ORIGINAL ARTICLE

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

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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 intervention. 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 adaption, 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.

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