

National Action Plan for Increased
Patient Safety in Swedish Health Care
2020–2024

Act for safer healthcare



Foreword

Swedish healthcare has a long tradition of active patient safety work. In the last two decades knowledge about patient safety has grown rapidly, and patient safety work has evolved in line with this knowledge. Yet many patients still suffer from avoidable injuries.

The Government sees the need for national efforts to strengthen the work of municipalities and regions on patient safety and to strengthen national coordination. The National Board of Health and Welfare has therefore been commissioned to create a National Action Plan for Increased Patient Safety, which will help develop and coordinate work on patient safety in the country.

The vision of the action plan is Good and safe care – everywhere and always - with the overall goal that no patient should have to suffer from adverse events.

The action plan is designed to be used by municipalities and regions that can establish principles, priorities and objectives for their patient safety work, through their own action plans. The beneficiaries of the National Action Plan are therefore the principals' decision-makers. However, authorities, national organisations, representatives of higher education institutions, experts and politicians are also affected.

The Action Plan is developed in broad cooperation with authorities, representatives from principals and national organisations, representatives of private caregivers, patients and relatives, experts and students and other stakeholders in the area of patient safety. The National Board of Health and Welfare would like to thank everyone who has contributed with their knowledge and experience.

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Introduction

Action Plan as support and guidance

In light of the changes and challenges facing healthcare, the government sees a need for a national mobilisation to increase patient safety. The National Board of Health and Welfare has therefore been tasked with developing a national Action Plan and with coordinating and supporting patient safety work in the country.

The Action Plan aims to strengthen the staunch work of the principals in the systematic patient safety work and to help prevent patients from suffering from adverse events. The Action Plan shall also support and coordinate work on patient safety across the country.

Efforts to increase patient safety in healthcare need to take further steps to address both the needs of both today and tomorrow, which include:

- medical and technological developments with new treatment methods and new medical technologies, increased digitisation and e-health
- organisational changes and new forms of care, such as the transition to close care
- the economic conditions and balance between different objectives and different types of care interventions and patient groups
- access to staff with sufficient skills.

The development towards safe care takes place gradually. In order to take the next step, development needs to build on the good work being done and stakeholders need to pool together in a number of areas to develop and strengthen patient safety. The Action Plan therefore highlights some basic conditions and focus areas that need to be strengthened for good and safe care.

Turning to decision makers

The beneficiaries of the National Action Plan are the principals' decision-makers. The Action Plan is designed to be used by municipalities and regions in order to establish principles, priorities and objectives for their patient safety work through their own Action Plans. The National Action Plan must therefore support the principals in their work on patient safety and be seen as a national concentration on this area. Authorities, national organisations, representatives of higher educational institutions, experts and politicians are also affected.

Developed in broad collaboration

The Action Plan has been developed in close consultation with the relevant authorities, representatives of the principals, national organisations, professional associations, representatives of private caregivers, patients and relatives, students and experts in area of patient safety.

National, regional and municipal efforts

In order to create strong implementation that contributes to increased patient safety, the following needs to exist at national level;

- access to experts who can contribute with knowledge and can provide education in patient safety
- resources for research and development to both follow and develop knowledge in the field
- resources to develop new tools and methods to both work with and to monitor safety in healthcare
- a national platform and structure for the coordination and implementation of national measures and the feeding back of experiences.

In the design of the National Action Plan, it has also been important to take into account the ongoing patient safety work in the country, in order to prioritise actions and measures where the needs are greatest.

At municipal and regional level, a number of areas have been identified to create good and safe care. There needs to be;

- a safety proficient management that moves towards increased patient safety and at the same time creates the conditions for a good safety culture
- sufficient staff with sufficient skills who understand and have knowledge of patient safety
- safe and user-friendly technology
- a sustainable working environment and
- ability to take advantage of the knowledge and experience of patients and relatives.

Content and structure of the Action Plan

Based on the needs and conditions described, the National Action Plan has been designed with the aim of contributing to increased patient safety.

The Action Plan shall provide greater knowledge and guidance, a structure in which priority areas have been clarified and a link between objectives, actions and follow-up.

Vision and overall goals

The vision for our joint patient safety work is: *Good and safe care – everywhere and always*. The overall goal is that: *No patient should have to suffer an avoidable injury*.

The vision and goal are formulated to emphasise a broad approach to the safety work, which both includes the perspectives *presence of safety* and *absence of injury*. All areas of activity are affected in all situations throughout healthcare.

Affect the development of safety at all levels

The aim of the Action Plan itself is to influence the way in which safety at all levels of healthcare is developed. This can be done by strengthening the patient safety work of the principals through municipal and regional Action Plans, so

that the principles, priorities and objectives for increased patient safety are developed and implemented. The Action Plan shall also contribute to coordinating activities between authorities, national organisations and other stakeholders.

Background

In the background, the basis for good and safe care is described. Swedish healthcare has good medical results but many patients still suffer from injuries that could have been avoided. Prevention is central to creating safe care.

National assignments and initiatives

Several ongoing national initiatives and initiatives in health care are affecting and linked to patient safety. It is therefore important to continuously follow ongoing efforts and have knowledge of new initiatives in the national patient safety work and work on the Action Plan.

International work

Global patient safety work is briefly described in the international work section. The World Health organisation (WHO) has established new resolutions for increased patient safety and initiated the work with Global Action on Patient Safety. In order to learn from other countries' patient safety work, the National Board of Health and Welfare has carried out an international overview in which three international organisations and the control documents of ten countries have been analysed.

Cooperation and support

The section on cooperation and support describes the forms of cooperation and support available at municipal and regional level and how national cooperation and support for the implementation of the Action Plan is intended to work.

Basic conditions for safe care

In order to work towards the vision and the overall goal, four basic conditions are highlighted:

- Committed management and clear governance
- A good safety culture
- Adequate knowledge and competence
- The patient as co-creator

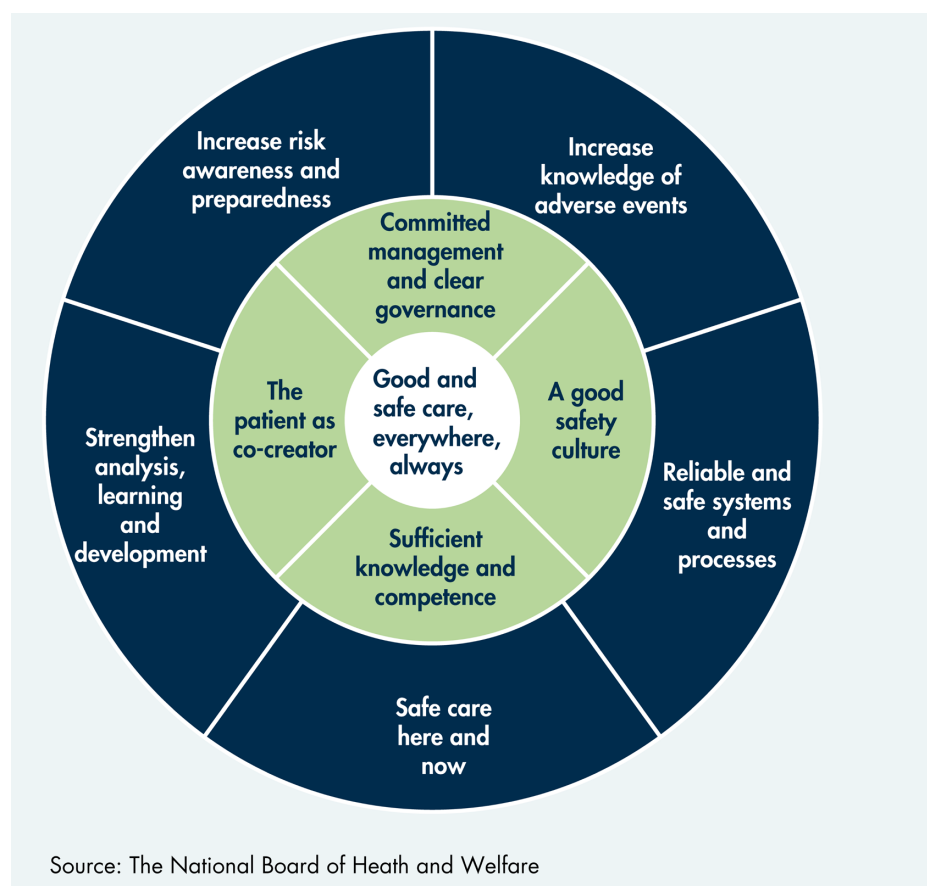
Five priority focus areas

The Action Plan contains five priority focus areas for the work towards safer care. The focus areas are based on the main challenges within patient safety work and provide a structure for the Action Plan's actions nationally. The focus areas are:

- Increase knowledge of adverse events
- Reliable and safe systems and processes
- Safe care here and now
- Strengthen analysis, learning and development
- Increase risk awareness and preparedness

Within each focus area there is; an introductory text as an explanation and justification, what the focus area is aimed at, examples of what principals need to ensure that healthcare providers do, national measures to enable and facilitate the work of principals and examples of the stakeholders.

Figure 1. Illustration of the areas of the action plan



Follow-up

National follow-up in the field of patient safety needs to be broadened to reflect the development needed for safer care. This section describes how it will evolve. Follow-up needs to be based on the basic conditions and focus areas of the action plan and to monitor the implementation of the action plan's actions.

Stakeholders with assignments and responsibilities in the field of patient safety

Many stakeholders have responsibilities and assignments that contribute to safer care and which directly or indirectly affect patient safety. Joint action on the basis of each stakeholder's tasks and responsibilities is a prerequisite for achieving strong patient safety work. This section describes the tasks and responsibilities of the relevant authorities and national organisations in the field.

Background

Good and safe care

The safety of healthcare is a cornerstone of all healthcare quality work. In addition to laws and regulations, there are ordinances and general advice from the National Board of Health and Welfare and other authorities. Common to most regulations is that they ultimately aim for good and safe care for patients.

The Healthcare Act (2017:30) states that healthcare must be carried out in such a way that it meets the requirements for good healthcare. The concept of patient safety is closely associated with the concept of good care. Good care means that care should in particular:

- be of good quality with a good standard of hygiene
- meet the patient's need for security, continuity and safety
- be based on respect for the patient's self-determination and integrity
- promote good contacts between the patient and the healthcare professional
- be easily available.

The most central law on patient safety is the Patient Safety Act (2010:659). The law aims to promote high patient safety in healthcare. By patient safety the law refers to protection against adverse events. Adverse events means suffering, bodily or psychological injury or illness, and deaths that could have been avoided if sufficient measures had been taken in the patient's contact with the healthcare system.

Good results, but still patients are injured

Swedish healthcare has good results in important respects, according to several international comparisons. However, today's Swedish care can still be safer. An estimated 100,000 patients are affected each year by injuries in somatic hospital care of adults, which corresponds to approximately one injury per ten instances of care. This has consequences for the patients affected, for staff, in patients' confidence in healthcare and in society's utilisation of common resources.

Adverse events lead to extended hospital stays for about 50,000 patients each year. Approximately 2,000 patients receive permanent pain and adverse events is estimated to have been a contributing factor in about 1,200 deaths each year. The cost just for the additional days of care due to adverse events is estimated to be approximately SEK 8 billion per year. This represents about one seventh, just over 12 percent, of the total costs of somatic hospital treatment. More unclear is what the situation looks like outside somatic hospital care for adults, that is, in paediatric healthcare, home healthcare, prehospital care, primary care, psychiatry and dental care.

Much is already being done to provide safer care

Swedish healthcare has a long tradition of active patient safety work. 80 years ago, the lex Maria introduced requirements for notification of injuries as a result of care and treatment.

In recent decades, knowledge of patient safety has grown rapidly, and the work has developed in line with this. Important areas have been state regulation (e.g. the Patient Safety Act and the National Board of Health and Welfare Regulations and General Advice [SOSFS 2011:9] on management systems for systematic quality work) and regional and municipal work in the form of investments, control documents and knowledge management.

The patient safety agreement between the state and the then Swedish Association of Local Authorities and Regions for the period 2011-2014 was also an important step by focusing on safety culture, monitoring and visibility of the results of healthcare.

At national level, there are currently a number of actions and initiatives aimed at strengthening patient safety in various ways.

Sweden is also actively involved in the international patient safety work, including through the WHO's resolution work in Global Action on Patient Safety.

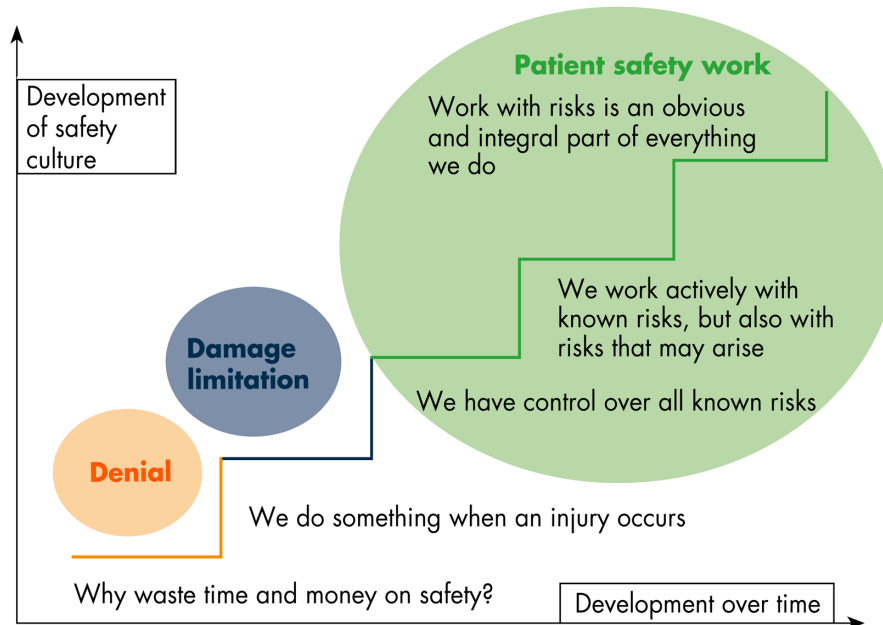
Safety is about maturity

Further important factors are to continue the development away from blaming individuals to seeking out the causes at system level and integrating patient safety work even more into the broad quality and work environment work.

When a system matures and safety develops, there is a focus shift, which is visualised in Figure 2. First of all, we do not realise in general that we are causing injury, that is, *denial*. When we realise that we are actually causing injury, our focus is mainly shifted to dealing with the damage, that is, *damage limitation*. The next big step is when we realise the importance of primarily identifying risks of injury and preventing or minimising the risks of injury from occurring at all, that is, active preventive *patient safety work*.

The Action Plan is based on this reasoning.

Figure 2. The road to active preventive patient safety work – a focus shift in three steps



Freely after: D Parker, NPSA, Managing risk in healthcare: understanding your safety culture using the Manchester Patient Safety Framework (MaPSaF), Journal of Nursing Management, 2009, 17.

Source: The National Board of Health and Welfare

The preventative work is essential

Healthcare is a complex business in constant change that is dependent on the interaction between people, technology and organisations. The risks in such a system are many and varied. Safety and safety work are therefore crucial.

Measuring injuries and adverse events that have occurred is an important part of patient safety work. The outcome, i.e. the adverse events, are a central perspective for patients affected, and for healthcare it is important to know where the injuries are and where the risk lies.

However, in order to achieve successful work in patient safety, it is necessary not only to focus on what has already happened, but also strengthen the *prevention work*. Central to this is that work is risk-conscious and preventive with the ultimate goal that injuries never occur. Through this, we can approach the two perspectives *absence of injury* and *presence of safety*.

National assignments and initiatives related to patient safety

In the work on patient safety, it is important that there is continuous monitoring of external conditions and monitoring of ongoing and new initiatives. However, not all work needs to be carried out within the framework of the Action Plan. Some missions and initiatives need to be carried out in already established structures.

Several ongoing national initiatives and initiatives in health care affecting and linked to patient safety. In the national patient safety work and the work on the Action Plan, it is important to continuously follow ongoing work and know about new initiatives. This is important in order to prioritise the implementation of national measures and to participate in and strengthen the patient safety perspective in the work that is underway, but also to avoid ambiguity and duplication.

Furthermore, not everything related to patient safety can and should be carried out within the framework of the National Action Plan, but some work needs to be done in the structures already established.

These may be assignments and initiatives that influence and strengthen both the basic conditions for safe care and particular focus areas, such as:

- Improved strategic leadership in municipally funded healthcare and social care
- Good and close care – A transition in healthcare with a focus on primary healthcare
- Initiatives to strengthen leadership in healthcare
- National pharmaceutical strategy
- National coordinator for sustainable supply of skills in municipally funded care and social care for the elderly
- National follow-up of the transition to close care
- National council on the supply of health professionals
- National system for knowledge management
- Coherent knowledge management and national and cohesive follow-up
- Coordinated development for good and close care
- Standardised courses of care
- Cross-sectoral Action Plan antibiotic strategy 2018-2020
- Developed conditions for healthcare employees
- Vision e-health 2025

Continuous monitoring of external conditions is necessary and needs to be one of the tasks for the group that will coordinate work on the Action Plan at national level. A selection of the measures and initiatives deemed to affect the work on patient safety and the choice of measures in the Action Plan are

comprehensively described in the report; *Development of national Action Plan for increased patient safety, reporting government assignments 2018/04111/FS.*

International work

Swedish patient safety work is affected by what is happening in the rest of the world. In order to learn from the patient safety work of other countries, the National Board of Health and Welfare has undertaken an international overview that has contributed many lessons to the national work.

Sweden's contribution to Agenda 2030, and specifically to the goal of improved global health, is made in a number of arenas and in different contexts. 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 what happens 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.

International overview

The National Board of Health and Welfare has made an international overview, to learn from the strategic patient safety work of other countries and organisations and its effects. We have analysed the strategies and Action Plans of ten countries and reviewed the work of three international organisations with patient safety.

The international overview has shown that a national Action Plan cannot impact the effects of patient safety work, but that the context in a country is very important. The analysis has shown that a strategic overview is important and that there must be a clear and logical link between indicative concrete activities, as well as the fact that the ongoing regional patient safety work must take on board. It also needs to be clear who the recipient is, and how the responsibilities and roles are distributed. Having a broad and inclusive process in developing the Action Plan has proved to be a factor of success, likewise that national coordination is central to strong implementation. Starting from in-depth current analyses in selected areas can provide a fact-based picture of the most pressing needs and challenges, and help focus on the areas to be most prioritised within the field of patient safety.

The analysis has also shown that it is essential to have an implementation plan and a follow-up model, where results can be linked to the measures described in the Action Plan. Relevant indicators for follow-up are also needed. A conscious and adapted communication strategy is important throughout the work of developing a national Action Plan. This also applies to the launch and implementation of the Action Plan's measures.

The international overview has contributed many lessons to the national work and is also translated into English. It can be downloaded and ordered in its entirety via socialstyrelsen.se.

National cooperation and support

In order to give raise to the Action Plan in its implementation, stakeholders need to work together – municipally, regionally and nationally. It is proposed that the implementation of national measures be carried out in conjunction with a National Council for Patient Safety and the aim is for it to be carried out within the framework of the respective authorities' and organisations' tasks.

Coordination is needed for strong implementation

Efforts to increase patient safety involve stakeholders at all levels of healthcare, municipal, regional and national. The stakeholders, authorities and organisations need to cooperate and coordinate national actions and measures, in order to gain momentum in the implementation of the Action Plan and to clarify responsibilities and roles.

Many authorities, The Swedish Association of Local Authorities and Regions (SALAR), national system for knowledge management in healthcare, patient representatives, County Councils' Mutual Insurance Company (Löf) and various professional associations are affected, in addition to municipalities and regions. Higher educational institutions, students and experts are also affected, as well as representatives of patient and relatives organisations.

Based on meetings with collaboration partners, workshops and the international overview, the National Board of Health and Welfare sees a need for strengthened efforts to implement the Action Plan's measures and for coordination and cooperation between authorities, national organisations and stakeholders who support and complement existing cooperation structures at national, regional and municipal level.

The cooperation and support of the regions

The National Cooperation Group for Patient Safety (NSG patient safety) is part of the national system for knowledge management. The system is an agreement between all the regions of the country, supported by SALAR and in cooperation with the country's municipalities. The goal of the system is for the best possible knowledge to be accessible and easy to use in each individual patient meeting throughout the country, in order to achieve equal standards of care.

NSG patient safety leads and coordinates the work of the regions and is based on the regional healthcare patient safety groups. NSG patient safety monitors and drives the development of national patient safety work based on the needs of the regions. The task includes monitoring future and international developments in healthcare, in particular with a focus on the restructuring of healthcare to close care. The group's task is also to disseminate knowledge, in order to ensure that patient safe working methods permeate all national programme areas within the framework of the regions' knowledge management.

The task of NSG patient safety also includes collaborating to evaluate existing follow-up tools and indicators at national level and, if necessary,

introducing new ones. Based on the needs of the regions, NSG patient safety can form national working groups (NAG) for specific parts of the patient safety field. Initially, two such working groups have been formed: *NAG care hygiene* and *NAG global trigger tool*.

NSG patient safety consists of a representative from each healthcare region and a representative from SALAR. Cooperation takes place primarily with other groups within the national system for knowledge management and with SALAR and the National Board of Health and Welfare.

Cooperation and support by the municipalities

The National Board of Health and Welfare and SALAR work together with representatives of the Regional Cooperation and Support Structures (RSS) through a partnership between local, regional and national level. The purpose of the partnership is to contribute to increased cooperation, dialogue and coordination of initiatives that can contribute to knowledge development, to better support implementation and the use of knowledge.

Increased support and national coordination of efforts in the work to increase patient safety in municipal healthcare are required, with a particular focus on the transition to good and close care. The corresponding structures contained in regional patient safety work do not exist at municipal level and therefore need to be developed.

There shall be at least one Medically Responsible Nurse (MAS) with specific designated responsibilities in the municipal healthcare system, but there may be several MAS in the same municipality responsible for the area of activity determined by the municipality. MAR is the corresponding position in rehabilitation. Anyone who has the role of MAS and MAR has a central function in patient safety work.

Within the framework of SALAR's patient safety work, there is a network of contact persons in the municipal healthcare system. The convener is SALAR's patient safety officer.

The Collaboration for Safe Care network

Collaboration for safe care is an informal network that meets regularly to share relevant information on patient safety and to highlight initiatives that can contribute to safer care. It is convened by the Chief Medical Officer at the County Council's Mutual Insurance Company (Löf).

The network includes the National Association of Dietitians, Famna, the Swedish Association of Physiotherapists, the Swedish Municipal Workers' Union, the National Cooperation Group for Patient Safety, the Swedish Society of Medicine, the Swedish Society of Nursing, the Swedish Association of Occupational Therapists, SKR, the Swedish Medical Association, the Swedish Dental Association, the Swedish Association of Health Professionals and the Association of Private Care Providers. The National Board of Health and Welfare can be co-opted if necessary.

National measures for better coordination

The Action Plan contains a number of comprehensive measures to achieve strong patient safety work at a national level. Good collaboration and coordination of national efforts, as well as clear roles and responsibilities, can contribute to and provide guidance and support in the work on patient safety. The measures aims to

- develop interaction between relevant authorities, national organisations, principals and other stakeholders in a ***National Council for Patient Safety***
- implement ***initiatives to develop and strengthen the cooperation*** between national stakeholders in the work to improve patient safety
- contribute to ***increased dialogue and dissemination of knowledge*** at national, regional and municipal level
- participate in and ***support the international patient safety work.***

Collaboration in the Council for patient safety

Collaboration on the implementation of national measures in the Action Plan needs to take place through a National Council for Patient Safety. The National Board of Health and Welfare will lead this collaboration. The Council needs to have representatives from the relevant authorities, organisations and principals. Collaboration needs to be done on the implementation of the actions of the Action Plan in order to make it as effective and clear as possible. A reference group made of representatives of patients and relatives and experts with special expertise in patient safety must be set up to support of the Council.

The tasks of the Council are:

- in cooperation, to give concrete expression to, prioritise and distribute the actions and measures set out in the Action Plan,
- anchor priority efforts and actions within their own organisations,
- collaborate on the follow-up and revision of the Action Plan.

The representatives on the Council also need to contribute with knowledge and information on ongoing national initiatives and initiatives that have effect on patient safety, based on the role and mandate of each authority and organisation.

Examples of stakeholders

The Swedish Work Environment Authority, E-Health Authority, Public Health Agency of Sweden, Forte, representatives of patient boards, Health and Social Care Inspectorate, County Councils' Mutual Insurance Company (Löf), the Swedish Medical Products Agency, the Swedish Health and Social Care Analysis Authority, National Cooperation Group for Patient Safety, National Board of Health and Welfare, National Committee for Medical and Social Evaluation, National Accident Commission, Swedish Radiation Safety Authority, Swedish Association of Local Authorities and Regions, Swedish Higher Education Authority (UKÄ).

Support for municipalities and regions

The Authority provides a platform to provide support for municipalities and regions within the framework of the National Board of Health and Welfare's knowledge management mission. It is central to the implementation of the Action Plan, as well as for coordination and follow-up at national level. The aim is to create long-term and sustainable patient safety work and provide the conditions to be able to

- work in accordance with the National Action Plan for Increased Patient Safety
- support municipalities and regions in the transition to good and close care, and
- contribute to ensuring that patients receive secure and safe care.

The National Action Plan is valid for the period 2020-2024 and will be reviewed as needed. Ongoing work and updates are presented on the National Board of Health and Welfare's website *Samlad stöd för patientsäkerhet* (*Gathered support for patient safety*), patientsakerhet.socialstyrelsen.se.

Basic conditions for safe care

So what is needed for us to achieve the overall goal? Four basic conditions have been identified for the continued work: committed management and clear governance, a good safety culture, sufficient knowledge and competence and the patient as co-creator.

Committed management and clear governance

A basic prerequisite for safe care is committed and competent management and clear governance of healthcare at all levels – from the political level to decision-makers at regional and municipal level, as well as from operational managers to leaders in patient-oriented activity.

The caregiver has an overall responsibility

Management positions, knowledge, attitudes, actions and decisions are crucial for high patient safety. All caregivers should have a management system for systematic quality work and systematic patient safety work. This is subject to law and regulations.

It is the responsibility of the caregiver to ensure that business is conducted in accordance with the laws and regulations. Among other things, the caregiver shall plan, lead and control the business in such a way that the requirement for good care in healthcare is fulfilled.

Management is the bearer of organisational culture

Management is a key role model and has a crucial role in strengthening and maintaining a high level of safety. Good quality and patient safety are best developed in organisations with good working environment, psychological security and a culture where employees are involved and, with the management, strive to continuously improve in order to maintain a sustainable operation.

Managers at all levels can create the conditions for systematic improvement and patient safety work, through self-checks where information about the performance of the business is obtained, and by taking responsibility for implementing and evaluating measures.

Factors at all levels affect patient safety

Many important factors are found in the patient-oriented care process, such as conditions for staffing with the right skills and development of and maintenance of effective processes. Communication and information exchange within units and across organisational boundaries with other healthcare providers and principals also needs to function safely and effectively.

Factors that are not always close to care and traditionally not associated with patient safety also have a major impact. Examples of such areas include resource allocation, work environment, financial management, skills provision,

competence development, organisational structure and principles for scheduling and staffing. Here, too, collaboration needs to be done with regard to quality and patient safety.

Patient safety is a responsibility of politicians, as well as management and managers at all levels of the healthcare organisation. Decisions at a political level, for example in matters of economics or accessibility, can lead to a negative conflict of objectives, which risks adversely affecting patient safety. Therefore, patient safety must always be taken into account.

Knowledge of patient safety and understanding of the central importance of management for high patient safety is thus needed at all levels of the health system. Conditions must be in place for sustainable and competent leadership and for management and governance that effectively strives for a sustainable business with high patient safety.

A good safety culture

Another basic prerequisite for safe care is a good safety culture. The organisation then provides the conditions for a culture that promotes safety. In order for as few patients as possible to suffer from injuries, the safety culture needs to be characterised by

- active work in identifying risks and injuries and equally active work to minimise them
- an open working environment where staff can safely report, discuss and ask questions about safety
- a no-blame approach
- an organisation where everyone learns from the negative incidents that have occurred and the risk of such incidents, as well as benefiting from positive results.

Active, long-term and visible work

A good safety culture means that everyone in healthcare is aware of and vigilant about the risks that may arise. It also means that the organisational culture creates an open dialogue about the risks, conditions and circumstances that can affect patient safety. The safety culture affects all the work – from the highest management levels of healthcare to the daily work of healthcare teams and staff. The work to create a good safety culture needs to be prioritised by senior management and to be both long-term and visible.

Approach and responsibility

Safety culture is about individual approaches, attitudes towards each other and a common awareness of risks. How everyone takes responsibility and reacts, both with colleagues and patients, behaves in relation to each other and collaborates with each other affects how risks are managed and lessons are learned from both positive and negative incidents.

If a patient suffers from an adverse event, it is important that the patient is well taken care of. It is also crucial that the staff involved in the incident are supported. The organisation may also need support after a serious incident. These factors contribute to security and a good safety culture.

Clarity and persistence

Healthcare managers and leaders have a stated responsibility to ensure that safety-related issues are taken seriously and are actively addressed, but everyone in the organisation contributes to and affects the safety culture – regardless of profession or role. Managers and leaders, however, need to create the conditions for staff to be able to work systematically to prevent injuries and for the business to maintain a high level of quality and safety.

The work for increased patient safety and a good safety culture requires clarity and perseverance among all managers and leaders – from the political leadership to first-line managers.

Patient safety and the working environment are linked

Both overall work environment factors (e.g. response and behaviour or support from managers and in the working group) as well as more work-related environment factors (e.g. high workload, unclear roles or lack of time for recovery) affect the ability to perform a safe job. Here, integrated systematic patient safety, work environment, collaboration with safety representatives and employee representatives can provide both predictability and security in healthcare. It can also help staff to report the risks and deviations that are observed.

A good safety culture means that experience – both of staff, patients and relatives – is taken advantage of and used as a basis for learning, development and improvement, which can reduce the risk of injuries and similar events occurring.

Adequate knowledge and competence

Competence for safe healthcare

Wherever healthcare activities are carried out, there must be the staff required to provide good care. A basic prerequisite for safe care is that there are sufficient staff who have sufficient skills and good conditions to carry out their work.

Supply of skills is one of several collaborative factors that affect the risks of adverse events. A good supply of skills means ensuring that the operation has access to staff with sufficient skills in both the short and long term. Competent and committed employees who are given the opportunity to work at the peak of their skills are a prerequisite for safe and secure quality care.

Changes make new demands

Professional competence ensures that staff have mastered both the tasks and the care and treatment they perform. New demands are placed on staffing and skills with more person-centred and coordinated care, the rapid development of knowledge and restructuring into more home healthcare and primary care with staff from different healthcare providers and increasingly advanced care in the patient's home.

In addition, new skills will be needed. Digitalisation with increased opportunities for virtual and digital care meetings and online treatment will affect the conditions for both the supply of skills and patient safety work. Ensuring introduction programmes for new graduates and new employees and

promoting continuous training for healthcare employees promotes both the ability to adapt and the supply of skills.

Special knowledge of patient safety

Knowledge of patient safety is needed at all levels of healthcare, among individual employees, managers and leaders, as well as decision makers and politicians. It is important to make decisions based on relevant research and based on the knowledge in the field, which includes, for example, behavioural science, psychology, medicine and nursing science, leadership and organisational theory, economics and decision theory. Knowledge is not only needed to be able to make balanced decisions based on systemic factors, but also to assess risks and to propose and take action regarding the individual patient.

With patient safety included in both basic and continued training, healthcare professionals can make conscious demands and contribute to a safe workplace for both themselves and patients. Increased awareness and knowledge of the risks and the ability to manage these risks also require knowledge of the improvement and implementation work.

Knowledge of the impact of the system is also needed to understand what creates safe care. With a system-based approach, there is an opportunity to detect and address shortcomings in the organisation. Other important educational needs are knowledge of inter-professional working methods, information security and change management.

Technical and non-technical skills

Technical skills include practical knowledge of, for example, how diagnostic examinations, assessments of findings and procedures should be carried out. It is also a question of being able to manage increasingly digital solutions and advanced medical devices in patient-oriented work safely.

Non-technical skills is about situational presence, communication, leadership, decision-making, work in teams and management of stress. It is also about the response and ability to familiarise themselves with the patient's needs and problem solving.

Both technical and non-technical skills need to be trained and continuously developed in the work for safer care.

Competence is knowledge, abilities and behaviour

Teamwork means that everyone on the team contributes their specific skills. This is also a prerequisite for a high level of patient safety. The team consists of the staff closest to it, but teams higher up the organisation also affect safety. Therefore, knowledge of effective cooperation at all levels of organisation, respect for everyone regardless of their role and a climate of open dialogue is needed. It is also valuable to have knowledge of how processes of group dynamics affect decisions.

It is important to take into account the individual professional skills, skills and experience of team members when planning staffing and composition of teams, in order to create the conditions for a wide range of skills and experience. Planning staffing, scheduling and composition of teams requires collaboration across business and professional boundaries. Cross disciplinary

collaboration and training the ability to work in teams needs to start during undergraduate education and then continue throughout professional life.

Importance of the working environment

Healthcare professionals need the conditions to be able to do good work with high motivation and need to be given the opportunity for reflection in their daily work. Stress, workload and lack of recovery are examples of factors that affect the ability to perform work safely. In other words, knowledge of the importance of the working environment is key for patient safety.

The patient as co-creator

Another basic prerequisite for safe care is the participation of patients and their relatives. Care shall be designed and carried out in consultation with the patient as far as possible. The fact that the patient is treated with respect and can rely on the provision of care on an equal footing creates trust and confidence but aspects such as accessibility, coordination and continuity are also key.

Care will thus be safer if the patient is well informed, actively participates in their care and can influence care based on their wishes and conditions. Relatives can also have a central role, in cases where the patient wants it. It is also important that patients and their relatives are given the opportunity to participate in patient safety work.

The patient's unique knowledge of her/himself

The patient's story and their needs and resources are crucial. The relationship between patient and staff needs to be characterised by mutual respect and understanding. The forms and degree of patient participation need to be based on the patient's needs and wishes. A patient who does not want to, or cannot, take an active part in their care and treatment should not risk receiving poorer care, the healthcare professionals must work to ensure that the patient's perspective is taken into account.

Involve the patient

A patient who is familiar with why and how different parts of the examination and treatment should be carried out also contributes to the care plan being as intended and that attention is drawn to deviations and can be addressed. A well-informed patient also has better conditions to take responsibility for their own care.

Being able to participate in one's own care requires knowledge and insight. The patient therefore needs to receive good and adapted information about their care, treatment and about possible risks. Communication and dialogue are key. This means that everyone who works in care needs to involve and request the patient's views, meet the patient with empathy and share their knowledge.

Involve the patient at every level

The patient as a co-creator means that the patient is involved at every level of the care system: in the meeting between the patient and the staff, as well as at regional and national level. The patient also needs to be involved in planning new healthcare, in the training of health professionals, in research and in the design of policies and regulation of healthcare.

The Health and Social Care Inspectorate shall, in its supervision, hear from patients and their relatives. In addition, the caregiver shall give patients and their relatives the opportunity to participate in patient safety work.

Healthcare needs to make better use of patients' and their relatives' experiences, knowledge and resources in patient safety work and strengthen the patients' position. Methods and support need to be developed to create the conditions for patients to be co-creators in their own care at all levels and to actively contribute to safer care.

Priority focus areas

The Action Plan contains five priority focus areas that can strengthen the work for safer care. These focus areas are based on the main challenges of patient safety work and form a structure for the action plan's national actions.

Focus area 1 - Increase knowledge of adverse events

Identification, investigation and measurement of injuries and adverse events, increase knowledge of what affects patients when the result of care is not as intended. Quite a lot is known about the injuries in somatic hospital care for adults, but less about the injuries, for example, in primary care, municipal health care, paediatric care, psychiatry, prehospital care and dental care. The consequences and suffering caused to patients by adverse events is also not clear enough.

Knowledge of patients' experiences in health care is limited, and these sources, like the information contained in complaints and comments, are only used to a small extent for development and improvement work. At the same time, there is a transformation of structure and organisation in health care, including level structuring and centralising of certain care and movement of other care from hospitals to other forms of care. This can provide new opportunities for good and safe care, but may also create new risks.

When it becomes known what kind of injuries affect patients, the development can be followed over time and it becomes easier to understand what contributes to adverse events and how to work preventively. Knowledge of underlying causes and consequences for the patients provides a basis for the design of measures and prioritisation of interventions.

To move forward, work on identification, investigation and measurement of adverse events needs to be developed to include all parts of the healthcare system. Both existing and new methods of identification, measurement and follow-up need to be developed. Research surrounding methods contributes to effective working methods.

This focus area aims to

- increase knowledge about the presence of injuries and adverse events
- provide evidence for analysis of underlying causes at system level
- improve the ability to monitor the development of patient safety.

How do we get there?

Principals who have knowledge of the occurrence of injuries and adverse events get there by ensuring that caregivers:

- monitor and investigate events that have caused or could have caused a injury, identify underlying causes and take sufficient measures
- use sufficient methods for the identification and measurement of adverse events or the risk of such events and adapt methods based on the conditions of the activity

- train in measurement and investigation methods
- request and use patients' and related parties' complaints and comments in healthcare
- minimise adverse consequential effects by supporting patients and staff involved in events that have or could have caused an injury.

National actions in focus area 1

In order to enable and facilitate the work of principals, the following is needed:

- Promote national joint development of models, methods, knowledge support and training for the identification, measurement and investigation of injuries, adverse events and underlying causes.
- Identify needs and promote the design of new methods for the compilation, aggregation and visualisation of data surrounding adverse events from care and from other sources, so that the conditions are improved for overview and effective decision-making bases.
- Demand, compile and analyse patients' and relatives' experiences of care and complaints and comments received, so that factors affecting patient safety and risk of care injury can be identified.
- Demand development and adaptation of IT-based support to facilitate the identification of injuries and provide an overview of the results.

Examples of stakeholders

Public Health Agency of Sweden, Forte, Health and Social Care Inspectorate, the County Councils' Mutual Insurance Company (Löf), the Swedish Medical Products Agency, National Cooperation Group for Patient Safety, patient boards, the National Board of Health and Welfare, the Swedish National Accident Commission, the Swedish Radiation Safety Authority, the Swedish Association of Local Authorities and Regions.

Focus area 2 - Reliable and safe systems and processes

Systematic quality and patient safety work is necessary to create good care and prevent patients from suffering from adverse events. A caregiver shall be responsible for the existence of a management system to be used to systematically and continuously develop and ensure the quality of the business. Provisions on management systems are contained in the National Board of Health and Welfare's Regulations and General Advice (SOSFS 2011:9) on management systems for systematic quality work. The regulations shall also apply in the systematic patient safety work that caregivers are to carry out in accordance with the Patient Safety Act. Another essential regulation is the National Board of Health and Welfare's Regulations and General Advice (HSLF-FS 2017:40) on the systematic patient safety work of caregivers.

Healthcare is complex. It covers many different processes with both known and unknown risk elements in the activities. The right patient should receive the right care, in the right place, at the right time. Reliable and secure systems, processes and procedures create conditions for healthcare professionals to work safely, efficiently and according to the best available knowledge.

These include, for example, assessment and diagnosis, interaction in the care chain, information transfer or prescription and drug management. It is central in understanding why and how organisations maintain good and safe care under varying conditions.

The ongoing transition of healthcare’s organisation to more home healthcare and primary care, the rapid development of knowledge and technological and digital development means that healthcare needs to rethink established processes and working methods, premises and equipment, as well as the need for staffing and competence. New methods, working methods and procedures must be introduced and out dated must be phased out.

It is important to create the conditions for cohesive care where continuity for the patient is ensured. Effective cooperation requires structures and processes that facilitate action and ability to solve problems when they arise. In healthcare there are several different areas where work with safety is central, even if they are governed by different conditions and requirements. These include, for example, the safety of personnel, the safety of medical devices, pharmaceutical safety, information security, radiation safety, fire safety and transport safety (figure 3). In order to create good and safe care, all the different parts of the business need to be taken into account.

Figure 3. Different healthcare safety systems



Effective processes and procedures, documentation systems and equipment contribute to patient safety. With a consensus on how different processes and tasks can be performed, less unwanted variation in how the work is performed and follow-up and feedback of results, a predictability of work and increased patient safety can be created.

Staff need to have knowledge, competence and the conditions to work safely – in terms of knowledge support, equipment and work environment.

This focus area aims to

- meet the changes in healthcare by developing effective processes with a focus on the patient's path through care
- create safe, coherent, accessible and equal care
- strengthen patient safety by reducing unwanted variations.

How do we achieve this?

Principals who have reliable and secure systems and processes achieve this by ensuring that caregivers:

- meet the requirements for management systems in healthcare and conduct systematic quality and patient safety work in all aspects of healthcare
- continuously develop, adapt and apply systems, processes and procedures that make it easier to do the right thing and make it difficult to make mistakes
- involve patients and relatives in the planning and design of processes
- promote good accessibility and continuity
- are organised for collaboration and cohesive care
- adapt and use experience and evidence-based methods and tools to identify and manage situations that may threaten patient safety
- introduce and phase out methods, equipment and procedures safely
- follow reliability in processes and systems through self-monitoring, and compliance with regulations, guidelines and procedures.

National actions in focus area 2

In order to enable and facilitate the work of principals, the following is needed:

- Contribute to the development of safe care and work processes through, for example, standardised care processes, national guidelines and guidance.
- Participate in the development and implementation of knowledge support and guidance, focusing on security-critical processes and phasing out non-current knowledge support, guidelines and procedures.
- Support efforts to identify, evaluate, further develop and disseminate knowledge of methods, tools and working methods for safe care.
- Support the structured introduction of need-based and effective digital support and technology.

Examples of stakeholders

Public Health Agency of Sweden Forte, Health and Social Care Inspectorate, the County Councils' Mutual Insurance Company (Löf), the Swedish Medical Products Agency, National Cooperation Group For Patient Safety, the National

Board of Health and Welfare, the Swedish Radiation Safety Authority, the Swedish Association of Local Authorities and Regions.

Focus area 3 - Safe care here and now

Healthcare is characterised by constant interactions between people, technology and organisation, and the conditions for safety can quickly change. Safe care here and now is about having the ability and knowledge to detect risks and be aware that unforeseen events or interruptions may occur, but also be able to handle and act here and now before patient safety is threatened.

Care requires constant adjustments

It is key that healthcare is adapted to interruptions and risks, so that it can be sustainable and safe even during stressful or changing conditions. There is a need for constant overview, adaptation, preparation and learning for an activity to function effectively. Variations, interruptions, adaptations and response to opportunities are a necessary and normal part of a complex and dynamic reality. It is central to understanding why and how organisations maintain good and safe care under varying conditions.

Everyone has a responsibility to contribute to safe care

Everyone has a personal responsibility to contribute to safe care, regardless of the role they have within the organisation. But individuals cannot perform better than the environment allows. As a manager and leader, it is important to have a clear picture of the business, and understand the variations that always exists and when a variation causes an interruption that poses a risk to patient safety and what is required to manage it. A risk awareness and ability to manage interruptions and risks requires both professional know-how and knowledge of patient safety. This includes managers as well as employees.

Further education and training is needed

Systematic education and training for new tasks and new technologies is needed. Introduction programmes for new graduates and new employees promote both the ability to adapt and the supply of skills within the organisation. It is also important that there are opportunities for continuous further education and skills development.

Leadership that promotes safe care

Both managers and employees need to be aware of the risks that may arise and have an open dialogue about conditions and circumstances that may affect patient safety. Maintaining a safe way of working requires a good safety culture where everyone in the organisation contributes and acts on their own. This requires leadership that promotes and creates the conditions for a good working environment and safe care.

In order to create an overview of the business and understand how safe care is here and now, manage risks and interruptions, methods and tools need to be adapted and applied based on specific conditions in the different parts of care. For example, these may be methods of risk assessment, real-time data, safety

rounds, safety dialogue forums, conversations, and meetings in workgroups and teams and between managers and employees.

Patients' participation can make care safer

Patients' participation can make care safer. Patients who understand the purpose of their treatment – what will happen and the possible risks of treatment – can alert health professionals to something that is not right. It is important to have a way of working where staff and management actively request the patients' and relatives' experience of care, in order to identify factors that create safe care.

This focus area aims to

- raise awareness, ability and flexibility to pay attention to and act at all organisational levels of healthcare and to respond to imminent interruptions and reduce the risk of patients suffering injuries
- increase knowledge about patient safety in employees, managers and decision makers
- strengthen the participation and involvement of patients and relatives in patient safety work.

How do we get there?

Principals who have an awareness of what safe care is like here and now get there by ensuring that the caregivers;

- have a good safety culture that permeates all aspects of healthcare and promotes open communication in the daily work surrounding identified risks and creates time for learning and reflection
- have a high level of risk awareness, and the ability to manage risks and act at all organisational levels
- monitor and ensure patient safety at all levels on a daily basis
- ensure professional competence and knowledge of patient safety through skills development and further education at all levels
- promote a good working environment and apply safe staffing and scheduling based on knowledge of employees' experience and skills and promote continuity
- create the opportunity for patients and relatives to actively contribute to patient safety work.

National actions in focus area 3

In order to enable and facilitate the work of principals, the following is needed:

- Take measures aimed at all levels of the healthcare system to raise awareness and knowledge about patient safety, such as communication and information efforts and target group training efforts within patient safety.
- Support actions throughout healthcare to promote introductory programmes and regular training of technical and non-technical skills.
- Support efforts to make identify, evaluate and further develop existing methods, tools and working methods for safe care.
- Promote an increased focus on patient safety in healthcare's basic and specialist education.

- Take on board and explore the possibility of a Swedish adaptation of the WHO's Patient Safety Curriculum.
- Carry out efforts that help increase the involvement of patients and relatives in patient safety work.
- Stimulate and support research on patient safety.

Examples of stakeholders

Public Health Agency of Sweden, Forte, Health and Social Care Inspectorate, Mutual Insurance Company of the County Councils, the Swedish Medical Products Agency, Higher education institutions, National Cooperation Group For Patient Safety, patient boards, The Swedish Radiation Safety Authority, the Swedish Association of Local Authorities and Regions, the Swedish Higher Education Authority (UKÄ).

Focus area 4 - Strengthen analysis, learning and development

Analysis and learning of experiences are part of the ongoing work within healthcare. When the results are used to understand what contributes to safety, sustainability, desirable flexibility and good results, the business can be developed to increase quality and safety and reduce the risk of adverse events. It is also important to understand what contributes to risks, deviations and injuries. An overall perspective is necessary, so that factors at system level are also analysed and provide the basis for improvement work.

Information about factors affecting safety can be integrated from different sources to provide an overall picture of the situation. Then you can analyse relationships, prioritise and act effectively. These may include risk analyses, results from investigations of events and deviations, data on injuries and compilations of comments and complaints from patients and relatives. Results from Health Technology Assessment (HTA) analyses of new methods as well as trends and patterns in metrics and results can also contribute useful information.

Analyses are also needed to increase understanding of how practical work is carried out and what contributes to safety and good results. Results from analyses of underlying causes and conditions that have affected events are important, regardless of whether the results are positive or negative. The analyses provide a basis for preventive measures that improve the ability to maintain safety and achieve desirable results, and reduce the risk of quality deficiencies and adverse events.

The analyses require special competence, organisation and allocated resources, and need to be available at several organisational levels – from national level with a comprehensive system perspective to individual activities and departments. Research contributes to both the development of effective analytical methods and an increased understanding of the factors in the business that provide important conditions for high safety.

Analytical results and conclusions need to be fed back to the level in the organisation where the identified factors can be changed. It is therefore important that the communication and information transfer between different

parts of the organisation is effective, and that conditions exist for joint and more effective and analysis-based learning with long-term effects.

This focus area aims to

- increase systemic understanding about underlying causes of adverse events and strengthen the organisational memory within healthcare
- strengthen preventive patient safety work by stimulating knowledge development and individual and organisational learning, thereby increasing the conditions for safe care
- provide better support for research so that knowledge increases about how working methods in healthcare contribute to safety and risks
- identify factors that, overall, affect patient safety and manage them.

How do we get there?

Principals who learn and develop get there by ensuring that the caregivers:

- have the expertise and resources for analysis, at different organisational levels
- continuously use tools and jointly developed methods to analyse data, trends and patterns
- at all levels, use information from several different sources to analyse and learn from past experience, both positive and negative
- feed back results and follow-up actions systematic work to develop quality and patient safety in the organisation
- involve patients and relatives in analysis, learning, action and follow-up.

National actions in focus area 4

In order to enable and facilitate the work of principals, the following is needed:

- Develop collaboration around compilation, analysis, learning and feedback between authorities and national organisations whose activities affect the conditions for patient safety.
- Improve the conditions for enabling system analyses of aggregated healthcare outcomes.
- Work to strengthen competence, organisational conditions and capacity for analysis nationally and at other organisational levels.
- Work to carry out coordinated risk analyses from an HTO perspective (human, technology and organisation) at national level.
- Establish long-term interaction between regions, municipalities, patient boards and relevant authorities for analysis and feedback of comments and complaints that contribute to the learning, development and strengthening of patient safety.
- Contribute to disseminating lessons on increased patient safety through publications, meeting forums and seminars.
- Develop principles and forms for establishing health-economic aspects of patient safety, so that the consequences and costs of adverse events and preventative measures are made clear in the face of priorities and decisions.
- Support the development of IT support for data compilation, analysis, overview and dissemination of knowledge.

Examples of stakeholders

Swedish Work Environment Authority, Public Health Agency of Sweden, Forte, the Swedish Health and Social Care Inspectorate, the County Councils' Mutual Insurance Company (Löf), the Swedish Medical Products Agency for Health and Social Care Analysis, National Cooperation Group for Patient Safety, the National Board of Health and Welfare, The Swedish National Accident Commission, the Swedish Radiation Safety Authority, The Swedish Association of Local Authorities and Regions.

Focus area 5 - Increase risk awareness and preparedness

All parts of healthcare need to plan for a healthcare that can be flexibly adapted to short-term or long-term changing conditions while maintaining functionality, sustainability and safety. Changes can be, for example, overall strategic changes such as the transition to close care and digitisation of health services. They may also be about changes in resource allocation that require reprioritisation in the business or about changes in the panorama of the disease, such as increased incidence of intractable infections that require a change in the care process.

Long-term skills provision is a prerequisite

Access to healthcare professionals with sufficient skills can quickly change but is key, and long-term skills provision is a prerequisite for adaptable and safe care. Collaboration increases the conditions for good preparedness and foresight. Collaboration needs to take place both at national level and in different parts of the organisation and concerns changing external factors, identified risks and what measures need to be taken.

Monitoring of external conditions is necessary

Tomorrow's challenges require high preparedness to identify and manage risks that may be unknown today. Monitoring of external conditions with inventory and systematic analysis of risks at both overall system level and business oriented level can reduce the element of surprise and provide greater room for manoeuvre for adaptation. Emergency and disaster exercises and analysis of scenarios are examples of activities that increase the conditions for good preparedness and foresight at several levels of healthcare.

Business oriented levels require preparedness for, for example, periods of increased workload, lack of skills supply, technical interruptions and delivery problems for medicines or materials. Method and proficiency training, training of communication and collaboration through various forms of team training and simulation exercises can improve the conditions to withstand stress while maintaining patient safety.

Conditions are necessary for prevention

Management is responsible for ensuring that conditions exist to alert and analyse risks, create preparedness and organise the work so that a good working

environment can be maintained with the possibility of redistribution of tasks and with room for recovery.

Good safety culture consists of open communication about both risks and results, both when everything runs as planned and when the unexpected. Patients and relatives can provide valuable information about risks from a different perspective.

This focus area aims to

- achieve robust and adaptable healthcare activities where the assignment is managed with good patient safety and good working environment even in unexpected conditions.

How do we get there?

Principals who have a risk awareness and preparedness get there by ensuring that the caregivers:

- have patient safety strategies that govern and support local work
- identify, communicate and plan for long-term risks
- strengthen their preparedness through training, simulation and competence development
- conduct active monitoring of external conditions
- analyse risks and create preparedness for interruptions in the physical environment, the IT environment and the supply of medicines and materials
- conduct systematic environment work
- take into account long-term consequences for patient safety in their planning and prioritisation decisions and have a good foresight of their skills supply
- create the opportunity for patients and relatives to contribute to patient safety work.

National actions in focus area 5

In order to enable and facilitate the work of principals, the following is needed:

- Promote proficiency training and clinical simulation efforts, such as
 - identify the knowledge position
 - identify the need for national support and guidance.
- Strengthen access to and use of tools, methods and working procedures to identify and manage risks. Identify the healthcare needs for new and complementary tools to identify risks.
- Contribute to and support efforts to monitor and systematically analyse risks from a patient safety perspective and disseminate the information.
- Contribute to increased collaboration and coordination between higher education institutions and principals on skills provision.

Examples of stakeholders

Health and Social Care Inspectorate, the County Councils' Mutual Insurance Company (Löf), the Swedish Medical Products Agency, national cooperation group for patient safety, the National Board of Health and Welfare, the Swedish Radiation Safety Authority, the Swedish Association of Local Authorities and Regions, the Swedish Higher Education Authority.

Follow-up in the field of patient safety

Systematic follow-up and analysis must make the situation in the field of patient safety visible and be a base of knowledge in the systematic quality and patient safety work. The follow-up must help to create motivation to continue to develop a high level of patient safety in all areas of healthcare.

Follow-up contributes to development

National follow-up within the field of patient safety needs to be broadened to reflect the development needed for safer care. Follow-up will be based on the basic conditions and focus areas of the action plan.

Areas with limited follow-up will be prioritised

A large part of today's indicators and measures highlight aspects of patient safety from the perspective of the caregiver and profession and with a focus on the somatic inpatient care of adults. Follow-up needs to reflect more closely patients' and relatives' experiences of how safe care is and also reflect forms of care such as paediatric healthcare, primary care including municipal healthcare, psychiatric care and dental care.

The ongoing transition of the healthcare organisation with a change in the allocation of resources and responsibilities, as well as digital and technological development, also places demands on the development of adapted indicators, measures and methods to monitor how safe the care is or if these changes may pose increased risks to patient safety.

The ambition is also to integrate indicators and measures that reflect patient safety in the follow-up of national guidelines and other national knowledge bases.

Follow-up is divided into three areas

- National follow-up and accounting of developments in the field of patient safety through a comprehensive picture of the current situation and over time.
 - Annual progress reports
 - Indicator-based follow-up
 - In-depth analyses in priority areas
- Development of indicators, measures and methods for follow-up
 - For example, on the basis of the basic conditions and focus areas of the action plan, as well as in areas where there are no indicators or data sources
- Follow-up of the implementation of the National Action Plan for increased patient safety.
 - The National Board of Health and Welfare will follow the impact of the Action Plan at national, regional and municipal level.

Follow-up of the implementation of the National Action Plan

The National Board of Health and Welfare will follow up the implementation of the National Action Plan. The follow-up shall show the extent to which the principals have developed action plans or equivalent and follow the movement of patient safety work sought by the National Action Plan. Furthermore, the caregivers (principals are also caregivers) can be encouraged to describe the movement of patient safety work in the annual patient safety report (PSB). In the long term, the national follow-up can be based on content analysis of PSBs. The method of following up the National Action Plan is set in the implementation of each action.

The Action Plan operates in a context with national, regional and municipal patient safety work and other efforts related to patient safety. The National Board of Health and Welfare considers that an external stakeholder needs to monitor and assess the impact of the implementation of the National Action Plan and national coordination of patient safety work. Furthermore, the National Board of Health and Welfare considers that there is a need for follow-up research into developments in the field of patient safety.

Several stakeholders follow up, report and develop assessments

A number of authorities are responsible for monitoring different aspects of patient safety, as well as the caregivers themselves. Several national stakeholders report follow-up in the field of patient safety and there are different registers and databases at authorities and national organisations. There are also several national efforts and initiatives to develop the assessments and reporting of data for healthcare.

A prerequisite for a need-based development of follow-up, with the aim of promoting the administrative burden of care not increasing, is a broad interaction and dialogue between relevant authorities, national stakeholders and principals. It is also important to take into account ongoing national efforts and initiatives, so as to create synergies and not duplication.

Examples of stakeholders

Public Health Agency of Sweden, Health and Social Care Inspectorate, the County Councils' Mutual Insurance Company (Löf), the Swedish Medical Products Agency, the Swedish Health and Social Care Analysis Authority, National Cooperation Group For Patient Safety, the National Board of Health and Welfare, the Swedish Association of Local Authorities and Regions.

Stakeholders with assignments and responsibilities in the field of patient safety

Many stakeholders have responsibilities and assignments that contribute to safer care and which directly or indirectly affect patient safety. These stakeholders are found in different parts of the healthcare system.

Many stakeholders contribute to safer care

The healthcare system itself is complex and difficult to monitor. In addition, different healthcare activities have different needs, depending on the conditions. Joint action on the basis of each stakeholder's tasks and responsibilities is a prerequisite for achieving strong patient safety work.

The Action Plan is aimed at municipalities and regions, so that they can develop their own action plans. Authorities and national organisations are affected and will contribute to the implementation of national measures.

The aim is to ensure that the measures are in place within the framework of the existing appropriations of the authorities concerned, against the background that the majority of the action plan's measures are in line with the existing tasks of the authorities. But there are also a number of other resources that contribute to the overall work. Many stakeholders have responsibilities and assignments in their activities that contribute to safer care and directly or indirectly affect patient safety in healthcare. This applies to principals as well as authorities, organisations, higher educational institutions and individual researchers.

Safety is created in the meeting between patient and professional

The meeting between the patient and the individual employee, where both contribute with their specific knowledge and competence, is central to creating safety. Within healthcare personnel there are also positions and roles that require a certain responsibility for patient safety, e.g. heads of operations, MAS and MAR and chief medical officers. The caregivers and principals create the conditions for the safety work in their operations. In addition, the professional associations in healthcare work actively with quality and patient safety work and develop methods and tools to support healthcare.

The national political level

The Riksdag (Parliament) provides the framework for health care through legislation in this area and decides on the budget. The government has overall responsibility for the political direction of travel, decisions on commitments, strategies for specific investments and initiatives and makes decisions on how public government funding should be used. Within the Cabinet Office, the

Ministry of Social Affairs has overall responsibility for issues related to patient safety and health care.

Authorities have assignments that promote patient safety

Several authorities shall provide principals and caregivers with sufficient conditions to promote a high level of patient safety. The authorities govern in different ways, for example through regulations and general advice or supervision. Many have knowledge support assignments aimed at supporting principals and caregivers with knowledge, knowledge development and method development. Some assignments are registered in the instructions of each authority or the regulatory letter decided annually by the government for each authority. The assignments are financed both in the form of administrative appropriations and through funds in specific government assignments.

The following section presents a selection of the authorities that have assignments in patient safety or whose area of responsibility is linked to patient safety in different ways.

Swedish Work Environment Authority

The Swedish Work Environment Authority is tasked with ensuring that companies and organisations comply with work environment and working hour's laws. The aim is to reduce the risks of ill health and accidents at work and improve the working environment from a holistic perspective.

All employers shall regularly investigate whether there are risks in the working environment and remedy them. The working environment covers both the physical, psychological and social environment in a workplace.

The Swedish Work Environment Authority is responsible for producing regulations clarifying the Work Environment Act (1977:1160), where some of the most basic rules are about systematic work environment work. Furthermore, the authority is responsible for verifying compliance with the legislation, as they do to a large extent by inspecting workplaces. Producing statistics about the work environment and promoting cooperation between employers and workers in the field of the work environment are some other key tasks.

Swedish eHealth Agency

The eHealth Agency coordinates government initiatives and national E-Health initiatives. The authority shall contribute to a better exchange of information within health, care and welfare and is also responsible for registers and IT functions that caregivers and pharmacies need, including for prescribing and dispensing prescriptions.

Public Health Agency of Sweden

The Public Health Agency of Sweden is a national knowledge authority with comprehensive responsibility for public health issues and the mission to promote health, prevent ill health and protect against health threats.

The Public Health Agency of Sweden also has overall national responsibility for the protection of the population against communicable diseases and

coordinates infection protection at national level. This includes coordination of national work on antibiotic resistance and healthcare-related infections.

The Authority is also a national coordinating authority for suicide prevention work. The Authority follows-up and evaluates different methods and initiatives and provides knowledge and methodological support as well as expert support.

Many of the authority's activities are directly or indirectly linked to patient safety. Among other things, the Public Health Agency of Sweden is responsible for monitoring antibiotic resistance, antibiotic use and healthcare-related infections.

Forte

Forte is a state research council that finances research in three areas of responsibility: health, working life and welfare. It is therefore research that affects all people and gives us knowledge to develop, both as individuals and as a society.

Research into health includes, the presence of illness and the factors that affect the risk of suffering from them. The research also concerns efforts to promote health and prevent illness, rehabilitation and nursing, as well as the processes and systems of healthcare.

Health research is also included in the responsibility area of health, which aims to develop the care and welfare of patients, the sick and their relations. In order to improve clinical results, both coordinated research on healthcare as a sector and an evaluation of effective implementation methods are needed.

Health and Social Care Inspectorate

The Health and Social Care Inspectorate (IVO) oversees all healthcare in Sweden (except healthcare within the Armed Forces) by inspecting the health activities and investigating certain notifications. IVO is also responsible for supervising licensed healthcare professionals. The results of the inspections are returned to the caregivers and the general public, both in individual cases through decisions and by systemising and analysing observations at national and regional level.

IVO also takes patients' experiences into account. In addition, in order to contribute to the development of patient safety and promote learning in healthcare, IVO works with dialogue and guidance in its work.

Swedish Medical Products Agency

Patient safety is a fundamental perspective in the Swedish Medical Products Agency's public and animal health responsibility. This includes, among other things,

- scientific review of efficacy and safety prior to drug approval and monitoring of efficacy and safety during use
- authorisation in clinical treatment research
- treatment with licensed medicinal products
- hospital exemptions for advanced therapies
- supervision of medical devices as well as the bodies that CE-label.

The Authority also supervises outpatient and hospital pharmacies, manufacturers, clinical treatment research and the safety systems of pharmaceutical companies.

Adverse drug effects due to drug handling, overdose, abuse, exposure at work and also adverse reactions in so-called "off-label use" shall be reported to the Swedish Medical Products Agency, as well as accidents and incidents with medical devices.

National regulation responsibility, which links to patient safety, is prescription freedom for medicines, drug prescriptions in outpatient care (prescription regulations), drug substitutability, limitations in doctors', nurses' and other professions' prescription rights and exemptions. The Swedish Medical Products Agency also investigates substances for drug classification, and works against illegal trade and illegal marketing. The Swedish Poisons Information Centre and the Medicines Information Agency are other national bodies that contribute to patient safety through information and advice.

The Swedish Agency for Health and Care Services Analysis

The Swedish Agency for Health and Care Services Analysis is responsible for following up and analysing activities and conditions in healthcare, dental care and care from the perspective of a patient, user and citizen. The aim is to help improve and streamline care, dental care and strengthen the position of patients and users. Healthcare analysis produces knowledge documentation and recommendations on the functioning of healthcare and welfare to decision-makers at national, regional and local level. The focus is on areas that are important to patients, users and citizens in areas where there is great potential for improvement.

National Board of Health and Welfare

The National Board of Health and Welfare is a knowledge authority whose activities are directed towards healthcare and social services. The Authority has been instructed by the government to coordinate and support patient safety work in Sweden. The National Board of Health and Welfare's patient safety work is cross-governmental and is carried out in collaboration with several different authorities and parties.

The Authority develops binding rules in the form of regulations as well as knowledge support and guiding products that help healthcare to develop practices and working methods. These may be national guidelines, other recommendations and indicators. In addition, the National Board of Health and Welfare manages and develops several different registers and is the statistical authority for the field of health and social care. Furthermore, it is the National Board of Health and Welfare that examines and issues IDs for healthcare professionals.

Swedish Agency for Health Technology Assessment and Assessment of Social Services

Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) is an authority responsible for carrying out independent evaluations of methods and initiatives in healthcare, dental care, as well as for methods and initiatives in social services and the area of disabilities. The Agency shall compile the evaluations in a simple and easy-to-understand

manner and disseminate them so that principals (i.e. regions and municipalities), caregivers and other interested parties can acquire knowledge.

The Agency shall continuously develop its work in disseminating evaluations in order to apply them in practice and lead to desired changes in healthcare and social services. The Agency shall systematically identify and communicate actively on such practices in healthcare and social services whose effects are lacking with sufficient knowledge.

The Swedish Accident Investigation Authority

The Swedish Accident Investigation Authority (SHK) is responsible for investigating all types of serious civilian or military accidents and incidents from a safety point of view. An investigation aims to provide answers to three questions in particular:

- What happened?
- Why did it happen?
- What can be done to ensure that a similar event does not occur in the future, or to reduce the consequences if it does?

The accident investigation activities are mainly governed by the Law (1990:712) on accident investigation, and the Regulation (1990:717) on accident investigation.

SHK is independent of healthcare stakeholders, both principals and regulatory and inspection authorities.

SHK has analysed the conditions for carrying out further investigations in healthcare and concluded that, with the current financial framework, one or two investigations should be able to be carried out per year starting in 2020. Work is underway to analyse how to use the selection of the events to be investigated more closely, as well as to link medical expertise to the authority.

In addition to the results of the individual investigations and possible recommendations, SHK can contribute with knowledge and competence in accident investigation methodology.

The Swedish Radiation Safety Authority

The Swedish Radiation Safety Authority works proactively and preventively for radiation-safe examinations and treatments in healthcare and dental care. The Authority makes binding rules in the form of regulations. The Authority monitors through regulation and licensing that healthcare complies with the laws and regulations on radiation safety. This work includes, for example, reviewing risk analyses.

Legal requirements also include reporting events relevant from a radiation protection point of view, i.e. those that have led or could have caused serious accidental exposure to patients. In connection with these notifications, the authority examines event analyses.

The Swedish Higher Education Authority (UKÄ)

The Swedish Higher Education Authority (UKÄ) reviews the quality of higher education and education institutions' systems for quality assurance of higher education and research. Furthermore, UKÄ monitors and analyses developments and trends within Swedish colleges and is also responsible for all

official statistics in the field of higher education. UKÄ also exercises legal oversight of all universities and colleges. The Authority actively participates in international cooperation on higher education.

National organisations contribute to safer care

Several organisations at national level have assignments related to patient safety or are working on key issues in patient safety.

The Swedish Association of Local Authorities and Regions

The Swedish Association of Local Authorities and Regions (SALAR) is an employer and association as well as member organisation for all local authorities and regions. The task is to support and contribute to the development of local authorities' and regions' activities. SALAR acts as a network for knowledge exchange and coordination.

For many years SALAR has coordinated national patient safety work, at both operational and strategic level and initially primarily for regions. After the regions have established a knowledge management system, which includes the National Cooperation Group on Patient Safety, the coordination of operational patient safety work has been taken over by the cooperation group. However, SALAR continues to coordinate the national patient safety work within local authority healthcare.

SALAR's patient safety work is moving more towards a strategic level with a focus on the future challenges of care such as close care, strategic concentration of care and digital and technological development. To achieve this, SALAR will in cooperation with the regions and local authorities, based on the National Action Plan, collaborate with the National Board of Health and Welfare, with the prioritisation and implementation of national measures with a view to facilitating principles' patient safety work.

The County Councils' Mutual Insurance Company (Löf)

The County Councils' Mutual Insurance Company (Löf) is a nationwide insurance company owned by the regions. Löf insures the caregivers financed by the regions.

The assignment is to investigate and provide compensation according to the Patient Injury Act (1996:799) to patients who are injured in care and work towards increased patient safety. Löf therefore performs injury prevention through targeted initiatives, training and research support. Löf, together with professional organisations, has started several patient safety projects aimed at healthcare.

Patient boards

Patient boards are located in each region and some municipalities. They are tasked with supporting and helping patients and their relatives in virtually all publicly funded healthcare.

The main task of the boards is to help patients to make complaints to caregivers appropriately and to ensure that they are answered. They also help patients get the information they may need. If the patient is a child, the patient board should pay particular attention to the best interests of the child.

Patient boards also give feedback to care about observations and abnormalities that matter to patients. The purpose of this is to make the healthcare aware of any improvements that need to be made. By annually analysing the complaints and comments received, the boards pay attention to the region or municipality in risk areas and obstacles to the development of healthcare. Furthermore, the Patient Board is not a supervisory body and has no disciplinary powers.

Almega Employers' Organisation

Almega Employers' Organisation is an employer's and industry association for private caregivers in the Swedish service sector. The goal is for members to provide high-quality, safe and effective care and welfare. The organisation participates in national collaboration groups and pursues issues of transparency, national quality indicators and providing information to professionals, patients and related parties.

Professional associations in healthcare

The professional associations in healthcare work actively with quality and patient safety work and develop methods and tools to support healthcare.

One example is the publication *Säker vård – en kärnkompetens för säker vård* (*Safe Care – a core competence for safe care*) produced by the Swedish Society of Nursing, the Swedish Society of Medicine, the Swedish Association of Occupational Therapists, Physiotherapists, the Swedish association of clinical dieticians (DRF) and the Swedish Dental Association. The publication describes what knowledge employees need to provide safe care, and what characterises an organisation where patient safety puts a stamp on the entire business.

National Board of Health and Welfare's assessments of overall responsibility and roles

Stakeholder	Responsibility
Parliament and government	<p>The Riksdag (Parliament) provides the framework for health care through legislation in this area and decides on the budget.</p> <p>The government has overall responsibility for the political direction of travel, decisions on commitments, strategies for specific investments and initiatives and makes decisions on how public government funding should be used.</p> <p>Within the Cabinet Office, the Ministry of Social Affairs has overall responsibility for issues related to patient safety and health care.</p>
National Board of Health and Welfare	<p>Support patient safety work in the country.</p> <p>Initiate collaboration in patient safety advice.</p> <p>Participate in the implementation of the National Action Plan on patient safety, within the framework of the Authority's mission.</p> <p>Contribute to and create a forum for dialogue and dissemination of knowledge at national, regional and municipal level.</p> <p>Manage, develop and make the website "gathered support in patient safety" accessible, and in order to raise awareness and knowledge in the field, to promote the development of patient safety training efforts.</p> <p>Through progress reports, in-depth analyses and follow-up of the implementation of the action plan, follow national developments in the field of patient safety.</p> <p>Participate in and support the international patient safety work.</p>
Relevant authorities	<p>Participate in the implementation of the National Action Plan on patient safety, within the framework of the relevant Authority's mission.</p> <p>Collaborate in patient safety advice.</p> <p>Collaborate and cooperate in relevant assignments that have bearing on patient safety.</p> <p>Contribute to development and follow-up within the framework of each authority's assignments.</p>
Relevant national organisations	<p>Contribute to and support the implementation of the National Action Plan.</p> <p>Participate in the implementation of the National Action Plan on patient safety, within the framework of the relevant Organisation's mission.</p> <p>Cooperate and cooperate with authorities and other stakeholders on patient safety issues.</p> <p>Contribute to increased awareness and learning about patient safety and participate in disseminating lessons from improvement work.</p> <p>Contribute to development and follow-up within the framework of each organisation's assignments.</p>
Regions and municipalities	<p>Regions and municipalities must be able to develop their own action plans to establish principles, priorities and objectives for patient safety work, based on the National Action Plan.</p>
National Cooperation Group - Patient Safety (NSG)	<p>Contribute to and support the implementation of the National Action Plan.</p> <p>Cooperate and cooperate with authorities and other stakeholders on patient safety issues.</p> <p>Participate in the implementation of the National Action Plan on patient safety, within the framework of the NSG's mission.</p> <p>setting up national working groups in priority areas</p> <p>leading and coordinating patient safety work of the regions</p> <p>contribute to development and follow-up</p>

Stakeholder	Responsibility
Professional associations and trade unions	Cooperate with authorities and other stakeholders on patient safety issues. Support the implementation of the National Action Plan for patient safety. Contribute to increased awareness and learning about patient safety. Contribute to development and follow-up within the framework of each organisation's assignments.
Patient, relative and user organisations	Contribute to the work of authorities and stakeholders for increased patient safety so that the patient, relatives and user perspective is visible at the individual, process and system level. Contribute to development and follow-up from a patient and relatives perspective

This list shall not be seen as an exhaustive list and will be updated as necessary.

Dictionary

Definitions, terms and explanations of words are taken from the relevant legislation, the National Board of Health and Welfare's term bank socialstyrelsen.se/termbank and from the website *Samlat stöd för patientsäkerhet*, patientsakerhet.socialstyrelsen.se.

The term bank contains terms for the specialist area of health and social care that have been analysed according to the methods and principles of terminology and anchored internally on the National Board of Health and Welfare and in referral to municipalities, regions, private caregivers, authorities and other organisations.

The explanations of words are produced by experts in patient safety and terminology at the National Board of Health and Welfare in cooperation with national experts in the field.

Deviation, term: event that caused or could have led to something unwanted

Diagnostic error, word explanation: Deficiency in the diagnostic process that leads to a diagnosis not being made, not being accurate or not put in place in time to take sufficient measures.

Preventive action, term: (in health and social care) action to prevent the emergence of or affect the course of diseases, injuries, physical, mental or social problems.

Non-avoidable patient injury, term: injury to patients occurring despite sufficient measures taken during the patient's contact with the healthcare system.

Management system, definition according to the Board of Health and Welfare's management system regulation (SOSFS 2011:9): systems for establishing principles for the management of the business.

Drug management, term: prescription, requisition, storage, dispatch, preparation, supply and administration of drugs.

Relative, term: person to whom the individual considers her/himself to have a close relationship.

Patient safety, definition according to the Patient Safety Act, PSA: protection against injury (Chapter 1. section 6 PSA).

Patient safety work, term: part of a caregiver's systematic quality work aimed at protection against adverse events.

Patient safety culture: word explanation: How patient safety is perceived, prioritised and managed in the organisation. Patient safety culture is the result

of the values, attitudes, competences and behaviour patterns of individuals, leaders and groups. It reflects the commitment and ability to create protection against adverse events at all levels of the organisation.

Risk analysis, term: systematic identification and assessment of risks in a particular context.

Risk area, term: area in which injury to people, environment or property may be feared, or where further injury may occur.

Injury to patient, term: suffering, bodily or psychological injury or illness, and death suffered by a patient.

System safety in healthcare, word explanation: Characteristic in healthcare which eliminates or limits the risk of injury to a person, property or the environment to an acceptable level.

Safety, word explanation: In patient safety work, work has to be carried out from two perspectives. It is both a matter of preventing errors and ensuring that it is right. The first perspective is usually referred to as safety I in English, and the second, safety II. The first perspective is based on the view that underlying causes of negative events can be identified and addressed so that there are fewer errors. The second perspective is based on the view that variations in everyday work mean that sometimes things are right, sometimes wrong. The work aims to understand and manage the variations so that more is right. Writing safety I and safety II can lead to the idea that there would be two different safety concepts. It is therefore better to talk about safety from two different perspectives than to translate the English expressions into Swedish.

Safety culture in healthcare, word explanation: Safety culture in healthcare is how safety is perceived, prioritised and managed in the organisation. Safety culture is the result of the values, attitudes, competences and behaviour patterns of individuals, leaders and groups. It reflects the commitment and ability to create safety at all levels of the organisation.

Relocated patient, term: enrolled patient who is cared for in a care unit other than that with specific competence and medical responsibility for the patient.

Care-related infection, term: infection occurring in a person during inpatient care or as a result of action in the form of diagnostics, treatment or care in other care, or welfare incurred by staff working in healthcare as a result of their professional practice.

Adverse events, definition according to PSA: suffering, bodily or psychological injury or illness, and death that could have been avoided if sufficient measures had been taken in the patient's contact with the healthcare system (chapter 1 section 5 PSA).

Overcrowding, term: event when an enrolled patient is cared for in a care space that does not meet the requirements of available care space.

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Källorna nedan ska inte ses som en uttömmande lista utan är en sammanfattning av de mest centrala källorna som används vid framtagningen av handlingsplanen. För ytterligare information hänvisas till; Nationell handlingsplan för ökad patientsäkerhet. Socialstyrelsens rapport i regeringsuppdrag S2018/04111/FS.

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To healthcare agencies, organisations and professionals

An estimated 100 000 patients are affected of adverse events each year. It is far too many. To strengthen and coordinate the patient safety work, the National Board of Health and Welfare has developed a national action plan that addresses and support municipalities and regions, as well as authorities and national organisations. The work has been carried out in broad collaboration with relevant agencies, organisations and experts. The common goal is clear – no patient should have to suffer from preventable harm.