Jenny West

Finnish patient safety/guidelines and patient safety in World Health Organization Learning material

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Patient safety is the fundamental principle in health care and social services. Despite this, adverse patient safety events are common and their burden on the economy is huge. Different stakeholders, within health care and social services, have their own definitions for patient safety and implement different actions for continuously safer health care. Patient safety is the largest component of quality health care and it consists of care/treatment safety, medicine/medication safety and equipment safety. World Health Organization (WHO) is internationally working towards safer health care and is providing knowledge, networks and guidelines on the subject. In Finland health care and social services are regulated by acts, and different authorities are responsible for the guidance and monitoring of patient safety.

The aim of this project was to find out the official, legislation based, Finnish patient safety guidelines on national level, and then to classify them, in order to develop a learning material. The learning material was developed for Metropolia University of Applied Sciences. The purpose of this project was to understand how patient safety issues are organized in Finland and also familiarize how patient safety is organized within World Health Organization. This project is done according to the research based developing method and the developmental findings are gathered together into the learning material booklet.

Learning material booklet contains the definitions of patient safety and guideline definition, development and usage. After overall patient safety introduction, it is represented the patient safety in World Health Organization (WHO) and in Finland. WHO's work towards safer health care are explained and Finnish patient safety actors and national patient safety guidelines are represented.

Patient safety is very important, but sometimes a forgotten component of health care in general. Overall it would benefit from an increase in co-operation between its stakeholders, organizations and governments. This project revealed only slightly, the current patient safety status in Finland.

Keywords	Patient safety, Guideline, WHO, Finland

Contents

1 Introduction

Patient safety is the fundamental principle of health care and adverse patient safety related events can happen during any step of care-giving path. Throughout any health care process, there is always a certain level of uncertainty present. According to the World health Organization (WHO), as many as 1 in 10 patients are harmed while hospitalized and approximately 43 million patient safety incidents occur every year. Medication errors cost an estimated 42 billion USD annually. These adverse patient safety related events can, for example, result in increased lengths of stay in health care facilities, they can result in permanent injury or even death. Effective and participating involvement of patients, organizational leadership, skilled health care professionals and clear policies are all of them needed to ensure development and improvements in health care, that are sustainable and significant enough. In addition to this, reliable research data helps to lead patient safety towards more developed health care processes. (Patient safety.)

In Finland, and actually all over the globe, patient safety is seen as the key component of quality, when taking care of patients. Safe patient care is effective, when it is done correctly and at the right time. Patient safety is not just good for its patients/customers, but it also helps doctors and nurses, and all other health care professionals practice safer and better medicine. Patient safety in Finland is regulated by acts and European Union directives. All the patient safety related authorities are expressed in the acts and their responsibilities come from the national legislation. (Potilasturvallisuus, STM; Patient safety.)

This project focuses on Finnish patient safety and the Finnish patient safety guidelines on national level, and what kind of legislation/authorities is behind them? In addition to this, the author will familiarize herself with how patient safety is organized in the World Health Organization (WHO). Project is part of the Transnational co-operation project, in developing quality health care and patient safety, between Metropolia University of Applied Sciences and Kyungpook National University (SACU). The need for this thesis stems from there, but Metropolia also needs this kind of research related to the patient safety issues, especially, here in Finland. When the patient safety guidelines have

been found, the author will create a learning material in English, for Metropolia, that is specifically targeted towards the students of Health Business Management.

The aim of this project is to find out the official, legislation based Finnish patient safety guidelines on national level and then to classify them in order to develop a learning material out of them. National level guidelines will be classified according to the responsible authorities behind the guidelines.

The purpose of this project is to understand how patient safety issues are organized in Finland and to go through all the possible sources which contain Finnish patient safety guidelines on a national level. The author's target is to find the official guidelines, which are based according to the Finnish legislation. In addition to that, the aim is to also familiarize how patient safety is organized by the World Health Organization. With this gathered knowledge, the author will develop a learning material for Health Business Management students. The learning material will be prepared in English.

2 Patient Safety

What does patient safety consist of? One way to define it is, that patient safety is the absence of preventable harm during the health care process. It is very important in health care, to try to minimize all the risks in health care processes, that could potentially harm patients and clients. Patient safety is about minimizing these risks. Every step in the health care process contains uncertainty and risk, and these risks should be decreased with all available resources. In health care, there is always a need to evaluate the advantages and disadvantages that health care processes can have on the people using its services. With this gathered knowledge, it is evaluated whether a person needs health care or not. When health care is needed it must be produced as safely as possible. (Patient Safety.)

Patient safety, in health care and social services, is more about the quality of the service themselves. It is always more difficult to measure the quality of a service, than the quality of a product. When comparing quality in general, it has a wide variety of meanings. Quality of a service can simply be the relation between the customer's expectations and the resulting customer's outcome. Health care quality can have three different

types of quality: patient experience, patient safety and clinical decision making. All of these quality types should have unique measurements and unique improvement strategies. (Lillrank 2015.)

Patient safety must be seen as a global health concern. In the aviation industry, there is a one in a million chance of being harmed while flying, but in comparison to health care, the risk is one in 300. So the safety record in health care is significantly poorer than that in aviation and this record is also laying a big burden on the global economy. For example, it is estimated, that medication errors alone cost billions US dollars annually. Ten significant facts on patient safety are shown in Table 1. These facts are provided by the WHO. (Patient Safety; 10 facts on patient safety.)

Table 1. Ten facts on Patient Safety (10 facts on patient safety.)

1) Patient harm is the 14th leading cause of the global disease burden, comparable to diseases such as tuberculosis and malaria
2) While in hospital, 1 in every 10 patients is harmed
3) Unsafe use of medication harms millions and costs billions of dollars annually
4) 15% of health spending is wasted dealing with all aspects of adverse events
5) Investments in reducing patient safety incidents can lead to significant financial savings
6) Hospital infections affect 14 out of every 100 patients admitted
7) More than one million patients die annually from surgical complications
8) Inaccurate or delayed diagnoses affect all settings of care and harm an unacceptable number of patients
9) While the use of radiation has improved health care, overall medical exposure to radiation is a public health and safety concern
10) Administrative errors account for up to half of all medical errors in primary care

These facts prove the importance of patient safety as a subject. For example 15 % of health spending is wasted on dealing with adverse patient safety events, 14 out of every 100 are affected by hospital infections, and more than one million patients die

annually from surgical complications. Patient safety must not be overlooked, but taken very seriously all over the globe, and its economical impact is substantial. Patients safety research: an overview of the global evidence reminds, that harm from medical care, appears to have a substantial burden on the world's population. In this study researchers identified structure, process and outcomes of unsafe care. Then the evidence was examined and divided between developing, transitional and developed nations. This study clearly explained about the gaps between developing and developed countries. It seems like a lot of the evidence about patient safety, in relation to adverse events, comes from the developed countries. The lack of knowledge and ability to record in developing countries, has an effect on their records, and sometimes it is difficult to get a straight answer about the state of patient safety in these countries. After all they were able to state in the research, that even though health care systems cure and alleviate pain, they also causes harm and suffering to the people using them. This is why it is so important to try to minimize all the risks produced by health care worldwide. (Jha, A K – Prasopa-Plaizire, N – Larizgoitia, I – Bates, D W 2008: 42-45; 10 facts on patient safety.)

2.1 Main concepts of patient safety

Patient safety is the key concept in this subject. Patient safety has many explanations that differ from each other, sometimes only a little and sometimes quite a lot. The WHO stated, that patient safety is the absence of preventable harm during the health care process. In the European patients forum it is explained to be both a goal and a practice. The goal could ideally be seen as being a reality free from harm and a practice where processes and structures aim to make health care safer. The Finnish Ministry of Social Services and Health explains patient safety to be the right care at the right time and done in as safe a way as possible. Finnish patient safety association define patient safety to be: Patient safety is that patients get the needed care and that it is done medically correct. This care causes as little harm as possible. Patient safety consists of all care, medicine/medication and equipment safety. Different definitions of the concept patient safety are listed in Table 2.

Table 2. Different definitions of patient safety.

Patient safety is absence of preventable harm during the health care process. (WHO, Patient safety)
Patient safety is right care at the right time and done as safe way as possible. (Finnish Ministry of Social Services and Health)
Patient safety is both a goal (being free from harms) and a practice (processes and structures that aim to make health care safer). (European Patients Forum)
Patient safety is that patients get the needed care and that it is done medically correct. This care causes as little harm as possible. Patient safety consists of all care, medicine/medication and equipment safety. (Finnish Patient Safety Association)

All in all it could be stated, that all patients want to be as safe as possible during their health care processes and that health care should help them and not cause any harm. One of the shortest definitions for patient safety is to do no harm to patients. Sometimes patients can also be called clients. In the Finnish Safety Strategy patients and clients are linked together. This emphasizes the fact that patients are actually clients as well. Client safety can have exactly the same meaning as patient safety. (Patient safety, EPF; Potilasturvallisuus; Patient safety; Suomen Potilasturvallisuusyhdistys Ry.)

A patient or client, is the person who is using the health care or social service when needed. Sometimes clients can be referred to more as the persons who are using social services, but in Finland it is nationally emphasized that patients are clients too. **Health care and social services,** are the services which are promoting people's health, well-being and social welfare. These services can be said to be all the functions that are implemented for people's health and social welfare. (Patient and client safety strategy 2017-2021.)

What are the dimensions of patient or client safety? When the main concept is patient safety, then the sub concepts can be **medication safety, care/treatment safety and equipment safety**. Their linkages are expressed in the Figure 1. (Suomen Potilasturvallisuusyhdistys Ry.)

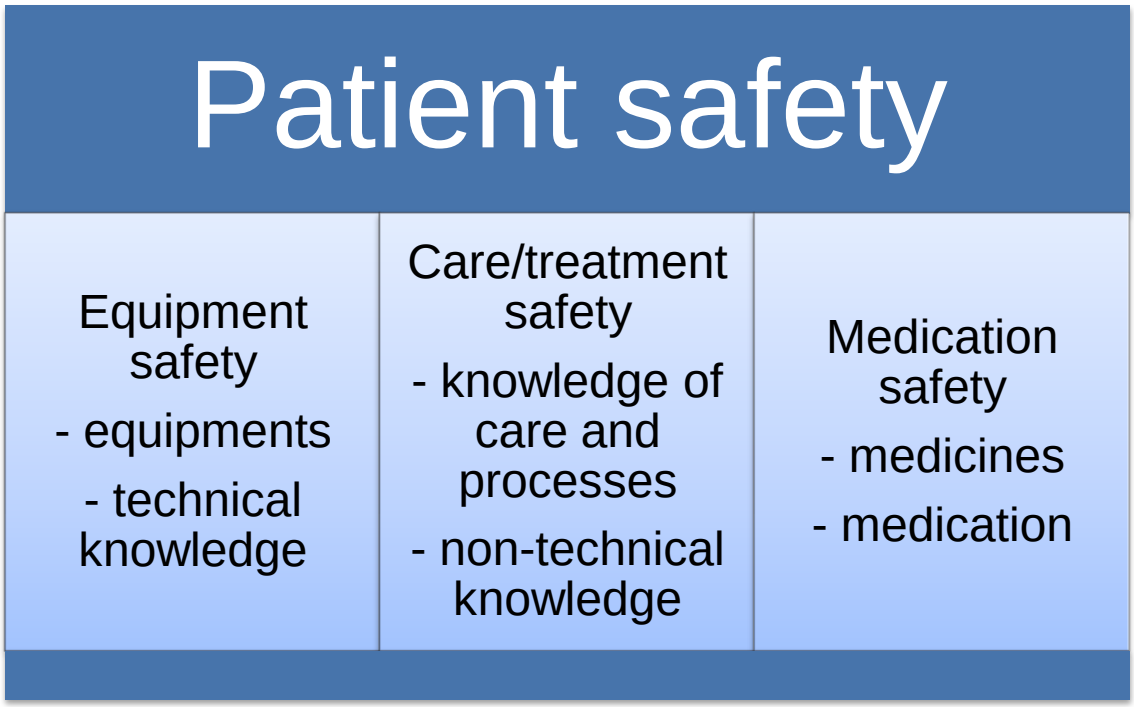

Figure 1. Concepts of patient safety (Adapted Suomen Potilasturvallisuusyhdistys Ry).

Equipment safety consists of the right and proper use of equipment in health care, but also the safety and functioning of that equipment, and the whole physical environment. First of all, equipment in health care must be accepted and revised by national authority. A medical device in health care can be referred to as any equipment, instrument, software, material or other device, that is used alone or together with necessary software, for human health care:

a) to diagnose a disease, preventing, monitoring, treating or palliating diseases
b) to diagnose a disability, monitoring, treating, palliating or compensating disabilities
c) to examine, support or replace anatomical or physiological functions
d) to regulate fertilization

In Finland, only medical devices that comply with existing regulations, can be placed on the market. The National Supervisory Authority for Welfare and Health, Valvira, is responsible to monitor that medical devices are following all the legislation and regulations. They are also following the marketing of medical devices and one of their tasks is to promote the safe use of devices. Before manufacturers can place a new product on the market, they must be able to prove its safety, reliability, suitability for its intended use and performance of it. All of the medical devices in Finland must have a CE mark-

ing. CE marking indicates that a device is meeting with required regulations. Properly used medical device must not endanger the safety or health of the patient, or its user or any other persons. All the adverse events relating to medical devices must always be reported to Valvira, as soon as possible. (Terveydenhuollon laitteet ja tarvikkeet; Health Technology.)

Care/treatment safety consists of all the knowledge related to care and processes, but also all non-technical knowledge, education and so called silent knowledge. This part also consists of all health care processes and management. Health care processes include all the actions, from aseptic safety, to IT processes and infection control to radiation safety. This part contains all the other safety issues, but not medicine/medication and equipment safety. Patients deserve the best care possible without any adverse events, that could harm their health. Management and processes need to build the frame for patient safety. Thus everyone in the system needs to fulfill their duty as well as possible, to ensure that patients get the best care possible. An important part of this is, to remember not to blame anyone and do the co-operation together with all other professionals involved. (Potilasturvallisuuden lyhyt oppimäärä.)

In Finland the health care act requires all health care and social services actors to develop and maintain a patient safety plan. In addition to this overall patient safety plan, all kinds of checklists are commonly used in health care in Finland. These checklists are targeted to reduce all patient safety incidents and injuries, that are preventable. These checklists also help to follow the right care and treatment processes and make sure that all knowledge available is used for the patients in health care. An important part of patient safety is, to learn from mistakes, and have the ability to follow the patient safety at its required level. (Volmanen – Alahuhta 2015: 332-337.)

Medication safety. Medical treatment safety is a big part of patient safety in general. Medical treatment safety can be divided into pharmaceutical/medicine safety and medication safety. Pharmaceutical safety means, that any medicines pharmacological features are known, as well as its medicinal effects, when consumed. In addition to that, medicines must be produced with high quality and they should be packed and labelled correctly. Essential parts of pharmaceutical safety are to know their medicinal effectiveness and evaluation of their safety. Finnish Medicines Agency Fimea regulates pharmaceutical safety in Finland, but medicine manufacturers are also responsible for monitoring the safety of their medicines.

Medication safety on the other hand consists of the correct and appropriate usage of medicines and their correctly implemented use for treatment. Organizations and health care units are responsible for this medication safety and they follow different guidelines, actions and principles related to medication safety. Medication safety can be developed further for example by monitoring adverse effects with different systems. One example could be the nationwide IT-instrument called Haipro. Pharmaceutical safety relates always in to the product and on the other hand medication safety relates to the human factors of people, who implement medications. (Lääke- ja lääkitysturvallisuus.)

So patient safety is the overall major subject, which consists of all the other subjects of safety in health care and social services, from medicines to equipments. Patient safety can be promoted both nationally and internationally and guided by acts, directives, plans, checklists, orders and guidelines. Patient safety has many different definitions, but is also related to concepts which are used simultaneously or equally. (Potilasturvallisuus; Patient safety.)

2.2 Related concepts to the patient safety

Patient safety has many different definitions and as already mentioned maybe the shortest one is: to do no harm to the patients. Patients can also be seen as clients and especially in Finland patient safety and client safety actually mean the same. One important related concept to patient safety is the quality of care. The quality of care can be seen as a major subject that consists within patient safety as well. The quality of care is a more abstract concept than patient safety, and so one way to define it is that, quality is an optimal balance between the possibilities realised and a framework of norms and values. Quality of health care is seen being more like a benchmark standard for health care. Of course values, standards and norms are really important parts of patient safety too. Quality and patient safety are important safety concepts in health care, no matter what way they are explained or used in literature, but more importantly how they are implemented in practice. (Patient Safety and Quality: An Evidence-Based Handbook for nurses; Patient and client safety strategy 2017-2021.)

One related concept to patient safety is safety culture. Safety culture is usually referred to as shared values, attitudes, perceptions, competencies and behaviours of an organization and the people within the organization. Safety culture includes all the practices

that support safe operation, all the leadership inside the organization, and actually also inside the community. Safety culture promoting methods are assessment of risks, preventive actions and continuous development of the operations. Safety culture responsibilities must be shared inside the organization and strengthening the safety culture allows better management to the risks related, to the operations and services. Safety culture is the way people are acting towards safer services to both patients and clients. (Patient and client safety strategy 2017-2021.)

Patient safety and related concepts have as many definitions maybe as there are people. In one conference, an exploratory survey was conducted on hospital executives, board members and physician leaders, were they were asked to define patient safety with one word. The top three definitions were communication, falls and quality. More than 4200 words were used as definitions. The board members most frequently used word was communication, physician leaders used quality and hospital executives used communication. This emphasizes how broad and wide a concept patient safety is, and how difficult it is to define a similar way even on national or organizational level, let alone internationally. (Schmidt 2012.)

In 2009 an article stated that patient safety would deserve an international language. If we would like to have global progress in patient safety, it would require the classification of key concepts. Patient safety has gained more knowledge, but a common, and especially internationally agreed patient safety concepts are still missing. During that same year the conceptual framework towards an international classification for patient safety was started by the WHO. The International Classification for Patients Safety (ICPS) was developed for this purpose. In 2016 a study was published, that investigated how applicable these ICPS classification were to the surgical population. That study proved classification for patient safety to be applicable in surgical environments and that patient safety was enhanced through the classification. (Donaldson 2009; McElroy etc. 2016.)

2.3 Guideline definition and development process

One way to promote patient safety is by having guidelines produced to the issue. The WHO has published the WHO guideline handbook. Guidelines are explained to be any documents containing recommendations about health care or social services interventions. A recommendations purpose is to provide information for all the actors within

health care and social services, not just policy-makers, but also for the patients, professionals and anyone related to the issue. Guidelines and the recommendations within them, are meant to assist with information and help to make informed decisions. Guidelines usually summarize research evidence from the issue and their aim is to transfer this evidence into practice. The WHO uses internationally recognized standards in their guidelines, to prevent any bias, and to ensure that the guidelines meet the needs of health care and are consistent. All the WHO guidelines are following these two principles:

1) Recommendations are based on a comprehensive and objective assessment of the available evidence.

2) The process used to develop the recommendations is clear. That is, the reader will be able to see how a recommendation has been developed, by whom, and on what basis. (WHO guideline handbook 2012:1-3.)

Before the guideline is produced, it is very important to consider the guideline audience and timeline for it. Sometimes guidelines are needed to done very fast, if there is some urgent situation at hand, but usually the guideline development process in the WHO follows the steps seen in the Figure 2. (WHO guideline handbook 2012:1-3; Taylor etc. 2014.)

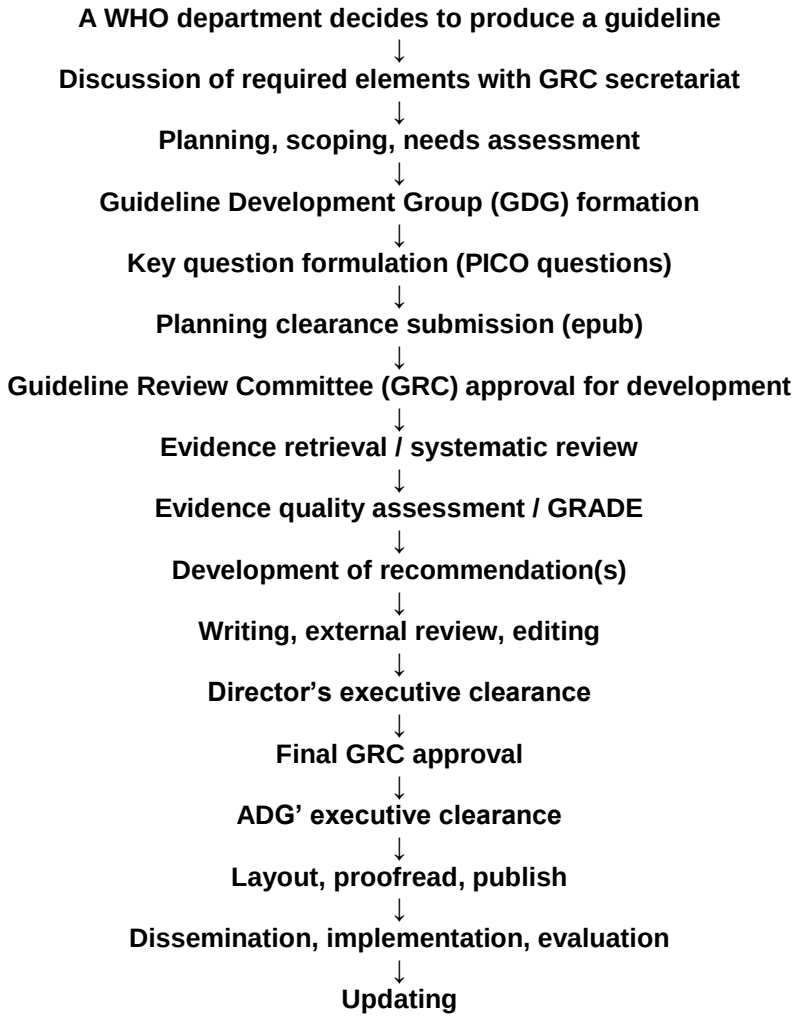

Figure 2. Guideline development process, WHO (Adapted from WHO guideline handbook 2012: 2).

Anne V. Irving (2014) stated in the article that policies and procedures has a number of important purposes, but at the same time they can be very problematic. Problems occur when there is several policies in similar issues. These situations can lead to the confusion and debate which policy should be used. She wrote, that very important part of the policy, is definition of terms. Definitions must be in the beginning of the policy. Another important part is implementation of the policy. If the organization fails to implement policy effectively, staff members follow then outdated policies. Health care units are in many cases very complex organizations. In complex units, standardizing the policies across the organization, would benefit implementation process. All the policies and procedures have a very important purpose in the health care units. Risk managers and senior leaders of the organization should work together towards standard-

ized policy system in their units. This would definitely have an impact on patient safety of the organization. (Irving 2014.)

2.4 Usage of the patient safety guidelines

When the guideline is developed and published, the next step is to use it the proper way. Researchers were investigating in a study: What do primary care physicians and researchers consider the most important patient safety improvement strategies. In this study they aimed to identify the most important strategies in patient safety, and it was done by consulting an international panel of primary care physicians and researchers, via a web-based survey. This survey demonstrated that education on patient safety was seen as the most important factor to improve patient safety and especially the presence of relevant patient safety guidelines was found to be very important. The researchers clarified that the guidelines needed to consists of different strategies and suggestions on how to improve patient safety in primary care. The presence of a guideline got 81% importance rate amongst the replies, but only 15% felt that guidelines where implemented in their units. (Gaal – Verstappen – Wensing 2011.)

The presence of guidelines is seen to be very important, but still existing guidelines aren't used or implemented in their units properly. The other study conducted a research about the implementation of a national guideline. In this study it was expressed that clinical guidelines are an essential part of health care and a lot of work has been done for good quality guidelines. Usually implementation of a guideline requires a health care professionals behavior to change, but this component is overlooked and the implementation of the guideline can fail for this reason. Sometimes environmental and social systems are so complex that implementation fails or gets delayed. A lot of attention must be given to the implementation of the guideline, so that it will create the wanted effect on patient safety. Guidelines are seen to be very important, but of course only if they are used properly. They will create the wanted effect to patient safety only, when implemented and then used accordingly. (Taylor etc. 2014.)

Simultaneous development of guidelines and quality indicators; how do guideline groups act? A worldwide survey was investigating, if guidelines and quality indicators could be developed and implemented simultaneously. The study reminds that the golden standard for this purpose is missing worldwide. The survey conducted in this study revealed the variety of approaches and methods, on how these two subjects are dis-

covered and the lack of formal procedures around the subjects. Guidelines and quality indicators are a really important part of patient safety and the quality of health care. Such standards would be an important part of improving patient safety. (Blozik etc. 2012.)

3 Aim, purpose and objectives

The aim of this project is to find out what the official, legislation based Finnish patient safety guidelines are on national level and then to classify them in order to develop a learning material out of them. National level guidelines will be classified according to the responsible authorities behind the guidelines.

The purpose of this project is to understand how patient safety issues are organized in Finland and to go through all the possible sources which contain Finnish patient safety guidelines on a national level. The author's target is to find the official guidelines, which are based according to the Finnish legislation. In addition to that, the aim is to also familiarize how patient safety is organized by the World Health Organization. With this gathered knowledge, the author will develop a learning material for Health Business Management students. The learning material will be prepared in English.

Research objectives of the study:

1. How patient safety is organized in WHO?

2. How patient safety is organized in Finland?

3. What kind of patient safety guidelines (legislation based) exists in Finland on a national level?

4. Develop a learning material, which will rest in the findings of the three above questions.

4 Methodology

This project is done by using the research based development method. In this method, the need for developing something, rises from practice, and is usually used to create new knowledge for that specific need. In order to be able to develop it, it is important to gather information systematically and critically to support the developing work. Information in this method, can be searched from practice and from theory, and it is essential to use different methods for gathering information. In this method the goal can also be in creating new information from a specific practice. The research based developing method settles in the middle with scientific research and developing by common sense at the other ends. Figure 3 represents this (Ojasalo – Moilanen – Ritalahti 2015: 17-19.)

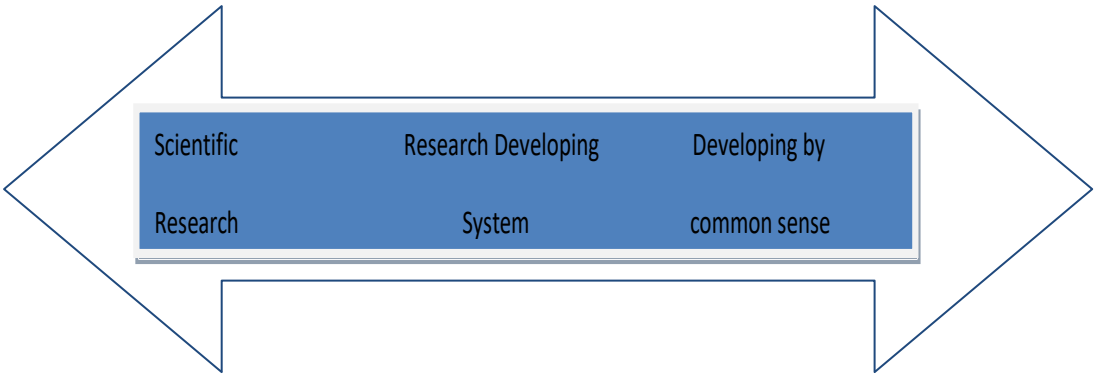

Figure 3. Character of Research based developing method.

The research based developing method is led by practical rather than theoretical goals. The research developing method starts from an idea, and after going through many different development stages, it ends with the solution, implementation and evaluation (Ojasalo – Moilanen – Ritalahti 2015: 20). The need for this project came from the SACU-project and also from Metropolia, which requires a new learning material to be added to the Health Business Management program.

Throughout the process, the writer has to remain: systematic, analytical, critical, ethical and active. Also it is important to remember for whom you are developing something. The process of the research development method goes like this:

1) Identify the development need and set preliminary goals
In this project the development need is identified to be a new learning material and information source for the SACU project. The goal is to find out what the Finnish patient safety guidelines are on national level and create a learning material out of them.

2) Orientate yourself in the development need in theory
Find out the national level patient safety guidelines in Finland and how patient safety is organized in Finland and the WHO.

3) Define the development need and filter it
The development need is to provide information about Finnish patient safety for the SACU-project and for Metropolia's health business management students.

4) Compose the findings from the step 2
Define what information is to be used in the learning material. All of the development findings of the project will be used in the learning material. In addition to the findings, the patient safety introduction and definitions will also be included.

5) Produce the learning material
The learning material is produced upon the objectives of the Health Business Management curriculum.

6) Evaluate the process
The process can be evaluated during the project, but the learning material will be evaluated by the health business management students.
(Ojasalo – Moilanen – Ritalahti 2015: 24.)

Overall, the development actions have a specific goal, and target and their development aims to the make changes in actions. Usually the aim is for better changes to lead to more effective actions (Toikko – Rantanen 2009: 16). This project' goal and target is to provide better information about Finnish/WHO patient safety, and Finnish patient safety guidelines for the SACU-project, and result with a new learning material for Metropolia.

This development project started by theory orientation. The first phase, examined what patient safety definitions there are and what are the main parts of patient safety. After

this, four different patient safety definitions were selected to be represented, and all the sources related to them that are looking at the subject from different perspectives. Patient safety and related concepts where examined from different sources and relevant studies were selected for this thesis. The second phase in this development project, was to discover how patient safety is organized in the WHO and in Finland. Information on these subjects was examined, from all the possible sources that provided information. One of the most important parts of this development project was to find out which Finnish patient safety guidelines are official and provided by national authorities. All the relevant authorities are introduced and their guidelines are listed in the sections developmental findings. Authorities were selected by Finnish legislation. The research based development method is open to all the information that is possible to find. For this reason, it was selected as the method for this project. It was really important to make sure that all the information possible could be used in this project.

5 Development setting

This development project was done in co-operation with Metropolia University of Applied Sciences. The need for the development project rose from the SACU-project and from the Health Business Management degree programme. The SACU-project is a transnational co-operation in developing health care quality and patient safety. The SACU- project is done in collaboration between Metropolia and Kyungpook National University, Daegu, South Korea.

The SACU-project's purpose is to develop health care quality. The SACU-project is trying to develop the quality of health care by improving safety practices and investigating the possibilities of IT-solutions related to adverse events reporting. The idea of the project is to learn from studies made in two countries and the purpose is to educate these two countries, to prevent adverse events in health care and social services. One part of the project is IT-solutions in preventing adverse events and enhancing patient safety. What kind of electronic reporting systems could be linked to the patient safety? This development project is focusing on Finnish national level patient safety, and patient safety guidelines, in order to find out how patient safety is organized in Finland. This information is then provided to the SACU-project according to project's needs.

The other need for this development project is from the Health Business Management degree programme, and specifically from the course Safety and Quality processes and Management in social services and health care. This development's project findings will be organised into a learning material for this specific course within the Health Business Management degree programme. The learning material will be used according to the course needs in future implementations. The learning material's contents will come from the courses objectives and goals. These are presented in the section which covers the learning material.

6 The developmental findings for the learning material: Patient safety in the World Health Organization (WHO)

Firstly this project is focused on the WHO and patient safety within the WHO. The WHO was selected for this project due to the international content of this subject, and the international work the WHO is doing for the subject. The main objective for this section of the project was to find out how patient safety is organized in the WHO. The material for this section was selected from the sources that reviewed patient safety in the WHO. The author selected to represent the WHO briefly in the beginning. The aim was to give a short introduction about the organization. Then the focus was on patient safety. The patient safety topics that were selected for this project were the patient safety introduction within the WHO, patient safety publications, guidelines and patient safety networks of the WHO. These topics gave a good understanding about the content on the WHO's level, and also the WHO's significant influence on patient safety on an international level.

6.1 About WHO

Better health for everyone and everywhere, is the slogan of the WHO and one of its principles states, that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being, without distinction of race, religion, political belief, economic or social condition. WHO's principle constitution also reminds that health is not only an absence of disease. Health is also a complete state of mental, physical and social well-being. The Constitution of the WHO is adopted from the Inter-

national Health Conference, which was held in New York, in 1946. All the WHO's constitution principles can be found in Table 3. (Constitution of WHO: principles.)

Table 3. Constitution of the WHO: Principles (Constitution of WHO: principles).

● Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.
● The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.
● The health of all peoples is fundamental to the attainment of peace and security and is dependent on the fullest co-operation of individuals and States.
● The achievement of any State in the promotion and protection of health is of value to all.
● Unequal development in different countries in the promotion of health and control of diseases, especially communicable disease, is a common danger.
● Healthy development of the child is of basic importance; the ability to live harmoniously in a changing total environment is essential to such development.
● The extension to all peoples of the benefits of medical, psychological and related knowledge is essential to the fullest attainment of health.
● Informed opinion and active co-operation on the part of the public are of the utmost importance in the improvement of the health of the people.
● Governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures.

The WHO was founded in 1948 and is working in 150 country offices, with more than 7000 people. The WHO headquarters are located in Geneva and it has 6 regional offices. The WHO's goal is to build a better, healthier future for people all over the world. The WHO works side by side with governments and other partners to ensure the highest possible level of health for all people. Together with these parties, the WHO fights against infectious diseases like HIV, but also against non-communicable diseases like cancer. The WHO helps mothers and children to survive and look forward to healthy,

long lives. WHO also tries to ensure the safety of the food people eat, drink they consume, air people breathe and the safety of the medicines and vaccines they need. (About WHO.)

The WHO is the coordinating and directing authority on international health. It provides standards and norms, but also leadership and ethical and evidence-based policy options. They provide technical support and is active in influencing research. Combined with all this, it provides help internationally to areas in need, and also monitors the global health situation and assess health trends. The WHO works in the following designated areas of health which are: health systems, non-communicable diseases, promoting health through the life-course, communicable diseases, preparedness, surveillance and response and corporate services. All this work is done to support member states in their efforts towards national health policies and strategies. The WHO supports member states in their coordinating tasks, with multiple sectors involved in health care issues. (What we do; Where we work.)

6.2 WHO and patient safety

Patient safety and the quality of care on a global scale, were first discussed in 2002, at the World Health Assembly. Since then, the WHO has continued the discussion about safer health care internationally and has managed to create several international initiatives. These initiatives have brought the importance of the subject much closer to many policy-makers and initiatives have influenced in many countries. These initiatives and discussions have also included important topics worldwide, which are shown in Table 4. In the Fifty-fifth World Health Assembly, the WHO urged the member states to "*pay the closest possible attention to the problem of patient safety*". These actions and discussion by the WHO illustrated, that patient safety is a significant benefit to health care, all over the world and not just in low-income countries, but also in high-income countries and that they have to maintain the goals towards safer health care. (Policies and Strategies.)

Table 4. WHO patient safety discussion topics internationally (Policies and Strategies).

- Development of global norms and standards
- Promotion of evidenced-based policies
- Promotion of mechanisms to recognize excellence in patient safety internationally
- Encouragement of research
- Provision of assistance to countries in several key areas

In 2004 the WHO launched a patient safety programme in response to the World Health Assembly, where patient safety issues had been brought up for discussion. This WHO's programme aims to coordinate and accelerate improvements in patient safety worldwide, and it will act as a major force for patient safety improvements all over the world. This programme also offers a platform for international collaboration and delivers programs for systematic and technical aspects, in order to improve patient safety. The WHO's patient safety programs vision is "*A world where every patient receives safe health care, without risks and harm, every time, everywhere"* and its mission is as per below. (About us.)

> Our mission: To facilitate sustainable improvements in patient safety and managing risks to prevent patient harm.
>
> The mission of WHO Patient Safety is to coordinate, facilitate and accelerate patient safety improvements around the world by:

- being a leader and advocating for change;
- generating and sharing knowledge and expertise;
- supporting Member States in their implementation of patient safety actions. (About us.)

The WHO is working towards safer patient care worldwide. This is done by facilitating development of patient safety strategies and policies in member states, and its core function is to articulate evidence-based and ethical health policy options. The WHO gives guidance on policies and strategies through its publications and it hopefully strengthens the efforts of WHO member states, in developing safer and more sustainable health care systems for improving patient safety. By multilingualism, the WHO ensures, that the information reaches the people who need it, and by this it makes the access to health information more effective and equitable. (Who we are.)

6.3 WHO and patient safety networks, publications and guidelines

WHO is supporting global patient safety in its member states by its publications, guidelines and forums, for all the parties who are involved in patient safety issues in their own countries. WHO has created and maintained an online platform, which is called Global Patient Safety network. This network is intended for the stakeholders in the member states and in this network it is possible to discuss approaches, ideas and best practices from around the world. In addition to this network, the WHO has developed different collaboration centres for patient safety. These centres are located in different places and are dealing with subjects like human factors and communication, patient engagement, patient safety and the quality of care. Despite all these actions made for policy makers, and parties involved in the patient safety, the WHO hasn't forgot patients either. They have a network for patients, families and health professionals called WHO Patients for Patient Safety Network, where all the people can engage themselves to this important issue in health care. It is very important also to learn and educate health care from the best practices which already exist. For this reason the WHO has brought hospitals in Europe and Africa together in a partnership program, which initially concentrates on hospital partnership in Europe and Africa, but of course this model and resource is applicable to all regions of the world. (Networks and partnership; Collaborating Centres and NGOs in official and working relations for with WHO for Patient Safety.)

WHO is working towards more safe health care by proving tools also for its member states by its publications and guidelines. All the publications can be found from WHO's channels on the internet and they are done in different languages to reach as many as possible. The publications cover a wide range of topics. For example, the WHO's third global patient safety challenge is called, Medication Without Harm, and it was launched in October, 2017. It reminds that everyone, including patients and health care professional, have a role to play in ensuring medication safety. Another publication from the year 2017, is the Making health care safer-brochure, which reminds about the financial aspects that unsafe care causes. In 2011, the WHO published the Multi-Professional Patient Safety Curriculum guide. This guide was developed to assist teaching of patient safety issues in universities and schools in the fields of medicine, dentistry, pharmacy, nursing and midwifery. Its purpose is also to support the on-going training of all health care professionals. Publications are divided in the WHO's channels by topic or by type.

Areas they cover can be found from Table 5. (Publications; Medication Without Harm; WHO Multi-Professional Patient Safety Curriculum guide.)

Table 5. WHO publications examples (Publications).

Publications by topic	**Publications by type**
- African Partnerships for Patient Safety	- Policies and strategies
- Assessments and research	- Guidelines, frameworks and toolkits
- Blood transfusion safety	- Tools, checklists, manuals and guides
- Education and training	- Evaluation and progress reports
- High 5s:Standard Operating Procedures	- Advocacy materials
- Infection prevention and control	- Meeting Reports
- Injection safety	- Posters and banners
- Medication safety	
- Patient safety solutions	
- Policies and strategies	
- Radiation safety	
- Reporting and learning systems	
- Safe Childbirth	
- Safe surgery	
- Safe primary care	

The WHO is providing guidelines for its member states and there are also guidelines for patient safety subjects. These guidelines are approved by the Guidelines Review Committee. The core functions of the WHO are to ensure the appropriate use of evidence and developing global guidelines for this purpose. These guidelines and recommendations are meant to have an impact on health policies around the world. WHO guidelines concerning patient safety cover topics like: the WHO guidelines on hand hygiene in health care, Towards 100% voluntary blood donation, Blood donor selection, Best practices for injections and a related procedures toolkit, Global guidelines on the prevention of surgical site infections, Guidelines on core components of infection prevention and control programmes at the national and acute health care facility level, Natural ventilation for infection control in health care settings, and Screening donated blood for transfusion-transmissible infections; recommendations. (WHO guidelines approved by the Guidelines Review Committee; WHO guidelines on patient safety.)

7 The developmental findings for the learning material: Patient Safety in Finland

The second part of this project was to find out how patient safety is organized in Finland and what kind of official, legislation based patient safety guidelines exist locally. The content and material for this section are gathered from sources that the corresponding authorities and Finnish legislation provide. At first, the patient safety legislation and national level patient safety actors, were chosen to be presented. The second important part of this project was to present the guidelines these actors provide. In addition to these, some other patient safety related materials provided by these actors, were also selected to be presented. Also some other relevant actors were introduced. A really important part of these developmental findings, is to present the Finnish patient safety strategy on national level and this is also covered in this section. Especially the developmental findings on Finnish patient safety are a crucial part of the learning material. The learning material is targeted towards the needs of Finnish patient safety.

Finland has a fairly well-organized system for health care and social services. Despite these well-organized services, patient safety hasn't received the amount of attention that it deserved. In 2005 the Finnish Ministry for Social Affairs and Health launched an initiative towards a more coordinated and strategically unified patient safety system on national level. Steering groups were established and the first patient safety strategy was created for the years 2009-2013. The second patient safety strategy is now valid and it is for the years 2017-2021. Patient safety actors are quite wide spread in Finland and in Figure 4 some of the main patient safety actors in Finland can be seen. (Edistämme potilasturvallisuutta yhdessä, Suomalainen potilasturvallisuusstrategia 2009-2013.)

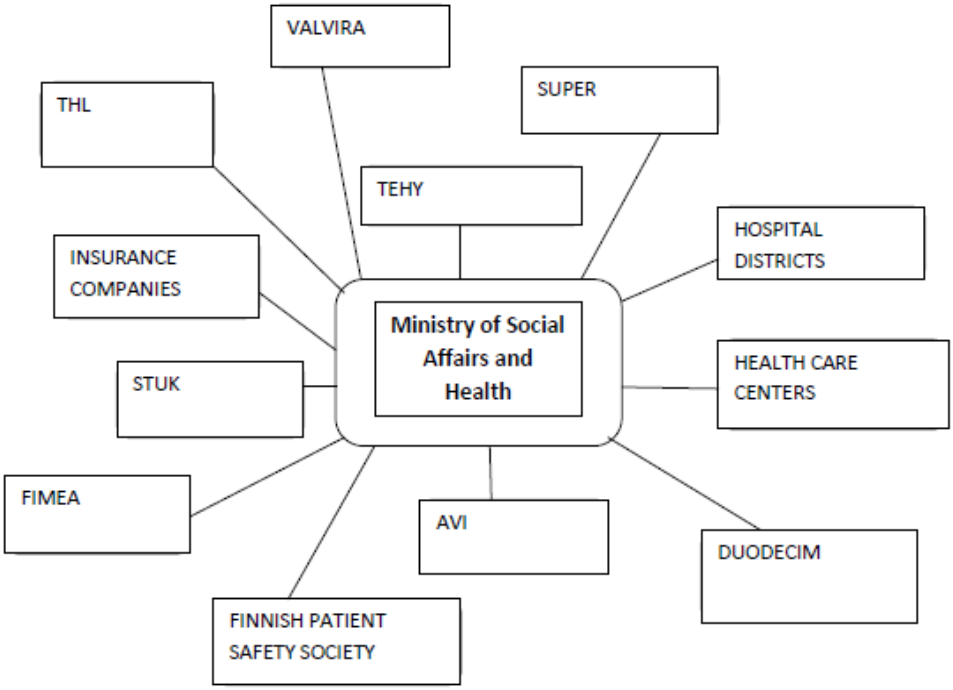

Figure 4 . Some of the main patient safety actors in Finland. (Adapted from Doupi 2009: 13.)

All these actors work towards a safer health care system, but only some of them have legal responsibilities dictated by the national legislation. Patient safety in Finland is regulated by acts and the state's responsibility to promote health, welfare and security is expressed in the constitution of Finland (The Constitution of Finland 731/1999). The Municipal authorities duties, to arrange social and health care, are stipulated by act in accordance to social and health care planning. (Act on Social and Health Care Planning and Government assistant 733/1992) The services municipalities must produce are dictated by the act on Social Welfare (Social Welfare Act 1301/2014). One of the most important Acts concerning patient safety, is Health Care Act, which came into effect in 2011. More detailed information is in the decree 341, which came into effect in May 2011. Patient safety and quality control are regulated by this act and decree. Within the health care act it is stated, that health care must be based upon the evidence and good care and action policies. Health care must be of the highest quality, safety and executed in an appropriate way. Every health care unit, which is providing health care or social services, must have a patient safety plan, and decree 341/2011 stipulates, what the plan should include. In Table 6, the content of the patient safety plan is

illustrated. (Lainsäädäntö; Legislation; Potilasturvallisuus, STM; Terveydenhuoltolaki; Sosiaali- ja terveysministeriön asetus 341/2011 laadunhallinnasta ja potilasturvallisuuden täytäntöönpanosta laadittavasta suunnitelmasta.)

Table 6. Content of the patient safety plan Decree 341/2011 (Sosiaali- ja terveysministeriön asetus 341/2011 laadunhallinnasta ja potilasturvallisuuden täytäntöönpanosta laadittavasta suunnitelmasta).

1) Responsible person for patient safety, all the actors and how the management is responsible about the possibilities to promote safety in the unit
2) Principles for good quality and safe personnel management
3) Actions how the personnel participate to the patient safety and develop it. Feedback about the actions personnel have done.
4) How personnel and student familiarization is organized safe way with highest quality possible.
5) Actions how patients and family members can give feedback or report about patient safety and the ways they receive knowledge after possible adverse event.
6) All the quality control documents used in the unit.
7) Anticipation of the safety and quality problems and safety risk management and recognition.
8) Adverse event recognition and reporting and corrective actions protocol.
9) Co-operation with the other actors in the municipality

Act on the Status and Rights of the patient (785/1992) reminds, that the patient has the right to good quality health care and medical care. Health care must be arranged by respecting the patients privacy and human dignity. Acts on primary health care, health care and specialized medical care, cover all the health services. The Medicine Act 395/1987 and Medicine decree 693/1987 are covering the medicines used in the health care, while the act on Medicine safety and development center (593/2009) and decree 616/2009, are providing the framework for medicinal safety in Finland. The Act on Health care devices and equipment, and the radiation act, stipulate the safety of the equipment used in health care and social services. These and other important laws concerning patient safety are expressed in Table 7. There are some other specialized laws that regulate health care in more detail. These laws are presented in Appendix 1. (Lainsäädäntö; Legislation.)

Table 7. Finnish acts regarding health/social care and patient safety (Lainsäädäntö; Legislation; Kansallinen lainsäädäntö).

The Constitution of Finland 731/1999
Act on Social and Health Care Planning and Government assistant 733/1992
Social Welfare Act 1301/2014
Health Care Act 1326/2010
Decree 304/2011
Act on the Status and Rights of the patient 785/1992
Act on the Status and Rights of the patient in Social Care 812/2000
Primary Health Care Act 66/1972
Act on Specialized Medical Care 1062/1989
Act on Supporting the Functional Capacity of the Older Population and on Social and Health Services for Older Persons 980/2012
Occupational Health Care Act 1383/2001
Mental Health Act 1116/1990
Communicable Diseases Act 786/1986
Act on Qualification Requirements for Social Welfare Professionals 272/2005
Act on Health Care Professionals 559/1994
Act on Cross border Health Care 1201/2013
Medicine Act 395/1987
Medicine decree 693/1987
Act on Medicine Safety and Development Center 593/2009
Decree on Medicine Safety and Development Center 616/2009
Act on Health care devices and equipment 629/2010
Radiation act 592/1991 (New act coming on December 2018)

Some of these acts are currently undergoing reformation. For example the new radiation act will come into force on the 15.12.2018. The Act on the Status and Rights of the patient and the Act on Health Care professionals will probably also be renewed in the near future. The Ministry of Social Services and Health are currently drafting new customer and patient acts. (Alustava luonnos 25.4.2018; Säteilylainsäädännön uudistus.)

Finland is part of the European Union (EU). In the EU health care and social services are organized and ensured by national governments. The EU's role in this scene is to complement the national policies by pooling resources, shared objectives and challenges. EU health policy are implemented by health strategies, that focus on prevention, equal changes, tackling serious health threats, supporting health systems and new technologies, and trying to keep people healthy into old age. The policy Investing in Health affects economic aspects into EU area health systems. EU actions for health and social services concern EU-wide laws and standards for health services and products (for example medicines) and enhance the co-operation between EU members to identify best practices. The EU also funds health projects through EU health programs, while also helping member states with disease prevention and disease response. All the pharmaceuticals in the market must be accepted by national or EU level authorities before entering any market, and use of the pharmaceutical begins. Research and innovation is an important part of the EU actions towards a healthier EU. If necessary, the EU also supports cross border health care with the member states. Internationally, the EU co-operates with strategic partners such as the WHO. (Health.)

The European Union's Network for Patient Safety and Quality of Care main focus is to improve patient safety by sharing information, experience and good practices. This network is co-funded and supported by the European commission. The European patients forum (EPF) is an umbrella organization which works with patient groups in public health across Europe. The EPF empowers patient organizations through policy initiatives, projects and educational seminars. Patient safety is a strategic goal of the EPF and they try to enhance patient centered and equitable health care systems throughout Europe. The EPF sees that patient involvement is a very important factor in patient safety health care. They have organized seminars which have focused on How patients and their families involvement can improve patient safety. (European Union Network for Patient Safety and Quality of Care; Patient Safety, EPF; About us, EPF.)

7.1 National patient safety actors and guidelines provided by

7.1.1 National institute for health and welfare (Terveyden- ja hyvinvoinninlaitos, THL)

The national institute for health and welfare (THL) is a Finnish expert agency that provides reliable information for the health and welfare sector. The THL began operating in

2009, when two separate institutes (KTL and Stakes) joined their forces, and merged into a new agency where expertise and research where combined. The roots of these agencies are even further in the past. The THL is national level agency and funding for it comes mainly (79%) from the state's budget. The rest is coming from co-financed operations (15%) and chargeable services (6%). The THL's main task is to study, monitor and develop health and well-being on a national level. They gather information from research and statistics, but also provide expertise and solutions for the stakeholders, who then can utilize the information in their actions. The THL is an independent agency, which works under the Ministry of Social Affairs and Health. The THL's focus areas and priorities are shown in the list below. (About us, THL; Funding; What is THL?)

THL focus areas (What is THL?)

- sustainability of the welfare society
- reducing inequality and social exclusion
- changing spectrum of diseases
- preparing for health threats
- transition of the service system

THL is also responsible for organizing and directing special services within the social welfare and health care sector. (About us, THL; Funding; What is THL?)

In the first Finnish patient safety strategy of 2009, the THL was named as the national coordinator in patient and client safety. The THL is responsible of producing information and knowledge about the subject. Many of the Finnish national level patient safety materials/publications are done by the THL. These materials will be presented in more detail later. The THL's materials for patient and client safety are the Patient Safety Guide (Potilasturvallisuusopas), Patient Safety with the Required Skills (Potilasturvallisuutta taidolla), Safe Medicinal Care (Turvallinen lääkehoito) and the Patient Guide (Potilaan opas). The THL has also had a major role in producing the national level patient and client safety strategy for Finland. (Potilasturvallisuus. 2018.)

7.1.2 The National Supervisory Authority for Health and Welfare, Valvira (Sosiaali- ja terveysalan lupa- ja valvontavirasto)

Valvira's role is to promote health and welfare through effective supervision. Valvira is a national agency working under the Ministry of Social Services and Health and it is in charge of the supervision of the social services and health care, alcohol and environmental health sectors. Valvira provides guidance to the Regional State Administrative Agencies (AVI) in all social and health care related matters and provides licences for social and health care actors nationally. Valvira's target is to achieve harmonised guidance, supervisory practises and licensing throughout Finland and it is working closely together with AVI agencies towards a harmonised supervisory. Valvira is also part of the National Committee on Medical Research ethics. Valvira's licensing and supervisory activities are presented in Table 8. (Valvira.)

Table 8. Valvira licensing and supervisory activities (Valvira).

Licensing activities:	**Supervisory activities:**
Professional licensing	Social care
Commercial licenses	Health care
Commercial licenses	Medical devices
	Gene technology
	Health Protection Act
	Alcohol Act
	Tobacco Act
	Adoption
	Biobanks

Valvira provides licensing to social welfare and health care professionals and protected occupational titles. It is also responsible of fixed-term licences. The other role for health care is to provide national licenses for private social and health care providers. Valvira's supervisory activities cover social and health care professionals, units, medical device safety, and compliance. With these licensing and supervisory activities Valvira has a huge role within national level patient and client safety. (Valvira.)

Valvira's strategic agenda is presented by mission, vision and values. The Mission and vision for the year 2020 are:

Basic Mission

Valvira has national oversight for ensuring that everyone in Finland has the right to wellbeing, high-quality services and safe living conditions.

Vision

Valvira is an influential, international and highly-regarded regulatory actor.

Strategic objectives for the years 2016-2020 are customer oriented services by renewed operations through digitalisation and by developing methods, strengthened pro-active supervision and guidance. Valvira is targeting to be pro-active and responds quickly to changes in the operating environment. Valvira's role in the patient safety is not just supervisory, but it also gives guidance to health care. Valvira's guidelines contain both care and treatment safety, and equipment safety due to its responsibilities. These guidelines are presented below in Figure 5. (Strategic agenda; Ohjeet.)

Valvira: Care/treatment safety (Unofficial translation)

Guidelines:

Terveydensuojelulain 13 §:n mukaisen ilmoitusmenettelyn soveltamisohje, Sosiaalihuollon ja varhaiskasvatuksen toimintayksiköt/
The application instructions and notification procedure of Article 13 of Health Protection Law for Social Services and Early Childhood Education units
Vaatimukset työskenneltäessä toisen johdon ja valvonnan alaisena lääkärin tai hammaslääkärin tehtävissä/
Requirements when working under other administration and supervision as a doctor or dentist
Sosiaalihuollon ammattihenkilön ammatillisen toimintakyvyn ja terveydentilan selvittäminen/
Investigating occupational performance and health status from social care professionals
Ohje terveydensuojeluviranomaiselle varautumisesta ja toiminnasta säteilyvaaratilanteessa/
Guidance for the health protection authority to prepare and act in radiation danger
Terveydenhuollon ammattihenkilön vastaanottotoiminnan ja terveydenhuollon toimintayksikön toiminnan tarkastaminen/
Investigating health care unit operation and health care professionals reception
Hoitosuunnitelmat ja DNR-päätös pitkäaikaishoidossa sekä ensihoito/
Care plans and DNR-decision in long-term care and first aid
Yksityistä sosiaali- ja terveydenhuoltoa koskevan lainsäädännön soveltaminen yksityisten koulutuksen järjestäjien tuottamiin sosiaali- ja terveyspalveluihin/
Private social- and health care legislation application in privately produced social- and health care services in private education
Terveydenhuollon ammattihenkilön ammatillisten tietojen ja taitojen selvittäminen/
Investigating health care professional's occupational knowledge and skills
Tietojenantovelvollisuutta ja toiminnan aloittamista koskevien säännösten rikkominen sosiaali- ja terveydenhuollon lupa-, ilmoitus- ja valvonta-asioissa/
The violation of provisions regarding the obligation to provide information upon inception within the permit, notification and control of social and health care related issues
Terveydenhuollon ammattihenkilön ammatillisen toimintakyvyn ja terveydentilan selvittäminen/
Investigating health care professional's occupational performance and health status
Ensihoitohenkilöstön tulee pyytää hoito-ohjetta lääkäriltä vähänkin epäselvissä tilanteissa/
First aid unit must ask guidance from doctor in unclear situations
Avoin turvallisuuskulttuuri edistää potilasturvallisuutta ja auttaa työnantajaa valvomaan toiminnan asianmukaisuutta/
Open safety culture enhance patient safety and help employer to supervise appropriate actions
Metotreksaatin käyttö nivelreuman hoidossa/
Use of methotrexate in the care of rheumatoid arthritis
Hammashoidossa on käytettävä potilaskohtaisesti steriloituja hoitovälineitä/
It must be used individually sterilized equipments in dental care

Figure 5. Valvira care and treatment safety guidelines (Ohjeet).

Due to Valvira's supervisory role, it also gives orders to health care and they are presented in Figure 6. These orders are mandatory to follow. (Määräykset.)

Valvira: Orders (Unofficial translation)

Määräys 1/2014 - Yksityisten sosiaalipalvelujen ja julkisten vanhuspalveluiden omavalvontasuunnitelmasta /*Self-monitoring plan for private social services and public elderly services*
Määräys 2/2012 - Yksityisen terveydenhuollon palvelujen tuottajien omavalvontasuunnitelman sisältöä ja laatimista koskevat määräykset /*The provisions on content and drafting of a self-monitoring plan for private health care providers*
Määräys 3/2011 - In vitro diagnostiikkaan tarkoitettujen terveydenhuollon laitteiden suorituskyvyn arviointitutkimukset ja niistä ilmoittaminen */The evaluation examinations of the performance of equipment designated for In Vitro diagnostics and its related reporting*
Määräys 2/2011 - CE-merkinnän käyttö terveydenhuollon laitteessa ja tarvikkeessa /*The application and use of CE-labelling on health care equipment and supplies*
Määräys 1/2011 - Terveydenhuollon laitteen ja tarvikkeen vaatimustenmukaisuuden arviointi /*The conformity and compliance assessment of health care equipment and supplies*
Määräys 4/2010 - Terveydenhuollon laitteesta ja tarvikkeesta tehtävä ammattimaisen käyttäjän vaaratilanneilmoitus /*The notification of an incident report regarding a professional user's operation of a health care equipment or supply*
Määräys 3/2010 - Terveydenhuollon laitteilla ja tarvikkeilla tehtävät kliiniset tutkimukset /*Clinical examinations intended to be done with health care equipment and supplies*
Määräys 2/2010 - Terveydenhuollon laitteesta ja tarvikkeesta tehtävät laiterekisteri-ilmoitukset /*The log registry notifications to be recorded by health care equipment and supplies*
Määräys 1/2010 - Terveydenhuollon laitteesta ja tarvikkeesta tehtävät valmistajan vaaratilanneilmoitukset /*Dangerous situation reports done by manufacturers of health care equipments and supplies*

Figure 6. Valvira orders (Määräykset).

7.1.3 Regional State Administrative Agencies (Aluehallintovirasto, AVI)

AVI is the regional authority which is in charge of directing, overseeing and licensing health care. This agency's aim is to make sure that high-quality health care services are available for all the citizens in Finland. The AVIs also work closely together with municipalities and other agencies like Valvira and THL, in efforts striving towards more safer health care and social services. An AVI's task is to direct and oversee the public and private health care services. If citizens feel that there are shortages in the health care services, or lack of quality of the services, the nearest AVI is the agency which needs to be contacted and informed. AVI's tasks are shown in list below.

AVI agency's task include:

- direction and oversight of health care services,
- granting licences to private health care service providers
- supervising health care professionals
- quality management
- complaints
- discretionary and specified government transfers. (Health care.2013.)

If patient/client is unhappy with the health care received or is feeling that his/her patient safety is compromised, the patient/client can make a complaint to the nearest AVI or Valvira. These complaints are usually done and handled in regional AVIs, and if necessary, they are responsible of transferring the complaint to the right agency. If complaints are transferred, AVI needs to make send a formal notice to the original informant. The AVIs are working very closely and co-operating with Valvira, and an AVI can be stated as a regional office of Valvira. This is reason why AVIs are following exactly the same guidelines and orders than Valvira, and they are not providing any extra guidelines of their own. (Health care. 2013; Potilasturvallisuus. 2018.)

7.1.4 Radiation and Nuclear Safety Authority (Säteilyturvakeskus, STUK)

The STUK is the radiation and nuclear safety authority in Finland and administered by the Ministry of Social Services and health. Its aim and purpose is to protect citizens, the environment, society and future generations from the harmful effects of radiation. This authority's mission is to ensure the safety of radiation in Finland. The STUK's operation is based on legislation and it provides safety regulations and guidelines. It grants licences for the use of radiation and regulates the use of radiation in health care, training and research. The STUK monitors the radiation situation around the clock and an important part of the operation is the co-operation with other authorities and international actors. The STUK's vision for the years 2018-2022 is to gain a radiation safe Finland by the happiest civil servants, the best government agency, and the most satisfied customers in the world. This agency's strategic targets are in Table 9. (About us, STUK; STUK's strategy 2018-2022; Strategic targets.)

Table 9. STUK strategic targets (Strategic targets).

1. The happiest civil servants in the world
2. Ability to understand complex entities
3. Cost-aware operations
4. Risk-informed and commensurable oversight
5. Flexible and efficient working methods
6. Effective national radiation safety research
7. Emphasizing the responsibility of the operators
8. People understand the risks of radiation
9. Society is resilient to disturbances

A third of the STUK's budget is funded by government and the rest is collected by regulatory fees. The STUK is providing guidelines related to health care radiation issues and the guidelines are illustrated in Figure 7. The radiation act will be renewed during December 2018. The new radiation act will come into effect on the 15.12.2018. In addition to the new act, there will be three different decrees and approximately nine different STUK orders, to address the radiation regulations in Finland. All these new acts, decrees and orders will replace the old policies. (Finance; STUKin viranomaisohjeet ja päätökset; Säteilylainsäädännön uudistus.)

STUK: Radiation safety (Unofficial translation)

Guidelines:
Säteilytoiminnan turvallisuus, 23.5.2013/
Safety of the radiation actions
Säteilylähteiden varoitusmerkit, 9.12.2013/
Warning signs of radiation sources
Säteilyn käyttöorganisaatio, 2.11.2011/
Organization which uses radiation
Säteilyn käytön vapauttaminen turvallisuusluvasta, 12.9.2013/
Release of radiation usage from the security permission
Säteilyturvallisuus työpaikalla, 10.12.2009/
Radiation safety in the work place
Säteilysuojelukoulutus terveydenhuollossa, 10.12.2012/
Radiation protection training in health care
Säteilyn käyttöorganisaatiossa toimivien henkilöiden pätevyys ja säteilysuojelukoulutus, 25.1.2016/
Competence and radiation protection training for the persons who work in the radiation usage organization
Säteilytoiminta ja säteilymittaukset, 23.11.2016/
Radiation action and radiation measurements
Säteilylähteiden käyttötilojen suunnittelu, 14.7.2011/
Planning of the premises where is used radiation sources
Säteilylähteiden turvajärjestelyt, 21.3.2017/
Security actions in radiation sources
Sädehoidon turvallisuus, 18.4.2011/
Safety of the radiation therapy
Hammasröntgentutkimukset terveydenhuollossa, 13.6.2014/
Dental x-ray examinations in health care
Röntgentutkimukset terveydenhuollossa, 8.12.2014/
X-ray examinations in health care
Säteilyturvallisuus mammografiatutkimuksissa, 25.1.2013/
Radiation safety in mammography examinations
Säteilyturvallisuus isotooppilääketieteessä, 14.1.2013/
Radiation safety in nuclear medicine
Säteilyaltistuksen seuranta, 14.8.2014/
Monitoring the radiation exposure
Säteilyaltistuksen enimmäisarvojen soveltaminen ja säteilyannoksen laskemisperusteet, 8.8.2014/
Appliance of the maximum values of radiation exposure and radiation dosage calculation principles
Annosrekisteri ja tietojen ilmoittaminen, 8.12.2014/
Dosage register and informing the data

Figure 7. STUK guidelines to patient safety issues (STUKin viranomaisohjeet ja päätökset).

7.1.5 The Finnish Medicines Agency, Fimea

Fimea is responsible for the monitoring and developing the pharmaceutical industry in Finland, but it also works toward enhancing the reasonable use of medicines to ensure

the health of all people. Fimea is operating under The Ministry of Social services and Health and it is the national authority for regulating pharmaceuticals. It ensures, that medicines are safe to use, there are enough medicines on the markets, and that medicating is done rationally. Fimea also provides and transmits information for improving medication effectiveness. Before any medicines gets licensed to enter the market, they are inspected by authorities and evaluated for medicinal safety issues. After medicines have got their licences, they are evaluated constantly, and if necessary, the license can be revoked. Fimea is collecting information about the adverse effects of medicines in a register they maintain. Fimea sends all the information gathered to the European medicine agency (EMA) and the EMA sends the information to the World Health Organizations register. (About us, Fimea; Lääketurvallisuus ja -tieto; Lääkkeiden turvallisuus.)

Fimea has three core roles, that are based on legislation and are prescribed to be its duties:
1) A public service agency providing services to the business community,
2) A regulatory and supervisory agency,
3) A development agency.

Fimea's organisation has three core processes, which are:
1) enforcement and inspections in the pharmaceutical sector,
2) regulating medicinal products,
3) The evaluation of pharmaco-therapies. (Organisation.)

Fimea provides the regulations and guidelines related to medicine and medication related safety issues within the health care and social services. All of Fimea's publications are shown in Figure 8.

FIMEA: Medication/Medicine safety (Unofficial translation)

Guidelines:
Hakemusmenettelyt varastointivelvoitteen järjestämiseksi erityistapauksissa/*Application procedure for organizing the storage obligation in special cases*
Lääkkeiden haittavaikutusten ilmoittaminen/*Reporting the adverse events that medicines cause*
Lääkevalmisteen myyntipäällysmerkinnät ja pakkausseloste/Labelling the medicine packages and package leaflets
Ohjeistus huumausaineiksi luokiteltujen lääkkeiden kuukausiseurannasta/*Guidance how to monitor medicines in monthly which are categorized narcotics*
Luettelo lääkeaineista ja -valmisteista, joita saa toimittaa ainoastaan lääkemääräyksellä/*List of the medicines that can be supplied only by prescription*
Guideline on Nordic packages

Administrative regulations:
2/2018 Lääkevalmisteen myyntiluvan ja rekisteröinnin hakeminen ja ylläpitäminen/*Applying for and maintaining a marketing authorization and registration for a medicinal product*
1/2018 Veripalvelutoiminnan laatujärjestelmään liittyvät hyvät toimintatavat/*Good practices that apply for the blood products quality system*
1/2017 Velvoitevarastoinnin lupa- ja ilmoitusmenettelyt/*Storage obligation license and notification procedures*
2/2016 Lääkkeiden toimittaminen/*Medicine supply*
1/2016 Elinluovutustoiminnassa kirjattavat luovuttajaa koskevat lisätiedot ja elinirrotuspöytäkirja/*Additional information about the donor in organ donation and organ detachment transcript*
2/2015 Veripalvelutoimintaa koskevan määräyksen 6/2013 muuttamisesta/*Change of the regulation 6/2013*
1/2015 Yhteisen tunnuksen käyttö apteekin verkkopalvelussa/*Using shared identifier in pharmacy online service*
5/2014 Pitkälle kehitetyssä terapiassa käytettävien lääkkeiden (ATMP)valmistaminen yksittäisen potilaan hoitoon/Pre*paration of advanced therapy medicinal products (ATMP) for the treatment of individual patients (hospital exemption)*
4/2014 Lääkevalmisteen rinnakkaistuonti/*Parallel import of medicinal products*
3/2014 Kudoslaitostoiminta/*Action in tissue department*
2/2014 Elinluovutus- ja elinsiirtotoimintaa koskevat laatu- ja turvallisuusvaatimukset/*Quality and safety demands in organ donation and organ harvesting*
1/2014 Lääkkeiden toimittaminen eurooppalaisen lääkemääräyksen perusteella/*Medicine supply according European prescription*
6/2013 Veripalvelutoiminta/*Blood service actions*
5/2013 Lääkkeiden hyvät jakelutavat/*Good distribution practice of medicinal products*
4/2013 Lääketurvatoiminta/*Pharmacovigilance*
3/2013 Lääkevalmisteen myyntipäällysmerkinnät ja pakkausseloste/*Labelling and package leaflets for medicinal products*
1/2013 Laadunvalvontamaksu/*Quality control fee*
6/2012 Sairaala-apteekin ja lääkekeskuksen toiminta/*Operation in hospital pharmacy and medicine centrum*
5/2012 Lääkkeiden hyvät tuotantotavat/*Good practices in producing medicines*
2/2012 Kliiniset lääketutkimukset/*Clinical trials on medicinal products*

6/2011 Apteekkien lääkevalmistus/*Producing medicines in pharmacy*
2/2011 Apteekin verkkopalvelu/*Pharmacy online service*
1/2011 Apteekin palvelupiste/*Pharmacy service point*
7/2010 Lääkkeellisen kaasun toimittaminen lääketehtaasta ja lääketukkukaupasta/*Supplying medicinal gas from medicine factory and medicine wholesale*

4/2009 Tuotevirheet (määräys ja ohje)/*Product defects*

Figure 8. Fimea regulations and guidelines. (Ohjeet, Fimea; Määräykset, Fimea).

7.2 Current Care Guidelines (Käypä hoito)

In addition to the introduced actors, there is a completely separate group of specialists, who provide guidelines for the health care and social services in Finland. These guidelines are called Current care guidelines (Käypä hoito in Finnish) and they are independent, evidence-based, national clinical practice guidelines for the Finnish health system, medical treatment and also for the prevention of diseases. Guidelines intended to be used for basic treatment decisions and ones that can be used by all the health care and social care professionals, while they are also intended for Finnish citizens as well. Current care guidelines are developed by the Finnish Medical Society Duodecim. These guidelines are developed in co-operation with various medical specialist associations. The current care editorial team is responsible for the guidelines and the Current Care board directs the operations. The editorial team consists of different specialists from different fields related to the subject, such as doctors, technical specialists and technical editors. (About Current Care Guidelines (Käypä hoito).)

Current care guidelines are national level guidelines for health care and social services, and they are applicable to all medical practice in Finland. This way all the actors in the health system of Finland receive and can use exactly the same guidelines. Guidelines are done to support health care decision making and to support patients. Actors in the field can trust that these guidelines are evidence-based and designed especially for the Finnish health system. The guidelines are intentionally built to be easy-to-read and easy to use. They sometimes might consist of some well-founded comments related to health issues, even when there is no scientific evidence available. Current care guideline subjects usually come from the different associations within the field and before launching any guidelines, they are circulated with the specific interest groups for any comments or corrections. Then the guidelines are edited if necessary and their implementation is supported by summaries, patient versions, online courses, and power point slide series. Completed guidelines are communicated via any appropriate manners and updates are published when needed. (About Current Care Guidelines (Käypä hoito).)

These guidelines are a very important part of Finnish patient safety. Even though the guidelines are for medical practice decisions, all of them can also be seen as patient safety guidelines, because they are created to help and unify the actions of all Finnish

health care and social services. All together there are 103 valid guidelines at this moment and they mainly deal with the subjects shown in the Appendix 2. (Suositukset.)

7.3 Patient and client safety strategy 2017-2021

A very important part of Finnish patient safety and the patient safety guidelines, is the national Patient and client safety strategy. The Ministry of Social Services and Health has published a governmental resolution for the Finnish patient and client safety strategy for the years 2017-2020. The first strategy about patient safety in Finland was prepared for the years 2009-2013. The new health care act entered into force in 2011, and was a good point to promote patient safety. Between the years 2009-2013, the strategy was only about patient safety, but the existing strategies have since been updated to include both patient and client safety. This strategy was made together with institutions, The Finnish Patient Safety Association and all the other operators in the field. In the existing strategy, patient and client safety has been defined like this:

Patient and client safety means that the treatment, care and services provided to a person promote his or her physical, mental and social well-being and cause as little harm as possible.

The strategy's desired state by 2021 is, that patients and clients are equal actors in planning and executing health care processes. Everyone taking part in the health care process should have a chance to influence, make choices and take responsibility within patient and client safety. The objectives of the strategy are shown in the list in Table 10. (Patient and Client Safety Strategy 2017-2021.)

Table 10. Objectives for Patient and Client Safety Strategy 2017-2021 (Patient and Client Safety Strategy 2017-2021).

● Patients, clients and family members actively participate in ensuring and developing patient and client safety.
● Quality as well as patient and client safety are part of risk management.
● The service processes and practices are safe and protect the patients and clients against patient safety incidents.
● Resources and competence required by safe care have been ensured.
● Monitoring and developing quality and safety have been ensured.

The strategy reminds about the fact that patient and client safety is not dependent of any operators, structures or processes, as it is work that is needed to done under any circumstance or situation. Promoting patient and client safety is the responsibility of all actors within the field, who are providing social and health care services. This strategy aims towards a cohesive safety culture in the Finnish social welfare and health care, and tries to promote its implementation. The essentials content of the strategy is shown in Figure 9. (Patient and Client Safety Strategy 2017-2021.)

Figure 9. Essentials contents of the Finnish patient and client safety strategy 2017-2012 (Adapted from Patient and Client Safety Strategy 2017-2021).

Patient and client safety includes competent personnel, the appropriate and correct use of instruments, equipment, medication and facilities. An equally important part of safety is also documentation and information flow, which needs to be safeguarded as well. Patient and client safety covers all the aspects of social welfare and health care services like preventive, therapeutic, rehabilitative and reconstructive aspects. Patient and client safety targets the safety of care, but also tries to protect against injuries. The strategy states that strengthening safety culture will reduce risk and harm caused to patients and clients during the health care and social services process.

The Finnish patient and client safety strategy is aiming towards safer care nationally with all the operators and processes involved. It focuses on six different key points in the strategy and has set goals related to these points which should be in place by the year 2021. These key points are stated below and the desired state in the year 2021 is in Appendix 3. (Patient and Client Safety Strategy 2017-2021.)

1) The patient, client and family members are actively involved in ensuring and developing patient and client safety: Professionals provide information to patients/clients/family members, but they all together plan, participate and implement services. All the health care and social service processes are realised by mutual understanding. This way patient and client safety is everyone's responsibility.

2) Quality as well as patient and client safety are part of risk management: Safety and quality of care are improved by risk management. These risks are taken into consideration on strategic and practical levels. Continuous development of information, structures and processes provides key methods for minimising risks.

3) Resources and competence required by safe care, treatment and services have been ensured: The management is responsible for providing the adequate resources required. Resources must be appropriately educated and orientated in order to be able to ensure safe patient/client care.

4) The service processes and practices are safe and protect the patients and clients against patient safety incidents: All the processes/practices must be safe and effective. The core processes are carried out identically despite the service provider. The organisations need to prepare patient safety plans and the public social and health care providers are responsible for the services they have been funded.

5) Monitoring and developing quality and safety is ensured: The development is continuous and it is monitored regularly. All the organisations providing services are acting with safe and high-quality procedures. The personnel will report about all the patient/client safety incidents transparently.

6) Patient and client safety is promoted nationally: The entire service system is developed on national level and all the needed research about the phenomena is supported at national level.

The patient and client safety strategy leads Finnish social- and health care towards a unified safety culture and works for its fulfillment on a national level. This strategy could be stated to be the most important national level guideline in Finland. (Patient and Client Safety Strategy 2017-2021.)

7.4 Finnish patient safety association

Finnish patient safety association is a joined forum for all the operators in the Social services and health care sector. This forum combines patients/clients together with professionals and specialists in Social services and Health care. The patient safety association's mission is to develop safety culture within the Health care and social services. Their desire is to be part of the safety culture and ensure that patients get safe and quality care, within the health care and social services environment. The association provides knowledge about subjects, organizes training for patient safety issues, and helps to progress research. They also provide knowledge for the patients and support any patients own actions towards safer health care. The association is not only supporting patients, but also advancing their own actions. (Suomen Potilasturvallisuusyhdistys Ry.)

The Finnish Patient Safety association defines patient safety to be a part of ensuring that patients are getting the correct care needed in a medicinal aspect. Patient safety also means, that during required care, a patient is harmed as little as possible. Patient safety is a part of the co-operation between patients and professionals, and it is always required to work together towards safer health care. Safe health care is done correctly and at the right time, and has an influence on any patients health problems. Patient safety covers medication safety, device safety and care/treatment safety. (Suomen Potilasturvallisuusyhdistys Ry.)

For patients and family members the Finnish Patient safety association provides knowledge and information about patient safety in Finland. It explains how the patient safety is organised in Finland and who are the key actors related to the subject. It is from the association's sources where the patient rights can be found, and how the patients can get involved in the issues and also promote a better patient safety culture throughout their own care path. If something anyways does go wrong in the patient's care, the association provides information about what the patient can do for about the

situation and where to report about incidents that have happened. (Potilaille ja omaisille.)

For health care professionals, the structure behind the patient safety culture in Finland is defined and information is provided about the required patient safety plan. For professionals patient safety is divided between medication safety and care/treatment safety. The association has produced a learning video called Better patient safety and present the national and international checklists for health care professionals. In these checklists the checklists provided by the WHO can also be found. For researchers, the association maintains knowledge about required permissions and the admission process behind the research. The association promotes research on patient safety and encourages interdisciplinary research on the subject they promote. (Ammattilaisille ja opiskelijoille; Tutkijoille.)

Overall the Finnish Patient Safety Association takes into consideration all the actors and does not forget the students who are the future of health care. All the knowledge, education, information can be found from the same source from their internet page and all the people can participate in the association's actions by applying to be a member of the society. Board members are expressed clearly and member letters can be found from there also. (Tietoa yhdistyksestä.)

7.5 National patient safety materials and events

In the early 20th century, health care professionals and national leaders woke up to think about patient safety in health care. Everyone realised, that the situation is not as good as it was thought about and that maybe health care would benefit from attention given to the subject patient safety in health care and social services. There have been several initiatives on the subject and the national strategy for patient safety has been developed. One of the most important instances related to the subject, is the nationally held **Patient Safety days (Potilasturvallisuuspäivät)**. These information and education days are for public and private health care and social services professionals, but also for the lecturers and students and anyone who is interested or involved in subject. In 2018 these days concentrated on the status of patient safety now and in the future, how information systems could support patient safety, and what is required from managers in order to be able to promote and maintain an adequate level of patient safety. (Potilasturvallisuuspäivät.)

The Patient safety guide (Potilasturvallisuusopas) was first created by the National institute for health and welfare in 2011. The guides purpose is to give instructions and guidance on how to advance patient safety issues within heath care and social services units. Instructions given in the guide are based on national legislation. The previous strategy for the years 2009-2013 is also included as a part of the patient safety guide. A big part of the guide deals with the patient safety plan, which is required from all the operators in the health care and social services. This guide gives instructions on how to do the patient safety plan and what it should contain. It also looks into the future and how to maintain and develop already existing patient safety cultures. (Potilasturvallisuusopas.)

The other guide/program done by the National institute for health and welfare, is called **Potilasturvallisuutta taidolla (Patient Safety with skills**). It started in 2011 and the second phase ended in 2015. This program explains a little bit deeper, the meaning of patient safety and what happens when patient safety is deceiving in health care units. The patient safety strategy for 2009-2013 is also behind this program. National legislation is a big part of it too, but it gives a very straight forward target, which is to reduce patient safety incidents by half, by end of the year 2020. This program also tries to give very concrete tools for patient safety issues. From the Figure 10, all of the parts of the program can be seen. (Potilasturvallisuutta taidolla: 3-28.)

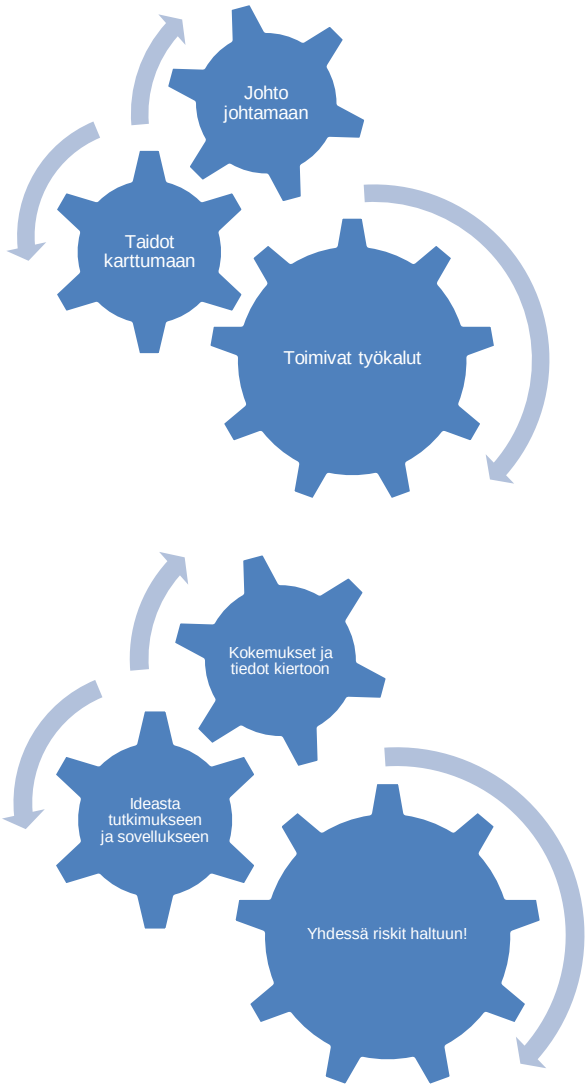

Figure 10. Parts of the program (Adapted from Potilasturvallisuutta taidolla: 16).

These program parts are:

1) Yhdessä riskit haltuun= co-operation for dealing the risks
2) Johto johtamaan=management to manage
3) Taidot karttumaan= Develop the skills
4) Toimivat työkalut käyttöön=functioning equipments
5) Kokemukset ja tiedot kiertoon=share all the experience and knowledge
6) Ideasta tutkimukseen ja sovellukseen=from idea to the research and implementation (Potilasturvallisuutta taidolla: 16-18.)

This program is lead by the National institute for health and welfare and it is one of main projects of the institute. The program is fulfilled together with all the operators in the field and it reminds, that the Director of the institute is the leader of the program, but one who will consult everyone part of the program and that the program is done in co-operation, not by only one institute and by one leader. (Potilasturvallisuutta taidolla: 28.)

National institute for health and welfare has also created the **Patient Guide (Potilaan opas)** for patients and their family. This guide gives instructions on how the patients and their families can influence the safety of their health care during their whole care path and it is divided to these sections: 1) When you are seeking care, 2) When you are having/getting the care, 3) How your care continues?, 4) For the patient family. The patient guide explains, that good quality care starts from the very beginning, when the need for the care emerges, and it explains the rights of the patients and gives ten tips for safer treatment. (Potilaan opas; Patient guide.)

Medication safety is an important part of patient safety. The National institute of health and welfare have created a guide called **Turvallinen lääkehoito (Safe medication care)**. This guide was firstly done by the Ministry of social services and health in 2006 in co-operation with a wide range of professionals participating in health care. It started to need updating and in 2014 the National institute of health and welfare began the work. Once finished, the updated guide was published in 2016. This guide was created to secure the patient safety aspect in medication and with medicines. The guide's purpose is to create a homogeneous framework for health care to operate medication and medicine safety. The guide also explains the principles of medication/medicine safety and emphasizes the medication plan, which is mandatory in every unit. The guide emphasizes education and learning in order to enhance medication/medicine safety in health care. It provides examples of good practices and explains the responsibilities. Ministry of social services and health recommends this guide for every unit in health care and social services. (Inkinen – Volmanen – Hakoinen 2016.)

The Ministry of Social Affairs and Health has published a guide called **Medicine policy 2020 (Lääkepolitiikka 2020.)** This guide is aiming towards the safe and appropriate use of medicines as economically as possible. This guide is aiming toward achieving joint objectives for the social and health care authorities and other stakeholders in the field of medicines by the year 2020. These objectives are:

1) Pharmaceutical service is a part of the social and health service system
2 Pharmaceutical service is of a high quality, efficient and cost-effective
3) Rational pharmacotherapy and good medication safety enhance the wellbeing of the population, improve public health and decrease the health care expenditures
4) Clinical trials on medicinal products enhance health, wellbeing and employment
5) Veterinary medicine safeguards public health and promotes the wellbeing of people and animals

Work for this guide started in 2010 and all these objectives have been stated to the responsible authorities. The impact of the guide and practical actions made will be evaluated. (Lääkepolitiikka 2020.)

8 Learning material

One of the objectives of this project was, that the developmental findings of this project are gathered into a learning material, for the future Health Business Management students in Master of Social Services and/or Health Care degree. The learning material is produced for Metropolia University of Applied Sciences and it is developed for the course Safety and Quality processes and management in social and health care. Course objectives for the students are:

- The student knows what causes quality, how quality is ascertained, and how quality work is managed in an organization.
- The student understands the cornerstones of safety and quality systems and the process development approach.
- The student understands safety and quality improvement methods and tools
- The student is able to apply the most common methods of quality management as part of a team.
- The student recognizes client requirements as well as internal and external stakeholders. (Moodle workspace: Safety and Quality processes and management in social and health care.)

The learning material is targeted towards the objectives that discuss: the cornerstones of safety and quality systems, safety and quality improvement, and methods for quality management. Target group for the learning material is masters students in Health Business Management programme, but Metropolia is allowed to use the learning material also in other needs. The learning material is produced to provide background information about patient safety and then it can be used in different occasions.

The first part of this project was to gather all the information for the learning material. The developmental findings of this project are gathered from several different sources, which provided the information for the project objectives. All the reliable sources were accepted to be part of the information. The reliability of the information was assessed by using only original sources for information. The patient safety information from WHO was gathered from the WHO's own original sources, while the Finnish patient safety information was gathered from national sources. The author was able to gather information also in Finnish and these sources are also part of the findings.

Once the developmental findings were gathered, the tutor of this project and lecturer of the course, for which the learning material is produced, checked the content and gave instructions. A decision was made to create a booklet, in which there would be an introduction of patient safety and all the developmental findings of this project. The purpose for the learning material is to give a brief introduction about patient safety as a subject and introduce patient safety within the WHO. For this reason the sections Patient Safety and Developmental findings for the learning material: Patient Safety in the WHO is part of the booklet. The second purpose of the learning material is to introduce patient safety on the Finnish level for the students. The booklet contains the complete section of Developmental findings for the learning material: Patient Safety in Finland. Patient safety in Finland and on a national level is an important part, when fulfilling the course objectives. It will give the framework for the students to build their knowledge about the subject. Health care units in Finland have a lot of responsibilities to organize their patient safety issues. The booklet tries to illustrate what are the aspects regarding this issue on a national level. All the developmental findings are included in the learning material, as they were found and expressed here. The learning material booklet is done as a word- and pdf- document. It is provided to Metropolia and the author has given permission to Metropolia to use it as such whenever needed. All the references are marked according to Metropolia's instructions.

This learning material is to be used for the future implementations of the course. The exact evaluation of the learning material will then be done by students from the course. The cover page and abstract of the learning material can be found as Appendix 4.

9 Discussion

This development project articulated the importance of patient safety, but also the diversity of it as a subject. Patient safety is a fundamental principle of health care and social services and we all deserve to be treated in as safe a way as possible. Still there remains a huge variety in how people/organizations describe it and as to what is included within patient safety. The WHO was selected to be part of the project because of its international presence and impact on the subject. The WHO can provide information, give guidelines and build networks for the subject, but the actual work for patient safety is done within the units that provide health care and social services. The study indicates that professionals think that guidelines are useful, but that they are not adequately enough implemented within the units. There are also challenges with the implementation phase that need to be tackled. Patient safety is seen as a key component of quality, but still 1 out of every 10 patients is harmed during their time in hospital and medication errors costs billions of US dollars annually. (10 facts on patient safety; Gaal – Verstappen – Wensing 2011.)

During the project, Finnish patient safety was explored in more depth. In Finland every unit that provides health care or social services, must create a patient safety plan by law. Still during the process it felt like the subject is way too widespread in Finland. All the authorities had some guidelines, but I think patient safety itself would have deserved more specific guidelines and much more attention. One suggestion that arose during the project was that, why not include patient safety to the current care guidelines. Current care guidelines have a very significant role in Finland. Patient safety would deserve to be handled more specifically and have its own headline in these guidelines. Current care guidelines are done by a separate group of specialists and they are independent, evidence-based and act as the national clinical practice guidelines, for the Finnish health system. It would be very useful to gather all the patient safety guidelines into this existing system. All the authorities could also be part of this project and then all the guidelines could be found from one place. We already have a

very thorough Patient Safety Strategy for the years 2017-2012. This would give a perfect framework to develop in co-operation between all the actors from the field. One study proved that international classification of patient safety is creating safer care in surgical conditions (McElroy etc. 2016). This definitely encourages efforts toward more unified actions in patient safety in Finland. The other study suggested that more specific measurement and improvement tools are required for the subject (Lillrank 2015). All of this is more than welcome in Finland, because patient safety has not received the attention it deserves yet.

This project emphasized the fact, how much, patient safety adverse events already now cost the economy worldwide. Health care costs and patient safety costs are predicted to increase due to ongoing demographic changes, the growing demand for health care and all the advancements that technology are providing nowadays. According to an OECD report, about 15% of hospital expenditures in European countries are related to patient safety related incidents. (Healthcare professionals stand together to foster patient safety.) It is extremely important to give more attention to patient safety and foster it, due to its economical impact and because it is a fundamental right that we all have. Health care professionals are playing an important role in patient safety. Does employee safety have any role in patient safety? According to the Journal of patient safety, yes there is. In health care environments, where there is more positivity towards workplace health care and its safety climate, there is more positive assessment towards the patient safety culture in general. This suggests that patient safety and employee safety cultures reinforce each other and that improvements and investments in one aspect could also accumulate the positive impacts on the other as well. Investing and supporting health care staff is equal to investing and supporting patient safety. (Does employee safety matter for patients too? Employee safety climate and patient safety culture in health care.)

It was very important to be open to all the sources possible when searching for information about this subject. The idea was to gain more knowledge about the subject and more specifically concentrate on patient safety in Finland. The research based development method gave all the possibilities to discover the information needed. In this method it is really important to be active and open to all sources and that nothing mandatory is left out due to a research context. This method was more than suitable for this subject. More conventional scientific research would have given a too strict framework

for this project, but the research based development method provided all the tools necessary to succeed in this project.

The learning material itself will be evaluated by the students, if it is used in upcoming courses. For the target group, who were Health Business Management students, the learning material will hopefully provide the framework with which to build their expertise on this issue. This learning material alone will not provide enough information for the students. During this project several sources and topics where examined before the developmental findings for the learning material were selected. The topic patient safety is infinite and the discussion around the topic could continue perhaps endlessly. Everyone has their own definition in their own mind and then all the other organizations, institutions and governments have their own definitions too. The learning material booklet was chosen to present the overall introduction about patient safety and then explain in more detail about patient safety within the WHO and in Finland. These all together will give food for thought to the students where to build their knowledge. The learning material is not perfect and there could always have been other topics selected for the issue. For example patient safety and the different levels of patient safety would earn a learning material themselves. The author has completed the course to which this learning material is targeted for and the background of the course was clear. Hopefully future students will get the needed framework for their learning. It is definitely really important to understand the state of Finnish patient safety and its acts, rules and guidelines, because the school and programme is in Finland. Many of the students have an international background, so this material will introduce Finnish patient safety to them. Finnish patient safety topics are covered widely within the learning material.

9.1 Reliability and validity of the project

Reliability, validity and confirmability need to be thought about during the different thesis phases. A central part of reliability is repeatability. It is important, that other researchers are able to get the same results, when conducting similar research. In the research based development method, reliability and repeatability can be difficult to achieve on the same level than in scientific research. One important factor is, that the material used in this method needs to be broad enough to be able to reach a satisfied level of reliability. This especially needs to be thought about when searching for national level guidelines in Finland. Validity means, that the research is measuring what it should measure and in this thesis a good level of validity comes from the adequate use

of the available resources when exploring the materials to be used for this thesis. Inner validity means, that the thesis is made in logical order and prepared consistently throughout the thesis process. This can be achieved by very careful planning. Outer validity means, that all the interpretations made respond to the material used. One important aspect to consider is confirmability and credibility. This project needs to be convincing and dependable. This can only be achieved by having a transparent project process, where all the stages are completed carefully. One part of credibility comes from the commitment of the participants. This project is done by only one author so the commitment if of high level and doesn't need to be questioned (Toikko – Rantanen 2009: 121-125.)

In this project the author was doing their best to use as broad a material enough to maintain the adequate level of reliability, confirmability and credibility. Good validity comes from careful planning and in this project, the planning phase was done carefully and on a really good level of guidance that was a huge help when starting the project. When the project itself started the structure of the project was already very clear. This project has demanded a huge level of searching for resources and this gives a good level of credibility to the project. All the stages have been done carefully and in a planned order. As it has already been stated, this project was done by only one author so the commitment level has been high throughout the project. The author has been also really interested personally about the subject, which gives a perfect framework for succeeding in the project.

Self evaluation is a very important part of the research based development method. It is specifically emphasized due to reason, that this method cannot be evaluated exactly the same as the methods used in more conventional scientific research. These kind of projects are usually one of a kind, and because of that, the author's self evaluation plays a larger role. This project was done by one person and so is its self evaluation as well. Keeping a diary is one method to do reflective self evaluation and it was used in this project. The author has followed the phases and steps of the project carefully and evaluated the sections as they have been completed. The outcome of this thesis is learning material for the HBM students. The learning material will be used in future implementations if needed and of course the evaluation of the learning material will then be evaluated by the students of the program. (Seppänen – Järvelä 2004; Vilkka – Airaksinen 2003: 154-161.)

A really important part of self evaluation is to go through the whole process from idea to the end. The idea of the project was really clearly defined. The idea was to produce new learning material and it specifically needed to cover patient safety in Finland. The author's goal was to source official, national Finnish patient safety guidelines. This project revealed a lot of guidelines. The author anyway kept thinking about did she find all of them? An important thing to realize is that despite being very careful when searching, something might have been missed out. One part of the project is to evaluate the report that is written here. In the research based development method, it is really important to evaluate how well the author manages to explain the process to its readers. In this project the author tried to explain what was done during the process, why these actions were done and what choices were made. Feedback from the instructor, was to clarify these aspects more and the author did so. Now the author feels that the process is explained clearly in the report and that hopefully it is easy to follow the process and decisions. The feedback about the learning material will come in the future. Right now there is no implementation of the course. One idea was to gather feedback from the author's fellow students who already have completed the course. The idea was to gather ideas about what kind of material they want. The author thinks, that it would have been a good idea to gather feedback from ready-made learning material. This idea just came too late. One idea was to make a learning material video about the same subject. Students are really busy nowadays and maybe a video would have been more interesting than a booklet. Overall the process was executed as planned and the author thinks that the Finnish patient safety part was the most successful. Patient safety itself could have been more broader, because that subject is huge. (Vilkka – Airaksinen 2003: 154-161.)

9.2 Ethical questions

The European code of conduct for research integrity has published a guide about good research practices. These practices are based on four fundamental principles, which are: reliability, honesty, respect and accountability. Researchers must be honest and respect others. Researchers need to be reliable and accountable throughout the whole process. All of these principles have been respected in this project. All the information found, has been published correctly and in the way it was found. Sources are marked in the references. References are done according to Metropolia's instructions. This project did not contain any personal information of participants or any confidential in-

formation from organizations. All information used, has been found from public sources. (European Code of Conduct for Research Integrity 2017.)

This project was done by research based development method which differs from conventional research. The target was to find information about the objectives of the project. The learning material is developed from the findings of the project and the learning material contains all the information discovered and nothing has been left out or altered.

10 Conclusion

This project's objective was to gather the information for the learning material. So nothing new was developed, but "old" information was gathered into one learning material booklet. What new did this project then develop? The new thing in this project was to find information about Finnish patient safety and then put it into one "place". It was decided to support Finnish patient safety as a subject by patient safety introduction and with the WHO patient safety information. Now there is all this mentioned information in one learning material booklet, so future students don't have to gather the knowledge about the subjects themselves.

The author was very surprised about the fact how common adverse events are in all of patient safety. Even more surprising was discovering that patient safety in Finland has gained most of its knowledge and attention in the early years of 20th century. This subject would deserve much more attention here in Finland. Think about the costs patient safety has on the economy and the harms it causes to people. Finnish patient safety is very shattered. All the units need to have a plan, but I would suggest much more co-operation on the issue. International studies have implied that patient safety would benefit from co-operation and more unified definitions or maybe even a universal language on patient safety.

How many patient safety guidelines are there in Finland that are created by separate units of the health care? Do they have any co-operation for example between public and private healthcare or between different health care districts? The author would suggest a study where to investigate actually how shattered patient safety is in Finland

and how "big" the subject is. What kind of co-operation already exists and then what should be done to be able to unify Finnish patient safety. It could be, that this kind of a more unified patient safety, would gain savings in the long run. More importantly all of us citizens could have more trust in Finnish health care and social services and the patient safety level they provide. Finland is going through big organizational and national changes in health care and social services renovation. This change should give an opportunity to enhance and develop patient safety too.

It would be very beneficial to gather all the unofficial guidelines that exits from the different health care and social services units. Then explore what these guidelines are based on and how many similarities there are. Patient safety is a subject that deserves all the attention and resources possible. Then all together these guidelines could be developed into national guidelines and maybe used with the current care guidelines platform to foster it. The upcoming social and health care reform in Finland could definitely be a perfect situation to update patient safety issues. Unfortunately it looks like sometimes patient safety is forgotten from public discussion completely and maybe the new social and health care reform is so big change, that there is no room for other subjects like patient safety. By the statistics found, it would have earned a place in the new reform.

References

10 facts on patient safety. World Health Organization. Internet document. < http://www.who.int/features/factfiles/patient_safety/en/>. Read 27.9.2018.

About Current Care Guidelines (Käypä hoito). Duodecim. Internet document. < http://www.kaypahoito.fi/web/english/about-current-care-guidelines>. 13.11.2018.

About us. World Health Organization. Internet document. <http://www.who.int/patientsafety/about/en/>. Read 25.9.2018.

About us, Fimea. Fimea. Internet document. < https://www.fimea.fi/web/en/about_us>. Read 1.2.2018.

About us, STUK. Säteilytyrvakeskus. Internet document. <https://www.stuk.fi/web/en/about-us>. Read 17.10.2018.

About Us, THL. Terveyden- ja hyvinvoinninlaitos. Internet document. < https://thl.fi/en/web/thlfi-en/about-us>. Read 16.10.2018.

About us, EPF. European patient's forum. Internet document. < http://www.eu-patient.eu/About-EPF/whoweare/>. Read 6.11.2018.

About WHO. World Health Organization. Internet document. <http://www.who.int/about/en/>. Read 14.2.2018.

Alustava luonnos 25.4.2018. Asiakas- ja potilas laki.

Ammattilaisille ja opiskelijoille. Suomen Potilasturvallisuusyhdistys Ry. Internet document. < http://spty.fi/ammattilaisille/>. Read 10.10.2018.

Blozik, Eva – Nothacker, Monika – Bunk, Thomas – Szecsenyi, Joachim – Ollenschläger, Gűnter – Scherer, Martin. 2012. Simultaneously development of guidelines and quality indicators-how do guideline groups act?: A worldwide survey. International Journal of Health Care Quality Assurance. Emerald Group Publishing Limited.

Collaborating Centres and NGOs in official and working relations for with WHO for Patient Safety. World Health Organization. Internet document. < http://www.who.int/patientsafety/partnerships/WCCNGO/en/>. Read 26.9.2018.

Constitution of WHO: principles. World Health Organization. Internet document. <http://www.who.int/about/mission/en/>. Read 24.9.2018.

Does employee safety matter for patients too? Employee safety climate and patient safety culture in health care. 2018. Journal of patient safety. 181-185.

Donaldson, Sir Liam 2009. An international language for patient safety, Global progress in patient safety requires classification of key concepts. International Journal for Quality in Health Care.

Doupi, Persephone 2009. National Reporting Systems for Patient Safety Incidents, A review of the situation in Europe. National Institute for Health and Welfare. Jyväskylä.

Edistämme potilasturvallisuutta yhdessä, Suomalainen potilasturvallisuusstrategia 2009-2013. 2009. Sosiaali ja terveysministeriö. Helsinki.

European Code of Conduct for Research Integrity 2017. Revised edition. Germany.

European Union Network for Patient Safety and Quality of Care. Internet document. < http://www.pasq.eu/>. Read 6.11.2018.

Finance. Säteilyturvakeskus. Internet document. < https://www.stuk.fi/web/en/about-us/finance>. Read 17.10.2018.

Funding. Terveyden- ja Hyvinvoinninlaitos. Internet document. < https://thl.fi/en/web/thlfi-en/about-us/funding>. Read 16.10.2018.

Gaal, Sander – Verstappen, Wim – Wensing, Michel 2011. What do primary care physicians and researchers consider the most important patient safety improvement strategie? BMC Health Services Research.

Health. European Union. Internet document. < https://europa.eu/european-union/topics/health_en>. Read 6.11.2018.

Health care. 2013. Aluehallintovirasto. Internet document. < https://www.avi.fi/en/web/avi-en/healt-care>. Read 16.10.2018.

Healthcare professionals stand together to foster patient safety. Internet document. < http://healthfirsteurope.eu/news/healthcare-professionals-stand-together-to-foster-patient-safety/>. Read 27.11.2018.

Health technology. Valvira. Internet document. < https://www.valvira.fi/web/en/healthcare/health-technology>. Read 16.2.2018.

Hoidon turvallisuus. Internet document. < http://spty.fi/hoidon-turvallisuus/Z>. Read 11.10.2018.

Inkinen, Ritva – Volmanen, Petri – Hakoinen, Suvi 2016. Turvallinen lääkehoito, Opas lääkehoitosuunnitelma tekemiseen sosiaali- ja terveydenhuollossa. Tampere. National institute of health and welfare.

Irving, Anne V. 2014. Policies and Procedures for Health Care Organizations: A Risk Management perspective. Patient Safety and Quality Healthcare.

Jha, A K – Prasopa-Plaizire, N – Larizgoitia, I – Bates, D W 2008. Patient safety research: an overview of the global evidence. BMJ Quality & Safety. 42-47.

Kansallinen lainsäädäntö. Fimea. Internet document. < https://www.fimea.fi/valvonta/lait_ja_ohjeet/kansallinen_lainsaadanto>. Read 6.11.2018.

Lainsäädäntö. Sosiaali- ja Terveysministeriö. Internet document. < https://stm.fi/sotepalvelut/lainsaadanto?p_p_id=56_INSTANCE_7SjjYVdYeJHp&p_p_lifecycle=0&p_p_state=normal&p_p_mode=view&p_p_col_id=column-

2&p_p_col_count=1&_56_INSTANCE_7SjjYVdYeJHp_languageId=fi_FI>. Read 6.11.2018.

Legislation. Sosiaali- ja Terveysministeriö. Internet document. < https://stm.fi/sotepalvelut/lainsaadanto?p_p_id=56_INSTANCE_7SjjYVdYeJHp&p_p_lifecycle=0&p_p_state=normal&p_p_mode=view&p_p_col_id=column-2&p_p_col_count=1&_56_INSTANCE_7SjjYVdYeJHp_languageId=en_US>. Read 6.11.2018.

Lillrank, Paul. 2015. Small and big quality in health care. International Journal of Health Care Quality Assurance. Emerald Group Publishing Limited.

Lääke- ja lääkitysturvallisuus. Kliinisen Farmasian seura. Internet document. <http://www.kliinisenfarmasianseura.fi/kliininen-farmasia/laake-ja-laakitysturvallisuus/>. Read 23.1.2018.

Lääketurvallisuus ja -tieto. Fimea. Internet document. < http://www.fimea.fi/laaketurvallisuus_ja_tieto>. Read 30.1.2018.

Lääkkeiden turvallisuus. Fimea. Internet document. < http://www.fimea.fi/laaketurvallisuus_ja_tieto/laakkeiden_turvallisuus>. Read 30.1.2018.

Lääkepolitiikka 2020. 2011. Ministry of Social Affairs and Health. Helsinki.

McElroy, L.M. – Woods, D.M. – Yanes, A.F. – Skaro, A.I. – Daud, A. – Curtis, T. – Wymore, E. – Holl, J.L. – Abecassis, M.M. – Ladner, D.P. 2016. Applying the WHO conceptual framework for the International calssification for patient safety to a surgical population. International Journal for Quality in Health Care.

Medication Without Harm. World Health Organization. Internet document. < http://www.who.int/patientsafety/medication-safety/en/>. Read 14.2.2018.

Moodle workspace: Safety and Quality processes and management in social and health care.

Määräykset. Valvira. Internet document. < https://www.valvira.fi/julkaisut-ja-maaraykset/maaraykset>. Read 12.11.2018.

Määräykset, Fimea. Fimea. Internet document. < https://www.fimea.fi/valvonta/lait_ja_ohjeet/maaraykset>. Read 30.10.2018.

Networks and partnership. World Health Organization. Internet document. < http://www.who.int/patientsafety/partnerships/en/>. Read 26.9.2018.

Ohjeet. Valvira. Internet document. < https://www.valvira.fi/julkaisut-ja-maaraykset/ohjeet>. Read 25.10.2018.

Ohjeet, Fimea. Fimea. Internet document. < https://www.fimea.fi/valvonta/lait_ja_ohjeet/ohjeet>. Read 30.10.2018.

Ojasalo, Katri – Moilanen, Teemu – Ritalahti, Jarmo 2015. Kehittämistyön menetelmät, Uudenlaista osaamista liiketoimintaan. Sanoma Pro Oy. Helsinki.

Organisation. Fimea. Internet document. < https://www.fimea.fi/web/en/about_us/organisation>. Read 18.10.2018.

Patient guide. Internet document. < http://www.potilaanopas.fi/en/index.html>. Read 13.11.2018.

Patient safety, EPF. European Union. Internet document. < http://www.eu-patient.eu/whatwedo/Policy/Patients-Safety/>. Read 19.10.2018.

Patient and client safety strategy. 2017. Government resolution. Ministry of Social Affairs and Health. Helsinki.

Patient Safety. World Health Organization. Internet document. <http://www.who.int/patientsafety/en/>. Read 27.9.2018.

Patient Safety and Quality: An Evidence-Based Handbook for nurses. Internet document. < https://www.ncbi.nlm.nih.gov/books/NBK2681/>. Read 5.11.2018.

Policies and Strategies. World Health Organization. Internet document. <http://www.who.int/patientsafety/policies/en/>. Read 24.9.2018.

Potilaan opas. Internet document. < http://www.potilaanopas.fi/fi/index.html>. Read 13.11.2018.

Potilaille ja omaisille. Suomen Potilasturvallisuusyhdistys Ry. Internet document. < http://spty.fi/potilaille-ja-omaisille/>. Read 10.10.2018.

Potilasturvallisuuden lyhyt oppimäärä. 2014. Suomen Potilasturvallisuusyhdistys Ry.

Potilasturvallisuuspäivät. Internet document. < https://potilasturvallisuuspaivat.fi/>. Read 11.10.2018.

Potilasturvallisuusopas. 2011. National institute of health and welfare. Tampere.

Potilasturvallisuutta taidolla. 2011. National institute of health and welfare.

Potilasturvallisuus. 2018. Terveyden- ja hyvinvoinninlaitos. Internet document. <https://thl.fi/fi/web/sote-uudistus/palvelujen-tuottaminen/potilasturvallisuus>. Read 16.10.2018.

Potilasturvallisuus, STM. Sosiaali- ja terveysministeriö. Internet document. < http://stm.fi/potilasturvallisuus>. Read 29.11.2017.

Publications. World Health Organization. Internet document. < https://www.who.int/patientsafety/publications/en/>. Read 14.2.2018.

Schmidt, Brooke. 2012. We can all define patient safety...or can we? Internet document. < https://www.psqh.com/analysis/we-can-all-define-patient-safety-or-can-we/>. Read 7.11.2018.

Seppänen-Järvelä, Riitta. 2004. Prosessiarviointi kehittämisprojekteissa, Opas käytäntöihin. Sosiaali- ja terveysalan tutkimus- ja kehittämiskeskus. STAKES. Helsinki.

Sosiaali- ja terveysministeriön asetus 341/2011laadunhallinnasta ja potilasturvallisuuden täytäntöönpanosta laadittavasta suunnitelmasta. Given in Helsinki 6.4.2011.

Strategic agenda. Valvira. Internet document. < https://www.valvira.fi/web/en/valvira/strategic_agenda>. Read 18.10.2018.

Strategic targets. Säteilyturvakeskus. Internet document. <https://www.stuk.fi/web/en/about-us/stuk-s-strategy-2018-2022/strategic-targets>. Read 17.10.2018.

STUK's strategy 2018-2022. Säteilyturvakeskus. Internet document. <https://www.stuk.fi/web/en/about-us/stuk-s-strategy-2018-2022>. Read 17.10.2018.

STUKin viranomaisohjeet ja päätökset. Säteilyturvakeskus. Internet document. < https://www.stuk.fi/saannosto/stukin-viranomaisohjeet>. Read 18.10.2018.

Suomen Potilasturvallisuusyhdistys Ry. Suomen Potilasturvallisuusyhdistys Ry. Internet document. < http://spty.fi/>. Read 10.10.2018.

Suositukset. Duodecim. Internet document. < http://www.kaypahoito.fi/web/kh/suositukset>. Read 13.11.2018.

Säteilylainsäädännön uudistus. Säteilyturvakeskus. Internet document. <https://www.stuk.fi/saannosto/sateilylainsaadannon-uudistus>. Read 22.11.2018.

Taylor, Natalie – Lawton, Rebecca – Moore, Sally – Craig, Joyce – Slater, Beverley – Cracknell, Alison – Wright, John – Mohammed, Mohammed A. 2014. Collaborating with front-line healthcare professionals: the clinical and cost-effectiveness a theory based approach to the implementation of a national guideline. BMC Health Services Research. London.

Tietoa yhdistyksestä. Suomen Potilasturvallisuusyhdistys Ry. Internet document. < http://spty.fi/tietoa-yhdistyksesta/>. Read 10.10.2018.

Terveydenhuollon laitteet ja tarvikkeet. Valvira. Internet document. https://www.valvira.fi/terveydenhuolto/terveysteknologia/tuotteen_markkinoille_saattaminen/terveydenhuollon_laitteet_ja_tarvikkeet>. Read 15.2.2018.

Terveydenhuoltolaki. <https://www.finlex.fi/fi/laki/ajantasa/2010/20101326#L1P8>. Read 9.1.2018.

Toikko, Timo – Rantanen, Teemu 2009. Tutkimuksellinen kehittämistoiminta. Tampereen Yliopistopaino. Tampere.

Tutkijoille. Suomen Potilasturvallisuusyhdistys Ry. Internet document. < http://spty.fi/ammattilaisille/>. Read 10.10.2018.

Valvira. Valvira. Internet document. < https://www.valvira.fi/web/en/valvira>. Read 18.10.2018.

Vilkka, Hanna – Airaksinen, Tiina 2003. Toiminnallinen opinnäytetyö. Kustannusosakeyhtiö Tammi. Helsinki.

Volmanen, Petri – Alahuhta, Seppo. 2015. Olemmeko potilasturvallisuuden edistämisen eturintamassa? Finnanest.

What we do. World Health Organization. Internet document. < http://www.who.int/about/what-we-do/en/>. Read 24.9.2018.

What is THL? Terveyden- ja hyvinvoinninlaitos. Internet document. < https://thl.fi/en/web/thlfi-en/about-us/what-is-thl->. Read 16.10.2018.

Where we work. World Health Organization. Internet document. < http://www.who.int/about/where-we-work/en/>. Read 24.9.2018.

WHO guideline handbook. 2012. World Health Organization.

WHO Multi-Professional Patient Safety Curriculum guide. World Health Organization. Internet document. < http://www.who.int/patientsafety/education/mp_curriculum_guide/en/>. Read 14.2.2018.

WHO guidelines approved by the Guidelines Review Committee. World Health Organization. Internet document. < http://www.who.int/publications/guidelines/en/> Read 26.9.2018.

WHO guidelines on patient safety. World Health Organization. Internet document. < http://www.who.int/publications/guidelines/patient_safety/en/>. Read 26.9.2018.

Who we are. World Health Organization. Internet document. < http://www.who.int/about/who-we-are/en/>. Read 14.2.2018.

Social and Health Care Acts that regulate services

Sosiaali- ja terveyspalveluja säädellään seuraavilla erityislaeilla:

- Lastensuojelulaki 417/2007 (Child Welfare Act)
- Varhaiskasvatuslaki 36/1973 (Early childhood ecucation Act)
- Päihdehuoltolaki 41/1986 (Act on rehabilitation services)
- Laki kehitysvammaisten erityishuollosta 519/1977 (Act on special care for the disabled)
- Laki vammaisuuden perusteella järjestettävistä palveluista ja tukitoimista 380/1987 (Act on services and supportive actions for disabled persons)
- Laki omaishoidon tuesta 937/2005 (Act on relative care support)
- Perhehoitolaki 263/2015 (Act on family care)
- Laki kuntouttavasta työtoiminnasta 189/2001 (Act on rehabilitative work activity)

Current Care Guideline subjects and number of the relevant guidelines:

- Allergologia (5)/ Allergology
- Anestesiologia ja tehohoito (9)/ Anesthesiology and intensive care
- Endokrinologia (14)/ Endocrinology
- Farmakologia (1)/ Pharmacology
- Foniatria (1)/ Phoniatrics
- Fysiatria (11)/ Physiatrics
- Gastroenterologia (2)/ Gastroenterology
- Geriatria (5)/ Geriatrics
- Hallinto (1)/ Administration
- Hammaslääketiede (10)/ Dentistry
- Hematologia (1)/ Hematology
- Ihotaudit (9)/ Dermatology
- Infektiosairaudet (13)/ Infectious diseases
- Kardiologia (11)/ Cardiology
- Keuhkosairaudet (9)/ Lung diseases
- Kirurgia (11)/ Surgery
- Kliininen elektrofysiologia (1)/ Clinical electrophysiology
- Kliininen farmakologia (6)/ Clinical pharmacology
- Kliininen fysiologia (2)/ Clinical physiology
- Kliininen kemia (2)/ Clinical Chemistry
- Kliininen mikrobiologia (3)/ Clinical microbiology
- Kliininen neurofysiologia (3)/ Clinical neurofysiology
- Korva-, nenä- ja kurkkutaudit (6)/ Otorhinolaryngology
- Kuntoutus (50)/ Rehabilitation
- Käsikirurgia (1)/ Hand surgery
- Lastenneurologia (5)/ Children neurology
- Lastenpsykiatria (4)/ Children psychiatry
- Lastentaudit (15)/ Pediatrics
- Liikuntalääketiede (1)/ Sports Medicine
- Naistentaudit ja synnytykset (11)/ Women's diseases and Childbirth
- Nefrologia (3)/ Nephrology
- Neonatologia (2)/ Neonatalogy

- Neurokirurgia (3)/ Neuro surgery
- Nuorisopsykiatria (6)/ Young psychiatry
- Oikeuslääketiede (2)/ Forensic medicine
- Ortopedia ja traumatologia (11)/ Orthopedics and traumatology
- Patologia (3)/ Pathology
- Plastiikkakirurgia (2)/ Plastic surgery
- Psykiatria (10)/ Psychiatry
- Psykogeriatria (1)/ Psycho geriatrics
- Päihdelääketiede (3)/
- Radiologia (14)/ Radiology
- Raskaus (5)/ Pregnancy
- Ravitsemuslääketiede (3)/ Nutrition medicine
- Reumatologia (6)/ Rheumatology
- Silmätaudit (4)/ Ophthalmopathy
- Sisätaudit (16)/ Internal medicine
- Suu- ja leukakirurgia (3)/ Oral and maxillofacial surgery
- Sydän- ja rintaelinkirurgia (1)/ Heart and thoracic surgery
- Syöpätaudit (6)/ Cancer
- Työterveyshuolto (47)/ Occupational health care
- Urologia (5)/ Urology
- Verisuonikirurgia (5)/ Vascular surgery
- Yleislääketiede (92)/ General Medicine

Patient and Client Safety Strategy, Desired state by year 2021.

Patient and client safety is apparent in structures and practical operations: services are effective and safe.

The patient and client are equal actors in the service process and in planning it. Everyone has an opportunity to influence, make choices and take responsibility on patient and client safety.

2.1 The patient, client and family members are actively involved in ensuring and developing patient and client safety

By the year 2021

- Patients and clients will be equal actors in their own service process as well as its planning and safe implementation. Patients and clients will be encountered openly and respectfully and their involvement will be supported in accordance with their preconditions.
- Patients and clients will have enough information about the available treatment and service alternatives and potential related risks to support their decision making.
- Patients and clients will participate in planning, developing and evaluating social welfare and health care operations and processes.

2.2 Quality as well as patient and client safety are part of risk management

By the year 2021

- The measures of risk assessment and management have been described in a quality or patient safety plan or self-monitoring plan. The organisation has agreed procedures used in assessing the significance of risks and maintaining a register of risks.
- Regular assessment and prediction of patient and client safety will be included in the risk management of organisations and reported on transparently.
- When planning processes of change, risks are evaluated beforehand and decisions are made on the necessary actions to ensure the safety and quality of operations during the change.

2.3 Resources and competence required by safe care, treatment and services have been ensured

By the year 2021

- Personnel and other resources as well as competence required in safe care, treatment and services is defined and ensured in the organisations' own and outsourced services.
- The operational environment, medicines, equipment and instruments as well as their use will be safe. There will be clear instructions on the prevention of infections related to treatment that are binding for all professional groups.
- Patient and client safety will be part of the orientation, annual supplementary education and assessment of competence of the personnel. Division of duties between different professional groups will take into account patient and client safety.
- Patient and client safety will be taken into account in the professional basic, advanced and supplementary education as well as management training in the social welfare and health care sector.

2.4 The service processes and practices are safe and protect the patients and clients against patient safety incident

By the year 2021

- Care, treatment and services will be planned as smooth processes, service chains and entities without any delays or overlapping or unnecessary phases.
- The quality and patient safety plan and self-monitoring plan are tools used to promote safety and develop risk management.
- Cohesive processes and practices of producers protect clients and patients against patient safety incidents. The processes create value for patients and clients.
- Commitment to following the agreed processes and practices will be ensured with orientation, change management as well as monitoring and assessment practices.

2.5 Monitoring and developing quality and safety is ensured
By the year 2021

- The development of patient and client safety will be based on versatile and cohesive monitoring in organisations. The instruments used by the organisation in monitoring patient and client safety have been determined. These will also include instruments monitored at the national level.
- There will be an agreed procedure as well as sufficient resources and competence for more detailed investigation of serious patient safety incidents. Particular attention will be paid to developing operations based on the investigation of patient safety incidents.
- Patient and client safety as well as the quality of care and treatment will be improved based on research as well as monitoring and follow-up data. Research will be used to ascertain that the services are high-quality and effective. It will also be guaranteed that the development measures promote the set objectives.

2.6 Patient and client safety is promoted nationally
By the year 2021

- The national instruments prepared for the assessment of the quality and effectiveness of service production will also include patient and client safety instruments.
- Indicator data reflecting quality and patient safety can also be obtained from social welfare and health care statistics and registers. This information is publicly available.
- An annual review of patient and client safety in social welfare and health care is prepared in collaboration of the authorities at the national level. This document may also be utilized in the national steering of the service providers.

(Patient and Client Safety Strategy 2017-2021.)

The learning material cover page

Metropolia University of Applied Sciences

Patient Safety

Patient safety and guidelines in Finland and in World Health Organization

Jenny West 10.12.2018

Patient Safety is a fundamental principle in health care and social services. Everyone deserve to be as safe as possible during the health care and social services processes. This booklet contains information and definitions on patient safety. World Health Organizations actions towards safer health care and social services are introduced and then the focus is in Finland. Patient safety in Finland is examined more closely and official, national Finnish patient safety guidelines are expressed. This booklet is targeted to the Master's students in Health Business Management programme.