barriers to increase the willingness to report.^[4,7,8] In this study, we were rather interested in using incident reporting in healthcare as a case to show the development and changes of roles and responsibilities for patient safety improvement in the Swedish healthcare system over the last 20 years.

The Swedish healthcare system has since 1937 used a system, regulated by legislation, for external investigation of severe incidents by a regulatory authority and even before. To Err is Human arguments were raised for additional non-punitive incident reporting.^[9] Regardless of financial constraints and political change, the system with healthcare providers reporting severe incidents to a regulatory authority has stayed virtually intact. However, during the last ten years, there have been certain modifications of how to use the data from the incident reporting system. In 2005 the Swedish Association of Local Authorities and Regions introduced, as a new patient safety tool for all healthcare providers, a methodological support for conducting mandatory internal incident investigations.^[10] In 2011 a legislative change pinpointed the healthcare providers' specific responsibility for patient safety improvement within their organisations.^[11] Therefore, in comparison, Swedish healthcare providers today have a substantially larger and a more regulated responsibility for their improvement of patient safety. But even when systems undergo national change, it is unlikely that they will achieve improvement if the change is focused merely at a single organisational level.^[12] In a previous study,^[13] we focused on the construction of patient safety in healthcare providers' internal incident investigations. Our findings raised a series of questions regarding the relationship between a healthcare provider and the regulatory (and surveillance) authority. What happens when an incident is reported to the authority? Who are the individuals that investigate the organisations? How do they work during an investigation, and why?

In this study we analysed whether the constructions of patient safety, expressed in the external incident investigations, have changed over time. Furthermore, we set out to study the perceived change of the regulatory authority's role from the perspective of its inspectors and heads of unit. Based on the questions raised in our previous study, the first purpose of this study was to identify the demands for action and follow-up processes reported on external incident investigations from a Swedish hospital from 1995 to 2014. The second purpose of this study was to determine the perspective of incident investigations from the inspectors and heads of unit at regional authority offices in Sweden. Our specific research questions have been the following: To what organisational levels have demands for actions been targeted over the years from 1995 to 2014? Have these levels changed over

time? What has been the process(es) over the studied years by which demands for action have been constructed?

Background

In the Swedish healthcare system, the role of the regulatory authority has changed in the last decade, even if the official message always has been to be both "auditing" and "supportive" in surveillance of the healthcare system.^[11,14-16] Looking specifically at the incident reporting system, and the use of data regarding incident investigations, three separate time-periods can be identified. First a period before the end of 2005 when the National Board of Health and Welfare (NBoHaW) formally acted as the sole investigator of adverse events severe enough that the healthcare provider decided to perform an investigation. The second period is after the introduction of the methodological support to perform incident investigations in December 2005. This period lasted until 2010 and is characterized first by the healthcare provider conducting an internal incident investigation after an adverse event. If the adverse event had resulted or could have resulted in a serious incident, the regulatory authority conducted a separate external investigation. In the third period, beginning in January 2011 and still ongoing, regulations state that the authority "...ensures that reported incidents have been investigated to a necessary extent, and appropriate actions have been taken by the healthcare provider to reach a high level of patient safety".^[11] In this last period, the internal investigation conducted by the healthcare provider is by practical means the sole investigation of the adverse event, since the authority now has a defined role of surveillance of the process and examination that the internal incident investigation is complete according to legislation. A new regulatory authority, the Health and Social Care Inspectorate (HaSCI), was established in June 2013 and commissioned to take over the supervision of the healthcare system from NBoHaW.^[17]

In an internal investigation, the commissioning body is ultimately responsible for taking action to implement the reported recommendations. In an external investigation conducted by the regulatory authority, the healthcare provider is ultimately responsible for the implementation of the demands for action.

In Swedish healthcare, the incident investigation by the regulatory authority is called a Lex Maria investigation (LM). A completed LM investigation is, after de-identification, made publicly available.

2. METHODS

In search for potential changes in the construction of patient safety resulting from external incident investigations (LM), we used a two-stage method. First, we conducted a con-

tent analysis of external incident investigation reports from a Swedish university hospital, from 1995 to 2014, to identify, examine and code all demands for action and follow-up. Second, we conducted semi-structured interviews with investigators - inspectors and heads of unit (I&H's) - at regional authority offices in Sweden, seeking explanatory factors to findings from the content analysis

2.1 Content analysis of LM investigations

2.1.1 Design

The study of the LM investigations was set up as a content analysis, with an approach similar to our previous study.^[13]

2.1.2 Sample

LM investigations from 1995 and onwards were compiled and de-identified by the HaSCI. Those LM investigations deriving from adverse events in which the Department of Anaesthesia and Intensive Care was involved were selected. This was done as the first author is an anaesthesiologist, ensuring (1) a comprehensive data set through contacts with important actors, as well as (2) full understanding of the incidents, regardless of domain complexity, and (3) comparability of data and results from our previous study. This resulted in 87 complete and separate LM investigations from November 1995 to April 2014.

2.1.3 Procedures

The investigations were categorized in three different time periods as described above: (1) 1995 to 2005, (2) 2006 to 2010, and (3) 2011 to 2014. The investigations and demands for action were numbered as they were received from the HaSCI. Data were examined according to (1) whether or not further demands for actions were taken from the authority in comparison to actions presented by the healthcare provider, (2) the number of specific demands for action from the authority, (3) if any reference was made to previous cases, and (4) if there was a stated plan for follow-up by the authority.

2.1.4 Data analysis

In order to identify the hierarchical level of the target of action, such targets were coded according to a micro-meso-macro perspective.^[13,18] A micro-level action could be handled within a single department, for example local procedures, technical skills or staff issues. A meso-level action required collaboration outside the department but within the hospital, for example another department or hospital management. For a macro-level action, the boundaries of the hospital had to be crossed, for example collaboration with other hospitals, authorities, politicians or pharmaceutical companies.

2.2 Interview study

2.2.1 Design

To gain a deeper insight into the decision-making process and find explanatory mechanisms to the findings in the content analysis, we conducted semi-structured interviews with I&H's at all 6 regional regulatory authority offices.

2.2.2 Sample

All of the six regional offices were asked to identify I&H's with substantial experience of conducting external incident investigations. In all, 11 I&H's volunteered to participate; 4 from the regional office of the university hospital and 7 from the other 5 offices. All respondents received written information before the interview about the background and aims of the project, and all provided written consent to being interviewed.

The 11 interviewed I&H's had an average employee time of approximately 12 years (range 4 to 23 years). All respondents had a professional background in healthcare, and all but one had predominantly done so before their work at the authority.

2.2.3 Procedures

The interviews focused on the overall process of decision-making in an investigation, and with the possibility for the respondent to reflect freely on questions asked.

The respondents were de-identified and given a random number. The interviews were carried out between April and November 2014 by the first author at a place suggested by the respondent (7/11) or by phone (4/11). All interviews were audio recorded. The quotations presented have been translated from Swedish to English by the first author and are all tagged with the code-number of the respondent.

All interviews included a minimum of six questions. Subsequent questions were asked depending on given answers:

- (1) Has your *professional background* been an advantage working at the authority?
- (2) Has the authority given you some *methodological support* for conducting/supervising an incident investigation?
- (3) Does the authority have a system to *recognize similar* adverse events while you are working with a current incident investigation?
- (4) Regarding incident investigations, how has the *investigation process changed* during your time at the authority?
- (5) Does your office conduct a *follow-up* after completing an investigation/supervision?
- (6) What is your *personal view* on your assignment at the authority?

2.2.4 Data analysis

The qualitative data was categorised according to the main questions asked above. Significant statements of agreement, or disagreement between the respondents were extracted in order to interpret the process of LM investigation over the years of the study.

3. RESULTS

3.1 Results from content analysis of LM investigations

In 26 of the 87 complete investigations, the regulatory authority required further demands for action, for a total count

of 34 actions. In the last time-period, a decline in demand for further action was seen. Twenty-two of 34 required actions were targeted at the micro-level, 10 at the meso-level, and 2 at the macro-level. This pattern remained unchanged throughout all time-periods. A specific follow-up plan was expressed in 9 out of the 87 investigations. Also this pattern was virtually unchanged over the time periods (see Table 1).

In 5 of the 87 incident investigations, the regulatory authority in their decision referred to previous incident investigations. In four of these five cases the inspector was the same individual in the present and previous investigation.

Table 1. Content analysis of 87 complete Lex Maria investigation reports from a Swedish university hospital 1995 to 2014

Time period	Number of complete LM-investigations	Number of investigations where further demand for action is required	Number of further demands for action required	Target level of further demands for action required	Follow-up plan
1995-2005	23	10/23 (43%)	13 (0.57 per investigation)	8/13 micro 4/13 meso 1/13 macro	3/23
2006-2010	35	14/35 (40%)	18 (0.51 per investigation)	12/18 micro 5/18 meso 1/18 macro	4/35
2011-2014	29	2/29 (7%)	3 (0.10 per report)	2/3 micro 1/3 meso 0/3 macro	2/29
Total	87	26/87 (30%)	34 (0.39 per report)	22/34 micro 10/34 meso 2/34 macro	9/87

Note. Complete = investigation done by both healthcare provider and regulatory authority; Further demands for action required = the regulatory authority has required further demands for action(s) than the healthcare provider proposed in their internal investigation

When analysing expressions in decisions and possible changes over time the following observations were made. In the first period, the most common expression (12 of 23) in the closing comments of the report was “*The NBoHaW assumes that actions are taken. . .*”. In the second period, the most common expression (22 of 35) was, even when no further action was taken by the authority, “*A report on actions taken shall be sent to the NBoHaW. . .*” with a time frame of approximately 4 to 6 weeks. After 2010 the most common expression (21 of 29) was “*The NBoHaW (note: from June 2013 HaSCI) makes the assessment that the healthcare provider has investigated the adverse event to a required extent*”.

3.2 Results from the interview study

We here present semi-quantitative and qualitative data, including quotations from interviews, to identify factors important (or not) in the construction of patient safety as identified in the incident investigations. This section is divided according to the themes of analysis that were formulated during the process of analysis. The themes are well in accordance

with the main questions asked in all interviews (see method section).

3.2.1 Professional background

Nine of 10 judged it advantageous that the regional office had staff with a background in healthcare because of their professional expertise in medicine, whereas one respondent saw it as a disadvantage because of the lack of judicial training. The remaining 11th respondent had predominantly done administrative work in different organisations, and saw this as an advantage:

“It requires quite a lot of competence to look into an investigation done by the healthcare provider and it requires knowledge of the actual work (. . .) When I decide which one in my staff that will perform the investigation focus turns to whom has the best knowhow in this case. . .for example an orthopaedic case will be given to one of our investigators with a background in orthopaedics and so forth.” (5)

The authority also seemed to promote a way of working in which inspectors are even more specialised in terms of the fields that they work with:

"... and then one of the inspectors says 'That case is mine because I've recently had a couple of cases at that department!' (...) This is quite a natural allocation of work depending on our backgrounds." (3)

Our data suggested that the authority actively had recruited based on a principle that it should be able to assign inspectors with actual experience of the field being investigated:

"... and when it comes to the need of employment we look closely to see what we lack in terms of competence. (...) Yes, almost only from the healthcare system... mostly nurses." (6)

Furthermore, it seems that a combination of background in healthcare and personal experience of investigations at the authority was perceived to be needed to gain results:

"... I mean that it requires plenty of skill to analyse what the healthcare provider presents... and this competence is something one has to gain by working along with a knowledge of how things looks out there. (...) This is something that we talk a lot about here at the office. Inside your head you make a judgement call... and to get there you need experience." (3)

3.2.2 Methodological support

The apparent emphasis on micro aspects we observed in the content analysis led to us asking questions regarding the methodological support for analysis. All 11 respondents claimed that the main knowledge of how the work is done, is merely by doing it without any certain methodology:

"No, this is something that one learns gradually while getting exposed to it... and, of course, discussing certain issues with senior colleagues occasionally." (4)

In 2010-2011 the authority occasionally held internal mini-courses in supervision. A couple of years ago a checklist was introduced to support the assessment that all parts of an investigation process had been covered as stated by the authority. All newly employed inspectors have a tutor their first year and two of the 11 respondents pointed out that they had taken academic courses in supervision. Still, there is an expressed lack of methodological support among all respondents:

"No, when I began there was nothing... there were a lot of ideas and I've seen documents from 1990 with visions for the authority and these document could have been written today. (...) Sometimes one wonders why there hasn't been any progress. It seems like many of these ideas and visions haven't had an impact." (9)

The respondents also expressed willingness for change and finding ways to improve the process by some kind of methodological support:

"There is a lot to do here! We've done as we've always done it and nothing else has happened... and there is quite a need for developing methods of investigation and supervision... so, yes, there is a need for tools." (11)

3.2.3 Organisational memory

Our observation that only five out of 87 analyses referred to previous analyses, and that four of these were written by the same investigator as in the current report, made us ask questions regarding the perceived need (or not) for an organisational memory of past cases. All 11 respondents reported that the system in use for the recognition of similar adverse events (case management system) was working poorly:

"Oh, this system could be so much better... and then when it comes to trying to find specific previous investigations – it's almost impossible! We can't use all the archived investigations that actually exist because it's so difficult to find them. And nothing is indexed in a way that is useful to me." (8)

One regional authority office was so dissatisfied working with a suboptimal system that they improvised a new system:

"No, the authority doesn't have a functioning case management system... We've built a minor homemade system here at the office just to keep some kind of track of what we are doing and perhaps give some support to the healthcare providers, but it's very unprofessional and without any real structure." (1)

Several respondents referred to their own memory and experience of previous cases as their only tool to refer to previous cases:

"The most important thing is that I as an investigator remember the cases because we have a case management system that, to say the least, isn't at its optimum when it comes to identifying similar adverse events." (3)

The respondents with the longest employee time expressed concerns of this sole tool and the future for the authority:

"In my own case there has of course been quite a few investigations that have passed by my desk through the years... and therefore I personally know what has happened and have knowledge about different healthcare providers' history and things like that... If I would quit my successor would not know any of this!" (6)

3.2.4 The investigation process

All of the respondents had been involved in at least one legislative change that supposedly could have had an impact on the investigation process. Given the question "Regarding incident investigations, how has the investigation process changed during your time at the authority?" they were able to reflect freely and subsequent questions were asked for

confirmation. All in all, the 11 respondents identified a total of 25 changes in the investigation process. The identified changes were divided into groups of answers as follows:

- Less inspections/less field work/less contact with staff in the field – 7 of 11
- More office work – 5 of 11
- Standardized expressions/uniformity in language – 5 of 11
- Reduction in man-hours spent per investigation – 3 of 11
- More team-work/more contact with other inspectors – 2 of 11
- Increase in man-hours spent per investigation – 1 of 11
- A more confusing assignment – 1 of 11
- Increased waiting for external documents – 1 of 11

3.2.5 Follow-up and implementation

All respondents stated that the system for follow-up was insufficient. Nine of 11 described an absence of an established follow-up-system regarding decisions made:

“No, unfortunately not yet... but listen to this. There is one healthcare provider in our region that recently has employed a nurse where their ambition is that she will look into all the specific decisions from our investigations. What she actually thereafter will do is to focus on if the healthcare provider has yet implemented what has been decided... Do you see? They really want to do a follow-up of their own! This is beyond all quality improvement or patient safety culture improvement that anyone else has done before, as far as I know.” (5)

Two of 11 respondents described that they do random follow-up when there is time, but that it ends with a personal visit and nothing further:

“At large, no. It happens, but is quite rare, unfortunately. That’s exactly the way in which we would like to work. Especially... we notice the patterns and we know that staff is struggling and some departments have more problems and our investigations at large look alike et cetera... and then something happens again in the same department... and one of their own decisions states that they’re now employing. We have to believe them, but it’s frustrating.” (8)

“No, we don’t have a system for this. We do follow-ups far too rarely. This is something that I personally hope we will do more of in the future...however, I’ve twice during the last six months done two un-notified inspections at departments and asked a couple of questions to staff regarding things that the healthcare provider has stated as implemented and wondered if they can see that there has been a change. And then it shows that many things haven’t changed. They might

have heard about plans and visions. (...) Yes, I’ve talked with heads of departments as well... the same problems exist year after year without any change.” (9)

3.2.6 The role of the authority

Even if the judicial framing of an assigned task for I&H’s at any authority is regulated and explicit, the legislative changes over the years have not changed the officially stated role of being both “auditing” and “supportive”. Bearing this in mind, we asked the respondents to reflect on their personal view of their assigned task. The question was openly asked; hence we got a diverse set of answers. We grouped the answers as belonging to an “auditing perspective”, a “supportive perspective” or a “system perspective”.

Five of 11 respondents expressed what we labelled as an “auditing perspective”, *i.e.* a perspective where the investigator emphasises his or her role as an external, and clearly separated from the healthcare provider, auditing body assigned the task to improve the system by an unbiased expert judgement:

“This is what: to put forward decisions that are understandable, standing on a solid medical and judicial basis without the involvement of any personal opinion... that we can make the healthcare system safer because we create the lessons, not only lecturing. That’s how I look upon my assigned role!” (5)

Three respondents expressed their role to be more of a support function than an auditor in their relation to the healthcare provider. This “supportive perspective” is one in which the inspector emphasises the dialogue between authority and healthcare provider as a mean to contribute to patient safety initiatives:

“It’s in the personal meeting with the healthcare provider, the heads of department and politicians that I can change things... and then contribute to the improvement of healthcare.” (9)

Three respondents discussed their own role in terms of a macro level reflection focused on how to make the system as a whole function in the most progressive way. Since this perspective is one focusing on the interactions and relations within this system rather than any specific role, we have labelled this perspective the “system perspective”:

“Yes, here I feel a divided loyalty both as it is and what I would like it to be, so to speak. ... and I would like to work more with the overall development of the meaning of uniformity, quality improvement... and things like that... one could say development of the methodology... but the days are just filled with being a decision-maker. (...) To me it’s

not just reaching uniformity. The decision should end up at the right level.” (4)

4. DISCUSSION

Regardless of organisational position in society, the essence of any aspect of patient safety work must be the ambition of improvement when there are signs of weaknesses. Since Swedish legislation frames the certain responsibilities for each and every one of the actors within the healthcare system, one could assume that there would be continuous follow-up, not only of procedural issues, but also of the implementation of decisions made, of actions taken in the process of auditing and organisational changes within the system. The recurring question should be whether healthcare providers and the regulatory authority have adequate tools for the improvement of patient safety. In this study we aimed at exploring the construction of patient safety from a perspective inside the Swedish healthcare system. We do not draw general conclusions from this study, but expect that our findings are not unique to the speciality, the hospital or to the I&H's studied.

Our previous study showed that a majority of the recommendations presented in internal incident investigations were targeted at the micro-level of the organisation, and a majority of actions thereafter taken had been at the micro-level.^[13] Our present study showed a similar pattern; in the small portion of incident investigations where further demands for action were required, a majority of these over a long period of time have been targeted at the micro-level of the organisation. The use of a micro-meso-macro perspective gives an indirect reflection of the decision-maker's view of a root cause in accordance with an underlying accident model. Along with findings from the interviews, *e.g.* that the authority actively recruits professionals predominantly with healthcare experience, we suggest that this rather reflects an organisational structure within the authority by means of staffing and in-job training, rather than the micro-level being the most meaningful target of intervention. One could then raise the question whether recurring signs of system weaknesses in Swedish healthcare almost always evolve from the micro-level, or if the professional background and training that is similar regarding the individuals behind the internal- and external incident investigations, is a more likely explanation. Contemporary safety science research^[19-21] would hesitate to accept the first conclusion.

The content analysis also raised concern regarding two additional matters where similarities to our previous study also evoked. First, were the very few cases where the incident investigation referred to a previous case. The pattern that appeared, which was confirmed during the interviews, was that of an absence of a functioning case management system.

Having professional personal knowledge is by all means a procedural strength, but if organisational memory within an authority is more dependent on the sustainability of its employees, than of a system built for such a cause, this could be considered a severe weakness. Having a system that at an early stage recognises previous similar adverse events could probably help any organisation working at large scale to become more vigilant in discovering system weaknesses. The problem with a poorly functioning case management system at the HaSCI has recently been acknowledged by a report from the Swedish Agency for Public Management.^[22] Our contribution to this discussion is how the authority investigators themselves share the frustration.

Second, and most possibly as a consequence of the first matter, the feedback to the authority of actual implementation of decisions taken through an established follow-up system was rarely seen in the reports. Also, the interviews showed that this was not a natural part of the I&H's daily work even if this is clearly regulated by legislation.^[11] A question not asked was if this phenomenon had to do with active prioritisations or possibly restraints, but perhaps the answer can be found in the interviews where the respondents reflected over the changes in the investigation process. Our impression was that focus within the authority, nowadays, is on the administrative part of the investigation process and less fieldwork, and thereby a loss of contact with the healthcare providers. In a report by the Swedish Agency for Public Management there is a comparison to the systematic approach on legislated obligations done at the Swedish Migration Board where uniformity and efficiency has been acknowledged and appreciated. However, we argue that regardless of what historical role the regulatory authority has had in society, the bottom line of fulfilment to legislated obligations should be, by means of a follow-up system, to what extent their different decisions and demands for action are implemented in the supervised organisations. Unfortunately, what we here see are signs of parallel system weaknesses within the Swedish healthcare system with a clear absence of formalised organisational memory both as regards the healthcare providers and the regulatory authority. This is probably, alongside noted practical administrative changes, an important factor in a malfunctioning follow-up system of both internal and external incident investigations.

So then, what is the role of this regulatory authority today?

Without denial of important legislative matters, we have tried to look beyond the judicial framings to explore the personal reflections of the individuals working within the authority in search for the core of duty despite intermittent procedural adjustment to organisational change. A clear observation from analyses of the interviews is the sincere ambition of the

respondents to fulfil their duties, even when it has a tendency to surpass the limits of their working capacity – in summary, a dedication to the job. But what is the job? On a daily basis this basic question is probably not in focus during an investigation. However, it is nevertheless interesting to pose the question when observing and listening to the recurring views of being both “auditing” and “supportive”. One possible bias in the interview data is the wide range of employee time with a risk of being a “prisoner of time”. By this we mean: could it be that the individual investigator’s view of the job is related to the time era when he/she was employed by the regulatory authority? Another possible bias could be cultural adaptation, perhaps through tutor influence, and adjusting to local procedures at the office. These possibilities make our observations even more interesting – within this authority individuals emerge as sincerely reflecting cornerstones regardless of organisational change, most with the ambition of auditing, some with a devotion to be supportive and a few with a desire to grasp the whole system. Trying to cope with this work in the absence of methodological support, organisational memory and a functioning follow-up system, the most important role this authority has is to attend the cornerstones and cherish their knowledge of work in search for new and sustainable pathways for improvement in the construction of organisational patient safety.

5. CONCLUSIONS

Numerous actors continuously interact at and between different organisational levels in the efforts to enhance patient safety in Swedish healthcare. This makes it a challenge, but yet necessary, to define the roles and responsibilities of those involved. When change, with the ambition of improvement, occurs at any level such definitions could easily become unclear for stakeholders in the system. Our study

shows that when the Swedish healthcare system has undergone procedural or legislative change regarding the roles and responsibilities in incident investigations, looking over time, it seems unclear what has actually been improved. Along the way, the role of the healthcare systems regulatory authority has stepwise changed with gradually less involvement in the on-spot process of an incident investigation, and at the same time more effort has been put into finding uniformity and structure in the practical administrative part of the job. This is partly as a consequence of what is appreciated at the authority level, but mostly because of legislation. Looking back 20 years, Swedish healthcare providers today have more or less taken over the role of investigating and recommending actions. Today, there is typically no difference between the recommendations made in the healthcare provider’s internal investigations, and the demands for action as formulated by the authority. This gradual change has most likely taken place with the overall societal ambition of improving the incident investigation process within the system. However, the absence of a formalised organisational memory, and a functioning follow-up system at the regulatory authority regarding required demands for action, are consequences tightly bound to this change. Today this regulatory authority is operating with inspectors and heads of unit without specific in-job training ambitiously occupied with “auditing at the office” the healthcare providers’ struggle with their construction of organisational patient safety at the same level as the authority was doing two decades ago.

ACKNOWLEDGEMENTS

The study was approved by the Regional Ethical Review Board in Lund, Sweden. The authors would like to thank the staff at the HaSCI for their searching and compiling of all the necessary data requested for the content analysis.

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Paper III





One event, three investigations: The reproduction of a safety norm



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ARTICLE INFO

Article history:

Received 25 June 2016

Received in revised form 9 March 2017

Accepted 10 March 2017

Keywords:

Adverse event

Healthcare

Causal factor

Investigation

Discourse

Safety norm

ABSTRACT

Following an adverse event in a Swedish university hospital in 2010, three separate investigations seeking causal factors were conducted. We here review each of the analyses to see whether they together generate the kind of epistemological pluralism that could contribute to a systemic understanding of, and learning from, the event. Our content analysis shows that, while using vastly different amounts of time and resources, all three investigations make the same analytical choice to construct the causal factors as a deviation from norm in the event's immediate temporal and spatial proximity. We recognise that this both represents a strong discourse in the community analysing adverse events and seems to fulfil certain psychological purposes. Furthermore, we suggest that thorough analysis of adverse events in healthcare need to include aspects of system interaction from the micro to the macro, cognitive work configuration and design, as well as variability as a resource to harness rather than a threat to limit and control.

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1. Introduction

The discourses of healthcare quality and safety were merged through the convincing argument that healthcare errors should be an important focus for quality improvement. This argument, made by the Committee on Quality of Health Care in America in the report *To Err is Human* (Kohn et al., 2000), has since then guided efforts on patient safety (and quality) improvements in healthcare systems worldwide. Sweden is not an exception. For Swedish healthcare provider organisations, it is under certain circumstances mandatory by law (The Swedish Patient Safety Act, 2010) to report adverse events to the regulatory authority - formerly the National Board of Health and Welfare (SoS) and from June 2013 the Swedish Health and Social Care Inspectorate (IVO) - and also to conduct incident investigations themselves. For such investigations, methodological support has since 2005 been available from the Swedish Association of Local Authorities and Regions (Swedish Association of Local Authorities and Regions, 2009). Regardless of body responsible for analysis, identification of causes and prevention of recurrence are the major goals.

We have in two previous studies explored how Swedish healthcare provider organisations, in their internal investigations after adverse events, construct targets of intervention and system

improvement (Wrigstad et al., 2014), as well as how the Swedish regulatory authority's constructions of adverse events causation and targets of action has changed over the last 20-year period (Wrigstad et al., 2015). Together these studies draw a picture of how healthcare provider organisations, as well as the regulatory authority, construct causal factors to adverse events at the micro organisational level: close in both time and space to the adverse event itself.

Our epistemological starting point of analysis is that 'causes' of adverse events are *not found*; as if they were out there readily waiting to be discovered or uncovered. Our perspective is that 'causes' are *chosen* and *selected*; typically, by those given the mandate to choose and construct authoritative causal accounts (Rasmussen et al., 1990; Lundberg et al., 2010). Summarised as the WYLFIFYF-principle (What You Look For Is What You Find) (Lundberg et al., 2009), our hypothesis is that if different bodies with differing public functions investigate the same adverse event, there is a possibility (or risk) that the different investigatory bodies explore, analyse and construct causal factors in different ways and further, that it would make them draw different conclusions and suggest different targets of intervention.

The field of Safety Science has since the 1930s developed several schools of thought in the construction of accident causation. The global healthcare safety community seems to owe much to Heinrich's theory of industrial accidents as linear chains of events, triggered by a root cause being either mechanical or (most often) human, and with a direct relationship between major accident

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<http://dx.doi.org/10.1016/j.ssci.2017.03.009>

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consequences and minor accident consequences (Heinrich, 1931). Based in Heinrich's theorems of accident causation, measures such as incident investigations and searches for 'the root cause', become meaningful activities to safety enhancement efforts. It was much later that Turner introduced the idea that accident causation needs to be constructed in terms of organisational learning and information-sharing deficiencies over long time periods (Turner, 1978). This notion of how organisational learning and culture are at heart of accident causation was further developed by Vaughan (1996) and Snook (2000). Additional theories, introducing the notion of complexity, include Perrow's 'pessimistic' account of how tightly coupled and complex systems will always hold a catastrophic potential (Perrow, 1984), and the more 'optimistic' Rasmussen school constructing accidents in terms of dynamics and hierarchies (e.g. Rasmussen and Lind, 1981; Rasmussen, 1997; Rasmussen and Svedung, 2000). It is followers of the Rasmussen school constructing accidents in terms of dynamics and hierarchies (e.g. Rasmussen and Lind, 1981; Rasmussen, 1997; Rasmussen and Svedung, 2000). It is followers of the Rasmussen school of Safety Science who have introduced the notion of resilience, studying how people and organisations sustain operations by adapting to the various stresses and threats that their complex environments (often healthcare) face (Bergström et al., 2015; Wears et al., 2015; Hollnagel et al., 2013; Nemeth, 2007; Woods, 2005).

Given the broadness of perspectives on accident causation found in the literature, we are in this study interested in whether three different Swedish public investigatory bodies, with different purposes of analysis, conduct their analyses of the same adverse healthcare event in different ways. The research question is how a Swedish healthcare provider organisation (healthcare provider), its regulatory authority at the time, SoS, as well as the Swedish Accident Investigation Authority (SHK), respectively constructs and understands the causal factors leading up to the same adverse healthcare event. This specific adverse event is, to our knowledge and to this date, the only adverse event in Swedish healthcare that has been investigated by three different investigatory bodies at approximately the same time. Trusting the principle of epistemological pluralism (March et al., 1991; Healy, 2003), we believe that three different perspectives of the same adverse event could contribute to a systemic explanation and understanding of not only the system behaviour, but also of meaningful system interventions. In the following sections we choose, for simplicity reasons, to use the expression incident, as equivalent to accident, with the same sense and meaning as used in our previous studies.

1.1. Background

1.1.1. The adverse event

A severely ill patient with cardiac valve disease was admitted to the Department of Thoracic Surgery at a Swedish university hospital. The patient was scheduled for surgery to receive a mechanical valve-prosthesis. During the valve-replacement procedure on 12th of October 2010, an external pacemaker was placed to be able to stimulate the heart postoperatively, if necessary. After surgery, the patient was cared for in the Thoracic Intensive Care Unit (TICU). On the first post-operative day, the patient had an episode with grave cardiac arrhythmia and underwent successful cardiopulmonary resuscitation, otherwise the condition of the patient improved as expected. The stay in the TICU lasted in total four days, and plans were made to transfer the patient to a regular ward on the 17th of October.

In the evening of the 16th, a shortage of beds was upcoming in the TICU. A decision was made by the doctors on call on the TICU and the Cardiology Intensive Care Unit (CICU) to transfer the patient to the CICU as a so-called satellite patient. This meant that care was given by staff at the CICU, but the patient was formally under medical supervision by the TICU. On arrival at the CICU,

monitoring device for detection of arrhythmia was connected to the patient.

At a routine check by a nurse during the night shift the patient was found lifeless in bed. Resuscitation was attempted without any result, and the patient was declared dead. An autopsy was performed a couple of days later.

1.1.2. The incident reporting system

The Swedish healthcare system has since 1937 used a legislated model for external incident investigation of severe adverse events by a regulatory authority (The Social Welfare Board, 1940). The supporting foundation of this law states that if an adverse event has resulted, or could have resulted, in a serious incident, this should be reported to the regulatory authority for an external incident investigation. This model with a healthcare provider reporting incidents to a supervising regulatory authority has since then stayed virtually intact even though certain modifications, including name changes, have been made over the years. The regulatory authority has in recent years issued specific regulations governing the responsibilities of the healthcare provider; for example using an incident reporting system and carrying out internal incident investigations. In 2011 a legislative change pinpointed the healthcare providers' specific responsibility for patient safety *improvement* within their respective organisations. These regulations state that the regulatory authority "...ensures that reported adverse events have been investigated to a necessary extent, and that appropriate actions have been taken by the healthcare provider to reach a high level of patient safety" (SFS 2010:659). A new regulatory authority, IVO, was established in June 2013 (Prop. 2012/13:20) and commissioned to take over the supervision of the healthcare system from SoS. Both of these authorities act under the Ministry of Health and Social Affairs.

In general, the chief medical officer of a healthcare provider determines when and what to report to the regulatory authority regarding adverse events from the incident reporting system. A commissioning body within the healthcare provider is assigned to conduct an internal incident investigation. The commissioning body is most often the chief medical officer or the clinical head of department where the adverse event occurred. An analysis team is set up to perform the investigation and thereafter presents a report with recommendations on actions to the commissioning body. The external incident investigation by the authority is preceded by the internal incident investigation. In the external incident investigation the regulatory authority presents a decision to the healthcare provider addressing the fulfilment (or not) of their legislated role as previously stated.

SHK is an independent governmental authority under the Ministry of Justice that investigates all types of serious civil or military accidents and incidents with the aim of improving safety, regardless of whether they occur on land, at sea or in the air. Examples of areas where SHK carries out investigations include civil aviation, civil maritime transport, rail and road transports, as well as fires, building construction failures, mining, environmental pollution, nuclear power and medical technology. In some situations an investigation is mandatory while in others it is up to the authority to decide on the basis of the anticipated safety gains of an investigation. SHK is by the Swedish Accident Investigation Act limited to only target its recommendations to regulatory authorities. The adverse event studied here is, to our knowledge, the only incident in the medical field ever investigated by SHK.

1.1.3. The three investigatory bodies

- (i) The healthcare provider organisation (healthcare provider)

The chief medical officer of the healthcare provider assigned a commissioning body, the clinical head of department were the

adverse event occurred, and an investigation team was set up. The assignment for the healthcare provider's investigation team was to identify causes of the event, and find a routine that, if possible, avoids the recurrence of a similar event.

In this event, the investigation team consisted of 5 members of staff; 4 from the Department of Cardiology (includes CICU) and 1 from the Department of Thoracic surgery (includes TICU). The healthcare provider used the methodological support for conducting investigations provided by the Swedish Association of Local Authorities and Regions since 2005. The team leader had undergone internal training in incident investigation by the hospital. The explicit questions for the investigation team to answer were: (1) What happened? (2) Why did it happen? and (3) How is the recurrence of a similar event avoided?

The healthcare provider's investigation took 4 months to be complete and was presented in a 14-page report including a 3-page graphic layout with chronologically organised boxes showing defined minor events leading up to the adverse event.

(ii) The National Board of Health and Welfare (SoS)

The chief medical officer of the healthcare provider initiated the regulatory authority's external incident investigation by writing a report to SoS while the internal incident investigation was being completed. The assignment for SoS was to recognise if the healthcare provider had fulfilled their legislative obligation as described in Section 1.1.2. Thus, the guiding questions of SoS were: has the healthcare provider done enough to ensure that healthcare is both safe, of high quality and works best to serve its recipients?

The investigation team of SoS consisted of 1 inspector, 1 investigator and 1 head of unit at the regulatory authority. During the investigation, the team acquired expertise knowledge from a medical scientific advisor connected to the authority. SoS refer to 4 specific Swedish legislative regulations that form the base for their decision. The investigation took 24 months to complete and was presented in an 18-page report; 8 pages from the investigation team and 10 pages from the medical advisor.

(iii) The Swedish Accident Investigation Authority (SHK)

SHK initiated its external incident investigation as a self-imposed assignment with no particular commissioning body. In this investigation of an adverse healthcare event, SHK recommendations upon completion were, as legislation states, targeted to the successor of SoS, namely IVO as mentioned in Section 1.

The investigation team of SHK was composed of 3 members; 1 chairman, 1 team leader and 1 investigator in behavioural science. During the investigation, the team acquired expertise knowledge from 5 specialists; 2 in behavioural science, 2 in medicine and 1 in medical technology. The investigation by SHK should result in answers to three explicit questions: (1) What happened? (2) Why did it happen? and (3) How is the recurrence of a similar event avoided?

SHK's investigation took 33 months to be completed and was presented in an 81-page report.

A timeline of the duration for each of the three investigations is presented in Fig. 1.

2. Material and methods

Our study was conducted as a content analysis of three official, and on request publicly available, adverse event reports; all focusing on the same event. Following our research question (see Fig. 2), the content analysis had the following guiding questions: (1) How do the three investigation bodies construct causal factors of the adverse event in temporal and spatial spaces? (2) How do they, more conceptually, understand the adverse event? and (3) What perspectives were *not* taken, i.e. what narratives of adverse event-causation were *not* constructed as meaningful to guide future targets of intervention?

The claim that incidents need to be understood and constructed in spatial and temporal dimensions is raised in several of the schools of safety thought introduced in Section 1. Turner (1978) suggested already in the 1970s that incidents are preceded by an "incubation period". In Rasmussen's 'mapping' of incidents hierarchy and time forms the dimensions of causal construction (Rasmussen and Svedung, 2000). This approach is further used by Snook (2000) who uses these dimensions to show how complex organisations practically "drift" towards incident prone states. Further, sociologists like Vaughan has adopted a similar perspective focusing on deviance (from original norm) as a normalization process (Vaughan, 1996). More recently Dekker and Pruchnicki (2013) argued that such theorizing is still highly relevant. In our content analysis of the three reports on the adverse event the expression 'space' represents at what organisational level the causal factors are found and the expression 'time' represents how distant the causal factor is from the adverse event.

First, in order to identify the organisational level ('space') of the causal factor, we arranged codes according to a micro-meso-macro perspective (Cedergren and Petersen, 2011; Wrigstad et al., 2014, 2015). A causal factor at a micro organisational level is a factor identified within the department where the adverse event occurred, for example a local procedure, technical skills or staff issues. A causal factor at a meso organisational level is a factor that is identified outside the department where the adverse event occurred, for example the collaboration with another department or hospital management. A causal factor at a macro organisational level is a factor identified outside the organisation, for example the collaboration with another healthcare provider, authorities, politics or pharmaceutical companies. Second, to identify and code the distance in 'time' from the adverse event to a causal factor described in the incident investigations, we arranged a timeline (see Fig. 3) where "far" was the code for causal factors identified before admittance to the hospital, "close" was the code for causal factors identified from the admittance to the hospital until departure from the TICU and "very close" was the code for causal factors



Fig. 1. Timeline showing the duration of the three investigations.

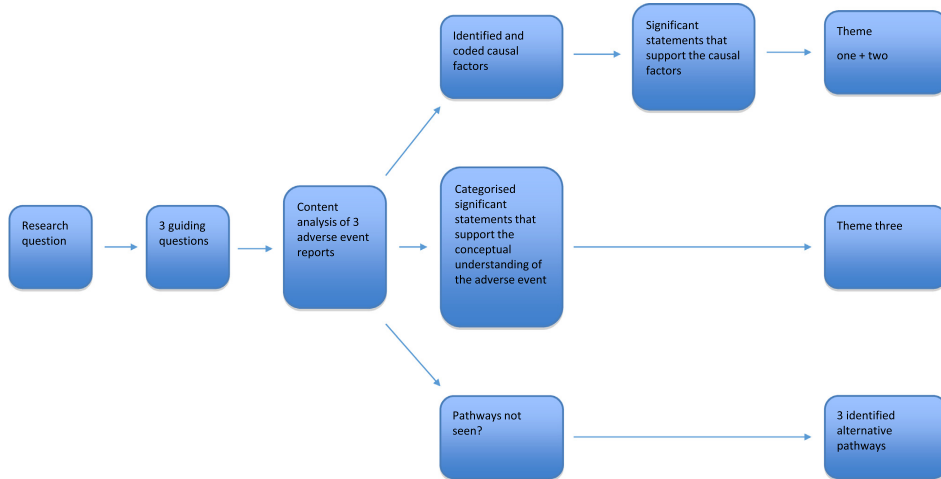


Fig. 2. An illustration of the method used in the study.

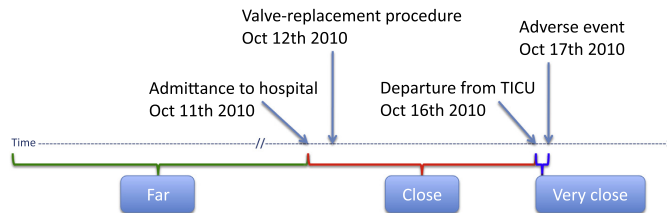


Fig. 3. Timeline showing the coded distance to causal factors from the adverse event.

identified from departure from the TICU until the adverse event occurred.

As shown in Fig. 2, in the first part of the content analysis (guiding question (1) we identified and coded all the causal factors from the respective investigation reports according to 'space' and 'time'. Thereafter we highlighted significant statements from the investigations that supported the construction of the causal factors. In the second part of the content analysis (guiding question (2) we highlighted and categorised significant statements that supported the conceptual understanding of the adverse event. Finally, as the last part of the content analysis (guiding question (3), we searched for pathways that the investigatory bodies tended *not* to see and were *not* taken when constructing the causal factors in accordance to the views given in Section 1.

All significant statements were thereafter thematised according to the first two guiding questions. Thus, the first guiding question resulted in themes one and two, whereas the second guiding question resulted in theme three. For the third guiding question three different alternative pathways were identified in accordance to theories mentioned in Section 1. The themes constructed and the alternative pathways identified through the content analysis are introduced in Section 3 (see also Fig. 2). The significant statements presented have been translated from Swedish to English by the first author and all are tagged with a number that represents an investigatory body.

3. Results

Based on a content analysis of the three investigations, guided by the questions introduced in Section 2, we defined three main *themes* of adverse event construction and three *alternative pathways* that could have better aligned the investigations with contemporary safety science (see Fig. 2).

The first theme is the construction(s) of the adverse event as one that occurred in the adverse event's immediate temporal proximity. The second theme relates to how all three investigations locate the causal factors as occurring in the patient's immediate spatial proximity. The third theme focuses on the underlying conviction that the adverse event represents a deviation from a safety norm.

The focus of the first alternative pathway is the possibility for an investigation to address the macro level of the Swedish healthcare system. The second alternative pathway relates to the possibility of studying normal work. The third alternative pathway deals with the possibility of an investigation to acknowledge and appreciate human adaptive capacity. We will in this section present the themes and support them by using some, out of a total of 35, significant statements from the investigations. Furthermore, we will present the alternative pathways and support them by raising several questions not asked in the investigations.

Table 1

Distribution of organisational level and distance in time from the adverse event in all of the identified causal factors from the three investigatory bodies. The letter in brackets represents the tagged letter after the significant statements under the different themes.

	Healthcare provider (A)	Distance	SoS (B)	Distance	SHK (C)	Distance
Macro	0		0		0	
Meso	<ul style="list-style-type: none"> • Failure of hand-over between staff and departments • An absence of a formal routine and distinct responsibilities when transferring patients from one unit to another 	Very close	0		<ul style="list-style-type: none"> • Failure of hand-over between staff • How patients in the satellite system were taken care of 	Very close
Micro	<ul style="list-style-type: none"> • Not sufficiently enough nurses on the night shift • Staffs' know-how of the cardiac monitoring system, interpretation of the given data and temporary pacemaker treatment 	Very close	0		<ul style="list-style-type: none"> • Routines and the usage of the cardiac monitoring system • Staffs' feasibility of giving surveillance to the patient 	Very close

3.1. Theme one: Immediate temporal proximity

The graphic layout from the healthcare provider's investigation defines the time that is investigated from the day of surgery until the fatal cardiac arrest; in total 6 days. The most extensive part of the investigation, where broken barriers and causal factors are identified, is from the transfer from the TICU to the CICU until death, with 9 of 13 boxes in the graphic layout covering this 6-h period. This converts to 2½ of the 3 pages in the report where the event is described, and where all 4 causal factors are identified, thus in the immediate temporal proximity of the event (see Table 1 and Fig. 3).

As stated above, the role of SoS is not to conduct its own investigation as much as it is to review and comment the investigation process of the healthcare provider. Consequently, the causal map of SoS regarding the timeline is identical to the causal map of the healthcare provider (see Table 1).

SHK's description of the adverse event is a time line that starts on the day the patient is admitted to the hospital and ends at the autopsy, thus approximately 10 days. When describing and framing the event 3½ of 4½ pages in the report comment on the time period of approximately 6 h from the transfer from the TICU until her death in the CICU. This is equivalent to the time period where all 4 causal factors are identified, thus in the event's immediate proximity (see Table 1 and Fig. 3).

3.2. Theme two: Immediate spatial proximity

Of the presented causal factors in the different investigations the first one presented in the healthcare provider's report and SHK's report are identical: failure of hand-over between staff (and departments). We coded this as a causal factor on a *meso* organisational level (see Table 1).

"A hand-over was made by telephone from a nurse at the TICU to nurse 1 on the evening shift at the CICU. The CICU nurse took handwritten notes on a piece of paper, since she was not able to report the patient directly to nurse 2 taking over the night shift as she was assigned to immediately transfer and give care to another patient on the way to an examination at the department of neuroradiology." (A)

"Nurse 2 on the night shift received the handwritten piece of paper with information of the TICU patient from nurse 1 on the evening shift. Since nurse 2 on the night shift wasn't able to take immediate care of the patient, she handed over the responsibility for this patient, and all of her patients, including the handwritten notes to nurse 3 on the night shift. Nurse 3 on the night shift knew nothing about the patient beside the handwritten notes she had received." (B)

"Because of the workload there was no time for a normal hand-over from the evening staff to nurse 1 on the night shift. There-

fore, nurse 1 on the night shift just took a brief oral report about the patients in her care." (C)

The system with so called satellite patients is an informal, but well-known, routine in Swedish healthcare to cope with recurring shortages of beds in different departments, intensive care units and wards. The second presented causal factors core message is also identical in the healthcare provider's investigation and SHK's: an absence of a formal routine and distinct responsibilities with the satellite system. We coded this as a causal factor on a *meso* organisational level (see Table 1).

"The physician on call at the TICU consulted his colleague at the CICU. They decided to transfer the patient to CICU since there was a need for cardiac monitoring. Care was supposed to be given as a so called satellite patient meaning that she still was under medical surveillance of the TICU, but care was given at the CICU." (A)

"Since there was a need for cardiac monitoring with the possibility to detect arrhythmia, the physician on call at the TICU made a judgement call that CICU was an appropriate intensive care unit in waiting for transfer to a ward at the thoracic department the next day." (C)

"When there was a shortage of beds at the TICU during the evening on the fourth postoperative day, it was decided to transfer the patient temporarily over night to the CICU for cardiac monitoring, before moving to a ward at the thoracic department the following day. A shortage of beds is unfortunately a recurring phenomenon in most organisations that involve thoracic surgery because of sudden emergency cases." (B)

Shortage of staff is a reappearing and well-known problem in Swedish healthcare. In the healthcare provider's investigation, this problem is identified and presented as the third causal factor: not sufficiently enough nurses on the night shift. The causal factor is supported, yet not stated, in the reports of the other investigations as well. There is no discussion in any of the investigations regarding shortage of staff being a problem in general and thus, this was coded as a causal factor on a *micro* organisational level (see Table 1). It should be noted that the ward was normally staffed during the night when the adverse event took place.

"When assistant nurse 1 on the evening shift was about to connect the patient to the cardiac monitoring device she was suddenly interrupted by the janitor who asked for help to transfer another patient going for an examination at the department of neuroradiology." (A)

"While nurse 2 on the night shift was away from CICU the workload was high for nurse 3 on the night shift. Beside the patients in her care other patients had arrived as well..." (A)

"The consequence of a high workload at the CICU was that assistant nurse 1 on the evening shift alone took immediate basic care of the patient upon the arrival from TICU..." (C)

“The staff situation seems to have been poor. This caused an unacceptable workload for some of the nurses as well as non-existing time to deal with the handover in an appropriate way.” (B)

Training and competence of staff is crucial for any healthcare provider with the ambition of maintaining safe healthcare. The fourth presented causal factor by the healthcare provider is merely identical to the third causal factor presented by SHK, the core message being: routines for staff regarding the cardiac monitoring system and its interpretation. This was coded as a causal factor on a *micro* organisational level (see Table 1).

“Interpretation of cardiac monitoring is an advanced task. (...) It takes years of clinical experience in combination with repeated training to accomplish competence in the field to guarantee a high level of patient safety.” (C)

“There is a lack of knowledge within staff regarding how the cardiac monitoring functions and interpretation of monitoring data including how a temporary pacemaker is used for treatment. Training of newly employed nurses and assistant nurses is continuously ongoing within the department, but there is no follow-up with repetition and testing over time.” (A)

“The responsibility lies on the nurse on the shift to check that monitoring is connected and verified correctly. It seems that this has not been fulfilled in this case.” (B)

An intensive care unit environment can often be a stressful workplace, a dynamic workload constantly changing, different alarms from different devices and sudden interruptions of work because of unforeseen processes. Therefore, the physical premises where the work is done and the location of control centres is of importance to maintain standard of care and staff's ability to work. The fourth presented causal factor by SHK identifies this: the staff's feasibility of giving surveillance to the patient. This was coded as a causal factor on a *micro* organisational level (see Table 1).

“When SHK performed individual interviews approximately half a year after the adverse event, staff said that no alarms had been detected from the patient. However, from the manufacturers' files one can find that four 'red alarms' actively have been silenced from the control centre...” (C)

“The monitoring alarm from 01.04 a.m. is disturbing and should have resulted in immediate contact with the physician on call.” (B)

3.3. Theme three: The event as a deviation from norm

We will here present and comment on a number of statements, where the core message is that the adverse event represents a deviation from a safety norm; a norm which the system could and should adhere to, through means of management structure and staff compliance. This presentation relates to our second guiding question from the content analysis. All the investigations shared the same conception of an underlying model as to why adverse events occur; a linear chain of events from a human root cause.

From all three investigations we conclude that work performance variability, i.e. degrees of freedom in how to conduct work at the staff level, is constructed as a threat to patient safety. Inherent in this idea is that there is one best practice for each task, and that any deviation from such best practice represents a violation and calls for increased formal structuring of work.

“From a management point of view, the daily practical work and work methodology has to a large degree been handed over to the employee's knowledge and experience. This includes the memorandums that have been created in the department without any formal approval.” (C)

“We look upon the event seriously and claim that the patient in this case has not been treated according to standard procedures during transfer to the CICU and during the stay at the CICU.” (B)

It's pointed out in the different investigations that staff needs to be more vigilant and focused when giving care to the patient.

“When a patient has a temporary pacemaker certain precautions should be taken since it means an increased risk, partly because of the ability of the monitoring system to sufficiently alert and partly because a temporary pacemaker needs specific routines that were not carried out during the night shift. In this case there was an increased risk that there would not be an adequate alarm from the monitoring system since it was not connected appropriately.” (A)

“Assistant nurse 1 on the evening shift, who was aware of the patient's pacemaker, obviously did not check that assistant nurse 2 on the evening shift had marked this important information.” (B)

Inherent in the idea of the accident representing a deviation in an inherently safe (if only complying with the norm) system, is also the 'Heinrich-ian' and dualistic search for causal factors at *either* the level of unsafe human behaviour or malfunctioning technology. Consequently, the potentially complex interaction between humans and technology is not discussed at all in any of the three reports. SHK's investigation identifies that during the period 2006 to 2012 there has been 17 reported adverse events into the hospital's incident reporting system related to “cardiac monitoring” in this CICU. Instead of constructing this as a problem of human-machine configuration and interaction, the investigations are satisfied with concluding that no defects have been found in the monitoring system after examination by the manufacturer. The SHK investigation notes that the full Swedish instruction manual comprises 366 written pages.

“No faults have been recognised in the technical equipment according to the manufacturer, meaning it has worked as intended.” (C)

“The technical device has functioned without any faults and the missing alarm was due to the fact that pacemaker detection had not been marked.” (B)

The reports acknowledge how the staff was coping with time pressure, a perceived shortage of staff and an increased workload during the work-shift. However, rather than analysing staff behaviour as a product of this environment, all three reports make the analytical choice to fundamentally attribute the unfolding of events to staff behaviour rather than the work environment. Again, the idea is that staff members could, and should, work according to a safety norm that would not have allowed the adverse event to take place:

“In this case the impression is that formal handover was done too quickly. There was not even time to give the compulsory oral report and instead a handwritten piece of paper with notes on a new patient was handed over.” (B)

“The CICU had no established system for formal handover supported by a checklist. (...) According to SHK, it is obvious that the absence of a formal system for handover in a setting like the CICU's with advanced intensive care can be a patient safety risk.” (C)

3.4. Alternative pathway one: Addressing the macro level of the Swedish healthcare system

The two identified causal factors on the meso organisational level are identical, as regards the core of interest. First, there was

a failure in communication between staff and between the intensive care units when the patient was transferred. Second, there were insufficient guidelines when transferring a patient between the two current intensive care units. We believe that an event like this gives opportunity to formulate much more systemic explanations of adverse events. Additional questions, targeted at the macro level of the Swedish healthcare system, includes:

- Do healthcare staff recognise negotiating the occupation of bed spaces between wards to be an intricate part of their work life?
- Is limits to ICU beds a generic problem in Sweden? And if so:
- For how long has limits to ICU beds always been a problem in the Swedish healthcare system?
- How did this problem emerge? In what political environment? In what (perhaps gradual) structural change of the Swedish healthcare system?
- What makes an informal routine with satellite patients a reasonable solution?
- What makes the solution to move a patient to a resource constrained CICU preferable to keeping the patient in an overcrowded TICU or sending the patient, who's condition had not changed at the time, just a few hours earlier than initially planned, to a ward tightly coupled to the TICU, and that on a daily basis receives these kinds of patients with exactly this monitoring? The fact that transfer of the patient to the CICU was perceived as the best option must prove that it was reasonable to do so, but what system structures and relations made it so?

3.5. Alternative pathway two: The possibility to study normal work

In a seemingly dualistic manner none of the investigations found any defects of the matter (the monitoring system), and hence looked for the defects of the mind (human behaviour). Both the healthcare provider and SoS present a similar scenario on the micro organisational level with inadequate technical skill of the staff in cardiac monitoring and not adhering to procedures in surveillance of the monitoring system. SHK, with vastly more resources put into their investigation, comes with a similar causal construction. SHK recognizes numerous reported adverse events from the past focusing on human-machine interaction. Still, their report focuses mainly on insufficient management and controlling of staff. We see this as a lost opportunity to analyse how human and machine actors are configured in their working environment. An analysis of the implementation of, and relation to, technological devices, interfaces and functions could reveal sources of brittleness and resilience not only of this hospital but perhaps the Swedish healthcare system as a whole. Our second additional pathway includes the following questions:

- Why does cardiac monitoring (devices) have to change at all when a patient is moved from one intensive care unit to another, especially within the same organisation?
- What is the process for implementation of technological equipment?
- How is this cognitive system of humans and technology configured? How does it coordinate its actions to achieve its purpose? Are there recurring unintended (and undesired) consequences such as coordination failure, alarm fatigue, or automation surprises?
- Is it reasonable to believe that 350+-page manuals regarding complex monitoring equipment are read and understood by all intended users?
- How can cognitive work analysis become a part of the process to implement new technology to Swedish healthcare working environments?

3.6. Alternative pathway three: The possibility to acknowledge and appreciate human adaptive capacity

Among the three investigations, SHK seems to avoid making direct judgement calls on the role of staff. However, the focus of analysis is still on the unreliable and risky staff behaviour. While the countermeasures suggested by the healthcare provider are targeted to working procedures and staff behaviour, SHK targets SoS in stating that the authority needs to ensure that the healthcare provider implements, and adheres to, a safety management system. Ultimately, in all three investigations the individuals fail to adhere to safety standards and norms. In none of the investigations adaptive human behaviour is seen as a valuable resource with the ability to adjust and adapt to risky, messy and complex situations. Instead, humans are constructed as a problem to manage and control. We encourage an analytical shift of focus into one that acknowledges how human action and agency as a vital resource to harness in complex and variable working environments and even how human adaptive capacity sometimes (perhaps in this case?) can work to 'hide' system brittleness. Thereby, this event offers the possibility to ask the following questions:

- Do staff members at the involved units believe that organisational levels higher in the hierarchy understand the difference between work-as-imagined and work-as-done (see [Patterson et al., 2006](#))?
- Do staff members perceive that they, within their 'margins of manoeuvre' (see [Woods and Branlat, 2011](#)), have the degrees of freedom necessary to adapt to the dynamic environment in which they are configured?
- To what degree do members of staff at the different units involved perceive that they are appreciated for the work they do?
- How much of their work do staff members perceive to be adaptation to situations that are not part of a prescribed routine?
- What is the stress level as perceived by the staff at the involved units?

4. Discussion

The adverse event in focus of this study represents one of the most thoroughly investigated in Swedish healthcare history. It is the first healthcare case to ever attract the attention of SHK. The main focus of our study was to examine if a parallel dissection of the three investigations would reveal an epistemological pluralism that could generate a systemic understanding of the event and thereby serve as an indicator of a way forward when learning about safety from events, or experience, in history ([March et al., 1991](#)). This could be expected, given the differences in resource availability for the investigations, the different targets of recommendations for the different investigation bodies and the different societal roles they play in the healthcare system.

However, rather than a study of the different ways in which three different public investigation bodies contribute to the knowledge of how patient safety is compromised, we were struck by the extent to which the three investigations share the same assumptions on how an adverse event represents a deviation from system norm which is built up in the event's immediate temporal and spatial proximity. In other words, instead of drawing a broader picture of the adverse event the different investigations confirm each other's findings when acting according to regulations. Perhaps this should not be seen as surprising, though. For investigations conducted by healthcare bodies we have seen this tendency to locate adverse event causation close in time and space of the event itself ([Wrigstad et al., 2014](#)). [Cedergren and Petersen \(2011\)](#) made similar observations of SHK's construction of factors contributing to adverse events in the railway domain. In the way the incident

reporting system is constructed in this healthcare system a completed incident investigation by a healthcare provider organisation will always be a main source of information for the upcoming authority investigation(s) and thereby possibly framing and guiding the understanding of the event. However, having a main source does not rule out the opportunity of any authority to broaden its sources of information regarding an event by, for example, performing on-spot inspections where the event occurred, using an alternative adverse event causation model or widening the perspective by expanding on background information through more and various accounts related to the event.

According to Dekker (2014a–c) incident investigations provide meaning by fulfilling four psychological purposes: (1) epistemological explanation of *what* happened linking causes to effects, (2) preventative explanations of how to avoid similar events to reoccur in the future, (3) moral explanations drawing the boundaries of behaviour for a profession (in a vocabulary typically dressed up as epistemological) and (4) existential explanation helping us to cope with the suffering of how even the systems institutionalized to cure can cause us harm. Our observation that a safety discourse, which makes three different public bodies in their investigations of the same event choose highly similar causal constructions, seems strong in the adverse events prevention-domain, can perhaps be explained by how effectively they meet the four purposes of incident investigation as introduced here. Summarizing all four psychological purposes: The three investigations allows for us to move on, ensured that suffering stems from unreliable human behaviour in systems that only require more structured control. Further, as Foucault (2002) would argue, a discourse determines not only what *can* be stated (in terms of causal factors of adverse events in healthcare), but also what *cannot* be stated. Consequently, we focused parts of our analysis on what perspectives that *were not* taken, and what narratives of adverse event-causation that *were not* constructed.

While we acknowledge how all three investigation bodies write accounts that make them satisfy the psychological purposes of incident investigation we still see them as a missed opportunity to embrace more complex epistemologies and diverse accounts of the event. Answering the questions from our first alternative pathway would require a broader analysis in both temporal and spatial scope. It would require studies of the structural as well as functional organisation of the Swedish healthcare system and the relationship between functions such as primary care, general internal medicine, intensive care and surgical care. It would further require a study of how the current state of affairs in the Swedish healthcare system has been configured by political and professional decisions made perhaps over decades. Such examples do exist in the history of adverse event investigation. For instance, the board investigating NASA's second loss of a space shuttle; Columbia, introduce one of their chapters in the following way:

"The causal roots of the accident can also be traced, in part, to the turbulent post-Cold War policy environment in which NASA functioned during most of the years between the destruction of Challenger and the loss of Columbia. The end of the Cold War in the late 1980s meant that the most important political underpinning of NASA's Human Space Flight Program – U.S.-Soviet space competition – was lost, with no equally strong political objective to replace it. No longer able to justify its projects with the kind of urgency that the superpower struggle had provided, the agency could not obtain budget increases through the 1990s. Rather than adjust its ambitions to this new state of affairs, NASA continued to push an ambitious agenda of space science and exploration, including a costly Space Station Program."

[Columbia Accident Investigation Board, 2003, p. 99]

The questions asked in Section 3.4 could possibly guide an analysis towards similar causal factors of the adverse event studied here.

Additional (scientific) studies of adverse events as configured in a hierarchy from the sharp end-operations to the political level, and over a long period of time, include Snook's account of a friendly fire incident over northern Iraq in 1994 (Snook, 2000) and Vaughan's comprehensive analysis of the cultural environment of production contributing NASA's first loss of a space shuttle, Challenger (Vaughan, 1996). Further analytical language could be provided by Cook and Rasmussen (2005) who have provided a dynamic model discussing the behaviour of a "solid" healthcare system in which the coping resources and buffers are exhausted.

Looking at the second alternative pathway, the investigations studied in our analysis pictures a fixed technological environment for which humans need training and motivation to fit. Our questions above, on the contrary, suggest an analytical possibility that the joint cognitive working environment is configured in a way that makes the synchronising of functions, and activities between human agents and technological agents, inherently prone to regularly produce unexpected results and conditions. SHK does recognise that there are 17 reported adverse events related to "cardiac monitoring" in this CICU alone; but does not open up for the possibility that this says something about an inherently risky configuration of a working environment.

Also this alternative analytical pathway would rest on an extensive research base of how to design and understand joint cognitive healthcare working environments (Cook and Woods, 1996; Woods, 1995; Schmid et al., 2011; Raymer et al., 2012; Raymer and Bergström, 2013; Klein et al., 2004; Hollnagel and Woods, 2005).

The questions in the third alternative pathway emerge as a consequence of the different causal factors presented in the investigations that all seem rooted in the logic that variability is a problem to control rather than a resource to harness (to paraphrase Dekker, 2014a–c). Again, there is literature suggesting that not only risk is a result of system variability; so is safety (Cook and Woods, 1994; Dekker, 2014a–c; Hollnagel, 2014; Hollnagel et al., 2013). Understanding adverse events as unexpected products of normal (and 'normal' typically complex and dynamic) work allows for an analysis that not only can allow itself to go beyond easy targets of erroneous behaviour, but also opens up the ethical discussion of what working conditions and environments that could be accepted (Bergström et al., 2015).

5. Conclusions

We have here provided an analysis of how three different public bodies analysed the same adverse event that occurred in a Swedish hospital. We have recognised how they, while spending vastly different amounts of time and resources, all make the same analytical choice to construct the causal factors of the event, as a deviation from norm in the event's immediate temporal and spatial proximity. Further, we have suggested that this strong discourse prohibits more complex constructions of the adverse event as a symptom of the structural and functional configuration of Swedish healthcare, as developed over several years, or of how humans and their technology are configured in their working environment. Finally, we suggest that this strong discourse seems to fulfil psychological purposes for an organisation to move on after an event while at the same time it ignores contemporary research suggesting that variability is not only a source of risk to be controlled, but also a resource that makes a Swedish healthcare organisation at all function in the complex and dynamic environment in which it is configured.

We do recognise that the three investigation bodies studied find themselves, and what causal constructions that they can formulate, configured in a wider political and societal system with legislated boundaries that frame their ability to act respectively. Hence, a discussion regarding incident causation model used and additional questions to be asked in the wake of adverse events in healthcare cannot avoid a political dimension. We believe that such a societal discussion is necessary in order to go beyond moral stories of deviation from norm in the event's immediate temporal and spatial proximity.

Acknowledgements

The study was partially funded by a grant from the Swedish National Patient Insurance Company. The authors appreciate and wish to thank dr Urban Nylen for his assistance with inspiration, background information and proof reading of the manuscript.

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Paper IV



RESEARCH ARTICLE

Open Access



On safety ontology: a cross-section analysis of incident investigations in a public healthcare system

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Abstract

Background: Due to new legislation in 2011 and 2013, the Swedish public healthcare system has undergone change as regards incident reporting and supervision. Focus has turned to learning from adverse events and sharing this learning with actors within the system. The aim of this study was to explore with what underlying safety ontology adverse events in the incident reporting system are investigated.

Methods: A content analysis of 90 official and recently completed incident investigations from all six regional supervisory authority offices in Sweden was performed. Data was examined per nature of the investigation, number of targets for intervention, specific final comments in the investigation and the decision from the supervisory authority. A coding scheme was used to identify the organisational level of the targets for intervention.

Results: With different investigation methods in use, this incident reporting system still seems to contribute to a reproduction of an organisational micro-level understanding of how risks emerge with a focus that operates in the event's immediate spatial proximity. There are no signs of constructive dialogue on exposed matters between the main actors: the healthcare provider organisation and the supervisory authority. There are strong examples of mistranslation of social infrastructure from other safety-critical organisations. Actors and individuals at the blunt end of the healthcare system adapt to new legislation and organisational change by balancing rhetoric and practice during fulfilment of stated obligations.

Conclusions: Our findings support that traditional linear causality construction and traditional norms remain intact despite new legislation and recent organisational change. Through efficient and adapted working procedures by the main actors, this model still brings societal closure of harm and thereby a way to focus on moving on forward.

Keywords: Adverse event, Incident investigation, Healthcare, Legislation, Ontology

Background

Lessons learned from adverse events and incidents have for decades been used for the development of safety interventions. Incidents in safety-critical organisations have throughout the twentieth century served as epistemological crossroads for further understanding of system behaviour and meaningful system intervention [1–3]. The Institute of Medicine's report *To Err is Human* [4] in 2000 pointed out that reporting and subsequent system analysis of adverse events are key in quality and safety

improvement in the healthcare field. Numerous healthcare organisations worldwide have since invested in, established and institutionalised incident reporting systems, most often adapted from other safety-critical organisations, arguing that economic advantages and increased patient safety are the overall aim [4–6].

Within this discourse, a Swedish legislative change took place in 2011 with the introduction of the Patient Safety Act [7] and thereafter in 2013 with the creation of a new supervisory authority: the Health and Social Care Inspectorate (HaSCI) [8]. Both legislation and the HaSCI emphasise the responsibility of the healthcare provider organisation (HPO) to learn from adverse events, as well as sharing this learning with others. However, contemporary

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safety science research has shown that such learning and sharing can be difficult for organisations to apply in practice [9, 10] and that organisational forgetting is a common phenomenon [11, 12].

Since 1937, the Swedish healthcare system has used a model, regulated by legislation, for external investigation of severe incidents by a regulatory authority [13]. The foundation of this law states that if an adverse event has resulted, or could have resulted, in a serious injury, this should be reported to the regulatory authority for an external incident investigation. This model with a HPO reporting incidents to a supervising regulatory authority has since then stayed virtually intact, even though certain modifications, including name changes, have been made over the years. Despite changes in political governance, Sweden has predominantly continued to have a public healthcare system.

The regulatory authority has in recent years issued specific regulations governing the responsibilities of the HPOs: for example, using an incident reporting system and carrying out internal incident investigations. In 2011, the aforementioned legislative change pinpointed the specific responsibility of the HPOs for patient safety improvement within their respective organisations [7]. These regulations state that the regulatory authority ‘... ensures that reported adverse events have been investigated to a necessary extent, and that appropriate actions have been taken by the HPO to reach a high level of patient safety’.

With the creation of the HaSCI in June 2013 [8] came the commission to take over the *supervisory* role of the healthcare system from the National Board of Health and Welfare, both acting under the Ministry of Health and Social Affairs. The HaSCI has six regional authority offices respectively covering certain geographical regions of the nation.

Since 2005, methodological support for conducting the internal incident investigation has been provided to HPOs by the Swedish Association of Local Authorities and Regions [14].

In our previous studies on a local and regional level, we focused on describing changes over time regarding the incident reporting system, identified targets for intervention from the different actors in the healthcare system and suggested alternative pathways for analysis of adverse events [15–17].

In this study, we were interested in simultaneously exploring the most recent data from all regional incident reporting systems in the Swedish public healthcare system, searching for the mechanisms that could describe, understand and answer our research question: with what underlying safety ontology are adverse events in Swedish healthcare investigated? Our guiding questions were (1) what organisational levels are targets for intervention in

incident investigations today? (2) what role do the actors, the HPO and the new supervisory authority, play in incident investigations today? and (3) can regional similarities or differences be seen in incident investigations today?

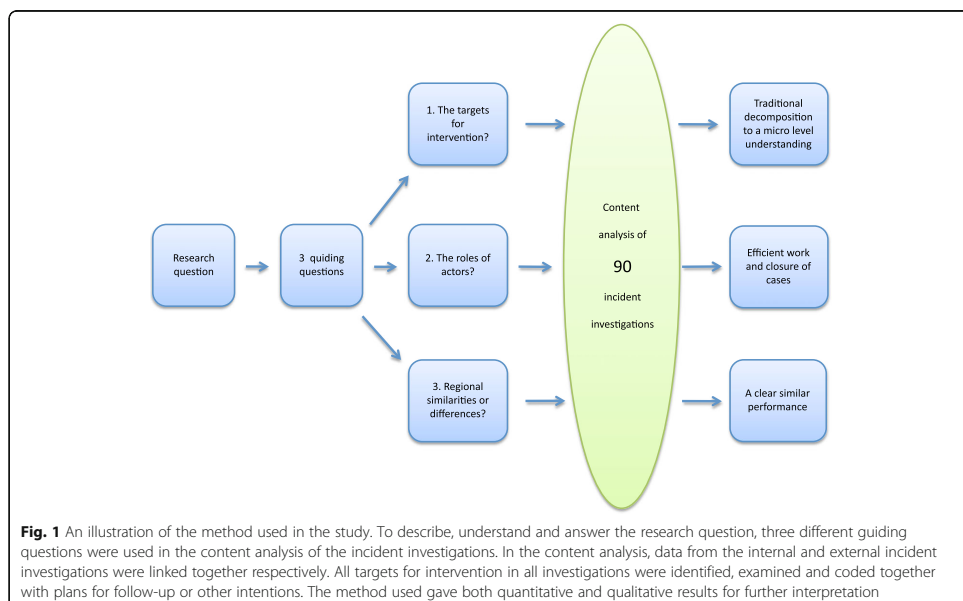
Methods

According to the policy activities that constitute research at our institution, congruent with both the Regional Ethical Review Board and the national *Act concerning the ethical review of research involving humans* (2003:460), this study meets criteria that are exempt from ethics review.

In general, the chief medical officer (CMO) of a public HPO determines when and what to report to the supervisory authority by using data from the incident reporting system. Upon decision to report, a commissioning body within the HPO is assigned to conduct an internal incident investigation. The commissioning body is most often the chief medical officer or the clinical head of department where the adverse event occurred. An analysis team is set up to perform an internal incident investigation and thereafter presents a report with causal factors and recommendations on actions to the commissioning body.

Recently, within some HPOs, these investigations have changed in nature, now having the character of a ‘short internal report’ performed by either the clinical head of department where the adverse event occurred or by the CMO who decided to report. Whichever pathway the HPO chooses a report with causal factors and recommendations on actions to take is a mandatory part of the assignment. The internal incident investigation, with or without comments from the CMO, is thereafter sent to the supervisory authority. The external incident investigation by the supervisory authority is always preceded by the HPOs’ internal incident investigation (or ‘short internal report’). At the authority, an inspector is assigned to perform the external incident investigation, but since the latest change in legislation, an *auditing* of the HPOs’ own internal incident investigation is the actual assignment. The report from the external incident investigation is presented to the head of unit at the authority, and after a decision addressing the fulfilment (or not) of the HPOs’ legislated obligations, the report is sent to the HPO.

Our study was conducted as a content analysis of the most recent official, and on request publicly available, completed internal and external incident investigations from all six regional supervisory authority offices in Sweden (Fig. 1). The internal and external incident investigations were both compiled and de-identified by the HaSCI. We asked for the 15 most recently completed incident investigations from each region, excluding primary healthcare, psychiatry and private healthcare organisations. This resulted in 90 internal and external



incident investigations dating from December 2015 to May 2016.

The internal incident investigation from the HPO and the external incident investigation from the supervisory authority were linked together respectively and numbered as received from the HaSCI. The content analysis aimed to identify, examine and code all targets for intervention from all incident investigations and short internal reports, together with the investigations' plans for follow-up or other intentions. Therefore, data was examined per (a) the nature of the internal incident investigation, (b) the number of targets for intervention from the internal incident investigations, (c) attached final comments from the CMO to the supervisory authority regarding the adverse event and (d) the supervisory authority decision in the external incident investigation.

A coding scheme was used to identify the organisational level of the targets for intervention in the different incident investigations. The targets for interventions were coded according to a micro-meso-macro-perspective in equivalence to previous studies [15–18]. A target for intervention at a micro-level is within the department where the adverse event occurred: for example, a local procedure, technical skills or staff issues. A target for intervention at a meso-level is outside the department where the adverse event occurred: for example, the

need for collaboration with another department or hospital management. A target for intervention at a macro-level is outside the specific HPO: for example, the collaboration with another HPO, authorities, politics or pharmaceutical companies.

Due to the semi-quantitative and qualitative nature of the study, we carried out no further statistical analyses than presented below.

Results

Internal incident investigations

In the 90 investigations analysed, a total of 313 targets for intervention were identified. The total distribution of these targets was as follows:

- Micro organisational level 263 (84%)
- Meso organisational level 48 (15.3%)
- Macro organisational level 2 (0.6%)

On examining the nature of investigations, 43 of 90 had the character of a 'short internal report', compared to the more traditional 'internal incident investigation' done by an analysis team. The number (n) of targets for intervention was higher in the group of 'internal incident investigations', but the relative distribution (%) of targets for intervention was similar in the two groups:

Short internal report:

- Micro organisational level $n = 86$ (86%)
- Meso organisational level $n = 13$ (13%)
- Macro organisational level $n = 1$ (1%)

Internal incident investigation:

- Micro organisational level $n = 177$ (83.1%)
- Meso organisational level $n = 35$ (16.4%)
- Macro organisational level $n = 1$ (0.5%)

In 5 of 90 investigations, no targets for intervention were presented by the HPO. In these 5 investigations, the supervisory authority closed the case with no further intention.

In 16 of 90 investigations, the CMO recognised that 'similar events' had occurred within the HPO. In 1 of these 16 investigations, there was a follow-up plan by the supervisory authority. In the remaining 15 investigations, the supervisory authority closed the case.

In 8 of 90 investigations, the HPO, on its own initiative, tried to improve standards of patient safety through system intervention either using lateral distribution of knowledge on a meso- and macro-level or by performing a risk analysis as a consequence of acquired knowledge from the investigation. In none of the 8 investigations did the supervisory authority do anything further.

External incident investigations

In 70 of 90 investigations, the supervisory authority closed the case without further intention after reviewing the internal incident investigation. In the following investigations, one or more action(s) were taken by the supervisory authority:

1. In 15 of 90, the supervisory authority called for a completion of the investigation, and thereafter closed the case in 13 of them. The 2 remaining were planned for follow-up or a site visit.
2. In 3 of 90, there was a plan for follow-up
3. In 3 of 90, a 'new supervisory case' was opened for a separate investigation
4. In 2 of 90, a site visit took place before decision

In one regional supervisory authority office, examination revealed the following from one individual (= one head of unit):

1. 5 of 15 calls for completion came from the same individual
2. 2 of 3 plans for follow-up came from the same individual
3. 1 of 3 'new supervisory case' was created by the same individual

4. 2 of 2 site visits before decision were called upon by the same individual

In the following two sections, a sample of quotations from the investigations is presented for clarification of the results. They have all been translated from Swedish to English by the first author and are all tagged with one (x) or two ($x-x$) italic numbers. The first number represents an investigation and the second number a target for intervention:

Examples of targets for intervention

The micro organisational level:

'A review at the department regarding what kind of straps that are in use to secure patients on an operating table will be performed.' (8–35).

The meso organisational level:

'Develop a routine within the organisation to ensure which department or unit that is responsible for the follow-up of newly diagnosed prostate cancer.' (18–90).

The macro organisational level:

'A regional programme for all HPOs will be produced during 2016 for this group of diagnoses with the aim of shortening the delay for a group of patients.' (50–183).

Examples of decisions from the HaSCI

'The HaSCI finds that the HPO has fulfilled its demands of reporting and investigating. The HaSCI closes the case.' (71).

'The HaSCI closes the case and will not take any further action.' (51).

'The HaSCI finds that the HPO has not fulfilled its demands of investigating since remains of flaws are noticed and actions have not been taken. The HaSCI closes this case and opens a new supervisory case to audit the HPO's patient safety work.' (11).

Discussion

Using the three guiding questions in the study, we here present an analysis of the semi-quantitative and qualitative results by answering the questions chronologically as stated in the 'Background' section, and at the end of this section, an interpretation of these answers as an explanation to the research question raised.

First, in the short time span of 6 months, Swedish HPOs and their supervisory authority have handled numerous investigations of serious incidents that have jeopardised patient safety in a variety of ways. From one point of view, this incident reporting system appears to be well-functioning and aligned both with the Patient Safety Act [7] from 2011, and a recent report in 2015 from the Swedish Agency for Public Management, where a systematic approach and efficiency on legislated obligations was acknowledged and appreciated [19]. From

another point of view, despite revisions of the methodological support from the Swedish Association of Local Authorities and Regions [14], the same linear and narrow accident causation model for conducting incident investigations remains. The model has now been in use for over a decade, suggesting that the procedure for dealing with adverse events has become a well-established standard routine within the healthcare system, and thereby has contributed to an understanding of how incidents evolve. Arguments can also be made that the healthcare system has implemented a model where a certain 'local technical fix' is the solution to whatever incident that occurs [20] and that the incident report processing of large volumes of adverse events perhaps is inadequate [21]. Since this study shows that usage or not of provided methodological support for internal incident investigations does not alter the target for intervention after an adverse event, Hollnagel's two principles WYLF (What You Look For Is What You Find) and WYFIWYF (What You Find Is What You Fix) seem highly applicable [22, 23]. The investigation method(s) seems to contribute to a reproduction of an organisational micro-level understanding of how risks emerge and incidents occur, meaning that the operating focus of the different incident investigations to a large extent is in close spatial proximity to the adverse event. This is congruent with conclusions from our previous studies in which we used geographically more constrained sets of data analysing targets for intervention and causal factors respectively [16, 17]. We cannot draw any general conclusions on actual adverse event causation models used in this newer investigation form, but since the proportions of identified targets for intervention stay nearly intact, the investigators, probably unaware of it, use an equivalent methodological approach with less effort and manpower needed to complete the assignment.

Second, we noticed a lack of constructive dialogue between the different actors: the HPO on one side and the supervisory authority on the other. On the one side, the HPO fulfils its administrative obligations, but only few practical attempts can be traced regarding the system's effort to enhance the level of patient safety, through for example lateral distribution of acquired knowledge or by shedding light on recurring organisational weakness. On the other side, the supervisory authority plays its auditing role by merely seeking the fulfilment of stated obligations. Rarely does it ask for completion of an investigation from the HPO. Further, it is remarkably rare that the supervisory authority tries to broaden the investigation by for example more accounts from the adverse event, follow-up plans or site visits. A dialogue on exposed matters, in which interaction between the two main actors probably could make patient safety issues take leaps forward, is hardly noticeable between the two

with the actual power to initiate this. This uncovered 'lack of dialogue' between main actors of the system can be seen as a strong example of mistranslation of incident reporting systems from other safety-critical organisations to healthcare, where the highly essential social infrastructure for investigation has been missed and instead the processes of filing investigations have been more in focus [10]. We also argue that the entire process of promoting the use of an incident reporting system and performing incident investigations can be regarded as part of a moral enterprise [24, 25] that has important implications for the ability of an organisation to move on by constructing narratives addressing societal purposes of closure [26–28]. In summary, the fulfilment of these purposes ensures that the system has control of the unreliable parts that occasionally emerge, and in such a context, the authoritative auditing and filing role becomes unquestionable.

Third, our data showed that in a vast majority of reported adverse events, the same investigatory approach was observed in all the regional supervisory authority offices; the case was closed after the first reviewing of the internal incident investigation. However, we here made an observation on variability and human behaviour. One individual authority investigator both identified the necessity of more accounts in various cases and used the given authority role as a catalyst for safety improvement within the system. With our limited data, we can only speculate if this finding was coincidental, due to education and in-job training, a high level of work-related vigilance or maybe due to the personal view of the assignment. In previous studies, we have raised concerns about the lack of in-job training of staff being a factor behind the finding of targets for intervention on a micro organisational level and that individuals within the authority mainly look upon themselves as auditing the process [16].

Finally, focusing on all the guiding questions together, we argue that the results in this study picture the consequences that can emerge in a system with mandatory incident investigations in a resource-constrained environment, such as the Swedish public healthcare system. Actors and individuals at the blunt end of the system need to adapt to new matters, such as in this case legislative change and ministerial construction, but mostly by finding pragmatic working solutions to their performance that balance rhetoric and practice beneath a continuous flow of new adverse events and incidents [29]. However, this example of human behaviour also opens a discussion on alternative pathways for conducting incident investigations in the healthcare field. Other organisations in society, and recently even healthcare systems, have established the use of independent investigation teams

to ensure that unfiltered and system-wide causal factors are identified [30, 31]. The traditional idea of adverse event causation that emphasises decomposition or reduction into malfunctioning system components was for decades the major theory in activities enhancing safety. In the report *To Err is Human* [4], this idea seems to be conceptualised and adhered to in the way construction of an incident reporting system evolves and is acknowledged. However, since the dawn of Heinrich's theorems in the 1930s [32], several schools of thought in safety science have developed alternative approaches to the construction of adverse event causation and changed the epistemological starting point on how adverse events evolve, including Perrow's ideas on potential multiple incidents in complex tightly coupled systems [1], Vaughan's description of individuals and organisations accustoming to deviant behaviour from an original norm [2] and Snook's analysis of the slow 'practical drift' of an organisation that uncouples practice from formal routine [3].

In summary, looking at the research question raised through findings in this present study with a limited sample of recently completed internal and external incident investigations, our analysis is that traditional norms including hierarchies of power and control stay intact, that translation of investigation infrastructure from other safety-critical organisations have taken a narrow diverged focus and that traces of adjustment to contemporary safety science research suggesting focus on interactions at different organisational levels are weak regardless of the latest organisational and legislative changes in the Swedish healthcare system. So far, we see these changes, which in rhetoric promotes 'the responsibility of learning from adverse events', as a lost opportunity to alter the direction of a non-fruitful yet long-lasting incident reporting system. Under other circumstances—for example, a shift towards the usage of a variety of incident causation models, establishing routines for handling large volumes of adverse events, redesigning the social infrastructure of the incident reporting system, raising discussions on the core purpose of performing incident investigations and enhancing knowledge (meaning power) by acknowledging the importance of professional training of investigation teams—this incident reporting system could play a significant role and be a powerful tool in a patient safety improvement strategy not only in the public healthcare system such as the one studied.

Conclusions

This study seeks to understand in what safety ontology the Swedish healthcare system presently exist. Using both semi-quantitative and qualitative methods, an analysis of a data set in recently completed incident investigations covering all regional supervisory

authority offices was performed. Obvious signs of a healthcare system using traditional linear causality construction with a focus on the event's immediate spatial proximity were found. Furthermore, strong signs of mistranslation of social infrastructure from other safety-critical organisations together with investigation work efficiency and closure of cases as essential parts of the main actors' performance were also found. Despite new legislation and recent organisational change at different levels within the healthcare system, with rhetoric stating both improvement and high levels of patient safety, traditional norms of power and hierarchy stay intact. However, we believe that such findings represent an adaption made by the main actors to their different obligations. Through this adaption, the system still brings societal closure of harm, changing focus to a move on forward and a contribution to the legitimacy of care in the Swedish healthcare system.

Abbreviations

CMO: Chief medical officer; HaSCt: Health and Social Care Inspectorate; HPO: Healthcare provider organisation; WYFIWYF: 'What You Find Is What You Fix'; WYLFWYF: 'What You Look For Is What You Find'

Acknowledgements

The authors would like to thank the staff at all the regional supervisory authority offices at the HaSCt for their contribution by providing the compiled and de-identified incident investigations.

Funding

The study was partially funded by a grant from The Swedish National Patient Insurance Company without any further involvement.

Availability of data and materials

The datasets analysed during the current study are, on request, publicly available and are also available from the corresponding author on reasonable request.

Authors' contributions

JW designed the study, collected and interpreted the data, made the first analysis and wrote the manuscript. JB and PG contributed to the study design, analysis of the data and revision of the manuscript. All authors read and approved the final manuscript.

Ethics approval and consent to participate

Not applicable

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

Publisher's Note

Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

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Received: 4 July 2017 Accepted: 17 October 2017

Published online: 30 October 2017

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