

International overview – action plans in the field of patient safety

Background report to the Swedish National Board of Health and Welfare for the creation of a National Action Plan for Patient Safety



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Foreword

The government has commissioned the National Board of Health and Welfare to develop a national action plan for increased patient safety, which will help develop and coordinate the country's patient safety work.

The Swedish patient safety work is affected by what is happening in the rest of the world. Sweden's contribution to Agenda 2030, and specifically to the goal of improved global health, takes place in a number of arenas. Sweden actively participates on an international level and contributes with knowledge and experience as well as gaining important experiences from other countries. This means that Swedish patient safety work is affected by developments within the Nordic region, the EU and also globally. The WHO has established resolutions for increased patient safety and initiated the work Global Action on Patient Safety. The Global Ministerial Summits on Patient Safety and the establishment of Global Patient Safety Day are two other examples of initiatives and forms of cooperation at a global level that both inspire and guide the Swedish patient safety work.

Throughout autumn 2018 the National Board of Health and Welfare analysed patient safety from an international perspective in order to learn from other countries' previous work.

Strategies and action plans belonging to ten countries and three international organisations have been reviewed and analysed.

This report addresses all involved actors, both at a national and international level, including authorities, principals, national and international organisations, professional associations and experts. The National Board of Health and Welfare would like to thank everyone who has contributed their knowledge and experience.

January 2020

Olivia Wigzell
Director-General

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Summary

In 2018, the Swedish National Board of Health and Welfare was commissioned by the Government to develop a national action plan on patient safety. In order to identify relevant lessons for the development of the action plan, an international analysis has been carried out, based on a selection of national, Nordic and international strategies and action plans (policy documents) within the area of patient safety.

Lessons/Experiences from ten countries and three international organisations

A total of 10 countries' patient safety policy documents have been analysed and complemented by a review of the work on patient safety carried out by three international organisations. In order to increase the understanding of what lessons from the international analyses are relevant from a Swedish perspective, an overview of the Swedish patient safety context has also been developed. The analysis of the other countries' policy documents has been carried out with a systematic and structured approach based on five main dimensions: context, structure, content, process and results. In addition to document analysis, interviews have been conducted with representatives of the countries and organisations.

Context, structure and recipients are central aspects

One overall reflection on the international analysis is that context has significant meaning on the structure and impact of patient safety work. Therefore, the national action plan alone cannot have an impact on the effectiveness of patient safety work. The context, within which the policy document operates, is essential in order to create the conditions for solid and sustainable management of patient safety work.

The structures of the policy documents differed between the countries, both in terms of scope and design, and the extent to which the different parts of the policy documents were connected and related. One lesson is that when it comes to the development of a national action plan, it is important to have an overview of the field. That there is a clear and logical link between the more guiding elements and the sections describing the concrete activities. It also needs to be clear to the recipients of what responsibility each and every actor hold.

In-depth analyses increases the ability of a successful action plan

Another observation is that there is a need to carry out in-depth situation analyses in selected areas as part of the development of the action plan. Situation analyses provide a factual view of the most pressing needs and challenges. This can help to focus the content of the action plan on objectives

and activities that can contribute to the improvement of the most prioritised parts of the patient safety area. There are a number of good examples from the investigated countries where gap analyses have been carried out in the preparation of the policy documents. An in-depth analysis of ongoing regional patient safety work increases the ability of the action plan to have an impact. Finally, a general lesson from the international analysis is that it is very important to have a plan for implementing the action plan, and a follow-up model where results can be linked to the actions outlined in the action plan.

Introduction

The Swedish National Board of Health and Welfare has the Government's mandate to develop a national action plan on patient safety

The Swedish National Board of Health and Welfare has the Government's mandate to coordinate and support patient safety work at national level. The task is to develop a national action plan for increased patient safety in healthcare (1).

According to the Government's mandate, the national action plan should include overall objectives and focus areas and actions. It should also include a plan for following-up at regional and national level. County councils, regions and municipal authorities will be able to use the action plan to establish principles, priorities and objectives for patient safety in action plans at regional level.

The action plan will be carried out in close consultation with the relevant authorities and organisations, the Swedish Association of Local Authorities and Regions (SALAR), the new organisation for knowledge management, representatives of private healthcare providers, professions and patient organisations and experts in the field of patient safety.

The report on the assignment will be made in January 2020 (2).

The purpose of the international analysis is to identify lessons prior to the creation of the action plan

In preparation for the national action plan, the Swedish Social Welfare board wants to identify and develop elaborate documentation that can help to clarify different key choices. In this context, an international analysis has been carried out. Lumell Associates was commissioned by the National Board of Health and Welfare to support the board in their work. The analysis has been based on a selection of national, Nordic and international strategies and action plans in the field of patient safety.

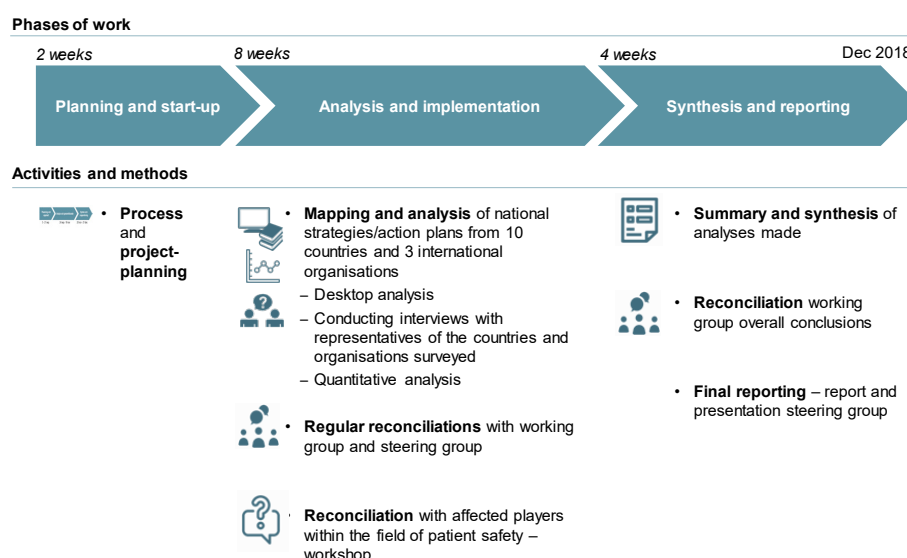
The purpose of the international analysis was therefore to produce comprehensive material that can provide lessons in the work with the introduction of a Swedish national action plan.

Method and approach

The work was carried out during autumn 2018

Work on the international analysis was carried out over 14 weeks during the autumn of 2018. The results and insights from the analyses have been discussed continuously with the National Board of Health and Welfare's internal project group. The overall conclusions have also been verified with a steering group and relevant experts in the field. See figure 1 for the phases and main activities of the work.

Figure 1. Overview of the main parts of the work on the international analysis



The international analysis examines both strategies and action plans

The National Board of Health and Welfare's Governmental mandate argues that an action plan for patient safety should be developed. To clarify the focus of the international analysis, the dividing line was defined between a strategy and an action plan at the start of the work.

A strategy can be seen as a long-term policy document that specifies wide-ranging directions, for example outlining vision and overall objectives. The strategy will guide decision-making and governance. An action plan is usually more concrete and explains how work or a process is to be carried out, for example by describing activities, responsibilities, schedule and more. In short, these different policy documents can overlap and, above all, they can complement each other.

In the light of the above and the way in which the Government's mandate is formulated, strategy elements will probably also need to be included in the action plan. In the context of the international analysis, it has therefore been

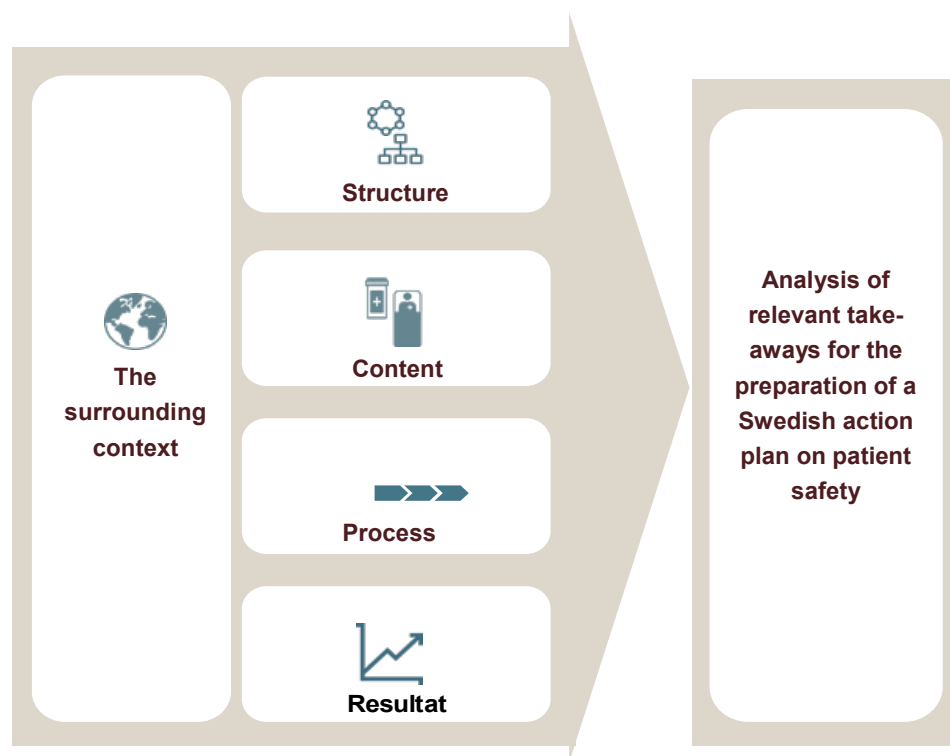
important to examine how other countries' policy documents look at the line between strategy and action plan: have strategies or action plans been established, or a combination of both? To facilitate legibility, the other countries' strategies and/or action plans have been referred to as "policy documents" in this report.

A specific framework has been the basis for the analyses of the countries' policy documents

An analytical framework (Figure 2) was used as a structure for the analysis of the respective country/organisation's policy documents. The framework aimed to contribute a structure to the review of the steering documents and to ensure that relevant dimensions were covered in the analysis.

The analysis framework was developed on the basis of the perspectives that were considered most relevant to the National Board of Health and Welfare for the process of developing an action plan. The analysis framework contains five main dimensions: context, structure, content, process, and results.

Figure 2. Analysis Framework for International analysis



A number of questions were formulated within each of the five dimensions. These served as guidance on the review and analysis of the strategies and action plans.

Context

Questions for analysing the context of the policy documents:

- What does the health care system look like in the country?
- Which actors are involved in the patient safety work?
- What does the current patient safety context look like (focusing on organisation and governance)?
- Who is the publisher of the strategy/action plan?
- Why has the strategy/action plan been developed? Was the development of the strategy/action plan based on a needs analysis?
- If only the action plan has been developed: has this led to some advantages or disadvantages in the implementation?

Structure

Questions for analysing the structure of the policy documents:

- How is the policy document structured? For example, what different parts does it consist of?
- What format does the policy document have and how extensive is it?
- Which recipients or recipient levels is the policy document aimed at?
- What is the life cycle of the policy document?
- Is there a specific communication plan for communicating the policy document?

Content

Questions for analysing the content of the policy documents:

- How is the concept of patient safety defined in the policy document?
- What content fills the policy document? For example, does it have a particular thematic focus?
- How detailed/concrete is the policy document?

When analysing the content of the policy documents, the activities described in the policy documents were categorised in thematic areas. The thematic classifications used were *outcome areas*, *foundational areas* and *areas of risk*.

Examples of activities within the *outcome area* are measures that link to concrete patient safety outcomes, such as the presence of healthcare associated infections, fall accidents, pressure ulcers etc. *Foundational areas* include activities that create conditions for improvement and safe care; for example, strengthening patient participation, improving communication, educating healthcare professionals, and supporting leadership. The category of *risk areas* includes activities to prevent incidents and adverse events, such as ensuring adequate medical competence, access to well-functioning medical equipment and early detection of diseases.

Process

Questions for analysing the processes that can be linked to the policy document:

- How has the policy document been developed?

- Have there been reconciliations and anchoring during the development?
- Is there a process for the implementation, updating, follow-up and accountability linked to the policy document? If there is, what is included in these processes?

Results

Questions for analysing the structure of the policy document:

- What possible results/effects can be derived from the policy document?
- How is the policy document perceived by various key interests? What foundational factors or obstacles have been observed?

A systematic selection of countries and organisations was made prior to the international analysis

The international analysis covers ten countries, which was assessed as a broad enough basis to be able to contribute general lessons within the work's main questions. In addition, perspectives were gathered from three international organisations with established work in the field of patient safety. In addition, the international analysis also included an overall compilation of the patient safety area in Sweden. The latter in order to facilitate assessments of how applicable the lessons from other countries are in a Swedish context.

Three criteria were formulated based on the selection of countries/organisations in order to obtain a relevant selection of countries and organisations:

- *Proximity*. Countries that are close to Sweden and also have a relatively similar context in certain key respects
- *Control system*. Countries that to some extent have similar control systems compared to the Swedish ones, i.e. a relatively decentralised healthcare system with a wide range of principals and/or actors
- *Good examples*. Countries and/or organisations that stand out positively in the field of patient safety

Based on these criteria, the working group selected the following countries and organisations:

- Countries based on the criterion of proximity:
 - Norway
 - Finland
 - Denmark
- Countries based on the control system criterion:
 - Germany
 - Australia
 - Netherlands
- Countries/organisations based on the criteria of good examples:
 - New Zealand
 - Canada
 - England

- Scotland
- Organisation for Economic Co-operation and Development (OECD)
- World Health Organisation (WHO)
- Institute for Healthcare Improvement (IHI)

In some cases it was deemed useful to examine policy documents at State level (or equivalent), rather than at national level. This was to identify good examples, or when the State level was similar to the Swedish context (which increases comparability). This was why Scotland and England were analysed independently, instead of studying Great Britain.

Initially, the plan was also to include three American healthcare organisations (Kaiser Permanente, Intermountain Healthcare and Centers for Medicare & Medicaid Services) in the international analysis. However, the desktop analysis proved to provide scant information about the organisations' work in the field of patient safety, among other things, neither the relevant documents with strategies/action plans for patient safety could be located, nor could respondents from the organisations be reached. In view of the above, it was considered that it was not possible to carry out an analysis of these organisations with the quality of the other countries/organisations, therefore they were excluded from the international analysis.

A combination of methods has been used to answer the questions

Document analysis

A large part of the data collection consisted of retrieving information available from web sites and/or in various documents. By analysing this data, an overview of the different countries' context related to patient safety was obtained and the relevant policy documents for analysis were identified.

Document analysis: the context of the surveyed countries for patient safety work

Initially, a web search was conducted to get an overview of the relevant country's healthcare system structure. In addition, information was collected about how the country's patient safety work has evolved over time, what has been done in the field of patient safety, and what relevant actors are involved in patient safety work.

Document analysis: identification and analysis of the policy documents of the surveyed countries

As a first step, a search was made for relevant policy documents (action plans or strategies) for patient safety at the highest possible level, i.e. Government or department. Where relevant documents at this level could not be found, a search was made for policy documents developed by State authorities or independent organisations that were deemed to be driving the national patient safety work in the country concerned.

The choice of the policy documents that would be the subject of the analysis in each country was based on two criteria. First, the selected document would have a clear link to national patient safety work and include strategic keywords such as vision, objectives and priority areas. Secondly, the pub-

lisher of the selected document would be the national actor considered to be the main promoter of patient safety work in the country.

In cases where the policy document was translated into English, this version was selected. In countries that did not have an English translation, the document was analysed either in the original language (Denmark, Norway) or after translation into Swedish (Germany and the Netherlands). The analysis of the Finnish policy document was based on the Swedish-language version of the document. Since there were linguistic limitations in this document, a Finnish language resource was used to clarify the interpretation of the Swedish-language version using the Finnish version of the policy document.

The document analysis of the policy documents was carried out in order to get a picture of the strategies' structure, content, processes, results etc. The analysis framework was the starting point for the analysis of the policy documents. The content of the relevant policy document was structured according to the framework's headings; context, structure, content, process and results, to create a prerequisite for comparing the different countries' strategies/action plans.

Document analysis: analysis of international organisations' patient safety work

Comparable strategies/action plans could not be identified for the International Organisations (OECD, WHO, IHI). Instead, desktop analyses, through the organisations' websites, focused on a picture of the work that the organisations are doing in the field of patient safety.

Document analysis: overview of Swedish patient safety work

The description of the Swedish patient safety context and ongoing regional patient safety work was based on information in publicly available documents. The purpose of this overview is to contribute to an overall understanding of the Swedish context, by highlighting some of the events that are considered to have been most important.

In the analysis of regional patient safety, some attention was paid to the regional strategies and action plans developed. These are examples of regions that have developed this type of policy document and have chosen to make the documents available on their public websites. A structured overview and systematic analysis of the strategies and action plans of the regions has not been carried out within the framework of this work. Nor has there been any analysis of the extent to which the regional policy documents can be linked to changes in patient safety outcomes.

Interviews

In addition to the document analysis, interviews were conducted with representatives from the countries and organisations surveyed. A total of 15 interviews were conducted. The purpose of the interviews with the representatives from the countries was to gain an in-depth understanding of the background as to why the analysed policy document was produced, the prevailing context, and the impact of the policy document. The interviews with representatives of the organisations were aimed primarily at obtaining lessons useful in the development of a national action plan.

The interviewees were selected on the basis of obtaining representation from the relevant national actors who are the publishers of the policy documents that had been identified and analysed. The interviews were conducted primarily with people involved in the development of the analysed policy document or with people who have a leading role in national patient safety work. See appendix 1 for the names and functions/roles of all interviewees.

Semi-structured interviews were conducted in order to capture as many relevant perspectives as possible. The starting point for the interview was an interview template with questions regarding the context, structure, content, process and results of the analysed policy document. Prior to the interview, the interview template was supplemented with questions specific to the country or organisation and the policy document. These specific questions had been identified during the initial document analysis. The interviewees also had the opportunity to speak freely about the national patient safety work at large and to convey any insights that they perceived as relevant. For international organisations, the interview questions focused primarily on the interviewees' observations and recommendations on the content and process that is appropriate for the design of a patient safety action plan, see appendix 2 Interview Guide.

The interviews were conducted by telephone and took an average of one hour.

Quantitative analyses

Additional quantitative analyses of certain key indicators were made in order to broaden the understanding of the context of the surveyed countries and to get an idea of patient safety outcomes within each country and developments over time.

The OECD database of patient safety indicators was used as a data source for the quantitative analysis. Data was not available for all countries surveyed in the international analysis. Data was analysed for Norway, Finland, Germany, Australia, Canada and Sweden. All the patient safety indicators for these countries available in the OECD database were studied. These seven indicators are:

- Foreign body left in during procedure¹
- Post-op sepsis after abdominal surgery¹
- Post-op wound dehiscence¹
- Post-op deep vein thrombosis after hip/knee replacement operation¹
- Post-op pulmonary embolism after hip/knee replacement surgery¹
- Obstetric trauma in vaginal delivery without instruments²
- Obstetric trauma in vaginal delivery with instruments²

Implementation of workshop with interested parties and actors

An important part of the National Board of Health and Welfare's mission to develop an action plan for patient safety is to consult widely with authorities,

¹ Number per 100,000 discharges. Discharge refers to patient discharge from hospitals.

² Number per 100 vaginal deliveries

principals and other affected actors. In the light of this, the National Board of Health and Welfare organises national meetings to which interested parties from a large number of actors and organisations as well as experts are invited.

One of these occasions was used to convey the observations from the international analysis, and to capture the participants' perspectives on what these observations mean for further work on the action plan. The meeting was conducted in the form of a workshop where participants were given the results of the international analysis and then discussed in groups what is important in developing a Swedish action plan. The participants' reflections within the five dimensions of the analytical framework were collated – partly in group discussions, and partly in writing, see appendix 3 Meeting for the report on the participation in the workshop and the compilation of the comments that were communicated in writing by the participants).

Analysis of data from County councils' patient safety reports

The description of the County councils' ongoing patient safety work is primarily based on the contents of the County councils' patient safety reports (PSR). These analyses are based on data from a systematic review of patient safety reports that the Swedish National Board of Health and Welfare conducted in spring 2018 within the framework of a survey and analysis of development in the field of patient safety (3). The purpose of the survey was to describe the status and development over time in patient safety work – based on the caregivers' own descriptions of the patient safety work in each PSR – and to identify development opportunities within the area of patient safety. The analysis was based on a structured review of the County councils' PSR for the years 2014 – 2017, as well as the latest available PSR from 20 municipal authorities. The review was conducted with regard to the objectives that have been formulated, how the organisation of patient safety work has been described, and what the caregivers have indicated they are working with and how this work has been done.

Additional thoughts when reading the report and reporting the parameters for the work

The focus of the report has been to identify lessons learned from the work of other countries and organisations with policy documents for patient safety, such as strategies and action plans. Lessons that may be useful in developing a Swedish action plan for patient safety. An important conclusion from the analysis is that all examined dimensions are dependent on the present context in which the policy documents have been developed, which means that lessons from one country cannot be applied directly to another country (including Sweden). The analysis and conclusions of this report have therefore been made with this in mind.

The part of the international analysis aimed at providing an overall picture of the context that characterises the policy documents has had the ambition of highlighting the most central elements of the context. Very extensive analytical resources would be required to portray a complete and comprehen-

sive picture of all patient safety work in each country. This was not feasible within the timeframe of the work.

An analytical framework has been used in order to facilitate a systematic review and comparison of national policy documents, see the description of the framework in the relevant section earlier in this chapter. When interpreting the results of the international analysis, it should be kept in mind that the analyses were limited to the areas defined in the analytical framework.

The OECD data used in the analysis of the different countries' quality outcomes are stated by OECD representatives as having certain limitations. Among other things, there is a degree of uncertainty about different definitions and methods for registering and reporting data in the different countries. The outcomes should therefore be interpreted with caution and comparisons between countries should be avoided.

When interpreting the results of PSR analyses, it is important to consider that PSR is neither a strategy paper nor action plan. Most County councils have regional strategies and action plans (to which PSR in some cases refer). This report includes an analysis of a limited number of regional policy documents.

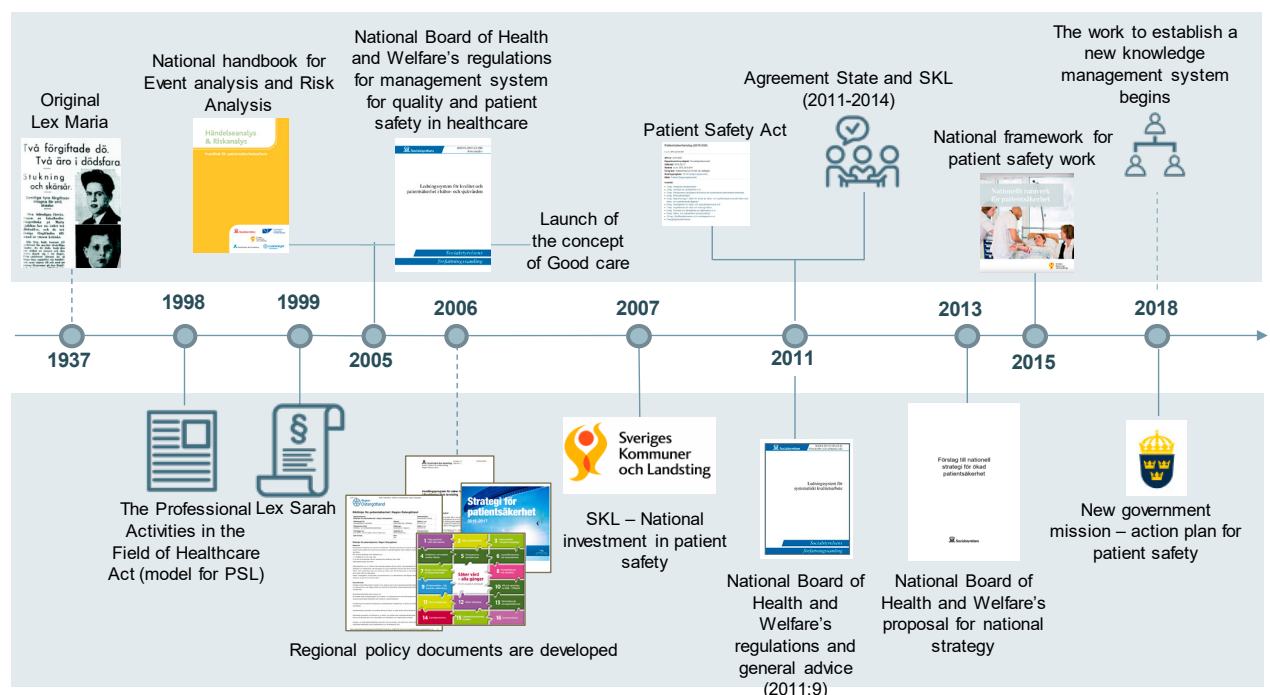
The governance of patient safety in Sweden – a starting point for the work on the national action plan

In the chapter that follows, we describe the Swedish patient safety context. Initially, a historical overview is given, and then we look at the patient safety work going on at regional level. The main purpose of the overview is to contribute to the understanding of what lessons from the international analysis may be relevant from a Swedish perspective.

National patient safety work has been conducted in Sweden for a long time

In order to draw relevant lessons from the analysis of the environment, the observations need to be put in a Swedish context. Figure 3 gives a historical overview of the Swedish patient safety work. It illustrates a number of examples of national policy documents that have had an impact on the development and growth of patient safety in the country. The following is a description of a selection of the different stages of the extensive national patient safety work that have occurred and are in progress. Also see appendix Country facts Sweden for and Swedish outcomes in the OECD patient safety indicators.

Figure 4. Overview of the Swedish patient safety work, focusing on policy documents within the healthcare sector



Sweden was early to note deficiencies in patient safety

Just over 80 years ago, in January 1937, "lex Maria" was created which can be regarded as the starting point for the patient safety work that is run and supported on a national level in Sweden. This happened with the entry into force of the decree of duty of notification to the Medical board and the Police authority and required that a report be made if someone had been inflicted with injury or illness of serious nature during treatment at a medical establishment. The reason was because of events that occurred at Maria hospital in Stockholm, which contributed to four people dying as a result of a mix-up between the anaesthetic agent etocain and mercury-oxycanide.

The decree from 1937 is the basis for today's duty of notification to the Health and Social Care Inspectorate (IVO) according to 3 chap. 5 § The Patient Safety Act (2010:659), PSA, which means that caregivers are required to report to the Health and Social Care Inspectorate any events that have resulted or could have resulted in a serious injury to health according to chapter 3. 5 § PSA, called "lex Maria".

Lex Maria is a major milestone in the Swedish patient safety work and, with its early appearance, makes Sweden unique from an international perspective.

The Patient Safety Act clarifies the responsibilities of caregivers and healthcare professionals regarding patient safety

The Act (1998:531) on occupational activities in the field of healthcare (LYHS) from 1999 was the model of today's Patient Safety Act (2010:659,) PSA. PSA marked a transition from an approach to patient safety with an individual perspective to a system perspective (7). This means that the causes of unwanted care incidents are sought and explained by deficiencies in the system rather than in the actions of individuals, and that the most important thing in the event of a patient safety incident is to investigate what can be done to avoid its recurrence.

The PSA aims to promote high patient safety in healthcare and dental care. The act includes provisions concerning caregivers' obligations to conduct systematic patient safety work and the responsibility of healthcare professionals to perform their work in accordance with science and proven experience and to provide care that is expert and diligent, and is designed and implemented in consultation with the patient. Healthcare professionals also have a responsibility to contribute to a high level of patient safety.

Replacement of LYHS with PSA was proposed in the State patient safety investigation report "*Patient safety. What has been done? What needs to be done?*" (8). The report also proposed replacing the current disciplinary responsibility for healthcare law by providing the State with other options for action against licensed healthcare professionals – for example, through probation and to impose demands on competence development. The investigation also noted that the former system of patients specifying who they considered responsible for the incident by a notification to the National

Board of Health and Welfare was not optimal. Therefore, in order to strengthen the patient's position, it was suggested that patients should only have to report the incident, for it then to be investigated from a broader and more unbiased perspective. The Government went ahead with the proposals (prop. 2009/10:2010 Patient safety and supervision.)

The Swedish National Board of Health and Welfare has the Government's mandate to support patient safety work

The Swedish National Board of Health and Welfare regulations on quality and patient safety management systems in the healthcare system were introduced in 2005 and the Swedish National Board of Social Affairs and general advice on management systems for quality of operations in accordance with SoL, LVU, LVM and LSS³ in 2006 (9),(10). These were replaced in 2012 by a common regulation (11). This brings together regulations that concern systematic quality and improvement work, regardless of the care or welfare activity responsible.

As part of the National Board of Health and Welfare's mission to provide comprehensive support for healthcare in the field of patient safety, the website "*Comprehensive support for patient safety*" has been developed (12). The website is a collaboration between 12 authorities and organisations, and is aimed at managers and supervisors as well as employees widely in the healthcare sector. The aim is for the website to provide support for patient safety work and thereby contribute to the reduction of adverse events. Here, general information is given about what patient safety is, about roles and responsibilities, current measurements and how patient safety can be carried out, what factors are important for high patient safety, and what responsibility healthcare has in the event of an adverse event. The website also contains links to key laws and regulations with a bearing on patient safety. The regulations are also put in context, partly through an explanatory text and partly by linking them with information and methodological support (where available) on, among other things, the Swedish Association of Local Authorities and Regions (SALAR) and the National Board of Health and Welfare's websites.

In connection with the publication of the introduction of 2005's annual regulations on quality management systems and patient safety, the collective concept of "*Good care*" was highlighted (13). The concept consists of six areas that are important prerequisites for achieving Good care: that healthcare is knowledge-based and efficient, safe, patient-focused, effective, equitable and given in a timely manner. In its work, the National Board of Health and Welfare has also developed a national indicators for following up good care and quality within healthcare (14).

Regulations are part of the Board's constitutional responsibility in the field of patient safety and thus one of the authority's management tools in the area.

³ Note: SoL = Social services law; LVU = Law with special provisions on the care of young people; LVM = Law regarding the care of addicts in certain cases; LSS = Law regarding support and service for certain disabled people

As a knowledge authority, the National Board of Health and Welfare also uses knowledge management as a means of control, for example through the Council for knowledge, the provision of knowledge support, including through the website, which also links to other actors in the field of patient safety, and development of follow-up indicators.

The patient safety agreement gave an increased focus on patient safety in the County councils

In order to stimulate the work for increased patient safety for the years 2011 – 2014, an agreement on improved patient safety (15) was concluded between the State and SALAR. The starting point for the initiative was zero risk in terms of adverse events and the goal was to reduce the number of adverse events. Furthermore, a desire for a healthy patient culture, characterised by the participation and involvement of patients, and preventive patient safety work, was expressed.

The agreement was aimed at intensifying patient safety and strengthening the management and control of patient safety work and as a control system, performance-driven remuneration was used. Every year in which the initiative was run, there were a number of basic requirements. The establishment of patient safety reports and the connection and use of National Patient Overview (NPÖ) was required in all four years. Other basic requirements were participation in national patient surveys, patient safety culture measurement, work with structured journal review (MJG) and collaboration against anti-biotic resistance. Linked to these basic requirements were six indicators, which were linked to financial compensation for the County councils.

In connection with the agreement, the National Board of Health and Welfare received the Government's mandate to follow-up and analyse developments in the field of patient safety and have published annual progress reports in the field of patient safety. The follow-up also includes the development of the municipal authorities' patient safety work. The National Board of Health and Welfare has also produced the report Open comparisons - Safe care, which had a slightly different focus to the annual progress reports. The aim of the reports was, among other things, to include a shift in perspective from the reporting of injuries to accounting for how safe care is by also focusing on processes that prevent adverse events, i.e. structural conditions that can affect the existence of adverse events and conditions that significantly affect the safety of care.

Follow-ups have found that the initiative has contributed both to an increased focus on patient safety in the County councils and to a higher level of knowledge about how systematic patient safety can be carried out (16), (17), and (3). For example, the use of methods and tools aimed at improving patient safety has spread over the years in which the initiative has run. The performance-based remuneration model also focused on measuring patient safety, which led to developed opportunities for both measurement and follow-up of indicators for patient safety at both local and national levels. At the same time, several caregivers state that the clear focus that has been on measurements has meant that analysis and reasoning about the results have

been given less space. Furthermore, it is highlighted that the clear focus of the patient safety initiative on particular measurement ranges has contributed to limiting the perception of what is included in patient safety work.

A proposal for a national strategy for patient safety was already developed in 2012

In 2012, on mandate from the Government, the National Board of Health and Welfare presented a strategy document in the field of patient safety (18).

The background to the development of the strategy was a need to create a long-term approach to patient safety at national level. Furthermore, it was considered that a clear organisation, which ensures both that the work is held together and that the desired results are achieved, was needed.

The work was based on literature studies of relevant documents and scientific publications. During the course of the work, knowledge and experience from a large number of relevant authorities and actors and experts in patient safety were also collected. During the period the strategy was developed, the patient safety agreement was concluded between the Government and SALAR.

No Government decision was ever made based on the authority's proposal for strategy. The experience of the process of developing the strategy has, at the same time, provided important lessons – lessons that are key for consideration within the framework of the current mandate. For example, the National Board of Health and Welfare has noted the importance of continuous consultation and interaction with involved actors and bodies.

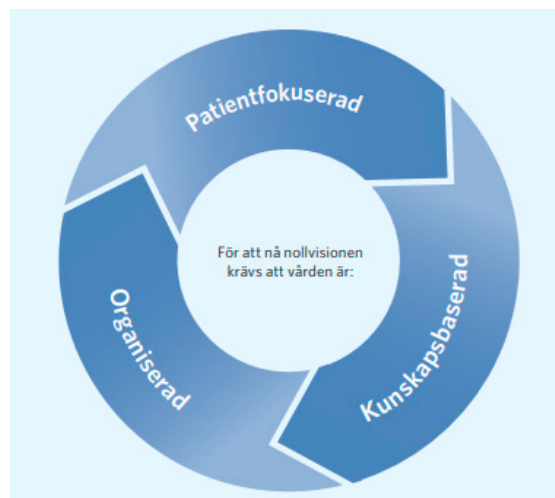
A framework for patient safety was developed in order to provide an overall picture and structure

SALAR has, together with the County councils and municipal authorities, developed a national framework for strategic patient safety work (19). The idea behind the framework is to show an overview and a context for patient safety work, to clarify what needs to be done at different levels in order to increase patient safety and to act as support for prioritisation.

The framework is centred around a zero risk strategy in the field of patient safety and contains three perspectives: that healthcare is *patient-focused*, that it is *knowledge-based* and that it is *organised in a way that creates the conditions for safe care*. For each perspective, it describes what this means for (i) patients and relatives, (ii) healthcare personnel, for (iii) the activity-related management at different levels, and (iv) senior management.

The basis of the framework is the patient's focus, and that it should be relevant at all levels of healthcare. All levels need to understand their role and responsibility, and the work on patient safety needs to be part of other follow-up and development work, see Figure 4.

Figure 5. National framework for patient safety work, SALAR



The development of the framework included inspiration from the patient safety frameworks in other countries, e.g. Australia, Canada, England and Scotland.

The Council for knowledge management

The National Board of Health and Welfare is a knowledge authority. State governance with knowledge in healthcare is regulated in regulation (2015:155).

The Council for knowledge management was established in 2015 and includes another eight authorities in addition to the National Board of Health and Welfare. Each authority is represented by its Director-General and the Director-General of the National Board of Health and Welfare is the Chair of the Council. In parallel with the Council, the Main principals group, whose members represent municipal authorities and regions, meet. The group informs the Council on areas where the principals need knowledge and how it needs to be designed and communicated.

The Council for knowledge management works to ensure that the governance with knowledge becomes a support for the principals and the profession, and that it is coordinated, effective and adapted to their needs. The Council also works to include views and experiences of patients and users and to ensure that communication to the user is coordinated. The Council shall cooperate with authorities not included on the Council and with other public and private actors. The Council will also be a forum for questions on knowledge development, research and innovation.

The Council continuously identifies areas around which the authorities need to work together for possible future initiatives. In August 2017, collaboration is underway in a number of areas. Examples include developing patient and user participation, collaboration in the field of welfare technology, developing coordination of systematic overviews and scientific evidence and faster initiation of research around gaps in knowledge and digital support for coordinated knowledge management.

Establishment of a new knowledge management system in the regions

During 2018, County councils and regions, with the support of SALAR, established a common system of knowledge management. The aim is to find a coherent structure that will, among other things, make it easier to coordinate the knowledge support used in healthcare. The objective of knowledge management is usually formulated as the “*best knowledge should be available and used in each patient meeting*” (20). Part of knowledge management is the development of knowledge support, another is support for follow-up and a third support for development and leadership. Knowledge support governs and supports decisions at different levels of health and welfare – ranging from political decisions to those taken by health professionals in meeting with the patient. Developed knowledge management is a means of achieving good health and care.

Patient safety is an important and natural part of the knowledge management process. With the development of the County council's common knowledge management system, a national collaboration group on patient safety has been set up, with representation from the six healthcare regions. The main task of the collaboration group is to manage and coordinate the joint work of the County councils in this area. This mission includes compiling reports and conducting analyses in the field of patient safety, as well as supporting management and governance and the implementation of measures in the field of patient safety.

Patient safety perceptions – minimising adverse events

Definitions of patient safety and adverse event are given in PSA (7). According to this definition, patient safety refers to “*protection against adverse event*”, and adverse event means “*suffering, physical or mental injury or illness as well as death, which could have been avoided if adequate measures had been taken at the patient's contact with the healthcare system*”.

The Swedish patient safety work has a focus on minimising the risk of adverse event and not on improving the overall quality of care i.e. based on Good care. This is reflected, among other things, in the activities carried out within the framework of the patient safety initiative.

In the workshop involving the relevant actors in the context of this international analysis, participants were asked to reflect on the definition of patient safety. It was consistently emphasised that the definition of patient safety should be broader than how the term is used today. A greater focus on foundational areas is demanded and several of the workshop participants believe that the work should be based on an analysis of what we are currently doing that leads to positive outcomes for patients.

Extensive regional patient safety work is underway

Effective national governance is an important part of the strategic patient safety work. However, systematic and strategic patient safety work is required at all levels of healthcare in order to achieve high patient safety.

Several County councils point out the aim of their patient safety work in regional strategies and action plans. It is up to each caregiver to decide how they want to organise and manage their patient safety work and there is no requirement for regional or local action plans to be developed. The establishment of an annual patient safety report (PSR), which describes the patient safety work during the year, is a statutory obligation for all caregivers. PSR must describe how patient safety work has been carried out, what steps have been taken to increase patient safety and the results achieved (3 chap. 10 § PSA).

Several regions have a strategy or action plan, on which patient safety work is described being based on

Three examples of regional action plans for patient safety are given below: from Jönköping, Östergötland and Västra Götaland.

The "Safe care – always" framework is the basis of Region Jönköping county's patient safety work

A common concept for guidelines and monitoring of work in the field of patient safety has been developed in Region Jönköping County (21). The concept is called *"Safe care – always"* and consists of 16 priority areas. Each of these areas contains a package of measures that describe how employees at different levels need to work to ensure patient safety.

A framework has been developed within the work, in which the 16 areas are illustrated as pieces of a jigsaw puzzle (see Figure 5). The region also has a website that gathers information about how work on the different areas should be conducted, and how the region's development work with patient safety connects to the different areas of the puzzle.

Figure 6. Safe care - always. Region Jönköping county

Säker vård - alla gånger



Region Östergötland has a strategy and action plan designed to achieve the zero risk vision for adverse events. The Region Östergötland website describes that, in their patient safety work, they have adopted a zero risk strategy for avoidable injuries, (22) in which vision, goals and strategies are described (see Figure 6). The strategy defines the initiative areas which are divided into the relevant organisational levels: region, hospital/centre and clinic/medical centre.

Figure 7. Patient safety strategy. Region Östergötland.



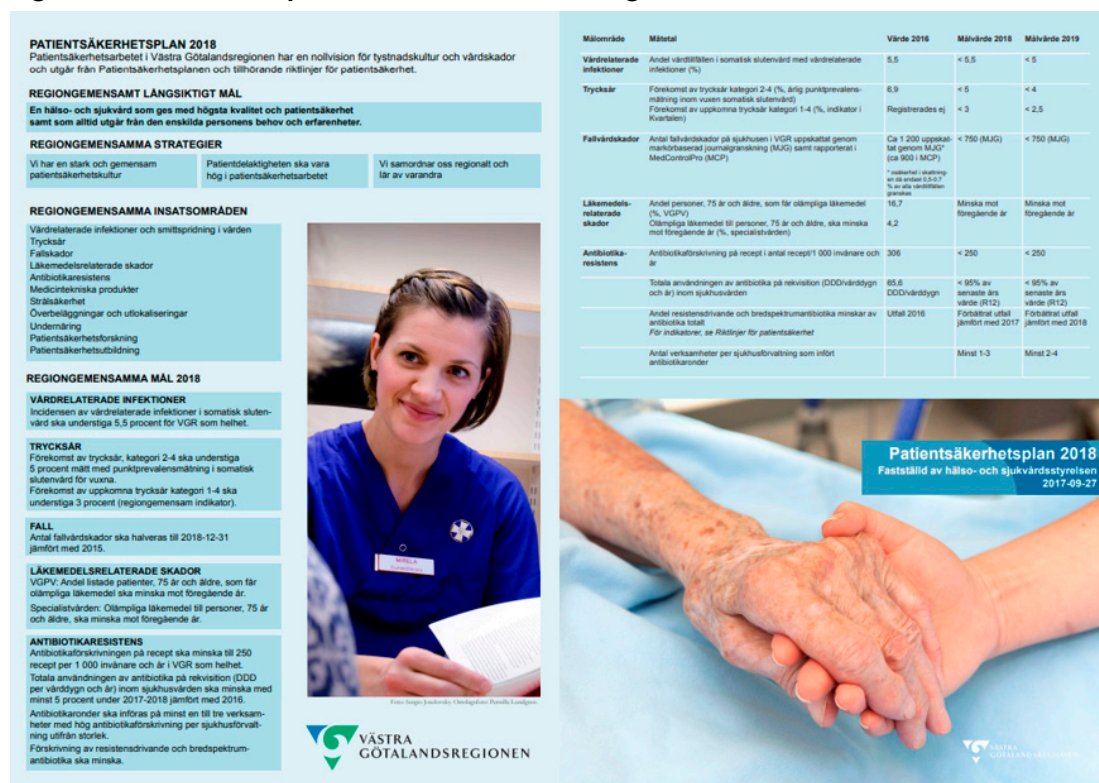
As a complement to the strategy, six priority patient safety areas have been defined: reducing hospital-acquired infections, safe care processes, safe medication management, safe nursing, safe communication and safe medical technology. These six areas have defined success factors, key indicators and an action plan.

The Västra Götaland region has a patient safety plan that describes the focus of the patient safety work

Each year, the Västra Götaland region presents a patient safety plan that identifies priority goals for improvement work in patient safety (23). The patient safety plan contains the region's common long-term objective and strategies for patient safety, as well as the most prioritised action and target areas. There are metrics for each objective area and a desired position for the coming year is defined (see Figure 7).

The region's "patient safety guidelines" is a more comprehensive document that describes, among other things, work in all focus areas of the region (24). The document describes responsibility for which activities within each focus area (group staff, administrations and healthcare providers), the region's objectives, and which indicators can be used for follow-up.

Figure 8. Patient Safety Plan, Västra Götaland region



The patient safety reports provide a picture of the healthcare providers' ongoing patient safety work. The patient safety reports (PSR) contain a description of the patient safety work of caregivers, thus giving a picture of the focus and content of the ongoing work.

In 2017, the National Board of Health and Welfare conducted a study of County councils' and municipal authorities' (regarding their role as caregivers here and below in this section) PSRs (3) and some of the conclusions based on the content of the County council's PSR from 2017 are given below.

In PSR, goals, objectives and strategies are often formulated at an overall level – even for those areas that involve concrete outcomes.

In the introductory section of PSR, the caregiver describes selected objectives and strategies for patient safety work for the year in which the report relates). Many of the formulations surrounding visions, objectives and strategies overlap. There is some ambiguity about what an objective is and what a strategy is and what connection these have to each other. There are also elements of some confusion in use of terms; a formulation designated as an objective goal in one County council's PSR is described as a strategy in another County council's report.

A further observation in the analysis of the type of objectives formulated in PSR, is that the objectives are generally formulated at a comprehensive and sweeping level; only about half of the objectives can be classified as measurable.

In conclusion, the objectives and strategies, as formulated in PSR, do not provide optimal support to County councils' patient safety work. A clearer distinction between the objectives and the strategies for achieving the objective would be likely to contribute to greater clarity in the direction of the work. The increased use of measurable objectives could potentially also make the objectives easier to follow-up and thus increase knowledge and facilitate priorities.

The areas mentioned as objectives for the coming year are different than those mentioned as objectives for the past year

Tabell 2 shows the thematic areas in which the County councils have formulated objectives and/or strategies for the year to which the PSR refers, respectively in which areas they have formulated objectives for the following year. Objectives and strategies for the following year are described in a concluding section of PSRs and most healthcare providers describe how they view future patient safety work based on current results and challenges.

Table 1. Number of County councils that formulated objectives/strategies within each field* in 2017's PSR

Patient safety area	Number of County councils describing objectives	Number of County councils describing PS work
Outcome areas		
Diagnostics	1	1
Infections	16	7
Medication	11	7
Nursing	11	9
Care areas and specialties	4	4
Foundational areas		
Information security	0	2
Communication and interaction with patients	10	10
Communication and collaboration between healthcare professionals and departments	6	9
Patient safety culture	11	7
Framework for patient safety work	4	2
Risk areas		
Availability	13	5
Skills provision and work environment	0	7

* All the County councils (21) had objectives and strategies formulated for the past year and 19 County councils had goals and strategies formulated for the following year.

Source: What do caregivers' patient safety reports say about developments in the field of patient safety?, National Board of Health and Welfare; 2018.

Objectives and strategy formulations are found in both outcomes, as well as in general foundational- and risk areas. As for objectives for the year that PSR refers to, most County councils have objective formulations in the area of outcomes; the most common objectives are regarding healthcare associated infections. In the objectives and strategies for the following year, outcomes are generally mentioned to a lesser extent. The area of availability (e.g. beds) is also more seldom covered for the coming year, while skills provision and work environment are mentioned more often: no County councils addressed this as part of the objectives and strategies for the current year, while a third mention it as something that they see as a priority for the following year.

With regard to the difference in the content of the objectives and strategies between the current and the following years, the analysis does not allow the conclusion that this indicate a real shift in the focus of the County councils in the patient safety work. A possible explanation for the differences may instead be that when space is given for more free reasoning about challenges and focus, the County councils choose to address other areas. The fact that the objectives and strategies for the year to which PSR relates are written down retrospectively, and are thus more likely to be linked to outcomes or results, may instead increase the focus on outcomes that are "simpler" in the sense that they can be measured and followed up.

Selection of objectives and strategies is rarely motivated in PSR based on a description or achieved results

In PSR it is shown to a limited extent why the County councils choose to formulate objectives and strategies in the areas they do, or why they choose to focus their patient safety work in a certain way. In only one PSR were the objectives for the current year based on a problem description. Therefore, for other objectives/strategies there is no stated reason why the objective has been formulated in a particular area.

When analysing the initial objective and strategy section for the last four years of PSRs, it is noted that there are few changes between the years regarding the areas mentioned as overarching objectives and strategies. In one case, exactly the same text was used two years in a row. This also indicates that the choices of the objectives described in PSR were not made on the basis of a current needs analysis.

In the description of objectives and strategies for the following year, it is more common for the objectives to be justified on the basis of the challenges described and the results measured. Of the 19 County councils that described the objectives for the coming year, *four* describe the link between the results achieved in the year reported and the objectives set for the following year.

That formulated objectives and strategies are motivated on the basis of a description to such a low degree, need not mean that needs analyses have not been carried out or that the target formulations are not based on current challenges. However, it can be concluded that the establishment of PSR does not take place on the basis that the link between current needs and objective strategies should be made clear.

In the outcome areas where there are available metrics, systematic patient safety work in PSR is more often described

A key part of the National Board of Health and Welfare's analysis of PSR was the evaluation of the extent to which "systematic patient safety work" was described for each patient safety area. By systematic patient safety work, this analysis referred to the extent to which a needs analysis structure was presented, if measured results were analysed and reflected on, whether the measures implemented relate to these analyses, and been followed up.

A general conclusion of the analysis is that the County council's work with patient safety – as described in PSR – rarely follows the systematics described above. Few County councils describe all the parts of the work and a connection between the different parts is also seldom made. A pattern can be seen that in PSR there are often descriptions of how results are identified and followed, but that analysis and reasoning regarding the results and descriptions of actions based on learning of the results are less common.

For some variables, it is relatively common for all steps in systematic patient safety work to be reported: work with *health care associated infections* (38% of the County council's PSR), work with *pressure ulcers* (33%), and work with *anti-biotic prescription* (29%). Common to the variables or areas where all the steps are described is that there are outcome areas and that there are both metrics and methods for monitoring them. They are all also "well-established" as outcomes in the field of patient safety and there is a habit of working with them.

The above demonstrates the importance of developing metrics and methods for following-up and analysis for all areas considered to be relevant from a patient safety point of view, including foundational and risk areas. An ambition can be to increase knowledge and experience about patient safety work in the thematic areas where there is no equally established tradition of working with patient safety.

There is no clear link in PSR between formulated objectives and strategies and what work has been done

An overall conclusion is that there is rarely a clear link between formulated objectives and strategies and the activities that are then described in PSR.

There are several examples that the thematic area that has been mentioned in objectives and strategies lacks work that is then mentioned in PSR. One example is "*Care areas and specialties*": of the four counties that have this in the objectives and strategies section of their PSR, only one mentions kind of work in the field.

Table 2 illustrates the extent to which PSR contains an analysis and proposed measures, where a thematic area is mentioned in the introductory objective and strategy section. Among other things, it can be noted that of those County councils that mention infections as one of their goals and strategies (17), the vast majority (15) describe some form of analysis. All 16 County councils describe actions within the area. For the medication area, three out of eleven counties describe some analysis, while more than half describe some measures. For the nursing area, it is more common for analy-

sis to be described (eight of eleven counties do this). Nursing is also the area, after infections, that County councils most commonly describe measures for.

Explanations for the results are likely to be partly explained by the reasoning in the previous section, that those areas where there is a habit of working with it appear to a greater extent in analysis and when selecting the measures to be implemented. However, for all areas, there is a general lack of a clear link between the thematic areas selected in the objectives and strategies and the areas chosen by the County councils to describe the reasoning or analysis and the measures to be taken.

A further observation concerns the area of patient safety culture. Of the eleven County councils that mentioned the area in the objective and strategy section, ten include an analysis of the results. One possible explanation for this high percentage is that reflection and dialogue are a natural component in the work to strengthen the patient safety culture, which is also reflected in the establishment of PSR. This is also an area where there is a possibility of obtaining result documentation (with the patient safety culture measurements being carried out). In this respect, the work in the field of patient safety culture can probably contribute to work with other areas – outcome, foundational and risk areas.

Table 2. Number of County councils describing work within each area.

Patient safety area	Number of County councils describing objectives	Proportion describing analysis	Proportion describing measures
Outcome areas			
Diagnostics	1	0 %	0 %
Infections	16	14 (88 %)	16 (100 %)
Medication	11	3 (27 %)	6 (55 %)
Nursing	11	8 (72 %)	9 (82 %)
Care areas and specialties	4	*	*
Foundational areas			
Information security	0	-	-
Communication and interaction with patients	10	2 (20 %)	5 (50 %)
Communication and collaboration between healthcare professionals and departments	6	1 (17 %)	4 (67 %)
Patient safety culture	11	10 (91 %)	7 (64 %)
Proactive patient safety work	4	*	*
Risk areas			
Availability	13	4 (31 %)	4 (31 %)
Skills provision and work environment	0	-	-

* No data available (analysis of completed analysis and measures not completed).

Source: What do caregivers' patient safety reports say about developments in the field of patient safety?, National Board of Health and Welfare; 2018.

PSR refers to some extent to County council's strategies and action plans

An overall analysis of the extent to which the County councils refer to their regional strategies or action plans in 2017's PSR, has been made for those three counties used as examples in the section on the County councils' regional strategies and action plans.

The Region Jönköping county's PSR describes how "Safe care – always" connects to the region's strategic approach, and it also provides several examples of work carried out in some of the different areas. However, it is not clear how the priorities between the different areas and the actions within the framework have been made.

Region Östergötland's PSR refers to the patient safety strategy in the section for the overall objectives of the strategy. However, the action plans are not mentioned and there is no description of how the region's patient safety work is linked to the strategy.

Västra Götaland region's PSR for 2017 references the patient safety plan, where the overall goals and strategies and patient safety work are described. PSR also has a summary of the extent to which the objectives of the patient safety plan have been met over the past year.

In conclusion, all three County councils are addressing the strategy as part of patient safety work, but they differ to the extent that there is any account of how the strategy/action plan is implemented in the concrete work.

The results of the international analysis

This chapter presents a summary of the results of the international analysis that was conducted, with a focus on lessons learned from work with policy documents. The structure of the chapter follows the structure of the analysis framework and the conclusions are sorted according to the area they concern: context, structure, content, process, and results. For the reporting of the respective country/organisation see compilations in appendix.

Policy document context

Context is important for understanding patient safety work

In the interviews with representatives from most countries and organisations, it became clear that the prevailing context plays a major role in the structure, design and impact of patient safety work. Below are a few examples of how the prevailing context has affected the design of patient safety work.

The Dutch insurance-based healthcare system distinguishes itself from other surveyed countries in the sense that it is characterised by a wide range of independent actors (hospitals, caregivers, insurance companies etc.), creating a complex chain with horizontal control. This places demands on how national patient safety work can be carried out. For example, it is not considered possible to control patient safety work “from the top down”, but a more supportive and motivating (indirect) approach has been chosen instead, where the work is based on the health organisations concerned. This is one reason why national patient safety work in the Netherlands focuses on *supporting* healthcare organisations to implement improvements, rather than *controlling* exactly what they do.

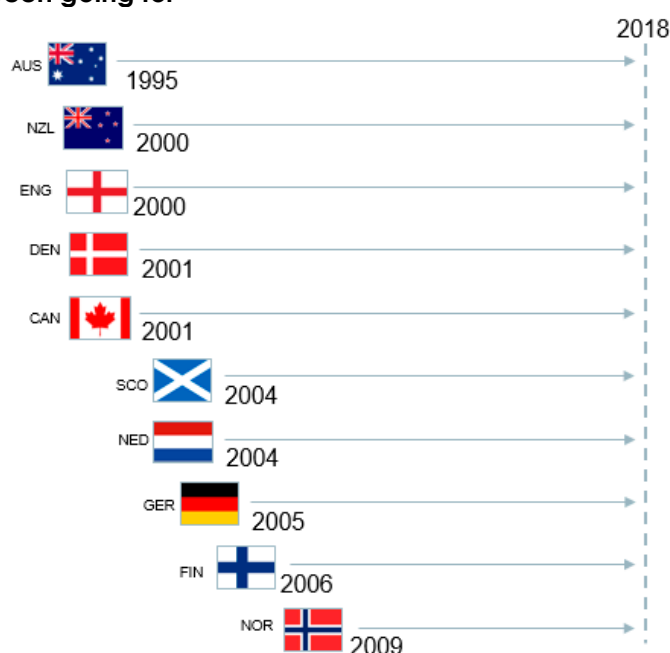
In Denmark, patient safety has been an important political issue in the past and, because of this, patient safety became an area on which there was a lot of focus. In recent years, patient safety has been given lower priority on the political agenda, despite the fact that important challenges remain. The variable attention from a political point of view is seen as an important reason why an independent organisation is needed to create continuity and to drive national patient safety work.

In Finland, extensive reform work is currently underway, including regionalisation of the healthcare system. The restructuring impacts patient safety work, in that the distribution of roles and responsibilities between the various national actors in patient safety work is somewhat unclear, among other things. This has resulted in the patient safety work slowing down.

Patient safety work in the surveyed countries has been active over the past two decades

In most of the surveyed countries, comprehensive patient safety work started at the beginning of the 2000s, see Figure 8. This was often the result of patient safety being seen as an urgent development in healthcare. The publication of the book *"To Err is Human: Building a safer Health System"* (25) by the US organisation, Institute of Medicine, was highlighted by several interviewees as a strong contributor to the reason of the strong focus on patient safety and why many countries paid attention to the importance of working focused and systematically with patient safety issues.

Figure 9. Overview of how long the various countries' patient safety work has been going for



In both Australia and Canada, attention was drawn to a number of patient cases, where care incidents led to injury or even death, these were the starting point of national patient safety work in healthcare. In Australia, a specific commission was set up to lead patient safety and quality work in healthcare, while in Canada a national steering group was created to investigate what needed to be done. The work of the Canadian steering group resulted in, among other things, the formation of the independent organisation that still runs the national patient safety work today.

In Scotland, national patient safety work began as a result of an initiative of the non-profit British organisation, *"The Health Foundation"*. Within the framework of this initiative, which was launched in 2004, a range of improvement activities were carried out in the field of patient safety in different hospitals around the country. The efforts showed good results and the interest

in patient safety grew steadily. The initiative was the foundation of the “*Scottish Patient Safety Program*”, which is still active.

The actors that run national patient safety work vary

In the international analysis there are examples of countries where State actors run national patient safety work, and other countries where the work is run by independent organisations.

In Australia and New Zealand, patient safety work is run by State committees, known as commissions. These commissions are tasked with running improvement work in quality and patient safety and have a statutory requirement to report their work to the Government.

In England and Scotland, the national health service system is instead run by the Government (*National Health Services, NHS*), which is the driving force for increased quality and patient safety within healthcare and parts of welfare. Specific bodies within the NHS have then been given the task of carrying out and running that work. In Scotland, as mentioned earlier, many of the activities of national patient safety work have been gathered together in a special patient safety programme.

In several countries, such as Denmark, Canada and Germany, independent, non-profit organisations runs the national patient safety work. Their work is often aimed at coordinating patient safety work and gathering the different healthcare professionals involved to jointly design activities in the field of patient safety. The economic links between the organisations and the State are different in the surveyed countries, which in some ways also affects the work. In Canada, the stand-alone patient safety organisation is largely funded by State resources, which can be an explanation for the organisation's objectives being somewhat in line with Government priorities. In Germany, the patient safety organisation is largely funded by membership fees and donations, and therefore has a looser financial connection to the Government. The organisation, however, has formal support from the Government to conduct patient safety issues and cooperate with the Government in several improvement projects.

Regardless of the type of organisation that runs the work, it is clear that patient safety work is usually based on interaction between the different actors in a country, for example, through the formulation of common priorities and objectives for improved patient safety.

Different actors with different mandates are publishers of national patient safety work

In addition to the differences between the surveyed countries as regards the type of driving force in the field of patient safety, there are also different types of control methods used.

In some of the countries, the use of “hard” control tools such as regulations, laws and requirements is common. While in other countries, a “softer” regulatory approach is applied, for example through accreditation systems. There are also examples of countries where the driving organisation has a mainly supporting and motivating role, and where “governance” is done through the development of tools, advice and support programmes to help

healthcare providers to implement patient safety work. The latter is seen mainly in countries where an independent organisation drives the national patient safety work. See Figure 9 for an overview of the type of mandate that characterises the governance of the surveyed countries.

Figure 10. Overview of mandates for patient safety work in the various countries

<u>State actor consignor</u>		<u>Independent actor consignor</u>	
Country	Mandate	Country	Mandate
• Finland	→ • "Hard-regulating"	• Denmark	→ • "Supporting"
• England	→ • "Hard-regulating"	• Germany	→ • "Supporting"
• Norway	→ • "Soft-regulating"	• Netherlands	→ • "Supporting"
• Australia	→ • "Soft-regulating"	• Canada	→ • "Supporting"
• Scotland	→ • "Supporting"		
• New Zealand	→ • "Supporting"		

When it comes to State publishers of patient safety work, the harder control tools are sometimes used. Forms of this may vary. In England, for example, there are a number of requirements for quality and patient safety improvement in the contracts signed between the NHS and the care providers. In Finland, there is a statutory requirement that operations within healthcare should develop a quality management plan and how high patient safety should be ensured. At the same time, a State publisher does not require the exclusive use of hard control. In Scotland, where the patient safety work is also run by the NHS, the participation of healthcare providers in the State patient safety programme is completely voluntary. Here, control is instead by offering caregivers the opportunity to participate in various projects within the patient safety programme and thus contribute with support and motivation to implement the improvement work in patient safety.

The commission in Australia, which pursues the country's patient safety and quality work, lacks regulatory powers. However, the commission is responsible, together with the Government, for developing national regulations in quality and patient safety. As the regulations are binding on healthcare providers, the commission can be said to be conducting indirect governance. In other words, the commission is in a real sense a major influence on national patient safety work.

Since independent non-State organisations by their nature do not have a governing mandate, it is natural for these actors to use supporting and motivating tools. In Germany, the stand-alone patient safety organisation primarily works to develop recommendations on how to improve patient safety in certain thematic areas. These then serve as a support for caregivers to perform improvement work in the operations. In Denmark, the independent patient safety organisation works together with healthcare providers to implement improvement projects in specific areas.

A mix of the different control tools is advocated in the interviews by the representatives of almost all the countries. Support and softer methods that

motivate caregivers to work with patient safety should therefore be complemented by tighter regulation to ensure that the work is carried out.

Policy document structure

In a number of cases, the patient safety action plan is part of a comprehensive policy document

When analysing the policy documents and in interviews with representatives from the different countries, it becomes clear that patient safety is closely linked to the broader term of quality in healthcare. There are a number of examples where the studied policy document for patient safety is included as part of a more comprehensive quality document.

For example, England includes patient safety as one of nine focus areas within the national healthcare strategy for the country. These focus areas contain a number of priority areas with objectives and improvement measures. All focus areas are linked to an overall vision, which creates a clear link between the focus areas and means that patient safety is linked together with the other parts for quality improvement in healthcare.

Another example where the patient safety strategy is part of a broader national policy document is Scotland. In this context, the national strategy for quality in healthcare has chosen to highlight "*Safe care*" as one of three foundational factors for realising the overall objective of national quality work. The other two are "*Person-centred care*" and "*Effective care*". Each of the foundational factors is linked in the policy document to a quality ambition, which serves as a starting point for national quality work.

The New Zealand strategy document also outlines patient safety as one of the priority areas for quality development work within the country's healthcare system. The objectives of each priority area are linked here with the ambitions of a national healthcare strategy for the country, including through the "*Triple aim*" framework, among others. The framework illustrates that quality and patient safety work should be carried out at three different levels (individual, population and system level), thus also becoming the starting point for the implementation of the four priority areas of the strategy document.

Like New Zealand, Australia's strategy document has patient safety as one of four priority areas for connected measures work within healthcare. Patient safety is linked here with other areas of quality, such as collaboration with patients/consumers, support for health professionals and cost-effectiveness. In other words, patient safety is seen as one of several factors needed to realise the vision of creating high-quality and safe care.

The policy documents often have elements of both strategy and action plans – they do not always follow a clear or logical structure

In most of the policy documents examined there is no clear distinction between a strategy and an action plan. Most of the documents from the countries surveyed have long-term elements such as vision, mission and

priority areas (which usually form part of a strategy) combined with more short-term elements such as action proposals and activities (which are more classical elements of an action plan).

In many of the policy documents, the various elements are also structured unclearly, which means that a separate interpretation is required in order to understand which elements are meant to be the strategy plan and which the action plan. One example is the Danish policy document, which contains several elements and has elements of both a strategy and an action plan. However, it is not clear how the different elements of the strategy are related. For example, it does not show how the described mission relates to the overall vision or to the strategy. There are also four different role descriptions. These are difficult to clearly relate to the other parts of the strategy and it is difficult to place the different parts that make up the policy document into any form of hierarchical structure.











Germany's policy document is another example where the structure of the policy documents becomes difficult to follow. Like the Danish document, it contains different elements that are not clearly linked to each other. The document consists of three key words, a vision and a mission as well as seven different areas of work. The three key words are interpreted as independent parts of the strategy, without any clear link to the vision, mission or work areas described in the strategy document. In addition to the overall policy document, there are also 17 additional documents containing concrete proposals for action within various themes, which can therefore be considered as action plans. These are separate documents covering a wide range of areas, but without a clear link to the comprehensive strategy document.

There are different levels of recipients for the policy documents

Often, the policy document lacks a clear description of who is the primary beneficiary of the strategy or action plan. The analysis has therefore made an interpretation of who the intended recipient is. The interpretation has primarily been based on the nature of the measures proposed in the policy documents.

Figure 10 provides an overview of who the beneficiaries addressed by the various countries' governing documents are. In the Swedish context, "Micro level" refers to patients and healthcare professionals, "Meso level" refers to management at the caregiver level and "Macro level" the highest strategic management (Government/Health department).

Figure 11. Intended recipient level of the strategy or action plan in each country

Intended recipient level				
SCO		Micro	Meso	Macro
FIN		Micro	Meso	Macro
NZL		Micro	Meso	Macro
AUS		Micro	Meso	Macro
CAN		Micro	Meso	Macro
ENG			Meso	Macro
DEN			Meso	Macro
GER			Meso	
NOR			Meso	
NED			Meso	

All the policy documents that have been analysed regard, solely or among others, the Meso level. For most countries, the content of the policy document is relatively broadly intended for all three levels, i.e. Micro, Meso and Macro.

For example, the Australian policy document has content that affects all three recipient levels. In an interview with the representatives from Australia, this broad approach justified by the fact that the objectives and aspirations described in the strategic plan can only be realised by all key actors – patients, healthcare professionals, caregivers and policy makers – being involved in the work.

In the Netherlands, the document is instead directed exclusively at healthcare organisations, i.e. Meso level. This is because this level is seen as self-governing in the design and implementation of patient safety work. The content of the strategy therefore takes as its starting point the responsibility of caregivers and the type of activities that should be carried out at this level in order to improve patient safety.









In several of the countries, such as Canada and Germany, the studied policy document has been developed by an independent organisation and in these cases it is the organisation's own members that are the primary recipients. In both Canada and Germany, the strategic priorities and activities of the policy document have been developed in cooperation with key actors within the healthcare sector. The content has thus been anchored and accepted by leading healthcare actors, which has led to credibility and a proliferation of documents, like a national governing document. One drawback is that this may create some ambiguity, for example around the mandates of the policy documents. For example, in Canada and Germany, the publishers of the documents do not have a formal or regulatory mandate.

Large variations can be seen in the scope and design of the policy documents

The analysed policy documents differ in their range and format, see summary in Figure 11.

Figure 12. Overview of the scope and design of the policy documents

The scope and design of the policy document

AUS		Very concise (2 A4). Powerfully packaged. Effective communication is seen as a key factor in achieving the desired results
GER		Very concise (2 A4). Lacks visual elements. Thematic action plans vary in format and scope
NOR		Short-medium in length (20 A4). Text heavy but transparent. Complemented with user-friendly website
DEN		Short-medium in length (20 A4). Text heavy but with some visual elements.
FIN		Medium length (28 A4). Text heavy. Lacks visual elements. Has explanatory annexes.
CAN		Medium length (30 A4). Text heavy but transparent
NZL		Medium length (30 A4). Text heavy but some visual elements
SCO		Long (58 A4). Mix of text and visual elements.
ENG		Long (75 A4). Text heavy. Simplified version has been developed for the public
NED		Website that is user friendly, but only available in Dutch.

The most common is that the policy documents consist of relatively heavy continuous text of approximately 30 A4 pages. Some documents are only two pages long and there are also examples of those of up to 75 pages in length. Some of the documents include visual elements such as diagrams, structure trees and frameworks, which make the content more accessible.

Australia's policy documents stand out slightly. The content of the strategic plan has been packaged into a very concise but powerful presentation of two A4 pages, with a stated aim of being visually appealing to the reader and useful from a communicative perspective. At the same time, the concentrated format means that the content of the document is relatively comprehensive. For example, more detailed descriptions of the development, implementation and follow-up of the strategy must therefore be obtained from other supplementary documents.

Norway's format is also slightly different to the others. The Norwegian strategy document (about 20 pages) is complemented by a user-friendly website that contains concrete measures and thus can be considered as a form of action plan. For example, on the website, caregivers can easily click through to different priority areas and proposed measures for improved patient safety. In an interview with representatives from the "Pasientsikker-

hetsprogrammet”, this format is explained by an ambition to make the content more accessible and user-friendly for caregivers, thereby facilitating the implementation of the improvement measures.

The most common perspective on the policy documents is four to five years

Most of the policy documents examined have a timeframe of four to five years. Germany's policy document stands out in this respect; the overall strategy from 2012 spans a total of eight years. The only policy document with a shorter perspective than four years is that of England, which only applies for two years. However, the document is an extension of a previous five year plan.

In the vast majority of cases, the reason for the chosen time perspective for the policy document is not clear, and in interviews it becomes clear that decisions about time frames are usually not based on any deeper analysis.

There are some examples of where the duration of the policy document is justified on the basis of its content or prevailing context. In the Netherlands, the decision on the timeframe of the policy document (four years) was based on the assessment that this was sufficient time for the improvement measures contained in the document to be implemented, generate results and be evaluated in an appropriate way. The time frame of the Finnish patient security strategy (four years) was chosen on the basis that the strategy could run over the entire period during which reform and reorganisation of healthcare in the country was underway.

Several countries and organisations have a deliberate communication strategy linked to the policy documents

Interviewed representatives from most countries say that effective communication of strategies and action plans is a key factor in ensuring that the policy documents have an impact and achieve the desired results. However, only half of the countries state that they have or use specific communication strategies.

Several interviews emphasise that communication must be adapted to the recipients and culture of the country in order to have an impact. In Australia, there is a stated communication strategy based on reporting facts and complex information in a simple and concise way, in order to attract attention to patient safety issues. This is based on the fact that factual messages are judged to work better than slogans and logos in the Australian context. Great emphasis is also put into disseminating information – both to relevant actors and to the public – through digital channels and social media.






In Norway, a major focus has been placed on building a brand around patient safety work. Within the framework of the Norwegian patient safety programme, both a logo and a slogan have been developed, as well as icons for different priority areas. Information material is available to everyone to print and can be used by individual caregivers for communication purposes. This creates recognition of the patient safety programme, both in healthcare

professionals and patients, and is expected to contribute to a higher degree of attention to patient safety.

See figure 12 for examples of different logos and slogans that the countries have developed in order to communicate patient safety work.

Figure 13. Logos, slogans and other examples of communication materials

Examples of communication materials used in the different countries

	<p>The Norwegian patient safety program logo and slogan "I Trygge hender 24/7". These are used to create recognition of the program in healthcare activities.</p>
	<p>The Scottish patient safety program logo and slogan "Every person, every time". These are used to create recognition of the program in healthcare activities.</p>
	<p>The logo of a patient safety project run by the NHS in England. This is used on the website and all information material that is distributed during the project.</p>
	<p>The logo for the previous patient safety program in the Netherlands. This was used to create recognition for the program in hospitals.</p>
	<p>A framework that visualises the vision of the Australian Commission for Quality and Patient safety. The framework is used to summarise the ambitions of the Commission's work and make it more accessible to the public.</p>

Policy document content

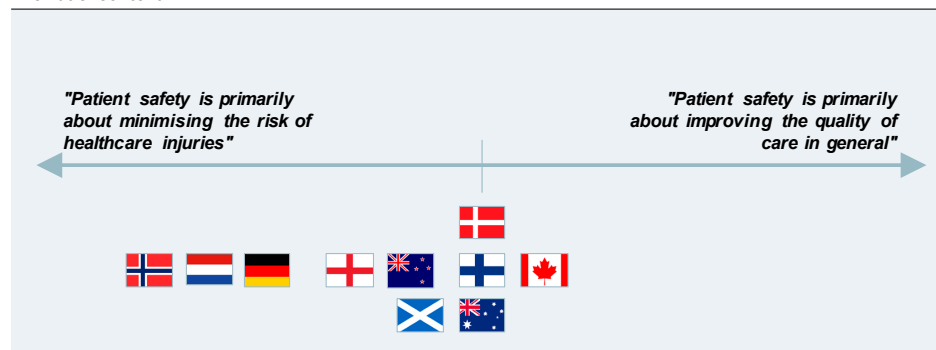
Most policy documents are based on a narrow definition of patient safety, but the quality perspective is highlighted

In general, the majority of the surveyed policy documents are based on narrow definition of patient safety – with objective formulations aimed at reducing the risk of healthcare-related injuries. However, some of the analysed policy documents have a greater element of general quality development. Figure 13 visualises a scale, at one end of which a "narrow" definition of patient safety is formulated (that patient safety is primarily about reducing the risk of adverse events) and the other end represents a broader definition (that patient safety is part of the quality work of care). The surveyed countries have been placed on this scale based on an overall assessment of how patient safety is defined in the policy documents. The analysis

is primarily based on the formulation of the objective descriptions in the documents, and the activities and actions described.

Figure 14. Distribution of countries based on focus on patient safety and overall quality

Thematic content



In Norway, the target description for the entire patient safety programme focuses on reducing healthcare related injuries, and the programme's prioritisation areas are characterised by reducing and preventing health care associated infections, pressure ulcers and fall accidents.

On the other hand, Canada's policy documents are an example of where the content is based on a relatively broad definition of patient safety. Among other things, both vision and mission are linked to safe healthcare rather than mere reduction of healthcare related injuries. The interviewed representatives from Canada confirm this image by emphasising that patient safety is not only the absence of injury but also the presence of safety.

There are also examples of where the policy document is based on a narrow definition of patient safety, but that through links to an overall vision it becomes clear that patient safety is considered to be closely interlinked with good quality of care. Examples of this are England and Scotland, where patient safety is part of an overall quality improvement policy. However, when it comes to descriptions of what should be done in the field of patient safety, the priority areas and actions relate primarily to minimising healthcare-related injuries.










Thematically, many policy documents are based on foundational areas and traditional outcome areas









A thematic division of patient safety areas that describes the work in the surveyed policy documents of the countries was carried out; outcome, foundational and risk areas⁴. For example, activities within the outcome area concern the reduction of health care associated infections and the reduction of medication related incidents. The most common activity within what is described as foundational areas is the training of managers and health professionals in improvement work. For risk areas, there are occasional

⁴The thematic division is explained in the method section.

examples of activities, such as the safe use of digital aids and medical devices.

Figure 15. Overview of the thematic content of the policy documents for the different countries

										
Vision										• Success
Objectives/Focus areas	• Success	• Success • Risk	• Success • Outcome	• Success	• Success • Outcome	• Success • Outcome	• Success • Outcome	• Success	• Outcome	• Success
Activities	• Success • Outcome • Risk	• Success • Outcome	• Outcome	• Success • Outcome	• Success • Outcome		• Success • Outcome	• Outcome	• Outcome	

										
Outcome areas	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Success areas	✓	✓	✓	✓	✓	✓	✓	✓		✓
Risk areas	✓	✓								

The thematic content of the respective countries' policy documents is visualised in figure 14. The top part of the figure describes which themes are contained in the policy documents' vision, focus areas and activities. The thematic areas included in the respective country's policy documents are summed up in the lower part of the table. A general conclusion is that, in principle, all analysed policy documents contain outcomes and foundational areas. A few countries also include risk areas.

The Finnish strategy has chosen to focus on foundational areas. One reason for this is, according to interviewed representatives, that the strategy document has a broad overall approach. The more detailed action plan to complement the strategy document is planned to include concrete outcomes to a greater extent.

When analysing and reviewing the content of the policy documents, it is noted that there are differences in the way in which work is described in each thematic area. For example, Norway's policy document contains a large number of activities in the classic outcome areas such as health care associated infections, medication treatment, pressure ulcers etc. They all relate to the sub-objectives in the strategy of reducing healthcare-related injuries. However, for the two objectives that highlight foundational areas in terms of improving patient safety culture and the creation of lasting structures for patient safety, only a few activities are described.

Representatives from international organisations reflect on the fact that many countries have so far been focused on outcomes, but that foundational areas are now becoming a major part of the work on patient safety. They advocate a focus on foundational areas, as it will contribute to the creation of more sustainable systems for long-term patient safety work by building

capacity for improvement work in the healthcare system. At the same time, interviewed representatives from a number of countries consider that outcome areas are also important to include in the policy document because results in these areas are measurable and therefore create good conditions for follow-up. The possibility of follow-up is considered a strong motivated factor for caregivers to work with patient safety, which is why methods for measuring both outcome areas and foundational areas are advocated, according to interviewed representatives of IHI.

There are several examples where the content of the action plan is based on a situational analysis

Interviewed representatives from both countries and organisations emphasise the importance of the development and updating of an action plan being preceded by a situation analysis in order to identify where the main challenges and needs are and what areas need priority.

In New Zealand, continuous analyses of variations in quality and patient safety are carried out. According to interviewed representatives, the results of these analyses contribute to formulating priority areas and activities in the field of patient safety. The results of the analyses can therefore be considered as the basis for identification of the high priority areas, such as hospital-acquired infections, fall accidents and medication related incidents mentioned in the priority area of patient safety in the policy document.

Another example is Norway, where gap analysis in the field of patient safety was carried out to identify areas with best potential for clinical improvement. The results of this analysis were then used as a starting point for selecting the priority areas outlined in the strategy.

Interviewed representatives from the OECD emphasise the value of conducting situation analysis on the basis that it is important to have knowledge of what activities are going on in the country, in order to ensure that the content of the national policy document complements the activities that are already carried out at regional level. If the activities at national and regional level are consistent, the conditions for better strategic governance and the possibility of achieving good results are improved.

Policy document processes

Most documents are reported to have been developed with a major element of anchoring among actors

All countries describe some form of involvement of the affected actors within healthcare in the process of developing the policy documents. Representatives from all countries and international organisations highlighted a broad and inclusive process for the preparation of the policy document as a foundational factor for the strategy or action plan to have an impact. However, the way in which this anchorage process has been seen varies between countries and between the policy documents, and various methods of including key actors have been used.











In Scotland, discussion forums were organised to obtain perspectives from caregivers, health professionals and patients/citizens. The citizens' views and priorities within the framework of quality and patient safety have since been taken into consideration in the formulation of the content of the policy document, in particular by summarising views of the six different priority themes that are tied to the overall objective.

In Australia, two qualitative studies were carried out to obtain perspectives from healthcare professionals and healthcare consumers (e.g. patients, relatives) for the development of the strategic plan. In one study, interviews were conducted with 34 focus groups comprising patients with different backgrounds and profiles. In the second study, several focus groups consisted of health professionals representatives from all over the country. The purpose of the studies was to identify respondents' perspectives on patient safety – which areas should be prioritised and what actions are requested from a national actor. The studies showed, among other things, the importance of adapted communication and readily available information, and that the commission for quality and safety should provide relevant knowledge, training as well as tools and resources for improvement work. In addition to an anchoring purpose, the studies also worked as a gap analysis to identify challenges in improvement work. The challenges raised were staff shortages and shortcomings in cooperation across organisational and operational boundaries.

The level of implementation varies between the different policy documents

The policy documents have also been analysed with regard to the level of detail in the description of the implementation and realisation of the policy document, see Figure 15. Most documents have a level of detail that is deemed to be "medium", which means that there is an overall description of proposed improvement measures or improvement projects, but that a clear description of how or when they are to be implemented is missing. In these cases, a self-interpretation is usually needed to get a concrete picture of the process. In a number of policy documents, only overarching objectives are defined without any description of implementation. Here the level of detail is assessed as "low". In some cases, a "main document" is supplemented by other documents detailing the implementation.

Figure 16. Overview of the recipient level and the level of detail for the description of implementation in the policy documents

Recipient level		Level of detail in the description of execution of the policy document		
		Low/execution not described	Medium	High
GER	 Meso	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FIN	 Makro; Meso; Mikro	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NED	 Meso	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SCO	 Makro; Meso ;Mikro	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
ENG	 Makro; Meso	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
AUS	 Makro; Meso; Mikro	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DAN	 Makro; Meso	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
NOR	 Meso	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
NZL	 Makro; Meso; Mikro	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
CAN	 Makro; Meso; Mikro	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

The Finnish strategy document contains only a comprehensive description of a number of sub-objectives and objectives, and a concrete description of the activities to be carried out in order to achieve these objectives is lacking. In the interview, it was stated that the policy document has been deliberately designed in this way; a complementary action plan is being developed, which will describe the implementation in detail.

The description of implementation in the Danish policy document is also quite sparse. The element of the description of implementation is mainly in the form of tables, where a number of different improvement projects to be implemented are listed. However, there is no description of what the projects include or how they are to be implemented.

In Canada's policy document, the description of the implementation is relatively detailed. The basis for this assessment is formed by a detailed description of several branches of activity, how activities within them are to be carried out and how they contribute to the achievement of the objectives.

As can be seen in figure 15, there is no clear correlation between the recipient level and the degree of detail, since policy documents with both a high and low level of detail are deemed to be appropriate for use at one level as well as at all three levels.

Follow-up is often highlighted as an important part, but it is difficult to get a picture of how the system and the process of this look

The interviews with representatives from international organisations highlight the need to develop better and more effective methods for following-up patient safety. By following up, developments in the area can be tracked and

it also contributes to learning about the actions that have an effect. There is a need for the development of both standardised measurement methods and relevant indicators. The OECD representative stressed the need for developed standardised measurement methods that can be used by all healthcare activities in the country and which also have the potential to generate comparable results between countries.

For the development of relevant follow-up indicators, indicators for follow-up in foundational and risk areas are called for. Increased opportunities for follow-up in foundational areas are considered to contribute both to increased knowledge of results and to the motivation of caregivers to work more closely with foundational areas. Predictive or proactive indicators in risk areas provide the possibility of measuring the risk of healthcare-related injuries instead of just measuring the injury that has already occurred. This would strengthen proactive patient safety work.

Need for development of patient reported measures in the follow-up is also highlighted. New Zealand is mentioned here as a good example; surveys are used to gather patients' perceptions and experiences of healthcare, and in this way deficiencies in patient safety are identified from the perspective of patients.

In the interviews, both with the representatives from countries and from the international organisations, there is a general view that follow-up is a key component of patient safety work. Nevertheless, only a few countries have a detailed description of the follow-up process in their patient safety policy document.

In Scotland, a framework for follow-up is included in the policy document. The framework includes twelve different indicators for following-up quality and patient safety, which can then be linked to desired outcomes and quality ambitions. The framework also shows how quality ambitions in turn lead to the achievement of the overall vision. Another example is Canada, where the analysed control document is complemented by a document that contains a description for the follow-up process. In the latter, a logic model is presented for how activities conducted by the patient safety organisation lead to different types of expected outcomes in patient safety and how they ultimately contribute to the Government's ultimate goals for healthcare in the country.

Policy document results

There is limited information about the effects the policy document has created

For all countries, it was difficult to find any kind of result that could be linked directly to the policy document in question. Most of the interviewed representatives point out that it is seldom possible to establish causality between a strategy or action plan and changed patient safety outcomes. The outcomes are influenced by a large number of factors, by several actors and parallel activities. The results presented in the field of patient safety in the

various countries are therefore usually based on the follow-up of individual activities, rather than on an evaluation of the strategy or the action plan itself.

In some countries, patient safety work has been evaluated in a structured way. One example is in Norway, where the patient safety programme was evaluated after being active for three years. The aim was to identify how employees in the healthcare sector felt that the programme had affected improvement work in patient safety. The evaluation was conducted with the help of interviews and questionnaires, and the respondents consisted of healthcare professionals from both hospitals and outpatient care. The results of this evaluation showed that a majority felt that the patient safety programme contributed to improved patient safety.

The independent organisation that operates the Canadian national patient safety work, regularly undergoes evaluation by an external party. The evaluation is based on an analysis of how well the organisation has fulfilled its delivery targets and whether the work carried out is relevant in relation to the current needs of the citizens of the country. The latest evaluation found that the organisation contributes to better patient safety in Canada and that there is a continued need for the organisation in the nationally coordinated patient safety work.

Lessons learned from the international analysis in preparation for a national action plan

Finally, there are some suggestions as to what is important to consider when creating a national action plan. The proposals are designed by the report author and are based on the lessons and insights from the international analysis and take the Swedish context into account. The chapter is divided into what is important to consider when (i) preparing for the introduction of the action plan, (ii) designing the action plan and (iii) at implementation of the action plan.

What is important to consider when preparing to develop the action plan?

Appoint a national actor, e.g. The National Board of Health and Welfare⁵, to organise and run the patient safety work and to bring clarity at all levels

Based on the analysis of the patient safety work in the various countries, it becomes clear that patient safety work needs to be coordinated at national level and that roles and assignments for different actors need to be clarified and refined. What is the division of responsibilities between the different actors at different levels? How does this division of responsibilities affect the impact of national patient safety work? How can these actors interact in the best way? This type of issue should be analysed and examined prior to the development of a national policy document in a Swedish context.

A clear and refined allocation of roles and assignments at national level is about creating sustainable conditions for guidance, support and governance in patient safety work, not least in terms of coordination of independent actors, in order to promote development and minimise obstacles to achieving successful results.

Develop the national action plan so that ongoing regional patient safety work is taken into account and supported in the best way

A wide range of activities for improved patient safety are carried out at regional and local level. One conclusion from the international analysis is that a national action plan needs to be created on the basis of the work that is already in progress and works well at regional and local level, and has the ambition to coordinate these activities in the best possible way. Unless this is

⁵ As described in the Government mandate (1)

done, there is a risk that caregivers will find it difficult to relate to the national action plan, which in turn risks reducing the impact of the action plan.

In order to ensure the design of a national action plan that is relevant to the regional (and ultimately local level), it is recommended to identify the regional action plans available today. What is the focus and content of the regional action plans available today? What does the process of development of these look like? How do they apply? Based on the mapping, a gap analysis can be made of how the action plan can best support regional work.

The mapping should also include the work that is done regionally, linked to the patient safety reports of the regions. An analysis should be made of appropriate methodological support that can support the development of patient safety reports that are integrated in and themselves support systematic patient safety work.

Another valuable lesson from the international analysis is that one cannot underestimate the value of clear, transparent and ongoing communication between national responsible actors and regional recipient levels.

A mixture of forms of governance is advocated

A general insight from the international analysis is that a mixture of both hard, soft and supportive control tools can usually complement each other and thus create good conditions for the desired impact. Therefore, a mixture of governance is advocated.

The management of patient safety work differs between countries and both hard, soft and supportive governance models can be observed. The differences can often be explained from the prevailing context. A conclusion is therefore that the chosen control model must be adapted to the structure of the healthcare system. For a control model that is characterised by a logical whole, an analysis should therefore be carried out of how different control tools – hard and soft – affect and complement each other in a Swedish context. As part of this, it is important to clarify the picture of what sort of control methods already exist, what policy documents are needed, and how these should interact with each other and with other control tools (such as legislation and regulations).

Against this backdrop, a national action plan can act as a cloak for existing governance, e.g. regulations, such as a national system for patient safety (including follow-up and evaluation), and/or as a summary of the support that the State is responsible for providing to healthcare providers in patient safety work.

What is important to consider when the action plan is designed and the content is determined?

Implement a broad and inclusive process for the development of the action plan

A key lesson from the analysis of the strategies/action plans is the need for a broad foundation of involved actors, including decision-makers, in the development of a national action plan. This is to ensure that there is a consensus among the actors in terms of the ambitions outlined in the action

plan and the prioritisation of what is to be done. If there is no consensus there is a risk that the action plan will lose its impact.

To ensure that the action plan is anchored, an inclusive process is proposed in the preparation of the action plan – that involves the relevant actors, including patients. This can be done in different ways, such as national discussion forums, workshops, survey studies etc. A focus during the development process should be to formulate common and concrete objectives for patient safety work, as this creates a clear picture for all involved actors of what is to be achieved in the implementation of the action plan.

Link the patient safety action plan with objectives and strategies for other quality work

Based on the international analysis, it becomes clear that patient safety is closely linked to other quality work. Patient safety is affected and thus affects the other components of healthcare quality such as efficiency, putting people at the centre, equality etc.

The national action plan needs to be linked to the other quality work that is taking place in the country, for example by ensuring that the objectives of the patient safety area coincide with the overall quality objectives for healthcare. One proposal is therefore for the national action plan to be linked to other quality work policy documents. This can be done by means of an overall vision or declaration of intent, for example by means of the already established Good care concept.

Ensure a clear link between the different parts of the action plan

A key lesson from the international analysis is that there are great advantages in establishing strategic governance, that is to say, governance based on an overall picture, where all the elements are connected in a clear way.

The National Board of Health and Welfare will most probably need to develop a policy document combining elements of strategies and action plans. Division of the elements that are more long-term and indicative, from the elements that more directly and concretely describe what is to be achieved needs to be clarified. In the development of the Swedish action plan, it will therefore be important to create a clear and logical link between the various parts of the action plan – with vision, objectives and priority areas that are connected with more concrete activities. This type of approach is also open to more comprehensive follow-up; where conclusions are made as to whether the actions contribute to overall objective attainment can be drawn by examining the outcome at operational level.

The primary recipients of the action plan should be clarified - preferably national and regional level

Based on the findings and results of the international analysis, it is necessary to indicate who will be the primary recipient of the action plan. Otherwise, there is a risk that there will be ambiguity about responsibilities and roles. In the Swedish context, the national framework for patient safety is often highlighted as a good example of where recipients and associated responsibility have been clarified.

The action plan intends to address the national and regional level because it requires the involvement of higher decision-making levels in order to create the right conditions for the implementation of the action plan. Measures at this level can be considered to lay the foundations for more sustainable and long-term patient safety work throughout the system and thus increase the impact of the action plan.

The content of the action plan must focus on the most pressing challenges and where the needs are greatest

An analysis of needs and challenges helps to focus the content of the action plan on the objectives and activities that can contribute to the improvement of the most vulnerable areas in the field of patient safety. The analysis can also help to identify what is already being done in the field of patient safety and thus can also be seen as part of the anchoring process with the regional actors. On this basis, the national action plan can be designed in a way that complements regional activities.

The implementation of in-depth situation analyses of selected areas is therefore key – to ensure that the content is relevant, that the document obtains legitimacy and support for national improvement work, and to increase the chances of successful outcomes. One suggestion is that the focus and content of a Swedish action plan is based on results from analyses of needs, challenges and gaps.

Combine different thematic areas of the action plan

All in all, it emphasises the importance of highlighting foundational areas such as leadership, learning and safety culture to a greater degree than has been done so far. The assessment is that these areas of improvement create the right conditions for sustainable patient safety, which in the long term results in patient safety outcomes, such as health care associated infections falling.

However, a greater focus on foundational areas should not be interpreted as meaning that work in outcome areas is unimportant. Outcomes, such as health care associated infections and fall accidents, are still important areas of work. As they are concrete and measurable, the results can also be followed up more easily. Measurable results are motivating for caregivers and healthcare professionals, so these outcomes are an important part of maintaining patient safety work on the agenda.

A combination of different thematic starting points (for example, different foundational areas and outcome areas) in formulating vision and objectives and priority areas and activities in the national action plan should therefore be pursued.

Ensure that the time frame of the action plan is based on the activities and actions to be implemented

In many of the countries surveyed, the timeframe for the strategy/action plan is not rooted in any decision-making process based on analysis, which makes it harder to know when and how often results are to be followed up.

If the timeframe of the action plan is too short, there is a risk that proposed activities will not be available or that results will not be generated. If the

timeframe is too long, the risk is instead that the action plan cannot be adapted to changing conditions. A proposal is therefore that the timeframe of the national action plan should be chosen on the basis of an assessment of the time needed to carry out the improvement work and to be able to measure the results thereof.

What is important to consider in the introduction, implementation and follow-up of the action plan?

There needs to be a deliberate and adapted communication strategy for the action plan

Communication of the action plan is considered to be key in order to disseminate the contents of the plan and thus achieve the desired impact.

A well-thought-out communication strategy should be adapted to the intended recipients of the action plan and based on the type of communication to which they are most susceptible. Targeted and tailored communication is therefore important in the anchoring and implementation of the content and dissemination of the Swedish action plan.

Ensure a clear description and support for the implementation of the action plan

In order to achieve the content of the action plan, there needs to be a clear description of how the work is to be carried out and which actor is responsible for what activities. If the implementation process is not concrete, there is a risk of non-compliance where the correct guidance is missing. If such a description does not appear in the policy document itself, it should be available in other documentation, preferably in an educational and target group adapted manner.

A clear description of the implementation should also be complemented by support for the implementation of the action plan, for example in the form of process, knowledge or methodological support. Based on the observations of the international analysis, it is considered important that there is a national coordinating organisation to continuously support the implementation of patient safety work in order to achieve greater impact for the action plan.

Describe the follow-up process for the action plan through a logical structure between the different parts

Causality between policy documents and patient safety outcomes can rarely be determined because many different activities and factors affect patient safety.

It is therefore important to ensure the possibility of following-up how activities in the action plan contribute to the objectives set, which, in turn, contribute to the achievement of the overall target image. One way to ensure the possibility of this type of follow-up is to create a logical link between activities, objectives and vision. It is also important to link the activities to objective and process indicators so that continuous follow-up can be carried out.

Develop relevant indicators for follow-up

Patient safety outcomes need to be followed-up with standardised measurement methods (which can ensure comparable results between different types of activities and different parts of the country) and should be based on patient safety indicators that are relevant. An area of development within follow-up is creating indicators within the foundational areas, as well as predictive indicators that measure the risk of adverse event. This is present both in the international analysis interviews and when the Swedish experts are consulted.

Developed follow-up opportunities also enable feedback of results in the field of patient safety to caregivers. This increases knowledge and creates motivation to continue developing the field of patient safety. It also enables identification of areas in need of improvement, which can, among other things, be the basis for gap analysis and the ongoing adaptation of the action plan.

References

1. Regeringsbeslut I:3, 2018-07-12 S2018/04111/FS (delvis).
2. Regeringsbeslut I:1, 2019-10-31, S2019/04518/FS.
3. Vad säger vårdgivarnas patientsäkerhetsberättelser om utvecklingen på patientsäkerhetsområdet? Socialstyrelsen; 2018.
4. Socialstyrelsen. Hälso- och sjukvårdens ansvar. Retrieved 2019-06-11 from: <https://patientsakerhet.socialstyrelsen.se/om-en-patient-drabbas/rapportera-och-anmala/halso-och-sjukvardens-ansvar>.
5. Wennergren, G. Fyra dödande injektioner ledde fram till Lex Maria. Läkartidningen 2005;102(4):242-43.
6. Socialstyrelsen. Lex Sarah. Retrieved 2019-11-15 from <https://www.socialstyrelsen.se/lexsarah>.
7. Patientsäkerhetslag (2010:659).
8. Patientsäkerhet - Vad har gjorts? Vad behöver göras? (SOU 2008:117).
9. Socialstyrelsens föreskrifter om ledningssystem för kvalitet och patientsäkerhet i hälso- och sjukvården (SOSFS 2005:12).
10. Socialstyrelsens föreskrifter om allmänna råd om kvalitet i verksamhet enligt SoL, LVU, LVM och LSS (SOSFS 2006:11).
11. Socialstyrelsens ledningssystem för systematiskt kvalitetsarbete (SOSFS 2011:9).
12. Socialstyrelsen. Retrieved 2018-11-07 from: <https://patientsakerhet.socialstyrelsen.se/>.
13. Nationella indikatorer för God vård. Socialstyrelsen; 2009. <https://www.socialstyrelsen.se/Lists/Artikelkatalog/Attachments/17797/2009-11-5.pdf>.
14. Handbok för utveckling av indikatorer för god vård och omsorg. Socialstyrelsen; 2017. <https://www.socialstyrelsen.se/Lists/Artikelkatalog/Attachments/20626/2017-5-19.pdf>.

15. Patientsäkerhetssatsning 2014 - överenskommelse mellan staten och Sveriges Kommuner och Landsting om förbättrad patientsäkerhet. Sveriges Kommuner och Regioner, Regeringen; 2013.
16. På väg mot en säkrare vård - Patientsäkerhetssatsningen 2011-2014. Sveriges Kommuner och Regioner; 2015.
17. Lägesrapport inom patientsäkerhetsområdet 2014. Socialstyrelsen; 2014.
18. Förslag till nationell strategi för ökad patientsäkerhet. Socialstyrelsen; 2012.
19. Nationellt ramverk för patientsäkerhet. Sveriges Kommuner och Landsting; 2015.
20. Etableringen av en sammanhållen struktur för kunskapsstyrning - hälso- och sjukvård. Sveriges Kommuner och Regioner; 2017.
21. Region Jönköpings län. Patientsäkerhet. Retrieved 2018-10-10 from <https://plus.rjl.se/infopage.jsf?nodeId=43116>.
22. Region Östergötland. Patientsäkerhet - strategi och styrande dokument. Retrieved 2020-01-08 from <https://vardgivarwebb.regionostergotland.se/Startsida/Verksamheter/Regiondirektor/Ledningsstaben/Patientsakerhet/Strategi-och-styrande-dokument/>.
23. Västra Götalandsregionen. Patientsäkerhetsplan 2018. Retrieved 2020-01-08 from <https://alfresco.vgregion.se/alfresco/service/vgr/storage/node/content/workspace/SpacesStore/6278e560-9740-4831-9b01-7c5324fa1d9c/Patients%C3%A4kerhetsplan%202018%20fastst%C3%A4lld%20av%20HSS%20170927.pdf?a=false&guest=true>.
24. Västra Götalandsregionen. Riktlinjer för Patientsäkerhet 2018. Retrieved 2020-01-08 from <https://alfresco.vgregion.se/alfresco/service/vgr/storage/node/content/workspace/SpacesStore/331fb302-4c4e-44cf-8227-d226ec8465b5/Riktlinjer%20f%C3%B6r%20patients%C3%A4kerhet%202018.pdf?a=false&guest=true>.
25. To Err is Human: Building a Safer Health System. Institute of Medicine. Washington DC: The National Academic Press; 2000.
26. Institute for Health Metrics and Evaluation. IHME: Sweden. Retrieved 2020-01-08 from <http://www.healthdata.org/sweden>.
27. World Health Organization. Countries: Sweden. Retrieved 2020-01-08 from <https://www.who.int/countries/swe/en/>.

28. OECD. OECD.Stat: Health care quality indicators. Retrieved 2020-01-08 from <https://stats.oecd.org/Index.aspx?QueryId=51884>.

Appendix 1. Interviewed representatives of surveyed countries/organisations

Country/Organisation	Name of the interview-ee	Function
Norway	Anne-Grete Skjellanger	Head of Secretariat, Pasientsikkerhetsprogrammet
Denmark	Inge Kristensen	Director, Danske Selskab for Patientsikkerhed
Denmark	Lena Gravensen	Departmental head, Styrelsen for patientsikkerhed
Finland	Taina Mäntyranta	Secretary-General of the Ministry of Social Affairs and Health
Finland	Outi Lyytikäinen	Professor, National Institute for Health and Welfare (THL)
Germany	Ilona Köster-Steinebach	Manager, Aktionsbündnis Patientensicherheit
Australia	Nonnie Oldham	CEO, Australian Commission on Safety and Quality
New Zealand	Janice Wilson	Chief executive, Health Quality and Safety Commission
Canada	Sandi Kossey and Markiit Armutlu	Senior Director and Senior Program Manager, Canadian Patient Safety Institute
England	Mike Durkin	Senior adviser on Patient Safety Policy and Leadership, Institute of Global Health Innovation, Imperial College London
Scotland	Joanne Matthews	Head of Safety, IHUB
Netherlands	Cordula Wagner	Executive Director/Professor of patient safety, NIVEL
WHO	Simon Feldbaek Peitersen	Consultant on patient safety
OECD	Ane Aaraaen	Health Policy Analysis
IHI	Tejal K. Gandhi	Chief Clinical and Safety Officer

Appendix 2. Interview guide – international analysis with focus on strategies/action plans in the field of patient safety

Short background

The Swedish Government has assigned the Swedish National Board of Health and Welfare (welfare) the task of developing a National action plan for increased patient safety. In preparation for this, the Board is conducting a worldwide analysis focusing on strategies/action plans regarding patient safety from other countries and organizations. An important part of this work is conducting interviews. The interviews aim, among other things, to increase our understanding of the prevailing context, the background to why the strategy or action plan was presented, the focus and content of the strategy/action plan etc.

We have tentatively identified your [INSERT NAME OF STRATEGY/ACTIONPLAN] as the most central strategy/action-plan-document, and the interview will thus mostly focus on this.

[Ask if the respondent has any questions about the project, process or interview before we begin]

Initial questions

- 1. Please tell us briefly about your background, current function and the organization that you represent**

Questions about context (patient safety work in general, motives and background to the strategy etc.)

- 2. Can you please describe the ongoing patient safety work in your country and how this relates to the strategy/action plan that we are analysing** (for example, how long has the work been a national matter, Would you describe the work as successful)?
- 3. What was the background to why the strategy/action plan was developed? Can you describe the motive/motives** (For example was it developed as a part of a broader national initiative? Was it developed because of a particular analysis focused on needs, challenges etc.)?
- 4. Do you know if any specific economic management is linked to the national patient safety work (including the strategy/action plan)?**

In that case, how would you describe it (have any financial resources been earmarked for this matter for example, is the management effective and so on)?

Questions about structure

5. **Do you have any reflections regarding the structure of the strategy/action plan** (for example thoughts about its structural focus, such as the balance between high-level strategy and more operational action/plan, the chosen timeline etc.)?

Questions about content

6. **Do you have any reflections regarding the content of the strategy/action plan** (for example the selection of and focus on certain thematic areas, the level of detail and so on)?

Questions about processes

7. **What can you tell us about the process underlying the strategy/action plan** (would you describe it as inclusive? Was it formulated based on any prior strategies or action plans etc.)?
8. **Can you describe key processes linked to the strategy/action plan** (for example regarding implementation, monitoring/evaluation or communication)?

Questions about results

9. **Do you know if the strategy/action plan has been evaluated? If so, can you tell us anything about the conclusions?**
10. **How would you describe the impact of the strategy/action plan? Has it led to increased patient safety? If so, what explanation factors would you emphasize?**

Questions about lessons learned

11. **Based on your overall knowledge and experience, what lessons have you learned when it comes to developing a strategy/action plan for improved patient safety** (If you could redo the entire process what would you do differently, and what recommendations would you give the Swedish National Board of Health and Welfare in this matter)?

[Ask if the respondent has any other thoughts or reflections that he/she wants to present]

Appendix 3. Cooperation meeting on 19th November 2018: National Action Plan for Patient Safety

Participants in the meeting

Name	Authority/organisation
Fanny Bergman	Public Health Authority
Charlotte Asker Hagelberg	Swedish Medical Products Agency
Ewa Sunneborn	Health and Social Care Inspectorate (IVO)
Axel Ros	National Collaboration Group Patient Safety (NSG)
Charlotta Nelsson	NSG
Marga Brisman	NSG
Maria Omberg	NSG
Lilian Carlsson	MAS/MAR
Rikard Johansson	Almega
Mona Ahlberg	Patient Board
Gunilla K Nordström	Patient Board
Hans Rutberg	The Swedish Society of Medicine
Marion Lindh	Swedish Forum for Quality of care
Michael Soop	Formerly National Board of Health and Welfare
Anna Dahlgren	Karolinska Institutet
Rita Fernholm	Karolinska Institutet
Marita Danielsson	University of Linköping
Mirjam Ekstedt	Linnaeus University
Jonas Wrigstad	Lund University
Charlotta George	National Board of Health and Welfare
Carina Skoglund	National Board of Health and Welfare
Louise Djurberg	National Board of Health and Welfare
Urban Nylén	National Board of Health and Welfare
Jonas Lundberg	Lumell
Fahim Sharan	Lumell
Anna Alassaad	Lumell

Background, purpose and implementation of the meeting

An important part of the Government mandate that the National Board of Health and Welfare has in drawing up an action plan for patient safety, is to consult with authorities, principals and other affected actors in the field of patient safety. In the light of this, the National Board of Health and Welfare organises national meetings to which interested parties from a large number of organisations are invited.

The purpose of the meeting on 19th November was to convey preliminary results from the international analysis carried out during the autumn of 2018, with the aim of generating lessons in the work of developing a Swedish national patient safety action plan. Another important aim was to listen to the participants' perspectives on what the preliminary insights from the analysis meant for the continued work on the action plan.

The meeting was conducted in the form of a workshop where participants were given the results of the international analysis and then discussed, in groups, what is important in developing a Swedish action plan.

Appendix 4. Country Facts Sweden

Review Country Facts – Sweden

Figure 17. Summary of basic country facts (25), (26)



No clear trend can be seen in the patient safety indicators in Sweden

Analyses of available data from the OECD (see Figure 17 below) show no clear trend regarding Sweden's outcomes in the field of patient safety over time.

Figure 18. Comparison of patient safety indicators (OECD data) over time in Sweden (27)



Certain changes can be noted for some indicators. For example, the number of left behind foreign bodies during surgery has oscillated during the period 2009 to 2015. For the post-op pulmonary embolism and post-op deep vein

thrombosis indicators, there was a decrease in the number of cases up to 2012 respectively 2013, but thereafter the number of cases began to increase again.

The other indicators have been relatively stable over the past five years, with no signs of major changes.

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Three international organisations – gathered lessons

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Introduction

The international organisations, the Organisation for Economic Co-operation and Development (OECD), the World Health Organisation (WHO) and the Institute for Healthcare Improvement (IHI) are all key actors in global patient safety.

In the first part of this report, we have focused on briefly describing the work carried out by the organisations, and given some examples of activities they carry out in the field of patient safety. The following is a section where we describe observations from interviewed representatives from the organisations, regarding what they consider to be important improvement factors in the field of patient safety. These are mainly related to the parts of the analytical framework that deal with content and process.

In conclusion, our analysis of the international organisations aims to obtain a comprehensive picture of what is being done in the field of patient safety at the global level and to gain a better understanding of what would be useful to consider when developing a national action plan for patient safety in Sweden.

Figure 1. The three international organisations that have been analysed in this report



Description of the organisations investigated

Organisation for Economic Co-operation and Development (OECD)

The OECD promotes policies for economic and social development at a global level

The Organisation for Economic Co-operation and Development (OECD) was established in 1961 by 18 European countries and the United States and Canada. The aim was to strengthen global co-operation for economic and social development (1). Today, the OECD consists of a total of 36 member countries. The organisation also co-operates with non-member countries, including fast growing economies such as China, India, Indonesia, South-Africa and Brazil. Together, these countries account for 80% of world trade, which gives the OECD a significant role in conducting issues related to world economy challenges.

One of the organisation's core activities is to collect and analyse data reported by member countries. Data are collected on a wide range of topics, including education, migration, climate and health. The collected data are used in analyses that are presented to OECD committees, which consist of representatives from the member countries. This, in turn, culminates in proposals for measures, agreements and guidelines which the member countries can use to guide and inform policy decision-making processes.

The OECD's collection of data in the field of healthcare aims to support countries in developing high performing health care systems with good accessibility, efficiency and quality of care in areas such as public health, health inequalities, health spending pharmaceuticals and medical devices, and quality and outcomes of healthcare. The results of the work are gathered in publications – often including statistical comparisons between countries, as well as policy recommendations on how specific challenges can be addressed and improved across OECD countries.

In the field of patient safety, the OECD focuses on international measurement, comparison and policy analysis

Patient safety is an important part of the OECD's work on healthcare quality and outcomes. In collaboration with the WHO and the World Bank, the OECD produced in 2018 a report highlighting the paramount importance of safety and quality in the work towards achieving universal health coverage. Ensuring both quality and safety requires measurement and generation of information (2). The OECD has worked on developing international patient safety indicators has been conducted for over ten years, and has resulted in a suite of indicators (3) covering acute and primary care and aligned to the WHO Global Challenges on Patient Safety. Results are regularly reported by many of the member countries and are based on the respective country's own data sources. However, given the complexity of the current acute care indicator calculations

and variations in data quality across countries, comparisons of relative performance between countries should be made with caution. The interviewed OECD representative underlined the importance of these indicators in drawing attention to patient safety issues, rather than a means of direct international comparison and benchmarking (4). Ongoing work is now focussed on improving the action ability of the existing indicators, exploring alternative data sources and developing new indicators along the pathway of care (5).

In addition to work on the development of indicators, the OECD has in recent years increased its focus on patient safety policies. The OECD produced reports on the *Economics of Patient Safety* for the Global Ministerial Summits in Bonn and Tokyo (6; 7). One example is the report *"The economics of patient safety: strengthening a value-based approach to reducing patient harm at national level"* from 2017 (7). This outlines the results of an investigation into the economic burden and consequences of patient harm. The report shows that the treatment of patient harm accounts for approximately 15% of the total public hospital costs in the OECD member countries. The majority of the costs are the consequences of hospital-related infections, blood clots (deep venous thrombosis), pressure ulcers, medication errors, and incorrect or delayed diagnosis. Because many of these adverse events are avoidable, this means a huge waste of resources. The report also explored international experts' views on best practices for improving patient safety, highlighting a number of important interventions including preventive work, active involvement of caregivers and patients, building positive patient safety culture, establishing effective measurement and monitoring systems, as well as a clear vision and robust leadership at the highest national level. The report underlined the importance of a systematic approach to patient safety, covering the entire pathway of care, including primary care, acute care and long-term care in nursing homes and in the community.

In 2018, the patient safety in primary and ambulatory care was addressed in the report prepared by the OECD for the Global Ministerial Summit in Tokyo. The findings of this paper show that safety lapses in primary and ambulatory care are common. About half of the global burden of patient harm originates in primary and ambulatory care, and estimates suggest that nearly four out of ten patients experience safety issue(s) in their interaction with this setting. Safety lapses in primary and ambulatory care most often result in an increased need for care or hospitalisations. Available evidence estimates the direct costs of safety lapses – the additional tests, treatments and health care in primary and ambulatory care to be around 2.5% of total health expenditure. Safety lapses resulting in hospitalisations each year may count 6% of total hospital bed days and more than 7 million admissions in the OECD.

The report concludes that cohesive policies across all levels of the healthcare system are needed to improve patient safety in primary and ambulatory care settings. Underpinned by the implementation of an integrated information infrastructure ensuring access to informed care and empowering patients to be an active participant in their own treatment, patient safety and health system efficiency can be improved (6).

World Health Organisation (WHO)

The WHO works to create a healthier future for people around the world

The World Health Organisation (WHO) was established in 1948 by diplomats from different countries, in order to create an organisation for enhanced co-operation in the monitoring and spread of dangerous diseases in the world (8). Currently, the WHO has 194 member countries and more than 7000 employees working all over the world.

The organisation's website describes the overall objective: *"Building a better, healthier future for people all over the world"*. To achieve this objective, the WHO co-ordinates international health work, by providing leadership in health issues, designing a research agenda for health and disease, formulating norms and standards, developing ethical and evidence-based guidelines and policies, providing technical support and monitoring health status and health trends abroad.

The WHO's work focuses on a number of key areas:

- Healthcare systems in different countries
- Non-contagious diseases, such as cardiovascular disease, cancer, diabetes
- Contagious diseases such as HIV, tuberculosis and malaria
- Healthy living habits
- Preparedness, monitoring and response to disasters and emergencies in countries which endanger the health of the population
- Process and methodological support, such as legal support in the development of international agreements or communication support for the dissemination of certain health-related information.

A report describing the WHO's work program for the years 2019 to 2023 presents three different priorities for the organisation (9):

- Achieve universal health coverage – with the aim that one billion people will have access to public health insurance.
- Address health-related emergencies – with the aim of protecting one billion people from health-related emergencies.
- Promote better health for the population – with the aim that one billion people will experience better health and wellbeing.

The WHO is working to support the building of global patient safety work

From a patient safety perspective, the WHO has an important global role, mainly through the compilation of knowledge information and by contributing leadership, expertise and innovative solutions. Co-ordinating international leaders, experts, patients, community organisations, industry and other key actors enables global collaboration to improve patient safety and manage healthcare risks.

The WHO has formulated a vision, a mission and an approach to patient safety (10). The vision is *"A world where each patient receives safe medical care without the risk of injury. Every time, everywhere."* And the mission is

formulated as *"Enable sustainable improvements for patient safety and risk management, in order to avoid patient injuries"*. The approach for the work is to co-ordinate, disseminate and accelerate improvement measures for patient safety and risk management in healthcare.

Four different strategic approaches to improvement work in patient safety are mentioned:

- to contribute with global leadership and promote collaborations.
- to develop guidelines and tools, and build capacity.
- to involve patients and their families in creating safer healthcare.
- to measure and monitor improvements in the field of patient safety.

By working on these strategic approaches, the WHO wants to achieve improved patient safety with the reduction of risks and injuries in healthcare, better health outcomes, improved patient experience and reduced costs.

The strategic approaches are, in turn, concretely implemented through a number of defined activities. Below are some examples of activities within each strategic approach.

To contribute with global leadership and promote collaboration

- **Global Patient Safety Challenge.** The aim of this project is to get countries to work with a specific thematic area that is considered to be a major risk to patient safety. The WHO contributes with leadership and guidance, together with member countries, experts and other key actors, to develop and implement measures that will create an improvement in the specified thematic area. Examples of thematic areas for implemented "Patient Safety Challenges" are healthcare-related infections and patient safety risks associated with surgery. A third project was started in 2018, which has a focus on medication related injuries. The aim is to reduce serious, avoidable medication related injuries by 50 percent globally in five years.
- **Global Ministerial Summits on Patient Safety.** Together with Germany and the United Kingdom, the WHO organises annual international meetings, where health ministers, politicians, experts and representatives from other organisations can gather and discuss priorities in the field of patient safety. These meetings aim to put patient safety on the political agenda, as well as create a common picture on which areas of work need to be pursued to improve patient safety.

To develop guidelines and tools, and build capacity

- **Multi-Professional Patient Safety Curriculum Guide.** The WHO has developed a guide to support universities, colleges and institutions around the world to incorporate patient safety as a subject in the training of health professionals (e.g. dentists, doctors, midwives, nurses and pharmacists).

- **The WHO Surgical Safety Checklist.** A checklist for surgical procedures has been developed in order to increase patient safety in conjunction with surgery. The checklist should facilitate communication and collaboration between healthcare professionals during operations. Currently, the checklist is used throughout the world, and has been shown to help significantly reduce morbidity and mortality in the course of surgery.

To involve patients and their families in creating safer healthcare

- **Patient for Patient Safety.** This is a program aimed at increasing the involvement of patients in the process of creating safer care. The project started with a number of patients, who themselves had suffered a healthcare-related injury, gathered in workshops with representatives from the professions to share their experiences. This was done in order to increase the awareness of patient safety and to create a better understanding of how patients experience safety in healthcare. Regular workshops are organised, in which patient representatives, health professionals, managers/leaders and representatives from healthcare organisations and politics exchange experiences and knowledge about patient safety. In addition to increasing knowledge about patient safety, the program contributes to making patients active actors in shaping measures to improve patient safety in healthcare.

Measure and follow-up changes in results in the field of patient safety

- **Development of measurement and follow-up.** The WHO collaborates with other international organisations, such as the OECD, World Bank Group and Health Data Collaborative, in the development of tools for measuring patient safety and guiding information on how results in the field of patient safety can be followed and evaluated. The WHO's main objective is to develop methods for building information collection and dissemination infrastructures in order to enable monitoring and follow-up.

Global Action on Patient Safety

In a recent report, the WHO has described a number of priority areas within the global patient safety agenda (11). These include:

- Implementation of patient safety improvement measures in all parts of the healthcare system.
- Improve patient safety in primary care.
- Use evidence and knowledge from current research in formulating policies and measures in the field of patient safety.
- Increased involvement of patients, relatives and other societal actors in patient safety work.
- Ensure effective leadership and that healthcare professionals have the right skills in patient safety.

- Make information about abnormalities and patient safety deficiencies available through good reporting and learning systems.
- Use digital aids to improve patient safety, for example when reporting abnormalities, analysis of reported data, following-up improvement measures and training of health professionals.
- Work with patient safety culture in the healthcare system to create improvements at system-level.
- Co-ordinate patient safety work at global level, which creates the conditions for countries to share information and learn from each other in the field of patient safety.

The report also outlines the roles of key actors in global patient safety work. For example, it is mentioned that Governments/at Governmental level should provide political support and resources to implement the necessary measures in the field of patient safety in the healthcare system. Governments also have an important role in creating the conditions for co-ordination and co-operation between different actors in national patient safety work. The WHO's role is to work together with countries, international organisations and other experts and provide knowledge and support in the development of patient safety in the countries.

On the basis of the report, work is underway to develop resolutions in the field of patient safety. A draft resolution was recently drawn up by a number of countries (12).

Institute for Healthcare Improvement (IHI)

The IHI drives improvement work in healthcare worldwide

The US organisation Institute for Healthcare Improvement (IHI) was formed in 1991 with the aim of working for improvement of the healthcare system to minimise abnormalities, waste resources, late diagnosis and unnecessary costs (13). In the beginning, the focus was on the American healthcare system, but the organisation has grown in size and gained a great deal of influence over the global improvement efforts.

The IHI works with healthcare organisations and other countries to improve quality, patient safety and outcomes in healthcare – mainly through the implementation of improvement science. The guiding of IHI's work is their vision: *"Everyone has the best care and health possible"* and their mission *"Improve health and health care worldwide"* (14).

According to interviewed representatives of the IHI, the organisation has a unique position when it comes to building knowledge and competence in improvement work, for example through training courses and forums for knowledge exchange. Over the years, the IHI has also developed a number of different tools to drive and implement improvement work for increased quality in healthcare. One example is the theoretical framework "Triple Aim" (15). The framework describes three main objectives for improvement work: to improve patients' experience, to improve the health of the population and to reduce cost per person. Several healthcare organisations and countries have made use of this framework in the design of their own healthcare quality strategies.

The IHI works with capacity building with focus on patient safety

The IHI's work focuses on five key areas, of which patient safety is one. The formulated objective of patient safety is *"To advance a total systems approach to safety around the world. Together with like-minded health care leaders, organizations, practitioners, and patients, IHI drives innovative thinking and bold leaps forward that none of us could achieve on our own "* (16).

The patient safety work carried out by the IHI is primarily focused on:

- **Galvanizing the safety agenda:** In the United States, IHI is spearheading a multi-organizational initiative to create a national action plan for the prevention of harm in health care. IHI is also currently offering guidance on patient safety projects in Latin America, the Middle East, Africa, and Europe.
- **Engaging leadership in change:** IHI provides strategic guidance and innovative thinking to help leaders at all levels embrace, create, and implement tools and strategies that drive change.
- **Fostering cultures of safety:** IHI provides tactical tools and frameworks to assess safety culture, identify areas for improvement, and implement system-wide changes that affect culture.
- **Building skills:** IHI offers a range of programs to teach key safety and improvement skills at every level — from students to executives.

IHI has developed a variety of tools to support the improvement work in patient safety and that can be used by healthcare professionals. One example is the framework for improved patient safety at a system level (Figure 2) (17). The framework is based on two pillars: culture and learning systems. In turn, the pillars are made up of nine different areas of work for improved patient safety. The framework was published in the report *"A Framework for Safe, Reliable and Effective Care"*, where a more detailed description of the elements of the framework is also reported.

Figure 2. Visualisation of the IHI's framework for improving patient safety at system level (17)



Another tool is the Global Trigger Tool method for finding and measuring healthcare-related abnormalities (18). The method is based on journal review and the use has spread internationally. In Sweden, the method has been established in hospital care and also developed for psychiatry and home care and has also been tried in Sweden.

In addition to the development of tools and resources for improvement in the field of patient safety, the IHI has actively participated in the development of specific patient safety programs around the world (19). For example, the IHI collaborated with the UK charity organisation "The Health Foundation" to launch the "Safer Patients Initiative" project. This was a four-year program focusing on the implementation of a range of different quality improvement measures in inpatient care across the UK. Another example was the co-operation that began with the Scottish government in 2008, with the aim of designing the Scottish Patient Safety Program. This program is internationally recognised for having achieved good results in the field of patient safety in Scotland.

According to representatives of the IHI, the organisation is currently carrying out work to develop a national action plan for patient safety in the USA. The role of the IHI in this work is to co-ordinate diverse health care, policy, and regulatory organizations with the aim of developing an action plan that can co-ordinate the country's patient safety work. The aim is to finalise the action plan in 2019.

Overall observations and input - what content should a policy document focus on?

This section presents interviewed representatives of the respective organisation's own observations, input and viewpoints.

Observations and input from the OECD

Safety should be part of an overall strategy for quality

It is difficult to draw a distinct line between patient safety and quality. It is important, according to the representative, that patient safety be linked to other aspects of quality in healthcare in an overall national strategic approach. Increased patient safety is an end in itself, but the systems and processes involved can also contribute to higher quality of care more generally, including the effectiveness and responsiveness of care.

Patient safety should be extended to cover the entire pathway or continuum of care

Historically, there has been a major focus on measurement and management of harm. However, the interviewee believes that the approach should be extended to cover the entire continuum of care; including primary care and long-term care in nursing homes and the community. One example is pressure ulcers that can occur in patients who are in acute care, nursing home accommodation and in the community. A pressure ulcer developed in the community can result in the patient needing to be admitted to inpatient care. Whereas a pressure ulcer that occurs when the patient is hospitalised, may have consequences in terms of the need for stay in acute care longer and have implications for long term care after discharge.

The interviewee also raises some challenges associated with the identification of healthcare-related harm outside hospitals. Among other factors, the availability of data is limited, which reduces the possibility of measurement. Given only a few countries have the capacity to routinely collect nationally representative data (for example, the US) on long term care, with greater consideration now being given by the OECD to the potential use of data from periodic point prevalence studies for international comparisons.

Observations and input from the WHO

Patient safety should be more closely integrated into the operation

It is important to strive to integrate patient safety as part of the entire operation. Patient safety should therefore not be regarded as a separate entity, but as a natural part of quality work in healthcare. The ambition should be to have a "splash of patient safety" in all the activities carried out within the healthcare sector, rather than driving patient safety in the form of specific activities. The construction of a patient safety culture is therefore seen as central.

Success areas should serve as a thematic starting points

Patient safety culture is promoted by allowing patient safety work to be based on success areas, including by developing the right competencies, promoting good leadership, and ensuring transparency in the system that can contribute to learning from abnormalities in healthcare. The WHO organisation tries to support other countries in building capacity and learning systems by providing advice, tools and knowledge in the field of patient safety.

Observations and input from the IHI

Patient safety should be seen as a critical component of quality

The interviewed representative from the IHI stresses, as does the OECD respondent that patient safety should be seen as part of the greater quality concept and is linked to all the other components that are part of quality – such as equality, accessibility and efficiency. Patient safety should be seen as a fundamental part of all quality work.

The focus of the patient safety work to date has been on preventing physical harm. However, the concept of adverse events should be extended from only physical damage, to include emotional and financial damage (e.g. costs of patients' adverse events).

Success areas ("foundational areas") add a good foundation for improvement work

As mentioned earlier, the IHI conducts work to develop a new national action plan in the USA. According to the respondent for the IHI, the organisation in this work has chosen to focus on "foundational areas" that influence all other safety work. Four foundational areas have been defined for the new action plan:

1. leadership and culture
2. learning system
3. patient involvement
4. workforce and safety among staff.

By working with these foundational areas, the interviewed representative believes that improvements will be possible in many of the patient safety outcomes.

However, it is expected to be a challenge to have organisations shift their focus from carrying out specific projects in areas of outcomes, such as infections and fall accidents, to working with success areas from a more long-term perspective. As part of this work, the IHI tries to gather all the actors in the American healthcare system to create a common understanding and consensus on the benefits of working with foundational areas.

Overall observations and input - what should central processes for implementation look like?

This section presents interviewed representatives of the respective organisation's own observations, input and viewpoints.

Observations and input from the OECD

Important to ensure strategic alignment of patient safety governance at national and regional levels

In many health systems, there are gaps between activities carried out at national regional and local levels causing misalignment of efforts to improve safety. Often, this misalignment exists because the national level is not well linked to the regional level and/or the national strategy is difficult to follow for those working at regional and local levels. For example, patient safety outcome indicators used to guide at the national level (PE/DVT after surgery) can be aligned to more actionable process indicators at the local level (compression socks, anticoagulant therapy), but often this is not well formulated.

Strengthening the linkages between the national and regional level can provide better conditions for achieving good results at the local level whilst allowing processes of good governance at the national level.

Balance between performance accountability and a safety culture that promotes learning and improvement

Based on a series of country quality of care reviews, the OECD has noted that the management of patient safety differs significantly between countries. For example, in the UK it was observed that England has been more oriented to a form of governance which involves a greater levels of performance assessment and accountability from healthcare providers, while Scotland is more focussed on learning and quality improvement, with a supportive approach to caregivers regarding patient safety.

Interviewed representatives advocate a balance between the supporting (formative) function and more performance (summative) oriented governance function to achieve better results. Countries must therefore work to undo a culture based on blame and hesitancy to surface safety issues to instead build up a safety culture of credibility, transparency and mutual learning throughout the system.

Provide formal structures and processes for mutual learning between professionals and services across the system

There is a great potential in creating forums or other structures allowing actors from different parts of the country to learn from each other. There are many examples of where successful projects and good initiatives are being conducted within a region – other regions could also apply to avoid "reinventing the wheel". The respondent's view is that the organisations usually want to share their experiences, but that there are not always good opportunities to do so.

Patients experiences of safe care should inform the monitoring and management of patient safety programs

Patient safety can be strengthened by combining clinical and patient perspectives on safety. Patient involvement is an important tool for patient safety work, helping ensure safety measurement and improvement efforts are focussed on what is important to patients.

The respondent believes that the measurement and use of patients' experiences of safety deficiencies could be strengthened. The patients' views could therefore be used more widely to complement existing clinical indicators used today and provide an avenue for further insights into safety issues. Furthermore, the involvement of patients in the design of the activities to be carried out in the field should be encouraged.

Observations and input from the WHO

Patient safety work requires both knowledge of the system and a systematic approach

Those who are to carry out patient safety work must have good knowledge of the structure, processes and culture of their own organisation. Based on this knowledge, patient safety can then be built into the entire system. According to interviewed representatives, the implementation must then be systematic in order to achieve the best results.

Softer control is usually preferable; when tougher control is required, it should have a constructive approach

The WHO focuses on work to support and motivate other countries, organisations or operations to perform improvement work. The interviewed representative sees many benefits of this kind of softer control of patient safety work – where activities are encouraged to improve and develop.

According to the respondent, a good approach is to focus on learning structures, where individuals and organisations are given the opportunity to learn from mistakes and improve care on this basis. One of the WHO's patient safety activities is based on helping countries to create reporting and learning systems for abnormalities in healthcare.

However, the respondent stresses that there must also be systems of supervision and overall legislation to ensure patient safety. However, the approach to this should be transparent and constructive, rather than building on blame and punishment.

Patients should give their views on what patient safety means

The interviewed WHO representative, like the OECD representative, highlights patient involvement as a very important aspect of patient safety work. Furthermore, the respondent says that there are many people who talk about patient involvement, but that there is not so much in practice.

Patients should be involved in patient safety work to the same extent as other key interests – both by being involved in defining what is important in the field of patient safety, and to gain an understanding of what is expected of them in the process of improving patient safety. Both patient organisations and individual

patients should be involved in the work, and this should be done within all levels of healthcare.

An example of how the WHO works for more patient involvement is the organisation's project "Patient for Patient Safety" which is described earlier in the report.

Observations and input from the IHI

Common objectives are needed – particularly important in complex systems

The American context is given as an example of a system where there are a number of different actors at different levels and within different activities, all of which work individually with their own priority areas. In a complex system like this, common objectives for co-ordinating patient safety work are important.

According to the respondent, a national action plan can create opportunities for all actors to jointly gather around which areas need to be focused on and agree on how the activities should be co-ordinated, in order to achieve the best possible results.

Effective balance in governance is required

The interviewed representative of the IHI believes that there are some advantages to a system of direct governance – as long as it is in line with the right priorities.

In many cases, governance mechanisms, such as financial incentives or punishments (such as penalty payments), may cause healthcare providers to focus on key and priority areas. At the same time, such governance risks having the consequence that other important areas are neglected. The respondent therefore believes that there must be a balance in how much you control healthcare providers.

Capacity building is a prerequisite for sustainable change

A focus of the IHI's work is to build capacity for improvement work within different organisations and operations. According to the interviewed representative, capacity building lays the foundation for long-term improvement work, and that this is important at all different levels (micro, meso, macro) in healthcare.

Capacity building can, for example, be done by investing in education and training of health professionals in improvement work. The IHI oversees a certification program for healthcare professionals, where staff who meet a number of different knowledge requirements can be certified as evidence of sufficient competence in the field of patient safety. Another way is the exchange of knowledge at the national and international conferences and meetings that the IHI organises.

Overall observations and input - what should central processes for follow-up look like?

This section presents interviewed representatives of the respective organisation's own observations, input and viewpoints.

Observations and input from the OECD

Measurement and follow-up is a central focus area for the organisation's patient safety work

As mentioned earlier, measurement and follow-up is a major focus of the OECD's work, as this is considered key to improve patient safety. A continuous effort is being made to identify indicators that can adequately reflect patient safety.

According to the interviewed OECD representative, a challenge is linked to the follow-up that different countries measure and report data in different ways. This complicates comparisons. Against this background, the OECD representatives are keen to develop standardised methods for collecting and measuring data so that all healthcare organisations can measure data in a consistent manner. The OECD report "*Measuring Patient Safety - Opening the Black Box*" summarises the organisation's three necessary components for a system that measures patient safety (5)

1. Reporting of abnormalities in healthcare
2. Routine data collection
3. Patient reported data.

Patient reported measures are needed to get a holistic view of the results achieved

Interviewed OECD representatives believe that "objective" data needs to be supplemented with patient reported measurements, with a view to obtaining a better overall picture of patient safety work. A project is currently being conducted within the OECD to develop methods for patient reported data, consisting of questionnaires with specific questions.

More proactive/predictive analyses are needed in the field of patient safety

So far, much of the measurement in the field of patient safety is based on retrospective follow-up of different outcomes. Interviewed representatives from the OECD feel that greater emphasis should be put on predictive indicators that can be used to identify risks – and not just to measure adverse events that have already occurred. As a good example, patient safety organisations are being highlighted in the USA, who have begun to think along these lines.

Observations and input from the WHO

Follow-up can contribute to learning

The aim of follow-up is to create a basis for learning about problem areas related to patient safety. Data collection and analysis helps to create an image of the areas in need of improvement. This thereby gives the opportunity to focus the work.

The WHO uses data from studies and investigations to define the thematic areas in which the organisation is to work. The interviewee believes that data related to patient safety should be used in the same way, as a basis for understanding the thematic areas in which the patient safety work should be focused.

Patient safety outcomes must be monitored at several levels in order to establish an overall picture

It is important to follow up on patient safety outcomes at all levels – activity, regional and national level. This is to be able to get an overall picture of the development.

In addition to the value of getting an overall picture of all levels, it also emphasises the importance of getting an idea of possible regional variations as well as an understanding of why these variations occur. Results of this type of follow-up can then be used to gain political support for improving activities.

Observations and input from the IHI

The methods of measurement generally need to be improved, for example to be able to follow the foundational areas

Measurement methods for monitoring patient safety need to be improved generally. The IHI cooperates in this respect with other international organisations, such as the OECD and the WHO, to develop better methods of measurement in the field of patient safety.

Today, there are opportunities for follow-up, mainly in the areas of outcomes. A need to find ways to measure and monitor developments in foundational areas, such as leadership and patient safety culture, are mentioned. The interviewed representative also believes that predictive indicators, which measure risk rather than retrospective outcomes in the field of patient safety, need to be developed.

Follow-up can contribute to increased motivation as it opens up for comparisons between different actors

Being able to measure and follow up results is a strong motivational factor for caregivers to work with certain areas of improvement. This is because the results can open up comparisons between caregivers, which in turn drives the willingness to perform well (especially in an American context).

In view of this, the interviewed representative sees it as particularly important to develop good measurement methods for foundational areas, in order to encourage caregivers to want to work with these areas.

References

1. OECD. About the OECD. Retrieved 2020-01-20 from <http://www.oecd.org/about/>.
2. Delivering Quality Health Services: A Global Imperative. Geneva: OECD/WHO/World Bank Group; 2018.
3. Drösler S, Romano R, Wei L. Health Care Quality Indicators Project: Patient Safety Indicators Report 2009. Paris: OECD; 2009.
4. Health at a Glance 2017, OECD Indicators. Paris: OECD; 2017.
5. Measuring patient safety. Opening the black box. Paris: OECD; 2018.
6. Auraaen A, Slawomirski L, Klazinga N. The economics of patient safety in primary and ambulatory care. Paris: OECD; 2018.
7. Slawomirski L, Auraaen A, Klazinga N. The economics of patient safety : Strengthening a value-based approach to reducing patient harm at national level. Paris: OECD Health Working Papers; 2017(96).
8. The Global Guardian of Public Health. World Health Organization; 2016.
9. Draft thirteenth general programme of work, 2019-2023. World Health Organization; 2018.
10. Patient Safety: Making health care safer. World Health Organization; 2017.
11. Patient Safety: Global action on patient safety. 144th Session, provisional agenda item 6.6. World Health Organization; 2018.
12. Global action on patient safety, Draft resolution. 144th Session, Agenda item 6.6. World Health Organization; 2019.
13. Institute for Healthcare Improvement. History. Retrieved 2020-01-20 from <http://www.ihl.org/about/Pages/History.aspx>.
14. Institute for Healthcare Improvement. Vision, Mission and Values. Retrieved 2020-01-20 from <http://www.ihl.org/about/pages/ihivisionandvalues.aspx>.
15. Institute for Healthcare Improvement. The IHI Triple Aim. Retrieved 2020-01-20 from <http://www.ihl.org/Engage/Initiatives/TripleAim/Pages/default.aspx>.
16. Institute for Healthcare Improvement. Patient Safety - Overview. Retrieved 2020-01-20 from <http://www.ihl.org/Topics/PatientSafety/Pages/Overview.aspx>.

17. Frankel A, et al. A Framework for Safe, Reliable, and Effective Care. White Paper. Cambridge MA: Institute for Healthcare Improvement and Safe & Reliable Healthcare; 2017.
18. Griffin F, Resar R. IHI Global Trigger Tool for Measuring Adverse Events (Second Edition), IHI Innovation Series white paper. Cambridge MA: Institute for Healthcare Improvement; 2009.
19. Institute for Healthcare Improvement. IHI Timeline 2018. Retrieved 2020-01-20 from http://www.ihi.org/about/Documents/IHI_Timeline_2018.pdf.
20. Measuring Patient Safety - Opening the Black Box. OECD; 2018. <https://www.oecd.org/health/health-systems/Measuring-Patient-Safety-April-2018.pdf>.
21. Global Action on Patient Safety EXECUTIVE BOARD 144th session Agenda item 6.6. World Health Organization; 2019. http://apps.who.int/gb/ebwha/pdf_files/EB144/B144_CONF8Rev1-en.pdf.

Country Report Australia

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Introduction

In the analysis of Australia, we focus on the national organisation *Australian Commission on Safety and Quality in Health Care* (hereinafter referred to as the Commission) and their policy documents. The Commission is a Commonwealth entity, which in this context and in brief means that it is responsible for the federal work to improve quality and patient safety in healthcare. In 2014, the Commission published a comprehensive strategy paper, "Strategic Plan 2014 – 2019", for the direction and focus of the work. This document is the starting point for our analyses.

The analyses have been supplemented with information obtained in an interview with Commission representatives and other relevant information, including from other internal policy documents and from the Commission's website.

Below are our conclusions from the analyses carried out based on the applied analytical framework.

Figure 1. Strategic Plan 2014–2019




Description of the current context

In this section we describe more closely the contexts that characterize the policy documents in different ways. For example, this answers questions about the possible needs that form the basis of the policy document and what management of the healthcare system looks like.

Review country facts – Australia

Figure 2. Summary of basic country facts (1), (2)

Country facts	
Population (million)	24.1 (2016)
Average life expectancy (males/females, years)	80.5/84.6 (2016)
Child mortality (< 5 years old per 1000/births)	3.9 (2016)
Health care cost (% GDP)	9.45 (2015)



The Australian healthcare system is universal but can be supplemented by private insurance

The Australian healthcare system can be described as relatively complex and it is governed at three different levels: federal level, state and territories and local level. (3) The federal level is responsible, among other things, for allocating financial resources to the states and territories for the operation of healthcare. The federal level of government is also responsible for providing both primary care and pharmacies. However, the majority of the responsibility for the provision of healthcare is at state and territory level. The states and territories provide specialist care, paediatric dentistry and geriatric services. This care is funded by both federal, state and territory resources. At local level, different types of public health programs are being pursued, such as vaccination programmes.

Australia, like Sweden, has a universal healthcare system, but this is complemented by private insurance options. The taxpayer part – called Medicare – gives all citizens access to primary care and specialised hospital-based care. In addition, it is possible for individuals to take out supplementary private health insurance. The insurance offers greater choice for the patient as regards the issuer and provides faster access to non-emergency care. In 2016, almost half of the population subscribed to private health insurance. According to interviewed Commission representatives, the private sector is

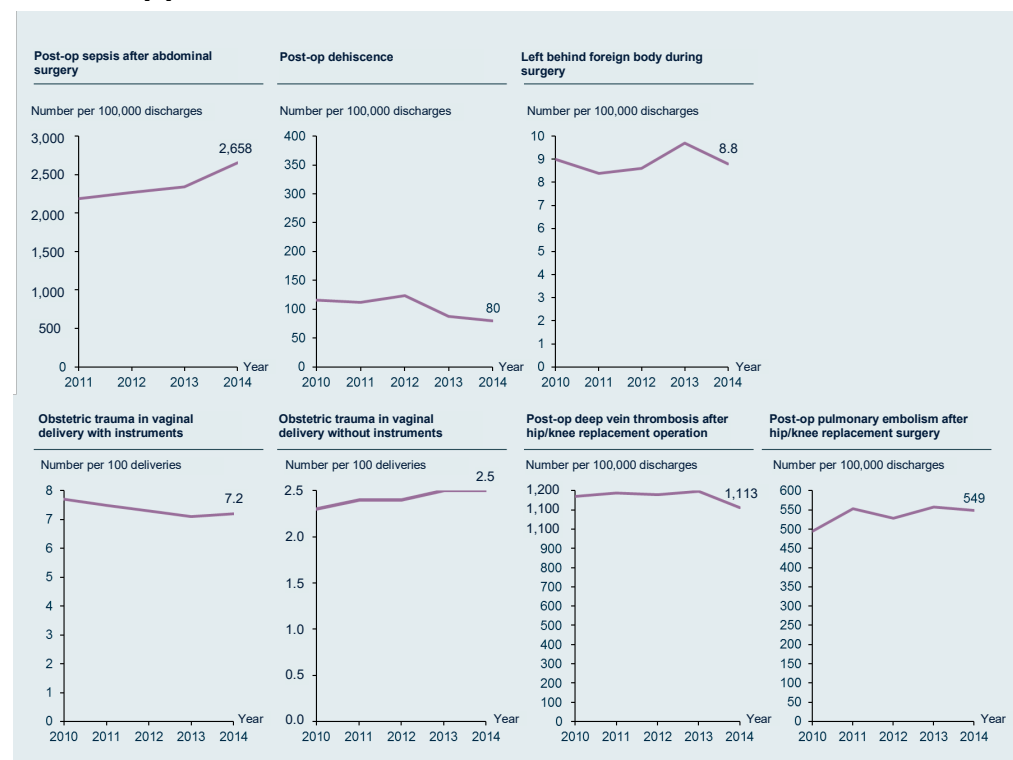
primarily focused on elective surgical treatment and the treatment of mental ill-health.

Small changes in patient safety outcomes over time

Analysis of available data from the OECD (see Figure 3 below) shows that Australia's outcomes in the field of patient safety have been relatively constant over the years studied.

Certain changes can be noted for some indicators. For example, post-operative sepsis after abdominal surgery increased slightly between 2011 and 2014. For the post-op dehiscence indicator, there has instead been a slight decrease (i.e. improvement); in 2010, there were nearly 120 cases of ruptures per 100,000 discharges and in 2014, this had dropped to 80.

Figure 3. Comparison of patient safety indicators (OECD data) over time in Australia (4)



National patient safety work goes back to 1995

A scientific study laid the foundation for the national improvement work with a focus on patient safety

In 1995, an Australian study was published that showed that incidents occurred in connection with nearly 17 percent of all hospital registrations (5). The results were widely recognised and, as early as 1999, it was decided at federal and territory level that nationally coordinated improvement work, including a focus on patient safety, would be introduced (6).

Against this backdrop, in 2000 a special Australian Council for Safety and Quality in Healthcare was established. The Council devoted itself to the

development of tools and guidelines and the organisation of national quality and safety work in healthcare. One of the Council's first tasks was to identify priority areas. The task was reported to the Ministry of Health by means of a national action plan ("National Action Plan") in 2000. The areas highlighted here were to work for: 1) more efficient data use in order to identify and prevent system errors; 2) better control system at clinic level; and 3) clear safety culture in healthcare. In summary, the priority areas were the basis for the Council's continued improvement work, and a number of programs and projects were initiated with the aim of improving the quality of care and patient safety.

In 2006 the Council was transformed into the National Commission on safety and quality

The Council for safety and quality was active in its original form until 2006. The government then decided that the work would be deepened and further developed. The Council was then transformed into the Australian Commission on Safety and Quality in Health Care (6). The Commission, which is still active today, has the main task of operating and working on important safety and quality issues at an overarching national level (7). It cooperates with a variety of actors such as patients, users, healthcare professionals, managers, caregivers, organisations and political management.

In 2010, for example, the Commission developed a national framework for safety and quality work in healthcare, and they publish ongoing reports that give a picture of the current situation and how the overall improvement work is going. As regards the organisation of Australia's public healthcare systems, the Commission's work does not include any focus on improving quality and patient safety in dental care or in the entire social services sector (only elderly care and care of people with disabilities).

The role of the Commission was changed by new legislation in 2011

The new legislation, the National Health Reform Act, entered into force in 2011 (8). The law aimed to increase cooperation between the federal government and the states and territories. With the amendment to the law, the Commission became a Commonwealth entity and it reports to the government. This includes the approval of a three-year work plan by the Minister responsible. The interviewed representatives describe the Commission as an unusual body whose activities are based on a harmonised approach to quality and safety.

*"We are an unusual body and it can be stated that we are **the heart of the government's approach** [...] We apply a harmonised approach with a focus on both **quality and safety** "
- Commission representative*

The Commission lacks regulatory powers, but it is responsible for the development and issuing of the equivalent of national regulations in the field of quality and patient safety (“National Safety and Quality Health Service Standards” NSQHS) (9). The regulations, which are binding, were drawn up by the Commission together with the federal government, state and territory co-operatives, patients (consumers) and representatives from the private sector. The purpose of these regulations is to protect the public from healthcare injuries and to improve the quality of healthcare. In addition to the binding regulations, since 2013 there has also been an accreditation system based on the quality objectives stipulated in the NSQHS. All caregivers, both public and private, must comply with the accreditation conditions in order to become accredited. If the healthcare provider does not meet the conditions, they have 90 days to try to comply with the quality objectives. If they do not succeed within this timeframe, the regional health department may take specific measures to ensure that fundamental patient safety requirements are met (10). The Commission's responsibility for regulations and accreditation systems means that, despite the lack of pronounced regulatory powers, they still have a relatively far-reaching mandate to steer and influence quality and patient safety within healthcare.

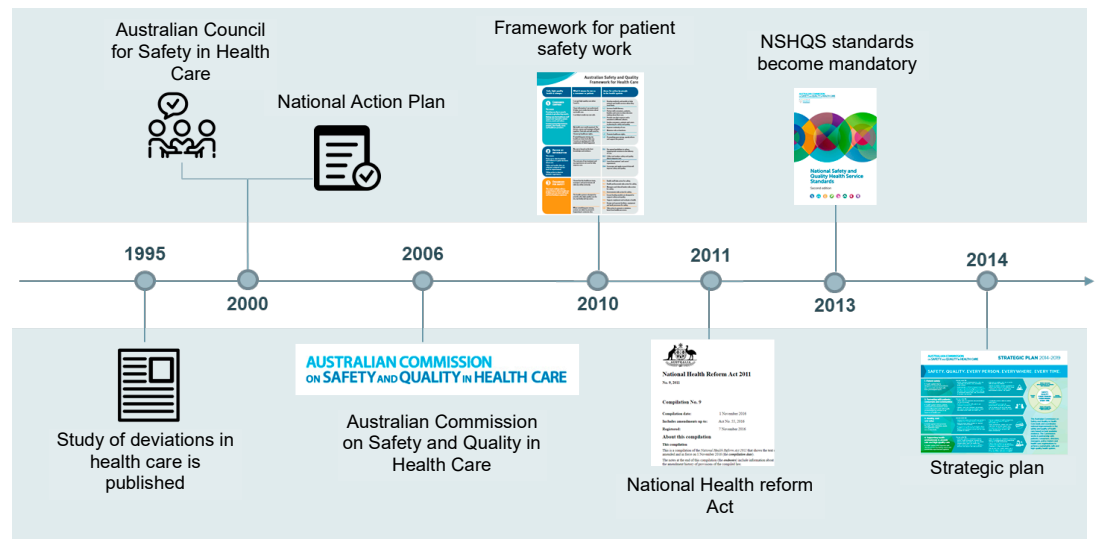
The Commission has developed a national strategic plan for improving quality and patient safety

In 2014, the Commission published a strategic plan for the period 2014 – 2019 (11). The strategic plan sets the direction for national improvement efforts with a focus on quality and patient safety. The plan, which briefly describes, among other things, ideal state and key focus areas, is the main subject of analysis in this country report. The analysis has also been supplemented, on the advice of interviewed Commission representatives, with information from the Commission's website and other internal annual policy documents, such as the Commission's work plan and the respective corporate plan (12). These documents almost exclusively describe the Commission's internal activities. Rather than specifying the direction of how improvement and change work must or should be done at lower, more operational levels.

Against this background, it was considered that in-depth analysis of these documents would not contribute to the relevant insights within the frame of this international analysis. Since the working and business plans largely describe certain key processes, such as implementation and follow-up, we are instead highlighting parts of its contents under the headings *"The description of implementation is limited in the policy document itself but appears in the Commission's Work Plan"* and *"The follow-up process is described in the Commission's Corporate plan"*.

In Figure 4, the development of patient safety work in Australia over time is visible and summarised.

Figure 4. Timeline of patient safety work in Australia.



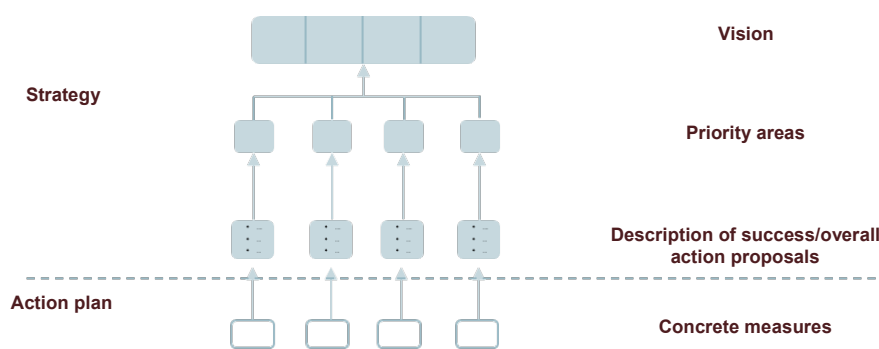
Policy document structure

This section describes the structure of the policy document. Questions about what parts the strategy plan consists of and the intended recipients are answered here. We also highlight the format of the documentation, i.e. whether they are comprehensive or summarised etc. Policy document here refers to the analysed document "Strategic Plan 2014 – 2019" (11).

The strategic plan can primarily be described as a strategy

Overall, the strategic plan consists of three parts: 1) a comprehensive vision including description of the intended long-term effects (as a result of the vision and the work of the Commission), 2) four thematic priority areas including objective description based on definitions of ideal state, 3) definitions of success in the respective priority areas, which indirectly provide a picture of planned overall activities. See visualisation of the structure of the policy document below in Figure 5.

Figure 5. Visualisation of the structure of the policy document.



Based on the above, the surveyed policy document can be described above all as a strategy. At the same time, it contains overall descriptions of planned activities, linked to the definitions of success. Based on this, the document can to some extent be seen as one strategy with certain elements that can be related to an overall action plan.

The strategic plan seems to be broadly in line with the Commission's work

It is not explicitly stated in the strategic plan who or what the main intended recipients are. At the same time it is expressly highlighted that the Commission is leading and coordinating the national improvement work with a focus on safety and quality. The strategic plan can therefore also, as mentioned earlier, be seen as the country's national policy document for improved

patient safety. It is also clear from the strategic plan that the Commission is working in partnership with a wide range of actors and interested parties such as patients, consumers, professions, management, decision-makers and caregivers. Furthermore, the content of the strategic plan (for more detailed review of the content of the policy document, see heading "Policy document content") is divided into four different areas that can be partly indirectly cut from a level perspective – from individual to system (micro/meso/macro). Based on this overall picture, we believe that the strategic plan is aimed at all individuals, functions and organisations that are directly or indirectly affected by the national improvement work with a focus on safety and quality. The broad cross-disciplinary approach of the strategic plan is also confirmed in the interviews conducted with Commission representatives. They clarify that the plan's ambitions can only be achieved in cooperation and through joint efforts with other key actors and bodies. Patients, healthcare professionals, caregivers, healthcare organisations, and the Government must also contribute to the work for objectives and priorities to be fulfilled.

*"The ambitions of the strategic plan **cannot be achieved solely by the Commission**, target fulfilment is also **dependent on other actors** in the health care sector **contributing to improvement work**"*

- Commission representative

The strategic plan can be described as concise and powerfully packaged, in an accessible format

In comparison with traditional policy documents of this kind, the examined strategic plan is brief. It consists of a total of two A4 pages, where the picture and text Interplay in a strategic way. The arrangement helps to clarify the main message of the document, without a large amount of body text.

Communication is seen as an important tool in achieving increased patient safety

According to interviewed Commission representatives, appropriate communication is a key factor in achieving the desired results. There is a well thought-out approach in order to ensure that relevant information is disseminated and communicated in a way that reaches the intended recipient. The interviewed representatives also emphasise that communication and dissemination of information within the relevant area concerned are challenging. This is not least because the group of recipients is both wide and varied, making it difficult to fully tailor the message and communication methods based on the needs and conditions of the group. A stated communication strategy mentioned by the interviewed representatives is to convey complex information in a simple and concise way, for example on one page. The Commission puts a relatively large amount of effort into communicating its principles in different channels, for example via social media. It also de-

scribes fact-based messages as a success factor in achieving the desired communicative impact. As an example, the representatives raise the value of highlighting the differences between different caregivers. The approach contributes to increased incentives for actors to push through improvement work. The Commission is generally stated as working continuously to develop its communication work, for example by analysing and evaluating selected methods.

The interviewed representatives also point to the value of consistently adapting the methods of communication to the prevailing cultural context. It is emphasised, for example, that more traditional marketing in terms of slogans, logos or similar would not lead to good results in Australia, because the approach is perceived to be contrary to national culture.

*"It is far too American to use **slogans etc.** It would **not work for us** because Australians would not react positively to it. They would rather have **factual messages**"*

- Commission representative

The selected strategy period is not based on thorough analysis

The policy document runs from 2014 to 2019 and so has a five-year timeframe. According to interviewed representatives, the timeframe was not chosen on the basis of a thorough analysis, but five years was considered a reasonable period of time in order to plan and carry out the activities linked to the content of the strategic plan.

Policy document content

In this section we report the content of the policy documents. For example, questions about the strategy's thematic focus or whether the content is based on a clear perspective are answered. We also describe the tangibility level in the policy document more closely. Policy document here refers to the analysed document "Strategic Plan 2014 – 2019" (11).

Four thematic priority areas form the basis of the strategic plan's content

The strategic plan defines the overall vision as: "*Safety. Quality. Every person. Everywhere. Every time.*" ("*Safety. Quality. Every person. Everywhere. Every time.*"). The vision also describes what can be interpreted as four intended long-term effects (as a result of the vision and the work of the Commission). These are:

- Increased sustainability
- Safety and quality systems enabling safe clinical activity
- Greater value
- Better patient and consumer outcomes and experiences

In the strategic plan, the vision is visible through a framework, see Figure 6.

Figure 6. The Commission's vision framework



As previously mentioned, four thematic priority areas are presented in the strategic plan. In the context of each area, ideal states are also described, which can also be interpreted to a certain extent as a target description. At the same time, the formulations reflect a *desired static condition rather than a*

desired change of condition, which means that they cannot be fully seen as complete objective formulations that are possible to follow-up.

The four thematic priority areas are:

1. **Patient Safety** – a healthcare system designed to reassure patients and consumers that they are protected from preventable injuries.
2. **Cooperation/partnerships with patients, consumers and society (communities)** – a healthcare system in which patients, consumers and other members of society, together with the care profession, are consistently involved as partners in care.
3. **Quality, cost and value** – a healthcare system that provides the right type of care, minimises waste of resources and optimises value and productivity.
4. **Support for health professionals with regard to the provision of safe and high quality care** – a healthcare system that supports safe clinical activity by having robust and sustainable improvement systems.

As mentioned above, the definition of success is described in the context of each priority area.

When it comes to the area of **patient safety**, success is defined as:

- That the quality objectives set out in the binding (or equivalent) National Safety and Quality Health Service Standards (NSQHS Standards) are to be implemented and followed in the field of emergency medical care, primary care and care and treatment of mental ill-health.
- That the introduction of NSQHS Standards leads to improved outcomes for patients and consumers in the areas of Hospital acquired infections (HAI), medication treatment incidents, avoidable clinical impairment of hand patients, fall accidents and incidents within psychiatric care in the form of a patient being separated or trapped.
- Increased attention and care for people with dementia or confusion.
- Introduction of monitoring systems for antibiotic prescription and antibiotic resistance.
- Agreement on a framework for improvement work in patient safety in primary care.

In the field of **cooperation/partnership with patients, consumers and society (communities)**, success is defined as:

- Patients' rights are respected and cooperation/partnerships in healthcare are encouraged.
- Healthcare sees patients and consumers as partners in the management of healthcare.
- Patients, consumers and healthcare professionals are given access to clear, personalised and evidence-based health and care information.
- Overall efforts are being made to address challenges linked to health literacy.
- All healthcare processes in the whole area are characterised by openness.
- End-of-life care responds to the needs of patients, families and caregivers/health professionals.

In the area of **quality, cost and value**, success is defined as:

- “Australian Atlases of Variation”(an annual report that compiles possible variations for healthcare in the country in different clinical areas) makes data on variations available.
- Reduction of unmotivated/unjustified variations, both in terms of treatment and the presence of certain illness conditions.
- Increased use of clinical knowledge data such as standards, guidelines and tools for "shared decision making" to increase the degree of effectiveness and the value of care.
- Tools that can be used by healthcare professionals, staff and consumers are available to support more appropriate care.
- Both healthcare professionals as well as patients and consumers use different types of decision support.
- An increased proportion of the population states that they are involved in decision-making by health professionals.

In the area of **support to healthcare professionals in the provision of safe and high quality care**, success is defined as:

- Integrated control systems are in place – systems that both support health professionals in measuring and conducting improvement work in patient safety at local level, and managing different types of safety and quality risks.
- The healthcare profession has access to guidance documents and tools that contribute to a safe clinical work.
- Safety and quality are seen and highlighted as key aspects of the healthcare profession's university degrees (both in basic and more advanced education).
- Patient safety incidents are noted, reported and analysed, and this information contributes to continuous system improvements.
- Safe and effective e-health systems are available, and these are used to improve coordination in healthcare in order to generate better outcomes for patients.

Possible activities are reported indirectly and at an overall level through the description of successful outcomes

As mentioned earlier, initially the first instance the strategic plan appears to be one strategy. This is because it highlights more long-term and general directions for national patient safety and quality assurance work.

At the same time, definitions of success are clearly described within the respective priority areas. To some extent, these descriptions give a picture of possible activities. In the context of the success descriptions of the "Patient safety" priority area, reference is made to the introduction of the Australian equivalent of the national regulations (i.e. NSQHS). The regulations contain, among other things, clear quality objectives and descriptions of activities to achieve them. Although from a governance perspective regulations cannot be compared with a national action plan, the chosen approach presents an

indirect picture of the improvement measures that can be taken to achieve the objectives of the strategic plan and ambitions.

The definition of patient safety used indicates a narrow and broad approach at the same time

Within the framework of the first priority area, "patient safety", the concept is defined indirectly by a description of the desired ideal state. Patient safety here relates to protection against avoidable healthcare-related injuries. In other words, the definition is relatively narrow and is similar to the approach of the Swedish Patient Safety Act.

That the plan and the Commission's work largely focus on safety are also confirmed in conducted interviews. At the same time, through the plan's descriptions of vision and other priority areas, it is clear that patient safety is seen as closely interlinked with good quality of care in a wider sense. Our interpretation is therefore that the document is characterised by both a parallel narrow and broad approach to patient safety.

The thematic emphasis is mainly on the areas of success and outcome

Overall, the strategic plan can be said to be characterised by a combination of success and outcome areas, particularly at the overall objective and focus area level.

The "Patient safety" priority area shows a clear focus on traditional outcome areas – both at the more comprehensive and at the somewhat more specific levels (describing successful outcomes). Examples of outcomes that are highlighted are "Health care associated infections (HAI)", "medication treatment errors" and "fall accidents".

For other priority areas, a clearer emphasis on success areas, such as "partnership between patients and profession", "good access to appropriate information" and "open and transparent processes" is consistently seen. To a limited extent, it also raises aspects which can be related (at least indirectly) to certain risk factors, such as "unjustified variations in treatment".

The plan's content is based on an analysis of challenges

According to interviewed representatives, the plan's focus and the Commission's work are based on an analysis of where the main challenges are.

*"We focus a lot **on safety aspects**, and the reason why we do this is simple – because this is where we see **the biggest shortfalls**. We **analyse** where the **main problems** are and **focus** on these areas until we reverse the negative development"*

- Commission representative

For example, thanks to the analyses, the prevalence of sepsis in healthcare is seen as a major problem and now efforts are being made to reduce the extent of this negative development. The interview emphasises that access to relevant and reliable data is particularly important in order to draw conclusions regarding which areas should be prioritised in national patient safety work.

Policy document processes

This section presents the central processes that can be linked to the strategy and the action plan. Examples of questions to be answered are whether the policy document was based on a particular process, for example through consultation or negotiation? Another important element is examining whether the policy document describes different central processes and in such cases what is included in them. Policy document here refers to the analysed document "Strategic Plan 2014 – 2019" (11).

The policy document has been developed based on a broad consultative process

The process of developing the strategic plan is not in the current document. On the other hand, relevant information regarding the development process is available on the Commission's website (13).

In conclusion, the strategic plan has been developed on the basis of a broad and inclusive process in which a variety of relevant representatives and actors have been given the opportunity to communicate the input values and viewpoints. Examples of the bodies, functions and persons involved in the work are national healthcare organisations, representatives from the care profession, citizens, patient and consumer representatives as well as the Commission's own staff. Descriptions of the consultation processes are available in two different reports: "Research Report: Consumer Research Regarding Safety and Quality in Healthcare" and "Strategic Planning: Report of focus groups and interviews with healthcare providers " (14) (15).

The first report presents the results of a qualitative study focusing on healthcare consumers' knowledge and attitudes towards safety and quality in healthcare (14). The survey was carried out with a view to producing a decision basis for the development of the strategic plan, with a particular focus on priority areas and their content. A total of 34 focus group interviews were conducted. The groups were divided according to different background factors such as gender, age, civil status, socio-economic status etc. In addition, special groups were added, including representatives from the indigenous peoples. Based on the results of the survey, the Commission received a picture of consumers' and patients' perspectives on key priority areas. Parts incorporated into the strategic plan based on the survey are the importance of efficient and adapted communication, easily accessible information, and a clean environment.

Interviewed representatives confirm the image that the patient perspective is generally a key part of all patient safety work. They also describe the fact that the Commission works with focus groups in several different contexts in order to obtain patients' perspectives on improvement areas and that this serves as a basis for change management. The respondents also highlight that the design of care based on the patients' perspective is one of the binding

quality objectives of the national regulations (NSQHS), which has made a real impression at caregiver level.

The second mentioned report, i.e. "Strategic Planning: Report of focus Groups and interviews with healthcare providers" was aimed at investigating caregivers and healthcare professionals' views on patient safety and quality in healthcare (15). This study was also used as a basis when the strategic plan was developed. A total of 52 focus group interviews were carried out with 350 healthcare professional representatives from all over the country. In summary, the results showed that quality is generally seen as an important aspect among healthcare professionals, but that there are some challenges that hamper the improvement work with a focus on quality and safety. Examples highlighted were staff shortages, communication gaps, limited engagement and cooperation difficulties across organisational and operational boundaries. There was a great deal of consensus among the participants that the link between the different parts of healthcare and the healthcare link with other community interventions needs to be strengthened. The participants pointed out that the Commission could contribute, among other things, by providing relevant information and knowledge, providing training assistance and using tools and resources.

The description of implementation is limited in the policy document itself but appears in the Commission's "Work plan"

Priority areas and activities are described in the Commission's "Work plan"

As mentioned earlier, a certain but relatively limited description of the possible activities in the context of the priority areas of the strategic plan is given. However, it is difficult to get an idea of concrete actions, programs or projects envisaged solely by taking part of the strategic plan's content. On the other hand, as mentioned earlier, the Commission must produce an annual work plan. The work plan serves as a central tool for the Commission's internal, short-term planning, and this is the basis for regular reporting of the Commission's work to the government. According to interviewed Commission representatives, this is drawn up on the basis of the structure and content of the strategic plan. The Commission shall report activities and delivery objectives for the next three years in the work plan, in accordance with government requirements.

The most recent version of the work plan for the period 2018 – 2021 (16) describes six different activity groups within the priority area "patient safety". These are:

- **NSQHS Standards:** In this area, the Commission will, in summary, continue to work with and support healthcare providers in the process of complying with national regulations for improved quality and patient safety.
- **Coordinate the accreditation system for healthcare at national level:** The Commission shall continue to assist in coordinating various actors,

such as regulators and accreditation agencies, in order to facilitate accreditation of caregivers. A reform of the accreditation system will also begin in 2018 – 19.

- **Nationally coordinated efforts to combat Health care associated infections (HAI) and antimicrobial resistance:** The Commission will continue to work at national level to prevent antimicrobial resistance and Health care associated infections (HAI) and to improve antibiotic prescription. The Commission has an ongoing project called "Antimicrobial Resistance and Antimicrobial Utilisation Surveillance Project (AURA)", which maps antibiotic prescription and antibiotic resistance at national level. In order to identify risks and prevent development of resistance. Based on the information collected from AURA, the Commission, together with the states, territories and the private sector, will develop improved guidelines in this area.
- **Safety in digital health:** The Commission will work to ensure that digital aids in healthcare, such as patient records, are used in different ways to increase patient safety. Digital tools can be improved in order to increase patient safety in drug treatment, for example, or when patients are moved between different parts of the care chain.
- **Patient safety in primary care:** Work to improve patient safety in primary care has been conducted since 2016. The Commission will continue this work by, for example, developing NSQHS Standards for primary care, support for implementing these regulations and tools for continued quality improvement.
- **Patient safety in emergency medical care:** The Commission will continue evaluating patient safety in emergency medical care and seek to identify areas where action needs to be taken at national level.

Each activity group contains multiple delivery objectives

Within each activity group, a number of delivery objectives are listed for the next three years (2018 – 2021). The objectives, for example, are formulated such that the Commission must produce handbooks for the application of national regulations (NSQHS Standards) in psychiatry, publish reports based on the AURA (Antimicrobial Resistance and Antimicrobial Utilisation Surveillance Project) project or produce a first draft for the equivalent of national safety and quality regulations for primary care etc. Delivery objectives are reported in tables per activity group, as shown in the example below.

Figure 7. Example of table that contains delivery objectives for the "NSQHS Standards" activity group.

Deliverables 2018-19	Deliverables 2019-20	Deliverables 2020-21
National Safety and Quality Health Service Standards		
18.1.1.1 Provide support for the implementation of the NSQHS Standards in health service organisations	19.1.1.1 Provide support for the implementation of the NSQHS Standards in health service organisations	20.1.1.1 Use metrics from the interactive resources and other data sources to maintain the effectiveness of NSQHS Standards implementation resources
18.1.1.2 Use metrics from the interactive resources to improve access and effectiveness of resources for the NSQHS Standards	19.1.1.2 Use metrics from the interactive resources and other data sources to continually review the existing resources and need for further implementation support for the NSQHS Standards	20.1.1.2 Monitor and update content of the interactive resource to ensure its currency and completeness
18.1.1.3 Expand content of the interactive resource to ensure its currency and completeness	19.1.1.3 Review and update content of the interactive resource to ensure its currency and completeness	20.1.1.3 Provide ongoing support for issues management of the NSQHS Standards via the Advice Centre and mediation services
18.1.1.4 Develop specialist resources and guidance for implementation of the NSQHS Standards including:		

The follow-up process is described in the Commission's "Corporate plan"

There are no descriptions of what the Commission's follow-up processes look like in the strategic plan. However, these processes are described in other internal policy documents such as in the Commission's annual Corporate plan (12). This shows, for example, that the Commission carries out regular performance analysis on the basis of the set delivery objectives (included in the annual work plan). In addition, individual projects and actions are followed-up separately. For example, in May 2018, an effective evaluation was published, focusing on the introduction of the equivalent of national regulations in the area of quality and patient safety (NSQHS Standards) (17). The Commission also examines the extent to which their work corresponds to the needs of different key actors on a regular basis. This analysis is done through consultations with relevant actors and feedback from the consultative groups of the Commission.

In addition to the above, the Commission is required by law to publish annual reports to the Minister of Health. The outcome reports summarise the level of target attainment within the respective priority areas contained in the strategic plan (18). In other words, the description gives a picture of how well the Commission has lived up to its commitments during the past year. The progress made in the implementation and adherence to national regulations in the context of the first priority area, namely "patient safety", is highlighted for example.

The Commission also works to develop national indicators in various fields that concern patient safety and quality (19). Examples of available indicators are preventable readmissions as well as hospital-related complications, such as infections associated with surgery and fall accidents resulting

in fractures and pressure sores. There are also defined indicators for measuring overall quality and safety in hospitals (Core, Hospital-based Outcome Indicators) (20). These include:

- Standardised hospital mortality (HSMR).
- Mortality in diagnosis groups with low mortality (DRG).
- Hospital mortality for acute myocardial infarction, stroke, neck of femur fracture and pneumonia.
- Unexpected readmission of patients who have been discharged after acute myocardial infarction, knee replacement surgery, hip prosthesis surgery and children who have undergone surgery to remove tonsils and glands.
- Healthcare-related infection caused by the bacterium *Staphylococcus aureus*.
- Infection caused by the *Clostridium Difficile* bacterium.

It is also apparent from the website that the Commission has produced forms/surveys to be able to identify patient experiences in healthcare (21).

Policy document results

The results of the policy document are presented below. Examples of questions to be answered are whether good results can be linked directly to the policy document or more to the governance or organisation at large? Policy document here refers to the analysed document "Strategic Plan 2014 – 2019" (11).

The annual reports indicate that good results have been achieved

Results reflecting how well the Commission has met the delivery objectives from the last working plan have not yet been published. However, some of the results of the work done to achieve the objectives of the strategic plan in the latest annual report (2017 – 2018) are outlined to the Ministry of Health (18). In the field of patient safety, progress has been made – progress that can be linked to activities within the framework of the success definitions highlighted in the strategic plan. Below are examples of good results achieved in the respective success description.

Figure 8. Results regarding the introduction of NSQHS Standards

“The quality objectives set out in the binding regulations (NSQHS) are to be implemented and followed in the field of emergency medical care, primary care and health care/treatment for mental ill-health”

Summary of results achieved based on the success description of the strategic plan

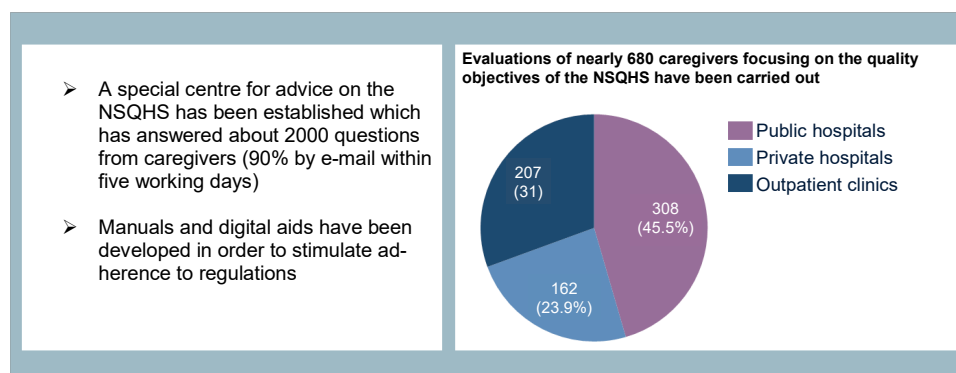


Figure 9. Results regarding the effect of the introduction of NSQHS Standards

“The introduction of NSQHS Standards leads to improved outcomes for patients and consumers”

Summary of results achieved based on the success description of the strategic plan

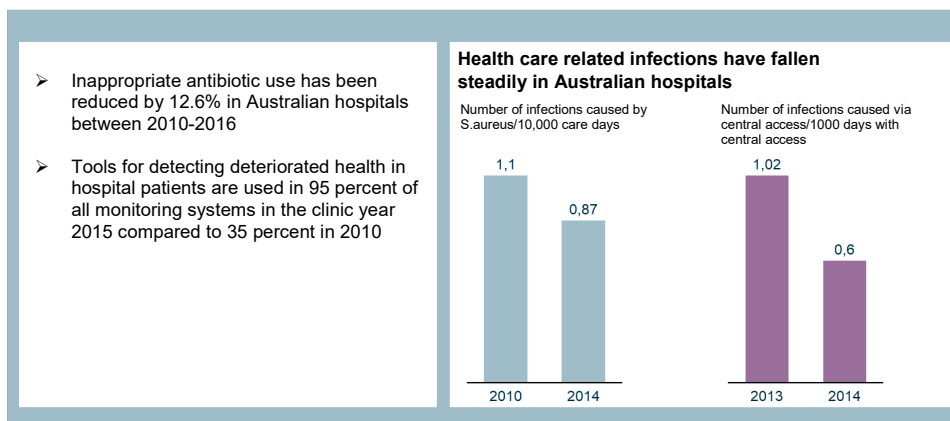


Figure 10. Results regarding work on the care of people with dementia or confusion

“Increased attention and care for people with dementia or confusion”

Summary of results achieved based on the success description of the strategic plan

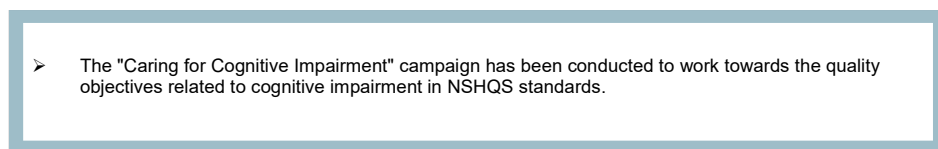


Figure 11. Results regarding the work on antibiotic prescription and antibiotic resistance

“Introduction of monitoring systems for antibiotic prescription and antibiotic resistance”

Summary of results achieved based on the success description of the strategic plan

- The Commission has published a report ("The Antimicrobial Use and Resistance in Australia (AURA) Surveillance System") based on data from the AURA project where areas with improvement potential in terms of antibiotic prescription have been identified.
- The Commission has published information material to help health care providers work on quality improvement in the area of "health care related infections".

Figure 12. Results regarding patient safety work in primary care

“Consensus on a framework of measures for patient safety work in primary care”

Summary of results achieved based on the success description of the strategic plan

- The Commission has published a report (Patient Safety and Quality Improvement in Primary Care) that describes key actors' views on how to improve quality and safety in primary care

Commission representatives indicate that the strategic plan has probably had a limited effect on outcomes

In the interviews carried out, the Commission representatives point out that overall it is difficult to comment on the impact of the strategic plan, that is, whether the policy document itself has generated good effects in the field of patient safety. At the same time, it is reasoned that the strategic plan has probably not contributed to the good results that can be seen today in this area. Instead, the respondents emphasise the value of other control tools and documents, such as the equivalent of binding national regulations (NSQHS) and the accreditation system as crucial in this context.

"The national regulations and the accreditation conditions for the providers are the factors that have contributed to changes in the area of patient safety for our part. It is not particularly about the strategic plan

- Commission representative

In short, the above means that consideration must be given to the surrounding context when it comes to analysing the impact of the policy document.

Key interests' views on the policy documents are awaited

According to the interviewed representatives, a formal evaluation of the strategy document is planned for 2019, and the opinions of key stakeholders will then also be collected. The general and informal feedback from other actors has, however, according to respondents, mostly been positive.

References

1. Institute for Health Metrics and Evaluation. IHME Australia. Retrieved 2020-01-15 from <http://www.healthdata.org/australia>.
2. The World Bank. Retrieved 2020-01-15 from <https://data.worldbank.org/indicator/SH.XPD.CHEX.GD.ZS%20/>.
3. The Commonwealth Fund. The Australian Health Care System. Retrieved 2020-01-15 from <https://international.commonwealthfund.org/countries/australia/>.
4. OECD.Stat: Health Care Quality Indicators. Retrieved 2020-01-15 from <https://stats.oecd.org/Index.aspx?QueryId=51884>.
5. Wilson R, Runciman W, Gibbered R, Harrison B, Newby L, Hamilton J. The Quality in Australian Health Care Study. The Med J Australia. 1995; 6;163(9):458-71.
6. Barraclough B, Birch J. Health care safety and quality: where have we been and where are we going? The Med J Australia. 2006;184(10): 48-50
7. Australian Commission on Safety and Quality in Health Care. Retrieved 2020-01-15 from <https://www.safetyandquality.gov.au/about-us/governance/>.
8. Commonwealth Consolidated Acts. National Health Reform Act 2011. Retrieved 2019-07-03 from http://www6.austlii.edu.au/cgi-bin/viewdb/au/legis/cth/consol_act/nhra2011216/.
9. Australian Commission on Safety and Quality in Health Care. National Standards and Accreditation. Retrieved 2019-07-03 from <https://www.safetyandquality.gov.au/our-work/national-standards-and-accreditation/>.
10. Australian Commission on Safety and Quality in Health Care. Retrieved 2020-01-15 from <https://www.safetyandquality.gov.au/our-work/assessment-to-the-nsqhs-standards/information-for-health-service-organisations/steps-for-implementing-the-nsqhs-standards/>.
11. Australian Commission on Safety and Quality in Health Care. Retrieved 2020-01-16 from <https://www.safetyandquality.gov.au/wp-content/uploads/2014/12/Australian-Commission-on-Safety-and-Quality-in-Health-Care-Strategic-Plan.pdf>.

12. Australian Commission on Safety and Quality in Health Care.
Retrieved 2020-01-16 from <https://www.safetyandquality.gov.au/wp-content/uploads/2018/08/ACSQHC-Corporate-Plan-2018-19.pdf>.
13. Australian Commission on Safety and Quality in Health Care.
Retrieved 2020-01-16 from <https://www.safetyandquality.gov.au/about-us/strategic-plan/>.
14. Consumer Research Regarding Safety and Quality in Health Care;
Prepared for The Australian Commission on Safety and Quality in Health Care. Woolcott Research; 2014.
15. Strategic Planning: Report on focus groups and interviews with healthcare providers. Australian Commission on Safety and Quality in Health Care; 2014.
16. Work plan 2018-21. Australian Commission on Safety and Quality in Healthcare; 2018.
17. Creating Safer, Better Health Care - The Impact of the National Safety and Quality Health Service Standards. Australian Commission on Safety and Quality in Health Care; 2018.
18. Australian Commission on Safety and Quality in Health Care. Annual Report 2017-2018. Australian Commission on Safety and Quality in Health Care; 2018.
19. Australian Commission on Safety and Quality in Health Care.
Retrieved 2020-01-16 from <https://www.safetyandquality.gov.au/our-work/indicators/core-hospital-based-outcome-indicators>.
20. Australian Commission on Safety and Quality in Health Care.
Retrieved 2020-01-16 from <https://www.safetyandquality.gov.au/our-work/indicators/core-hospital-based-outcome-indicators/>.
21. Australian Commission on Safety and Quality in Health Care.
Retrieved 2020-01-16 from <https://www.safetyandquality.gov.au/our-work/indicators/patient-reported-outcome-measures/>.

Country Report Canada

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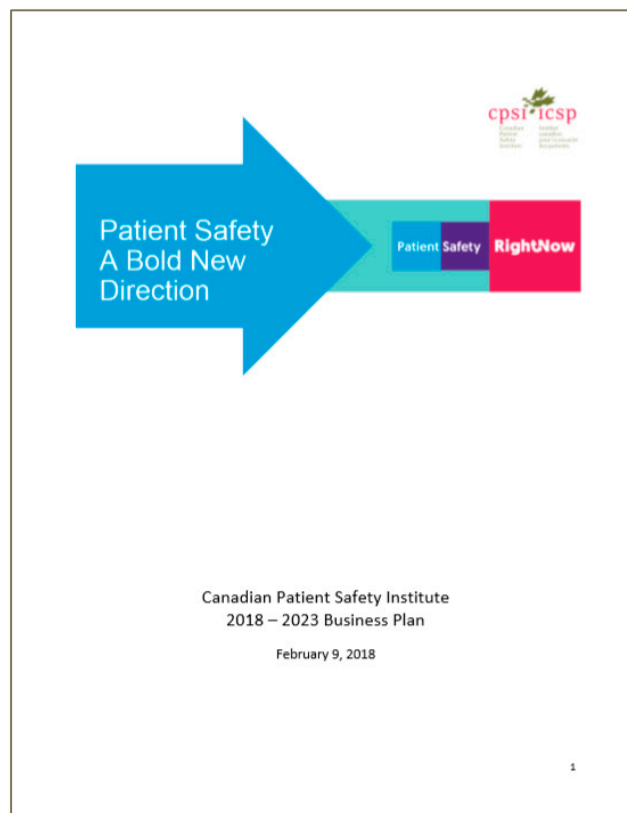
Introduction

In our analysis of Canada, we focus on the independent, non-profit, but government-funded organisation, the “Canadian Patient Safety Institute (CPSI)”. The CPSI is the organisation that works with patient safety at a national level in Canada. The Institute also has a co-ordinating role in the field of patient safety. The policy document, which is the main focus of our analysis, is the CPSI's equivalent to, “Patient safety a bold new direction” 2018 – 2023 Business plan. The business plan consists of a strategic plan called “Patient Safety Right Now”. This strategy lays the foundation for the CPSI's patient safety work over the next five years, that is, highlights the focus and performance of improvement work at national level. Against this background, we focus on the CPSI and their business plan, within the framework in the context of this analysis.

The analysis has been supplemented with information obtained in interviews with representatives of the CPSI.

Below are the results of the analyses carried out based on the framework used.

Figure 1. Patient Safety a bold new direction, business plan 2018-2023 from the Canadian Patient safety Institute (CPSI)




Description of the current context

In this section we describe more closely the context that characterises the policy document in different ways. For example, questions are answered about the possible needs that are the basis for the policy document and what the management of the healthcare system looks like.

Review country facts – Canada

Figure 2. Summary of basic country facts (1), (2)

Country facts		
Population (million)	36.3 (2016)	
Average life expectancy (males/females, years)	79.8/83.9 (2016)	
Child mortality (< 5 years old per 1000/births)	5.4 (2016)	
Health care cost (% GDP)	11.5% (2017)	

Healthcare can be described as decentralised in a federal system

Canada is characterised by federalism, which means that the federal state is complemented by regional self-governing provinces and territories. The Department of the Federal Government that is responsible for healthcare issues is called Health Canada (3). Healthcare is organised and provided at regional level, that is to say, within the framework of the provinces and territories. At the same time, the field is characterised by state governance through laws and regulations. Healthcare is financed both by regional and federal funds. The federal system for transfer of funds to the regional level is called “Canada Health Transfer”.

Each province/territory is responsible for providing health insurance for hospital and physician services for its citizens, in accordance with central national law (The Canada Health Act) (4). The legislation ensures that all Canadian citizens have access to the necessary medical care without patient fees. The public health insurance system – called

“Medicare” – includes both primary care and specialised care. However, the system does not automatically cover other care or welfare services, such as dentistry or care accommodation. The scope therefore varies between the regional provinces/territories, which can independently choose which additional services are included in the insurance. Most practicing doctors, both in open and in in-patient care, are self-employed and charge the provinces/territories for their services through the insurance system. Therefore, patients do not need to pay for healthcare through patient fees directly to healthcare providers.

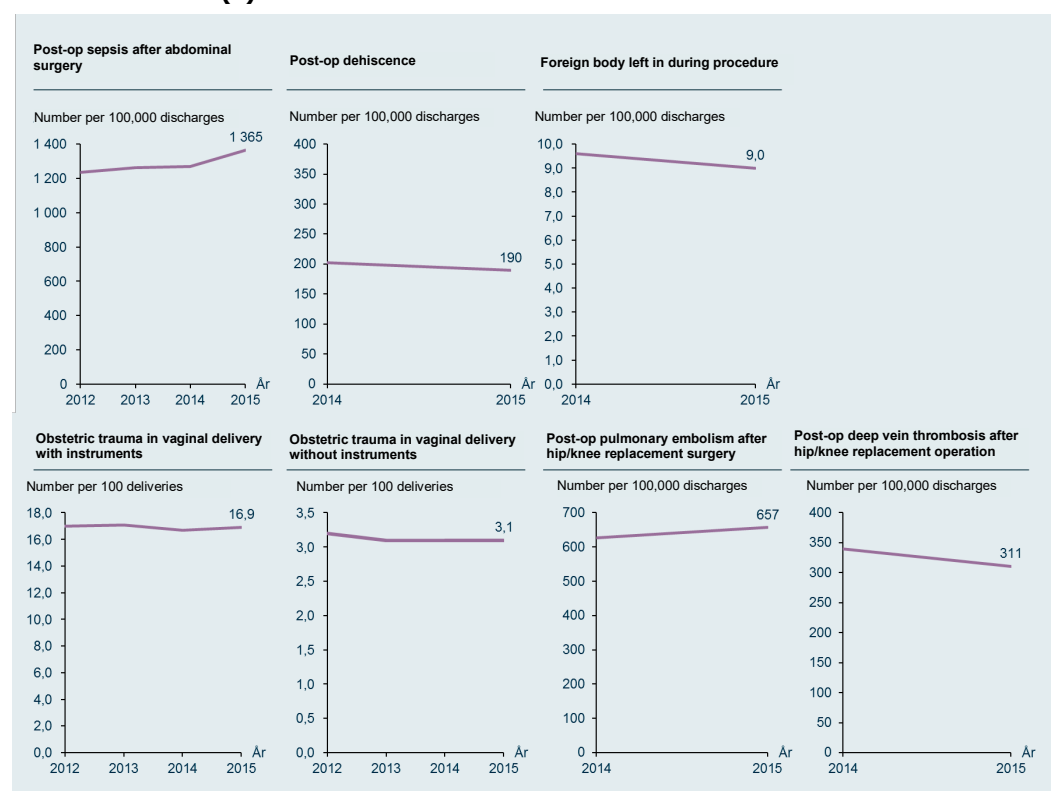
In addition to the public health insurance, there is also the possibility of taking out private health insurance which includes care and welfare not covered by the public health insurance system (3). Examples of such services are dental care, ophthalmic care, prescription medication, home healthcare and welfare.

Individual patient safety associated results indicate a slight improvement over time

Analysis of available data from the OECD (see figure 2 below) indicates that Canada's results in the field of patient safety have been relatively stable over time for all surveyed indicators.

However, the surveyed indicator of Post-operative sepsis after abdominal surgery showed a slight increase during the period of the years surveyed.

Figure 3. Comparison of patient safety indicators (OECD data) over time in Canada (5)



The national patient safety work started in 2000

A national patient safety steering group was appointed to develop recommendations on national work

At the start of the 2000s, patient safety was focused on at national level in Canada, and various case descriptions that highlighted healthcare-related injuries and deaths received relatively high attention (6). Against this backdrop, the Royal College of Physicians and Surgeons of Canada, which co-ordinates the training of specialist doctors, organised a national conference focusing on patient safety. The conference decided to appoint a national steering group for patient safety. The steering group consisted of representatives from academia, hospitals and other national organisations and was asked to produce proposals and recommendations on the appropriate design of national patient safety work.

The mission of the steering group was:

- Making patient safety a priority in healthcare
- Promoting a patient safety culture in healthcare
- Developing a framework for responsibility in issues related to patient safety
- Identifying methods for collecting relevant data and information that could be used in improvement work
- Developing a research agenda in the field of patient safety
- Developing a training agenda for the general public, consumers and caregivers with a focus on tools that contribute to increased safety for patients and users as well as society as a whole

The CPSI was formed as a result of the steering group's recommendations

The steering group's recommendations were compiled in the report "Building a safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care" was published in 2002 (6). In summary, the steering group concluded that broad co-operation is needed, not least because of the country's decentralised system, for national improvement work with a focus on patient safety to lead to good results.

On this basis, the steering group's first recommendation was that a national body for overall national patient safety with the task of co-ordinating the work should be established. The recommendation was implemented and the Canadian Patient Safety Institute (CPSI) was formed in 2003 on the initiative of Health Canada (7). CPSI is a non-profit organisation with members representing the profession, academia and patient safety and healthcare experts.

In particular, the CPSI has a supporting role in relation to the actors involved in patient safety

As previously mentioned, the CPSI is an independent organisation but is funded for the most part by federal funds from Health Canada, the

department of health within the federal government. The Institute leads the pan-Canadian patient safety work and, according to interviewed representatives, the CPSI acts independently and prioritises what issues and activities are to be conducted. The CPSI has no regulatory powers, but has the main focus on supporting policy makers, health care leaders, managers, providers and patients in the work towards improved patient safety. Furthermore, CPSI cooperates with the independent organisation “Health Standards Organisation (HSO)” (8), which is responsible for the development of quality standards in healthcare. These standards are the basis for the accreditation conditions for healthcare carried out by the national accreditation organisation “Accreditation Canada” (9). In some provinces/territories the regulations are binding on the health and social service provider organizations and thus have a direct governing function.

The interviewed representatives emphasised that co-operation between the CPSI and HSO means that the control of patient safety work is characterised by direct (“harder”) and more indirect (“softer”) control at the same time. This is also described as desirable, that is, the most appropriate way of controlling patient safety at national level in a decentralised system is to establish a balance between direct and indirect control signals.

*“CPSI has a **motivational** and **supporting** role, while HSO has a more **direct** role to play. Both parts are needed to drive patient safety work forward”*

- CPSI representative

Since the CPSI was founded, it has worked to gather the different actors within the healthcare system. The aim has been to identify common priorities in patient safety (7). CPSI has also assisted in the implementation of various national and regional improvement projects, in the collection of relevant data and information, and in the development of tools and making available resources for actors working with patient safety.

In accordance with the organisation's business plan for 2013 – 2018 (10) a number of national gatherings were organised with key health practitioners to jointly develop action plans within different thematic areas with a focus on improved patient safety. The action plans were published 2014 and have since been the guiding point for national patient safety work. A detailed description of the plans and their content can be found under the heading “*Thematic action plans have been developed since 2014*”

In 2017, the CPSI was evaluated by an external body on behalf of Health Canada (11). The main conclusion of the evaluation was that the CPSI is still a relevant institution and that the activities of the Institute are still needed in order to carry out successful national patient

safety work. In 2018, the CPSI published its business plan for the period 2018–2023 (12). The plan also includes the “Patient Safety Right Now” strategy, which is in focus within the framework of this analysis.

Work is underway to develop a national patient safety framework

According to the interviewed representatives from the CPSI, work is underway to develop a quality and patient safety framework. The CPSI used a special reference group (advisory group) in this work. The group consists of federal and regional government representatives, healthcare providers and representatives of quality and patient safety organisations. An international outlook has been made to identify lessons from other countries' developed frameworks, for example in terms of priority areas and structure. Further, analyses of the priority areas of patient safety at regional level in the country have been carried out and lessons from academic reports about patient safety in Canada have been considered, e.g. the report. *Beyond the Quick Fix: Strategies for Improving Patient Safety* (13).

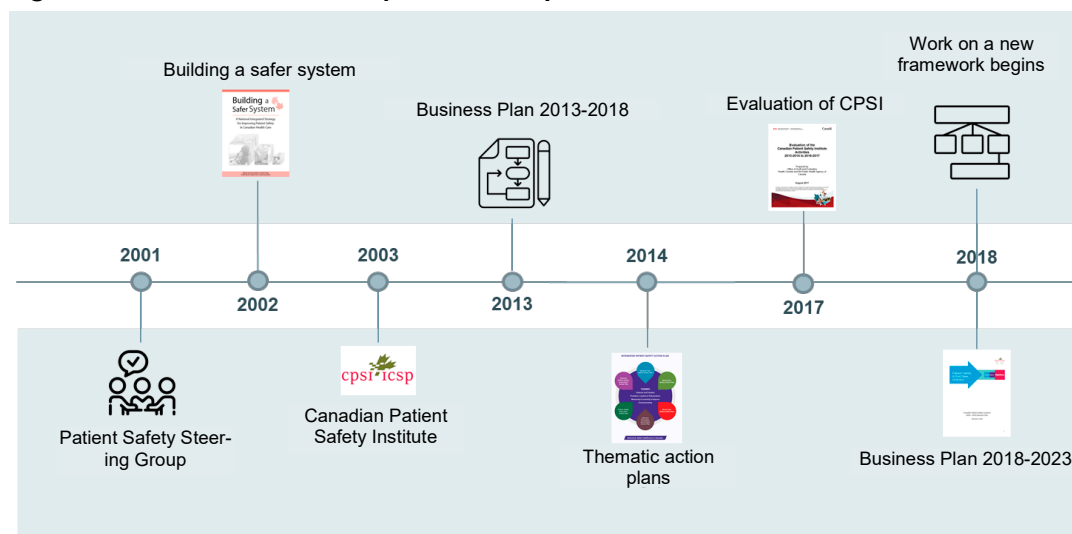
CPSI introduced a Policy Influence Framework in 2019 to lead discussions and actions from various Canadian stakeholders (e.g. governments, health regions or districts, regulators, Indigenous communities) to meet the goal of having the safest healthcare in the world). The Policy Influence Framework resulted from discussions with a Policy, Legal and Regulatory Affairs advisory committee that had representation from across Canada and from various stakeholder groups including patients. CPSI also met with assistant deputy ministers (or designates) from the provincial and territorial governments to identify similarities and differences in patient safety issues from across Canada and to highlight possible strategies (e.g. legislative changes) to support patient safety.

Since 2016, CPSI has been working within the Canadian health care system to apply the *Measuring and Monitoring of Safety Framework* (14) with the purpose of providing a conceptual model for a comprehensive and accurate, real-time view of patient safety that can be used to assess and evaluate safety.

Based on this overall work, five key priority areas, to be included in the framework, have been identified. The Canadian Quality and Patient Safety Framework will also highlight objectives and desired outcomes within each priority goal area. The aim is for the documentation to be able to support the national joint improvement work with a focus on quality and patient safety at regional level.

In Figure 4 the following, the development of patient safety in Canada over time is shown and summarised.

Figure 4. Timeline of national patient safety work in Canada



The CPSI's current business plan is in focus

Since the CPSI is the organisation that leads patient safety work at national level, we analyse their business plan for 2018-2023 (12), with a special focus on the strategy: “Patient Safety Right Now” in the framework of the development of this country report. Interviewed representatives from the CPSI confirm that the business plan, although an internal planning document, can be seen as a national strategy for patient safety.

We have also supplemented the analysis by examining, on the advice of our interview respondent, the CPSI's internal “Performance Measurement Strategy” (15). The document contains valuable information about the CPSI's follow-up processes.

Policy document structure

This section describes the structure of the policy documents. Questions about the parts of the policy document and the intended recipients are answered here. We also highlight the format of the documentation, i.e. whether it is comprehensive or summarised etc. The policy document referred to is the analysed document “Patient safety a bold new direction Business Plan 2018 – 2023” (12).

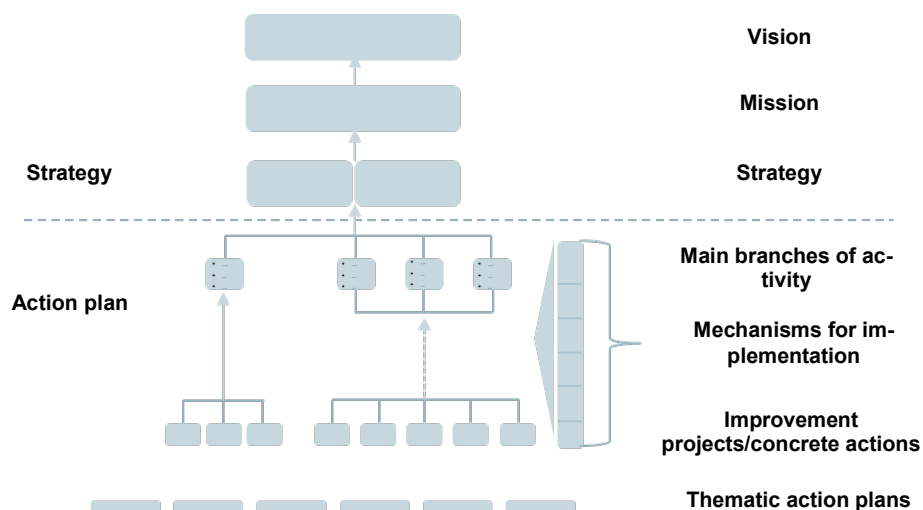
The business plan contains strategy elements but also describes improvement measures and implementation

Overall, the business plan consists of seven main parts: 1) an overall vision; 2) a mission 3) the pronounced strategic approach; 4) four main lines of business with associated objective descriptions 5) six implementation mechanisms; 6) description of three priority improvement projects and 7) five concrete action proposals

In addition there are, as mentioned, six thematic action plans in the field of patient safety that were developed in the previous business plan period. The action plans are not directly linked to the current business plan but do not have an end date and are likely to affect the direction of the ongoing patient safety work.

Visualisation of the structure of the policy document can be seen in Figure 5.

Figure 5. Visualisation of the structure of the policy document



In summary, the structure of the policy document consists of parts that are largely associated with a more comprehensive approach such as vision, mission and strategic approach. At the same time, the main lines of business, implementation mechanisms and concrete improvement

projects and proposals for action are also reported relatively extensively. These elements may relate in particular to a more operational policy document such as an action plan.

The business plan has an extensive structure but the logic between the different parts is relatively clear

The examined structure consists of many different parts and can thus be described as both extensive and complex. Nevertheless, the logic of the structure, that is, how the different elements are connected and relate to each other, is described in a relatively comprehensive manner. For example, a specific appendix presents all proposed activities/actions where clear links are made to the implementation mechanisms, objectives, priorities and the challenges that the measures aim to respond to.

In interviews with representatives from the CPSI, there is an awareness of the importance of the policy documents having a clear and logical structure and that this is something you have to come to understand over time. The respondents point out that the ongoing work to develop a national framework for patient safety is more characterised by this insight by comparison with previous policy documents.

*“We have understood that we must **link goals, priorities, desired outcomes** etc more clearly. We do this more in our new framework that is being developed”*

- CPSI representative

The policy document describes the internal work, but also addresses wider issues

The business plan can be described as an internal policy document which, among other things, presents the Institute's priorities and focus for the specified period. At the same time, the CPSI is a national arms-length organisation that includes health professionals such as patient representatives, caregivers, regional management and others, in their work. In other words, the business plan can, in theory, be used by the intended target groups as support in the work to improve patient safety at different levels. There are also examples of points raised in the business plan that are indirectly aimed at specific target groups. For example, it is emphasised that the CPSI will work to expand the “Patient for Patient Safety” network¹, which affects patients and relatives.

It is also clear from the policy document that the CPSI works to influence political decisions in the field of patient safety, and that is why the content can, to a certain extent, be turned to different political decision-makers. The picture is also confirmed by certain writings in the

¹ Note: “Patient for Patient Safety” is a patient-led program within the CPSI that aims to involve patients in patient safety work. All projects run under the program are designed and run by patients and their relatives.

institute's "Performance Measurement Strategy" (15), which expresses that the CPSI's current business plan aims to benefit three main groups: 1) patients and their families/relatives; 2) caregivers and 3) different management functions and management within healthcare organisations. Although the policy document does not explicitly address different functions and actors at all levels, it is nevertheless possible to divide the recipients along the micro/meso/macro-levels.

The document is relatively text heavy, but some elements make it easier for the reader

The business plan is written in Word and amounts to almost 30 pages. The document is relatively text heavy, but figures are available that make the main elements of the content clearer, making the document slightly more accessible. In addition, the various activities are summarised in table format in a specific appendix. The tables provide a good overview of the institute's planned work for the current period, which facilitates the reader's understanding.

Communication is stated to be a key part of the CPSI's work to make patient safety a priority

Among other things, the CPSI works to ensure that patient safety is generally seen as an important issue and to be consistently a key priority area in healthcare. Part of this work is to use communication as a strategic tool. In the Business Plan 2018–2023, the CPSI is to continue to use different communication methods and platforms such as social media, publication of patient stories and compilation of reports in a way adapted to the target groups.

Furthermore, the business plan describes that the CPSI places value on both the results and the evidence from their various projects and activities being effectively communicated – both directly to the relevant recipients (e.g. caregivers) and to more indirectly affected groups (for example, the public). This is because information dissemination is seen as an important precondition for bringing about changes in different areas. In this context, in accordance with the business plan, it will develop a specific model ("Knowledge Translation and Implementation Science model") to repackaging knowledge and research documentation to more accessible and comprehensible formats.

The Institute also uses its website and social media channels as central communication tools (16). Here, for example, they gather and make materials, documentation and information available that can be used to support improvement work with a focus on patient safety.

*"We **communicate** to a large extent directly with **patients and caregivers** in a way **adapted to the target group**"*

- CPSI representative

In the interview, CPSI, as part of its communicative work, states that it will also carry out specific information campaigns. For example, “Canadian Patient Safety Week” is an annual event. The campaign targets both patients and healthcare professionals, and the intention is to highlight a theme, raising awareness of relevant patient safety aspects.

The business plan spans a five-year period

The policy document runs from 2018–2023, i.e. over a five-year period. However, it is not stated, neither in the business plan nor in the interview with the representatives of the CPSI, why this lifecycle has been chosen. However, interviewed representatives state that Health Canada requires that the CPSI and its activities must be evaluated every five years, which may be a possible reason why this particular timeframe has been set.

Policy document content

In this section we report the content of the policy documents. For example, questions about the strategy's thematic focus or whether the content is based on a clear perspective are answered. We also describe the tangibility level in the policy document more closely. The policy document referred to is the analysed document "Patient safety a bold new direction Business Plan 2018 – 2023" (12).

The vision and mission of the policy document will be achieved through a special strategic approach

The overall vision of the policy document reads as follows: *"Canada has the safest healthcare in the world"*.

The CPSI's mission is: "To inspire and develop a culture for continued improvement towards safer healthcare".

The Institute has also developed a strategy for how best to respond to its mission, and this is formulated as: *"lead the development of strategies at system level to ensure safe healthcare by making visible what works and by contributing to enhance involvement/commitment"*.

The strategic approach is described as a combination of "pushing" and "pulling" actors in the right direction It is also described that the CPSI has used a more supportive and encouraging approach to its work so far, which is referred to in the policy document as having "pushed" the relevant target groups in the right direction within the improvement work. This has been done, for example, by highlighting different areas of improvement and by developing supporting tools and information documentation. However, the business plan states that it is not sufficient to apply this approach alone. It now complements the inspirational and motivational approach with clearer signals of responsibility and commitment. This part of the strategy means that the Institute to a greater extent "pulls" actors in a desirable direction. Against this background, the strategic approach is divided into two different parts, which are described as mutually reinforcing:

1. **Show what works ("push"):** Support for successful and measurable improvement of patient safety, and efforts must be evaluated/followed up in order to show what works.
2. **Reinforcing commitments ("pull"):** The empirical data around what works must then be transformed into standards/practices for caregivers throughout the healthcare system. The approach creates the conditions for the methods to be incorporated into a more robust system that is characterised by involvement/commitment, responsibility and expectations of patient safety.

The content focuses to a relatively large extent on implementation mechanisms and lines of business

As part of the implementation of the content of the business plan, the CPSI shall start from a total of six implementation mechanisms:

1. **Implement** – Implement improvement projects/programs with a focus on improving patient safety in prioritised areas to show what works
2. **Evaluate** – Ensure evaluation of all activities carried out by the CPSI in order to gather knowledge of what works
3. **Share with Purpose** – Develop methods for dissemination and learning of knowledge about improvement work
4. **Raise the profile** – Raise the patient safety profile by increasing expectations of improvement work
5. **Improve transparency** - Develop a solid framework that clarifies rights and obligations for transparency at all levels
6. **Reinforce the commitment** – Influence the commitment to patient safety through policies, regulation and accreditation

The policy document also describes the CPSI's various lines of business. The lines are based on the established strategic approach, that is, to show what works and to reinforce the commitment. They are described as a clear link between the strategic approach and the activities the Institute implements. The lines of business are:

1. **Safety improvement projects** – the CPSI, together with dedicated partners, will implement and evaluate measurable and sustainable projects that are in line with the priorities.
2. **Making patient safety a priority** – the CPSI will use the patient's voice in their reporting, campaigns and media to make patient safety a more prioritised issue within the healthcare system.
3. **Policy impact** – the CPSI will affect policies, standards and regulations so that they are based on the best available knowledge and practices regarding patient safety.
4. **Alliances and networks** – the CPSI will form strategic alliances and networks with patients, industry decision makers and other actors involved in making healthcare safer.

A number of objectives are also listed for each line of business. For example, the objective is highlighted of developing clear and transparent criteria for identifying and selecting priorities, dedicated partners and host organisations that can participate in projects to improve patient safety within the initial main process. A longer and more thorough review of the six implementation mechanisms and the four main lines of business can be found under the heading *“Implementation based on different principles and lines of business”*.

Some improvement projects were specifically highlighted in the business plan

A number of different improvement projects and improvement measures are also defined within the framework of the four lines of business. In particular, focus is on the first line of business in the plan, i.e. “improvement projects for patient safety”. Based on budget and priority criteria, the CPSI has identified three projects to be implemented in the first instance. These are:

- Measuring and monitoring patient safety
- Medication safety at care transitions
- TeamSTEPPS

A more detailed description of the projects is given below.

Measuring and monitoring patient safety

The CPSI has previously supported caregivers in the use of a framework for measuring and monitoring patient safety (Measuring and Monitoring of Safety framework). The data collected from this should now be evaluated and used to build capacity within organisations to proactively analyse, follow up and create the conditions for continuous learning.

Unified medication treatment in connection with healthcare transitions

The project aims to improve safety when it comes to medications, especially in connection with healthcare transitions. It is in line with the CPSI's work within the framework of the WHO's “Global Medication Safety Challenge”, which aims to reduce severe, avoidable harm from medications by 50 percent within five years.

TeamSTEPPS

The program aims to improve co-operation between and communication within healthcare businesses. The CPSI has developed a Canadian version (TeamSTEPPS Canada) and will now try and evaluate the effect of the program. The analysis made can then be used to influence how healthcare professionals are trained and how businesses are accredited.

In addition to these improvement projects, other improvement measures to be implemented within the other aforementioned lines of business are also described. These measures are:

- To carry out investments to develop better knowledge about how results can be translated and disseminated in healthcare and acquire knowledge of growing challenges.
- To develop the work done by the “Patients for Patient Safety Canada” network in order to strengthen the patient safety profile and public awareness.
- To use communication strategies to reach specific target groups.

- To implement targeted work to develop a framework to guide policy and legislation, health profession regulation, organizational policies, standards and accreditation, and public engagement and empowerment efforts in the context of evidence-informed public policy as a mechanism to improve patient safety.
- To establish systems, together with other actors, for co-operation with Governments and industry.

In addition to the projects and improvement measures highlighted in the business plan, the CPSI works in many other ways to support relevant actors in the improvement work towards increased patient safety. The Institute's website (patientsafetyinstitute.ca) includes, for example, the knowledge bank “SHIFT to Safety” (17) with tools, materials and information aimed at the general public, caregivers or business managers.

Thematic action plans also govern national patient safety work

Between the years 2014 and 2017, the CPSI organised an annual National Patient Safety Consortium (18) to which key healthcare actors were invited. For example, patient and related representatives, national and regional quality and patient safety organisations, health ministers, professional associations and caregivers were present. In the context of these annual gatherings, and in joint work with all participants, specific action plans for increased patient safety were developed in different thematic areas (19).

For example, action plans were developed in the areas of surgery, pharmaceuticals, home healthcare, infection prevention and patient safety education. Together, the plans are an integrated action plan for patient safety aimed at contributing to safer healthcare (see Figure 6 below). The various thematic areas are grouped into four overall themes in the integrated action plan, and these themes are:

1. Patients and families
2. Caregivers, managers and politicians
3. Measurement and learning for improvement
4. Communication

Figure 6. The CPSI's own visualisation of the integrated patient safety action plan based on the different thematic areas



The action plans, in turn, contain different priority areas with related process objectives and actions. Within the thematic area of surgery, the following seven priority areas and objectives are highlighted (20):

- **Measurement and analysis:** Develop common national indicators for patient safe surgical care and treatment.
- **Access to healthcare:** Examine the possibility for all provinces/territories to work together on an action plan for patient safety within surgery.
- **Evidence-based methods and approaches (“best practice”):** Improve the accessibility of evidence-based recommendations and guidelines for patient safe surgical care and treatment.
- **Patient involvement:** Develop a web-based knowledge bank with advice and guidelines for patient and relative involvement in areas related to safe surgical care and treatment.
- **Co-operation and communication:** Create working methods for co-operation and communication in order to improve safety throughout the surgical care chain.
- **Quality improvement infrastructure:** Politicians, management and directors are trained to develop their ability to create conditions for quality development.

- **Create conditions for learning from incidents caused by patient safety deficiencies in surgical care or treatment:** Conduct predictive analyses to create a better understanding of what causes injury during surgical procedures.

Each priority area then lists various improvement measures in order to achieve the objective. Examples of actions are to set up a working group to develop national indicators or to identify three to five of the best evidence-based recommendations or to launch a web platform for guidelines and tools, in order to increase the level of patient involvement.

The action plans were published in 2014. According to information on the website, the action plans are dynamic documents that can be adjusted and updated continuously (19). This means that they are always relevant.

The definition of patient safety appears to be relatively broad

Patient safety is not explicitly defined in the business plan, but the use of the concept and the policy document's thematic focus indicates a relatively broad approach. In short, the focus does not seem to be aimed at minimising the risk of healthcare-related injuries. The approach instead gives the impression of being more focused on general quality improvements in the healthcare system, which are closely linked to patient safety.

The application of a broader approach is also confirmed in an interview with representatives from the CPSI. The respondents believe that safety must be seen as being broader than just the absence of injury in order for desirable changes to occur.

*“We need to think about safety more **widely**, that is, instead of focusing on the ‘**absence of harm**’, we have to think in terms of the ‘**presence of safety**’ – it is a holistic approach that is based on the patient’s perspective”*

- CPSI representative

The thematic focus of the business plan is mainly directed towards the success areas

In conclusion, the business plan emphasises factors that can above all be sorted as success areas. For example, the CPSI's mission is clearly linked to the area of “patient safety culture”. When it comes to processes, actions and projects, these are generally focused on creating conditions for improvement work at different levels, which can also be related to success areas. Examples of this type of activity are patient involvement,

creating conditions for knowledge dissemination and learning, and increasing access to evidence-based recommendations. As mentioned above, the only outcome area raised in the business plan is the safe medication treatment in connection with healthcare transitions.

Policy document processes

This section presents the central processes that can be linked to the strategy and the action plan. Examples of questions to be answered are whether the policy document was based on a particular process, for example through consultation or negotiation? Another important element is examining whether the policy document describes different central processes and, in such cases, what they include. The policy document referred to is the analysed document, “Patient safety a bold new direction Business Plan 2018 – 2023” (12).

The business plan is based in part on the evaluation

In 2017, the CPSI was evaluated by an external body (21). The evaluation was carried out on behalf of Health Canada and the Public Health Agency of Canada. One of the conclusions of the evaluation was that the CPSI, as a means of conducting and co-ordinating national patient safety work, is still needed. The evaluation also highlighted a number of recommendations for the CPSI's continued work. The recommendations served as a basis for the development of the current business plan (Business Plan 2018–2023).

In addition, the business plan is based on a review of current research in the field of patient safety. The CPSI has also conducted an international outlook, including examining the ongoing national patient safety work in Scotland, Denmark and the United States. Consultations with relevant actors are also the basis for the development of the business plan.

The implementation is based on different principles and lines of business

As mentioned earlier, the implementation of the business plan is described by six implementation mechanisms. These are:

1. **Implement** – Implement improvement projects/programs with a focus on improving patient safety in prioritised areas to show what works
2. **Evaluate** – Ensure evaluation of all activities carried out by the CPSI in order to gather knowledge of what works
3. **Share with Purpose** – Develop methods for dissemination and learning of knowledge about improvement work
4. **Raise the profile** – Raise the patient safety profile by increasing expectations of improvement work
5. **Improve transparency** - Develop a solid framework that clarifies rights and obligations for transparency at all levels
6. **Reinforce the commitment** – influence the commitment to patient safety through policies, regulation and accreditation

The mechanisms are clearly linked to the main lines of business described in the previous sections. In the context of each line of business, a number of objective descriptions are also presented. The four lines of business, including the target descriptions, are:

Implement improvement projects with a focus on patient safety (safety improvement projects)

The CPSI, together with dedicated partners, will implement and evaluate measurable and sustainable projects that are in line with the priorities.

Objective descriptions:

- To develop clear and transparent criteria for identifying and selecting priorities, dedicated partners and host organisations that can participate in projects to improve patient safety.
- Ensure that partners and participants have the resources and capacity to implement improvement projects with successful results.
- Conduct improvement projects based on a structured/established method for quality improvement.
- Evaluate the projects carried out with the aim of acquiring knowledge about what works so that results can be disseminated and widely used to improve patient safety.
- Develop broad collaborations so that results can be disseminated to the entire healthcare system and to a larger target group.
- Develop methods for translating research results and knowledge into clear and comprehensible information for relevant target groups.
- Develop methods for acquiring knowledge from the healthcare system, and use the knowledge as a basis for priorities.

Making patient safety a priority

The CPSI will use the patient's voice in their reporting, campaigns and media to make patient safety a more prioritised issue within the healthcare system.

Objective descriptions:

- Strengthen the profiling of patient safety in the media
- Use patient stories to communicate with and reach out to patients and the general public.
- Use different types of social media and digital platforms to engage the public, caregivers, and managers to share ideas and strategies that can improve patient safety.
- Use and develop current reporting methods with a focus on the current patient safety situation.
- Develop and publish compilations and reports aimed at different target groups.
- Compile evidence and results from the CPSI's activity analyses and communicate this to everyone involved

Influence decision-making and governance (policy impact)

The CPSI will affect policies, standards and regulations so that they are based on the best available knowledge and practices regarding patient safety.

Objective descriptions:

- Provide evidence to inform about which rules and regulations best create the conditions for patient safety at an organisational and system level in healthcare.
- Work to incorporate requirements regarding patient safety in rules, regulations and accreditation conditions.
- Influence those who educate and accredit healthcare professionals to make patient safety a core competency of all healthcare providers and managers.
- Support the development of more effective transparent measurement and reporting of patient safety.

Create alliances and networks

The CPSI will form strategic alliances and networks with patients, industry decision makers and other actors involved in making healthcare safer.

Objective descriptions:

- Establish a new alliance between governments dedicated to working on common challenges in the field of patient safety.
- Engage partners in the healthcare system to meet persistent challenges that create barriers to patient safety.
- Create new networks with patient groups in order to disseminate knowledge and experience about patient involvement.
- Advocating common national priorities for patient safety in the healthcare system.

Activities are selected based on prioritisation criteria

As the CPSI operates within certain budgetary frameworks, priority is required between different activities. The goal is to focus on activities and improvement measures with the greatest impact. The CPSI's priority criteria for selecting different activities are:

- The activity should be in line with the priorities throughout the healthcare system.
- The results of the activity have the potential to be used to influence political decisions, rules and regulations.
- The activity is based on existing capacity and strengths and good results have previously been achieved
- There are partners willing to participate in the work.

During the strategy period, a Priority Decision-Making framework will be developed, and the above criteria will be included.

A model for translating knowledge and research results will be developed

According to the examined policy document, the CPSI's activities and work must be evaluated and communicated in a way adapted to target groups to achieve the desired impact. In this context, the Institute will develop a special model with a focus on translating knowledge and research (Knowledge Translation and Implementation Science Model). The idea is that the model should facilitate both dissemination and understanding of the information/knowledge that the CPSI collects/creates.

Patient engagement is critical to CPSI's work

The examined business plan states that the CPSI is to involve patients in all their work. The objective is to support the patients themselves to true partners in the national improvement work with a focus on patient safety. According to interviewed representatives from the CPSI, patient involvement is a central part of the Institute's work, and the overall aim is to have structured and systematic co-operation with different patient representatives.

The co-operation with the network “Patients for Patient Safety” is described in this context as an important method for making patients and related parties more involved in the improvement work. The work of “Patients for Patient Safety” aims to highlight patients'/relatives' views and opinions linked to patient safety at all levels within the healthcare system (22). The program gives patients' representatives the opportunity to participate in different working groups. All activities are designed in whole or in part by the patients themselves. An example of an activity is the development of contributions to a report on care abnormalities (“Never events for hospital care in Canada”).

*“We value and strive in different ways for meaningful and authentic patient partnerships **with patient representatives** in our work in general. For example, our staff collaborate with the “patient-for-patient-safety” network.*

- CPSI representative

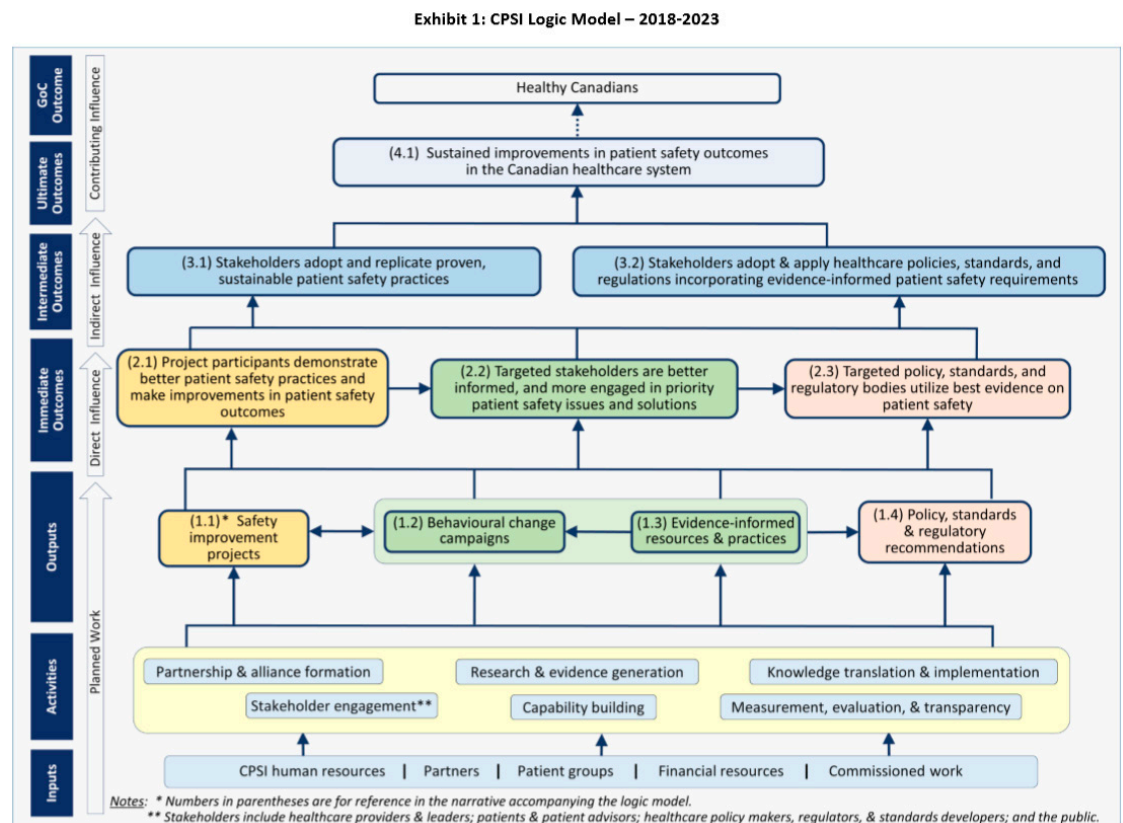
The follow-up process is carefully described in a separate but related document

A special program theory is used to evaluate and follow up the activities of the CPSI.

The examined business plan includes a specific framework for how CPSI measures and reports on its performance, and is detailed in the document, “Performance Measurement Strategy 2018–2023” (15). The

document presents a program theory (logic model) for the CPSI's activities, that is, how this will lead to direct, indirect and contributory intermediate and ultimate outcomes. In Figure 7 visualized, a picture is seen from the document “Performance Measurement Strategy” where the program theory is visualised.

Figure 7. Visualisation of the CPSI's program theory



The activities in the framework are grouped according to the main lines of business of the CPSI, that is, within the field of activities in the structure tree, the activities to be carried out have been grouped within the four different lines of business: 1) implement improvement projects with a focus on patient safety; 2) make patient safety a priority; 3) influence decision-making and governance and 4) form alliances and networks in six different categories:

1. Establishing partnerships and building alliances
2. Development of research and evidence
3. Translation and use of knowledge
4. Involvement of key actors
5. Capacity building efforts
6. Measurement, evaluation and transparency

In summary, activities within these six categories will lead to the CPSI achieving certain outputs that contribute to national patient safety work. This by:

- Implementing improvement projects with a focus on patient safety
- Conducting campaigns that lead to behavioural changes in the healthcare providers concerned regarding the approach to challenges and solutions in the field of patient safety
- The provision of resources and standards that builds on evidence-based knowledge
- Developing recommendations for policies, rules and regulations that are based on evidence-based knowledge and that aim to make patient safety a major priority in healthcare.

In accordance with the accepted program theory, the CPSI's work is expected to result in changes in direct and indirect outcomes/effects. The short-term outcomes, which the CPSI can affect directly, are:

- The CPSI's project participants use methods to improve patient safety, which in turn leads to improved outcomes
- Involved key actors are more aware and involved in identifying and prioritising patient safety issues (both challenges and solutions)
- The regulatory organisations that the CPSI has worked with base their patient safety data and regulations on evidence-based knowledge

Intermediate outcomes that the CPSI's work indirectly affects are according to the framework:

- Healthcare practitioners and providers generally use evidence-based and sustainable methods for improving patient safety
- Healthcare practitioners and providers comply with and implement rules and regulations that contain evidence-based requirements for patient safety

The overall ultimate outcome that the CPSI's activities contribute to is according to the framework:

- A sustainable improvement of patient safety outcomes within the Canadian healthcare system

This in turn contributes to the Government of Canada's objective of:

- Healthy Canadians

The ultimate outcome is achieved if the CPSI performs its activities successfully, but is also dependent on other partners and actors in the healthcare sector contributing to the work.

Delivery objectives are specified for each outcome level in a performance framework

A specific framework with objectives and indicators is presented in an appendix for the "Performance Measurement Strategy". The objectives are in line with the desired performance outputs and outcomes presented in the program theory (as above). In other words, the framework should be used to measure the extent to which planned performance is

achieved and whether the other desired outcomes are reached. An example of an indicator for one of the performance objectives that is reported in the framework is to:

- 60–80% of all participating groups show improvement in project-specific patient safety outcomes

The compilation of indicators, outcomes and information on the source of data collection, the frequency of data collection and the method for collecting the data are presented in tables. An example of such a table can be seen in Figure 8.

Figure 8. Example of a table for performance measurement

					project life cycle				As part of operating the KTS function, stakeholders will be surveyed to determine their awareness of, use of, and knowledge gained resulting from the use of CPSI knowledge products relevant to the stakeholder group. The results of these surveys will be aggregated and used to calculate indicators 2.2.1, 2.2.2, and 2.2.3.
2.2 – Targeted stakeholders are better informed and more engaged in priority patient safety issues and solutions	2.2.1 - Percentage of stakeholders indicating awareness of relevant CPSI knowledge products <i>Breakdowns to be provided by: stakeholder group.</i>	%	KTS evaluation data collection	Annual	20-30% increase in awareness of relevant CPSI knowledge products, among targeted stakeholders over baseline	Baseline to be established in 2018-19. Target reached by March 2023	<div> <div>< 20%</div> <div>20-24%</div> <div>>= 25%</div> </div>	Director – Safety Improvement Projects	
	2.2.2 - Percentage of stakeholders indicating that they have used relevant CPSI knowledge products <i>Breakdowns to be provided by: stakeholder group.</i>	%	KTS evaluation data collection	Annual	20-30% increase in use of relevant CPSI knowledge products, among targeted stakeholders over baseline	Baseline to be established in 2018-19. Target reached by March 2023	<div> <div>< 20%</div> <div>20-24%</div> <div>>= 25%</div> </div>	Director – Safety Improvement Projects	
	2.2.3 – Percentage of stakeholders indicating that they have gained knowledge as a result of having used relevant CPSI knowledge products <i>Breakdowns to be provided by: stakeholder group.</i>	%	KTS evaluation data collection	Annual	10-20% knowledge gain, among targeted stakeholders over baseline	Baseline to be established in 2018-19. Target reached by March 2023	<div> <div>< 10%</div> <div>10-14%</div> <div>>= 15%</div> </div>	Director – Safety Improvement Projects	
	2.2.4 – Percentage of stakeholders demonstrating increased prioritization of patient safety <i>Breakdowns to be provided by: stakeholder group.</i>	%	KTS evaluation data collection	Annual	10-20% demonstrating increased prioritization of patient safety over baseline	Baseline to be established in 2018-19. Target reached by March 2023	<div> <div>< 10%</div> <div>10-14%</div> <div>>= 15%</div> </div>	Director – Making Patient Safety a Priority	As part of operating the KTS function, stakeholders will also be surveyed to determine whether they are demonstrating increased prioritization of patient safety, relative to other priorities. The results of these surveys will be aggregated

An external evaluation of the CPSI is done every five years

In accordance with the requirements of Health Canada, which accounts for a relatively large part of the CPSI's financing, an external evaluation of the CPSI must be carried out every five years.

The performance measurement strategy, which is described in more detail above, states that these external evaluations should be based on a separate framework that examines two key aspects in particular:

1. Assessment of the relevance of the CPSI: This aspect examines whether the CPSI and its activities reflect the current needs of the citizens. It also examines whether, and to what extent, the CPSI's objectives and activities are in line with government priorities.
2. Assessment of the performance of the CPSI: Within this aspect, an assessment is made of whether the activities carried out resulted in desired outcomes and an analysis of resource use.

The framework that is being developed highlights the assessment perspective

In interviews with representatives from the CPSI, it appears that they prioritise and value measurement and follow-up, and work is ongoing to investigate how follow-up can be strengthened – not least from a patient perspective. The respondents also state that there are other organisations that follow-up and measure quality development in healthcare at national level. The CPSI cooperates with these types of organisations and various reports highlighting parts of the development of the patient safety area are published on an ongoing basis. An example of the areas under investigation is the degree of healthcare-related injuries in inpatient care.

The interview respondents state that a trend can be seen where measurement, follow-up and reporting of patient safety associated aspects are increasingly occurring. This is as new demands are placed on healthcare providers and healthcare organisations, not least from patients who demand that the area be investigated. Furthermore, the CPSI works, together with Health Canada and OEDC, to develop instruments to collect and investigate patient data with a focus on patient safety.

*“We think a lot about how to **strengthen measurement** in different areas, this is something that is **also demanded by patients**. Looking at the possibility to follow up based on **patient-reported data**”*

- CPSI representative

Reportedly, evaluation and follow-up is a relatively high focus of the new framework for patient safety that is currently being developed (see more detailed description under heading “*There is work underway to develop a national patient safety framework*”). As mentioned earlier, the respondents emphasise the importance of linking the different parts of the policy document, such as a strategy or action plan, in a clear and

logical way. This is so that it will be possible to follow-up on the effects and results at all levels, that is, in order to draw conclusions about whether activities at the caregiver level contribute to overall objective attainment.

Policy document results

The results of the policy document are presented below. Examples of questions to be answered are whether good results can be linked directly to the policy document or more to the governance or organisation at large? For the purposes of this the document “Patient safety - a bold new direction” is analysed. Business Plan 2018–2023” (12).

The business plan has not yet been evaluated but some results are available

As the business plan was published in 2018, there are currently no results that can be directly linked to the content of the policy document. However, the CPSI follows and compiles any progress in an annual report every year (23). The latest report from 2017–2018 states, among other things, that:

- 86% of all the measures in the Integrated Patient Safety Action plan have been implemented
- 66 patients have participated as volunteers in the “Patients for Patient Safety Canada” network
- 1924 individuals participated in “Canadian Patient Safety Week”
- 1117 individuals have undergone certification to educate others regarding patient safety issues

An external evaluation of the integrated Patient Safety Action Plan has been carried out

An external qualitative evaluation of the National Patient Safety Consortium and the Integrated Patient Safety Action Plan was carried out in the year 2017 (24). In summary, the evaluation shows:

- That the national collection helped to strengthen and create new co-operation between different actors in the healthcare sector.
- The co-operation to develop the integrated action plan resulted in a joint commitment to the implementation of the activities at national level.
- the CPSI had a central role in facilitating co-operation between the various actors involved in healthcare.
- The integrated action plan helped co-ordinate and create a better understanding of the patient safety issues in the country.
- The work resulted in all participants gaining an increased common understanding of patient safety.

The CPSI was last evaluated in 2017 and the overall conclusion is that their activities are needed

An external evaluation of the CPSI was last carried out in 2017 and the results show in brief that (11):

- there is still a need to work at national level for improved patient safety and that a national organisation such as the CPSI is needed.
- The CPSI's objectives are in line with the priorities of the Government and other key actors. However, some actors believe that a more focused strategy which more clearly guides the CPSI is needed.
- The CPSI meets existing requirements and also lives up to the expectations of running and co-ordinating a national collaboration in the field of patient safety at national level. However, some key actors highlight that it has to some extent been challenging for the CPSI to identify its role in the overall work for improved patient safety.
- The CPSI's work has resulted in evidence-based knowledge documentation in the field of patient safety. Some key actors point out that even more can be done by further focusing on measurement and follow-up.
- The CPSI's work has contributed to the inclusion of evidence-based knowledge of patient safety in the training of health professionals.
- The CPSI's work has generally resulted in an increased awareness and knowledge of patient safety issues among actors in the healthcare sector.
- Through the national gathering and the Integrated Patient Safety Action Plan, the CPSI has contributed to better co-ordination and co-operation in the healthcare system, which has resulted in a common patient safety agenda.
- Several key interests believe that the CPSI has contributed to a positive change in the patient safety culture, partly visible in new regulations and political decisions.
- The CPSI's activities have contributed to healthcare organisations having applied measures to improve patient safety. For example, 88 percent of all emergency care activities and 26 percent of all long-term care activities participated in the "Safer Healthcare Now!" program.
- The CPSI's collaboration with the Institute of Health Information (CIHI) to develop tools that measure healthcare-related injuries at hospitals (Hospitals Harm Measure) has brought progress in measurement and reporting on patient safety in Canada.
- The CPSI has contributed with tools that have resulted in the patient safety aspect being included in regulations, legislation and accreditation documentation.
- The CPSI has contributed to the involvement of patients and their families in national and international improvement work, for exam-

ple through the “Patients for Patient Safety Canada” program. However, no evaluation has been carried out to examine whether patient involvement contributed to improved patient safety related outcomes.

In conclusion, the report notes that the CPSI's work is expected to contribute to better patient safety in Canada. Although no noticeable improvement in patient safety has been measured since the CPSI was formed, many key actors are still of the opinion that the CPSI's activities lead to improved patient safety. Many also believe that patient safety would deteriorate if the CPSI's activities stopped, instead of being at a stable level.

Key interests seem to perceive the CPSI as a relevant body

The external evaluation of the CPSI every five years brings together, to a certain extent, key interests' views of the Institute and their policy document.

Overall, the external image seems to be that the CPSI's activities are appropriate, and in many ways, necessary to improve patient safety in the country. The organisation is needed, not least to ensure national coordination of the work.

References

1. Institute for Health Metrics and Evaluation. Retrieved 2020-01-16 from <http://www.healthdata.org/canada>.
2. Canadian Institute for Health Information. Health spending. Retrieved 2020- 01-16 from <https://www.cihi.ca/en/health-spending>.
3. The Commonwealth Fund. The Canadian Health Care System. Retrieved 2020-01-16 from <https://international.commonwealthfund.org/countries/canada/>.
4. Government of Canada. Canada's health care system. Retrieved 2020-01-16 from <https://www.canada.ca/en/health-canada/services/canada-health-care-system.html#a2>.
5. OECD. Retrieved 2020-01-16 from <https://stats.oecd.org/Index.aspx?QueryId=51884>.
6. Building a Safer System: A national Integrated Strategy for Improving Patient Safety in Canadian Health Care. The National Steering Committee on Patient Safety; 2002.
7. Canadian Patient Safety Institute. About CPSI. Retrieved 2020-01-16 from <http://www.patientsafetyinstitute.ca/en/about/Pages/default.aspx>.
8. Health Standards Organisation. Retrieved 2020-01-16 from <https://healthstandards.org/>.
9. Accreditation Canada. Health and Social Services Standards. Retrieved 2020-01-16 from <https://accreditation.ca/standards/>.
10. Ask.Listen.Talk. Business Plan 2013-2018. Canadian Patient Safety Institute; 2013.
11. Evaluation of the Canadian Patient Safety Institute Activities 2013-2014 to 2016-2017. Office of Audit and Evaluation Health Canada and the Public Health Agency of Canada; 2017.
12. Patient Safety A Bold New Direction. 2018-2023 Business Plan. Canadian Patient Safety Institute; 2018.
13. Performance Measurement Strategy 2018-2023. Canadian Patient Safety Institute; 2018.

14. Canadian Patient Safety Institute. Retrieved 2020-01-16 from <http://www.patientsafetyinstitute.ca/en/Pages/default.aspx>.
15. Canadian Patient Safety Institute. SHIFT to Safety. Retrieved 2020-01-16 from <http://www.patientsafetyinstitute.ca/en/About/Programs/shift-to-safety/Pages/default.aspx>.
16. Canadian Patient Safety Institute. National Patient Safety Consortium. Retrieved 2020-01-16 from <http://www.patientsafetyinstitute.ca/en/About/PatientSafetyForwardWith4/pages/national-patient-safety-consortium.aspx>.
17. Canadian Patient Safety Institute. Integrated Patient Safety Action Plan. Retrieved 2020-01-16 from <http://www.patientsafetyinstitute.ca/en/About/PatientSafetyForwardWith4/Pages/Integrated-Patient-Safety-Action-Plan.aspx>.
18. A surgical care safety action plan. Canadian Patient Safety Institute; 2014.
19. Evaluation of the Canadian Patient Safety Institute Activities 2013-2014 to 2016-2017. Office of Audit and Evaluation Health Canada and the Public Agency of Canada; 2017.
20. Canadian Patient Safety Institute. Patients for Patient Safety Canada. Retrieved 2020-01-16 from <https://www.patientsafetyinstitute.ca/en/About/Programs/PPSC/Pages/default.aspx>.
21. Annual Report Highlights 2017-18. Canadian Patient Safety Institute; 2018.
22. Evaluation of the National Patient Safety Consortium & Integrated Patient Safety Action Plan. Vision & Results; 2018.

Country Report Denmark

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Introduction

In the analysis of Denmark, we focus on the organisation: Dansk Selskab for Patientsikkerhed and their strategy (“Strategy plan 2017 – 2021”). The association is an independent organisation without a government mandate that works for increased patient safety on a national level. The organisation has been working on patient safety at a national level for a long time and is considered a driving and central actor in the field. There is no corresponding strategy at state level (i.e. produced by Parliament, the Government or any governmental administrative authority).

The analyses have been supplemented with information obtained in interviews with representatives from Dansk Selskab for Patientsikkerhed (The Danish Association for Patient Safety) and the Styrelsen for Patientsikkerhed (The Board for Patient Safety).

Below are the results of the analyses carried out based on the used framework.

Figure 1. Dansk Selskab for Patientsikkerhed (Strategy plan 2017 – 2021)




Description of the current context

In this section we more closely describe the context that characterizes the policy documents in different ways. For example, questions are answered about the possible needs that are the basis for the policy document and what the management of the healthcare system looks like.

Review country facts – Denmark

Figure 2. Summary of basic country facts (1), (2)

Country facts		
Population (million)	5.7 (2016)	
Average life expectancy (males/females, years)	78.8/82.8 (2016)	
Child mortality (< 5 years old per 1000/births)	4.1 (2016)	
Health care cost (% GDP)	10.8 (2017)	

The Danish healthcare system is similar in many ways to the Swedish one

As in Sweden, a large proportion of Danish healthcare is funded by tax revenue. The Danish healthcare system can be described as relatively decentralised, but the division of responsibility for the management of healthcare ranges from state to regional and municipal levels. The responsibility for legislation and enforcement in this area is at state level. The state work is largely concentrated on the Ministry of Health and Social Affairs (Sundheds- og ældreministeriet) (3).

There are a total of five regions responsible for and providing specialised healthcare and primary care. The 98 Danish municipal councils are primarily responsible for the care of the elderly, rehabilitation and a variety of social services.

National patient safety work started in 2001

In 2001, a scientific article was published based on the results of a Danish pilot study (4). The pilot study showed that almost ten percent of all patients

enrolled in Danish hospitals suffered from a healthcare-related injury. The injury resulted in an average of seven extra patient days in in-patient care. The article led to the issue of patient safety being high on the social agenda and thus became an important issue in the political debate around healthcare.

The independent organisation *Danish Association for Patient Safety* (*Dansk Selskab for Patientsikkerhed*) was founded against this background (5). The association consists of representatives from different parts of Danish healthcare, such as caregivers, patient representatives, regional and municipal representatives and representatives from the pharmaceutical industry. The organisation's goal at the time when it was founded was to influence and enable improvement efforts to increase patient safety in healthcare and that remains the objective to this day. In conclusion, the organisation strives to influence decision-makers and key actors to work increasingly systematically to improve patient safety.

When the association was formed, it was, among other things, the driving force for the establishment of a national reporting system for adverse events within the healthcare system. In 2004, a New Patient Safety Act ("*Lov patientsikkerhed in Sundhedsvaesenet*") was established. The new legislation made it mandatory for healthcare providers to report all healthcare-related injuries. The reporting system, which still applies, aims only to collect and compile knowledge. In other words, it is not linked to any disciplinary measures such as periodic penalty payments or equivalents (6).

The Danish Association for Patient Safety remains the organisation that operates and co-ordinates the work for improved patient safety at national level (7). Within the framework of its activities, the association works with hospitals, regions, municipalities and other interest groups. Since its foundation, a number of improvement projects have been carried out, such as "Operation Life", "Patientsikkert Sygehus", "Sikkert Patientflow" and "Sikre Födsler".

The Danish Association for Patient Safety is described as having a support mandate

Given that the association is independent, its mission and role can primarily be described as supportive. According to interviewed representatives, the Association has no regulatory powers, but works primarily to influence and enable improvement work with a focus on patient safety. Representatives of the association say that they value this independence from the state. Independence is perceived to create the conditions for the association to meet its basic mission. In addition, representatives state that there is the need for the association's mission, not least because the political will to prioritise national patient safety work varies over time.

"Patient safety was a major political issue some time ago and it was thought that the problem was solved, but it has not [...], we have major problems in terms of coordination between activities and principals"

- Representative of the Danish Association for Patient Safety

"Our independence is an important precondition for us to be able to respond to our mission in a good way"

- Representative of the Danish Association for Patient Safety

The state also has a role to play in pushing the continuous quality improvement work

Although a large part of the improvement work in Denmark can be derived from the Danish Association for Patient Safety, some work at state level also contributes to ensuring that continuous quality improvement work takes place within healthcare. It is primarily the government, through the Ministry of Health and Social Affairs (Sundheds- og ældreministeret), which is responsible for health issues at a national level (8). The authority “Styrelsen for patientsikkerhed” (The Board for Patient Safety) is another central actor (9). The latter is subject to the ministry and is responsible, among other things, for supervision and authorisation.

Among other things, the Board For Patient Safety has responsibility for the reporting system for healthcare-related injuries and it issues identification to healthcare professionals. According to an interviewed government representative, the Board for Patient Safety has certain regulatory powers, but this does not apply to all its areas of responsibility. In short, the authority therefore also has a supportive and co-ordinating role. For example, the authority focuses in particular on co-ordination and cooperation between the various actors with a focus on identifying areas for improvement.

In summary, the state’s responsibility for improvement work in the field of patient safety is described as limited. In particular, the main formal responsibility for development work is concentrated at regional level.

*“My department **does not have the mandate** to order caregivers what to do. However, **our inspection department** has such a mission. [...] Among other things, we work **to gather together various interested parties to promote co-operation**”*

- Representative of the Board of Patient Safety

*“**The co-ordination task** for patient safety should be at **national level**”*

- Representative of the Board of Patient Safety

In interviews with representatives from the Danish Association for Patient Safety and the Board of Patient Safety, the importance of streamlining the tasks of national actors is emphasised. In other words, according to the interview respondents, it is important to clarify what each and every actor’s responsibilities are and that the direct mandate is not combined or mixed up with the more indirect governing task at national level. Furthermore, the interviews underlined the importance of well-functioning national co-ordination in a complex and decentralised system.

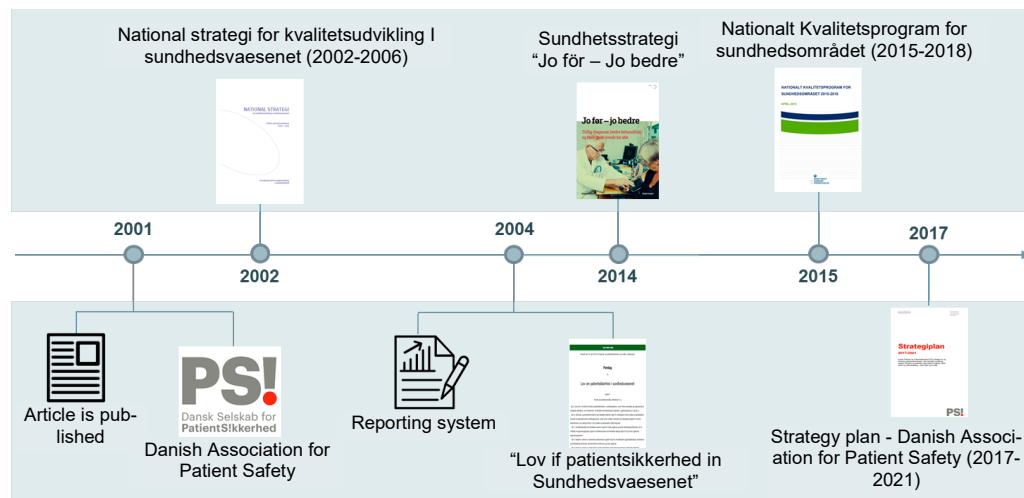
The government has published several policy documents with a link to the field of patient safety

Since 2001, the Government has published several different strategy documents across a wide range of areas. The documents are aimed at improving the quality of healthcare. Some examples of this type of policy document are “*National strategi for kvalitetsudvikling i sundhedsvæsenet (2002–2006)*” (10), “*Sundhedsstrategi*” *Jo før – Jo bedre: Tidlig diagnose, bedre behandling og flere gode leveår for alle*” (2014)” and “*Nationalt*

Kvalitetsprogram for sundhedsområdet (2015–2018)” (11) (12). The policy documents do not highlight the patient safety perspective in particular, but raise general guidelines for more long-term improvement work in healthcare. In the latest edition of the National Quality Programme, the patient safety perspective is one of several elements highlighted in the national quality objectives. The objectives focus almost exclusively on the presence of health care associated infections (HAI).

In Figure 3 the following, the development of patient safety in Denmark over time is visible and summarised.

Figure 3. Timeline of patient safety work in Denmark



The analysis is based on the policy documents developed by the Danish Association for Patient Safety

Although the Government is making certain efforts aimed at improving patient safety and has developed some comprehensive strategy documents that highlight the issue to some extent, in this analysis we focus on the strategy document produced by the Danish Association for Patient safety. The choice is based on an overall assessment of Denmark's national improvement work for patient safety, where the association has a particularly prominent role.

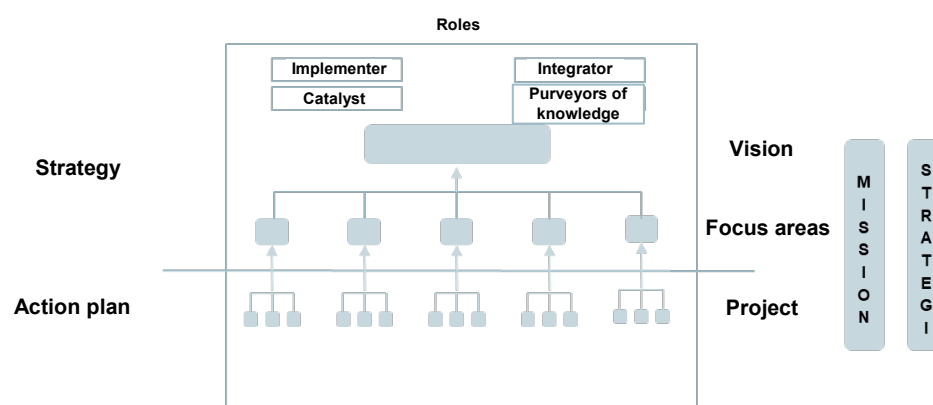
Policy document structure

This section describes the structure of the policy documents. Questions about the parts of the policy document and the intended recipients are answered here. We also highlight the format of the documentation, i.e. whether they are comprehensive or summarised etc. Policy document here refers to the analysed document “Strategiplan 2017–2021” from Dansk Selskab for Patientsikkerhed (13).

The policy document can be described as both an overall strategy and a more concrete action plan

Overall, the policy document consists of six main parts: 1) an overall vision for the work of the association; 2) a mission for the operation; 3) a description of the association's strategy; 4) a description of the different roles of the association; 5) five focus areas that frame the work done to achieve the vision, and 6) ongoing, planned and future projects that are sorted within each focus area (see the visualisation of the structure of the policy document below in Figure 4).

Figure 4. Visualisation of the structure of the policy document



It is not clear, simply by reading the policy document, how the various elements are connected and relate to one another. For example, it is not entirely clear how the mission relates to the Association's stated strategy for how they are to work (a longer reasoning about the content follows under the heading “Content of the policy document”). Neither does the Association representative give a clear explanation as to why the structure looks like it does or what the thought is behind the different parts.

The document, as its title implies, can be seen as a combined strategy and action plan as it sets out a broader framework for the business and describes relatively concretely what is being done and remains to be done to achieve

the overall vision. At the same time, the policy document has no stated purpose to act as a support in the change work at operational level.

The policy document is primarily aimed at the association's employees

The strategic plan is primarily aimed at people and functions that work within the association. In other words, it does not expressly claim to guide, for example, patients, healthcare professionals, caregivers or county councils in possible improvement work with a focus on patient safety. At the same time, both ongoing as well as planned and future projects are described, and in this way the policy document partly addresses caregivers, municipalities and regions, among others. The interpretation is confirmed by the interview respondents, who state that although the policy document is primarily internal, it can be used to communicate key messages externally.

*"The document is **primarily** aimed at **our employees**. However, we represent so **many key actors** that the strategy becomes a tool for **communicating central messages outward**"*

- Representative of the Danish Association for Patient Safety

The document is easily accessible

The policy document consists of a sequential text document of about 20 pages. The basis is relatively text heavy, but with visual elements that summarise the main elements of the policy document. In conclusion, the document can be described as easily accessible, especially as it is relatively concise.

Communication is an important part of the association's strategy

Being able to convey the association's message and vision is a central part of the strategy for the Danish Association for Patient Safety according to interviewed representatives from the association. This is achieved by monthly editions of the newsletter "Fagligt Nyt", among other things. The newsletter highlights current news in the field of patient safety and also any results or updates from the projects run by the association.

In addition to this, the association also publishes blog posts, organises conferences and lectures. The projects run by the association usually have a logo that is specifically designed for that particular project, which creates a recognition factor. The association also participates in various research networks in order to both disseminate and develop its own knowledge. Furthermore, interviewed representatives from the association stated that targeted and well thought-out communication is valued and that a well-thought-out strategy for communication has been developed. For example, the association has conducted various types of communication campaigns.

The policy document runs over a four-year period

The strategy period extends from 2017–2021, with an annual audit that takes place in November. The reason for the selected timeframe is not stated in the policy document, nor during an interview with representatives of the organisation.

Policy document content

In this section we report the content of the policy documents. For example, questions about the strategy's thematic focus or whether the content is based on a clear perspective are answered. We also describe the tangibility level in the policy document more closely. Policy document here refers to the analysed document "Strategiplan 2017–2021" from Dansk Selskab for Patientsikkerhed (13).

The content of the strategy plan is broad and extensive, but to some extent overlaps

The vision, mission, strategy and roles merge into each other

The association's vision, which is highlighted in the policy document, is formulated as: *"The Danish Association for Patient Safety works to improve patient safety in healthcare. Citizens and patients should experience security, efficiency and continuity – always and for everyone"*

The mission is in turn formulated as meaning that the association will: *"Accelerate the improvement of patient safety in a coherent health system".*

According to the document, the explicit strategy is that the Association: *"Develops, co-creates and promotes viable and scalable results that promote patient safety. We build culture, capacity and competence to change and improve in order to create results."*

The roles that the association will take according to the strategy plan, and which seem to be linked to the document's vision, mission and strategy, are:

- The role of catalyst – meaning that the association will inform, inspire and identify solutions to current challenges and thereby contribute to the mission.
- The role of integrator – meaning that the association will act as a link between different actors within healthcare and welfare to create a platform for broad co-operation within patient safety work.
- The role of implementer – meaning that the association will organise and lead concrete projects that increase patient safety.
- The role of knowledge carrier – meaning that the association will function as a national centre of knowledge and, among other things, through its national and international networks, gather relevant expertise, both in terms of patient safety and methods of improvement work.

It can be noted that both vision and mission, as well as strategy and roles describe what the association does or should do. This leads to difficulties in the interpretation of the various parts. For example, is the mission superior to the stated strategy or vice versa?

Focus areas lay the foundation for the projects that the association will implement

To work towards the vision, the policy document indicates a total of five focus areas:

- Person centring and safety
- Improvement methods
- Continuity
- Reliability and efficiency
- Knowledge and communication

See below for the description of each focus area.

Person centred and safety

In this area, great emphasis is placed on the patient/citizen being the starting point for all patient safety work, and taking their wishes, values, family relationships, social situation, lifestyle and preferences into account. An ongoing project that clearly connects to this area is the inclusion of patient ambassadors in the daily work of the association (14). In brief, the ambassadors are a network of patients who create a bridge between patients and caregivers, by, for example, participating in lectures and in quality committees.

Improvement methods

In this area, the association will continue to develop and improve methods for change management and disseminate the skills of improvement work in both healthcare and welfare. This is to assist healthcare providers to independently pursue continuous improvement work. An example of a planned activity within the focus area is to evaluate the project “I säkra handen” (“In safe hands”). The purpose of the evaluation is to identify learned lessons that form the basis of future projects.

Continuity

This means that the association will endeavour to work in areas that affect different sectors, such as the pharmaceutical sector. Within this type of cross sectional field, the association can act as a link between different professions and representatives to contribute to increased continuity. Enhanced continuity contributes to increased patient safety in the long term. An example of an ongoing project in this field, which is also highlighted in the policy document, is “Sikker sammanhaeng” (“Safe cohesion”) (15). The project is a collaboration between the Danish Association for Patient Safety, Copenhagen Municipality and Bispebjerg-Frederiksberg Hospital. The objective of the work is to create a better course of care for elderly patients (> 65 years old) in order to shorten the time the patient is enrolled in inpatient care, reduce waiting times for rehabilitation and prevent emergency care visits and registrations.

Reliability and efficiency

The area means that the association will focus on reducing waste resources, unjustified variations and waiting times in healthcare during the strategy period. The objective is safe care where all patients are treated equally across the entire system. Psychiatry is particularly emphasised in this context and an ongoing project highlighted in the policy document is called “Sikker Psykiatri” (“Safe Psychiatry”) (16). All five regions participate in the project and aim to prevent medication errors, involuntary treatment and suicide cases, and to ensure effective treatment of patients suffering from somatic and psychiatric comorbidity through various improvement measures.

Knowledge and communication

In the context of this focus area, according to the strategy document, the association will strengthen its co-operation with other relevant actors with valuable knowledge in the field of patient safety. The aim is to expand their own knowledge base and note the different perspectives of both patient safety and the challenges identified by different actors. The objective of the work is to strengthen the association's role as a national knowledge carrier in patient safety and improvement work. As part of the focus area, the association will also strengthen its own communication work during the strategy period. This is to ensure that their knowledge is disseminated throughout the healthcare system and to other relevant actors. Through stronger and more successful communication work, caregivers are better able to pursue continuous development work that benefits patients. Ongoing projects in this focus area that are particularly highlighted in the strategy are, for example, the organisation/participation of various conferences such as the “Patientsikkerhedskonferencen” (“Patient Safety Conference”).

Specific projects are described within each focus area

Within the scope of each focus area, both ongoing (Igangvaerande), planned (pipeline) and future (boblere) projects are highlighted. The planned projects mean that they are defined and that relevant partners have been identified, but that there is currently no funding for the project to begin. Future projects mean that interesting areas have been identified as well as extensive improvement. To get a clearer picture of how descriptions of different projects are presented in the strategy see Figure 5 below.

Figure 5. Example of a description of different projects within a focus area (patient centring and safety)

Igangværende	Pipeline	Boblere
PS' samlede opgaveportefølge skal understøtte patient-sikkerhed og et trygt og personcentreret sundhedsvæsen. Specifikke aktiviteter kan fremhæves:	Nationale projekter: Reduktion af overbehandling.	Nationale projekter: Udvikling og udvidelse af skadesbegreb
Hej Sundhedsvæsen (2014-31.12.2017)	Imødekomme patient- og pårørendes ønsker om den sidste tid.	Fejl og skader i sundhedsvæsenet som en del af sygdomsbyrdeopgørelse
Patientambassadører	National udbredelse af I sikre hænder	UTH-systemets anvendelse
	Netværk og anbefalinger vedr. digitalisering/medicinsk udstyr	
	Netværk og anbefalinger vedrørende curriculum for sundhedsuddannelser i kvalitet og patientsikkerhed	

The policy document mainly focuses on success areas, but the outcome and risk areas are also highlighted

The policy document can be said to have a constructive approach. It focuses primarily on “success areas”, that is to say, areas that can contribute to improved patient safety in different ways. In the context of the different focus areas and projects, for example, patient/person centring, knowledge and communication, improvement methods and continuity are highlighted which can be described as success areas. In addition, the document, in some cases indirectly, also highlights both the outcome and risk areas. For example, as mentioned earlier, reference is made to the “Safe Psychiatry” project which aims, among other things, to reduce and prevent medication error, involuntary care and suicide (16). These aspects can be sorted as outcome areas. It also mentions a few factors that can be defined as risk areas such as waste of resources, unjustified variations and waiting times.

The representative of the association confirms the image that success areas are seen as particularly important. For example, the culture of patient safety is highlighted as the most crucial factor in achieving improvements in the field of patient safety.

“Patient safety culture is the most important factor in the desired breakthrough”

- Representative of the Danish Association for Patient Safety

The policy document is based on a relatively broad approach to patient safety

The image given in the policy document is that the association has a relatively broad view of patient safety. In the context of the different focus areas, different projects will be conducted to stimulate improvement work and to shorten waiting times for example. The vision highlights concepts such as “security” and “continuity”, which can also be associated with broader quality work. In other words, the content of the plan is not exclusively about protection against adverse events, which is the Swedish definition of patient safety according to chapter 1, 6 § Patient Safety Act (2010:659). At the same time, quality is not explicitly mentioned as a dimension of the strategy plan, as opposed to efficiency.

In summary, the work of the association and the content of the strategy plan can be interpreted as aiming to improve the quality of healthcare in general, thereby contributing to increased patient safety.

The document embodies improvement measures by highlighting different projects

When it comes to the level of detail of the policy document, the plan specifies a broader vision, mission and strategy. It also highlights relatively concrete focus areas and related projects. Although the document does not explicitly highlight examples of improvement measures, the concrete project descriptions reveal the necessary efforts needed to achieve the overall vision.

Policy document processes

This section presents the central processes that can be linked to the policy document. Examples of questions to be answered are whether the policy document was based on a particular process, for example through consultation or negotiation? Another important element is examining whether the policy document describes different central processes and, in such cases, what is included in them. Policy document here refers to the analysed document “Strategiplan 2017–2021” from Dansk Selskab for Patientsikkerhed (13).

The strategic plan has been developed based on reconciliations with different actors

The strategy is based on a collection of views and thoughts from board organisations, patient ambassadors, employees and the “Patientsikkerhedsrådet”, an advisory body composed of various representatives from the Specialist Medical Association, Midwifery Association, different regions, universities, municipalities etc. The policy document also contains an annex listing the submitted proposals by the various interests. Inspiration from national and international co-operation partners, such as the IHI, has been gathered when the strategic plan was developed.

The association's work is continuously anchored in the Patient Safety Council

The Patient Safety Council contributes with a broad perspective and knowledge in health issues in general and also more specifically in the field of patient safety, which can be indicative of the decisions taken by the association. The association continuously reconciles the work with the Council. This is in order to formulate improvement measures that are in line with the interests of the various health practitioners.

The plan describes the implementation to some extent

The policy document does not contain detailed descriptions of how the work is to be carried out, but, as mentioned earlier, highlights ongoing, planned and future projects, which gives a picture of the association's work. It is also highlighted that the Board of the Association and the Patient Safety Council will be more involved in the daily work of the Secretariat. Among other things, the Board will continuously formulate objectives. The objectives should reflect the organisation's vision, mission and the degree of objective fulfilment shall be reported at each board meeting. According to the plan, the role of the Patient Safety Council should also be developed during the strategy period in order to better promote knowledge and perspectives within the field of patient safety.

Descriptions of how the work is to be followed up are missing

There is no clear description of how the follow-up of the strategy's different focus areas should be made in the policy document. However, on the association's website (7), there are some reports from previously completed projects that summarise and evaluate the results of the projects and the lessons learned. In an interview with association representatives, it was confirmed that systems for regular monitoring of the content of the document have not been established. It is clear that the policy document is undergoing an annual internal review, but it is difficult to define which indicators should be measured and followed. Representatives of the Board of Patient Safety also consider that there are no key structures and procedures for monitoring the patient safety area as a whole. There are currently no effective instruments to measure the development over time.

*"We **have no good system** for monitoring the impact within patient safety in Denmark"*

- Representative of the Board of Patient Safety

Policy document results

The results of the policy document are presented below. Examples of questions to be answered are whether good results can be linked directly to the policy document or more to the governance or organisation at large? Policy document here refers to the analysed document “Strategiplan 2017–2021” from Dansk Selskab for Patientsikkerhed (13).

Separate project evaluations are performed on a continuous basis, but there is no evaluation of the whole strategy

The strategy has not yet been evaluated since it was published in 2017. However, separate evaluations have been carried out on previous projects. Examples of these are:

- **Evaluation of “Sikkert Patientflow” (2014–2015) (17):** Twelve emergency hospitals participated in the project in order to find ways to improve the flow when it comes to the registration and discharge of patients. The objective was to prevent overcrowding of patients in hospitals. The overall conclusion of the evaluation is that it is difficult to express a general opinion on the results of the project. However, one of the participating hospitals, Slagesle Sygehus, can be described as a successful example. At Slagesle Sygehus a positive development could be seen and the program's actions resulted in a drastic reduction in the number of patients forced to stay overnight in corridors and a reduction in the number of patients who were placed in temporary beds at registration. In addition, the average duration of care decreased.
- **Evaluation of “Patientsikkert Sygehus” (2010–2013) (18):** A total of five hospitals participated in the project. During the project period, hospitals worked to implement a number of action packages and develop skills to improve patient safety in clinical practice. The objective of the project was that each hospital would reduce hospital mortality (according to HSMR) by 15 percent and accidental injuries by 30 percent. This would be achieved by reducing the number of unexpected cardiac arrests, eliminating a variety of hospital associated infections, reducing the incidence of pressure ulcers and preventing failures associated with surgical procedures and medication errors. The conclusions of the evaluations claim that several of the objectives were achieved before the project was completed in 2013. In addition, the evaluation shows that all objectives were achieved in at least one of the five hospitals. The aim of the project, in addition to reducing hospital mortality and healthcare-related injuries, was that it would also serve as an example of how structured change management can occur. According to the evaluation, the project contributed to the development of competences of health professionals in order to be able to

pursue further improvement work, thereby also achieving the aim of acting as a positive example.

- **Evaluation of “Operation Life” (2007–2009) (19):** As part of the project, a campaign was launched to get operations to actively work with measures to prevent hospital deaths. A total of 200 departments participated during the project period and implemented a number of different action packages within clinical operations. The evaluation shows that, over a period of two years, the number of expected deaths (according to HSMR) reduced to a total of 1654 cases in Danish hospitals.

As there is no overall evaluation of the strategy and the association as a whole, it is difficult to draw any general conclusions about the work of the association.

Key interests generally seem to support the content of the strategic plan

The general view of the content of the strategy document is positive, which is the result of the association's members consisting of different key actors in the healthcare system. This is also confirmed by association representatives who note that central formulations in the strategic plan, such as the association's mission, have been designed on the basis of priorities of the key interests.

References

1. Institute for Health Metrics and Evaluation. IHME: Denmark. Retrieved 2020-01-16 from <http://www.healthdata.org/denmark>.
2. World Health Organization. Countries: Denmark. Retrieved 2020-01-16 from <http://www.who.int/countries/dnk/en/>.
3. Healthcare in Denmark - an Overview. København: Sundheds- og Ældreministeriet; 2017.
4. Schiøler T, et al. Incidence of adverse events in hospitalized patients. The Danish Adverse Event Study (DAES). Ugeskr Læger 2001;163.
5. Lundgaard, et al. The Danish patient safety experience: the Act on Patient Safety in the Danish health care system. Italian J Public Health 2005; 2: 3-4.
6. Styrelsen for Patientsikkerhed. Rapporteringsordningen for utilsigtede haendelser. Retrieved 2020-01-17 from <https://stps.dk/da/sundhedsprofessionelle-og-myndigheder/laering/rapporteringsordningen-for-utilsigtede-haendelser/>.
7. Dansk Selskab for Patientsikkerhed. Retrieved 2020-01-17 from <https://patientsikkerhed.dk/>.
8. Sundheds- og Ældreministeriet. Retrieved 2020-01-17 from <https://www.sum.dk/>.
9. Styrelsen for Patientsikkerhed. Retrieved 2020-01-17 from <https://stps.dk/>.
10. National strategi for kvalitetsudvikling i sundhedsvæsenet 2002-2006. Sundhedsstyrelsen; 2002.
11. Jo för - Jo bedre: Tidlig diagnose, bedre behandling og flere gode leveår for alle. Köpenhamn: Ministeriet for sundhed og forebyggelse; 2014.
12. Nationalt Kvalitetsprogram for sundhedsområden 2015-2018. Ministeriet for sundhed og forebyggelse; 2015.
13. Strategiplan 2017-2021. Dansk Selskab for Patientsikkerhed; 2017.
14. Dansk Selskab for Patientsikkerhed. Patientambassadørerne. Retrieved 2020-01-17 from <https://patientsikkerhed.dk/projekter/patientambassadoererne/>.

15. Dansk Selskab for Patientsikkerhed. Sikker Sammenhang. Retrieved 2020-01-17 from <https://patientsikkerhed.dk/projekter/sikkersammenhaeng>.
16. Sikker Psykiatri. Retrieved 2020-01-17 from <http://sikkerpsykiatri.dk/>.
17. Sikkert Patientflow: Erfaringer fra et forbedringsprojekt. Dansk Selskab for Patientsikkerhed; 2015.
<https://patientsikkerhed.dk/content/uploads/2015/12/sikkertpatientflowfinal.pdf>.
18. Patientsikkert Sygehus: Et kvalitetsprogram. Fra Patientsikker Sygehus til forbedringsarbejde på sundhedsområdet. Dansk Selskab for Patientsikkerhed; 2015.
https://patientsikkerhed.dk/content/uploads/2015/11/psskatalog_webversion.pdf.
19. Slutrapport: Operation Life. Dansk Selskab for Patientsikkerhed och TrygFonden; 2009.
https://patientsikkerhed.dk/content/uploads/2015/12/operationlife_slutrapport.pdf.

Country Report England

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Introduction

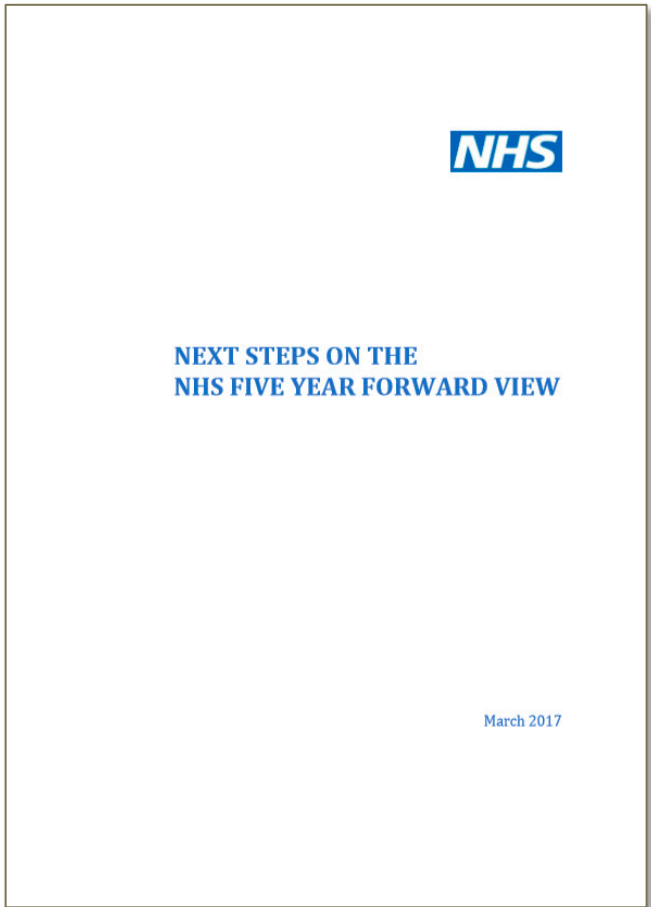
In this country report, we focus on the policy document "Next steps on the NHS Five Year Forward View" published in 2017. The document is an updated version of the "Five Year Forward View" – a five years strategic vision for the UK healthcare system (NHS England).

The "Next steps on the NHS Five Year Forward View" complements the longer-term vision with concrete actions to attain the desired target. Examples of proposals for action presented here are national efforts to improve patient safety. As the policy document is partly the basis for the overall quality work in healthcare at national level, and partly the national improvement work with a focus on patient safety, it has been selected as the main document for our in-depth analysis.

The analyses have been supplemented with information obtained in an interview with an expert from the Institute of Global Health Innovation with a history within NHS England.

Below are the results of the analyses carried out based on the used framework.

Figure 1. "Next steps on the NHS Five Year Forward View"




Description of the current context

In this section we describe more closely the context that characterizes the policy document in different ways. For example, questions are answered about the possible needs that are the basis for the policy document and what the management of the healthcare system looks like.

Overview Country Facts – England

Figure 2. Summary of basic country facts (1), (2)

Country facts		
Population (million)	55 (2016)	
Average life expectancy (males/females, years)	79.2/83.1 (2016)	
Child mortality (< 5 years old per 1000/births)	4.6 (2016)	
Health care cost (% GDP)	9.8 (UK) (2014)	

The English healthcare system is complex and is characterised by state governance

The healthcare system in England is called the National Health Service, and this is managed by NHS England (3). NHS England is subject to the Department of Health and Social Care, which in turn reports to parliament. The healthcare system in England is largely financed through tax. The government distributes financial resources through the state budget to NHS England, through the responsible department, which in turn procures different types of healthcare and welfare.

The procurement of hospital care, ambulance care, dental care, mental health services and certain welfare services are planned through local client organisations called "Clinical Commissioning Groups (CCGs). Some primary care is also procured by CCGs, but most primary actors (GPs) have contracts directly with NHS England. The specialised care in the form of hospitals, is owned by NHS Trusts. Local units which correspond to local authorities are responsible for providing social welfare. They also carry out certain public health measures.

The tax financed system gives all citizens of England access to primary care and specialist care, necessary dental care, eye care, care and treatment of

mental illness, care in the final stages of life, some rehabilitation and home healthcare. Certain preventative health measures, such as vaccination programs, are also part of the tax financed offer. This type of care is provided without any major patient fees.

Several bodies work with quality improvement at national level

In addition to NHS England, which plays a key role in the English healthcare system, there are a number of other key bodies, which are also subject to the responsible department, and which, in various ways, are important elements of national quality work. These organisations include:

NHS Improvement: responsible for monitoring and supporting healthcare providers in order to provide safe and sustainable healthcare, which is also economically viable (4). NHS Improvement works in close cooperation with healthcare providers to achieve national ambitions and objectives in terms of the provision of care.

Care Quality Commission (CQC): is an independent organisation tasked by the Department of Health and Social Care to carry out supervision of healthcare and welfare (5). The CQC was founded in 2008 with the support of the national legal framework for healthcare. The organisation reports to parliament and the government through the department responsible. Within the framework of the CQC's assignment, the work is to conduct supervision, inspection and regulation of health and welfare care through regulations and standards. This is to ensure that healthcare and welfare are up to national quality and safety requirements.

The National Institute for Health and Care Excellence (NICE): is an independent organisation tasked by the Department of Health and Social Care to develop normative decisions for healthcare providers on evidence-based methods (6). The normative decisionbases are not binding on healthcare providers, but serve as effective tools for monitoring and measuring quality and improvement work in various activities. NICE therefore serves as an advisory and supportive organisation for improved quality in healthcare and welfare.

Health Education England (HEE): Responsible for the national coordination of training and development of skills of health professionals in England (7).

A special quality board – National Quality Board – coordinates the various organisations working for quality development at national level

All national organisations described above are part of the national work to improve quality in healthcare. In order to improve the conditions for coordination and interaction between these actors, a special quality board – the National Quality Board – has been established (8). Representatives from all relevant organisations are represented on the board, and the idea is that these representatives will be able to discuss and exchange different ideas and information. The aim is that this exchange will lead to a greater consensus

and that this will create better conditions for the design of the activities in a more similar direction.

National patient safety work has been going on for a long time

A national report was the main contributor to national patient safety work

In 2000, an expert group in the NHS published a report called "An organisation with a Memory" (9). The report briefly described the consequences of a lack of safety work in healthcare. Examples of consequences that were highlighted were: deaths, injuries, side effects and costs.

The report was the basis for a solid national effort to improve patient safety in the UK (10). In connection with this, the organisation "National Patient Safety Agency 2001" (whose data was taken over by NHS Improvement 2016) was also established at the initiative of the NHS. The organisation was formed with the aim of making patient safety a priority within the NHS. One of the organisation's first tasks was to develop a national reporting system for incidents in healthcare. Great efforts were also made to achieve a cultural shift in dealing with incidents in healthcare – from penalties and accusations to openness and focus on mutual learning.

In 2004, the government formulated national quality objectives, one area of which was patient safety. Thus, patient safety was automatically a priority for all healthcare providers working within the NHS. In the same year, the non-profit organisation "The Health Foundation" also launched a special initiative in patient safety called the "Safer Patients Initiative". The initiative consisted of a four-year program focusing on the implementation of a range of different quality improvement projects in inpatient care around the country, for example with the aim of reducing incidents in medication treatments.

In 2008 a national patient safety campaign was launched

In 2008, another national campaign was launched in England called "Patient Safety First" (11). The campaign was sponsored by the "National Patient Safety Agency", "The Health Foundation" and "NHS Institute for Innovation and Improvement". The campaign aimed to bring about a cultural shift in healthcare where, for example, preventable adverse events and mortality are seen as completely unacceptable. Many healthcare providers joined the campaign and the work focused on five different areas: 1) reduction of injuries in event of clinical deterioration of hospitalised patients; 2) emergency medical care; 3) surgery; 4) hazardous medication and 5) leadership for safety.

The same year new legislation was introduced to the field (the Health and Social Care Act) (12). Together with the new legislation, the "Care Quality Commission" was established – that is to say, the independent national supervisory operator.

In 2014, national policy documents were published focusing on improved quality of care

In 2013, the National Advisory Group on the Safety of Patients in England published the "A promise to learn – a commitment to act" report (13). The report was produced in connection with an investigation of Stafford Hospital. The investigation showed that several hundred patients had died as a result of quality deficiencies in healthcare. The report presented various recommendations for increasing patient safety within NHS England.

Against this backdrop, the NHS in 2014 launched a new national patient safety campaign called "Sign up to Safety" (14), which continues to this day. In brief, the campaign aims to encourage healthcare providers and other relevant organisations to engage in the patient safety issue, through the establishment of learning and collaboration procedures, among other things. Currently, nearly 500 organisations have joined the campaign.

Also in 2014, the policy document "Five year Forward View" (15) was launched, a strategic vision with a focus on NHS development over the next five years. The policy document presented ambitions to overall improve the quality of care, and patient safety was highlighted as a key aspect to achieving this. The document focused in particular on the development of new care models in which the integration of primary healthcare and hospital care and social care was particularly highlighted. In interviews with representatives from the Institute of Global Health Innovation with a history within NHS England, it is stressed that an important part of the identification and development of new forms of care was to improve quality by reducing both costs and unjustified variations in healthcare.

"The main focus of "Five Year Forward View" was to 'find new models to deliver good quality care'"

-Expert England

In 2017, an up-to-date national policy document was published, where patient safety was given more priority

In summary, "Five Year Forward View" was the basis for broad improvement work with a focus on increased quality in healthcare. In other words, the patient safety perspective is not specifically highlighted in this document. In 2017, the NHS published "Next Steps on the Five Year Forward View" – a national policy document that more clearly highlighted the importance of patient safety in healthcare (16). For example, proposals for action are presented in order to achieve the overall vision, and patient safety is highlighted as one of three driving factors (enablers) for improved quality of care.

National patient safety work can be summed up in three steps

In our expert interview with the representative from the Institute of Global Health Innovation, national patient safety work has been conducted in three steps. The first step concerned the development and establishment of systems

for incident reporting in healthcare. This is to create the conditions for learning and feedback. Reportedly, a continuous effort is being carried out to include patients in incident reporting to a greater extent. This is justified on the basis that patients should be seen as experts on their own safety and therefore it is crucial that they are involved in patient safety work.

In the second stage, the work is focused on developing and strengthening the capacity of health professionals to perform improvement work, including with a focus on patient safety. In conclusion, the work has been focused as tasked on developing systems and procedures to improve the conditions for this type of work. One example is the establishment of the "Patient safety collaboratives" network (17). Here, different actors can gather to exchange knowledge and ideas in the field of patient safety, thereby creating the conditions for mutual learning.

In the third stage, the work has been focused on examining the obstacles to improved patient safety that can be seen, and how these can be bridged. The starting point for this work has been efforts to improve culture with a special focus on learning. Among other things, the goal is to raise awareness of the contribution of the human factor to mistakes and incidents.

According to the interviewed expert, the main starting point for national patient safety work in England has consistently been the individual patient's interface with care. It is at this level that change has to happen, something that improvement measures at other levels must take into account. In conclusion, the report is currently working on developing an updated long-term strategic plan for NHS improvement work.

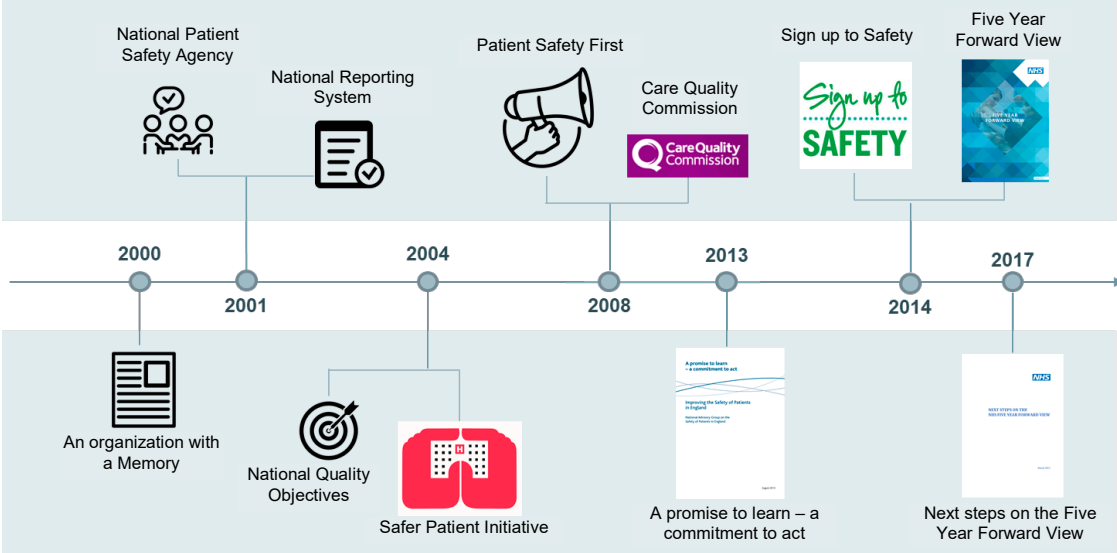
*"If the work we do at **higher levels** does not create **an improvement in the meeting with the patient**, it is a waste of time"*

-Expert England

In summary, our analysis focuses mainly on the "Next Steps on the Five Year Forward View" (16) policy document. This highlights the national priority areas and the proposals for action in the field of patient safety in a clear manner. The analysis is also complemented by information from the NHS website (www.nhs.uk) as well as valuable insights from our interview conducted with an expert from the Institute of Global Health Innovation who had also previously worked with patient safety at national level within the NHS.

The development of patient safety work in England is visible and summarised in Figure 3 below.

Figure 3. Timeline of national patient safety work in England



Policy document structure

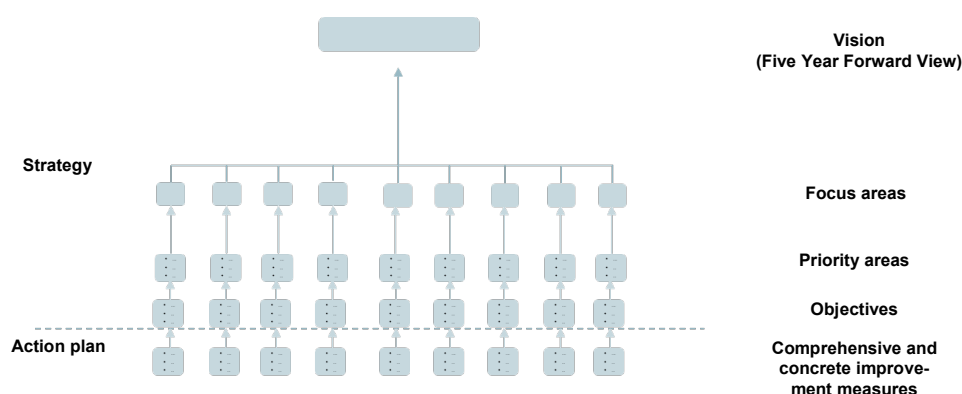
This section describes the structure of the policy documents. Questions about the parts of the policy document and the intended recipients are answered here. We also highlight the format of the documentation, i.e. whether they are comprehensive or summarised etc. "Policy document" means the analysed document "Next Steps on the Five Year Forward View" (16).

The policy document consists of many different parts

The strategy document can be said to consist of: 1) Reference to the overall vision underlying the document's focus 2) nine focus areas (our designation); 3) a number of priority areas (our designation) per focus area; 4) objectives in the respective priority areas (our designation) and 5) overall improvement measures and concrete improvement measures (our designation) in the respective priority areas (see Figure 4 for a visualisation of the key parts of the documents).

In addition to the above elements, the main challenges are also described as the basis for the focus and content of the policy document.

Figure 4. Visualisation of the structure of the policy document



In conclusion, there is a clear link between the various parts, for example between the selected focus areas, the priority areas and the improvement measures. At the same time, the document's approach requires much interpretation to establish an image of the structure, not least because it is extensive and that relevant concepts such as priority areas, objectives, improvement measures etc. are not used.

The policy document can be seen as a combined strategy and action plan

As an overall long-term vision is the basis for the document's strategic focus and that it highlights more broad focus and priority areas, the policy document can be described as a comprehensive strategy for the overall quality

work at national level. This is despite the fact that the document is described as a more operational complement to the overall strategy from 2014. At the same time, in line with its stated purpose, it is relatively short-term – it spans a two-year period – and highlights both overall and more concrete proposals for action. These aspects can be more closely associated with an action plan. Against this background, the document can be described as a combined strategy and action plan. In other words, it sets out both a broad framework for national quality work in the form of vision, objectives etc. (where patient safety is an area), and describes activities that can be implemented to achieve the broader objectives.

The policy document is broadly addressed through reported improvement measures

It is not expressly stated in the policy document which groups or levels are regarded as the main beneficiaries of its content. By taking note of the proposals for action presented in the different focus and priority areas, a picture of the beneficiaries is indirectly given. Some actions are addressed directly at healthcare providers, i.e. activity-oriented levels. Other proposed activities are instead addressed to national organisations such as the improvement body NHS Improvement. In other priority areas not directly linked to the patient safety perspective, action proposals are directed at the political leadership at national level. Against this background, we interpret this as the policy documents being aimed at different actors across the entire system – from the caregiver level to the overall system level.

The policy document is extensive and text heavy, but is also available in a simplified version

"Next steps on the Five Year Forward View" is a Word document of 75 pages. The content is mostly continuous text with a few visual elements (in the form of diagrams which compile results from certain statistical analyses). The document is divided into several chapters with clear headings. Priority areas and improvement measures are listed in a clear way, clarifying the logic and facilitating legibility.

A simplified and reduced version of the original document has also been developed. This is mainly aimed at the public and makes the key content available, through images among other things. The simplified and shortened version is likely to create good conditions for the policy document's content and message to reach the intended target groups and to have the desired impact.

Communication strategies are not significantly described

It is not clear from the policy document whether specific communication strategies are used to disseminate and anchor the content of the document. We have also not been able to identify this type of supplementary information on the NHS website or in our interview with experts from England.

The policy document runs for two years

The policy document is a supplement to the national quality strategy from 2014: "Five Year Forward View", whose vision runs until 2019. "Next steps on the Five Year Forward View" includes improvement measures for the last two years, i.e. the document runs from 2017 to 2019. The reasons for the selected time period are not highlighted in the strategy document.

Policy document content

In this section we report the content of the policy documents. For example, questions about the strategy's thematic focus or whether the content is based on a clear perspective are answered. We also describe the tangibility level in the policy document more closely. "Policy document" means the analysed document "Next Steps on the Five Year Forward View" (16).

The policy document contains nine different focus areas to achieve the future vision

The vision referred to in "Next steps on the Five Year Forward View" is the same as in the long-term strategy document "Five Year Forward View". According to our interpretation of the content of the document this can be briefly formulated/summed up as: *The NHS will work to improve the health of the population, better care with more equitable quality, and sustainable funding and a high degree of effectiveness*¹.

As mentioned earlier, the document is clearly divided into a number of chapters. We characterise these as overall focus areas. These are:

1. Emergency medical care
2. Primary care
3. Cancer care
4. Care/treatment of mental illness
5. Integration of healthcare at local level
6. Financing and efficiency
7. Enhanced labour force
8. **Patient safety**
9. Technology and innovation

Listed as a number of priority areas within the framework of the different focus areas that we name. We then highlight a varying number of proposals for improvement aimed at contributing to change in the relevant priority area – some at an overall level, others more concrete.

Several priority areas are highlighted for improved patient safety

In the focus area of patient safety, a total of eight priority areas are highlighted. Within the framework of each area, improvement work will take place between 2017 – 2019. The priority areas are:

- Prevent Healthcare Associated Infections (HAI)
- Improve patient safety in maternal healthcare.
- Obtain lessons from avoidable deaths

¹ Note: The vision is our summarised interpretation based on the content of the "Five Year Forward View" policy document, and specifically what appears on pages 6 – 8 of the document.

- Improve the quality of healthcare inspections
- Improve the conditions for the implementation of effective patient safety investigations in healthcare
- Reduce the rate of mistakes occurring in medication treatment
- Develop and establish incident reporting system with focus on patient safety
- Act as a global leader in the field of patient safety

For each priority area there are also objectives. In some cases, action proposals (more or less concrete) are also presented in order to achieve the objectives. These are formulated as follows:

Prevent Healthcare Associated Infections (HAI)

NHS improvement will lead work with the objective of reducing healthcare associated infections (HAI) caused by gram-negative bacteria such as E.Coli, Klebsiella and Pseudomonas. The objective is to halve this type of HAI by 2020/21.

In order to reach the target, relevant actors throughout the system must be involved. Concrete improvement measures highlighted are:

- Relevant actors shall increase the level of compulsory data collection and publication of results. Obtaining lessons from comparative data published by "Public Health England".
- Guidelines and tools provided by NHS Improvement will be followed by local healthcare providers in order to prevent blood infections caused by gram-negative bacteria.
- Prioritise infections caused by E.Coli bacteria in the same way as infections caused by MRSA and Clostridium difficile. For Example, by making information available about the number of current infections in the respective care department

Improve patient safety in maternal healthcare

During 2016, the NHS carried out a national evaluation of maternal health. The results were presented in a report entitled: "Better Births" (18). The report highlights a number of recommendations for improvement, linked to improved patient safety in maternity care among other things. The report's findings pointed to the need to improve collaboration and coordination between different healthcare providers.

As a solution to the current challenges, the development and introduction of "Local Mate Local Maternity Systems" was proposed (19). It was suggested that the systems should be cross-disciplinary and that the various healthcare providers and actors in the framework should cooperate in order to provide a more comprehensive and safe treatment together. A total of 44 local maternity systems were planned to begin their work from April 2017 and these will work to:

- Provide personalised, safer and evidence-based maternity healthcare. Increase the continuity of care for women before, during and after child-birth. The objective is for seven regions to be the first to implement the new improvement measures for maternal health, which will affect 125,000

births per year and more than 15% of the population until the end of 2018. Improved continuity in maternal health will benefit over 20,000 women.

- Reduce fetal deaths, neonatal deaths, maternal mortality and brain damage in neonates by 20% by 2020 compared with 2010. This is to approach the national target for improved outcomes (decrease of 50 percent) up to 2030.

Obtain lessons from avoidable deaths

The NHS is to become a world-leading organisation when it comes to taking heed and obtaining lessons from different sources. An example of a relevant source is the complaints by patients. The objective is to use relevant lessons as a basis for improvement in healthcare. NHS Trusts are expected to have adequate systems for continuous learning with a focus on avoidable-related deaths in healthcare. Since 2017, they will publish data for all deaths that have been assessed as being caused by incidents in healthcare. They shall also report on the actions taken in learning and prevention. This type of data shall be reported quarterly and they are reported in the respective healthcare organisation's quality report ("Quality Accounts"). Healthcare providers are required by law to publish such a quality report annually (20).

The NHS should also work to improve the support and communication of families/carers who have lost a loved one as a result of incidents in care. The standard and understanding of data on healthcare-related injuries and mortality should also be improved. The services aimed at individuals with cognitive impairments or mental disorders should also be included in the learning work around insights from avoidable deaths.

Improve the quality of healthcare inspections

The Care Quality Commission (CQC) will develop a more targeted, response orientated and collaborative approach to regulating healthcare. Special focus will be directed towards the regulation of new forms of care and healthcare providers with complex assignments. "Use of Resources" is a framework developed by NHS Improvement to evaluate how well caregivers use their resources to provide good quality care. CQC will co-operate with NHS Improvement to combine "Use of Resources" with CQC's rating system of hospitals within the NHS.

Improve the conditions for the implementation of effective patient safety investigations in healthcare

Adverse events that affect patient safety should be investigated effectively. This is to clarify any ambiguities and/or anxieties in patients, and also to disseminate lessons from incidents within the NHS. The policy document announces that a new organisation named "Healthcare Safety Investigation Branch" (HSIB) will be created and begin its work as of April 2017. According to the policy document, the organisation and its activities shall be financed by the Department of Health and linked to NHS Improvement.

HSIB has now been established and has the task of conducting independent investigations of patient safety events in the healthcare system (21). The organisation identifies lessons and provides recommendations to improve patient safety, but they do not have regulatory powers towards healthcare

providers. The goal is for HSIB to carry out up to 30 investigations each year. In addition to this, NHS Improvement will also produce new indicative information material on investigations of serious incidents in the care.

Reduce the rate of mistakes occurring in medication treatment

Different plans should be developed to reduce medication treatment incidents across the NHS. This is to assure all patients that the right type of medicinal product is prescribed.

Develop and establish incident reporting system with focus on patient safety

NHS Improvement will develop a new system called "Patient Safety Incident Management System (PSIMS)". The system facilitates the registration of incidents and also makes reporting more fruitful. This is because it promotes feedback and learning which creates the prerequisites for preventive action. The PSIMS system can be used in all healthcare environments.

Act as a global role model in the field of patient safety

NHS patient safety work is often described as world leading. In this context, the NHS will continue to work with national and international partners to promote patient safety in England. For example, by contributing to and leading the WHO's patient safety initiative and the European Expert Group on Patient Safety (pan-European Patient Safety Expert Group).

The policy document seems to be based on a relatively narrow definition of patient safety

It is not explicitly apparent from the surveyed policy document what definition of patient safety is being used. However, the chapter describing the focus area patient safety describes a relatively narrow approach, i.e. a focus on minimising risks for healthcare-related injuries rather than broadly working for improved quality of care. At the same time, patient safety is one of a total of nine areas in which the NHS works to improve healthcare and parts of social welfare, and the vision that the document refers to is aimed at both improved health and medical care that is, indicates a broader approach.

Thematically, the policy document focuses on the outcome and success areas

Thematically, the content of the document can primarily be categorised as the outcome and success areas. For example, outcomes such as Healthcare Associated Infections (HAI), medication treatment and avoidable deaths – both at target and priority area levels as well as at action level. When it comes to success areas, it highlights factors that can be linked to improvement methods, communication, and different types of structural and organisational aspects. For example, it emphasises, at both the target and priority area levels as well as the action level, the importance of systematic learning, improved inspections and investigations, knowledge gathering and so on.

Some key changes to the system are not reflected in the content of the document

Our expert interview indicates that some key content elements are not fully covered by the surveyed policy document. For example, the interviewee highlighted the fact that the healthcare system has undergone reforms over time that have a partial bearing on national patient safety work, but that this is not clearly reflected in "Next steps on the Five Year Forward View". The interviewed representative also emphasised that patient safety could have been given even greater scope in the strategy document, but that this perspective is likely to have an even more prominent role in the forthcoming document, which is currently being developed.

The interview emphasised transparency and openness, the culture of patient safety and respect for patients and healthcare professionals as three critical factors for a high level of patient safety. These factors are, to some extent, indirectly highlighted in the policy document, for example in connection with the importance of well-functioning reporting systems and mutual learning. They are not, however, in our judgment, highlighted in particular in document.

*"Our healthcare system has undergone **major changes**, and we have received new legislation but this **is not visible in the policy documents** that you are looking at"*

Expert England

*"**Transparency and openness, the culture of patient safety and respect for patients and healthcare professionals** are the most critical factors in achieving improvement in the field of patient safety"*

Expert England

Policy document processes

This section presents the central processes that can be linked to the policy document. Examples of questions to be answered are whether the policy document was based on a particular process, for example through consultation or negotiation? Another important element is examining whether the policy document describes different central processes and, in such cases, what they include. "Policy document" means the analysed document "Next Steps on the Five Year Forward View" (16).

The policy document is a more operational continuation of the original "Five Year Forward View" strategy

The examined policy document is a further development of the strategy published in 2014 – "Five Year Forward View" (15). This strategy was developed in a consensus with a wide range of actors and organisations such as patient representatives, health professionals, local organisations, and management teams within the NHS. "Next Steps on the NHS Five Year Forward View" aims to describe concrete measures that can contribute to the overall vision being met. The proposed measures are based on a survey of the progress made in the areas of improvement under the overall strategy (better health, better care, higher quality and financial sustainability). The survey showed that, despite key progress, there is still work to be done to achieve the vision.

The starting point for the priority areas of the surveyed policy document: "Next Steps on the NHS Five Year Forward View" is based in summary on:

- The NHS's annual mandate (from the government) indicating the objectives and budget
- The NHS's own consultations with the public, patients, healthcare professionals and other key actors in the system.
- An annual survey of the organisation "Healthwatch" which compiles a list of the five most prioritised areas where the public wants to see an improvement.

The policy document also points out that the right conditions must be created in order to achieve improvements in these areas, which is why the focus should also be on working in areas such as human resources, patient safety, technology and innovation, i.e. the enabling factors described earlier in our analysis.

The policy document describes the implementation process to some extent

The implementation process is clearly described in certain priority areas such as emergency medical care, primary care, cancer care and mental health. However, the process description is less detailed for the area of patient

safety. It appears that national bodies such as NHS Improvement and the Care Quality Commission (CQC) have an important responsibility for the improvement work being carried out at caregiver level. In order to get a clearer picture of how the implementation process is supposed to go, we have examined the information available on the organisations' websites (www.improvement.nhs.uk and www.cqc.org.uk) in particular.

NHS Improvement leads the improvement work

NHS Improvement is tasked with supporting healthcare providers in order to provide safe, high-quality healthcare. The organisation shall collect and analyse information about care incidents and provide advice and guidance to healthcare providers regarding risk minimisation. NHS Improvement has its own strategic plan (Business plan 2017 – 2019) (22), which is in line with the ambitions of "Next steps on the Five Year Forward View".

The strategy document outlines several activities to carry out the work. Examples of activities include:

- **The Operation of Patient Safety Alerts:** Patient Safety Alerts is a warning system regarding patient safety risks aimed at healthcare providers (23). The warnings are based on reported data on healthcare incidents and information from a National Patient Safety Response Advisory Panel, which consists of healthcare professionals, patients, experts in patient safety, institutes and other national bodies.
- **Implementation of Patient Safety Collaborative Program:** The Patient Safety Collaborative Program is a program designed to stimulate the establishment of local organisations (Patient Safety Collaborators) who work with quality improvement in direct contact with healthcare providers (17). The program is funded and coordinated by NHS Improvement, but is organised locally by "Academic Health Science Networks (AHSN's)". AHSN's are member organisations within NHS England with the task of bringing together healthcare providers, local organisations, industry and academia (24).
- **Implementation of The Maternal and Neonatal Health Safety Collaborative:** The Maternal and Neonatal Health Safety Collaborative is a three-year program that was launched in 2017 to support healthcare providers in the work of increasing patient safety in maternal health (in accordance with the national strategy "Better Births") (25).

The Care Quality Commission is responsible for the supervision of healthcare services

As mentioned above, CQC's main tasks are to monitor, inspect and regulate care and welfare services (5). This is to ensure that the services achieve adequate quality and safety standards.

The inspections are based on five fundamental questions concerning the activity:

- Is the activity safe?
- Is the activity effective?
- Is the activity caring?

- Does the activity meet the needs?
- Is the activity characterised by good leadership?

All inspections result in a grading report. The reports are available to the public, who can use the results to choose which healthcare provider to go to. If activities do not meet the quality requirements, the CQC has the opportunity to take specific measures (26). The organisation may, for example, place requirements on the activity to implement certain improvements, to issue periodic penalty orders, to limit the execution of the activity or even to withdraw the authorisation of the activity to carry out care or welfare unless quality improvements are implemented immediately.

The CQC is an independent organisation but cooperates with the NHS towards a common goal to improve the quality and safety of healthcare and parts of welfare (27).

Descriptions of how the content of the policy document is to be monitored are relatively limited

Descriptions of the follow-up to the content of "Next Steps on the Five Year Forward View" are not in the policy document itself. However, NHS England publishes annual reports where target fulfilment analyses are reported, i.e. how well the NHS has responded to the government's annual objectives. The most recent Annual Report 2017/18 highlights advances in primary healthcare, emergency medical care, cancer care, mental illness and the integration of health services in particular (28). However, progress linked to patient safety is not described in the same way. Descriptions of the implementation of the follow-up are missing here.

As regards key monitoring of incidents in healthcare, this is done through a National Reporting and Learning System (29). In our conducted expert interview, well-functioning reporting systems are an important prerequisite for continuous learning based on incidents and serious events. As tasked, the system is currently developing in order to facilitate reporting, to make it more fruitful and to involve patients more closely.

All hospitals have to report incidents through this system and the information is then compiled in monthly reports that NHS Improvement publishes, NRLS Monthly Report England (30). The incidents are graded in five levels; 1) no injury; 2) minor injury; 3) medium injury; 4) serious injury and 5) death. The reported data can then be used in other contexts to create the conditions for continuous learning.

"Reporting systems that are simple and quick to use are key to the work on patient safety"

-Expert England

Policy document results

The results of the policy document are presented below. Examples of questions to be answered are whether good results can be linked directly to the policy document or more to the governance or organisation at large? "Policy document" means the analysed document "Next Steps on the Five Year Forward View" (16).

No specific evaluation of the policy document has been identified, but the content seems to have had some impact

An evaluation of the policy document has not been identified within the frame of this analysis. The NHS Annual Report for 2017/18 primarily describes two advances that can be linked to the action proposals for patient safety that are presented in "Next Steps on the Five Year Forward Review" (28). One of the advances is that the hospitals have published a policy for how to learn from preventable deaths in hospitals in order to work preventatively and thereby reduce this type of mortality. The second advancement is that all Local Maternity Systems have now been established as part of the implementation of the "Better Births" program. As mentioned earlier, the program aims to improve patient safety in the field of maternal health.

In September 2018, a compilation of reported care incidents (NRLS National patient safety incident reports: commentary) was published. This shows in brief that nearly 500,000 incidents were reported to the system between January-March 2018, equivalent to an increase of 3.5 percent compared to the same period the previous year. The report also shows that almost 75 percent of all reported incidents between April 2017 to March 2018 did not result in a healthcare-related injury. More than 20 percent were classified as incidents that led to a minor healthcare-related injury, which is defined as an injury requiring extra observation or minor intervention/treatment. A summary of levels of harm can be seen in the table below.

Figure 5. Table showing injury level for reported incidents to NRLS (31)

Degree of harm	April 2016 to March 2017		April 2017 to March 2018		% change
	N	%	N	%	
No harm	1,362,324	73.2	1,443,863	74.3	6.0
Low	434,219	23.3	436,774	22.5	0.6
Moderate	55,084	3.0	51,495	2.7	−6.5
Severe	5,548	0.3	5,501	0.3	−0.8
Death	4,392	0.2	4,537	0.2	3.3
Total	1,861,567	100	1,942,170	100	4.3

Data for key interests' views on the policy documents missing

Based on the information available, we have not been able to locate an evaluation of how the policy document has been received by key interests. This is also not in our expert interview.

References

1. The Health Foundation. Spending on health care across the EU. Retrieved 2020-01-17 from <https://www.health.org.uk/chart/chart-nhs-spends-about-eu-average-as-percentage-of-gdp-on-health>.
2. Institute for Health Metrics and Evaluation. IHME: United Kingdom - England. Retrieved 2020-01-17 from <http://www.healthdata.org/united-kingdom-england>.
3. The Commonwealth Fund. The English Health Care System. Retrieved 2020-01-17 from <https://international.commonwealthfund.org/countries/england/>.
4. NHS Improvement. Retrieved 2020-01-17 from <https://improvement.nhs.uk/>.
5. Corporate Governance Framework. Care Quality Commission; 2015. https://www.cqc.org.uk/sites/default/files/20151111_Coporate_Governance_Framework_August_2015.pdf.
6. National Institute for Health and Care Excellence. What we do. Retrieved 2020-01-17 from <https://www.nice.org.uk/about/what-we-do>.
7. Health Education England. Retrieved 2020-01-17 from <https://www.hee.nhs.uk/>.
8. NHS England. National Quality Board. Retrieved 2020-01-17 from <https://www.england.nhs.uk/ourwork/part-rel/nqb/>.
9. An organisation with a memory. London: Department of Health; 2000.
10. Burnett S, Vincent C. Patient Safety in the United Kingdom: Evolution and Progress. Agency for Healthcare Research and Quality; 2007.
11. Feinmann J. Safety first. BMJ; 2009: 338.
12. Health and Social Care Act 2012. Retrieved 2020-01-17 from <http://www.legislation.gov.uk/ukpga/2012/7/contents/enacted>.
13. A promise to learn - a commitment to act. Improving the Safety of Patients in England. National Advisory Group on the Safety of Patients in England; 2013.

14. NHS. Sign up to Safety. Retrieved 2019-07-03 from <https://www.england.nhs.uk/signuptosafety/>.
15. Five Year Forward View. NHS England; 2014. <https://www.england.nhs.uk/wp-content/uploads/2014/10/5yfv-web.pdf>.
16. Next steps on the NHS Five Year Forward View. NHS England; 2017. <https://www.england.nhs.uk/wp-content/uploads/2017/03/NEXT-STEPS-ON-THE-NHS-FIVE-YEAR-FORWARD-VIEW.pdf>.
17. NHS Improvement. Patient safety collaboratives. Retrieved 2020-01-20 from <https://improvement.nhs.uk/resources/patient-safety-collaboratives/>.
18. Better Births: Improving outcomes of maternity services in England. NHS England, National Maternity Review; 2016. <https://www.england.nhs.uk/wp-content/uploads/2016/02/national-maternity-review-report.pdf>.
19. NHS England. National Maternity Review. Retrieved 2020-01-20 from <https://www.england.nhs.uk/mat-transformation/implementing-better-births/mat-review/>.
20. NHS England. About Quality Accounts. Retrieved 2020-01-20 from <https://www.nhs.uk/using-the-nhs/about-the-nhs/quality-accounts/about-quality-accounts/>.
21. Healthcare Safety Investigation Branch. About us. Retrieved 2020-01-20 from <https://www.hsib.org.uk/about-us/>.
22. NHS Improvement business plan 2017-19. NHS Improvement; 2017. https://improvement.nhs.uk/documents/1284/NHS_Improvement_Business_Plan_2017-19.pdf.
23. NHS Improvement. Patient safety alerts. Retrieved 2020-01-20 from <https://improvement.nhs.uk/resources/patient-safety-alerts/>.
24. The AHSN Network. About Academic Health Science Networks. Hämtad 2020-01-20 från <http://www.ahsnnetwork.com/about-academic-health-science-networks/>.
25. NHS Improvement. Maternal and neonatal health safety collaborative. Retrieved 2020-01-20 from <https://improvement.nhs.uk/resources/maternal-and-neonatal-safety-collaborative/>.
26. About us. What we do and how we do it. Care Quality Commission; 2017. https://www.cqc.org.uk/sites/default/files/20170504_CQC_About-us.pdf.

27. Agreement between Care Quality Commission and NHS Commissioning Board. Care Quality Commission and NHS Commissioning Board; 2013.
<https://www.england.nhs.uk/wp-content/uploads/2013/02/cqc-nhsceb-agree.pdf>.
28. Our 2017/18 Annual Report. NHS England; 2018.
<https://www.england.nhs.uk/wp-content/uploads/2018/07/Annual-Report-Full-201718.pdf>.
29. NHS Improvement. Retrieved 2020-01-20 from
<https://report.nrls.nhs.uk/nrlsreporting/>.
30. NHS Improvement. Monthly data on patient safety incident reports. Retrieved 2020-01-20 from <https://improvement.nhs.uk/resources/monthly-data-patient-safety-incident-reports/>.
31. NRLS national patient safety incident reports: commentary September 2018. NHS Improvement; 2018.
https://improvement.nhs.uk/documents/3266/NAPSIR_commentary_FINAL_data_to_March_2018.pdf.

Country Report Finland

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Introduction

In the analysis of Finland, we focus on the policy document: *"Patient and client strategy 2017 – 2021"* published in 2017. The government, through the responsible state council and the Ministry of Social Affairs and Health, is the publisher of the document. The strategy is also referred to as the "State council's decision-in-principle". The strategy sets the direction of Finland's national patient safety work at an overall level. In brief, it is primarily aimed at contributing to the development of the culture of patient safety within Finnish healthcare and welfare, as well as social care. Given that the strategy lays the foundation for overall patient safety work in Finland, the document is the policy document analysed. Below are the results of the analyses carried out based on the used framework. The analysis has also been supplemented with information from interviews conducted with representatives of the Ministry of Social Affairs and Health.

Figure 1. Patient and client safety strategy 2017-2021




Description of the current context

In this section we describe more closely the context that characterizes the policy documents in different ways. For example, this answers questions about the possible needs that form the basis of the policy document and what management of the healthcare system looks like.

Review Country Facts – Finland

Figure 2. Summary of basic country facts (1), (2)

Country facts		
Population (million)	5.5 (2016)	
Average life expectancy (males/females, years)	79/84 (2016)	
Child mortality (< 5 years old per 1000/births)	2.3 (2016)	
Health care cost (% GDP)	9.7 (2014)	

The Finnish healthcare system is characterised by municipal management

The Finnish healthcare sector is financed by tax revenue (3). The healthcare system can be described as relatively decentralised and responsibility for healthcare is currently distributed between the state and municipality. In short, the state governs healthcare and welfare through legislation and other provisions and through its authorities has responsibility for supervision, among other things. There are a total of 311 municipalities and these are responsible for both organising and performing primary and specialist care and for social services. A compulsory health insurance also covers the entire population. The insurance covers part of the costs for care provided by private physicians and dentists.

The type of healthcare and welfare to be carried out and provided is regulated by law. However, municipalities can independently define how the activities are to be organised and implemented. For example, primary care can be conducted within individual municipalities or in collaboration with several municipalities through "Joint municipal boards". Specialist care is organised instead within "Care districts". The districts consist of several municipalities that cooperate across geographical borders. There are also a

number of private care and welfare providers that are either procured by the municipalities, or provide directly to patients or users.

A comprehensive reform of both the healthcare and welfare systems in Finland is currently underway (4). The reform will lead to regionalisation of the operations by the formation of 18 autonomous provinces. The provinces will assume the municipal responsibility for the operation and organisation of care and welfare. The goal is for the new model to enter into force from 2021.

According to the interviewed representatives of the Ministry of Social Affairs and Health, it is difficult at present to define the role of the various actors in the country for patient safety in the healthcare sector and client work in welfare due to the reform work. The ambition is that in the future the newly created provinces will be able to take greater responsibility for patient and client safety within each region. There is an independent expert institution within the administrative area of the Ministry of Social Affairs and Health called the National Institute for Health and Welfare (Terveyden ja Hyvinvoinnin Laitos, THL) (5). The main task of this organisation is to collect research and statistical-based information in the field of welfare and health in the country, in order to provide support for policy makers and other actors. According to interviewed representatives, it is intended that THL will contribute to the follow-up of certain indicators in the patient and client area when they start to be used after the reform.

*"A **major reform** is underway in Finland at the moment, which makes it difficult to give an opinion on **which roles the various actors** should take in the field of patient safety"*

- Finland representative

Major changes have taken place in national patient safety work since 2006

The surveyed patient safety indicators from the OECD show that Finland has a variable performance

OECD data for seven different patient safety indicators in Finland shows slightly different results over time (see Figure 3).

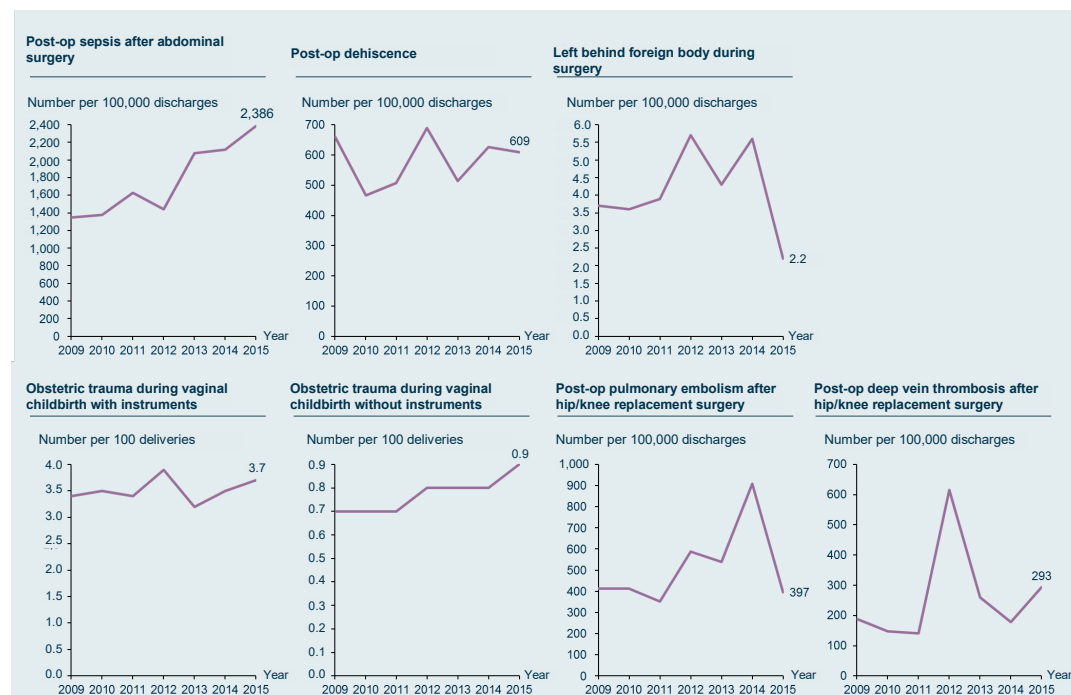
For example, the indicator for post-operative sepsis after abdominal surgery has seen a negative trend since 2012, i.e. that the number of cases is steadily increasing. No clear positive trends, i.e. reduction in the number of cases, are seen for any of the indicators. However, significantly fewer cases for two indicators, left behind foreign body during surgery and post-op pulmonary embolism, are seen during 2015.

In addition, the results of several indicators have varied over time, where the number of cases has fluctuated up and down. However, outcomes within

the two obstetric indicators have remained relatively stable during the years studied.

In conclusion, it is not possible to comment on a clear trend in the development of the patient safety area in Finland based on the results of these patient safety indicators.

Figure 3. Comparison of patient safety indicators (OECD data) over time in Finland (6)



Patient safety work started in 2006 through establishment of a new steering group

2006 can be described as the start of Finland's national work to improve patient safety. At that time, the Finnish government, through the Ministry of Social Affairs and Health, appointed a steering group to promote patient safety in the country. The steering group then developed the first national patient safety strategy entitled: "We promote patient safety together" (7).

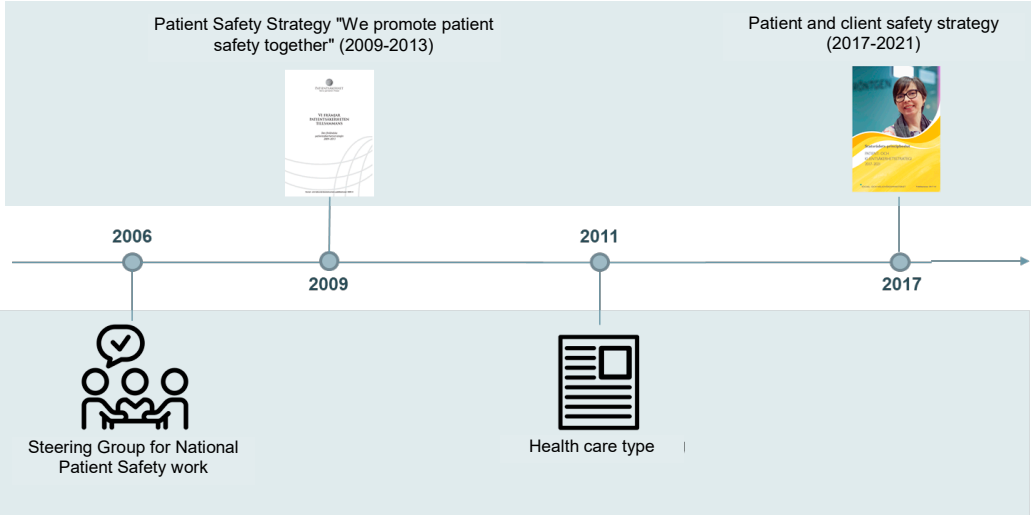
The strategy was published in 2009 and ran until 2013. During that period, the new health care act, which came into force in 2011, was also established (8). In this context, the act can be seen as groundbreaking when, for the first time, it provided legal support for the promotion of patient safety in the country. For example, the law states that healthcare activities should develop a plan for quality management and how patient safety should be satisfied. Subsequently, and on the basis of this, additional laws and regulations have been introduced, which in various ways aim to strengthen patient safety.

As a basis for further work, the government, through the Ministry of Social Affairs and Health, together with other actors, has, as mentioned earlier, developed an updated strategy in the field extending to 2021 (9). The new

strategy, compared with the model, is a broader approach, because social care is also covered.

In Figure 4 below, the development of patient safety in Finland over time is visible and summarised.

Figure 4. Timeline of patient safety work in Finland.



Policy document structure

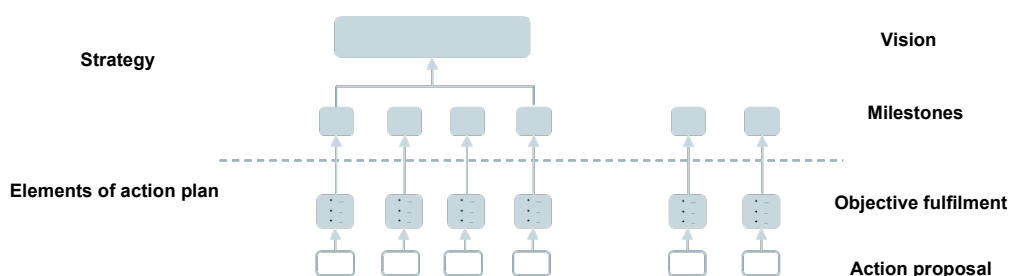
This section describes the structure of the policy documents. Questions about the parts of the policy document and the intended recipients are answered here. We also highlight the format of the documentation, i.e. whether they are comprehensive or summarised etc. Policy document here refers to the analysed document "Strategic Plan 2017 – 2021" (9).

The main documents describe the overall vision, objectives and target fulfilment

Vision, objectives and descriptions of fulfilling targets—the key to content of a strategy

Overall, the policy document can be said to consist of a total of five main parts: 1) a vision (target state) that guides patient safety work up to the year 2021; 2) four sub-objectives to reach the vision; 3) a more detailed description of what the target attainment would mean within the respective sub-objectives; 4) two sub-objectives related mainly to the monitoring of patient safety and 5) an account of the achievement of objectives in the two sub-objectives of national follow-up (see visualisation of the policy document structure below Figure 5).

Figure 5. Visualisation of the structure of the policy document.



The structure of the main document itself can, at an overall level, be likened above all to a strategy, that is to say, the document provides a more broad and long-term framework for the improvement work. At the same time, sub-objectives are defined and in some cases desirable conditions are described in a relatively specific way with reality based situational descriptions (a longer explanation of the document's content follows under the heading "*The content of the strategy*"). The concept of "action plan" is also used to describe this section. At the same time, concrete improvement measures are not presented and it is explicitly stated that the strategy can be supplemented by more detailed action plans.

According to the interviewed representative, the document analysed should be considered as an overall strategy. The respondent adds that work is

currently underway to develop a national action plan to complement the strategy. The action plan will contain concrete measures to meet the vision, objectives and sub-objectives of the current strategy.

"We are currently working on developing a concrete action plan to complement this overall strategy"

- Finland representative

Appendices clarify the definition of patient/client safety and explain basic concepts

In addition to the main elements of the strategy, a framework is also presented, which is referred to as "The central content of the strategy" (see Figure 6). The framework and its contents are presented in detail in an appendix describing different perspectives on patient and client safety. Our interpretation is that the framework clarifies, in particular, the definition of patient and client safety used in the policy document, and highlights and describes aspects that should be in place to achieve a high level of patient safety. Finally, some basic terms, such as "patient and client" and "quality", are clarified in an additional appendix.

Figure 6. The framework that is presented in the policy document and describes the definition of patient and client safety, as well as key principles and functions



The policy document is far reaching – from providers to patients and clients

The policy document is not clearly divided according to different recipient levels (i.e. micro/meso/macro perspectives). Activities or indicators aimed primarily at caregivers, patients and higher-level decision-makers are not highlighted separately for example. At the same time, the policy document is described as being aimed at healthcare providers, healthcare staff, patients, users and their relatives. The strategy applies to both public and private

actors. Against this background, the policy document can be said to be quite broad.

The policy document has a traditional format


The policy document consists of a text document of a total of 30 pages (including appendices) and it is relatively text heavy, and thus not very easily accessible. However, the document is not that large in terms of the number of pages, which means it is possible for the content to have an impact on the recipients.

The analysis is based on a Swedish translation of the Finnish original document. In some cases, it has been difficult to understand and embrace the content, probably because the translation is incomplete or not comprehensive. In this context, the analysis has been supplemented by a reading for quality assurance purpose by a Finnish speaking resource.

As mentioned earlier, the strategy consists of a main document and two appendices. One appendix contains a visual description of what patient and client safety are from different perspectives (see Figure 5) and the second appendix contains a list of definitions of key concepts used in the policy document. Clarifying definitions and concepts in this way is a way of clarifying the message and creating the conditions of the recipient. At the same time, the level of abstraction of the document is relatively high, which in some cases makes it difficult to get a picture of how the different parts and content of the policy document are connected. This risks affecting the accessibility of the document.

There is no specific communication plan

According to the interviewed representative, no specific efforts have been made to communicate the strategy. The representative states that the dissemination of information to relevant actors in the strategy has been poor from the Ministry of Social Affairs and Health, and that no specific communication strategies have been used.



*"We have not put much effort into communicating the strategy because we have been **busy with other reform work** going on in the country right now"*

- Finland representative

The strategy is valid for a four-year period

The strategy period runs from 2017 – 2021. The decision on the chosen time period for the strategy was taken on the basis that the strategy could span the period of the ongoing reforms (the ambition is for this work to be completed by the end of 2020).

Policy document content

In this section we report the content of the policy documents. For example, questions about the strategy's thematic focus or whether the content is based on a clear perspective are answered. We also describe the tangibility level in the policy document more closely. Policy document here refers to the analysed document "Strategic Plan 2017 – 2021" (9).

The overall vision is divided into two parts and lays the foundation for the work

The overall vision of the work is divided into two parts, and is formulated as: *"Patient and client safety is visible in structures and practical activities: the services are effective and safe" and "Patient and client are equal actors in the service process and planning. Everyone can influence, choose and take responsibility for patient and client safety"*.

In order to work towards the vision/objective, four sub-objectives have been identified and the related descriptions of what goal fulfilment entails. These sub-objectives are:

- The patient, client and related parties actively participate in the securing and development of patient and client safety
- Quality as well as patient and client safety are part of the risk management
- There are resources and knowledge to ensure safe care and welfare
- The processes of care and welfare services and the methods of operation are to protect patients and clients from risk situations

See below for the description of each sub-objective.

The patient, client and related parties actively participate in the securing and development of patient and client safety

Within the frame of this sub-objective, the patient and the client should play a key role in the patient and client safety work. They should be actively involved by receiving adequate and sufficient information about, for example, diagnosis and treatment possibilities. They should also be included in the discussion on the advantages and disadvantages of different treatment options.

The patient/client should also be able to express their views on deficiencies and development opportunities in the field of patient safety. The patient/client should be informed of where he or she can turn in the event of any questions. All adverse events that occur should also be discussed with the patient/client and any related parties, so that the consequences can be analysed together.

Finally, a number of points are listed which, in the form of desirable conditions, describe the fulfilment of the specific sub-objective. The strategy shows that these must be achieved before 2021. The points are:

- The patient/client is an equal participant in their own care and welfare, as well as safe planning and implementation. The patient/client is received in an open and respectful manner and the individual's participation is supported on the basis of the individual's conditions.
- The patients/clients have sufficient information on existing alternatives in terms of care and welfare services, such as regarding medication treatment, and any risks associated with them, in order to be able to make informed decisions about their own care and welfare.
- The patients/clients participate in the planning, development and assessment of the healthcare activities and processes.

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

This objective raises the importance of developing a good risk management process. The process should consist of continuous risk identification, assessment and adoption of measures on the basis of needs.

To achieve this, for example, risk surveys can be carried out, staff surveys can be carried out and reporting systems for dangerous situations can be established. A well-functioning system for exchanging information both within and between healthcare providers is also key, especially in view of the development towards increased digitisation.

In the context of this sub-objective, a number of points are also presented which describe the target attainment in terms of desirable conditions:

- Risk analysis and management methods are described in a quality and patient safety plan or in a self-monitoring plan. Agreements on how to assess the importance of risks have been developed and specific registers to identify risks have been developed.
- Risk management includes regular analysis of possible patient/client risks and transparent reporting.
- In planning to change processes, a proactive risk analysis and decision is made regarding what measures are needed, to ensure a safe and high-quality business among other things.

There are resources and knowledge to ensure safe care and welfare

In the context of this sub-objective, the important role of staff is emphasised in a relatively specific way. There must be sufficient staff with the right skills for patients/clients to be properly taken care of. The premises must also be suitably designed and the right equipment must be available.

There must always be staff with explicit responsibility for maintaining patient and client safety. Specifically designated persons responsible for monitoring quality must also be present onsite. In conjunction with the start of a new service, health and social care professionals must also be given an adequate introduction to their respective duties and responsibilities, as well

as patient safety issues. They must also continuously train to maintain and strengthen their skills – both in terms of professional practice and knowledge of patient/client safety. Both management and employees are responsible for this, for example through further training.

Finally, four points are listed, in the form of desirable conditions, which more specifically describe what objective fulfilment means in this case:

- The personal resources and other resources and knowledge necessary for the provision of safe care and welfare have been identified in individual activities.
- The premises where healthcare and welfare are carried out, pharmaceuticals, products and equipment are safe. There are clear guidelines aimed at all occupational groups regarding the prevention of Healthcare Associated Infections (HAI).
- Patient and client safety are included in staff induction training, annual training and continuous assessment of staff skills. Consideration is also given to patient and client safety in the division of work between different occupational groups.
- Patient and client safety are included in basic vocational education, further education and training and leadership training in both healthcare and welfare.

The processes of care and welfare services and the methods of operation are to protect patients and clients from risk situations

The sub-objective highlights that all operational processes must be secure, for example in terms of information exchange, registration and documentation – not least when patients/clients are moved between different levels of care or activities.

It is crucial that healthcare and welfare providers establish and follow a self-monitoring plan and a plan for managing quality and patient/client safety in accordance with existing legislation.

Four points, which describe desirable conditions to be met by 2021, are highlighted within this sub-objective:

- Care and welfare are planned and carried out as smooth overall processes without, for example, delays and overlap.
- The quality and patient safety plan and the self-monitoring plan are tools that help to promote safety and develop risk management.
- The uniform processes and working methods of the care and welfare providers protect clients and patients from dangerous situations. The processes result in a value for patients and clients.
- Among other things, job introduction as well as follow-up and assessment procedures ensure that healthcare providers follow the processes and working methods established.

Sub-objectives that are mainly associated with following-up the strategy have also been formulated

In addition to objectives and sub-objectives for patient and client work, sub-objectives for follow-up of the strategy have also been formulated:

- **Procedures for following-up and developing quality and patient safety are established and followed.** Within this sub-object, the value of continuously following-up and evaluating patient and client work is highlighted (a more detailed description of how follow-up/quality monitoring should be drawn up is shown under heading "*There are some descriptions of how to follow up the work*").
- **Patient and client safety are promoted at national level.** In the context of this sub-objective, the work on how to follow-up patient and client safety and continue to develop nationally (a more detailed description of how follow-up/quality monitoring should be drawn up is shown under heading "*There are some descriptions of how the follow-up of the work should be done*").

Appendices define patient and client safety

The first appendix presents as previously mentioned perspectives on patient and client safety. It presents the framework that clarifies the use of the definition of patient/client safety and the key perspectives for successful results (see figure 5). Patient and client safety is defined in the framework as: *Safe and efficient care, welfare and service at the right time, which causes as little harm as possible to the patient and the client.*

The second appendix of the policy document further elaborates the definition of the concept. It shows that patient and client safety means that: "*The effective care, welfare and service a person may promote their physical, mental and social well-being and cause as little harm as possible. Patient and client safety refers to the principles and functions of persons and activities in the healthcare sector as well as welfare that are aimed at ensuring a safe service, welfare and care and protect clients or patients from injuries. Patient and client safety includes preventive, caring and corrective, as well as rehabilitative, care and welfare. Patient and client safety includes the expertise of the staff working in the field of social and healthcare, the suitability of the premises and equipment, and the security of the documentation and information exchange within healthcare and welfare.*"

In other words, the definition takes on safety in the sense of minimising the risk of healthcare and welfare injuries, and also of the efficiency perspective. The first perspective is reminiscent of the aim in the Swedish Patient Safety Act (2010:659): to promote high patient safety in healthcare.

Highlighting the efficiency perspective is not unique to Finland, but it is also made in the policy documents of several other countries, such as Scotland and Denmark. The quality perspective is not expressly highlighted in the same way as efficiency. At the same time, quality is affected in different ways within the objective fulfilment descriptions. The term quality is also described in the second appendix of the strategy as a multidimensional term, without a uniformly accepted definition. Client and patient centring, care and

treatment at the right time, as well as patient and client safety within the term quality according to this explanation. Given this, the quality dimension is affected in different ways, although it is not a pronounced part of the strategy's definition of patient and client safety.

Perspectives for successful outcomes are listed in appendix

The perspectives for successful outcomes presented in the appendix are well in line with the used definition of patient and client safety, and these are:

- Safety Culture – managing quality and safety risks
- Responsibility – processes and operating methods
- Management - ensuring resources and knowledge
- Regulations - Continuous follow-up and development

Safety Culture – managing quality and safety risks

Strengthening the safety culture reduces the risk of health and welfare related injuries, and this requires a common responsibility and an inclusive approach. In the appendix, safety culture means, among other things, an open atmosphere where, for example, knowledge gaps, incidents and negative events are treated openly and seen as an important part of developing and improving the business.

This means, among other things, that all the actors involved in the operation must work together to improve patient and client safety. For example, healthcare and welfare professionals, patients, clients and relatives must be given the opportunity to make comments, express any concerns and receive adequate support on the basis of needs.

In order to achieve an improved safety culture, specific procedures are needed, and these must be based on research and experience.

Responsibility – processes and operating methods

The key responsibilities are highlighted and the responsibility chain for patient safety work is described within this perspective. For example, the caregivers' management and managers are responsible for ensuring patient and client safety, and they must create the conditions for this in different ways.

Individual employees within healthcare and welfare are also responsible for the safety of the task they perform, and all employees are responsible for their own work. The patient and the client contribute to patient safety to the extent that is possible, for example by providing background information or by emphasising when they are not receiving sufficient information.

The Ministry of Social Affairs and Health is responsible for the preparation of provisions regarding client and patient safety as well as other strategic management. Institutions and other authorities in the administrative sector are required to develop, coordinate and monitor patient and client safety at national level.

It is further described that there are three types of enforcement (prevention, plan-based and retroactive).

Management - ensuring resources and knowledge

The perspective highlights the key role of management for patient and client safety. The management must, for example, emphasise patient and client safety and quality in all activities carried out and through good working conditions, must ensure that care and welfare can be carried out safely.

Management must ensure, for example, that adequate resources, conditions and professional knowledge are in place to achieve good patient safety. It also has the overall responsibility for carrying out safety analyses and for promoting a safety culture where transparency is pursued, among other things.

Regulations - continuous follow-up and development

The legislation and regulations underlying patient and client safety are reported within this perspective. These are:

- The Health and Medical Care Act (1326/2010)
- The Social Welfare Act (1301/2014)
- Act on Supporting the Elderly Population's Functional Capacity and Social And Healthcare Services for the Elderly (980/2012)
- Regulation establishing a quality management plan and how patient safety is met (341/2011)
- The Regulations on Self-Monitoring in Healthcare (153/1990)
- The Medical Products Act (395/1987)
- The Healthcare Products and Equipment Act (629/2010)
- The Act on the Electronic Processing of Client Data in Healthcare and Social Welfare (159/2007)
- The Infectious Diseases Act (1227/2016)

The thematic classification of the policy document is primarily based on the foundational areas

In summary, the thematic content of the strategy is based primarily on foundational areas. This is seen both in the description of the objectives and the definition of objective fulfilment, as well as in the account of key perspectives for achieving good outcomes. Examples of areas highlighted include: "patient and client participation", "leadership" and "safety culture".

According to the interviewed representative, the idea is that this overall strategy should focus on the broader foundational areas, while the action plan (which is being developed at the moment) will also include objective descriptions of more concrete outcomes, such as infections and mortality in hospitals.

*"We chose to describe **broader areas** of the strategy because we wanted this to be at an **overall level**. In the **action plan** we are planning to highlight more **concrete areas** such as infections"*

- Finland representative

Policy document processes

This section presents the central processes that can be linked to the strategy and the action plan. Examples of questions to be answered are whether the policy document was based on a particular process, for example through consultation or negotiation? Another important element is examining whether the policy document describes different central processes and in such cases what is included in them. Policy document here refers to the analysed document "Strategic Plan 2017 – 2021" (9).

The policy document is based on the first patient safety strategy established in 2009

The first patient safety strategy “We promote patient safety together” was launched in 2009 and ran until 2013. This is stated to have served as a central starting point for the development of the current strategy.

According to the interviewed representative, there are two significant differences in the new strategy compared to the previous one. One difference is that the focus has been widened – from simply including “patient safety” to the inclusion of “patient and client safety”, where the latter includes not only healthcare but also social services. The other difference is that the new strategy highlights the patient's and client's role and participation in safety work to a greater extent compared to previous ones. The representative emphasises that since the publication of the first strategy there has been a change in so that patients and clients are now seen as an asset in the safety work – partly by sharing their experiences and partly by taking certain responsibility for their own care.

"The two main changes compared to the previous strategy are that we now also cover social services and that patients and clients are more involved in the safety work"

- Finland representative

Various actors were involved in the development

According to the interviewed representative, the Ministry of Social Affairs and Health cooperated with a number of different actors in the development of the new strategy. For example, representatives from healthcare organisations, regulators, governmental organisations, the patient safety association and some patient representatives were involved. Working groups and seminars jointly formulated the content of the strategy. The objectives were

discussed and established by various board groups within the ministry, and then decided by the government.

The respondent said that, in retrospect, the view is that the development process could have gained from being more extensive, for example through the involvement of more actors and more patient representatives. Another point made by the interviewed representative is the importance of involving decision-makers at an early stage in the development of a strategy/action plan, as patient and client work requires the release of resources.

*"We wish we had **involved more actors, especially patients** in the development of the strategy. It is also important to **involve decision-makers** at an early stage, as **resources need to be made available** in order to carry out patient and client work"*

- Finland representative

The strategy does not describe the implementation in detail, but does set the direction for some key processes

Clearly stated and detailed process descriptions of how the content of the strategy is to be realised are missing in the policy document. At the same time, a direction is given for certain implementation processes within the various sub-objectives and key perspectives. For example, the risk management objective describes concrete methods for identifying different risks. At the same time, there is no systematic process description that specifies how health and welfare providers implement the content of the strategy step-by-step.

According to interviewed representatives, the arrangement is in line with the strategy being complemented by the action plan that is being developed at the moment. As mentioned above, this should include more concrete measures that healthcare providers can use to implement patient safety and meet the objectives of the strategy.

There are some descriptions of how the follow-up should be implemented

As mentioned above, the policy document contains two sub-objectives which can be linked above all to the way in which patient safety follow-up is to be designed. The following describes what is included in each sub-objective for follow-up.

Procedures for following-up and developing quality and patient safety are established and followed

In the context of this sub-objective, the quality development and improvement work is described, among other things, with a focus on increased patient safety takes place in a number of steps through a continuous cycle. The steps are 1) plan; 2) do; 3) study and finally 4) act (the PDSA cycle). In addition, collaboration must be established at both regional and national level and common procedures for patient and client safety must be established.

It is stated that a safe and first-class operation is characterised by clear procedures for following-up and assessing patient safety. The operation is developed on the basis of information that is collected, such as quality incidents. The information is also the basis for continuous risk assessment and contributes to learning within the operation. There should also be procedures to systematically take care of the views of patients and clients. The operation shall also have procedures for reporting, handling and responding to dangerous situations that have led to serious consequences or that are of significance in other ways.

Again, it raises the importance of not blaming any party in the process of patient safety improvement, but rather of promoting open discussion. This is to bring about experience reversal and continuous learning.

In the same way as for other sub-objectives, a number of points are listed that describe the definition of objective attainment through desirable conditions. These points are:

- The development of patient and client safety is based on versatile and consistent follow-up within the operations. Indicators and measures to be used by the operations to comply with patient and client safety have been identified; including the identification of indicators at national level.
- Common procedures for investigating serious and dangerous events have been established including provisions on what may be described as sufficient resources and knowledge in this context. Particular focus is placed on the development of the business based on surveys.
- Patient and client safety, as well as the quality of care and welfare, are improved on the basis of investigations and follow-ups. Studies create the conditions for a high-quality and efficient operation. They also serve as a guarantee of fulfilment of set objectives.

Patient and client safety are promoted at national level

This sub-objective describes, among other things, that the development of patient and client safety is followed through national databases and registries. It also shows that quality and safety indicators are set at national level as part of the overall monitoring of the quality of care and welfare. National work is also linked to international collaboration.

It also emphasises that the implementation of the strategy is followed by indicators. According to the sub-objective, healthcare providers must follow-up and compare their own operations with other entities. The interviewed representative adds that a large number of indicators in the field of social and health care have been developed in the context of the major reforms that are taking place in the country. Some of these will measure quality and patient safety.

The importance of research in the patient and client area is highlighted in particular and it is stated that it is important to translate this knowledge into practical operations.

Finally, objective fulfilments are reported in a number of points that describe a desirable condition. These are:

- The indicators developed to assess the quality of healthcare should include measures with a focus on patient and client safety.
- Health and welfare statistics and records contain data on quality and patient safety. The information is public.
- Authorities work together to develop an annual patient and client safety overview of health and welfare at national level. The overview can also be used in the national governance of healthcare providers.

*"We have produced a number **of indicators** for social and health care in the context of the ongoing reform. Some of these should be used **to measure quality and patient safety**"*

- Finland representative

Policy document results

The results of the policy document are presented below. Examples of questions to be answered are whether good results can be linked directly to the policy document or more to the governance or organisation at large? Policy document here refers to the analysed document "Strategic Plan 2017 – 2021" (9).

No evaluation has been identified

Any evaluation that can be directly linked to the strategy has not been localized. The interviewed representative also confirms that there is currently no plan for how and when to evaluate the strategy. The respondent also states that there is limited access to data for results in patient safety at national level. Some hospitals report incidents, but as reporting is voluntary it is therefore difficult to comment on possible trends in the country.

A general view, according to the interviewed representative, is that patient safety is now being discussed more widely in the healthcare sector in Finland. The respondent believes that the strategy may have had a certain role in this development, but that the most important factor is the legislation that requires healthcare providers to develop a plan for how to respond to patient safety.

Key interests' views on the policy documents

According to interviewed representatives, it has been difficult for any actor to object to the content of the strategy because it is at such a comprehensive level that it covers the ambitions of most actors within the field of patient safety. The feedback has therefore mostly been positive about the existence of a national strategy for improving patient and client safety.

The interviewed representative believes that it is more likely that an action plan, which is in itself more concrete and detailed, will be criticised by key interests and that more people will have views on the priorities that are set out in the action plan. The interviewed representative stresses that it is important to have both a strategy and an action plan: the strategy can highlight the overall priority areas, while the action plan can describe concrete actions. This creates an overall picture for the healthcare providers.

*"A **comprehensive strategy** can highlight **priority areas**, while the **action plan** outlines more **concrete actions**. Both parts are important for creating an **overall picture** of caregivers"*

- Finland representative

References

1. Unicef. Country: Finland. Retrieved 2020-01-16 from <https://data.unicef.org/country/fin/>.
2. World Health Organization. Retrieved 2020-01-16 from <https://www.who.int/countries/fin/en/>.
3. Social- och hälsovårdsministeriet. Hälso- och sjukvården i Finland. Retrieved 2019-07-03 from http://julkaisut.valtioneuvosto.fi/bitstream/handle/10024/69952/URN_ISBN_978-952-00-3393-4.pdf. 978-952-00-3393-4.
4. Valtioneunosto. Retrieved 2020-01-16 from <https://alueuudistus.fi/sv/allman-information>.
5. Institutet för Hälsa och Välfärd. Retrieved 2020-01-16 from <https://thl.fi/sv/web/thlfi-sv/thl>.
6. OECD.Stat: Health Care Quality Indicators. Retrieved 2020-01-16 from <https://stats.oecd.org/Index.aspx?QueryId=51884>.
7. Vi främjar patientsäkerheten tillsammans. Helsingfors: Social- och hälsovårdsministeriet; 2009.
8. Hälso- och sjukvårdslag (1326/2010). Retrieved 2020-01-16 from <https://www.finlex.fi/sv/laki/alkup/2010/20101326>.
9. Statsrådets principbeslut: Patient- och klientsäkerhetsstrategin 2017-2021. Helsingfors: Social- och hälsovårdsministeriet; 2017.

Country Report Germany

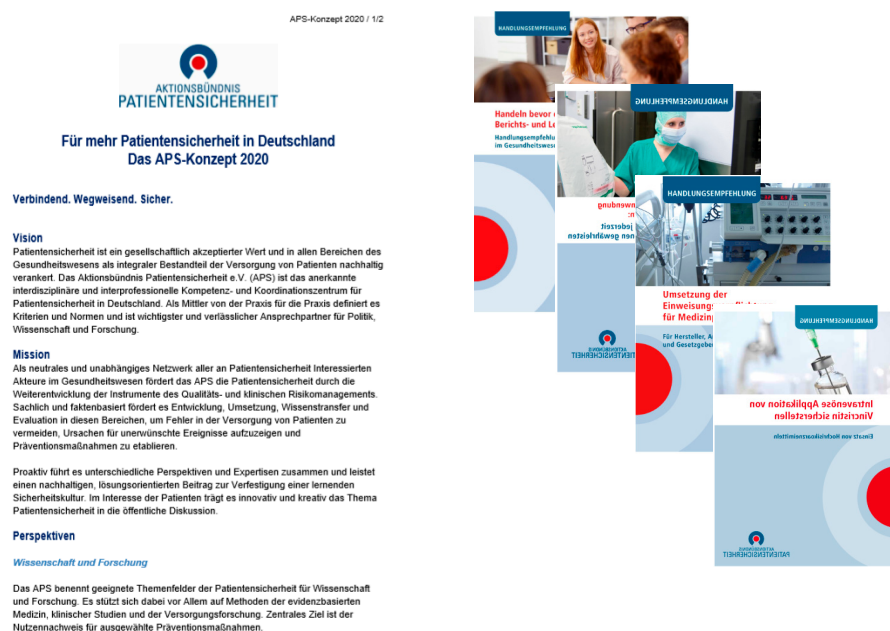
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Introduction

In the analysis of Germany, we focus on the strategy document "Für mehr Patientsicherheit in Deutschland – Das APS-Konzept 2020" which can be translated as: "For greater patient safety in Germany – the APS Concept 2020". APS stands for "Aktionsbündnis Patientensicherheit", which can be translated to "the German Coalition for Patient Safety". In other words, it is the APS strategy that has been analysed. As a complement, and in order to get an overview of the documents that form the basis of how the patient safety work is carried out at a national level in Germany, we have also examined the related action plans developed by APS. The action plans focus on various thematic areas such as digitisation, drug treatment, medical equipment etc. and complement the comprehensive strategy document. The reason why these documents are being studied is that APS is an important actor in the field of patient safety and the organisation's policy documents are in many ways indicative of the overall patient safety work in Germany. In addition, similar policy documents issued by a state actor such as parliament, government or an authority appear to be missing in Germany. The analysis has also been supplemented with information from an interview with a representative from APS and information from the organisation's website (<https://www.aps-ev.de/>). Below are the results of the analyses carried out based on the used framework.

Figure 1. The APS strategy document "Für mehr Patientsicherheit in Deutschland – Das APS-Konzept 2020" is seen on the left and the thematic action plans to the right




Description of the current context

In this section we describe more closely the context that characterizes the policy document in different ways. For example, questions are answered about the possible needs that are the basis for the policy document and what the management of the health care system looks like.

Review country facts – Germany

Figure 2. Summary of basic country facts (1), (2)

Country facts		
Population (million)	81 (2016)	
Average life expectancy (males/females, years)	79/83 (2016)	
Child mortality (< 5 years old per 1000/births)	3.7 (2017)	
Health care cost (%) GDP)	11.3 (2013)	

The German health care system consists of many different actors and is insurance based

The German health care system can be divided into three main areas: 1) ambulatory outpatient care; 2) specialised hospital care and 3) rehabilitation. (3) The responsibility for the implementation of the care is distributed to associations, professions and caregivers' representatives, health care companies, regulatory institutions, the Federal Ministry of Health, patient organisations and others. In other words, the health system consists of and is affected by a variety of actors and organisations.

Germany's health care system differs from the Swedish one in that it is insurance based. Part of the health insurance is compulsory. In short, this means that all citizens with a gross income below a certain level must have statutory health insurance. Citizens whose income exceeds this level can choose private insurance instead. Health care funding is mainly based on insurance premiums. The premiums are paid by insured employees and their employers. Surpluses from tax revenues also contribute to the financing of health care. Although the system is insurance based and partly based on private funding, it is characterised by a principle of solidarity, like the Swedish one. This means that citizens who are part of the compulsory

insurance component will jointly bear the risks of medical expenses. Everyone covered by the insurance is entitled to equal treatment and compensation for loss of wages in the event of sickness (equivalent to sickness benefit). Regardless of the income or premium they have. The private insurance is instead based on income. In other words, the system means that the more resource-strong groups carry a greater share of health care costs. However, these premiums have a financial ceiling (an "income threshold"). Individuals whose income exceeds a certain level still pay the same price for a maximum premium.

The German health care system can be described as decentralised. While the State governs health care by setting certain conditions, most of the responsibility (including the funding) of individual health services is delegated to self-governing bodies within the system. The bodies include representatives from the profession, such as doctors, dentists, psychotherapists, hospitals, insured persons etc. The highest self-governing unit within the statutory sickness insurance scheme is the collective Federal Committee (Gemeinsamer Bundesausschuss). The Committee is also responsible for quality assurance of health care. The work is supported by the Institute for Quality and Efficiency of care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen). Among other things, the Institute is responsible for assessing the benefits and risks of treatment and diagnosis.

The Federal Ministry of Health is responsible for decision-making at federal level. Their tasks include developing legislation and establishing administrative guidelines for the various self-governing entities in the health care sector. Under the Ministry, a number of institutions and authorities are responsible for health care issues such as pharmaceuticals.

National patient safety work

Surveyed patient safety indicators from OECD show no clear trend in Germany

Analysis of data from the OECD (see Figur 3 below) in various patient safety indicators shows no major variations for four out of seven patient safety outcomes in Germany.

A slight increase in the number of cases of post-operative sepsis after abdominal surgery can be seen during the period 2011 to 2015. However, the other two indicators in the surgical field (post-operative dehiscence and left behind foreign body during surgery) do not show any major change. Also, the number of cases of abnormalities within the obstetric field was relatively unchanged during the period 2011 to 2015.

However, a clear decrease in the number of post-op deep vein thrombosis cases after hip/knee replacement surgery can be seen in 2015 compared with 2011, which is positive.

In summary, data from the patient safety indicators surveyed show no clear trends in the development of the patient safety area in Germany.

Figure 3. Comparison of patient safety indicators (OECD data) over time in Germany (4)



Patient safety work is primarily driven by the independent organisation APS

In Germany, national patient safety work is mainly driven by the "Aktionsbündnis Patientensicherheit" (APS) ("The German Coalition for Patient Safety"). According to the representative from APS who was interviewed, the organisation was founded in 2005 by volunteers from various health care providers, such as health professionals, representatives from academia, insurance companies and patient organisations. This was in the context of patient safety research that was widely disseminated at this time.

According to the interviewed representative, there are currently over 7000 members of APS and the coalition's purpose can be summarised as bringing together relevant health actors to work jointly towards a safer health care system. APS is run as a completely independent organisation but cooperates with the federal government in some improvement projects. Financing of the coalition consists of two-thirds from membership fees and donations and one-third from government funds, to carry out specific projects.

APS has continuously developed its business and has worked on compiling knowledge, research and designing guidelines for how caregivers can more systematically work for increased patient safety. In 2009, the Institute for Patient Safety (Institut für Patientensicherheit, IFPS) was founded as the first

university-based institute to research and teach patient safety. Up to 2017, the Institute was supported by APS, including funding.

According to the interviewed representative, APS tries to promote patient safety in Germany by having a supporting role. The members of the coalition have a genuine interest in improving patient safety, which is why the right support and tools can help achieve good results. However, the interviewed representative believes that this supporting function needs to be supplemented by some form of tighter governance in order to ensure that all caregivers perform improvement work in the field of patient safety.

*"Patient safety work must be driven through both a **supporting function** that is motivational and also a **hard policy** that ensures that the work is done"*

- APS representative

In 2012, APS published a strategy paper called "Für Mehr Patientsicherheit in Deutschland – Das APS-Konzept 2020" (referred to as "Konzept 2020" hereafter), which describes the areas in which the coalition will work to improve patient safety (4). According to the interviewed representative, this document has served as a strategic guide for the coalition.

At present, work is underway to develop a new policy document with more specific and concretised focus areas. According to the interviewed representative, APS is thinking of anchoring the document with the Government, in order to have a national consensus on patient safety, but no decision has been taken yet. It has not yet been decided whether the new document should be an extension of "Konzept 2020" or completely replace "Konzept 2020". The new policy document is based on a review of international and national patient safety work presented in the report "APS-Weißbuch Patientsicherheit" (5). A member and researcher of APS has led the work for the implementation.

*"We are currently working on **developing a new policy document** with more concrete **focus areas**. This can contribute to more **focused** national patient safety work"*

- APS representative

APS also brings forward action plans for specific subjects in the field of patient safety (6). These action plans have a specific link to the areas of work found in the strategy document "Konzept 2020" – mainly by reflecting the thematic content of the work areas. The action plans contain recommendations on specific topics considered up to date by the members of the Coalition. A more detailed description of how these action plans are developed is

given in this country report under the heading "There is a clear process for the development of the overall strategy and action plans".

The state implements some efforts to improve patient safety but not as focused as APS

In parallel with the activities and efforts that APS implement, some other work is being done to improve patient safety at the overall level of the German health care system (7). Since 2016, the Federal Ministry of Health has organised an annual international conference on the subject of patient safety. The conference, "Global Ministerial Summit on Patient Safety", brings together leaders and representatives from different countries and global organisations such as WHO, the World Bank, OECD and the EU to jointly highlight and discuss patient safety. The overall Federal Committee (Gemeinsamer Bundesausschuss) is responsible, among other things, for quality assurance of health care by developing guidelines for caregivers to follow. There have also been requirements for caregivers to report deviations that occur in health care. However, according to the interviewed representative, it is unclear as to what extent there is follow up of how reporting occurs.

According to the interviewed representative, the commitment to patient safety and what interest issues are being pursued varies, depending on which representatives are in the Ministry of Health. There is no national strategy for patient safety from government level at present, however, some specific strategies, for antibiotic use for example, have been published by the government.

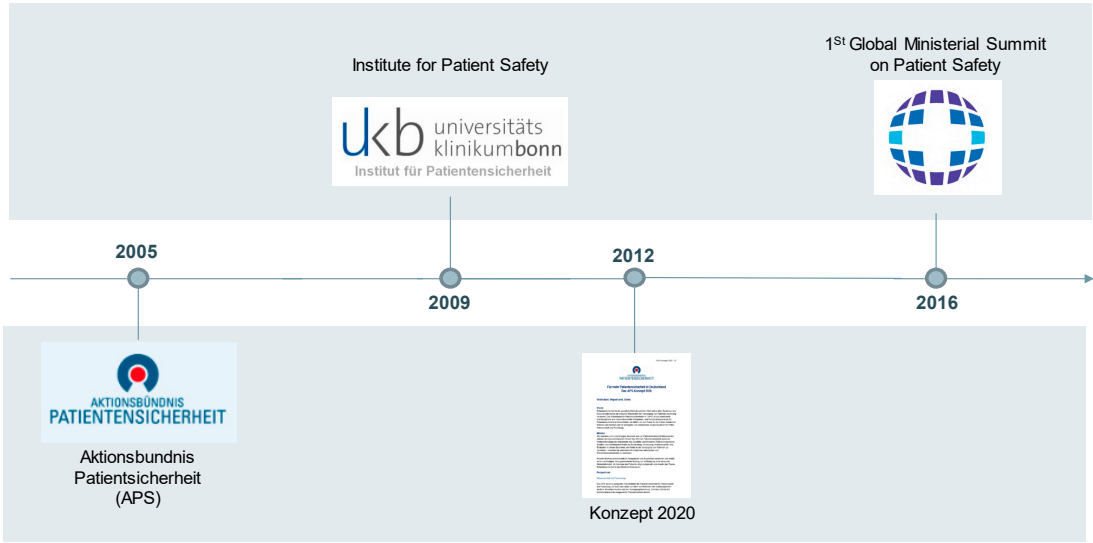
*"We currently **have no national strategy** for patient safety from **the government's side**"*

- APS representative

Based on the above, our assessment is that APS is the running organisation for patient safety at national level in Germany. Therefore, the strategy document "Konzept 2020", together with the action plans, is considered to be the most relevant policy documents for our analysis of national patient safety work.

See Figur 4 below for a visualisation that summarises how German national patient safety work has evolved over time.

Figure 4. Timeline of patient safety work in Germany



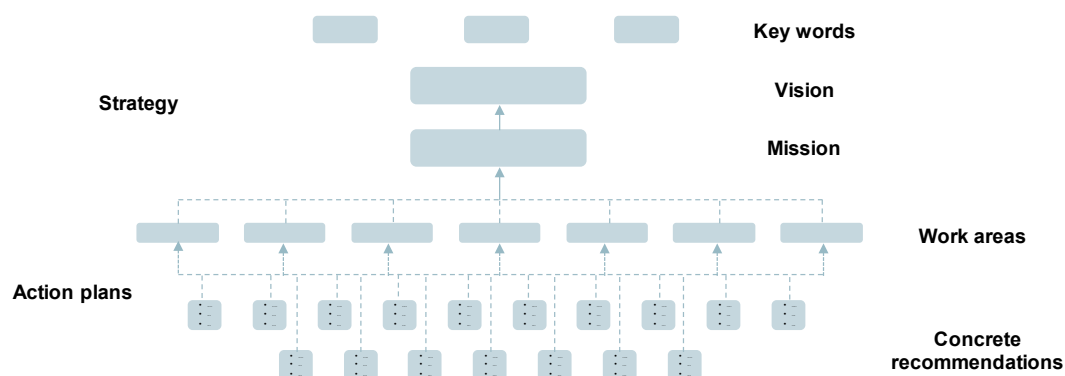
Policy document structure

This section describes the structure of the policy documents. Questions about the parts of the policy document and the intended recipients are answered here. We also highlight the format of the documentation, i.e. whether they are comprehensive or summarised etc. Policy document here refers to the analysed strategy document "Für mehr Patientsicherheit in Deutschland – Das APS-Konzept 2020" (4) and the thematic action plans (6).

There is a comprehensive strategy with related action plans

In conclusion, the comprehensive strategy document (Konzept 2020) consists of four main elements: 1) Three key words; 2) A vision that guides APS work up to the year 2020; 3) A mission for the organisation's tasks and 4) Seven different areas on which the organisation works. In addition to this more comprehensive strategy document, there are 17 complementary policy documents available on the Coalition website. These include proposals for action in different thematic areas related to patient safety. Since the content of the documents is linked to the keywords, vision and areas shown in the strategy and that they include proposals for clear areas for improvement, these can be described as concrete action plans which complement the strategy. For a visualisation of the different parts of the policy documents, see Figure 5 below.

Figure 5. Visualisation of the structure of the policy document



The strategy is primarily internal, but the action plans are aimed at caregivers and patients

The overall strategy (Konzept 2020) is addressed primarily to the members of APS. The purpose of the strategy is simply to guide the organisation's work in accordance with the overall vision. However, because the organisation's activities claim to contribute to improved patient safety, it can be interpreted that the strategy is indirectly aimed at the various actors within health care. On the other hand, the supplementary policy documents, that is to say what we are denoting as the action plans, are mainly aimed at health care providers and health professionals.

In summary, the policy documents are not based on different recipient levels (such as micro/meso/macro perspective).

The strategy is concise, while the action plans vary in nature

The strategy document (Konzept 2020) is a very concise body text document of only two pages. The document lacks any visual elements. The document has not been translated into English, and is only available in German. This complicates the ability of non-German speaking people to access the content, which can be problematic from an accessibility perspective. The format of the thematic action plans is more difficult to generalise as these look different. Some are concise and are similar in format to brochures or checklists. However, most are more extensive text documents (between approximately 20 – 50 pages) with or without visual elements.

The need for a communication strategy is now seen as more important than previously

In an interview with the representative from APS, the organisation has so far not put any major focus and effort into developing communication strategies on patient safety. One explanation given is that the members who are part of the coalition are already deemed to be interested in patient safety, are involved in developing the projects to be pursued, and to a large extent also involved in the implementation. Based on past experience, the organisation's projects often also have a lot of media attention and have thus been communicated naturally to the public. However, as the organisation grows larger and with the organisation's ambition to increase the influence of national patient safety work, the need for a communication strategy is deemed to have increased. The interviewee highlights that a plan for communication is likely to be developed in connection with the publication of the forthcoming policy document.

*"We have become more **aware** that **communication strategies** are needed and will probably have this in mind in the work on **the next policy document**"*

- APS representative

However, the annual "Patient Safety Day" (8) organised by APS, with the main aim of disseminating awareness about patient safety to the public, may be considered to be part of the organisation's communication to the public – despite the fact that this is not highlighted in interviews with representatives of the organisation.

The current strategy document is valid for eight years

The overall strategy (Konzept 2020) published in 2012 extends until 2020, that is to say, a total of eight years. The interviewed representative cannot provide any specific reason for the selection of this particular time period. Furthermore, the respondent states that the period of validity of the organisation's strategy document is not usually defined during the development; the documents are renewed or adapted as the members of the organisation think necessary. The same applies to the thematically-oriented action plans, which are published on an ongoing basis.

*"We have **not had time frames** for our documents, but have a **sense for** when they need to be renewed"*

- APS representative

Policy document content

In this section we report the content of the policy documents. For example, questions about the strategy's thematic focus or whether the content is based on a clear perspective are answered. We also describe the tangibility level in the policy document more closely. Policy document here refers to the analysed strategy document "Für mehr Patientsicherheit in Deutschland – Das APS-Konzept 2020" (4) and the thematic action plans (6).

The overall strategy is based on a vision that is linked to the association's mission and a number of focus areas

The three key words presented in the overall strategy (Konzept 2020) can be translated as 1) Unifying; 2) Guiding and 3) Safe.

The overall vision is broad and consists of several parts. The vision is formulated as: *"Patient safety is an accepted, long-term and well-anchored value in society, and an integral part of health care. APS is recognised as the central interdisciplinary and inter-profession co-ordination body for patient safety in Germany. APS defines criteria and norms in the field of patient safety. APS is the most important and reliable actor in the field of patient safety for politics as well as science and research."*

The accompanying mission is formulated as follows: *"APS is a neutral and independent network for all actors in the health care sector with an interest in patient safety. APS promotes a focus on patient safety through the further development of tools for quality development and clinical risk management. APS works for development, implementation, knowledge transfer and evaluation in an objective and fact-based way. This is to prevent health care associated injuries by identifying causes and actions for deviations/health care associated injuries. APS contributes to the proactive integration of different perspectives and areas of knowledge, as well as to the sustainable and solutions-oriented way to strengthen a learning safety culture. To protect the interests of patients, APS highlights patient safety in an innovative and creative way in public debate.*

As mentioned above, seven different areas are reported that the organisation is working on. Efforts within the various areas promote improved patient safety within the strategy. The seven areas are:

1. Science and research
2. Training and skills efforts
3. Guiding documentation
4. Economic analysis
5. Patient involvement

6. Structural and organisational conditions
7. Financial conditions

See below for the description of each area.

Science and research

APS identifies relevant research issues and potentially interesting studies in the field of patient safety. From this, clinical studies and research are conducted with evidence-based approaches. The main goal of this research is to identify the effects within different types of prevention programs.

Training and skills efforts

APS promotes the systematic anchoring of issues in the field of patient safety through education, training and continuing training of health care professionals. The aim is for all persons who work – directly or indirectly with patients – to have adequate knowledge and practical skills in the field of patient safety in health care.

Guiding documentation

In order to improve patient safety in the German health care system, APS, in co-operation with its partners, develops supporting documents in the form of guidelines and recommendations aimed at caregivers. The documentation is also available to the public.

Economic analysis

APS makes estimates of the possible financial consequences arising from the development and implementation of measures in the field of patient safety.

Patient involvement

APS should be seen as a representative of patients' interests. They include patients, relatives and other relevant actors in their activities.

Structural and organisational conditions

APS advocates and works to ensure that the appropriate structural and organisational preconditions for ensuring safe health care are always available.

Financial conditions

APS makes visible what financial conditions are needed to ensure stable financing of measures to improve patient safety. The organisation advocates in this context that the financing of development, introduction and follow-up of patient safety work is systematic and permanent at the operational level.

The action plans contain recommendations within specific areas

As mentioned above, complementary action plans have been identified. The action plans are in a number of thematic areas, such as:

- **Digitalisation and patient safety** with focus on risk management in health care.
- **Reporting and learning systems** in order to identify and prevent discrepancies.
- **Patient safety in the use of medical equipment** with a focus on the review of equipment and the importance of making consistent information available in this respect.
- **Clinical risk management systems in hospitals** and how these can be developed based on needs analyses.
- **Safe drug treatment in hospitals** with a focus on certain medicines.
- **Guidelines and checklists for fall accidents in hospitals** with a focus on the elderly.
- **Safety in surgical operations** including focus on preventive measures for the leaving behind of foreign bodies in the surgical field.

Special patient information is available in some cases

In some cases, the action plans are also supplemented with patient information. The information generally describes things that patients themselves can think about and take into account in contact with health care in order to protect their own safety. For example, there is an information document called: *"Being safe in the hospital – a guide for patients (Sicher im Krankenhaus – Ein Ratgeber für Patient)"* (9). The guide should act as a practical tool for the patient when it comes to what kind of information he or she should highlight from a patient safety perspective. For example, the guide reminds the patient to tell the health care professional what medicines she or he is taking, about possible side effects, allergies etc.

Ethical principles for patient safety have been published separately

APS has also produced a document summarising ethical principles for the work on improving patient safety (Ethische Leitsätze zur Stärkung der Patientensicherheit) (10). The principles are formulated on the basis of subjective claims of approach and should, according to the document, characterise the patient safety work of caregivers and health care professionals. These are:

- "Our work is based on patient wellbeing."
- "We create the conditions for patients to be independent, and take responsibility for their own safety in contact with health care, within the framework of their own conditions and abilities."
- "We work constructively and with confidence in each other; we also contribute individually to patient safety."
- "We share all the information that can contribute to increased patient safety."
- "We acquire knowledge of patient safety at the earliest possible stage and we ensure that it is constantly evolving."
- We take responsibility for and work actively to identify and communicate possible patient safety risks. We adapt our actions accordingly."

- In cases where we have organisational responsibility, we ensure that central structures and processes for patient safety are established. We follow-up and develop these continuously. We also ensure the availability of the necessary resources.

It is not possible to fully categorise the policy document content

When the focus of the policy documents (strategy and action plans) varies, it is difficult to completely define the thematic content of the policy documents. In the overall strategy ("Konzept 2020") there is a constructive approach emphasising the coalition stresses that they themselves will work on in an oriented and innovative way. Certain areas of success, such as the culture of patient safety, are explicitly highlighted in the mission. The overall vision is of a more instrumental nature and describes what the organisation should aim for in the long-term. The reported focus areas in the strategy can to some extent be described as areas of success given that they reflect the conditions for good patient safety, such as patient involvement.

The action plans are, in turn, relatively narrowly focused on the different thematic areas. These can be described as a combination of areas of success, risk areas and outcomes.

When it comes to the use of the definition of patient safety, this seems to be relatively narrow from the perspective of the strategy. It focuses primarily on a minimised injury rate rather than improving the overall quality of care.

To sum up, from the above, it is not possible to fully categorise the content of the policy documents.

Strategy processes

This section presents the central processes that can be linked to the strategy and the action plan. Examples of questions to be answered are whether the policy document was based on a particular process, for example through consultation or negotiation? Another important element is examining whether the policy document describes different central processes and in such cases what is included in them. Policy document here refers to the analysed strategy document "Für mehr Patientsicherheit in Deutschland – Das APS-Konzept 2020" (4) and the thematic action plans (6).

There is a clear process for the development of action plans and the overall strategy

The representative from APS who was interviewed tells us that the organisation has a standardised process for producing the documents that are published. This process has been used in the development of the overall strategy "Konzept 2020" and is also used continuously to develop the thematic action plans. The process is based on the work carried out within the framework of various working groups, consisting of members of APS, experts from different areas of health care, and patient representatives.

The process is described in detail in a document that can be downloaded from the organisation's website and called "Guide to develop recommendations for action" ("Leitfaden Zur Erstellung Einer Handlungsempfehlung") (11). It describes that the process can be divided into six different phases:

1. Proposals for a new working group or new tasks are developed in the management group
2. The Working Group is formed
3. The Working Group draws up recommendations
4. Decision on action plan taken
5. Publication and preparation
6. The action plans are monitored and updated continuously

See below for the description of each phase.

1. Proposals for a new working group or new tasks are developed in the management group

In this phase, the APS management team collects proposals for new working groups or new tasks for existing working groups. In this step, the relevance of the problem area is analysed and the area is demarcated and defined in order to make the task as concrete as possible. The process for further work is then determined. The management team then formally decides that the Working Group will be set up.

2. The Working Group is formed

The next stage identifies appropriate representatives to be included in the Working Group. It is desirable that at least one patient representative and representatives from the Institute for Patient Safety are included. Decisions are also made about the persons who will constitute the Working Group management and who will represent the working group of the APS management team. A preparatory meeting will be organised at the first stage and a notice on the appointment of the Working Group is communicated to the members of the APS. The Working Group then has its first meeting.

3. The Working Group draws up recommendations

This phase can be said to be at the core of the Working Group. It is at this stage that the Working Group formulates recommendations. The Working Group starts work on a timetable. They usually meet three to four times during the working period and telephone conferences are organised, if necessary. The aim is to develop the recommendations within 12 to 18 months. The work includes creating a common understanding within the Working Group on what to include in the recommendations. To help, the Working Group has external experts and specialists in the specific field. Relevant trade unions and patient organisations are also asked to submit their comments before the recommendations are set. For quality assurance purposes, the recommendations are presented in advance to a smaller target group. This is to get a picture of whether the recommendations can be considered comprehensible, complete and whether they are possible to translate into concrete action. The Working Group then establishes a preliminary draft of the action plan as a whole.

4. Decision on action plan taken

The preliminary version of the action plan is communicated to the APS management team. The management team forwards this to APS different members and makes it available on the website. The members and the public are then given the opportunity to submit comments on the documentation via a standardised survey. The comments are collected and are the basis for the Working Group's further processing of the action plan. Finally, the finished proposal is sent to the APS management team, which then formally decides that the action plan should be published.

5. Publication and preparation

After the formal decision has been taken, the content of the action plan shall be communicated and disseminated. There are special procedures for how this is to happen. First, the documentation undergoes proofreading and then the document's layout is processed by a special design department. All material is then published on the website and in some cases physical material is printed. To increase the communicative impact, APS sends out press releases and organises any press conferences or events. They also send out the information via e-mail, physical letters and special newsletters. Affected

or interested parties can also publish the action plan on their websites, or use it in different contexts such as workshops or conferences. The stated objective is that all caregivers should have access to and use the recommendations. The health care provider should adapt the recommendations to prevailing local conditions, i.e. integrating the measures into existing working methods.

6. The action plans are monitored and updated continuously

The content of the action plans shall be followed-up and monitored on an ongoing basis. In order to ascertain whether any updates are needed. This type of follow-up is done either by the APS management team, or by a person appointed by the management team. The frequency of follow-up usually varies between different documents, but it tends to be every three to five years. The responsible Working Group decides when the follow-up is to take place. There are also clear procedures for how the checks should take place. Initially, the management team examines whether any updates to the document are needed. The APS management team makes a joint decision with the Working Group management if the updates are to be made by the existing Working Group or if a new group is to be set up. The group responsible will then examine the action plan and make assessments of whether additional material needs to be developed.

There is no concrete description of the implementation process

The comprehensive strategy document "Konzept 2020" outlines seven different work areas for APS, but does not show any concrete description of the work to be done in these areas. The action plans developed by APS are published for the general public and it is then up to the caregivers to find processes to implement these. Because the representatives of the caregivers are usually part of the Working Groups that have developed the action plans, there is often an interest in implementing the measures from the outset.

In parallel with the development of the action plans, APS also works with running a few improvement projects. Examples of projects currently being conducted are "CIRSforte", which aims to help caregivers implement reporting and learning systems for health care associated deviations in their operations (12). An example of a previously implemented and highlighted project is a national campaign called "Aktion Saubere Hände" (13). In English, this can be translated as "Action for clean hands". The aim of this campaign was to increase awareness of hygiene of both health professionals and the general public in order to prevent health care associated infections (HAI).

The interviewed representative also stated that APS sees it as a priority to interact with authorities, organisations and other actors. For example, the involvement of patients is seen as an important aspect of all the work carried out by APS. The coalition is actively trying measures to get more patients/patient organisations to become members of the organisation, including offering free membership. APS also participates in discussions with the government and authorities to influence legislation in such a way that patient safety in the German health care system is strengthened. Furthermore,

participation by representatives of the Government in APS working groups is welcomed.

*"We are **actively trying to involve more patients** in our work"*

- APS representative

Follow-up processes are not described in the policy documents

No presentation of how the impact and results of the overall strategy or implementation of the recommendations in the action plans are to be monitored is described in the relevant documents. The interviewed representative of APS tells us that there are no plans to evaluate the "Konzept 2020" strategy document, but that work is underway to evaluate the impact of the action plans. Among other things, the sending of a questionnaire to healthcare providers (in hospitals) is planned to collect opinions on the recommendations of the action plans.

The interviewed representative adds that there are currently no good methods for measuring and following-up patient safety in Germany. Discussions are currently underway with research leaders in the area to develop a standardised programme for measuring patient safety in the country.

*"We have held meetings with **research leaders** to discuss **a proposal regarding measurement and follow-up of patient safety**"*

- APS representative

Results of the strategy

The results of the policy document are presented below. Examples of questions to be answered are whether good results can be linked directly to the policy document or more to the governance or organisation at large? Policy document here refers to the analysed strategy document "Für mehr Patientensicherheit in Deutschland – Das APS-Konzept 2020" (4) and the thematic action plans (6).

Results that can be linked to the policy documents do not exist because they have not been evaluated

Because the policy documents have not undergone any evaluation, neither are there any results regarding patient safety that can be linked to the documents. The interviewed representative confirms that no such results are available.

The compilation of reported deviations within the German health care system is also difficult to find through desk analysis. Regarding other follow-ups, the interview respondent describes that the overall Federal Committee (which provides health guidelines) follows up on certain quality indicators. However, these results are not available to the public.

Key interests' views on the policy documents

According to the interviewed representative, no assessment of key interests' views on the documents has been made. This is because most of these actors have been involved in the development of these documents themselves.

References

1. World Health Organization. Countries: Germany. Retrieved 2020-01-17 from <http://www.who.int/countries/deu/en/>.
2. The World Bank. Mortality rate, under-5 (per 1000 live births). Retrieved 2020-01-17 from <https://data.worldbank.org/indicator/SH.DYN.MORT?locations=DE>.
3. Health care in Germany: The German health care system. Cologne: IQWiG (Institute for Quality and Efficiency in Health Care); 2018.
4. OECD.Stat: Health care quality indicators. Retrieved 2020-01-17 from <https://stats.oecd.org/Index.aspx?QueryId=51884>.
5. Für mehr Patientensicherheit in Deutschland Das APS-Konzept 2020. Aktionsbündnis Patientensicherheit; 2012. https://www.aps-ev.de/wp-content/uploads/2016/08/APS_Konzept_2020_final.pdf.
6. Schrappe M. APS-Weißbuch Patientensicherheit. Berlin: Medizinisch Wissenschaftliche Verlagsgesellschaft; 2018.
7. Aktionsbündnis Patientensicherheit. Handlungsempfehlungen. Retrieved 2020-01-17 from <https://www.aps-ev.de/handlungsempfehlungen/>.
8. Bundesministerium für Gesundheit. Patientensicherheit. Retrieved 2020-01-17 from <https://www.bundesgesundheitsministerium.de/service/begriffe-von-a-z/p/patientensicherheit.html>.
9. Aktionsbündnis Patientensicherheit. Retrieved 2020-01-17 from <http://patient-safety-day.org/index.html>.
10. Staying safe in hospital: Recommendations for patients and their relatives. APS-Arbeitsgruppe "Informieren-Beraten-Entscheiden; 2016. <https://www.aps-ev.de/wp-content/uploads/2017/03/Staying-safe-in-hospital-1.pdf>.
11. The Ethical Guiding Principles to improve Patient Safety. Berlin: Aktionsbündnis Patientensicherheit; 2018.
12. Leitfaden Zur Erstellung Einer Handlungsempfehlung. Berlin: Aktionsbündnis Patientensicherheit; 2017. https://www.aps-ev.de/wp-content/uploads/2016/09/APS_AG_Leitfaden_2017.pdf.

13. Aktionsbündnis Patientensicherheit CIRSforte. Retrieved 2020-01-17 from <https://www.cirsforte.de/>.

14. Aktion Saubere Hände. Retrieved 2020-01-17 from <https://www.aktion-sauberehaende.de/ash/ash/>.

Country Report Netherlands

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Introduction

In the analysis of the Netherlands, we focus on the national initiative the Patient Safety Agenda (VMS Veiligheidsagenda). The agenda, mainly through focus areas, is the overall direction of national patient safety work. In the course of the interview it becomes clear that this national program is the foreground of past and future policy documents. However, it has not been possible to locate a physical policy document that covers the national agenda. The analysis of the agenda and its contents has therefore mainly been on the agenda's current website(www.vmszorg.nl) and was supplemented by an interview of representatives from the Dutch Institute for Research in Healthcare with expert knowledge in patient safety.

Below are the results of the analyses carried out based on the used framework.

Figure 1. The home page of the Patient Safety Agenda (VMS Veiligheidsagenda) which has been analysed in the framework of this country report.




Description of the current context

In this section we describe more closely the context that characterizes the policy document in different ways. For example, questions are answered about the possible needs that are the basis for the policy document and what the management of the healthcare system looks like.

Review country facts – Netherlands

Figure 2. Summary of basic country facts (1), (2)

Country facts	
Population (million)	17 (2017)
Average life expectancy (males/females, years)	79.9/83.1 (2017)
Child mortality (< 5 years old per 1000/births)	3.9 (2017)
Health care cost (% GDP)	10,9% (2014)



The Dutch healthcare system is characterised by a mandatory insurance scheme

The Dutch healthcare system is characterised by a mandatory sickness insurance scheme (3). Preventive efforts and social care services are not covered by the system, but are funded instead through general taxation. The Government has overall responsibility for the healthcare focus in the Netherlands. It identifies, for example, overall priorities and controls quality and costs.

The mandatory health insurance is purchased from private competing insurance companies with profit dividend bans (4). Individuals with insurance from the same company pay the same premium – regardless of age and state of health. The contributions are collected at central level and allocated to the various insurance companies on the basis of certain frameworks that take account of gender, health risks, age etc. According to existing legislation, insurance companies in the healthcare system must offer a standardised basic package. These include primary healthcare, hospital care and specialised care, dental care up to 18 years, prescription drugs, physiotherapy, some

forms of home care and some psychiatric care. The national Government, local authorities and insurance companies share responsibility for home care.

Health services are financed through both private and public funds. Adult private individuals, i.e. over 18 years old, pay a fee directly to the insurance companies. In addition, a Government health insurance fund is used to finance the corresponding fee for persons under the age of 18. In addition to this patient fee, employers are also required to pay an income-related health insurance fee for their employees. There are also public grants for the financing of health insurance contributions for low-income workers.

In addition to the compulsory insurance, most people take out voluntary supplementary insurance which includes, for example, dental care, medication costs or alternative medicine. This type of supplementary insurance does not mean quicker access to care or wider access to specialists or hospitals. The system is characterised by a large number of caregivers, and hospital doctors (apart from those who are active in University Hospitals), also working in private practices. Many insurance companies and caregivers are non-profit.

Besides healthcare, citizens are offered social care

Local authorities are responsible for preventive care efforts and social care services such as elderly care or efforts for people with different types of impairments (4). Funding is provided through local authority funds that allow the municipalities to procure the services. The Government is responsible for allocating these funds. Specific legislation also regulates certain long-term or permanent care services such as geriatric care or certain types of psychiatric efforts for example in the event of chronic discomfort. A total of 31 special healthcare administrative departments (Healthcare Administration Office) have the task of administering these health and care services based on the current needs, together with the patient. Thereafter, either the patient or the administrative unit can procure the required efforts. Financing of these services is via a fund that is financed mostly by tax resources. All citizens contribute to the fund via tax assessment. Part of the funding consists of patient fees and the Government can also provide resources if necessary.

Various Government agencies are working to control and ensure quality

As mentioned earlier, the Government has the overall responsibility for controlling the quality of healthcare, including by ensuring adherence to existing legislation. This responsibility is allocated to three authorities (5):

- **Health authority (Nederlandse Zorgautoriteit):** The authority ensures that insurance companies and caregivers comply with existing rules, for example, that insurance companies include all services that are required by law to be included in the "basic package" (6). The authority also decides on the ceilings for patient charges and also verifies that caregivers comply with these decisions.
- **Authority for consumers and markets (Autoriteit Consument & Markt):** The authority is responsible for promoting and ensuring

equal competition in the healthcare market in a way that benefits consumers (patients/users) (7).

- **Healthcare and Youth Inspectorate (Inspectie Gezondheidszorg en Jeugd):** The authority is responsible for ensuring quality and safety in accordance with existing regulations (8). For example, the authority may carry out investigations in case of complaints against caregivers or apply penalties or other punitive measures in the case of quality deficiencies.

Competition is significant for the quality of healthcare

Existing regulations set the framework for the desired quality of care. Given that the system is characterised by relatively high competition between different independent actors – both insurance companies and caregivers – the quality of care can be said, above all, to be regulated by the expectations, requirements and choices of the actors and patients (4).

National patient safety work took off thanks to international research reports focusing on healthcare-related injuries

At the beginning of the 2000s, patient safety issues were placed high on the healthcare agenda thanks mainly to American research reports. In brief, the reports showed that a relatively large number of patients generally suffer from avoidable healthcare-related injuries. Against this backdrop, a national program was launched in the Netherlands, entitled 'Better Faster' (9). The program aimed to improve the quality of healthcare and the objectives were increased transparency and quality.

During this period, there was an interest among professional organisations to investigate the frequency of care abnormalities in hospitals. That is why the Dutch institute for research in healthcare (Nederlands Instituut voor onderzoek van de gezondheidszorg, NIVEL) carried out a study focusing on healthcare-related injuries (10). The study, which was carried out on behalf of the professional organisations, showed that almost six per cent of 1.3 million hospital registrations in 2004 resulted in some form of care associated injury. Approximately 40 per cent of these could be prevented according to the study.

The result motivated four different professional organisations¹, with the support of the Ministry of Health, Welfare and Sport (Ministerie van Volksgezondheid, Welzijn a Sport), to jointly develop a national patient safety program (VMS Veiligheidsprogramma) named “Prevent harm, work safely” (11).

¹ The Association of Hospitals in the Netherlands (Nederlandse vereening van Ziekenhuizen, NVZ), the association of specialist doctors in the Netherlands (Federation of Medical specialists), the Association of Nurses and Caregivers in the Netherlands (Verpleegkundigen & Verzorgenden Nederland, V & VN) and the Association of University Hospitals in the Netherlands (Nederlandse Federatie van Universitair Medische Centra, NFU)

Through the National Patient Safety Program, healthcare-related injuries decreased significantly

The program ran from 2008 to 2012 and included all hospitals and its objective was to halve healthcare-related injuries (11). As part of the work, a special safety system was introduced with inspiration from the oil industry, in healthcare. In summary, the system meant improved conditions for risk identification and development work. The ambition was for the security system to be introduced within a total of ten pre-determined thematic areas at all hospitals (12). The prevention of wound infections after surgery, safer child care and pain treatment are examples of chosen thematic areas. The areas were identified, among other things, by the results of the NIVELS study on healthcare-related injuries.

In an interview with representatives from NIVEL, it appears that research studies were carried out to follow up the patient safety program on several occasions during the program period, among other things, to investigate changes in outcome. According to interviewed representatives, the follow-up study carried out in 2011–2012 showed that the rate of healthcare-related injuries had decreased significantly compared to 2008. The objective of halving the number of injuries was thus almost fulfilled and the program was concluded.

The program was transformed into a national agenda with clearer elements of autonomy

According to interviewed representatives, hospital representatives then expressed the opinion that the program had meant too stringent requirements for healthcare providers. This is despite the fact that the hospitals' participation and the implementation of the program's improvement measures were formally voluntary. In this context, the professional organisations concerned decided to change the nature of the program. The national safety work would continue, but the approach would be more supportive and motivating than before. The result of this was the “Patient Safety Agenda” (Veiligheidsagenda) which was introduced in 2013 (13).

Four focus areas were identified under the agenda, and these were: 1) Safe medication treatment; 2) Safe use of medical equipment; 3) Infections and antibiotic use, and 4) Vulnerable elderly. The focus areas were selected on the basis of a needs analysis. In brief, the least progress had been made in these areas within the framework of previous national safety programs. The participating hospitals were given the opportunity to prioritise more independently between the different parts of the agenda, compared with the previous program period.

A new outcome analysis focusing on healthcare-related injuries was carried out during 2017. According to the interview respondent, this does not show any significant changes relative to the previous measurement. The results have been reportedly disappointing for both the profession and the responsible health minister. In this context, the Ministry of Health, Welfare and Sport has given the professional organisations the task of developing a new action plan for national patient safety work. The action plan is to take effect from 2019, and it shall be based on a bottom-up perspective, that is to

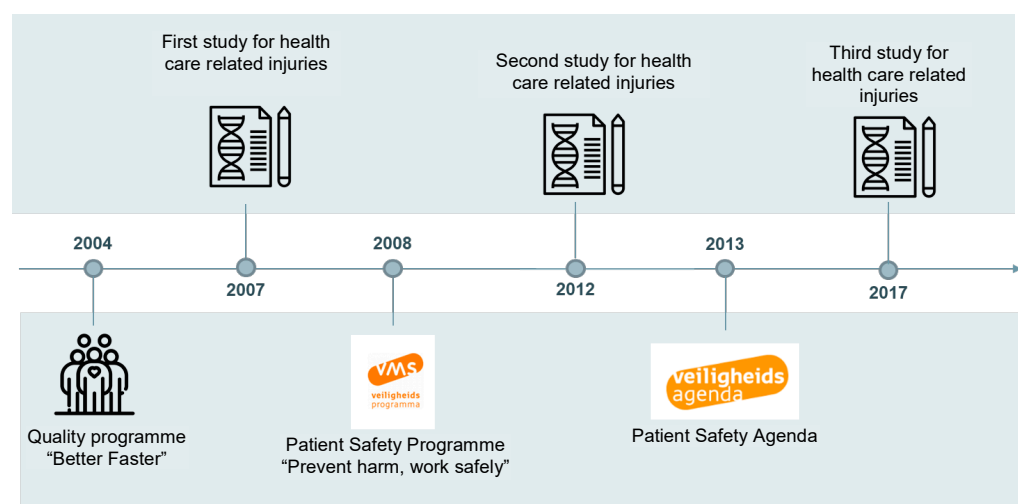
say, to a large extent, taking into account the needs and wishes of the care-givers. The Ministry of Health, Welfare and Sport makes no formal demands, but supports the work in various ways, for example through funding and public statements. In other words, the professional organisations are responsible for the design of the plan.

*“Within **our system** it is not possible to direct patient safety work from the top down, **one has to start with the relevant organisations**”*

- NIVEL representative

In Figure 3 below, the development of patient safety in the Netherlands over time is visible and summarised.

Figure 3. Timeline of national patient safety work in the Netherlands



Patient Safety Agenda in focus

Based on the above information, we have chosen to focus on the “Patient Safety agenda” in the context of this analysis. In summary, the agenda seems to lay the groundwork and focus of national safety work. No physical document linked to the agenda has been located, but descriptions of its contents are available on a website (vmszorg.nl) run by the Association of Hospitals in the Netherlands (NVZ) and the Association of University Hospitals (NFU). The analysis is based on the content of this website as well as additional information from the interview with representatives from NIVEL with expertise in the field of patient safety.

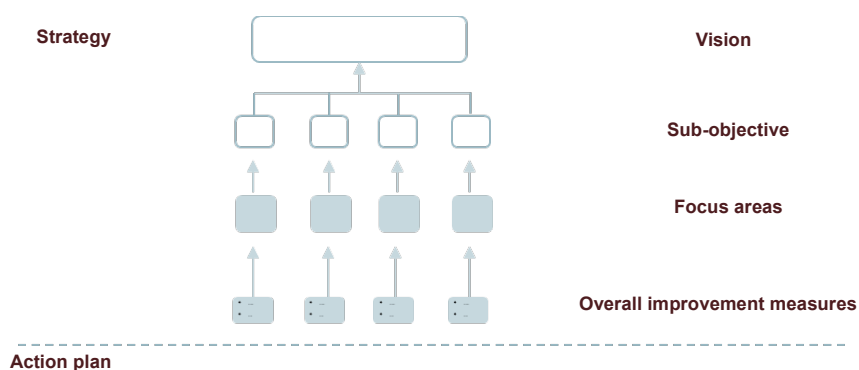
Policy document structure

This section describes the structure of the policy documents. Questions about the parts of the policy document and the intended recipients are answered here. We also highlight the format of the documentation, i.e. whether they are comprehensive or summarised etc. “Policy document” here means the “Patient Safety Agenda” (VMS Veiligheidsagenda) (13).

The Patient Safety Agenda is likely to provide some guidance but limited information on objectives and desirable activities

Overall, the agenda consists of two parts: 1) four focus areas and 2) overall improvement measures within each focus area. A visualisation of the agenda's structure can be seen in Figure 4.

Figure 4. Visualisation of the structure of the agenda



In short, traditional elements that can usually be associated with strategy documents such as vision, mission or overall objectives are not included in the National Patient Safety Agenda. The focus areas and the description of possible improvement measures are likely to provide some guidance on improvement work at a more operational level. Because of the lack of more comprehensive strategic elements, the agenda can be more closely related to more concrete policy documents such as an action plan. At the same time, there seems to be some shortfalls regarding the descriptions of what efforts and measures are needed, that is, the agenda gives a relatively limited picture of desirable activities, etc. at operational level.

The predecessor of the agenda had an overall quantitative objective

An interview with representatives from NIVEL shows that overall quantifiable objectives were formulated in the precursor to the National Patient Safety Agenda. The lesson from this, however, was that it is more appropriate to focus instead on activities that the participating hospitals can independently

choose from. This is described as particularly important in a complex and decentralised system in which the National Patient Safety Agenda is characterised by voluntary participation by caregivers.

*"There was an **overall measurable objective** within the framework of the previous programme. This time we **did not want to quantify**. Now the hospitals can **choose** between different **activities** instead. You can choose your own way"*

- NIVEL representative

At the same time, the interview respondent notes that different types of objectives are still needed. This is because common objectives create good conditions for aligning different actors and activities in one direction.

Participating hospitals are the main recipient of the agenda's content

The National Patient Safety Agenda only includes hospital care. The stated recipient of the content is therefore primarily hospital management. In conclusion, the agenda is only aimed at meso level.

The agenda is presented on a website

The contents of the agenda are presented together on a website (vmszorg.nl). Here you can find, for example, information about the four focus areas included in the patient safety agenda and related tools and advice. The website can be described as user-friendly and structured.

Communication occurs primarily through the professional organisations

According to interviewed representatives from NIVEL, there is no clear communication plan for National Patient Safety work carried out within the framework of the patient safety agenda. However, it states that some strategic communication work is still taking place. For example, the professional organisations communicate with the public in a partly target group adapted way. The research institutes involved produce concise and more readable summaries of research results – summaries that can be used in communication with both the public and the media.


*"**Communication** occurs primarily through the **professional organisations**. No major emphasis is placed on marketing methods, but we are working to a certain extent on **target group adapted** marketing, for example when communicating with the public"*

- NIVEL representative

Previous national patient safety programs have had special titles in order to increase the impact. However, other more traditional marketing methods, such as slogans or logos, have been reportedly not used to any great extent.

The Patient Safety Agenda has run for a four-year period

The current Patient Safety Agenda ran from 2013 to 2017. In other words, it had a four-year timeframe. The model for the agenda, that is to say the previous National patient Safety Program, was also four years. According to interviewed representatives from NIVEL, the timeframe has been chosen based on a strategic assessment of how much time caregivers need to start and run improvement work at the level, and for it to be possible to ascertain results from the efforts being made.



*"The agenda needs to have **a life cycle of a few years** to enable us to **measure relevant results**"*

- NIVEL representative

Policy document content

In this section we report the content of the policy documents. For example, questions about the strategy's thematic focus or whether the content is based on a clear perspective are answered. We also describe the tangibility level in the policy document more closely. "Policy document" here means the "Patient Safety Agenda" (VMS Veiligheidsagenda) (13).

The Patient Safety Agenda consists of four focus areas

The Patient Safety Agenda is largely comprised of four thematic focus areas, and these are:

- Safe medication handling/medication treatment
- Safe use of medical equipment
- Infection prevention and antibiotic use guidelines
- Efforts for vulnerable elderly

Safe medication handling/medication treatment

This area covers medication care abnormalities caused by medication associated with the preparation, delivery, administration or monitoring of medicinal products. Deficiencies in these processes can result in different types of abnormalities.

Safe use of medical equipment

The area includes different medical equipment such as medical appliances, consumables, software, implants and surgical instruments and it is defined in more detail in the Medical Equipment Act. According to Dutch research studies from 2015/2016, lack of medical equipment contributed to nearly 4% of healthcare-related injuries/deaths. Some of these could have been prevented, which justifies an increased focus on improvements in medical equipment.

Infection prevention and antibiotic use guidelines

Infection prevention is closely linked to antibiotic use and antibiotic resistance. The Netherlands is relatively good when it comes to the prevention of infections and the adequate use of antibiotics, but reports from the National Healthcare and Youth Inspectorate (Inspectie Gezondheidszorg en Jeugd) show that there is still room for improvement.

Efforts for vulnerable elderly

Hospital care poses a risk to the elderly due to increased risk of healthcare injuries such as infections, malnutrition, confusion and fall accidents. Early and systematic identification of geriatric problems is therefore a first necessary step to prevent avoidable healthcare-related injuries in the elderly as well as to improve function after hospitalisation.

Each focus area contains some guidance on improvement work

Within each focus area, some information, advice and tools regarding improvement work are communicated – information that caregivers can use as a basis for improvement. In some cases, more concrete improvement measures are also reported.

In the focus area **safe medication handling/medication treatment**, the following shows:

- The previous patient safety program included the establishment of procedures for medication review at registration to and discharge from hospital as an improvement measure. The objective was for everyone to undergo a medication review. A special “patient safety card for medication reconciliation” was developed. The card was used when updating the list of medication. In the Patient Safety Agenda, caregivers refer to this tool as a method of increasing the safety of medication handling. During the previous programming period, it was also noted that the medication related abnormalities can be associated with injection medication. These were therefore identified as 'high-risk medicines'. To improve safety, caregivers were recommended to use clear protocols for the preparation and administration of these types of medicines. A special handbook was also developed for healthcare professionals in support of medication injections. The Patient Safety Agenda also refers to this area and encourages healthcare providers to continue to work on improving safety in the field of 'high-risk medicines'.
- The national Healthcare and Youth Inspectorate (Inspectie Gezondheidszorg en Jeugd) will continue to review and control medicinal safety via quality indicators produced in 2015. Since 2017, the inspection has been conducted with a focus on safe medication prescription.
- A program for better information exchange between patient and caregiver (Versnellingsprogramma informatie-uitwisseling patiënten en Professionals, VIPP) was developed by the Dutch Association of Hospitals (Nederlandse Vereniging van Ziekenhuizen, NVZ). The work has been done in collaboration with the Ministry of Health, Welfare and Sport. The program aims to give the patient increased access to their own medical data via digital platforms. This creates the conditions for the patient to get better information about their state of health and for the patient to become more involved in their own care. A central part of the project concerns patients' access to up-to-date information about their potential medicinal treatment. Information availability improves the conditions for more secure medication use.
- Finally, the healthcare provider associations (e.g. NVZ) have signed agreements on guidelines for the management of pharmaceutical information. These guidelines mean, among other things, that doctors must ensure that a current medical overview is available in connection with the

medicinal prescription. For example, the overview should contain patient data and relevant medical data such as active substance, dosage, strength etc. Since 2013, doctors are required by law to give the reason for the prescription on the receipt when prescribing a number of different medicines. The current value of the patient's renal function should also be shown in cases where this is relevant.

In the **safe use of medical/medical equipment**, the following is stated:

- Agreements between the various parties in the healthcare sector concerning medical equipment have been signed. The agreements claim that all medical equipment must be labelled with unique, electronic codes so that it is possible to determine which equipment has been used for which patient. This also allows the registration of implants. Behind the agreement are hospital associations and various industry representatives. This implies a wide-ranging record of medical equipment registration.
- In 2011, national hospital associations developed a special agreement for medical products (the MT Agreement). The agreement, which includes, among other things, risk inventory of products for purchase and training of staff in product use, was updated in 2016.
- In 2014, the National Association of Medical Specialists (Federatie Medisch specialist) and the National Healthcare Institute (Zorginstituut Nederland) published guidelines for the introduction of medical products in healthcare activities.
- The national Healthcare and Youth Inspectorate supervises the adherence of hospitals to the criteria of the safety agreement described above (MT agreement). Hospitals that do not meet the criteria in the agreements are asked to take immediate action. A new law on quality, complaints and disputes (Wet Kwaliteit, klachten en geschillen zorg, Wkkgz) came into force in 2016, and this clarifies the requirement for the safe use of medical equipment.

The **infection prevention and antibiotic use guidelines** state the following:

- The previous patient safety program included two areas related to infection prevention. One was post-operative wound infections and the other was sepsis. The Patient Safety Agenda refers to the use of information materials and tools developed during the previous program period. Caregivers are also encouraged to register and monitor healthcare associated infections in their hospitals.
- A national structure to counteract antimicrobial resistance has been established with the help of financial support from the Ministry of Health, Welfare and Sport. The structure consists of a monitoring system and a number of regional networks. The aim is to increase cooperation across actors, institutions and sectors in healthcare in order to better control antibiotic resistance.

- A working group on the development of directives for the use of antibiotics (Stichting Werkgroep Antibioticabeleid, SWAB) brought forward guidelines for the prescription and use of antibiotics in 2012. In the framework of the guidelines, special 'antibiotics' groups have also been established in hospitals. The task of the groups is to check adherence to the hospital's overall antibiotic policy. According to the national Healthcare and Youth Inspectorate, the guidelines developed are not binding, but caregivers are only required to maintain a certain level of quality in the field.
- The national Healthcare and Youth Inspectorate will continue to monitor how hospitals are conducting preventative work with a focus on healthcare associated infections. Since 2013 the Inspectorate has regularly visited hospitals within the framework of a project called “Monitoring of infection prevention (Toezicht op infectiepreventie, TIP)”. In 2016, the authority published a report in the area where it was established that some improvement measures are needed, for example when it comes to cleaning and disinfection procedures, control of resistant bacteria and training on how isolation rooms should be used and maintained.

In **efforts for vulnerable** elderly, the following shows:

- Efforts for the vulnerable elderly group were a thematic area of improvement in the previous Patient Safety Program. During the program, a knowledge base was presented regarding the efforts that can be made in hospitals to reduce the risks of healthcare-related injuries in elderly patients. Hospitals are encouraged through the Patient Safety Agenda to continue these efforts at and on the basis of needs.
- Various guidelines have been developed to reduce the risk of healthcare-related injuries in the elderly. For example, the association for clinical geriatrics (Nederlandse Vereniging voor Klinische Geriatrie, NVKG) has developed guidelines on fall accidents in the elderly, confusion and polypharmacy and the implementation of geriatric investigations. The Association of Specialists in Geriatric medicine (Vereniging van specialist Ouderengeneeskunde) and the Dutch Institute of Psychology (Nederlands Instituut van Psychologen) have also developed guidelines for Dementia.
- A national program for improved elderly care was carried out between 2008 and 2016. The aim was to ensure adequate care for all elderly patients. Different projects were initiated as part of the program. This resulted, among other things, in evidence-based material for caring for the elderly.

The National Patient Safety Agenda also underlines the importance of an integrated approach between hospitals and care. The future care of the elderly will require individual adaption, the provision of care and the provision of services in the right place, carried out by qualified personnel etc. In

other words, care for the elderly will need to be adapted from these new conditions in order to respond effectively to the needs of patients.

The agenda seems to be characterised by a relatively narrow approach to patient safety

The main focus of the Patient Safety Agenda seems primarily to be focused on minimising risks to different types of adverse events. This approach is close to Swedish legislation's definition of patient safety. In other words, the agenda does not explicitly claim improved quality of care in a wide sense.

The thematic starting point is largely characterised by the outcome areas

The agenda focuses in a relatively large way on what can be called traditional outcomes, such as safe medication treatment, prevention of healthcare associated infections etc. In the context of the focus area around medical equipment (see more detailed description above), what can be described as a risk area, that is, risks in the structural or organisational conditions of healthcare that may increase the risk of patient safety are highlighted. In the focus area "efforts for vulnerable elderly", success areas are emphasised to some extent, in addition to traditional outcome areas such as the risk of infections and fall accidents. Examples of areas of success that are highlighted are cohesive care and knowledge and information exchange.

The interview confirms the image that historically has been taken from a relatively narrow thematic approach where the outcome area has been the main focus. It is stated that, for strategic reasons, the work of national patient safety was initiated on the basis of narrow areas, but that a broader approach is envisaged in connection with the development of a new agenda or a new policy document.

*"We started work on the basis of **narrow outcomes**, as this is easier to get started and highlight the issues. Now we want to broaden our scope and focus more on **instrumental broad areas** such as adherence and focus on results"*

- NIVEL representative

Policy document processes

This section presents the central processes that can be linked to the strategy and the action plan. Examples of questions to be answered are whether the policy document was based on a particular process, for example through consultation or negotiation? Another important element is examining whether the policy document describes different central processes and, in such cases, what is included in them. “Policy document” here means the “Patient Safety Agenda” (VMS Veiligheidsagenda) (13).

The agenda is based on the previous patient safety program

The Patient Safety Agenda is based on the previous patient safety program, which was developed in common understanding between different professions – associations representing hospitals, university hospitals, doctors, nurses and caregivers. The program can therefore be said to be based on a relatively broad consultative process.

When the program was completed in 2012, the Association of Hospitals in the Netherlands (NVZ) and the Association of University Hospitals (NFU) continued to carry out parts of the patient safety program in the form of the current patient safety agenda. The selection of focus areas in the patient safety agenda consists of, as mentioned before, areas from the patient safety program with continued improvement potential.

*“**The patient safety agenda** was a **continuation** of the work in those areas that had not achieved **sufficiently good results** under the Patient Safety Programme”*

- NIVEL representative

The interview also includes the involvement of patients/patient representatives in the development of the national program/policy document, which is being produced. It is also described that there are plans to more clearly include patients in the practical improvement work, for example, by patient representatives collecting relevant data on safety aspects from other patients.

*“Patients have been **involved in the development** of the forthcoming plan. Perhaps we should **use patient representatives** in the actual implementation, for example, by obtaining other **patients’ perspectives**”*

- NIVEL representative

The description of the implementation is limited

Concrete descriptions of how the patient safety agenda is supposed to be implemented are missing from the investigated website. Some reports of implemented or planned activities are shown, as described in more detail in the previous section. The descriptions provide an overview and, in all cases, an indirect picture of the implementation of some improvement efforts, but cannot be regarded as comprehensive. The fact that hospitals have a relatively large degree of autonomy and are ultimately responsible for improvement at operational level can probably be of importance for the degree of tangibility in terms of the description of implementation.

Descriptions of the follow-up process are limited but in the interview, it transpires that the previous program was followed up regularly

There are no descriptions on the investigated website of how the work on the National Patient Safety Agenda is to be followed up. The interview revealed that an external research-based follow-up focusing on preventable care abnormalities was conducted during 2017. This did not show any significant outcome changes. The interview also stated that the previous patient safety program was above all followed up in the same way, i.e. through external research studies. NIVEL has continuously investigated the occurrence of hospital care abnormalities. This is to get a picture of the degree of targets achieved. The follow-ups have been based on standard methods for journal review. This is reported to have contributed to good conditions for comparing the results at different hospitals.

According to the interview respondent, local follow-up of the patient safety work carried out by the participating hospitals in practice has resulted in different measurement methods. This has also meant limited possibilities for comparison and thus also for the results to be aggregated.

*"We have used **standardised methods** in our research to follow up on the results. When the hospitals were to follow up themselves, they used a lot of **different measurement methods**, which **hampered the comparability** of the results"*

Policy document results

The results of the policy document are presented below. Examples of questions to be answered are whether good results can be linked directly to the policy document or more to the governance or organisation at large? “Policy document” here means the “Patient Safety Agenda” (VMS Veiligheidsagenda) (13).

Previous research papers focusing on the previous program indicate good outcomes

As mentioned earlier, follow-ups of the previous program to the National Patient Safety Agenda showed good outcomes. The follow-up from 2011/2012 showed that preventable care abnormalities decreased by 45 percent compared with the previous follow-up occasion (14). For example, major changes were seen in surgery – an area previously characterised by relatively large challenges in terms of care abnormalities. According to previous studies, preventable care abnormalities were common in groups with a large proportion of elderly patients (80 years old and older). The follow-up from 2011/2012 showed a marked change for this group – from 4.4 percent to 0.9 percent between 2008 and 2011/2012.

One possible explanation for this positive development is that the efforts of the vulnerable elderly group was also a special focus area in the previous program. At the same time, an increase in preventable care abnormalities – from about two percent to three percent over the same period – was seen for the group of patients between 19 to 40 years old. Below are examples of diagrams that are reported in the study and describe the development over time.

Figure 4. Preventable abnormalities in care 2004, 2008 and 2011/2012 (14).

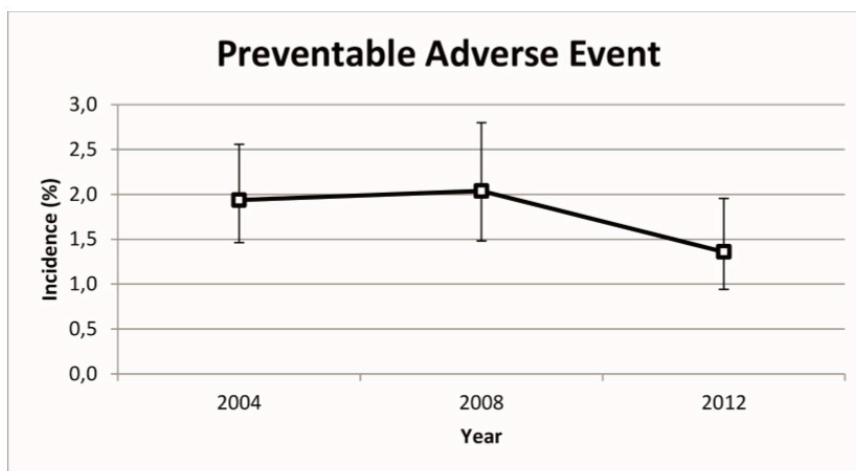


Figure 5. Preventable abnormalities in care for different care processes (14).

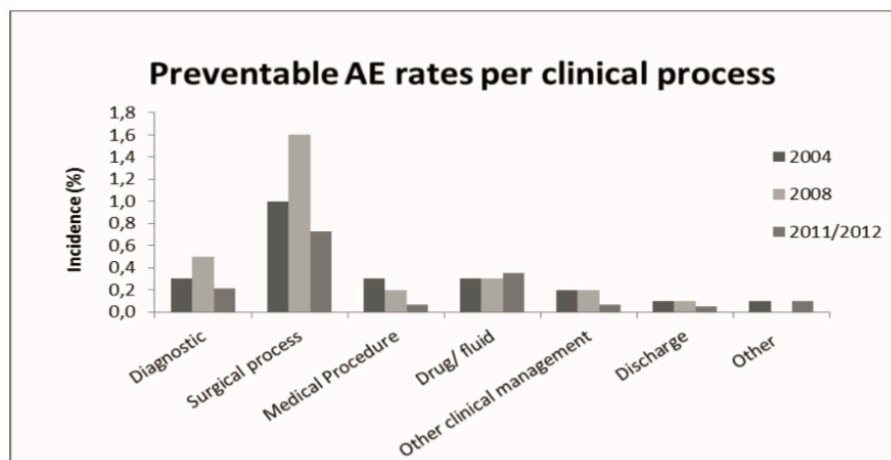
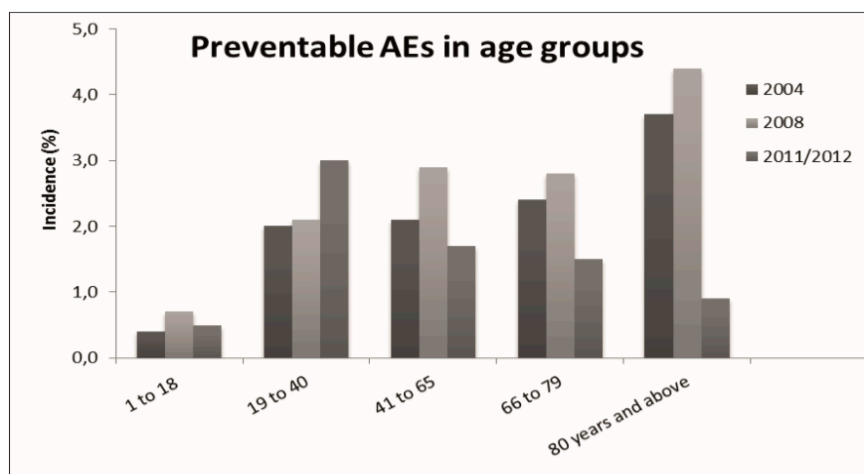


Figure 6. Preventable abnormalities in care for different age groups (14).



The corresponding follow-up report for the Patient Safety Agenda (Veiligheidsagenda) has not been located within the framework of this analysis. Therefore, it is not possible to draw any conclusions on the results of the patient safety area that the agenda has contributed to.

Key interests seem to be in favour of the agenda

In an interview with representatives from NIVEL, key interests' views on the agenda have not been analysed in a structured manner. However, it is described that since the national agenda was initially developed on the initiative of key actors, such as professional and hospital representatives, the general approach is likely to be positive. The interview respondent also reasoned that the national agenda was adjusted compared to the previous program based on the views of some key interests.

As mentioned earlier, hospitals generally experienced the previous national patient safety program as being too direct. Therefore, in the context of the

updated agenda coming into force, a more supportive and motivating approach was chosen by the initiators.

References

1. Institute for Health Metrics and Evaluation IHME: Netherlands. Retrieved 2020-01-20 from <http://www.healthdata.org/netherlands>.
2. World Health Organization. Countries: Netherlands. Retrieved 2020-01-20 from <https://www.who.int/countries/nld/en/>.
3. Vad kan Sverige lära av Nederländerna och Schweiz. Forum för Health Policy; 2017. <http://healthpolicy.se/wp-content/uploads/2017/12/Vad-kan-Sverige-lara-1.pdf>.
4. Healthcare in the Netherlands. Ministry of Health, Welfare and Sport; 2016.
5. Government of the Netherlands. Monitoring the quality of healthcare. Retrieved 2020-01-20 from <https://www.government.nl/topics/quality-of-healthcare/monitoring-the-quality-of-healthcare>.
6. Nederlandse Zorgautoriteit. Overview of the Dutch Healthcare Authority. Retrieved 2020-01-20 from <https://www.nza.nl/english>.
7. Autoriteit Consument & Markt. About ACM. Retrieved 2020-01-20 from <https://www.acm.nl/en/about-acm>.
8. Ministry of Health, Welfare and Sport. Retrieved 2020-01-20 from <https://english.igj.nl/>.
9. Baines R. Monitoring adverse events in hospitals: How safe are hospitals for patients? Amsterdam: Vrije Universiteit; 2018.
10. Sheldon T. Dutch study shows that 40% of adverse incidents in hospital are avoidable. BMJ 2007; 334 (7600): 925.
11. Nederlandse Vereniging van Ziekenhuizen. VMS Veiligheidsprogramma. Retrieved 2020-01-20 from <https://www.nvz-ziekenhuizen.nl/onderwerpen/vms-veiligheidsprogramma>.
12. Veiligheidsagenda. Tien thema's VMS. Retrieved 2020-01-20 from <https://www.vmszorg.nl/vms-veiligheidsprogramma/10-themas/>.
13. Veiligheidsagenda. Retrieved 2020-01-20 from <https://www.vmszorg.nl/>.
14. Baines R. How effective are patient safety initiatives? A retrospective patient record review study of changes to patient safety over time. BMJ Quality & Safety 2015;24(9): 561-71.

Country Report New Zealand

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Introduction

In the analysis of New Zealand, we focus mainly on a policy document from the "Health Quality and Safety Commission" (hereinafter referred to as the Commission). Among other things, the Commission works with patient safety at national level. The document analysed within the framework of this country report is called "Statement of Intent 2017-21" (see figure 1 below). Our assessment is that the document can be seen as the overall strategy for the Commission's patient safety work – an interpretation that is also reconciled with the interviewed Commission representatives.

Since the Commission is a significant public body in the studied area and that national patient safety work is mainly based on the Commission's activities, the Statement of Intent has been selected for in-depth analysis. The analysis has also been supplemented with information from the interview conducted with the Commission's representatives. Below are the results of the analyses carried out based on the used framework.

Figure 1. Statement of Intent 2017-21 for" Health Quality and Safety Commission"




Description of the current context

In this section we describe more closely the context that characterizes the policy document in different ways. For example, questions are answered about the possible needs that are the basis for the policy document and what the management of the healthcare system looks like.

Review country facts – New Zealand

Figure 2. Summary of basic country facts (1), (2)

Country facts		
Population (million)	4.6 (2016)	
Average life expectancy (males/females, years)	79.5/83.4 (2016)	
Child mortality (< 5 years old per 1000/births)	5.6 (2016)	
Health care cost (% GDP)	9.34 (2017)	

The healthcare system is publicly funded and is characterised by national governance

In New Zealand, healthcare is mostly publicly funded (3). The publicly funded healthcare system covers primary care, specialised care, preventative care efforts, certain prescription medicines, paediatric dentistry, and certain social services in the form of home care, services for the disabled and welfare.

The Government governs healthcare, through the national Ministry of Health, based on existing legislation and also allocates public funds for the activities.

Furthermore, there are "District Health Boards" (DHB). The boards are responsible both for the organisation and execution of care in their respective geographical areas. Their activities are based on the government's national requirements in this area and the Ministry of Health supervises the boards. Primary care is organised by special "Primary Health Organisations" (PHO). The Primary Health Organisations have special agreements with the DHBs, and they are responsible for supporting the country's primary care receptions.

All citizens have access to publicly funded medical care. Specialist care is free of charge while the patient has to pay a fee within primary care. The level of this is set by the individual surgery. In addition to publicly funded healthcare, there are opportunities for patients to purchase supplementary health insurance that covers, among other things, elective surgery and visits to private specialists. There is also a special body for the financing of medical expenses related to accident associated injuries or conditions – the "Accident Compensation Corporation" (ACC) (4).

National patient safety work was started in 2000 by the introduction of a national strategy

In 2000, for the first time, the Government, through the Ministry of Health, published a national strategy for healthcare and parts of welfare¹ in the country (5). The strategy – "The New Zealand Health Strategy" – included, among other things, national objectives for overall health development and for healthcare and welfare. The objectives included quality development, and patient safety was promoted as a part of this. For example, the need to reduce adverse events was emphasised.

The following Year, in 2001, New Zealand enacted a new law entitled "The Health and Disability Services (Safety) Act" (6). With the new legislation, patient and user safety work became compulsory in healthcare and welfare, which meant a significant shift for the area in many ways. The law was designed, in brief, to reward and strengthen the safety perspective in the operations. In short, this meant that caregivers were ultimately responsible for providing a safe care and welfare system and to continually work with quality development.

A national Commission on quality and safety to support relevant actors was established in 2010

In 2010, at the government's initiative, "The Health Quality and Safety Commission New Zealand" was formed (7). The aim was to improve, through the Commission, the conditions for more systematic, coherent and coordinated work at national level, focusing on quality and safety in healthcare and parts of welfare.

In the interviews conducted, the Commission is described as having a specific mandate in the field and a close collaboration with the Ministry of Health. According to interviewed representatives, the Commission's mandate consists of two main elements: 1) to establish and develop methods of measurement and quality and safety indicators for healthcare/welfare; 2) to support individual caregivers in improvement work with a focus on quality development and patient safety, for example, in relation to the identification of developing areas. Initially, the Government defined the priority areas of the Commission within the context of its activities. Over time, however, the Commission's scope has increased and today priority areas are formulated in consultation with the Government.

¹ Note: Social welfare refers to the provision of care for the elderly and disability services

The Commission has no regulatory powers, that is, it is not in a position to give binding directives for various kinds of care and welfare work. Instead, the Commission has a supportive role in relation to healthcare providers and the work is carried out through cooperation between various actors. In addition, the Commission strives in a general sense to influence decisions in the field of quality and safety at different levels. This is to contribute to key changes. The mission statement is in line with the picture given in interviews with Commission representatives.

*"We have **no regulatory mandate** but are working to **support the providers**. These are the parts that we **can influence and** make a difference and we must constantly **prove our value** upwards in the ranks "*

- New Zealand representative

Since its formation in 2010, the Commission has worked in various ways for quality development in healthcare at national level, including through a range of programs (8). One example is the Open for Better Care campaign (2013-2016) focused on reducing harm in the areas of, falls, healthcare associated infections, perioperative harm and medication safety. Another example is "The Adverse Events Learning Programme". This aims to support healthcare providers in the development of working methods for reporting, auditing, experience feedback and learning in connection with care abnormalities.

The Commission has developed a specific framework to facilitate work on quality and safety improvements. This was published in 2016 in the "From Knowledge to Action – A framework for building quality and safety capability in the New Zealand Health System" document (9). Among other things, the framework clarifies the division of roles and responsibilities in healthcare, with a focus on quality development and patient safety. Simply put, it describes what health professionals or healthcare managers can do to strengthen the quality or safety culture. The framework is described in the conducted interviews as one of several similar guidelines or decision supports that the Commission is developing in order to support healthcare providers and performers in the work to improve quality and patient safety.

*"The framework should be seen as a **source of knowledge** to **educate** actors within healthcare to **understand their roles** in quality and safety work"*

- New Zealand representative

The National Health Strategy was updated in 2016

In 2016, the government also updated the overall strategy for quality development in healthcare in the country – "The New Zealand Health Strategy" (5) and a new version was published. This strategy consists of two main parts.

The first part states the direction of healthcare in New Zealand over the next ten years ("Future direction") (10). It identifies five strategic themes that will characterise the future development of healthcare. These are: 1) people-powered; 2) closer to home; 3) value and high performance; 4) one team and 5) smart systems.

The second part of the Strategy is called "Roadmap of actions" (11). This can be described as an action plan to achieve the objectives of the five strategic themes highlighted in the first part of the document. Within the framework of the theme that highlights value and high performance, the patient safety perspective is highlighted. Three overall objectives are presented here at three different levels (micro/meso/macro) where patient safety is included.

The second part of the strategy (i.e. "Roadmap to Actions") also makes other connections to the patient safety perspective through action proposals with a focus on improved safety systems. In conclusion, patient safety is one of several parts of New Zealand's National health strategy.

As a comment to the description above, the interviewed Commission representative describes that changes in policy focus since the election in 2017 have resulted in the Roadmap not being progressed as planned.

The Commission is obliged to report on its operations to the Government

Legislation requires the Commission to produce, on a regular basis, a more long-term declaration of intent that sets the overall direction of the operations in the coming years. Against this background, in 2017 the Commission published a "Statement of Intent 2017–2021" (12). Among other things, it presents strategic priorities and objectives for the Commission's work. As the Commission's mandate largely covers the patient safety perspective, this area is given relatively large scope in the statement of intent. The Statement of Intent can be seen as the organisation's strategy for the implementation and realisation of the government's overall policy document: "The New Zealand Health Strategy". This can also be described as a national strategy for improving patient safety, which is also confirmed in interviews conducted with Commission representatives.

In addition, the legislation also requires the Commission to produce annual performance plans – "Statement of Performances Expectations (SPE)" (13). This document is linked with the Statement of Intent and the overall strategy, but describes concrete activities that the Commission will take during the year to best respond to its mission. The document also includes a financial plan for the coming year, such as data on expected revenue and expenditure. In other words, it aims to give the government a clear picture of the Commission's achievements during the course of the year, and can be likened to a type of business plan.

In conclusion, the Commission regularly presents a wide range of internal and external policy documents that define the direction of the organisation's work both in the short-and long-term.

*"We must, by law, have a **longer-term declaration of intent** that covers around three to four years. This indicates **our strategic focus** for the period. We then **establish annual performance plans (SPE)** that can be likened to action plans and based on the content of these we are then held to account"*

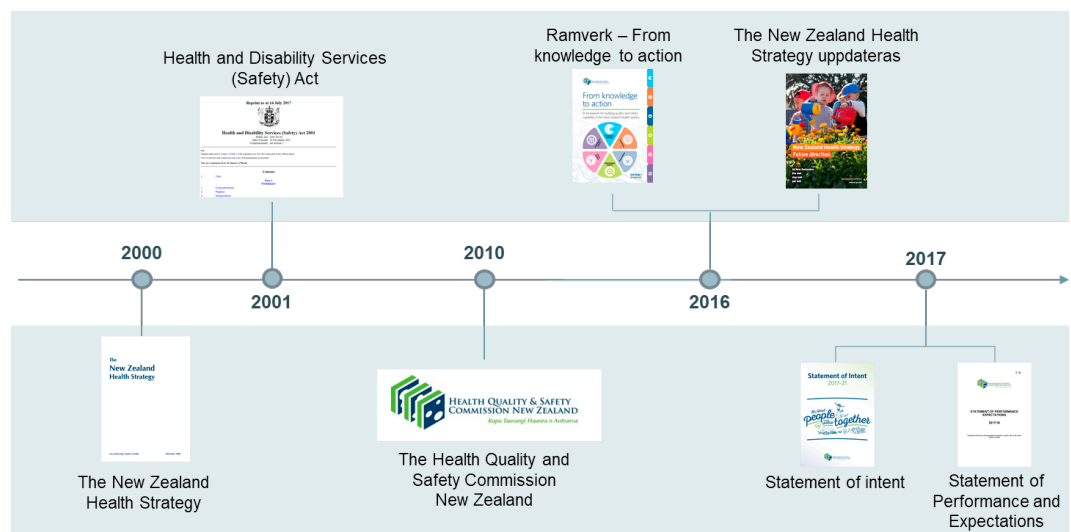
- Commission representative

Since the Commission has a particular role in terms of quality development and the work on improving patient safety at national level, we have opted specifically to focus on the Statement of Intent for 2017–2021 (12). Although the Statement of Intent is an internal policy document, as previously mentioned, it can be likened to a national strategy for patient safety at an overall level.

Interviewed Commission representatives also encouraged us to examine the Statement of performance expectations 2017/18 (13) as a short-term and more concrete complement (action plan) to the surveyed statement of intent. However, having taken note of the content of the Statement of performance expectations, it became clear that this largely describes the Commission's internal activities. Rather than specifying the direction of how improvement and change work must or should be done at lower, more operational levels. Against this background, it was considered that in-depth analysis of this document would not contribute to the relevant insights. Since the Statement of Performance expectations largely contain some key processes, we are instead highlighting parts of its contents under heading *"The annual statement of performance expectations clarifies the implementation processes"*.

In Figure 3 below, the development of patient safety in New Zealand over time is visible and summarised.

Figure 3. Timeline of national patient safety work in New Zealand



Policy document structure

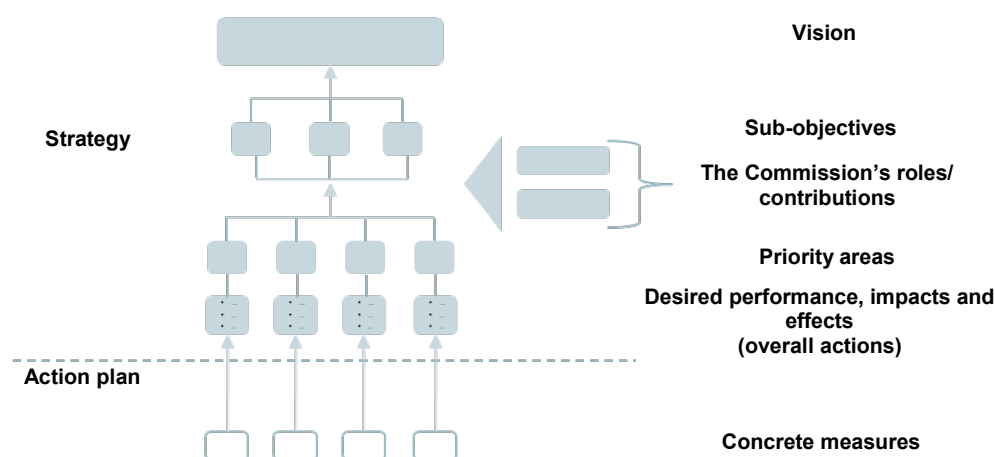
This section describes the structure of the policy documents. Questions about the parts of the policy document and the intended recipients are answered here. We also highlight the format of the documentation, i.e. whether it is comprehensive or summarised etc. "Policy documents" here refers to the analysis of the Statement of Intent 2017–21 (12).

The Statement of Intent contains the overall description of the desired performance

The examined policy document, Statement of intent, which can be described to some extent as a comprehensive approach to the work of the Commission, consists in summary of five main elements: 1) a vision; 2) three overall milestones for improved quality from three levels (micro/meso/macro level); 3) four strategic priority areas; 4) description of desired performance (which can also be seen as action proposals), impact and effects within the respective priority area and 5) a categorisation of the Commission's main roles/contributions to contribute to improved quality and patient safety in healthcare and parts of social welfare. The Commission's approach is also described at an overall level.

In other words, the Statement of Intent does not contain any concrete proposals for action aimed primarily at more operational levels for improving patient safety during the course of the year. A visualisation of the structure of the Statement of Intent can be seen in Figure 4.

Figure 4. Visualisation of the structure of the policy document



The structure of the Statement of Intent can be likened to a strategy but contains certain elements that can be related to an action plan

In summary, the Statement of Intent consists both of elements that can be related to an overall strategy and more concrete policy documents such as an action plan. For example, a vision, overarching milestones and priority areas are presented, which can be related to a comprehensive strategy document. At the same time, for example, the desired performance is stated, which also provides an overall picture of possible activities and actions, which is more associated with an action plan. At the same time, the description of desired performance etc. is relatively general and, as mentioned earlier, gives a limited picture of what kind of improvement work can and should be conducted at lower, more operational levels.

The policy document is targeted at different levels – from patients, employees to decision-makers at national level

On the one hand, the examined policy document can be seen as internal guidelines directed primarily at Commission staff. On the other hand, the Commission is a state actor, which, in the document, describes objectives and activities with a more or less direct link to the activities of healthcare actors. The objective formulations presented in the document are also scoured by three levels of actors, including the patient perspective. The Statement of Intent is also explicitly a tool for anchoring the Commission's work with the government. In other words, national political leadership is also the direct recipient of the documents' content.

Based on the above, the policy document can be said to be relatively broad to different target groups – at least indirectly. In other words, it is possible to sort the recipient levels based on a micro/meso/macro perspective, although this is not clearly expressed in the statement of intent.

The policy document can be described as extensive but at the same time relatively accessible

The Statement of Intent is written in Word format and amounts to about 30 pages. Most of the content is text, but there are also some visualising elements that make the content more accessible to the reader. For example, the document contains an appendix that presents the Commission's outcome framework. The framework shows how the Commission's strategic priorities are intended to contribute to the achievement of the Government's national objectives for healthcare. The figure gives the reader a good overview and facilitates the understanding of how the content of the Statement of Intent relates to the general national governance of healthcare and welfare.

The Commission has a well-thought out communication strategy

According to the interviewed Commission representatives, communication is a very important aspect of the Commission's work, and a precondition for the

work to have the desired impact. One part of the Commission's communication strategy is, for example, a regular digital presence. This is achieved through various digital channels such as the Commission's own website, digital newsletters and social media such as Facebook, Twitter and LinkedIn. Depending on the message to be communicated, for example on improvement programs targeted at a specific target group, the Commission can also adapt the information to the intended recipients.

The Commission also uses major campaigns to disseminate information about the focus areas of the work for improved patient safety – areas that involve a wider audience or even the public. Examples of such focus areas are hand hygiene. A "Patient Safety Week", which highlights a specific and important theme, is organised every year. In 2018, the Commission focused on the topic of "hand hygiene" and in "Patient Safety Week", the public, health professionals, caregivers and other actors, among others things, were targeted.

In other words, the Commission's communication strategy is generally well thought out, well executed and specially adapted to the intended target group.

The timeframes for the policy documents are based on the requirements of current legislation

The Statement of Intent extends from 2017–2021, i.e. over a four-year period. According to the interviewed Commission representatives, the Commission has no discretion in determining the time period for the policy document, but is entirely based on the requirements of the current legislation.

Policy document content

In this section we report the content of the policy documents. For example, questions about the strategy's thematic focus or whether the content is based on a clear perspective are answered. We also describe the tangibility level in the policy document more closely. "Policy documents" here refers to the analysis of the Statement of Intent 2017–21 (12).

The Statement of Intent generally focuses on quality of care, where patient safety is highlighted as a central part

In the statement of intent, the Commission's overall vision is formulated as: *"New Zealand will have a sustainable, world-leading and patient-centred healthcare system (disability system), which will lead to both attracting and retaining labour. This is thanks to the staff's commitment to continuous quality development and to help deliver fair/equitable and sustainable healthcare".*

As part of the pursuit of the overall vision, the Commission starts from three long-term milestones for improved quality, and these are accounted for in a special framework ("New Zealand triple aim") (the current framework is presented in Figure 5 below). The objectives and framework are originally taken from the National Health strategy described in previous sections ("The New Zealand Health Strategy") (10). In the context of the "value and high performance" theme highlighted in the overall health strategy, the framework is presented. The three objectives are:

- **At individual level:** Improved quality, safety and experience of care
- **Population level:** Improved health and fairness for all social groups
- **System level:** The greatest possible benefit for invested public resources

Figure 5. The "triple aim" framework originally taken from "New Zealand Health Strategy" (10)



A total of four strategic priority areas for the Commission's quality development work have been identified and included in the statement of intent, one of which is clearly based on patient safety. The areas are:

1. Improve the consumer experience
2. Improve the conditions for fairer and more equitable health ("health equity")
3. **Reduce injury and mortality**
4. Reduce unjustified variations in healthcare

The third area – "reduce injuries and mortality" – is the most relevant from a patient safety perspective. It is pointed out that some adverse events are possible to prevent, and therefore every opportunity to reduce injuries in healthcare should always be taken. The Commission's task is, according to the document, to lead and cooperate in the field of relevant quality developing initiatives.

The Commission also brings forward recommendations for reducing mortality among children and adolescents, foetuses and mothers, in connection with surgery and domestic violence. The recommendations are aimed at both caregivers and other societal actors or to the general public (14).

For each strategic priority area, the desired effects, successful impact and associated performance are stated
Desired effects (outcome), success (impact) and performance (output) are also reported, as mentioned before, for each strategic priority area. As regards the desired effects in the third priority area ("reduce injuries and mortality"), these are stated as:

- Reduce injuries in high-risk areas such as infection during surgery, fall accidents, clinical impairment of registered patients, safe surgery and safe medication treatment.
- Reduce the number of disability-adjusted life years (DALYs) associated with adverse events.
- Reduce avoidable injuries and avoidable mortality, by examining causes of death and issuing recommendations to reduce the risk of avoidable death.

Successful impact, linked to the above, is summarised in the document as:

- Increased use of evidence-based efforts and procedures.
- Increased clinical commitment and capacity for improvement.
- An increased partnership with patients/users, their relatives and caregivers in order to reduce injuries and waste of resources.

The outputs that are considered necessary to achieve the desired impact and long-term effects are also reported. In other words, in order to achieve target attainment, a number of activities are needed – activities that can also be seen as overall action proposals:

- To lead and coordinate different improvement programs where each program should have a specific improvement objective in order to improve collaboration with patients/users, reduce unjustified variations, focus on fair/equitable health and build leadership and capacity for improvement.
- Support committees examining different forms of mortality ("mortality review committees") to be able to issue evidence-based recommendations in order to reduce avoidable mortality and injury.
- Extend improvement programs to cover the entire healthcare system, i.e. not only hospital care (for example, care to treat mental illness, elderly care and primary healthcare).
- Work together with caregivers, healthcare professionals and consumers (patients/users) in the design and implementation of improvement programs in order to achieve measurable and long-term sustainable improvements
- Work in partnership with other organisations, such as the Accident Compensation Corporation (ACC), to jointly improve patient safety.

The document also describes The Commission's two main roles/contributions, which can be described as a core mission. These are: 1) contribute to the collection/building of information/knowledge ("Intelligence hub"/"intelligence") and 2) contribute in improvement work ("Improvementhub"/"improvement"). Since the roles/contribution can mainly be related to implementation processes, these are described in more detail under *"The implementation is described in different ways in several documents"*.

The policy documents are based on a narrow approach to patient safety but relate to improved quality of care

The vision and overall milestones presented in the Statement of Intent have a relatively broad approach. In short, the desired direction reflects an improved quality of care in a wide sense, rather than an exclusive focus on improved patient safety. At the same time, the use of the patient safety definition is mainly due to the minimisation of adverse events, which can be likened to the Swedish approach within the Patient Safety Act. At the same time, for example, achievements are described in the context of the strategic priority on patient safety, which can also be linked to quality work, such as patient involvement. The image that the Commission is based on a narrow definition

of patient safety but which is linked with quality of care in the broader sense, is also confirmed in the interview with Commission representatives. Respondents emphasise that safety is seen as part of the work to achieve increased patient safety.

*"Quality versus safety – the division is **not** always clear. Safety is a dimension of quality of care "*

- New Zealand representative

The policy documents have a main thematic focus on outcomes and areas of success

The thematic focus of the policy document is aimed, among other things, at the outcome areas – particularly in the description of objectives and desired effects/outcomes. Examples of outcomes that are highlighted include: "reduction of injuries", "healthcare associated infections", "medication use", "falls" etc. In other parts, such as the description of desired impact and performance, activities are instead described that can be more related to success areas, such as "clinical engagement", "partnership with patients", "evidence-based approaches and methods" etc. The interview describes the Commission's work and the thematic focus, among other things, on analyses and studies on what needs are being seen, i.e. where the biggest challenges are.

*"Through data analysis, we have investigated **where the shortfalls are the greatest within the different outcome areas** – the analyses are the basis for our priorities and our general governance"*

- New Zealand representative

Policy document processes

This section presents the central processes that can be linked to the strategy and the action plan. Examples of questions to be answered are whether the policy document was based on a particular process, for example through consultation or negotiation? Another important element is examining whether the policy document describes different central processes and, in such cases, what they include. "Policy documents" here refers to the analysis of the Statement of Intent 2017–21 (12).

The description of how the policy document has been produced is clear

According to the interviewed representatives of the Commission, the Statement of Intent was drawn up by the Commission after having carried out an evaluation of what other key actors in the healthcare sector, such as District Health Boards and the National Ministry of Health, had for priorities for patient safety work. Based on this and the gap analysis of the patient safety area carried out by the Commission, the strategic priorities set out in the Statement of Intent (2017 – 2021) were established.

It also shows in a clear way that the document is based, to a large extent, on the content of The New Zealand Health Strategy. For example, the three overall objectives set out above ("Triple Aim") are taken from the national strategy.

As mentioned earlier, the legislation requires, among other things, that the Commission produce a Statement of Intent approximately every three to four years. In addition, each year they must produce an annual performance plan. The documents are expressly aimed at the Government, which, by taking note of the policy documents, gets a clear picture of how the Commission is working to meet its mission and its objectives.

It is not clear from the strategy if patients are involved in the development of the strategy. On the other hand, interviews with Commission representatives emphasise the importance of including patients and patient perspectives in the work on improving patient safety at national level. The respondents describe patients as being included in the work by participating in regular surveys, which serve as improvement documents, and by establishing procedures for direct feedback to patients when certain patient safety deficiencies arise.

"Patient involvement is central when it comes to improved patient safety, both with a focus on patient reported measures but also open feedback to the patient when incidents occur"

- New Zealand representative

The implementation is described in different ways in several documents

The examined Statement of Intent describes how its content is to be implemented in different ways. Partly, a comprehensive picture of the Commission's work and efforts is given via the accounts of certain achievements and, partly, by an account of the Commission's main role and contributions in order to fulfil national targets for improved healthcare.

As mentioned above, the main roles/contributions, which can be seen as the Commission's core mission, are: 1) contribute to the collection/building of information/knowledge ("Intelligence hub"/"intelligence") and 2) contribute in improvement work ("Improvementhub"/"improvement"). The Statement of Intent describes activities that are within the scope of each role and contribution – in other words, activities which are intended to help meet the objectives at national level. In the first category, i.e. to contribute to collecting/building information/knowledge ("intelligence"), the Commission shall:

- Collect, interpret, analyse, annotate and disseminate information about quality and patient safety and develop advice and recommendations accordingly.
- Openly report on information related to quality of care.
- Analyse data for supportive purposes in order to stimulate improvement work in the whole healthcare sector.
- Continuously update existing data collection methods. Publish analyses and results in quality controlled articles in order to inform the public and to create discussions on quality and patient safety that lead to improved procedures and practices in healthcare.
- Act as a trusted organisation that caregivers, patients/users and their relatives/related parties, authorities, government, media etc. can turn to to obtain knowledge in the field.
- Prioritise and support the Commission's own work by using multiple sources of knowledge and identifying problem areas and areas of success, both nationally and locally.
- Report on quality in a transparent manner by publishing results from quality indicators in available formats, for example through a "quality dashboard" that facilitates interpretation and contributes to overview.
- Use data to identify and promote actions that work for quality work at local level. Comparisons between different methods should be available, for example through the website "Health Quality Measures New Zealand".
- Continue to investigate how the Commission can strengthen its role as a mediator of data and information that can be used for quality improvement.

In the second category, i.e. contributing to improvement work ("Improvementhub"/"improvement"), the Commission shall:

- Act as a central source of expertise, in order to help caregivers in the implementation of evidence-based changes at clinic level.

- Lead national quality improving programs that help to reduce risks and injuries.
- Lead and coordinate capacity building and establishment of networks in the field of quality and safety in healthcare.
- Lead and coordinate work that contributes to making the healthcare system more patient-centred, and where patients are involved in the design of the work – both within the Commission and in healthcare activities.
- Act as a trusted organisation that caregivers, patients/users and their relatives/related parties, authorities, government, media etc. can turn to to gain knowledge-based advice on quality and patient safety improvement in healthcare.
- Investigate whether different training programs and skills development for quality improvement can be delivered more efficiently.

The annual performance plan clarifies the implementation processes

In the annual performance plan, that is to say, "Statement of performance expectations" (13), the implementation process is further clarified. More specifically, the achievements/activities to be carried out by the Commission in the coming financial year are described in order to contribute to the achievement of objectives. The activities should be in line with the Government's expectations of the Commission's work, and also with the priority areas of the statement of intent.

The document collates and presents the planned annual performance of the Commission in two categories ("output classes"). The division is made on the basis of the Commission's two main roles/contributions, i.e. 1) contribute to the gathering/creation of information/knowledge ("intelligence") and 2) contribute to improvement work ("improvement"). The achievements/activities are then presented in various themes that are contained in the Commission's role/contribution.

A total of seven different themes are highlighted within the first category to help gather/create information/knowledge ("intelligence"). These are:

1. Measuring quality and safety in healthcare
2. Patient experiences
3. Quality variations
4. Reporting non-conformance
5. Quality and safety indicators
6. Mortality investigation/review
7. Provide public information and promote debate (in the sector and among the public)

Within each theme, the activities to be carried out in 2017/18 are specified. Examples of activities include the publication of reports on care abnormalities (theme 4), the development of quality and safety indicators, for example related to fall accidents in hospitals, hand hygiene and healthcare associated infections (theme 5).

The second category that is to say, contribute to improvement work ("improvement") also raises seven specific themes:

1. Expert advice, tools and guidance
2. Improvements in primary care
3. New improvement initiatives
4. Dissemination of good examples and innovation
5. Development of a greater commitment and cooperation with consumers and families
6. Capacity-building efforts with a focus on quality and safety work, including leadership development
7. Collaborate with other interests

Here, too, various concrete activities that can be linked to each theme are reported. Examples are the development of advice, tools and guidelines for the reduction of infections associated with surgery (theme 1); the organisation of conferences and workshops to disseminate lessons on deviations in care and creating a better understanding of how these are to be prevented (theme 4).

The various activities are summarised in tables in a way that facilitates evaluation and monitoring of the Commission's work. An example of such a table can be seen in Figure 6 below.

Figure 6. Example of a table from the performance plan

How we will assess the performance of output class 2

Deliverable	Quantity	Timeliness	Quality	Why are we doing this?
8 Expert advice, tools and guidance to support specific improvement programmes	<ul style="list-style-type: none"> Provide expert advice, tools and guidance to the sector on: improving teamwork and communication in DHB operating theatres reducing surgical site infections for people having hip, knee or cardiac surgery implementing a patient deterioration recognition and response system implementing and supporting the 2017 national adverse events policy 	30 June 2018	<ul style="list-style-type: none"> Resources and tools are based on evidence and developed in partnership with consumers, families and whānau. 	<ul style="list-style-type: none"> Leads to: reducing patient harm by improved levels of teamwork, a more inclusive culture, improved communication, improved preparation for operations and better recognition and response to patient deterioration.
9 Primary care improvement	<ul style="list-style-type: none"> Implement chosen primary care improvement programmes Identify and choose the next set of primary care improvement initiatives to implement in 2018/19 	30 June 2018	<ul style="list-style-type: none"> An evaluation of programme implementation will provide us with lessons to apply to the next set of initiatives. We will choose initiatives prioritising consumer engagement, equity and integration, and alignment with service-level measures (SLM), in partnership with the expert advisory group. 	<ul style="list-style-type: none"> Leads to: reducing patient harm by health professionals taking up new methods and improving their practice, and passing on their improvement skills and expertise to others.

In addition to the above, the "Statement of Performance Expectations" also describes a number of other activities that the Commission is planning to implement during the year, which can also be clearly linked to the patient safety area.

The Commission will produce guidance documents to support carers and other more operational actors

Another example of how the Commission carries out its mission is to produce various supporting and guiding documents aimed at operational activities such as caregivers. According to interviewed Commission representatives, the "From knowledge to action – A framework for building quality and safety capability" (9) framework is an example of this type of guiding documentation. Among other things, the framework clarifies the division of roles

and responsibilities in healthcare, with a focus on quality development and patient safety. It is aimed primarily at six different recipients (levels):

1. Patients/users and their dependents/relatives
2. Healthcare and welfare professionals
3. Operative or clinical management or team leaders
4. Experts in quality and safety
5. Organisational management
6. Governing entities or boards of directors

The Commission works on follow-ups in various ways

The starting point for following up the Commission's own work is the delivery objectives defined and reported in the annual performance plan ("Statement of performance expectations") (13). The objectives are linked to specific time intervals which create the conditions for continuous follow-ups of any progress. The scheme also facilitates reporting to the Government, i.e. it makes it visible whether the Commission is responding to its mission and the Government's expectations.

The examined Statement of Intent emphasises the importance of the Commission reporting of the results achieved and its work on the basis of the overall New Zealand Health Strategy. In this context, the Commission continuously follows up the development in four areas:

1. Avoidable costs caused by adverse events
2. Opportunity costs
3. Number of life years gained
4. Avoidable deaths

Follow-up is carried out through routine, "near automated", follow up of a set of indicators called *The quality and safety markers* (see below) on a quarterly or annual basis. A report describes how the results are disseminated. Examples of strategies and methods to disseminate the results are regular publication of specific performance reports, such as "Open4Results" published on a semi-annual basis, publication of articles in scientific and medical journals, on websites and through social media.

An interview with Commission representatives shows that the Commission's activities are largely focused on measuring and analysing available quality and safety data. For example, the representatives point to the conduct of surveys in both primary and specialised care to obtain patients' perspective and experience of care. It is stated that the data can be usefully used to identify different priority areas.

The Commission has also developed quality and safety indicators (15) that caregivers can use when monitoring the areas of healthcare-related infections, safe surgery and safe medication treatment, for example.

Policy document results

The results of the policy document are presented below. Examples of questions to be answered are whether good results can be linked directly to the policy document or more to the governance or organisation at large? "Policy documents" here refers to the analysis of the Statement of Intent 2017–21 (12).

No evaluation of the policy document has been identified but there is data on results obtained

The impact of the strategy does not seem to have been evaluated and access to the follow-up report focusing on fulfilled delivery objectives based on the 2017/18 performance plan is not yet available. The latest report evaluating delivery objectives is from 2016 and shows that the Commission achieved all its objectives for the year, for example by having published four reports on patient experiences in hospitals and organising a conference regarding mortality in surgery (16).

As mentioned earlier, the Statement of Intent emphasises the importance of continuous follow-up in four areas: 1) avoidable costs caused by adverse events; 2) alternative costs; 3) number of life years gained and 4) avoidable deaths). In June 2018, the Commission published an "Open4Results" report focusing on these four areas (17). The report shows the following results:

- 147 fewer cases resulting in hip fracture have occurred since 2013, which has meant savings for the healthcare system of close to 7 million dollars. This equates to 1.6 gained healthy life years per person where hip fracture has been avoided, which is valued at 42.6 million New Zealand dollars in total.
- 351 fewer cases of deep vein thromboses and clots in pulmonary vessels have occurred since 2013. This has meant savings for healthcare of 7.3 million New Zealand dollars. The reduction corresponds to 0.6 gained healthy life years per person where a blood clot has been avoided, which is valued at 38 million New Zealand dollars in total.
- The rate of surgical operations with infection as a complication has decreased from 1.2 percent in August 2015 to 0.9% in June 2018, which has meant savings for healthcare of nearly 3 million New Zealand dollars. This equates to 0.5 gained healthy life years per person where infection has been avoided, valued at 6.5 million New Zealand dollars in total.
- 138,000 fewer re-admissions of elderly since 2013, which has meant savings for healthcare of 106 million New Zealand dollars.
- 896 fewer deaths within the Child group (from 24 months to 24 years) have been recorded since 2010.

Responses from survey studies aimed at patients in inpatient care have also been compiled. In the latest report from August 2018 (18), the result is re-

ported in four different categories: 1) communication; 2) partnership; 3) co-ordination and 4) the response to physical and emotional needs. The national average rating of the different categories is presented in the report and these amounted to:

- Communication: 8.4/10
- Partnership: 8.5/10
- Coordination: 8.4/10
- The response to physical and emotional needs: 8.6/10

Finally, there are also national results from the quality and safety indicators developed by the Commission. The latest report from 2018 (19) states, among other things, that:

- 91 percent of all elderly patients had to undergo a fall risk assessment during the period April-June 2018.
- The practical guidelines for good hand hygiene were followed in 85% of cases in the period April-June 2018.
- 99% of all patients undergoing hip or knee replacement surgery received prophylactic antibiotic treatment 0 – 60 minutes before the operation commenced during the period January-April 2018.

Key interests' views on the policy document

It has not, in the context of our analysis or in the course of an interview with the Commission representatives, revealed how key interests have been in favour of the policy document "Statement of Intent 2017–2021". However, the interviewed representatives state that the Commission has involved key interests in the design of the content of this document, so it is reasonable to consider that their view of the document is positive.

References

1. Institution for Health Metrics and Evaluation. Retrived 2020-01-16 from <http://www.healthdata.org/new-zealand>.
2. The World Bank. Retrived 2020-01-16 from <https://data.worldbank.org/indicator/SH.XPD.CHEX.GD.ZS>.
3. The Commonwealth Fund. Retrived 2020-01-16 from https://international.commonwealthfund.org/countries/new_zealand/.
4. Accident Compensation Corporation. Retrived 2020-01-16 from <https://www.acc.co.nz/>.
5. The New Zealand Health Strategy. Wellington: Ministry of Health, New Zealand; 2000.
6. Health and Disability Services (Safety) Act 2001 (2001 No.93). Retrived 2020-01-16 from <http://www.legislation.govt.nz/act/public/2001/0093/latest/DLM119975.html>.
7. Introducing the Health Quality & Safety Commission. Best Practice Journal; 2011.
8. Health Quality & Safety Commission New Zealand. Retrived 2020-01-16 from <https://www.hqsc.govt.nz/our-programmes/>.
9. From knowledge to action – A framework for building quality and safety capability in the New Zealand health system. Wellington: Health Quality & Safety Commission; 2016.
10. New Zealand Health Strategy: Future direction. Wellington: Ministry of Healht; 2016.
11. New Zealand Health Strategy: Roadmap of actions 2016. Wellington: Ministry of Health; 2016.
12. Statement of Intent 2017-21. Wellington: Health Quality & Safety Commission; 2017.
13. Statement of performance expectations 2017/18. Wellington: Health Quality & Safety Commission; 2017.
14. Health Quality & Safety Commission. Retrived 2020-01-16 from <https://www.hqsc.govt.nz/our-programmes/mrc/>.

15. Health Quality & Safety Commission. Retrived 2020-01-16 from <https://www.hqsc.govt.nz/our-programmes/health-quality-evaluation/projects/quality-and-safety-markers/>.
16. Health Quality & Safety Commission. Summary of Quarter 4 report against the 2015/16 Statement of Performance Expectations. Retrived 2020-01-16 from https://www.hqsc.govt.nz/assets/General-PR-files-images/Accountability_documents/quarterly-report-summary-Q4-Jun-2016.pdf.
17. Health Quality & Safety Commission. Open4Results. Retrived 2020-01-16 from https://www.hqsc.govt.nz/assets/Health-Quality-Evaluation/PR/Open4ResultsJune2018_final.pdf.
18. Health Quality & Safety Commission. Retrived 2020-02-16 from <https://www.hqsc.govt.nz/our-programmes/health-quality-evaluation/projects/patient-experience/adult-inpatient-experience/>.
19. Health Quality & Safety Commission. Retrived 2020-01-16 from <https://www.hqsc.govt.nz/our-programmes/health-quality-evaluation/projects/patient-experience/adult-inpatient-experience/>.

Country Report Norway

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Introduction

In the analysis of Norway, we focus on the strategy document “Strategi 2014–2018 for Patientsikkerhetsprogrammet I trygge hender 24–7” and the associated website (www.pasientsikkerhetsprogrammet.no) (see Figure 1 below). The patient safety program is a national initiative initiated by the Health and Welfare department. In short, it aims to stimulate organised and similar patient safety work that extends across the country. The responsible steering group for the work has developed a strategy for the period 2014 to 2018, and this, together with the program's website, is the focus of the made analyses.

The choice to analyse both the strategy and the website is based on a comprehensive assessment of the content of the strategy and website. Focusing exclusively on the strategy does not give a complete picture of the program orientation and implementation. In other words, we interpret it as meaning that the website, which among other things describes priority areas, complements the program's strategy and has therefore been examined in parallel. The analysis has also been supplemented with information from the interview conducted with representatives from the Patient safety program. Below are our conclusions from the analyses carried out based on the applied analytical framework.

Figure 1. Strategi 2014–2018 for Patientsikkerhetsprogrammet I trygge hender 24–7 and the associated website




Description of the current context

In this section we describe more closely the context that characterizes the policy document in different ways. For example, questions are answered about the possible needs that are the basis for the policy document and what the management of the healthcare system looks like.

Review country facts – Norway

Figure 2. Summary of basic country facts (1), (2)

Country facts		
Population (million)	5.3 (2016)	
Average life expectancy (males/females, years)	81/84 (2016)	
Child mortality (< 5 years old per 1000/births)	2.7 (2016)	
Health care cost (% GDP)	8.9 (2013)	

The Norwegian healthcare system is characterised by both government and municipal management. Like Sweden, most of healthcare in Norway is financed by taxation (3). Healthcare is divided into primary healthcare (kommunale helsetjenster) and specialist care (spesialisttjenster). The municipalities, a total of 430, are responsible for the financing and operation of Norwegian primary care and also welfare services. Most patients are registered with their own primary care doctor. The doctor is in turn either self-employed or employed in a clinic. The municipality is also responsible for providing social welfare, and this includes, for example, personal assistance or elderly care in the form of home care or elderly accommodation.

Unlike Sweden, specialised hospital care is state run and is controlled within four geographical regions that each form a "Regional Helseforetag" (RHF). Each RHF conducts hospital activities, psychiatry, ambulance operations, hospital pharmacies and laboratories. All RHF's are ultimately governed by the Health welfare department through annual assignment documents (4). The documents collate the requirements and objectives that each RHF must meet in order to be allocated its budget.

National patient safety work over time – accumulated work since 2011

Surveyed patient safety indicators show that Norway has a variable performance over time

Analysis of OECD data (see Figure 3 below) shows that Norway has both worsened and improved outcomes over time within different areas. For example, it is noted that the number of cases for two indicators in the surgical field has increased in recent years. For the left behind foreign body during surgery indicator, a clear increase in number of cases is seen after 2013, but at the same time the diagram shows that the increase has levelled out slightly in recent years.

For three indicators, a clear improvement is seen, i.e. the number of cases have decreased, since 2012. For example, for the indicator for post-operative pulmonary embolism after prosthetic surgery of hip or knee, there seems to be a positive trend where the number of occurrences decreases for each year.

In summary, an improvement is seen in several areas between 2012 to 2015, but based on this data alone, it is difficult to express an opinion on any overall trend in developments within the patient safety area in Norway.

Figure 3. Comparison of patient safety indicators (OECD data) over time in Norway (5)



Efforts began with a national campaign

In 2009, the Norwegian health and welfare department commissioned the then "Nasjonalt Kunskapscentrum för helsetjenesten"¹ (National Knowledge Centre for Healthcare) – a unit within the department, with the task of strengthening the knowledge base with a focus on healthcare within the administration – with designing a national campaign for patient safety (6). The campaign was then run by a specially appointed secretariat, which was placed in the National Knowledge Centre. The objective of the campaign work was defined by the department, and this was formulated as: *"To reduce unwanted events on selected focus areas during the campaign period. Measures implemented should be knowledge-based and the results of the campaign effort must be measurable. The objective is also for the campaign to be the basis for lasting results, both in the focus areas and in terms of quality and patient safety in general"*.

The "Patient safety campaign – "I trygg hender" was launched and then started in 2011 and lasted until 2013. In short, the campaign involved more organised patient safety work at national level. However, the steering group considered that the timeframe for the work was too limited for it to have sufficient dissemination and impact. Against this background, it was decided that all activities from the campaign would instead continue within the framework of the "Patient safety program – I trygge hender 24/7" 2014 – 2018. A related strategy was also developed in connection with the launch of this program (7). Since 2014, the strategy has been revised on several occasions (8). In 2016, for example, different sub-strategies were excluded and a stronger focus on municipal care (healthcare and welfare) with an emphasis on "user participation" was incorporated.

The investment in patient safety takes place in parallel with other quality work within healthcare

In parallel with the "Patient safety program", the Norwegian government has also developed a number of different strategies and action plans with a focus on quality improvement areas within healthcare. In 2016, for example, the government published the policy document: "Nasjonal helse og sykehusplan" (9). The plan aims to describe the overall direction of specialised hospital care in the country and how to improve the quality of care between 2016 – 2019. In this plan, patient safety is promoted as a perspective within one of four objective formulations. This is expressed as: *"The government wants to continue its efforts to develop good and relevant objectives for quality and patient safety in specialised hospital care"*. In other words, the perspective of patient safety is a relatively limited part of this policy document, which is also directed only to specialised hospital care.

Examples of other policy documents describing the government's strategies and action plans for quality improvement in specific areas that can be related to the healthcare work in different ways are (10):

- Demensplan 2020

¹ The Centre is currently called "Kunnskapssenteret for Helsetjenesten" and is part of the Norwegian authority Folkehelseinstituttet operations.

- Handlingsplan mot antibiotikaresistens i helsetjenesten
- Handlingsplan for forebygging av selvmord og selvskading 2014–2017
- Nasjonal beredskapsplan pandemisk influensa
- Nasjonal handlingsplan for bedre kosthold
- Nasjonal overdosestrategi
- Nasjonal strategi mot Antibiotikaresistens 2015–2020
- Regjeringens plan for omsorgsfeltet 2015–2020
- Regjeringens strategi for god psykisk helse
- Regjeringens strategi for ungdomshelse

Patient safety work is reported annually to the Storting

Since 2014, the government publishes reports annually to parliament ("Melding til Storting"). These summarise the national work in the area of "quality and patient safety in healthcare". In the latest report from 2017 (10), incorrect use of medication and Healthcare associated infections (HAI) were raised as urgent challenges.

The value of establishing an organisation around national improvement efforts with a focus on patient safety is emphasised

The interview conducted with representatives from the patient safety program emphasised the value of building and establishing a collective organisation that works together. Especially in a system that is characterised by many actors and different levels. It is emphasised in the interview that the policy document itself is only part of a whole, and cannot alone contribute to sustainable change. Furthermore, the value is raised by direct and indirect control. The program and policy documents are both supportive and regulatory. This given that it is compulsory for parts of the care to take the program's presented actions. Municipal actors can choose to participate in the program on a voluntary basis and according to the interview representative, it has been generally challenging to achieve the desired impact at local level.

Work is underway to develop an updated policy document for patient safety

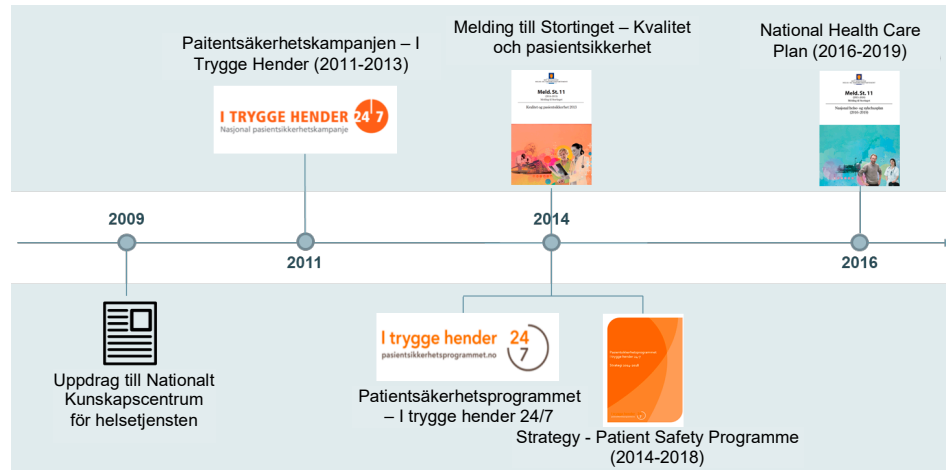
Because the current strategy expires in 2018, according to representatives from the patient safety program, work is underway to develop a new policy document. The focus of the new strategy/action plan, running from 2019 to 2023, is to transfer the work and knowledge established during the previous strategy period and, secondly, to extend the hospital's responsibility for patient safety work. In addition, actors aim to shine a light on new ventures and initiatives within the framework of the updated policy document. Representatives from the patient safety program describe identifying new focus areas in order to create commitment and arouse interest in patient safety issues as being key.

*"The next step is about **transferring all the knowledge** that has been built up within the programme, and to **increase the responsibility of the hospitals**"*

- Patient Safety Programme representative

In Figure 4 below, the development of patient safety in Norway over time is visible and summarised.

Figure 4. Timeline of patient safety work in Norway



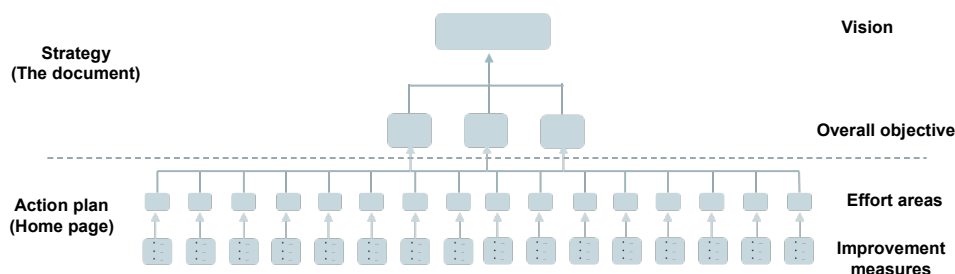
Policy document structure

This section describes the structure of the policy documents. Questions about the parts of the policy document and the intended recipients are answered here. We also highlight the format of the documentation, i.e. whether they are comprehensive or summarised etc. "Policy documents" here refers to the analysed document "Strategi 2014–2018 för Patientsäkerhetsprogrammet I trygge hender 24–7" (8) and the associated website (www.pasientsikkerhetsprogrammet.no).

The policy document consists of different parts based on an overall vision

In summary, the strategy document consists of two different parts: 1) a vision (Visjon) that guides the entire program's work and 2) three overarching objectives (Overordnede mål). The program's website, i.e. the equivalent of the action plan, also shows that a total of 16 focus areas (Innsatsområder) and a number of improvement measures (Tiltak) have been identified (see visualisation of the structure of the strategy in Figure 5 below).

Figure 5. Visualisation of the structure of the policy document



The strategy document provides a broader and more long-term guidance in the form of vision and overarching objectives. The information on the website, which can be seen as an action plan, instead provides more direct guidance by describing areas of intervention and proposing concrete measures. The document and the website are complementary and together provide an overall picture of the national strategy and the action plan for patient safety work.

The structure is partly clear but interpretation is needed to create an overall picture

In summary, the structure presented in the strategy document is relatively clear. In other words, it is possible to get an idea of how the vision relates to overall goals. At the same time, as mentioned earlier, the picture is complemented by information from the website which describes the priority areas

for action and the improvement measures that should be implemented. The structure therefore requires some interpretation to determine how all the elements are interrelated and affect each other.

The policy documents are aimed directly to healthcare providers

The strategy is not cut from outside or directed to different levels (micro, meso, macro) but is aimed exclusively to healthcare providers at state and municipal level. In the state healthcare system, i.e. specialist care, participation in the change measures is obligatory. For municipalities, participation is voluntary, but they are strongly recommended to try to implement the program's package of measures. This is because the measures can be considered as part of the municipality's regulated remit. For example, paragraph 4.2 of the Municipal Healthcare Services Act shows that municipalities should *"work systematically for quality improvement and patient and user safety"*.

The strategy is relatively concise but text heavy, the website is user-friendly

The strategy consists of a Word document of about 20 pages in total. It consists mostly of text, i.e. it lacks visual images of the different parts of the strategy, etc. However, the document can be described as relatively accessible because it is clearly divided into structured headings and sub-headings and is comparatively concise. The website, which includes areas of intervention, can most closely be described as user-friendly because it is easy to navigate among the different headings to find the right information. The website contains both text and images to make the work of the patient safety program visible. In addition, there is one in Norwegian called "extranet" where authorised persons can access diagrams to follow the results of quality indicators. The page also provides information about current events and a news feed that makes it easier for the user to keep up to date on the ongoing patient safety work.

Active communication work is seen as an important tool for the desired impact, but it must be combined with implementation support

In an interview with representatives from the Patient safety program, strategic communicative work is seen as an important means of bringing about sustainable change. The interviewed respondent stresses that during the course of the work, a lot of time has been invested in updating and creating attention to patient safety issues. For example, communication work is conducted through social media and digital channels such as Facebook, Twitter and the program's website. It is stated that the brand needs to be constructed to create a recognition factor. According to the interview respondent, it is not enough simply to produce a policy to achieve the desired impact.

While emphasising the importance of active communication, the interviewed representative of the patient safety program stresses that communica-

tion alone cannot replace establishment of good conditions for implementation. For example, supportive measures are needed in parallel as a basis or tool for improvement work.

*"It is very important to engage **in active communication**. However, it is equally important **to promote a good implementation environment**. We need to reach out and support the affected **actors**"*

- Patient Safety Programme representative

The strategy spans four years

The strategy was developed in 2014 and extends until 2018. Neither the examined documentation nor the interview conducted indicate why this strategy period was originally chosen. As the strategy expires in 2018, as mentioned earlier, work is currently underway to develop a new national strategy/action plan for improving patient safety.

Policy document content

In this section we report the content of the policy documents. For example, questions about the strategy's thematic focus or whether the content is based on a clear perspective are answered. We also describe the tangibility level in the policy document more closely. "Policy documents" here refers to the analysed document "Strategi 2014–2018 för Patientsäkerhetsprogrammet I trygge hender 24–7" (8) and the associated website (www.pasientsikkerhetsprogrammet.no).

The overall vision lays the foundations for concrete action

The vision presented in the strategy is formulated as: *"Patients, users and relatives should experience that Norway has the world's safest healthcare."*

In order to work more concretely towards the vision, it has been broken down into three overarching objectives. These objectives are:

1. Reducing patient injury
2. Building lasting structures for patient safety
3. Improving patient safety culture

In addition, it is listed on the website that is to say in the action plan, more concrete areas for action are to be pursued within. The areas are described as keen to bring about an improvement at a clinical level. The areas are:

- Safe surgery, with a special focus on post-operative wound infections
- Reconciliation of medication lists
- Proper medication use in nursing homes (accommodation)
- Reconciliation of medication lists and proper medication use in home care
- Treatment of strokes
- Prevention of suicide in psychiatric day wards
- Prevention of overdose deaths after discharge from an institution
- Prevention of infection in central venous catheters
- Prevention of pressure sores
- Prevention of falls in care facilities
- Prevention of urinary tract infections associated with catheter use
- Patient safety management
- Early detection of impaired conditions
- Early detection and treatment of sepsis
- Prevention and treatment of malnutrition
- Safe discharge with the patient as an equivalent party

These areas of intervention were identified by the policy group, working groups and expert groups through a formalised consensus process (the processes of strategy and action plan development are described in more detail under the heading *"The processes of the strategy"*) assessing the areas to be included in the campaign based on the following criteria:

1. Areas with great potential for clinical improvement in Norway
2. Measures that have documented effectiveness
3. There are good methods and data for evaluating the effects of the measures
4. There is support in Norwegian academic environments

As mentioned above, in the context of each area there are also a number of concrete measures that healthcare providers can or should take to bring about change. The measures are also presented on the program's website (the equivalent of the action plan) (11).

The importance of defining clear objectives is emphasised

In an interview with representatives from the patient safety program, the value of formulating clear and follow-up objectives is emphasised at an early stage. Common objectives with a focus on urgent content both create the conditions for strategic governance where all the actors involved work in a comprehensive direction and enable the desired impact.

The content indicates a relatively narrow focus on patient safety

The policy documents apply, based on an assessment of the main content, a relatively narrow approach to patient safety. The documents focus mainly on protection and minimisation of adverse events rather than on overall improving the quality of care. In other words, the approach is similar to the definitions and objectives of the Swedish Patient Safety Act.

The policy documents focus thematically on both the outcome and the success areas

On the basis of the above, it is clear that the strategy and the action plan within the framework have not exclusively chosen to focus the work on a specific thematic approach. Instead, in some instances, outcome areas (such as "pressure sores" or "infections") are combined with foundational areas ("patient safety culture" or "patient participation"). In an interview with representatives from the patient safety program, gap analysis is the basis for the thematic focus of the policy document. Furthermore, the interview respondent emphasises that there are ideas to build on a broader thematic approach in the updated strategy that replaces the current one.

"We selected thematic areas based on **surveys and analysis of risk areas**"

- Patient Safety Programme representative

Policy document processes

This section presents the central processes that can be linked to the strategy and the action plan. Examples of questions to be answered are whether the policy document was based on a particular process, for example through consultation or negotiation? Another important element is examining whether the policy document describes different central processes and, in such cases, what they include. "Policy documents" here refers to the analysed document "Strategi 2014–2018 för Patientsäkerhetsprogrammet I trygga hender 24–7" (8) and the associated website (www.pasientsikkerhetsprogrammet.no).

The strategy is based on the former "Pasientsikkerhetskampanjen" and has been broadly anchored

The overall vision, main objectives and priority areas of the strategy are based on the former "pasientsikkerhetskampanjen", which was conducted from 2011 to 2013. The program's steering group is relatively broad and consists of representatives from both the professions, trade unions, user associations and the Public Health Institute. The steering group, with expert advice, has worked out the overall objectives of the strategy. In addition, all healthcare providers in Norway have been included in the identification of focus areas at national level.

One of the main principles of the program is that it is for patients and users, so the involvement of patient and user organisations has been key to the development of all proposals for action. Therefore, for example, patient and user representatives in the organisation's various bodies, from steering group to advisory bodies and expert groups, have been involved. The development of the strategy can thus be said to have been based on a relatively broad consultative process. As part of the work, information from other national patient safety campaigns was also compiled, for example from Canada, Denmark, England, Scotland and the USA according to interviewed representatives.

The policy documents describe the processes of the implementation relatively well

When it comes to the implementation itself, that is, the realisation of vision, overarching objectives and so on, it is clear that, among other things, each individual healthcare provider within specialised care should appoint a person with responsibility for patient safety work. The person appointed is responsible for ensuring that the program is disseminated to all relevant departments. The responsible person shall also ensure that the measures of the program are tested, implemented and disseminated within the operation. Healthcare providers should document the implementation work and report their results to national registries according to given criteria.

Healthcare providers in the municipalities can choose whether they want to be included in the program on a voluntary basis, but a previously mentioned

it is strongly recommended that they start implementing the measures. This is because the proposed measures are in line with what is apparent from the current legislation in the field under section 4.2 of the Act on Municipal Healthcare services which describes that the municipality should "work systematically for quality improvement and patient and user safety".

The strategy also shows that a concrete action plan for the implementation of the work should be drawn up. However, such a document has not been located within the framework of the analysis carried out.

The responsible secretariat will also facilitate the patient safety work of all healthcare and welfare providers. This is done through a special training program. Learning networks have also been established with the aim of educating health professionals to perform structured patient safety work themselves.

Implementation objectives have been formulated, and these are:

- **Within specialist healthcare (mandatory):** All relevant measures packages should be tested, implemented and disseminated to all relevant units/departments before 2016.
- **Within municipal healthcare services (optional):** Efforts should be initiated in at least one field of intervention in 75 per cent of the municipalities until the end of 2018. "Correct use of medication" is the highest priority area at municipal level.

The follow-up of the work is described and it is reported to have several objectives

The follow-up of the work has two objectives. It aims partly to evaluate the actual "Patient Safety program" and its activities, and partly to follow-up the results of certain indicators of patient safety at national level. When it comes to evaluating the program itself, it is clear from the strategy document that an external actor, funded by the Helsedirektoratet (an authority under the Healthcare and Welfare department), will carry out the evaluation. A sub-report carried out by an external actor can be found on the program's website (12). A final report of the overall work is expected to be published in 2019.

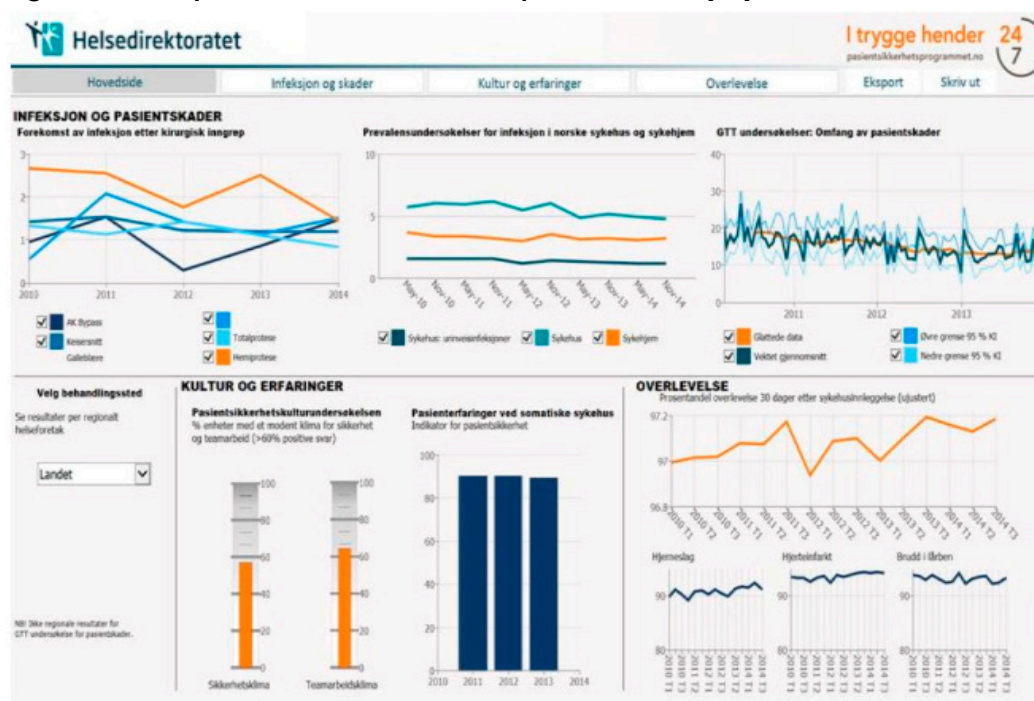
The results are analysed and reported through a "Dashboard"

Regarding the follow-up of results in the field of patient safety, there is not a single indicator that reflects the outcome of the overall patient safety work. Against this background, which is also shown as an ambition in the strategy document, a "Dashboard" has been created for the accounting and analysis of the results (one for specialist care and one for municipal care and welfare). The "Dashboard" can most accurately be described as a tool for visualising selected national quality indicators (see Figure 6 below) related to patient safety. A national objective is set for each individual indicator — a value that applies to an entire programming period. The results that are analysed to assess outcomes are usually retrieved through journal briefings.

The national quality indicators, including the set objective value for each indicator, are:

- **Patient Injuries:** To reduce injuries by 25 percent by 2018.
- **Infections:** To reduce post-op infections after hip replacement, caesarean section and cholecystectomy by 25 percent and reduce UTI in hospitals by 25 percent to 2018.
- **30-day survival:** Must increase by two percent after hip fractures and by 3% after strokes and general hospitalisation to 2018.
- **Patient safety culture:** At least 70 percent response to the "Pasientsikkerhetskultursundersøkelsen" sent out to hospital employees for 2018. At least 70 percent of employees should experience a good team-work climate and 60 percent of employees should experience a good security climate in the departments by 2018.
- **Patient Experience:** 90.4 percent of patients should experience that it is safe for patients according to the annual national report for patient experiences in Norwegian hospitals (PasOPP report).

Figure 6. Example of a "Dashboard" for specialist care (13)



Policy document results

The results of the strategy are presented below. Examples of questions to be answered are whether good results can be linked directly to the policy document or more to the governance or organisation at large?

No evaluation of the strategy paper or action plan has been identified

There seems to have been no evaluation focusing on the strategy itself or the action plan, that is to say an evaluation of whether these documents have affected the work or the outcome of the program in different ways. However, the program has been evaluated in its entirety through both interviews and survey studies. The respondents in the evaluation are employees who work in healthcare and welfare operations. An evaluation sub-report from 2017 (12) shows that:

- 52 percent of the respondents within primary care (who participated in the survey) and 54 percent of the respondents within specialist care (who participated in the survey) reported that the patient safety program has resulted in changed behaviour by management.
- About 60 percent of respondents believe that the program has contributed to patient safety being higher on the agenda of their units.
- The majority of respondents believe that the patient safety program has contributed to increased patient safety.

The sub-report also presents a number of proposals on how the program can make an even greater impact. It highlights, for example, that the program should focus more on local leadership and that further efforts are needed to involve doctors more in patient safety.

No clear results in terms of developments in the field of patient safety have been noted

It seems that there have not been any broad national evaluations in the field of patient safety as a whole, for example linked to the work of the program. In the latest edition of the government's report to Parliament on quality and patient safety ("Melding till Stortinget"), overall developments are described as having gone in the right direction (10). However, this does not explain what the development consists of, that is to say, which indicators have been analysed or for how long. The only outcome that can be clearly linked to the area of patient safety is the result regarding Healthcare associated infections (HAI) in inpatient wards. Here, a marginal increase can be seen – from 3.5 to 3.7 per cent between 2015 and 2016.

It is difficult to draw any clear overall conclusions about developments in the field of patient safety at national level based solely on the content of the report.

The national program seems to have contributed to putting patient safety on the agenda

According to interviewed representatives, national patient safety work has helped to make patient safety better prioritised and receive more attention in general. The interview respondent emphasises that the national collective work has brought about a change in the perception of patient safety across different levels of the healthcare system. On this basis, there is a view that the national work has contributed to a positive change with regard to the culture of patient safety in care related activities.

Key interests' views on the policy documents

In the analysis carried out, the key interests concerned are generally positive about the policy documents, and no direct resistance has been expressed. According to interview respondent, this is mainly because there is a general willingness among healthcare providers to work with patient safety, not least as part of improving healthcare. In other words, there is a clear ownership at different levels.

"Key interests have generally been positive and I believe this is due to the desire to work for improved patient safety. There is ownership of the issue"

- Patient Safety Programme representative

References

1. Country Note: How does health spending in Norway compete? OECD; 2015.
2. Institute for Health Metrics and Evaluation. Retrieved 2020-01-16 from <http://www.healthdata.org/norway>.
3. The Commonwealth Fund. Retrieved 2020-01-16 from <https://international.commonwealthfund.org/countries/norway/>.
4. Regeringen.no. Retrieved 2020-01-16 from <https://www.regjeringen.no/no/tema/helse-og-omsorg/sykehus/styringsdokumenter1/oppdragsdokument/id535564/>.
5. OECD.Stat: Health Care Quality Indicators. Retrieved 2020-01-16 from <https://stats.oecd.org/Index.aspx?QueryId=51884>.
6. Sluttrapport for pasientsikkerhetskampanjen I trygge hender 24-7. Pasientsikkerhetsprogrammet I trygge hender 24-7; 2014.
7. Pasientsikkerhetsprogrammet I trygge hender 24-7 Strategi 2014-2018. Pasientsikkerhetsprogrammet I trygge hender 24-7; 2014.
8. Pasientsikkerhetsprogrammet I trygge hender 24-7 Strategi 2014-2018, revidert versjon . Pasientsikkerhetsprogrammet I trygge hender 24-7; 2017.
9. Meld.St.11 2015/16: Nasjonal helse- og sykehusplan (2016-2019). Det Kongelige Helse- og Omsorgsdepartement; 2015.
10. Medl.St.6 2017/18: Kvalitet og pasientsikkerhet 2016. Det Kongelige Helse- og Omsorgsdepartement; 2017.
11. Pasientsikkerhetsprogrammet I trygge hender 24/7. Retrieved 2020-01-16 from <http://www.pasientsikkerhetsprogrammet.no/om-oss/om-pasientsikkerhetsprogrammet/i-trygge-hender-24-7>.
12. Pasientsikkerhetsprogrammet I trygge hender 24/7: Følgeevaluering av pasientsikkerhetsprogrammet, devaluering 2. Deloitte; 2017.
13. Pasientsikkerhetsprogrammet I trygge hender 24/7. Retrieved 2020-01-16 from <http://www.pasientsikkerhetsprogrammet.no/m%C3%A5linger/dashboard/dashboard-spesialisthelsetjeneste>.

Country Report Scotland

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Introduction

In the analysis of Scotland, we focus on the policy document "The Healthcare Quality Strategy NHS Scotland". This policy document was published in 2010 by NHS Scotland and its main purpose is to contribute to improving the quality of health care at a national level. Patient safety is highlighted as one of three key drivers for improved quality and patient safety, thus forming a relatively large part of the focus of the policy document. Our assessment is that the policy document contains elements of both strategy and action plan, and that it provides a central basis for national patient safety work in Scotland.

Against this backdrop, we have chosen to particularly focus on this document. The analysis has also been supplemented with information from the interview conducted with representatives from Improvement Hub (IHUB), which works on quality development within the NHS Scotland. Below are the results of the analyses made based on the analytical framework used in this work.

Figure 1. The Healthcare Quality strategy for NHS Scotland




Description of the current context

In this section we describe more closely the contexts that characterize the policy documents in different ways. For example, this answers questions about the possible needs that form the basis of the policy document and what management of the health care system looks like.

Review country facts – Scotland

Figure 2. Summary of basic country facts (1)

Country facts		
Population (million)	5.4 (2016)	
Average life expectancy (males/females, years)	77/81 (2015)	
Child mortality (< 5 years old per 1000/births)	4.1 (2016)	
Health care cost (% GDP)	?	

The health care system in Scotland is mainly centrally controlled, but with clear regional and local links

The health care system in Scotland, National Health Service (NHS Scotland), is funded primarily from taxation. (2) The Government possesses, through the appointed Minister (Cabinet Secretary for Health and Sport), the main and overall responsibility of the NHS and its operations. The Government is also obliged to report regularly to Parliament on the NHS and the state of health care.

NHS Scotland provides health care throughout the country and the system is divided into 14 different geographical boards. Each board is responsible for both primary and specialised care within their respective geographical area. Primary care consists mostly of private surgeries that act on behalf of the NHS. Health care providers or professions that are active in specialised care are directly employed by the NHS. The boards have some room for manoeuvre when it comes to organising health care, but they have to comply with existing legislation and other government requirements or regulations. An agreement is renewed annually between the government and the boards in the form of a Local Delivery Plan (previously known as HEAT-targets). The

plan sets out priority requirements for the board to comply with in the coming year. In addition to the regional boards, there are also 32 local councils responsible for various types of social services and welfare. Since 2016, efforts have been made to better integrate health care and welfare, and Integration Authorities have been formed. Here, representatives from each regional board and local councils are gathered by certain geographical areas in order to jointly develop plans for the integration of health care and welfare.

In addition to the above, there are several other national bodies within the NHS. These are known as Special Health Boards and consist of:

- Healthcare Improvement Scotland
- NHS Health Scotland
- Scottish Ambulance Service
- State Hospitals boards for Scotland
- NHS Education for Scotland
- NHS 24
- National Waiting Times Centre

For example, Healthcare Improvement Scotland has a central role in the quality development of health services in Scotland (3).

The national patient safety work started in 2004

National patient safety work in Scotland was initiated through a non-profit-driven patient safety programme called "The Safer Patient Initiative UK". (4) This was launched in 2004 by "The Health Foundation and Institute for Healthcare Improvement" (IHI) and extends across the UK. Scotland participated through a number of hospitals. Efforts to improve patient safety implemented within the frame of the programme showed good results and interest in patient safety work gradually grew in the country.

In 2007, NHS Scotland published a policy document entitled "Better Health, Better Care; Action Plan: Action Plan" with the ambition to increase the quality of health care at a national level. (5) A large part of the document focused on increased patient participation. The plan also pointed to the successful work started within the framework of "The Safer Patient Initiative UK", and it was found that this work would continue. Furthermore, it was stressed that a greater focus would be directed towards reducing health care related infections (VRI).

In 2008, against this backdrop, NHS Scotland launched the Scottish Patient Safety Programme, SPSP", in cooperation with IHI. (6) The launch of the programme entailed the establishment of a permanent platform for national patient safety work in the country. In the same year, a special working group for national work on health associated related infections ("Health Associated Infection (HAI) Taskforce") was also formed (7).

In 2010, in order to intensify efforts to develop a world-leading health care system with respect to good quality, NHS Scotland published a policy document entitled "The Healthcare Quality Strategy". (8) The document highlights patient safety as one of three quality aspirations (for a more detailed description of the policy document content see the heading "The content fo-

cuses on improved quality of care where patient safety is one of three dimensions". Since then, the policy document has continued to guide Scotland's national patient safety work. A year after "The Healthcare Quality strategy", an overall vision for the NHS entitled "2020 Vision" (9) was also launched with a clear connection to the content of the policy document.

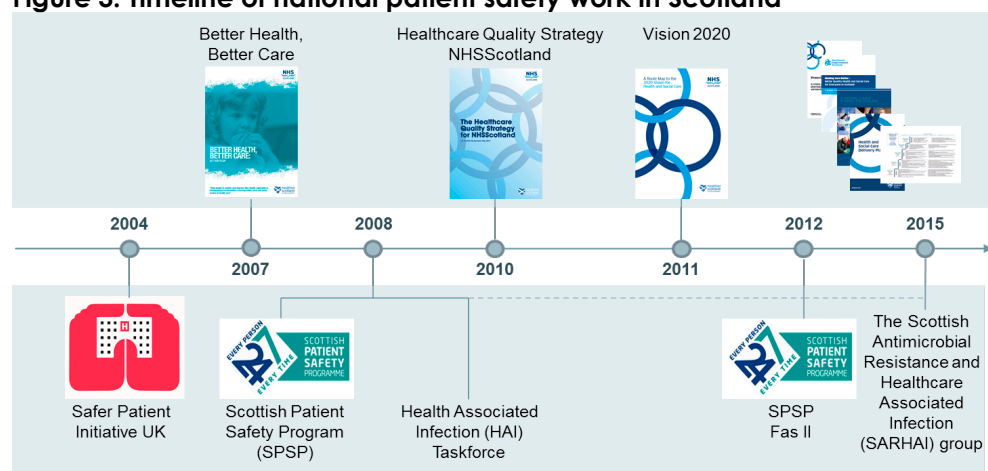
Following the launch of the national strategy and vision, the Scottish Government has developed a series of policy documents that can be related to national patient safety work. Examples of these are "Prescription for Excellence" (2013) (10) which deals with how the quality of prescription and management of medicines can be strengthened and the "Health and social care delivery plan" (2016) (11) that focuses on strengthening integration between social welfare and health care. This, in order to achieve improved interaction and care flow that benefits patients. Another example of a policy document related to the field of patient safety that has been established since 2010 is "A national clinical strategy for Scotland" (2016) (12) which sheds light on the longer-term challenges of health care and how these should be managed.

In parallel, SPSP's national patient safety work has continued and broadened. In 2012, phase two of the programme's work began. (13) In brief, SPSP's activities have expanded – from exclusive focus on patient safety within emergency medical care for adults to efforts for patient safety within Psychiatry (2012), Maternal and Child Health (2013), Primary Care (2013) and Drug Therapy (2016). In each area a number of projects are carried out, for example for the prevention of pressure sores. The SPSP supports health care providers to implement these projects in their clinical activities and so far SPSP's work has been greatly appreciated.

Work with HAIs has continued and in 2015 HAI Taskforce developed into the Scottish Anti-microbial Resistance and Healthcare Associated Infection (SARHAI) group in order to get a better grip on the HAI problem (14).

In Figure 3 the following, the development of patient safety in Scotland is visible and summarised.

Figure 3. Timeline of national patient safety work in Scotland



National patient safety work primarily has a supportive approach

In an interview with a representative of the Improvement Hub (IHUB) organisation that deals with quality development within NHS Scotland, it appears that the national improvement work focusing on patient safety is, above all, motivational and supportive. In other words, the control is more indirect ("softer"). The interview respondent points out that this approach has been the most appropriate in the current national context and advocates, in general, similar approaches in order to bring about changes in this area.

***"The improvement work is voluntary.
Believe more in this **supportive approach**
rather than hard control. Has worked well
here in Scotland"***

- IHUB NHS Scotland representative

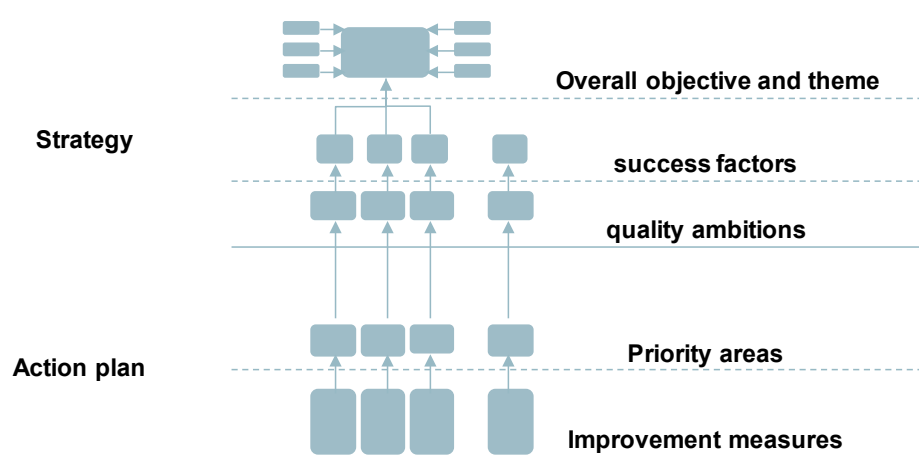
Policy document structure

This section describes the structure of the policy documents. Questions about the parts of the policy document and the intended recipients are answered here. We also highlight the format of the documentation, i.e. whether they are comprehensive or summarised etc. Policy document refers here to “The Healthcare Quality strategy (NHS Scotland)” (8) (8).

The policy document consists of elements of a strategy and overall action plan

In summary, the strategy document consists of six different parts: 1) an overall objective; 2) six themes related to the objective; 3) three key drivers; 4) three quality ambitions 5); three priority areas and 6) a number of improvement factors for each priority area. In addition, there is a key driver, quality ambition, priority areas and improvement measures for the implementation and the establishment of a follow-up system linked to the control document (see visualisation of the structure of the strategy in Figure 4 below).

Figure 4. Visualisation of the structure of the policy document



On the basis of the above, policy documents can be said to indicate an overall direction for the improvement work, especially through the overall objective and its associated themes, key drivers and quality ambitions. Priority areas and related improvement measures provide a somewhat more concrete guide to how the content of the policy document is to be put into practice. These elements can therefore be described as elements of an overall action plan.

The structure can be described as comparatively clear

On the basis of the above, the structure of the strategy can be described as comparatively clear. In other words, only by taking note of the policy document can one understand how the various elements are connected and related. In other words, the different levels are logically linked and the more

comprehensive elements such as objectives and key drivers are relatively clearly linked to the more concrete aspects such as improvement measures.

In the interview conducted with the representative of the improvement agency IHUB, the image that the NHS values a clear structure is confirmed. The importance of clearly links between the overall strategic elements, such as objectives and quality ambitions, and activities at the level of operational activity is also highlighted. It also emphasises the value of formulating common objectives within the framework of a national strategy. This is said to create the conditions for all affected actors at different levels to work in a single direction.

"A national strategy is needed, among other things, to clarify overarching objectives that all players and activities can work towards jointly"

- IHUB NHS Scotland representative

The policy document is aimed at four different levels – from the patient to the national system

The policy document stresses that successful results require broad efforts that extend across the entire health care system. Against this background, the policy document is aimed at four levels (micro/meso/macro/meta-macro level):

- **Micro level - Patient focus (patient-based):** On the basis of their unique experience, the individual should be given the right conditions in the form of support, advice and information to be involved in their own care and take care of their own health, together with caregivers and relatives.
- **Meso level – Personnel focus (staff-based):** The employees of NHS Scotland should be given the right conditions to fully use their skills. This is to improve and strengthen the employees' experience, commitment and capacity. With the right support, employees should feel that it is easy to do the right things.
- **Macro level - System focus (systems-based):** The management and the relevant organisation will work on the basis of common priorities. There should also be a balance between performance and development. The relationship between different governance and policy documents should be clarified and simplified.
- **Meta-macro level – Partnership focused (partnership-based):** NHS Scotland will cooperate broadly with other parts of the public sector, private sector, non-profit organisations ("Third Sector"), staff, patients and care givers.

The policy document is relatively comprehensive but still easily accessible

The policy document consists of a body text document totalling about 50 pages, a large part of which consists of text. Visualisations in the form of figures, however, illustrate the document, which contributes to a better understanding of both the structure and the content. The text mass is relatively airy and the document begins with a relatively comprehensive summary of barely ten pages, which makes it easier for the reader to follow and understand the overall content. In conclusion, despite its scope, the policy document can be described as easily accessible.

Communication is described as an important part of the realisation of the strategy's content

In the surveyed policy document, communication is seen as an important tool in realising the content of the strategy. This is both to raise awareness of the quality ambitions of NHS Scotland and to motivate affected actors and interests to contribute to the implementation of the content of the strategy. Three objectives for communicative work are presented in the strategy. These are:

1. Increase internal and external awareness of the Government's vision for NHS Scotland, in order to ensure that the population sees Scottish care as world leading.
2. Inspire both staff and the general public to understand their own part in realising the overall vision.
3. Illuminate national and local programmes that contribute to a good quality health care.

In order to achieve the above objectives, the aim is to position and clearly frame the purpose of the strategy in a way that, among other things, facilitates public understanding. It also shows that NHS Scotland will use available arenas and tools, such as campaigns, publications and digital channels, to reach and engage different target groups, actors and interests at national and local levels.

The policy document explicitly does not specify an end date

In the policy document there is no clear period of time for the strategy, but the overall objective and the closely interconnected vision expire in 2020. The reason for the selected time period is also not mentioned in the interview conducted with the representative from the improvement agency IHUB.

Policy document content

In this section we report the content of the policy documents. For example, questions about the strategy's thematic focus or whether the content is based on a clear perspective are answered. We also describe the tangibility level in the policy document more closely. Policy document refers to the analysed document "The Healthcare Quality strategy NHS Scotland" (8).

The content focuses on improved quality of care where patient safety is based on one of three dimensions

The overall objective presented in the policy document is formulated as: *"To deliver the highest-quality health care to citizens in Scotland, ensuring that NHS Scotland is seen as a world leader by the Scottish population"*. The objective formulation is based on a clear citizens' perspective, as it is based on studies of what themes the population prioritises especially within health care. These themes are:

1. Thoughtfulness and empathy among staff
2. Good communication of medical conditions and treatment
3. Effective co-operation between health care staff, patients and other relevant bodies
4. Clean and safe health care environment
5. Continuity
6. Excellent clinical knowledge

The three key drivers that are highlighted and that tie in with the overall objective are:

1. Person-centred care
2. Safe care
3. Effective care

Safe care can thus be said to be a central part of the strategy. Each individual key driver is linked to a quality ambition in the policy document. Quality ambitions serve as a starting point for national quality work and they contribute, according to the policy document, to the realisation of the overall objective. The quality ambition for each key driver is formulated as:

1. **Quality ambition for Person-centred care:** A mutually beneficial partnership between patients, relatives and caregivers that respects individual needs, values; is based on compassion, continuity, clear communication and patient involvement in decision-making.
2. **Quality ambition for Safe care:** No avoidable HAI should occur and all care and treatment should always be given in a clean, safe and suitable environment.

3. **Quality ambition for Effective care:** The most appropriate care should be given at the right time to all those benefiting from it, and unnecessary or harmful variations in care should cease.

Priority areas are also described in the policy document and frame the reported quality ambitions thematically. In the field of patient safety, two priority areas are described:

1. To secure the success of SPSP and extend the programme to several parts of NHS Scotland.
2. To support a National action programme (HAI Taskforce) to reduce the incidence of HAIs.

A number of improvement measures, linked to the priority areas, are also listed in the policy document. Measures that can be linked to patient safety are:

- Increase the start-up rate of SPSP in emergency care with the aim of reducing mortality and HAIs in hospitals.
- Expand SPSP and implement the program in primary care and psychiatry.
- Strengthen the work for extended medical reconciliations, in connection with healthcare transitions.
- Ensure synergies between the work carried out within the framework of HAI Taskforce (The group that works with HAIs) and other patient safety work to continue to reduce the number of HAIs.
- Expand and enhance the availability of central digital patient data (Electronic Care Summary).

As mentioned earlier, a key driver, quality ambitions, priority areas and improvement measures are also reported for the actual implementation and follow-up of the policy document content. A more detailed description of these parts follows under the heading "Processes of the policy document".

A relatively narrow description of the patient safety perspective is given, while being put in a broad context

Given the clear focus on adverse events and care in a clean, safe and suitable environment, a relatively narrow approach is applied to the concept of patient safety (similar to the Swedish one). At the same time, the patient safety perspective is set in a broad context that clearly links to an improved quality of care in general. In the interview with the representative from the IHUB, it was confirmed that patient safety should be seen as one of several parts of the overall quality work.

"Work on improved patient safety must be part of the general quality development, just as in the strategy, where patient safety is one of three parts"

- IHUB NHS Scotland representative

Success and outcome areas characterise the thematic content

At the most comprehensive level, the objectives of the document and the related themes, the focus is mainly on "success areas" (rather than areas of risk or outcomes). Examples are "Person-centring", "Clean and safe healthcare environment" and "Continuity".

When it comes to quality ambitions, priority areas and improvement measures, the policy document focuses mainly on more traditional outcomes such as "prevention of adverse events" with a more specific focus on HAIs and hospital-related mortality. At the same time, concrete activities linked to success areas, such as "strengthened medical reconciliations in connection with healthcare transitions", are also highlighted at this level. In addition to these thematic areas, the action proposals focus more on overall processes, such as extending SPSP's activities.

In an interview with a representative from the improvement agency IHUB, it is confirmed that different thematic starting points should be combined. It is described that outcomes such as the reduction of adverse events should be combined with, for example, a focus on success areas such as improvement culture and leadership.

Policy document processes

This section presents the central processes that can be linked to the strategy and the action plan. Examples of questions to be answered are whether the policy document was based on a particular process, for example through consultation or negotiation? Another important element is examining whether the policy document describes different central processes and, in such cases, what they include. Policy document here regards "The Healthcare Quality Strategy NHS Scotland" (8).

The policy document has been developed based on a broad consultative process

The policy document is described as having been developed based on a broad consultative process. Views and thoughts have been obtained from both patients and citizens, as well as health professionals, representatives from both NHS Scotland and the rest of the welfare sector. Consultations have been conducted among other things within the framework of a number of discussion forums and events such as "Patient Rights Bill consultation" and "Big Cancer conversation". Acquiring the citizens' perspective is highlighted as a key element in the development of the policy document, which is also made visible by the six themes based on citizens' priorities and related to the overall objective.

Another central starting point for the development of the policy document has been to build on and adhere to existing strategies and supporting documents, such as "Better Health, Better Care: Action Plan (2007)" (15) and the work that fits within the framework of the SPSP.

The policy document describes the process of implementation at an overall level

A picture of the implementation process is provided in the context of the improvement measures

The policy document partly highlights, within the framework of improvement measures, processes for implementing the content of the strategy with a focus on patient safety. For example, it is described that efforts should be made to accelerate and expand SPSP's activities, and that efforts for more systematic work against health care associated infections should be conducted. This type of description gives an indication of which implementation processes are to be carried out within the framework of the policy document. At the same time, these only provide a limited picture of how the content should be translated into concrete activities at lower levels, such as for individual caregivers or their employees.

There is a key driver, quality ambitions and action proposals specifically for the implementation of the strategy

As mentioned earlier, there is a key driver with associated quality ambitions, priority areas and improvement measures for implementation and follow-up. The key driver and quality ambition are formulated as:

- Quality Infrastructure: Create the necessary governance and implementation structures to integrate the improvement measures in a clear and efficient way.

Priority areas to meet the quality ambition are summarised in three points:

- Develop a Quality Measures Framework to drive and follow the development.
- Provide information that provides rapid feedback to the NHS Boards in order to identify and manage risks. The boards should raise the quality issue at all meetings.
- Develop appropriate control systems.

Suggestions for improvement are also described within the framework of priority areas:

- Establish Quality Ambitions at the latest May 2010.
- HEAT (now LDP) – objective 2011/12 must conform to the content of the policy document by October 2010.
- The follow-up framework, including the identification of relevant overall outcome indicators, shall be completed by October 2010.
- Determine areas of responsibility as well as control processes for increased quality that minimise potential risks.
- Ensure that national and local supervisory bodies are involved in the development of relevant quality indicators. The supervision shall also highlight any variations in health care that are considered inappropriate.
- Develop, support and use the skills, knowledge and leadership that employees possess to ensure quality in health care that extends across all levels.
- Develop "The Quality Improvement Hub", which is a new partnership between NHS National Services Scotland (NSS), NHS Quality Improvement Scotland (QIS), NHS Health Scotland, NHS National Education for Scotland (NES) and the Scottish Government Health Directorates Improvement and Support Team (IST).

The above improvement proposals are relatively concrete. At the same time, several of these are scheduled for the year 2010 and thus give a limited picture of the continuous implementation work up to the year 2020.

A specific implementation section also complements the picture of the implementation

In addition to the above, the policy document also describes the implementation of the strategy in a specific section. This part stresses the importance of strategic governance that is to say that different actors and activities that

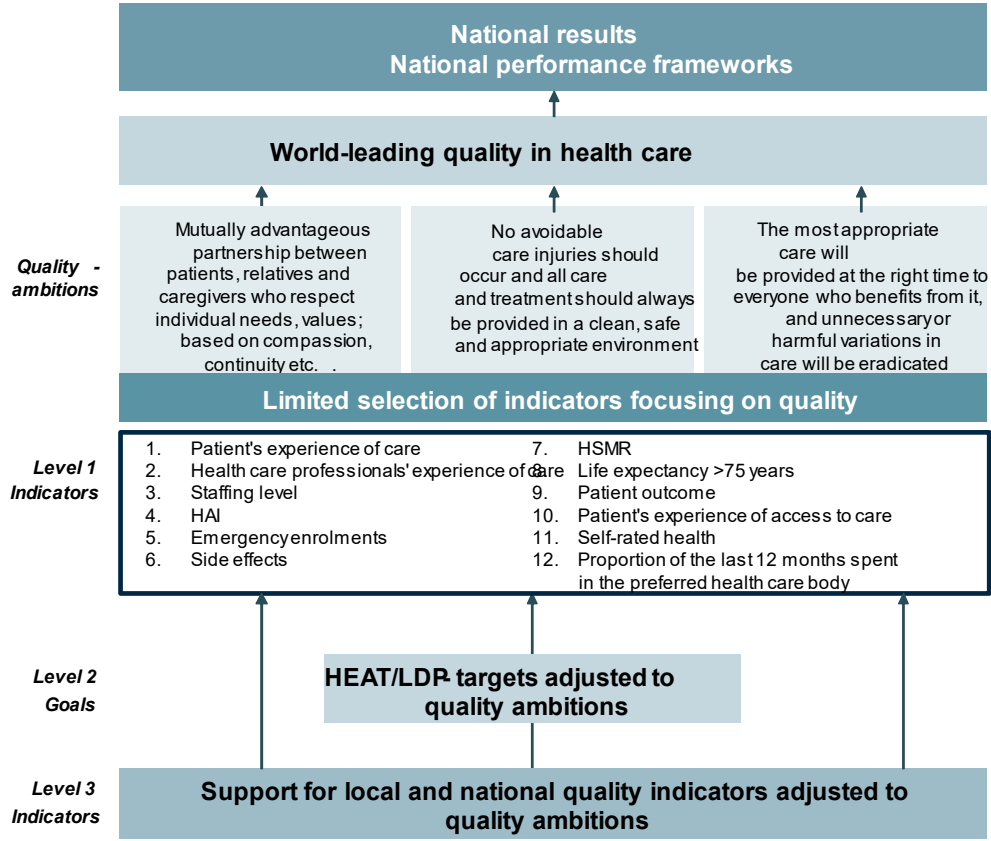
work with or are affected by the content of the strategy must be synchronised in order to ensure coherence and thus good conditions for the desired impact. Against this background, it is proposed that a Quality Alliance be formed. The alliance brings together key actors, such as the representatives from NHS Scotland's management and the relevant government ministers. This alliance has, among other things, the task of monitoring the implementation of the strategy. Cooperation is also opening up for greater cohesion between new political decisions and ambitions and priorities within the policy document. The Quality Alliance exists today (16), which means that the policy document has had the desired impact in this part.

The follow-up of the strategy's ambitions is described relatively well and attempts are made to reconcile this with existing follow-up structures

The policy document proposes a new Quality Measurement Framework. The framework is interlinked with follow-up within several different sectors at national level, but focuses on measuring the quality ambitions that are highlighted in the policy document. The framework consists of three levels:

- 1) Twelve quality indicators reflecting the quality ambitions of the policy document
- 2) Annual national performance (previously HEAT objectives, which that have now been replaced by LDP objectives)
- 3) Existing national and local indicators that coincide with the quality aspirations of the policy document (see visualisation of the structure in Figure 5).

Figure 5. Visualisation of the existing framework for following-up quality of health care as described in "The Healthcare Quality Strategy for NHS Scotland" (8)



The overall quality work for several different areas is based on a national performance framework. The performance framework is also the basis for the national follow-up of quality work in health care (see Figure 6).

Figure 6. The National Performance framework (17)



In conclusion, efforts have been made to link the follow-up that takes place within the framework of the policy document to existing structures for measuring outcomes in several areas. This approach reflects the ambition of achieving strategic governance. At the same time, the link between the different frameworks is completely logical.

The importance of following-up continuously is emphasised in the interview

The interviewed respondent emphasises the value of continually following up the content of the strategy. It is highlighted that this type of follow-up is needed in order for the content and work to be continuously adjusted based on identified results.

Evaluation of the strategy is ongoing, but there are still no results.

"Continuous follow-up of the strategy is needed, not least for the work to be adapted based on observed results"

- IHUB NHS Scotland representative

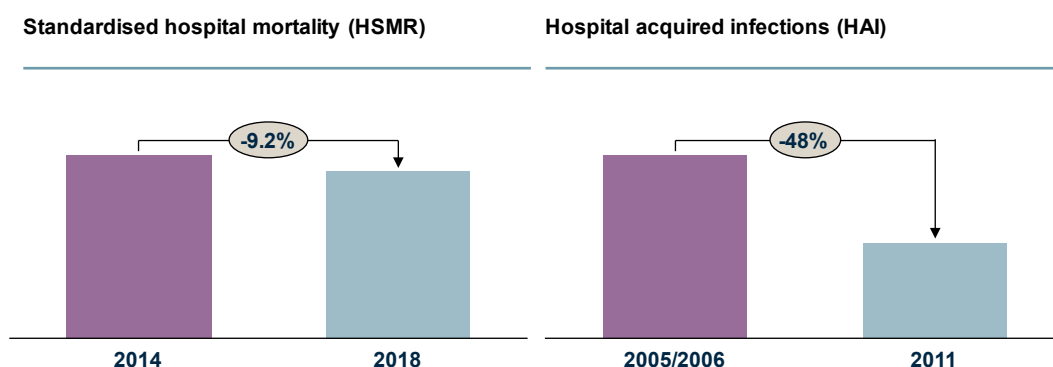
Policy document results

The results of the policy document are presented below. Examples of questions to be answered are whether good results can be linked directly to the policy document or more to the governance or organisation at large? Policy document refers to the analysed document "The Healthcare Quality strategy NHS Scotland" (8).

No evaluation of the policy document appears to have been carried out, but some results can be seen in the field of patient safety

There does not appear to be an evaluation of the actual policy document, which makes it difficult to draw any conclusions about the impact of the document. At national level there are results from certain outcomes that are linked to patient safety. Analysis of the latest available data shows that improvements have taken place over time.

Figure 7. Results showing a reduction in HSRMs between 2014 – 2018 (18) and HAIs between 2005/06-2011 (19)



In addition, an evaluation focusing on one of the SPSP's work areas "emergency adult health care" has been carried out (20). The evaluation shows that the efforts within the framework of the programme have resulted in:

- A reduction in standardised hospital mortality (HSMR) by 16.5% compared with 2007
- A decrease of 21 percent in the 30-day mortality rate for sepsis patients
- A reduction in patients suffering cardiac arrest of 19%, reported by eleven hospitals during the period 2012 – 2015
- Eight out of fifteen NHS boards have reported that more than 95% of patients have been discharged without any care injury in the period 2014 – 2015

References

1. Institute for Health Metrics and Evaluation. IHME: United Kingdom - Scotland. Retrieved 2020-01-15 from <http://www.healthdata.org/united-kingdom-scotland>.
2. Robson K. SPICe briefing: The National Health Service in Scotland. SPICe: The information centre; 2016.
http://www.parliament.scot/ResearchBriefingsAndFactsheets/S5/SB_16-100_The_National_Health_Service_in_Scotland.pdf.
3. Healthcare Improvement Scotland. About us. Retrieved 2020-01-15 from http://www.healthcareimprovementscotland.org/about_us.aspx.
4. Learning report: Safer Patients Initiative. London: The Health Foundation; 2011.
5. Better Health, Better Care: Action Plan. Edinburgh: The Scottish Government; 2007.
6. Healthcare Improvement Scotland. Scottish Patient Safety Program: About us. Retrieved 2020-01-15 from <https://ihub.scot/spsp/about-us/>.
7. The Healthcare Associated Infection (HAI) Task Force. The Scottish Government; 2011.
8. The Healthcare Quality Strategy NHS Scotland. Edinburgh: The Scottish Government; 2010.
9. 2020 Vision. The Scottish Government; 2010. Retrieved 2020-01-15 from <https://www2.gov.scot/Topics/Health/Policy/2020-Vision>.
10. Prescription for Excellence. Edinburgh: The Scottish Government; 2013.
11. Health and social care delivery plan. Edinburgh: The Scottish Government; 2016.
12. A national clinical strategy for Scotland. Edinburgh: The Scottish Government; 2016.
13. Healthcare Improvement Scotland. 10 years of SPSP. Retrieved 2020-01-15 from <https://ihub.scot/improvement-programmes/scottish-patient-safety-programme-spsp/spsp10/>.

14. Reilly J, Mullings A. The national agenda for Healthcare Associated Infection, Antimicrobial Resistance and Infection Prevention and Control in Scotland: Structures, current priorities and programmes. *Journal of Infection Prevention*. 2017; 18(4): 2010-12.
15. Better Health, Better Care action plan. NHS; 2007.
16. The Scottish Government. Quality Alliance Board. Retrieved 2020-01-15 from <https://www2.gov.scot/Topics/Health/Policy/Quality-Strategy/Quality-Alliance-Board>.
17. The Scottish Government. Scotland's National Performance Framework. Retrieved 2020-01-15 from <http://nationalperformance.gov.scot/>.
18. Hospital Standardised Mortality Ratios. NHS National Services Scotland; 2018. <https://www.isdscotland.org/Health-Topics/Quality-Indicators/Publications/2018-08-14/2018-08-14-HSMR-Summary.pdf>.
19. ISD Scotland. Quality Measurement Framework: Summary of progress. Hämtad 2020-01-15 från <http://www.isdscotland.org/Health-Topics/Quality-Measurement-Framework/Summary-of-Progress/>.
20. SPSP Acute Adult: End of phase report. Healthcare Improvement Scotland; 2016.

The government has commissioned the National Board of Health and Welfare to create a national action plan for increased patient safety, in order to help develop and coordinate the country's patient safety work.

To learn from previous work within the patient safety field, an international overview has been conducted, based on a selection of countries and international organisations.

The overview is also addressing the actors who has been involved in the work, both nationally and internationally, including authorities, principals, national and international organisations, professional associations and experts.