SO ALIKE, YET SO DIFFERENT

A Comparative Case Study of the Structure of Medical Error Reporting Systems in Norway, Sweden, and Denmark

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So Alike, Yet So Different

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ABSTRACT

BACKGROUND: After the release of the report of the Institute of Medicine in USA in 2000, dedicated on making healthcare safer, the emphasis on patient safety all around the world increased rapidly. A variety of documents, articles, books, and reports have been published that have raised significant concerns about the high levels of medical injuries. In difference to other industries, in healthcare does not appear to rely heavily on learning from mistakes. That is why it is important to improve the way medical mistakes are perceived and study the different reporting systems as they are a possible solution to this problem.

RESEARCH QUESTION: What are the important dimensions that differentiate the structure of medical error reporting systems (MERS) in Norway, Denmark, and Sweden, and how could they be explained? To answer this question, I will identify the similarities and the differences between the structure of MERS in the three countries, distinguish the significant dimensions and discuss possible reasons for divergence between the dimensions.

METHODS: This comparative research is composed by selecting important documents on MERS and reviewing them. The review is done to identify dimensions that are crucial for being able to classify the MERS in question. The selected eight dimensions will act as benchmarks for the succeeding country presentation and analysis. For the purpose of this research, I will be using secondary and tertiary sources.

FINDINGS: There were significant differences in MERS’s structure in the three countries with regard to the level of reporting, the type of the system and reporting groups, the implementation method, the types of incidents reported, and the healthcare provider organizations with right or duty to report incidents. The possible explanation for these differences appeared to be dependent on a variety of factors, including interconnectedness between the dimensions.
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Oslo, May 2016
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<tr>
<td>APA</td>
<td>American Psychological Association</td>
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<tr>
<td>DDKM</td>
<td>Danish Healthcare Quality Programme</td>
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<td>DPSD</td>
<td>Danish Patient Safety Database</td>
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<td>EFTA</td>
<td>European Free Trade Association</td>
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<td>ETTO</td>
<td>Efficiency Thoroughness Trade-Off</td>
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<td>EU</td>
<td>European Union</td>
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<td>FMEA</td>
<td>Failure effectiveness analysis</td>
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<td>FRAM</td>
<td>Functional resonance analysis model</td>
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<td>HFMEA</td>
<td>Healthcare Failure Mode Effect Analysis</td>
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<td>IDT</td>
<td>Innovation Diffusion Theory</td>
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<td>IOM</td>
<td>Institute of Medicine</td>
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<td>LÖF</td>
<td>Landstingens Ömsesidiga Försäkringsbolag (The County Council's Mutual Insurance Company)</td>
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<td>MERS</td>
<td>Medical Error Reporting System</td>
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<td>MSSD</td>
<td>Most Similar System Design</td>
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<tr>
<td>NAPRC</td>
<td>National Agency for Patient’s Rights and Complaints¹</td>
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<td>NHS</td>
<td>National Health Service²</td>
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<tr>
<td>NOKC</td>
<td>Norwegian Knowledge Center for the Health Services</td>
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<tr>
<td>NPE</td>
<td>Norsk Pasientskadeerstatnin (Norwegian System for Patient Injury Compensation)</td>
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<td>NPM</td>
<td>New Public Management</td>
</tr>
<tr>
<td>NPR</td>
<td>National Patient Register³</td>
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<tr>
<td>NPSA</td>
<td>National Patient Safety Agency⁴</td>
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<td>NRLS</td>
<td>National Reporting and Learning System</td>
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<td>RCA</td>
<td>Root cause analysis</td>
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<td>Regional Health Authorities</td>
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<td>STS</td>
<td>Sociotechnical Systems Theory</td>
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<td>Technology Acceptance Model</td>
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<td>WHO</td>
<td>World Health Organization</td>
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¹ Refers to Denmark  
² Refers to the United Kingdom  
³ Refers to Denmark  
⁴ Refers to the United Kingdom
1. INTRODUCTION

“All wrong-doing is done in the sincere belief that it is the best thing to do.” – this quote from the English writer Arnold Bennett easily sets the tone to the importance of human errors (Bennett, 2007). People make mistakes in their attempt to master a certain craft, create something better, invent something new, develop and evolve. People learn from mistakes and experiences of others, as well as their own. This is not only a general statement. It is also very relevant to the healthcare environment, where one mistake can cause a human life. In addition, it can increase hospital costs. Often these mistakes represent unintended negligence in the exercising of patient care.

The importance of medical errors and their reporting is tightly connected with the quality of information, and increases with the fast development of healthcare technology. One of the main problems in improving the quality of healthcare services and patient safety is that it is difficult to learn from “invisible” mistakes. Healthcare professionals can report: (i) errors that harm patients, (ii) errors that occur but do not result in patient harm, and (iii) errors that could have caused harm but were mitigated in some manner before they ever reached the patient (Wolf & Hughes, 2008).

Many different error reporting and learning systems have been created with the intention to prevent errors, to raise the level of transparency of the healthcare environment, and thus, to cope with them in a more structured and unambiguous way. However, the different countries are using various systems for healthcare professionals to report their mistakes which again can lead them to reporting different types. One of the most important extrinsic determinants that may affect the decision to report is law regulation and sanctions rules. The harsher the punishment for a healthcare professional who made a mistake is, the less probability there is for him/her to report the incident. Thus, many countries established acts for non-punitive policies with the hope to stimulate reporting. A vital role for the decision to report is the organizational culture and the personal traits of the healthcare professionals. When it comes to a serious patient injury, involved healthcare persons may experience a
dilemma caused by the feelings of shame and guilt. A state of self-consciousness can be caused by the fear of admitting a mistake and losing trust and/or respect from colleagues and patients. Anonymous reporting may reduce such feelings to some extent. According to WHO Draft Guidelines for Adverse Event Reporting and Learning Systems, the characteristics of a successful reporting system are: non-punitive, confidential, independent, expert analysis, timely, system-oriented, and responsive (WHO, 2005).

Important for the improvement of the reporting of healthcare errors is the evolvement of informational technologies and software development. The transition from a single institution database toward multi-institutional ones could meliorate the understanding, coordination, and communication between healthcare professionals, and thus lower the risk of making the same mistake again. Furthermore, the digitalizing could facilitate the process of reporting itself as well as reducing the bureaucratic costs.

2. RESEARCH QUESTION AND MOTIVATION

The area of research in the current study is the structure of medical error reporting systems (MERS) in Norway, Sweden, and Denmark. This includes a description and analysis of the organizational frameworks, the regulatory bodies, the types of reports, the procedures and components of the systems in these three countries. In doing such a comparative study, I will apply the Most Similar System Design (MSSD) that I will describe later on in the current study. I have chosen these three countries on the basis of location\(^5\). These three countries are closely related as concerning geography, history, language, culture, and form of government. However, the healthcare systems in each of the three countries are not organized in similar ways, which makes it interesting to study whether the MERS in the same three countries are similar or not.

\(^5\) The term “Scandinavia” is commonly used for Norway, Denmark and Sweden, while the term “Nordic Countries” includes Norway, Denmark, Sweden, Iceland, Finland and their associated territories Åland Islands, Faroe Islands, Greenland and Svalbard. (Wikipedia, 2016)
My research question is as follows: What are the important dimensions that differentiate the structure of medical error reporting systems (MERS) in Norway, Denmark, and Sweden, and how could they be explained? Thus, my objective is to identify the similarities and the differences between the structure of MERS in the three countries, to distinguish the significant dimensions and to discuss the possible reason for divergence between the dimensions.

My attempt is to lay the groundwork that will lead to future studies of this kind. The emphasis will not be on recommendations regarding how the systems should work. I’d rather concentrate on supplying the reader with information concerning the current state of the incident reporting systems in Norway, Denmark, and Sweden, and analyzing what could be the possible reason for different approaches in some of the identified dimensions. Performing such an international comparison can also help understanding the level of significance of medical mistakes and can provide a starting point for further analysis looking at potential improvements and solutions when it comes to the structure and/or organization of reporting systems (Papanicolas & Smith, 2013). The identification of differences can help to understand the various setups available, and the advantages and disadvantages they may deliver (European Commission, 2014).

I have chosen to compare the structures of the reporting systems because the way a system is organized is influencing the way the system is functioning. In a broad sense “structure” have the meaning of a “framework of identifiable elements (components, entities, factors, members, parts, steps, etc.) which gives form and stability, and resists stresses and strains” (Business Dictionary, 2016). Structure helps straightening the connection and the communication between the elements. However, if one structure works in one setting, it does not necessarily mean that it will work for other settings.

The thesis starts with Abstract, Introduction and the presentation of the research question and motivation. In chapter 3, I define medical errors and medical error reporting systems, as well as presenting some theories with relevance that may be relevant. In chapter 4, I present the the methodology chosen for conducting this
research. In chapter 5, I display relevant documents used for distinguishing between MERS. In chapter 6, Norway, Denmark, and Sweden are individually reviewed. In the chapter 7, Analysis and Discussion, the focus is on the evaluation of the findings and answering the research question. The last chapter is devoted to general conclusions.

3. BACKGROUND

In the recent years there have been many innovations and inventions in terms of technology (smart heart monitors, 3D ultrasound robots, different apps and machines) that can improve the quality of life and patient safety, but this can’t be compared with the progress reached in other sectors and industries, such as transportation, information and communication, etc.

In difference to other industries, healthcare it is not learning significantly from mistakes. Studies across many countries have raised significant concerns about the high levels of medical injuries. In seeking to improve safety, one of the most frustrating aspects for patients and professionals is the failure of the healthcare systems to learn from their mistakes. That’s why it is important to control and improve the way medical mistakes are perceived and it is worthwhile studying the different reporting systems as they are a solution to this problem. (WHO, 2005)

The field of patient safety is an inseparable part of the healthcare sector and knowledge can help us to prevent harm to patients during treatment and care. “The belief that one day it may be possible for the bad experience suffered by a patient in one part of the world to be a source of transmitted learning that benefits future patients in many countries is a powerful element of the vision behind the WHO World Alliance for Patient Safety” (WHO, 2005). However, it is important to mention that reporting in itself does not improves patient safety but rather the response to the reporting.

Medical mistakes can have a strongly negative emotional impact on the doctors who commit them. Ideally, every healthcare professional should report his/her
mistakes in order to have enough data to develop strategies for improvement. However, the reality can be different since there are various MERS with different attributes. This makes it difficult to measure the level of the influence of the systems on the quality of healthcare and patient safety.

3.1. Definitions (medical errors and MERS)

A medical error is a preventable adverse effect of care, whether or not it is evident or harmful to the patient (Murphy, 2014). This includes an inaccurate or incomplete diagnosis (Diagnostic mistakes), errors in the administration of drugs and other medications (Medication errors), errors in the performance of surgical procedures, in the use of other types therapy, in the use of equipment, and in the interpretation of laboratory findings (NCBI, 1997). IOM (Kohn, Corrigan, & Donaldson, 2000), however uses a slightly different classification of the error types (see in Figure 1). Globally it is estimated that 142000 people died in 2013 from adverse effects of medical treatment (Reddy, 2015). Medical errors are differentiated from “malpractice” in that the former are regarded as honest mistakes or accidents while the latter is the result of negligence, reprehensible ignorance, or criminal intent (NCBI, 1997).
Figure 1. Types of errors (Kohn, Corrigan, & Donaldson, 2000)

Errors can be classified as slips or mistakes. Slips are errors that occur as part of daily routines as result of distraction or heavy work load, while mistakes result from incorrect choices, usually due to insufficient knowledge, lack of experience or training, inadequate information or applying the wrong set of rules to a decision. (Öhnn, 2012)

Often in relation to medical errors or mistakes, the terms “adverse event” and a “near-miss” are used. Figure 2 clarifies the typology of medical errors. Adverse event is an injury related to medical management, in contrast to complications of disease. Medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Adverse events may be preventable or non-preventable. Severity of the injury to the patient is classified by the WHO classification into five categories: None, Mild, Moderate, Severe and Death. There is always an aspect of judgment involved in the classification of errors. “Near-miss” or “close call” is serious error or mishap that has the potential to cause an adverse event but fails to do so because of chance or because it is intercepted. Also called potential adverse event. (WHO, 2005; Saastad &
Reporting of errors can be done by doctors, nurses, and other healthcare professionals within a hospital or healthcare organization, and by the organization to a broader audience through a system-wide, regional, or national reporting system (WHO, 2005).

In his analytical study, Grepperud (2005) finds that near-misses are only voluntary self-reported when the feeling of guilt from non-reporting exceeds the feeling of shame from reporting. Thus, a high degree of underreporting suggests “shame-dominant” cultures in health care sectors” (Grepperud, 2005). Factors that influence the volume of reporting are (i) confidentiality of the information and data protection; (ii) reporter’s perception and abilities, i.e. “belief by reporters that the information is actually used assures them that the time taken to file a report is worthwhile”; (iii) clarity with regard to standards, definitions, and tools; (iv) fear of formal sanctions if being held liable (fines, compensations), (v) fear of informal penalties (shaming and blaming) (Kohn, Corrigan, & Donaldson, 2000; Grepperud, 2005). Figure 3 shows the barriers that may affect the reporting of medical errors.
Relevant to my research is also the, so called, ETTO principle, i.e. Efficiency Thoroughness Trade-Off. It characterizes organizations as “socio-technical systems, which means that they depend on effective interaction and collaboration between humans, technologies and organizations” (Öhrn, 2012). Karsh, Escoto, Beasley, and Holden (2005) describe MERS as “a technology, and like any technology, a health care organization must decide to adopt it or engage in it, and once implemented, individuals must decide whether or not to use it – even if the reporting system is supposedly mandatory” (Karsh, Escoto, Beasley, & Holden, 2005).

Vincent (2007) emphasizes on the ability of the reporting systems to provide warnings, point to important problems, and provide some understanding of causes. They serve an important function in raising awareness and generating a culture of safety. (Vincent, 2007)
According to Judy L. Smetzer and Michael R. Cohen, MERS “promote the goal of providing the best possible patient care in a safe, compassionate environment by helping those involved to learn about the potential risks, the actual errors, the causes of errors and the prevention of recurrent events” (Cohen & Smetzer, 2007). Therefore, feedback is important as it may motivate persons to report incidents. Reports can be presented in a structured text that requires specific information or in the form of narrative text that more freely describes the event (WHO, 2005).

The datasets exchanged between local and central levels of Reporting and Learning Systems (RLS) usually include the basic profile of the patient (age, gender, ethnicity), location of the incident (care setting, organization, department, specialty), identity of the provider organization, timing of the incident, type of the incident, patient outcome, description of what happened, what was the immediate action taken, what was the ground cause of the event, and what preventative measures were taken.

For such an exchange to happen, a big importance has the dataflow automation that can be done with the help of a cloud platform (when healthcare providers do not have existing local risk management systems) or through integration (when healthcare providers have existing local risk management system). After a report has been sent, the next step is to conduct an analysis. This can happen on central or regional level, or on local level. Analysis on central or regional level are performed by direct human review of the incoming reports which allows identification of new and unsuspected hazards. A successful review process is one that is evaluated by experts, has credibility and is performed timely. The review process should result in preventative recommendations. When referring to analysis at local level, on the other side, it should be clear that incidents are analyzed only at the level of the healthcare provider.

Depending on the type of the incident, there exist three different types of model analysis: (i) Sequential analysis (e.g. “5 Why”), (ii) epidemiological models (e.g. RCA, NITHA, Alarm method, PRISMA, Failure Mode and Effects Analysis), (iii) systemic approaches (e.g. FRAM) and (iv) other types (e.g. Descriptive statistics, Aggregated qualitative analysis). Different countries use different models. One country can also apply more than one type of analysis (European Commission, 2014). Due to the their highly specialized nature, the different analysis models are here only mentioned, but
not discussed, as the aim of this study is more general and have less detailed character.

There are also several methods of learning from reporting: alerts regarding significant new hazards, investigation of serious events, analysis of large datasets, system analysis and development of recommendations. (WHO, 2005)

3.2. Theories with relevance for error reporting

The process to improve patient safety, suggested in NHS’s guide “Seven steps to patient safety” (NHS, 2004), includes the following recommendations: (i) building a safety culture, (ii) leading and supporting the staff, (iii) integrating risk management activity, (iv) promoting of reporting, (v) involving and communicating with patients and the public, (vi) learning and sharing safety lessons, and (vii) implementing solutions to prevent harm (NPSA, 2004).

The development of systems for reporting medical mistakes can also be connected to theories on Organizational Learning, Risk Management, New Public Management (NPM), as well as theories on technological acceptance, adoption, and implementation.

The theory for the organizational learning is “a piece of the puzzle” of patient safety as it represents the process of creating, retaining, and transferring knowledge within the organization. Organizations aim to develop over time. With this development they gain experience, and through the experience they create knowledge (Garvin, 1993). Knowledge is an indicator of organizational learning and it can be measured by tracking the change in practices over time, by the distribution of information, by the correlation between learning and experience, projected by “learning curves” and affected by different factors such as the increased proficiency of individuals, progress in technology, or improvement in its structure. The image of an organization guided by optimization principle has been gradually transformed into an image of an organization based on the principle of trial and error. There are five processes through which organizations distribute information and acquire knowledge. The first one is Congenital
learning, which is also called “inherited knowledge”, and exists at the birth of the organization as provided by founders. The second is Experimental learning. Here organizations acquire knowledge through own experience, in difference to the third process called Vicarious learning, where organizations use corporate intelligence to learn from the mistakes and successes of other organizations. The fourth type of learning is Grafting – organizations obtain information with the help of new members who have the needed knowledge. The last way to acquire knowledge is by Searching and Noticing, i.e. monitoring of the internal and external environment. (Gherardi, 2006) (Huber, 1991) (Argote, 2005).

According to the Encyclopedia of Public Management, risk management is “the process of minimizing risk to an organization by developing systems to identify and analyze potential hazards in order to prevent accidents, injuries, and other adverse occurrences; and by attempting to handle events and incidents which do occur in such a manner that their effect and cost are minimized. Effective risk management has its greatest benefits in application to insurance in order to avert or minimize financial liability.” (Kirch, 2008). Implementation of an error reporting system is based on risk management because it will lead to minimizing and monitoring the probability of medical mistakes.

The usage of system for reporting medical mistakes is also connected also to the theory for New Public Management (NPM) as it represents “an approach in public administration that employs knowledge and experience acquired in business management and other disciplines to improve efficiency, effectiveness, and general performance of public services in modern bureaucracies” (Vigoda-Gadot, 2009). In a way, there is a common surface between the Risk Management and the NPM theories – the idea of accountability. Clearly defined reporting system, e.g. transparency on what mistakes are reportable can hold providers accountable for their performance, and in this way, reduce the risk and increase the patient safety. The main goal of NPM is “to become more market oriented by holding public institutions accountable for their work performance and increasingly base base resource allocation on performance” (Peyton, 2009). There are multiple performance measurements across nations. Considering that the aim here is to make the performance of public institutions more
transparent, measurable, and comparable, all data that can be collected is useful, including data from reported medical errors.

Theories of technological acceptance, adoption and implementation are relevant when talking about MERS as technology is an unavoidable part of every sector. There are three theories relevant to acceptance, implementation, and adoption of MERS: Technology Acceptance Model (TAM), Innovation Diffusion Theory (IDT), and Sociotechnical Systems Theory (STS) (Karsh, Escoto, Beasley, & Holden, 2005). TAM is a model used at user level, i.e. it is concerned with the individual users’ acceptance of new technology evaluated on the base of whether the system increases the job performance (usefulness), and whether it is timely and easy to operate (Davis, 1989; Gardner & Amoroso, 2004). IDT is concerned with the adoption of technologies on organizational level, and relies on the same factors as TAM, plus assessment of the influence on an organizations’ culture and the attitude of the individuals reporting, of whether or not the technology improves the user’s image of the organization, whether one sees others using the system, and whether the technology is compatible with the organization’s practices and policies (Rogers, 1983; Karsh, Escoto, Beasley, & Holden, 2005). STS focuses on all system components, and how they interact with each other, as it paid attention not only to the design of the technology, but to the organization’s social system as well (Karsh, Escoto, Beasley, & Holden, 2005).

4. METHODOLOGY: A comparative study based upon documents

4.1. Study design

Comparative case studies involve the analysis and synthesis of the similarities, differences and patterns across two or more cases that share a common focus or goal (Goodrick, 2014). In order to see and understand the differences and similarities of the error reporting systems across the study objects, it will be most appropriate to apply a
descriptive method and an explanatory method for analyzing the possible reasons for the differences according to the later suggested dimensions.

This study is categorized as a cross-national comparative study as it examines a particular phenomenon – MERS in three different countries. Linda Hantrais, known for her work in the field of international comparative research, states: “More recently, as greater emphasis has been placed on contextualisation, cross-national comparisons have served increasingly as a means of gaining a better understanding of different societies, their structures and institutions.” (Hantrais, 1995). The purpose of comparative studies on health care research is “to explore, interpret or explain the similarities and differences between comparable items or phenomena in different areas, in order to improve health and the functioning health services” (Øvretveit, 1998). In comparative studies, it is common to use of “methodological pluralism”, which is “an approach that advocates flexibility in the selection of social research methods, based on the principle of choosing the most suitable methods for the nature of the problem being researched” (Payne, 2012).

Pentti Routio, author of multiple publications about research methods and styles, divides the comparative research into two groups, based on the aim of the research – descriptive and comparative. My comparative research is then categorized as descriptive one because it does not aim at generating changes in the objects. Instead, it aims at revealing the general underlying structure which causes or allows variation between the objects of the study (Routio P., 2007). A descriptive research study describes systematically and provide information about a certain phenomenon, situation, problem, service or programme. The goal of a descriptive comparative study is to describe the similarities and differences in comparable items.

According to another typology, described by researcher Ranjit Kumar, a study can be classified as descriptive, correlational, explanatory or exploratory. Based on his classification, my study can be perceived, not only as descriptive, but also as explanatory one, as it attempts to clarify why there are differences along some dimensions of the structures of the three incident reporting systems, and how they relate to other aspects of the systems. (Kumar, 2011; Øvretveit, 1998)
Peter Johan Lor has done a great job describing the methodology in comparative studies in Chapter 4 of his book “International and Comparative Librarianship” by identifying different types of methodologies, strategies and designs. On the base of his findings, this study can be categorized as both quantitative and qualitative. Quantitative methods are used to generate results and statistical data, while qualitative methods are used to gain understanding of reasons and motivation, and to uncover trends, mainly in the Discussion chapter (Lor, 2010). Hantrais supports the “mixed methods” approach and indicates that for many researchers choosing only one is no longer so important (Hantrais, 2008).

Given the fact that I am concentrating only on a specific area, I chose to use the Most Similar System Design (MSSD) for comparing the MERS. According to this model, the subjects to the research should be very similar in many aspects and different in few variables where the emphasis will be. (Lor, 2010)

4.2. Method for data collection

My comparative research will be composed by selecting important documents on MERS and reviewing them. The document review is done to identify dimensions that are crucial for being able to classify the MERS in question. The dimensions selected will acts as benchmarks for the succeeding analysis. My emphasis will clearly not be on recommendations regarding how the MERS should work but on the current structure of the MERS in Norway, Denmark, and Sweden.

Classification according to certain pre-specified dimensions is one important way of revealing similarities and differences (Routio P., 2007). The definition of WHO reads: “A classification comprises a set of concepts linked by semantic relationships. It provides a structure for organizing information to be used for a variety of other purposes” (WHO, 2009). However, in many cases it is not possible to classify an object or a person into a single category. Here comes the issue with “pigeonholing”. “Pigeonholing” describes the attempt to classify an object or a person into a category that does not completely reflects the reality, e.g. this object or a person could fit into
two categories at the same time or does not really fit in either category. To avoid “pigeonholing” in this classification, I will take under consideration dimensions that are relevant for all three countries. They will be chosen on the base of availability and comparability of information.

For the purpose of this research, I will be using secondary and tertiary sources. Secondary sources are government or semi-government publications, earlier research, mass media or other documents (Kumar, 2011). Tertiary sources are books and articles that synthesize and report on secondary sources, i.e. textbooks, articles in encyclopedias, and mass-circulation publications (Booth, Colomb, & Williams, 2008). In the matter of referencing, I chose to use the “author-date system” from the four referencing systems of Butcher (1981). With regard to writing a bibliography, I will use the American Psychological Association (APA) system (Kumar, 2011).

4.3. Potential problems and limitations

A problem that can occur during the research could be biased and sensitive information, and lack of transparency. Another issue is connected to the usage of data from secondary sources. When accessing such sources it should be taken under consideration that: (i) the validity of information can vary from source to source, (ii) there could be a problem of personal bias in articles from newspapers and magazines, (iii) the availability of data is not as complete as expected, or (iv) the format of the data could be different in different sources, e.g. evaluation of the system is made during different years or for different periods of time (Kumar, 2011). It also exists a potential language barrier when accessing documents about Scandinavian countries as a big part of the relevant information is written in the official for these countries languages.

4.4. Selected sources

The documents that have been helpful for constructing my work, are as follows:
(A) The Institute of Medicine report (IOM) “To Err Is Human: Building a Safer Health System”

This is the most cited publication on how to deal with medical mistakes. It was officially published in year 2000. The report circles around the idea that preventable adverse events in hospitals were a leading cause of death in the United States, and highlights the understanding that incidence reporting systems can “hold providers accountable for performance” and “provide information that leads to improved safety”. (Kohn, Corrigan, & Donaldson, 2000). The IOM committee addresses the following three points: (i) preventing, (ii) recognizing, and (iii) mitigating harm from error by including actions to enhance the knowledge safety, raise standards for improvements in safety through the actions of oversight organizations, and identify and learn from errors through both mandatory and voluntary reporting systems. IOM also reports on the frequency and the cost of errors (Grepperud, 2005).

(B) European Commission’s report “Key findings and recommendations on Reporting and learning systems for patient safety incidents across Europe”

This report was published by “The reporting and learning subgroup of the European commission” in May 2014. It serves as a “catalogue” on how 22 European countries have chosen to organize their medical reporting system and it gives a general but clear comparison of these systems. The main goal of the report is to give recommendations based on the key findings. (European Commission, 2014)

(C) WHO’s “Draft Guidelines for Adverse Event Reporting and Learning Systems: From Information to Action”

WHO and its partners initiated work to develop Draft Guidelines for Adverse Event Reporting and Learning Systems to outline the core principles and functions for developing learning organizations through organized and systematic data collection (WHO, 2005). This third report will help me in understanding the purpose and methods of reporting, the process and the types of reporting systems, etc.
There is a variety of reports and documents for Norway, Sweden, and Denmark in the area of the incident reporting systems and patient safety that are in big help for conducting this research. Some of the authors of these works are S. Grepperud (2005), H.K. Bekke et.al. (2005), S. S. Kilsar et.al. (2015), A. Öhrn (2012), etc. In addition, information from reports from The Norwegian Knowledge Centre for the Health Services (NOKC), the European Observatory on Health Systems and Policies, WHO, etc. will be used.

The only document selected for the identification of dimensions that can be used to conduct a classification is the European Commission’s report “Key findings and recommendations on Reporting and learning systems for patient safety incidents across Europe”.

5. RELEVANT DIMENSIONS FOR THE CLASSIFICATION OF MEDICAL ERROR REPORTING SYSTEMS

Eight dimensions that are considered to be important for comparing MERS, are presented below. The eights dimensions are taken from the European Commission’s report “Key findings and recommendations on Reporting and learning systems for patient safety incidents across Europe” (European Commission, 2014), and each of the dimensions will, in the following, be presented more in detail.

**DIMENSION 1 (D1): The level of the reporting**

By level of reporting is meant the rank that is set to control the process of reporting. A country can have: (i) one nationwide reporting system, (ii) nationwide reporting system combined with several regional and local systems, or (iii) a local independent reporting system (European Commission, 2014). The level of reporting represents, in a way, the entry of the process, i.e. a report for a medical error is sent
to a national, regional or local institution for processing.

**DIMENSION 2 (D2): The type of the reporting system**

By type of error reporting systems here is meant whether the system is voluntary or mandatory. According to the European Commission, “countries that use mandatory systems have laws or guidelines to regulate the reporting scheme, including principles such as confidentiality and anonymity”. These regulations cover the level at which reporting systems operate, the level of seriousness of the incident and whether it should be reported or not, who has responsibility for reporting, who is responsible for acting on reports. They also often ensure that the person reporting is free from sanctions. Both mandatory and voluntary systems have their advantages and disadvantages (European Commission, 2014). The purpose of the mandatory reporting systems is to hold providers accountable. Most of them are operated by state regulatory programs that have the authority to investigate specific cases or issue fines for misconducts. However, according to experts, errors that result in serious harm or death are only the “tip of the iceberg” (Kohn, Corrigan, & Donaldson, 2000). To reach a higher level of patient safety and quality improvement, the attention on less serious adverse events and near-misses are emphasized. This is the main goal of the voluntary reporting systems. Characteristic for this type of systems is that there are no penalties or fines associated with the occurrence and reporting of medical mistakes (Kohn, Corrigan, & Donaldson, 2000). As stated by Sverre Grepperud in his report “Medical Errors: Mandatory Reporting, Voluntary Reporting, or Both?”, IOM identifies a need for both mandatory and voluntary reporting systems.

**DIMENSION 3 (D3): The organizational framework**

As stated in the European Commission’s report (2014), there are three types of framework:

- Central regulatory framework (health framework)

The responsibilities for the reporting systems in the Member States can lie with the
Ministry of Health, Department of Health, agencies on lower level of authority or other health regulatory organizations. In countries where there is no nationwide reporting system, the responsibility for the reporting systems is taken by individual hospitals. A country that have health organizational framework is, for example, United Kingdom.

➢ Self-regulatory framework (professional framework)

The professional framework is used in Member States where doctors and hospitals tend to be private, and the funding is undertaken by both employers and employees through payroll deduction. Examples for countries that use professional frameworks to organize and control reporting of mistakes and other adverse events are France, Germany, Hungary, the Netherlands, and Slovakia.

➢ Local regulatory framework

Such organizations exist in Belgium, France, Cyprus, Latvia, and Luxemburg. There is no nationwide database in these countries to which hospitals have to report their incidents systematically. The reporting and learning systems for incidents and near-misses is hospital-wide and it is applicable for all incidents. (European Commission, 2014)

**DIMENSION 4 (D4): The reason for establishing the reporting system**

As different countries have different history and background, the idea for establishing a system for reporting medical errors may come as a result of different reasons. One of these reasons is political pressure coming from public and professional circles as a consequence of unsafe practices that gave bad outcomes to patients. Another motivation for implementing reporting systems is the effort to prevent errors and incidents by developing patient strategies and programs, i.e. benchmarking on patient safety. A key role also played by accreditation programs for hospitals, as
well as the justification for establishing reporting systems, was the EU Council recommendation of 2009. (European Commission, 2014)

**DIMENSION 5 (D5): The implementation method**

Research of the European Commission shows that the error reporting systems are implemented using different methods depending on local context. These methods are “Pilot project”, “Step by step implementation”, and “Full-scale operation at launch” (European Commission, 2014). Pilot project means executing a trial version of a system that is in preparation for implementation (Partners for Health Reform plus, 2004). Step-by-step implementation refers to gradually putting into effect the planned action. The third method, a full-scale operation at launch, implies implementation of all functions of the system along all departments without trial periods.

**DIMENSION 6 (D6): The types of incidents reported**

In different countries there are different types of incidents reported. In some the duty or the right to report will depend on the severity of the incident, in others – on particular error type. There are also countries where reporting is based on combination of both, or such where near misses are also reported along with other incidents. (European Commission, 2014)

**DIMENSION 7 (D7): Right to report**

Errors can be reported by healthcare personell, as well as from technical staff and others who has witnessed an incident. In many countries, both patients and their relatives also have the right to report about mistakes. (European Commission, 2014)

Healthcare professionals may be protected by regulations which gives them the opportunity to report incidents without sanctions or disciplinary punishments. This is done to motivate them to report medical errors.
**DIMENSION 8 (D8): The method of reporting**

Data collection from reports can be done in two main ways – paper and electronic. Recommended by the European Commission is the electronic method as it is easier to analyze and it is more accurate. In some countries an option is telephone and app reporting. There are also different approaches for support and help – by email helpdesk, by call center, by manuals, or by colleagues. In most countries the person who is reporting is the one providing the description of the incidence and the consequences. (European Commission, 2014)

**6. COUNTRY PRESENTATION**

As mentioned above, these three countries have many similarities as location, history, language, culture, form of government, and social and economic conditions. They are also Member States according to the European Committee6. In 2009 the EU Council provided Recommendation regarding reporting and learning systems on incidents, according to which Member States should “support the establishment or strengthen blame-free reporting and learning systems on adverse events that: 1) provides information on the extent, types and causes of errors, adverse events and near-misses; 2) encourage healthcare workers to actively report through the establishment of a reporting environment which is open, fair and non-punitive...; 3) provide, as appropriate, opportunities for patients, their relatives and other informal caregivers to report their experiences; 4) compliment other safety reporting systems...”. The main goal of this recommendation is to enhance patient safety by learning from occurred incidents and mistakes, while the role of the reporting and learning systems is to use the results of data analysis and investigations to improve healthcare directly and help healthcare professionals do safer work (European Commission, 2014).

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6 Norway is not part of the EU but it is Member of EFTA. In this document the term “Member States” refers to EU Member States and Norway.
6.1. Norway

6.1.1. General information

The Norwegian healthcare system can be characterized as semi-decentralized. The specialist care is responsibility of the state, represented by four regional health authorities (RHAs), and the primary care is responsibility of the municipalities. Dental care is regulated by counties. The organizational structure of the Norwegian healthcare system is built on the principle of equal access to services for all inhabitants, regardless of their social or economic status and geographical location. In 1999 was created the Specialized Healthcare Services Act, according to which every hospital must have a quality assurance commission as part of its mandated system of internal control in order to meet quality standards. In 2003, the Ministry of Health started focusing on the inequalities in healthcare and in 2007 the National Strategy to Reduce Social Inequalities in Health became the first report based on the cross-sector reporting system that monitors measures aimed at reducing social inequalities. In 2011 there was another Act created – the Municipal Health and Care Act, which includes similar requirements as in the Specialized Healthcare Services Act but targeted at primary healthcare providers. Each municipality must insure that services are provided in a coordinated manner and that the healthcare professionals have the necessary competence. In 2012, the reporting system was altered due to underreporting and assumptions of poor reporting culture among health personnel caused by fear of administrative sanctions, and a new National Reporting and Learning System (NRLS) was put in place at the NOKC (Kunnskapssenteret).

Reporting of serious adverse events and “near-misses” is mandatory for hospitals and other providers of specialized care. Currently, the reporting system is on national level and excludes providers of primary care. Furthermore, each report must be submitted, preferably electronically, within 24 hours of the discovery of the mistake, and it is anonymous and sanction-free. Figure 3 shows “the big picture” of the structure of the reporting system. The number of reports indicates the institution’s ability to detect and report adverse events. It does not necessarily represent the occurrence of adverse events. The number of the messages cannot be used for assessment of the quality of different organizations as the number of incidents is also affected by the size, type, patient base and level of treatment. The purpose of reporting is learning, not counting
and measuring. Reasonably the picture has a form of a circle as the systematical learning from mistake has a major role for the patient safety improvement. (Ringard, Sagan, Saunès, & Lindahl, 2013; Kilskar, Melby, Øren, & Lippestad, 2015; Saastad & Flesland, 2015)

As of 1st of January 2016 the responsibility for the notification scheme was transferred from NOKC to the Norwegian Directorate of Health. The change was made on the ground of revised national budget in 2015, where it was decided that the central healthcare administration should be gathered in fewer agencies. The reporting requirements will still be regulated by the Specialized Healthcare Services Act, Section 3-3, from June 24, 2011, that reads: “The purpose of the reporting duty is to improve patient safety. The messages will be used to clarify the causes of incidents and to prevent similar incidents happen again”. Considering the fact that this transfer happened very recently, there is not enough sufficient data that can support my research at this point. (Helsedirektoratet, 2016)

![Figure 4. The national reporting system for incidents and adverse events in Norway (Kilskar, Melby, Øren, & Lippestad, 2015)](image-url)
6.1.2. Level of reporting

The incidence reporting system in Norway is quite standardized and operated on national level (European Commission, 2014). That means that all reports are sent directly to an institution at the “top”. Until 1\textsuperscript{st} of January 2016 the reporting of all incidents and adverse events was done to NOKC, but after this date the responsibility for the notification scheme lays with the Norwegian Directorate of Health (Helsedirektoratet, 2016).

6.1.3. Type of reporting system

Kilskar, Melby, Øren and Lippestad are describing it as “under-implemented, yet oversold”. According to §3-3 of the Specialized Healthcare Services Act, all hospitals and other specialist healthcare services carry the reporting responsibility for all serious patient injuries that result from healthcare or from one patient injuring another. This requires them to maintain a system that will allow employees to report events. However, healthcare personnel do not have any legal responsibility yet although the system in use is mandatory for all healthcare professionals from public private and pre-hospitals. On the other hand, the present-day system does not allow to patients, relatives or public to report errors that occurred in the healthcare setting. (Kilskar, Melby, Øren, & Lippestad, 2015; European Commission, 2014)

6.1.4. Organizational framework

The NRLS is undertaken by a government-funded unit but “it does now have the instruction power towards the healthcare system or personnel, nor any power to impose penalties”. In this way, Norway had created a balance between independence and financial security. (European Commission, 2014)

6.1.5. Reason for establishment

The motivation for Norway to establish incident reporting system in healthcare came from political pressure of public and professional circles as a consequence from unsafe practices that gave bad outcomes to patients. Another catalyst was, as in many
other countries, the effort to prevent errors and incidents by developing patient strategies and programs, i.e. benchmarking on patient safety. (European Commission, 2014)

6.1.6. Implementation method

The implementation of the incident reporting system in Norway was planned to happen with the help of pilot project and step-by-step implementation, i.e. trail and graduate implementation (European Commission, 2014).

6.1.7. Types of incidents reported

All incidents that lead to serious injury and/or could have led to serious injury (“near-misses”) should be reported. An incident must be reported even if it arises from the lack of provision of health services. The Norwegian Directorate of Health categorizes “serious” or “substantial” injury as injury that will have significant consequences for the patient’s disease/disorder or involves significant pain or decreased expression of life in the short or longer term. Examples of serious injuries are events leading to death, incidents where life-saving treatment measures were necessary, events leading to prolonged hospital stay, events leading to the need for additional treatment, rehabilitation or similar, events that led to the injury that lasted or is likely to last more than two weeks, etc. (Helsedirektoratet, 2016).

In fact, Kilskar, Melby, Øren and Lippestad (2015) have done some significant work when it comes to report system evaluation in the Norwegian healthcare. They have conducted multiple interviews and surveys to lead them to imperative conclusions. According to theirs research, there has been a considerable difference between reported events before and after the reforms in 2012. In 2011, the Norwegian Board of Health Supervision received reports on 2146 events while in 2013 the corresponding number of reported events to NOKC was 9531. After splitting the events into categories, became clear that the greatest part of the increase was in near-misses, where there was hardly any change in the amount actual injuries. (Kilskar, Melby, Øren, & Lippestad, 2015)
6.1.8. **Right to report**

All health institutions covered by the Specialized Healthcare Services Act, private and public, are obliged to notify in case of incidents. In practice, employees of the institution must report the incidents in compliance with the institution’s contingency procedures and reporting systems (Helsedirektoratet, 2016; European Commission, 2014). There is no separate system where patients can report incidents but there is a government agency subject to the Ministry of Health, called NPE (*Norsk pasientskadeerstatning*) that process claims from patients who believe they have suffered injury after failure of the healthcare service, and appointing compensations. (NPE, 2016)

6.1.9. **Method of reporting**

The selected forms of reporting by Norway are electronic and paper. Health institutions can send reports form their internal reporting system directly to the national patient safety unit at NOKC electronically. Health institutions that do not have electronic reporting systems can use the web-based form through a separate browser. Support and help associated with the reporting systems can by received by email helpdesk, by call center, and by manuals. (European Commission, 2014)

From December 2014, all institutions obliged to report have been established with integrated solution for message submission and information flow. (Saastad & Flesland, 2015)

Furthermore, in some hospitals, each worker reports directly to NOKC, while others send the report via a local leader, the Quality Department, or both, before the report reaches NOKC. A report form Kilskar et. al. shows that having different practices, e.g. some workers reporting straight to NOKC and others – indirectly, causes confusion of the reasons why the certain method has been chosen. Moreover, the two electronic methods cause disparity as professionals in healthcare institutions with existing electronic patient records do not need to adapt to another system because of the easy integration while the shift is more challenging for those who are newly introduced to the web-based reporting system. Thanks to a survey carried out in 2013,
there is a proof of the effect of the incident reporting system. It shows that the level of dissatisfaction among users is lower which serves as a measurement of the quality of the system for reporting medical mistakes. Nonetheless, there is another factor that influences this result – the actual number of adverse events. As it appears, the increase in the reported cases did not influence the number of incidents. This brings the authors to their second assessment: “Reporting of adverse events does not contribute to patient safety unless the obtained knowledge is converted into learning and, in turn, changed practice”. But how can knowledge be converted into learning if there is no knowledge to obtain in first place? Implementing a system is not simply instructing the professionals how to use it. It is a whole workflow that needs all of its units to maintain strong presentation in order to function properly. In that sense, learning cannot exist without quality and fast feedback from NOKC which can come only from detailed information about the occurrence. (Kilskar, Melby, Øren, & Lippestad, 2015)

6.2. Sweden

6.2.1. General information

The Swedish healthcare system is organized into three levels: national, regional and local. There are 4 regional bodies, 20 county councils (two of which are referred to as regions), and 290 municipalities7 are responsible for the funding and provision of healthcare services, i.e. the responsibility is decentralized. There is no hierarchical relation between the municipalities, county councils and regions since they have their own self-governing local authorities. Healthcare in Sweden is regarded as a public responsibility and is largely tax-financed. The parliament, Riksdagen, is the supreme political decision-making body. (Anell, Glenngård, & Merkur, 2012; Swedish Association of Local Authorities and Regions, 2016)

In Sweden, the first regulation for mandatory incident reporting by providers was launched in 1996. After this, it has been revised in 2005 and once again in 2011. The legislative requirement to report all severe mishaps, complications or adverse events

7 Gotland municipality has the same responsibilities as the county councils.
is called Lex Maria and it was imposed by §35 of the Patient Safety Act. According to Lex Maria, all serious adverse events should be reported to the National Board of Health and Welfare that is a government agency under the Ministry of Health. During the last decade, investigations in connection with Lex Maria have become more oriented towards system failures than individual errors. In 2015 the number of submitted reports to Lex Maria was 2373, compared to 1050 in 2005 (IVO, 2015). Annica Öhrn (Öhrn, 2012) declares in her report that “an increase in the number of reports should not be taken as an indication of deterioration in patient safety but rather as an indication of increased openness and willingness to report, i.e. improved safety culture”.

Another system in place in Sweden is NITHA. This is a national information system aimed at supporting Root Cause Analysis (RCA) of adverse events, which is required when a patient has or could have had serious healthcare-related injury. Other analysis technique used in the country is the Healthcare Failure Mode Effect Analysis (HFMEA), used mainly for risk analysis. Healthcare professionals are required by law to undertake event analysis in order to improve patient safety. (Epractice Editorial Team , 2012; European Commission, 2014; Öhrn, 2012)

There are also several national quality registries that are focused on quality improvement and healthcare planning and are funded by the Swedish Association of Local Authorities and Regions. Furthermore, medical data reported by healthcare staff on hospital stay and outpatient visits can be found in the national medical records, while data on sex, age, date of admission, surgical procedure and discharge is kept in the National Swedish Spine Register (Swespine). Additionally, type pf data as patients’ claims including hospital discharge data, diagnostic codes, injury type, decision on compensation, etc. is reported by patients and/or relatives to the County Councils’ Mutual Insurance Company (LÖF). The reporting and learning system for incidents and near-misses is meant to be hospital-wide and applicable for all accidents. (European Commission, 2014; Öhrn, 2012)
6.2.2. **Level of reporting**

The level of reporting in Sweden is national, regional, and local. This means that there are several reporting systems at different levels. Healthcare professionals report incidents that have cause or could have caused serious adverse events to the healthcare provider, and the healthcare provider, including private healthcare – to the National Board of Health and Welfare, i.e. this level of reporting is considered regional. Reporting on national level can be done by healthcare staff to Swespine. Moreover, all data found in medical records have been reported on national and regional level. (European Commission, 2014; Öhrn, 2012)

The identified problems with regard to the organization of the incident reporting system are: (i) poor and slow feedback, (ii) lack of confidence in reporting incidents that have a negative impact, (iii) poor patient safety culture, (iv) lack of standardization with regard to classification of events (Öhrn, 2012).

6.2.3. **Type of reporting system**

Reporting of medical errors in Sweden is mandatory for healthcare professionals and healthcare organizations, voluntary for patients, relatives and the public, and it is regulated by law.

For all healthcare professionals, regardless if they work in private hospitals, public hospitals, pre-hospitals, primary care, private care agencies, GPs, pharmacies, and other practitioners, reporting of incidents is mandatory. However, reporting to NITHA database and to other reporting systems is voluntary. Since 2011, patient and relatives can also file complaints both on national and regional level – to the Inspectorate, to the healthcare providers, to the Patient Insurance LÖF, and to the Patient Advisory Committees. (European Commission, 2014; Öhrn, 2012)
6.2.4. **Organizational framework**

The regulating authority in Sweden is The Swedish National Board of Health and Welfare (Socialstyrelsen) that has the responsibility to investigate complaints against medical officials in conjunction with the new Patient Safety Act introduced in January 2011. However, all errors and other adverse events are reported by the healthcare providers to the Health and Social Care Inspectorate. (European Commission, 2014; Scancomark.com Team, 2013)

6.2.5. **Reason for establishment**

As a country that established its system before 2009, the Swedish motivation to establish nationwide reporting system was prompt by foreign studies, i.e. benchmarking on patient safety. (European Commission, 2014)

6.2.6. **Implementation**

Step by step implementation was used for the new reporting system for incidents in the healthcare in Sweden. (European Commission, 2014)

6.2.7. **Types of incidents reported**

Sweden is one of the countries where all reports are accepted, regardless of severity of the incident or the incident type. This enables the people reporting to simply report any concern they have without having to think if they are using the proper way to report it. (European Commission, 2014)

6.2.8. **Right to report**

Public hospitals, private hospitals, pre-hospitals, primary care, private care agencies, GPs, pharmacies and other practitioners are all allowed to submit report for incidents that happened in healthcare (European Commission, 2014). The Swedish
healthcare system is well equipped with different institutions where, depending on the source, the report can be submitted.

6.2.9. Method of reporting

There are both electronic and paper reporting in Sweden, as well as special form for patients and relatives. Help and support can be received only by colleagues (European Commission, 2014). Approximately 1100 mandatory and 2400 voluntary reports are received annually (WHO, 2005).

6.3. Denmark

6.3.1. General information

The Danish healthcare system, according to the European Observatory on Health Systems and Policies, can be described as “fairly decentralized, with responsibility for primary and secondary care lies with regions and municipalities”. The system is organized according to three administrative levels: state, regional and local. The state holds the overall regulatory and supervisory functions. The five regions in Denmark are responsible for hospitals and self-employed healthcare professionals. Lastly, the municipalities are accountable for disease prevention and health promotion. Healthcare expenditures are higher than the average of the EU Member States. More than 80% of these expenditures are funded by the state through combination block grants and activity-based financing. Quality of the healthcare has significant importance when a national healthcare system is being evaluated. The Danish Healthcare Quality Programme (DDKM) has been implemented in all hospitals. Thus, since 2000s there has been more and more emphasis on reducing healthcare-related harm. One of the initiatives is creating a national reporting system regarding adverse effects and analysis of identified causes and feedback to inspire preventative interventions. (Olejaz, Nielsen, Rudkjøbing, Birk, Krasnik, & Hernandez-Quevedo, 2012)
Denmark has had its problems with mistakes in medical care but has made a sincere effort to address the problem of medical errors by “requiring more stringent documentation and risk-free error reporting system for physicians” (Armstrong, Fischer, Parsa-Parsi, & Wetzel, 2011). In fact, the country was the first country to introduce a separate law on patient safety by creating the Act on Patient Safety in 2004. In 2010, reporting of adverse events applied for the entire healthcare system, and in 2011 this included patients and relatives. Both municipalities and regions have for several years focused on informing patients about the possibility of reporting an adverse event (Agency for Patient Safety, 2016). In 2013, the number of submitted reports was 182,000 (1.5% of them – from patients and relatives) and in 2015 – 183,445 (175,243 of which are completed), compared to less than 6000 in 2004. Figure 5 shows the changes in the number of completed cases of adverse events in DPSD for the period from 2004 to 2015. Moreover, in 2006, 2/3 of the doctors and nurses said that reporting had lead to positive changes. Currently, the reporting system in use is the Danish Patient Safety Database (DPSD), according to which, the “purpose of the Act is to gather, analyze and communicate knowledge of adverse events in the Danish hospital system”. (Bakke, 2005; DPSD, 2007; European Commission, 2014; Pedersen, 2007)

![Figure 5. Changes in the number of completed cases of adverse events in DPSD for the period from 2004 to 2015 (Styrelsen for Patientsikkerhed [Agency for Patient Safety], 2016)](image-url)
The DSPD is anchored to the National Board of Health that is responsible for the central administration of the reporting system for adverse events in healthcare and contributes its accumulated knowledge from reports of such events translated into changes in treatment, better instructions to the medical staff, etc. (Styrelsen for Patientsikkerhed, 2015)

The Danish compensation systems for patients is a big plus for improving patient safety. However, although that data that has been collected from patients’ claims is freely shared with researchers, injury and error rates are not published for patients to use the when choosing providers. By design, there is no communication between the claims and the disciplinary systems. (Pierce & Allen, 2016)

The analysis techniques used in Denmark are somewhat similar to those used in Sweden. On local and regional level are adopted the epidemiological analysis models RCA and FMEA. In practice are also the system analysis model FRAM, i.e. Functional resonance analysis model, and the aggregated qualitative analysis. On central level are applied descriptive statistics and aggregated qualitative analysis. (European Commission, 2014)

6.3.2. Level of reporting

All reports are submitted to the National Board of Health, i.e. the level of reporting is national. Moreover, Denmark is considered to have “the finest of its kind” nationwide database – the Danish National Patient Register (NPR) (Lynge, Sandegaard, & Rebolj, 2011).

6.3.3. Type of reporting system

Denmark has had a mandatory reporting system for healthcare professionals since 2004. In order to encourage the learning process, the system is kept separated from sanctions. To insure a proper protection of healthcare professionals, the learning system is strictly separated from the three other systems for handling adverse events: the supervision system (operated by the National Board of Health), the complaint system, and the patient insurance system. As stated in the European Commission’s
report from May 2014, “Reporting on adverse events from the regional council and the municipal council to the National Agency for Patients’ Rights and Complaints shall be anonymized with regard to the patient concerned as well as the reporting individual”. Frontline healthcare professionals connected in hospitals, primary care, private care agencies, etc., are obliged to report all adverse events (in difference to healthcare organizations), the hospital owners act on the reports, and the National Board of Health communicates experience form the report. The analysis and the risk assessment of an adverse event are usually performed locally by the head of the department where the event has occurred, in cooperation with the respective region’s Patient Safety Unit. (Vist, Holte, Mathisen, Lidal, Nøstberg, & Lindahl, 2014; DPSD, 2007; European Commission, 2014)

6.3.4. Organizational framework

As described in the report by the European Commission from May 2014, the health framework in Denmark is represented by the Danish patient safety database (DPSD) that was established in 2004 under the National Board of Health under the Ministry of Health. In 2011, the DPSD moved to the new Danish National Agency for Patient’s Rights and Complaints (NAPRC), which is an independent state institution under the Ministry of Health that focuses on patients’ rights, compensations, adverse events and learning. (European Commission, 2014)

DPSD works in cooperation with the National Board of Health and the Danish Medicines Agency. In 2015, it also had partnerships with Danish Medicines Information A/S. IKAS, Pharmakon, the Pharmaceutical Association, University College Capital, etc. (Agency for Patient Saferty, 2016)

6.3.5. Reason for establishment

Similar to Norway, the motivation for Denmark to establish incident reporting system in healthcare came from political pressure of public and professional circles, and benchmarking on patient safety. (European Commission, 2014)
6.3.6. **Implementation**

The method used for implementing a reporting system in Denmark was a full-scale operation at launch. (European Commission, 2014)

6.3.7. **Types of incidents reported**

There are three types of events that are obligatory to be reported in Denmark: (i) adverse events in connection with medication, (ii) adverse events in connection with surgical or invasive procedures, and (iii) other serious adverse events. Both actual adverse events and “near-misses” must be reported (Lundgaard, Raboel, Jensen, Anhoej, & Pedersen, 2005). There are many requirements on base of which is decided what types of adverse events must be reported in the different healthcare sectors. For example, hospitals must report all types of incident, while pharmacies report only medical incidents. (European Commission, 2014)

6.3.8. **Right to report**

Permission to submit reports about healthcare incidents can be submitted by healthcare professionals working at public hospitals, private hospitals, pre-hospitals, primary care, private care agencies, by GPs, pharmacists and other practitioners. (European Commission, 2014)

6.3.9. **Method of reporting**

The only method for reporting in Denmark is electronically. Help and support are provided by email helpdesk, by call center, by manuals, and by colleagues. (European Commission, 2014)
7. ANALYSIS AND DISCUSSION

WHO states: “Reporting on the occurrence and consequences of patient safety incidents, or adverse events, is one of the primary objectives of agencies and health-care managers aiming to improve patient safety” (WHO, 2016). After the release of the IOM’s report “To Err Is Human: Building a Safer Health System”, the emphasis on patient safety have increased rapidly in a global aspect. WHO and relevant accountable organizations in many countries started putting more efforts into improving the quality of patient safety by creating recommendations about communication strategies, sets of culture values, development of new technology, etc. Most attention in this area is given to the impact of incidents and adverse events that occurred in healthcare.

The main intention, however, is not to eliminate the occurrence of such events all together, but rather to motivate learning from these events in order to decrease the problem and increase the patient satisfaction. Considering such improvements are done over time, a comparative study seems like an adequate choice to highlight the areas where progress and/or consideration of change still is needed. Being among the top countries with best healthcare systems and having plenty characteristics in common, Norway, Denmark, and Sweden serve as suitable cases for a comparative study (WHO, 2000).

On the basis of all the information presented so far, I am now ready to compare the three countries with respect to differences and the similarities as concerning MERS. Table 1 provides an overview of all eight dimensions for each of the three countries. In addition, in Table 1, I report the number of regions and the names of the reporting systems.
Comparison of the most significant dimensions in the error reporting systems in Norway, Sweden and Denmark

<table>
<thead>
<tr>
<th>Regions</th>
<th>Norway</th>
<th>Sweden</th>
<th>Denmark</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of the reporting system</td>
<td>Incident reporting system</td>
<td>Lex Maria; NITHA; The National Quality Registries; Annual national medical record reviews; The County Councils’ Mutual Insurance Company (LÖF); The RLS of Patients Advisory Committees</td>
<td>Danish patient safety database (DPSD)</td>
</tr>
<tr>
<td>D1: Level</td>
<td>National</td>
<td>National</td>
<td>National</td>
</tr>
<tr>
<td>Reporting by healthcare professionals</td>
<td>Mandatory</td>
<td>Mandatory</td>
<td>Mandatory</td>
</tr>
<tr>
<td>Reporting by healthcare organizations</td>
<td>No</td>
<td>Mandatory</td>
<td>No</td>
</tr>
<tr>
<td>Reporting by patients</td>
<td>No</td>
<td>Voluntary</td>
<td>Voluntary</td>
</tr>
</tbody>
</table>

Similarities are marked in lighter shade, while differences are marked in darker shade.
<table>
<thead>
<tr>
<th>D3: Reporting by relatives</th>
<th>No</th>
<th>Voluntary</th>
<th>Voluntary</th>
</tr>
</thead>
<tbody>
<tr>
<td>D4: Public reporting</td>
<td>No</td>
<td>Voluntary</td>
<td>No</td>
</tr>
<tr>
<td>D5: Regulated by law</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>D3: Organization framework</td>
<td>Central regulatory framework</td>
<td>Central regulatory framework</td>
<td>Central regulatory framework</td>
</tr>
</tbody>
</table>
| D4: Reason for establishment | ➢ Political pressure  
➢ Benchmarking on patient safety | Benchmarking on patient safety | ➢ Political pressure  
➢ Benchmarking on patient safety |
| D5: Implementation method  | ➢ Pilot project  
➢ Step by step implementation | Step by step implementation | Full-scale operation at launch |
| D6: Types of incident      | Only serious harm to patient | All reports are accepted | Depends on the severity and |
Table 1. An overview of all similarities and differences between the incident reporting systems in Norway, Sweden and Denmark

There are dimensions for which MERS are similar in the three countries, and there are dimensions that differ. As concerning similarities, they are only briefly described but will not be objects of a further analysis to answer the question “why the MERS are similar along the particular dimensions?”. Differences, on the other hand, are the main choice of focus and will be discussed in more detail. The most significant dimensions that show divergence in the three Scandinavian countries with regard to MERS are the type of reporting for some groups (D2), the implementation method (D5), and the types of incidents reported (D6). Along these dimensions, the Norwegian, Danish and Swedish systems are completely contrasting. There are also differences in the level of reporting (D1) and the right to report (D7), but these differences are not tripartite, which makes them not as significant as the dimensions that show differences across all of the countries.

When looking at the level of reporting (D1), it is detectable that there are both similarities and differences between the reporting system in the three Scandinavian
countries. While all of them operate systems with a national level of reporting, in Sweden adverse events, near-misses and other incidents can be reported on regional and a local level as well. A possible explanation for this inclusion is the fact that Sweden administers more than one reporting systems. On one side, being able to report on “lower” levels, i.e. regional and local, gives more flexibility to the reporters and the reported adverse events and near-misses are more standardized and better classified in comparison to having one common system (Pronovost et al., 2009). On the contrary, however, the collected data can end up scattered in the different reporting systems and this can affect its accessibility to healthcare managers and clinical teams (Öhrn, 2012).

With regard to the type of the system (D2), the variance between the countries is trilateral. The reporting requirements are invariable only for the group of healthcare professionals where reporting is mandatory in all three systems. Evidently, the Swedish reporting system offers each and every group the possibility both to mandatory and voluntary report errors. The Danish system takes a role of a “hybrid” as it permits voluntary reporting by patients and relatives, whereas the Norwegian system has mandatory reporting for healthcare professionals, only. The different types of reporting depend to a large extent on the approach that the countries have chosen to follow. Systems with reporting open to many groups emphasize on quantitative data, while those with reporting that is more concentrated and open to less groups accentuate on the quality of the gathered data. The advantage of receiving reports from organizations is that it signifies that the institution has some commitment to making corrective system changes (Kohn, Corrigan, & Donaldson, 2000).

The organizational framework (D3) for the three countries is absolutely identical – centrally regulated.

The reason for establishment (D4) will not be taken under consideration for the current analysis as the observed difference is not very significant.

The “boom” of interest in patient safety and preventable adverse events after the publishing of IOM’s report caused agile reactions towards introducing Patient Safety Acts and implementing reporting systems in many countries. The
implementation methods (D5) chosen by each country seem to depend on the local context. The difference in the chosen methods for implementation could be due to the history, the background and the experience with dealing with adverse events. Pilot project offer the advantage of "trying out", generating lessons, and taking greater control, but are also often consuming excessive human and financial resources. Therefore, they could be a better choice for countries that do not have plenty experience into a given field, and are searching for a way of implementation that will be less risky, as is the case with Norway (Partners for Health Reform plus, 2004).

Another method is the "step-by-step" implementation. It requires for both long- and short-term objectives to be decomposed into manageable steps, which should be controlled at all times (Kohon, 1982). This method takes time to be fully enforced the system but it also gives more time for reaction in case of unexpected changes. As Swedish healthcare is completely decentralized, thus it seems logical to apply a "step-by-step" implementation that could improve coordination.

The third and most common method is a full-scale operation at launch. This approach is risky but aims at a vast quality improvement, i.e. this choice of implementation method is logical Denmark was first to introduce separate Law on Patient Safety. Another reason that could advocate for this choice is that Denmark has the smallest area and population out of the three countries, plus that fact that it is separated into five regions (one more than Sweden and Norway), i.e. the maintenance for smaller amount of people coordinated into more regions, could be easier.

The types of incidents (D6) reported is another category that reveals differences in the way the three reporting systems are structured. In Norway, the severity of the incidents determines whether it should be reported or not. In Sweden, all reports are accepted. In Denmark, the decision for submitting a report is depending on the incident type and the severity of the incident. Furthermore, it is different for hospitals and pharmacies, as example. The difference in the chosen types is a consequence of different healthcare priorities. A list that explicitly specifies the reportable incidents is usually easier to understand by the reporters. However, a broader definition enables reporters to simply report any concern they may have, without having to think if they are using the proper way to report (European Commission, 2014).
As concerning the healthcare provider organizations and *the right to report* (*D7*) incidents (as parts of the healthcare system), Swedish and Danish reporting systems show similarity, i.e. healthcare professionals from public hospitals, private hospitals, pre-hospitals, primary care, private care agencies, by GPs, pharmacists and other practitioners are all eligible to report, whilst the NRLS “accepts” reports only from healthcare staff in public hospitals, private hospitals, and pre-hospitals, i.e. secondary care.

As stated in OECD’s report from 2014, “Norwegian quality policies traditionally focus on nurturing a culture of quality improvement, but it should now be completed by more robust quality assurance mechanisms…Of particular importance is the establishment of a good data and reporting structure for supplemented primary health care units, which will benefit greatly from good information about successes and weaknesses, both across Norway and between different providers” (OECD, 2014). A possible explanation for the lack of connection between primary and secondary healthcare is maybe the fact that the healthcare services are very distinctly divided, i.e. primary healthcare services are run by the municipalities, and specialized healthcare services are run by the state. In contrast, the separation of these two groups is not so drastic or hierarchical in Sweden and Denmark (Orley, 2013).

*Methods of reporting* (*D8*) can be perceived as being uniform for Norway, Sweden and Denmark as they are all using electronic formats for reporting. The addition forms for patients and relatives in Denmark and Sweden are in direct link to the *type of reporting* (*D2*) as there are no error reporting systems for patients and relatives, thus, there are no separate forms for them in Norway.
8. CONCLUSION

To my knowledge, this is the first study to undertake the MERS of Norway, Sweden and Denmark, to identify what are the most significant components of the systems for those three countries, to assess the similarities and differences, and to explain the possible reasons for the discovered divergence considering the context.

The dimensions that showed the greatest variance between Norway, Sweden, and Denmark’s MERS structures, are the level of reporting, the type of the system and reporting groups, the implementation method, the types of incidents reported, and the healthcare provider organizations with right to report incidents. The analysis is showing the “interaction” between some of the discussed dimensions in a reporting system and the way they are influenced by external factors, like history and experience can influence the method of implementation. Finding out the most significant dimensions that bring the difference in the structure of the MERS, identifying the possible reason for them, and describing the advantages and disadvantages of the chosen approaches can offer a better understanding of the system as a whole. Other relevant dimensions that could have been included in the study and could be a subject of further research are the funding of the MERS, the presence or lack of nationwide database, the technological support, the training and education programs, etc.

Assessing the components of the systems separately and comparing them with the same components in other countries, could challenge further studies to evaluate the synergy in the MERS, i.e. whether the functioning of the whole system would produce better results than the sum of its components.

Potentially, this work can also be a starting point for “lesson learned” type of studies where concentrating and analyzing one of the components can lead to being one step closer to the ultimate medical error reporting system.
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## Characteristics of Successful Reporting System

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-punitive</td>
<td>Reporters are free from fear of retaliation against themselves or punishment of others as a result of reporting.</td>
</tr>
<tr>
<td>Confidential</td>
<td>The identities of the patient, reporter, and institution are never revealed.</td>
</tr>
<tr>
<td>Independent</td>
<td>The reporting system is independent of any authority with power to punish the reporter or the organization.</td>
</tr>
<tr>
<td>Expert analysis</td>
<td>Reports are evaluated by experts who understand the clinical circumstances and are trained to recognize underlying systems causes.</td>
</tr>
<tr>
<td>Timely</td>
<td>Reports are analysed promptly and recommendations are rapidly disseminated to those who need to know, especially when serious hazards are identified.</td>
</tr>
<tr>
<td>Systems-oriented</td>
<td>Recommendations focus on changes in systems, processes, or products, rather than being targeted at individual performance.</td>
</tr>
<tr>
<td>Responsive</td>
<td>The agency that receives reports is capable of disseminating recommendations. Participating organizations commit to implementing recommendations whenever possible.</td>
</tr>
</tbody>
</table>

Multilevel systems model of technology design and implementation

Source: Report “Toward a theoretical approach to medical error reporting system research and design” (Karsh, Escoto, Beasley, & Holden, 2005)