Improve patient safety and patient safety culture

Phase 4

Support for improving quality of healthcare and patient safety in Slovenia

RFS REFORM/SC2020/021
AARC - Consortium

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ABBREVIATIONS

AQuAS	Catalan Agency for Health Quality and Evaluation
CRM	Clinical Risk Management
DALY	Disability-Adjusted Life Years
EC	European Commission
EU	European Union
GRC	Centre for Clinical Risk Management and Patient Safety
HSA	Health and Safety Authority
HSE	Health and Safety Executive
ICT	Information Communication Technology
KSA	Knowledge, Skills, Attitude
LMIC	Low-Medium Income Countries
MaPSaF	Manchester Patient Safety Framework
NAKVIS	National Agency for Quality in Slovenian Higher Education
OECD	Organisation for Economic Cooperation and Development
OWG	Operational Working Group
PS	Patient Safety
PSC	Patient Safety Culture
PSI	Patient Safety Indicators
PSMS	Patient Safety Management System
PSS	Patient Safety System
QI	Quality Improvement
QIPS	Quality Improvement and PatientS
QoC	Quality of Care
SAQ	Safety Attitude Questionnaire
SOPS	Survey On Patient Safety Culture
WHA	World Health Assembly
WHO	World Health Organisation
TAPIC	Transparency, Accountability, Participation, Integrity, Capacity

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PART 1: Proposal for the Slovenian Comprehensive Patient Safety System

1. INTRODUCTION

The overarching objective of this project, of which Patient Safety (PS), Patient Safety Culture (PSC), and competencies for PS area part, is to contribute to institutional, administrative, and growth-sustaining structural reforms in Slovenia, in line with Article 4 of the SRSP Regulation.

In healthcare, the main objective is providing safe healthcare to large numbers of people at a reasonable cost and without avoidable harm. A sense of safety is one of the patients' essential needs and it is a **fundamental human right**. Every patient's contact with a care process can comprise an intrinsic risk. The challenge for health systems and all facilities providing health care is maintaining PS by detecting and analyzing errors. This is a retrograde approach and is the subject of PS-I, a system defined as freedom from unacceptable harm or as little as possible goes wrong. Humans are often considered the culprit. Investments in learning from errors and standardization are then the usual response. Another recently recognized system is Safety-II, an approach where as much as possible goes well. Safety-II focuses on daily adaptive activities contribution to safety.

Humans are considered as adaptive, flexible agents who manage complex situations. The organisation examines what goes right and spreads the good practice. Investment is in capacity and competencies. In many parts of the world the person approach and Safaty-I tends to be focused on the assumption that errors happen due to individual actions, thoughts and beliefs and leads to “shame and blame culture” thus heavily inhibiting learning from errors and prevention of avoidable patient harm in the future. A system approach, in contrast, depicts errors as expected since humans are fallible. It follows that systems have to be designed to involve safeguards for preventing errors on all levels of health care. A system approach has to be taken to enhance PS (1,2).

Recently a new insight into errors in healthcare has occurred. Drawing from resilience engineering, the Safety-II approach has been developed. Safety-II, the alternative view to Safety-I, argues that everyday performance variability provides the flexibility to excel under diverse conditions. Humans – the most flexible system components – are key to elasticity and resilience in systems. Humans deliver positive outcomes despite uncertainties and prevent safety lapses more often than they cause them. Therefore, it is more valuable to study how, despite inconsistencies and ambiguities, systems primarily produce the proper care and good outcomes (3,4).

The main problem in Slovenia is that there is no awareness that PS is a public health crisis. Almost nobody wants to publically expose the problem as this is among politicians and many providers’ organisations a tabu.

“No one should be harmed while seeking care”.

WHO

Health care systems and facilities provide variable degrees of performance in PS. This can be seen across the world and within countries. Errors because of flawed systems are common and keep causing harm to individuals. These problems are not unique to anyone's health system; however, they have been mostly intractable for many years. Any harm caused to a healthcare recipient must not be tolerated and be thus a new paradigm in health care based on every strategy, every step in the design of every program, every clinical encounter, every occasion to learn when something goes wrong (5,6).

Governments, health systems and providers have to protect patients and the public from harm. PS is a strategic priority for any health care and is central to **Slovenia's** efforts in working towards safe care. The efforts to prevent avoidable harm are tightly coupled with a high-quality health system that optimises health care and consistently delivers care that is valued and trusted by all people and by responding to changing population needs. Quality should not be seen as a word to represent one's greatness. It has to be judged primarily on their impacts, including better health and its equitable distribution, on the confidence of people of the health system and their economic benefit and care processes, involving competent care and positive user experience. Four values should know high-quality and safe health system: it is for people, equitable, resilient, and efficient (7).

The purpose is to propose a comprehensive **PS system** based on PS science. A detailed Clinical Risk Management (CRM) system has been presented in Phase 3 of this project. The PS system design aims to create structures, processes, technology, environments, and behavior in health care to reduce avoidable harm.

This document is based on PS science and experience in different countries with many years of improvement efforts worldwide. Core sources were papers on PS of European Commission, Organisation for Economic Cooperation and Development (OECD) and World Health Organisation (WHO), Ministry of Health of the Republic of Slovenia, chosen European Union (EU) states and other countries and contribution of Slovenian stakeholders and researchers.

Safety culture is a necessary fundamental prerequisite for the improvement of PS. Developing a safety culture is essential to any sustainable efforts towards PS improvement. Policy and legislative interventions can provide a favorable environment for a thriving safety culture. The safety culture must interweave with the overall organizational philosophy and culture. PS culture is multidimensional with several features: culture of knowledge and system thinking, flexible culture, just culture, a culture of reporting and risk management and culture of learning.

Competencies for quality and PS are prerequisites for high quality and safe health care**.** As healthcare is a sociotechnical domain, it is not enough for healthcare professionals to obtain and further develop only technical competencies but also competencies in QI and PS. Thus quality and PS are also social processes that influence behaviour.

1.1. Magnitude of the problem of patient safety

1.1.1. Global burden of preventable patient harm

Two or three decades ago, not much was written or said about pS worldwide. More attention to PS problems ensued following the publication "To Err is Human," which estimates that at least 44,000 and possibly as many as 98,000 Americans die in hospitals each year due to errors (8). Although the assessed death toll from adverse events raised some dust among the regulators and physicians in Slovenia, the "solution" was not directed to systematically improving PS problems (9).

Much has been learned about safety epidemiology since “To Err Is Human” was published. Although numerous effective solutions have been developed for some safety issues, their implementation and practice have been inconsistent. Progress in preventing patient harm such as pressure ulcers, deep venous thrombosis, embolism, and falls have been variable. Even “never events” such as wrong-patient and wrong-site surgery still occur. In recent years, the attention has also been on economic losses and access problems due to unsafe care that may become a significant barrier to safe care.

The extent of the problem with preventable patient harm is taking pandemic expansion.

a) Physical and mental harm to patients

- The occurrence of patient harm due to unsafe care is most likely one of the 10 leading causes of death and disability in the world
- In high-income nations, it is estimated that one in every 10 patients is harmed while receiving hospital care (2)
- The harm can be triggered by a range of adverse events, with almost 50% of them being avoidable (3,10)
- Every year, 134 million adverse events occur in hospitals in low -and middle- income countries (LMICs) because of unsafe care, resulting in 2.6 million deaths (11)
- It is suggested that, globally, unsafe care results in the loss of 64 million disability-adjusted life years annually (referred to as disability-adjusted life years, or DALYs) occur in LMICs (12)
- Worldwide, as many as 4 in 10 patients are injured in primary and outpatient health care. As much as 80% of harm is avoidable. The most detrimental errors relate to diagnosis, prescription, and the use of medications (13)
- Estimation in **Slovenia** would thus be around 35.000 patient harms and approximately 1000 deaths per year in acute hospitals; however, a proper study was never conducted after piloting for unknown reasons (9)
- An example of prevention is engaging patients, and if done well, it can reduce the burden of harm by as much as 15% (13)
- The SARS-CoV-2 pandemic has exposed the real risk of patient harm. The estimated percentage of hospital-acquired Covid-19 cases ranges from 12.5% to 44%. A third of these cases are related to healthcare staff (14)

b) Economic burden

Governments, health systems, and providers should move from analysis to action to make decisions about safety strategies, programmes and interventions that can be implemented in a context of limited resources to generate the best value and return on investment across a system.

- In OECD countries, 15% of total hospital activity and expense is a result of adverse events. The economic cost of unsafe care can be seen in two ways: the direct cost due to resource wastages and the indirect costs of loss of productivity in the population
- The cost of harm in hospital, primary and ambulatory care is estimated 3% of GDP in developing countries (13)
- Estimation in **Slovenian hospitals** is around 240 million euros hospital expenditure in 2016, based on OECD assessment of 15% of total hospital activity and expense as a direct result of adverse events. This can be translated into approximately 10.000 employments in health and social care, taking the average gross salary of around 1950 in 2019. Slovenian Statistical Office of Republic of Slovenia (https://www.stat.si/StatWeb/) (accessed 23.8.2021)
- Eliminating harm could boost global economic growth by over 0.7% a year (14)

c) Investment

Investments in decreasing patient harm can result in considerable financial savings, and more importantly, better patient outcomes. Interventions to avoid avoidable harm to patients and staff require mobilising significant resources. These are currently small compared to the direct and indirect costs generated by harm. Therefore, investing in safety is a first-rate value suggestion because it improves health outcomes and reduces costs linked with harm. The resources can then be allocated where they will generate additional benefits.Value can be created through allocation and investment at three levels of a health system: clinical, organisational and systemic. This cannot be accomplished with a fragmented approach (15).

1.1.2. Burden of preventable patient harm in Slovenia

In Slovenia, there were some fragmented efforts to improve PS. Unfortunately, there has never been proper governance of the system of PS, neither at the national level nor at the level of healthcare facilities and not much support from some professional organisations. Particulars are described in Situation analysis - National context of Quality of Care (QoC), PS and CRM and patient compensation (Deliverable 2).

PS is somewhat neglected because of the assumptions and public communication from the regulator and top management of healthcare facilities that patients are safe.

The reality is that unintended harm occurs in Slovenian hospitals every 2 hours*

Every 8 hours, someone dies*

Patient safety incidents are the fourth leading cause of death in Slovenia*

*These data are based on extrapolating data from studies in developed countries -around 35000 preventable haram and 1000 preventable deaths in hospitals each year.

1.1.3. Barriers to patient safety

There are many complex and safety-critical industries where many resources are invested into safety systems. Comparison between healthcare and other safety-critical industries shows the differences in approaching safety (box 1) (16).

Box 1: Comparison of healthcare safety barriers to other safety-critical industries

- Insufficient understanding of safety due to the intrinsic motivation and professionalism of clinical staff in healthcare, whereas better safety understanding due to the commercial, political, social and humanitarian pressures in others
- More money investment to design safer systems in other safety-critical industries
- Better procurement process in other safety-critical industries
- Better recognition of the task analysis in other safety-critical industries
- Better knowledge management on quality and PS in other safety-critical industries
- Better reporting systems (including near misses, potential incidents) in other safety-critical industries
- Poorly developed safety culture, whereas others strive to become proactive safety cultures
- More efficient systematic management of the hazards of the business in other safety-critical industries
- Medical staff are more likely than aviation staff to deny the effects of stress and fatigue
- Surgeons are less likely to advocate flat hierarchies than cockpit crews
- On-going measurement of safety culture is less common in healthcare, whereas direct assessment of safety culture in others
- Accident investigation is fragmented and decentralized in healthcare, whereas very centralized in others
- An extraordinarily diverse set of activities in healthcare, whereas usually have a limited set of activities in others
- High levels of uncertainty in some areas (e.g. emergency) in healthcare, whereas ideally routine in others
- Much of healthcare work is very 'hands-on', whereas operators perform routine control and monitoring activities of others
- Better standardized methods of investigation, documenting and disseminating errors and their lessons to others
- Surgeons are worse than pilots at working in teams
- Better training conditions for safety in other safety-critical industries
- Healthcare systems are designed to rely on individuals' error-free performance and not on a system of safety
- CRM depends on a small number of people in healthcare, whereas safety is the responsibility of everyone working in safety-critical industries

Public opinion revealed that civil society (over 90%) still sees PS as an issue in the EU. The most important barriers recognized were:

- Lack of budget and resources mainly concerns when combined with the lack of political will and healthcare professionals' engagement in PS
- At the healthcare setting level, a top-down attitude by clinicians predominantly regarding patient involvement
- Failure to achieve awareness in hospitals of the significance of PS
- Prevailing “blame-cultures” which prevents concentrating on causes of errors and ways to eliminate them
- Reporting, which is still not understood as a learning enabler and insufficient IT infrastructures to support data analysis (17)

The Eurobarometer survey showed Slovenia citizens' responses about PS and QoC. In 2013 citizens thought that the possibility to be harmed in hospitals and other facilities of healthcare is high, around 50%. Adverse events occurred to them in 31%. Eleven percent of citizens reported the adverse event to the authorities. Most of them seek the help of layers (18).

In **Slovenia**, healthcare staff lives in a culture of fear instead of having just culture. Physicians' reactions are typical in hiding the errors, ascribing them to complications, avoiding risky procedures, and practicing defensive medicine (19). The culture of fear is also responsible for the poor reporting of avoidable patient harm and near misses. For example, in 2020 in a small

hospital, there were only 5 reports in the internal reporting system and 40 in a larger hospital. Sentinel events reporting to MoH are also scarce.

Usual scenarios occurring when there is preventable harm to a patient are:

- The patients were told that this is due to their illness or treatment complication
- If the real cause of the harm was an error, it was hidden from the patient and family

Some of the reasons for such behaviors were glorifying doctors' perfection and keeping quiet about these problems in teaching medical students and junior doctors and other health professionals. The usual analysis of adverse events is outdated, damaging to patients and providers with rare exceptions, mainly following the Health Services Act and Criminal code. Customarily, internal and external control teams do not find anything wrong, or an individual doctor or other medical professional is blamed. Slovenian Criminal code and judiciary practice is focused on an individual healthcare worker who made a human error if a patient suffers harm and the systemic issues are always ignored. It has not yet been realized that the healthcare staff works in an imperfect system or a process inclined to contribute to avoidable patient harm. The courts do not ask themselves why errors continue to occur, despite the accusations of individuals for human error.

Gaps between the present situation in Slovenia and a comprehensive PSS are described in the situation analysis paper (Deliverable 2) and the most important are:

a) National level

- No comprehensive law on PS and quality
- No up to date policy and strategy on PS
- Gaps in the governance of PS, including gaps in capability
- Political influence/agenda - with every change of the government political plan, it has changed with different emphases on quality and PS priorities, awareness and commitment of the MoH
- No independent body for quality and PS
- No involvement of all relevant stakeholders
- Poor following of EC recommendations
- No adequate information communication technology (ICT)
- No budget for research in QoC and PS and for projects to improve and research on health services, for training in PS and CRM at healthcare facilities
- No political agenda of any kind for the type of compensation scheme for medical injuries, either fault or no-fault based
- No political position or legal opinion on the current Criminal Code, which contains in its provisions several different criminal offenses healthcare professionals may commit
- No comprehensive regulated requirements for education for graduate, postgraduate, and healthcare employees for quality and safety
- No data and no studies on the type and extend of defensive medicine and what are health and medical, economic and legal consequences and implications due to defensive medicine

b) Healthcare organizations

- Gaps in the clinical governance of PS and quality
- No standardized capacity and competencies for quality and PS management
- Missing many QoC and PS tools
- Inappropriate management of indicators
- Lack of competencies for QoC and PS
- Significant unjustified variability among healthcare providers regarding results of care

- Almost no projects for the improvement of quality and PS
- An inconsistent learning environment for PS and QoC
- Lack of physician and patient involvement in PS and QoC
- Lack of Governing board and healthcare professional accountability for PS and QoC
- Many professionals and the general public have a cultural notion that individual healthcare staff is responsible and accountable for errors

c) Consequences of no action

Figure 1 displays outcomes of no actions from the government, health systems and providers.

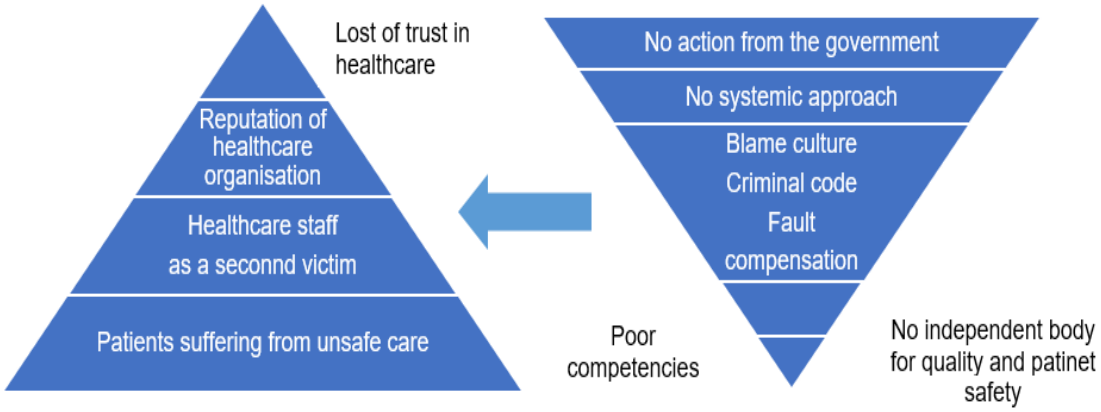

Figure 1. Consequences of no action

Source: Prosunt©

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2. METHODOLOGY

2.1. Compilation of information – Desktop review

A non-exhaustive **literature review** on systems of PS, PS strategies and action plan, patient safety culture (PSC) and competencies for quality and PS of healthcare professionals in the developing countries, concentrating mainly on relevant documents of European Commission (EC), OECD, WHO, previous work at the national level, international accreditation standards used in Slovenia and ISO 9001 were assessed. The gaps identified in the situational analysis were also considered.

The primary document for PS strategy and action plans used in this report was *Global Patient Safety Action Plan 2021–2030 - Towards eliminating avoidable harm in health care*. Large groups of international experts and organizations like International Hospital Federation, International Council of Nurses, OECD, International Pharmaceutical Federation, International Society for Quality In Health, Joint Commission International, Institute for Healthcare Improvement, World Medical Association, International Ergonomics Association, World Organization of Family Doctors, International Alliance of Patients' Organizations, WHO, and many member states of EU and WHO contributed significantly to the development of the initial draft of the global action plan. This plan has taken into account all that is at present known about PSS and does not focus only on some aspects of PS.

2.2. Comparative analysis of patient safety used in EU and other countries

State of the art of PS and in three states and two regions was studied: Tuscany (Italy), Ireland, Catalonia (Spain), Australia, and Denmark as a part of phase 3 of the project. The details are provided in a complementary document in pdf format name: *SRSS - QoC PS - T3.2. on Comparative analysis and the appendix A.*

The conclusion of these benchmarks showed that all analysed countries own **governance structures** (public organizations or institutions) responsible for overseeing QoC and PS issues (except for the Tuscany region whom institution focuses on CRM and PS).

Each of the analysed countries have an adequate governance structure to its specific characteristics and all of them depend on their respective MoH.

Plans for QoC and PS revealed that all have one or more strategic plans specifically about Quality and PS. Objectives are similar, but the approaches are different.

Common goals are:

- Importance of **continuous QI** to achieve better QoC
- Improvement based on **patient-centred** culture and patient experience
- Promotion of **safety culture** through the oversee, identification, and prevention of **adverse events**
- Support to health professionals through PS **education/training programmes**
- Establishment of a **PS strategy** and development of a **communication plan**

All analyzed countries implement a **PSC** prioritizing **education, training, and research** on patient safety to healthcare professionals, making the special focus on Managers and Directors capacitation. Particular strategies differ among countries, but they pursue these goals through initiatives like specific training programs, masters, forums, newsletters, etc.

Details for each county are described in appendix A.

2.3 Workshop

2.3.1 Identifying relevant existing national documents with OWG

A workshop with OWGs was conducted in the Slovenian language on 16th September 2021 at the MoH as a part of the celebration of World Patient Safety Day. The task for the OWG was, following the inception report (T4.1) to identify the relevant national documents on PS and PSC and competencies on quality and patient safety for healthcare professionals.
The OWG and experts identified the most important national documents and references literature in the Slovenian language and opportunities for improvements in PSS, PSC, and competencies for quality and PS (Appendix B).

2.3.2 Prioritization of proposed strategic goals, strategies, and action plans in PS for consensus with the named OWG

In the workshop on 14th of March 2022, the patient safety system was presented to 15 chosen providers with the topics on comprehensive patient safety system, clinical risk management, patient safety culture and competencies for patient safety. Current gaps and strategic goals were shown. In the discussion, there was a mention of lack of financial resources for future implementation of strategy. The participants were informed on the planned survey of the present organisation and the delivery of patient safety in their facilities. The list of strategic goals and strategies for patient safety for the timeline prioritization proposal was delivered to OWG. No answers after several reminders to comment were received and thus it was concluded that OWG agreed to the proposed timeline.

2.3.3 Identify and develop an assessment questionnaire for PS culture, addressed to and customized for different types of healthcare providers.

A survey In 2019 an electronic survey among the hospitals' leaders was conducted with the current opinion of hospital leaders before starting the national measurement of safety culture. 35 questionnaires from a total of 19 hospitals were included in the analysis (55). Results are shown in Part 2 – section 3 - measurement of patient safety culture.

2.3.4 Support selected healthcare providers for their local plans for patient strategies and action plans

On the 4th of May 2022 presentation in person was conducted on how to implement PS strategy and action plans at the local level of healthcare. There were 9 participants from 6 facilities of 15 invited (3 tertiary hospitals and 3 secondary hospitals). Nurses and one physician represented these providers. They were mainly from quality commissions of their institutions. From MoH there was only one representative. Structures necessary for the implementation, processes, and expected outcomes were discussed. The responsibilities and accountabilities for the implementation at the different levels a healthcare organisation was also shown. A concrete example of how to practically implement a strategy and action plans was explained likewise. The final discussion was in the form of a round table and the main concerns were that there is not enough time for the implementation as there are no full-time personnel for QoC and PS and management just gives the staff additional work above their regular work duties. Lack of support from the top management and lack of a specific budget for QoC and PS was also emphasized and a desire of helping the implementation of strategy and action plans conducted by an independent national body for QoC and PS (that does not yet exist) or MoH.

2.3.5 Preparation lists of competencies for quality and patient safety

A comprehensive list of competencies divided into the necessary knowledge, skills and attitudes was prepared and is a part of this report (Part 3 - Section 3).

3. GOAL, CONTENT, AND OBJECTIVES OF PATIENT SAFETY SYSTEM AND PATIENT SAFETY CULTURE

The goal is to propose a comprehensive PSS based on the science and experience of PS. The PSS design aims to create structures, processes, technology, environments, and behavior in health care to reduce avoidable harm.

The objectives PSS is to propose a framework for PS, policy and principles, governance, a partnership of stakeholders, strategic goals, strategies, action plan, tools, implementation of indicators concerning strategic goals to judge execution at national and health care facility levels.

The objectives PSC is to propose national requirements to promote and improve PSC in healthcare facilities, processes, tools, measurement, and assessment of PSC.

The objective of a framework for competencies is to list KSA for PS that current healthcare systems require of their practitioners.

4. PATIENT SAFETY SYSTEM

"Patient safety is prevention of avoidable harm to patients".

WHO

4.1. Outline of patient safety system conceptual framework

PS is a science and relies on many disciplines like health services research, applied psychology, behavioural science, human factors - ergonomics, communication science, accident theory, and systems research (1).

The global objective is to reach zero avoidable harm and as it looks now, it cannot be reached if we stick to old approaches to improve PS (Figure 2). A mindset of zero harm and frames of concept, policy, governance, and strategic goals with the implementation of action plans of delivering health care would be a great change from the current status quo. We have the potential to make an enormous decrease in death, disability, physical and psychological injury from unsafe care.

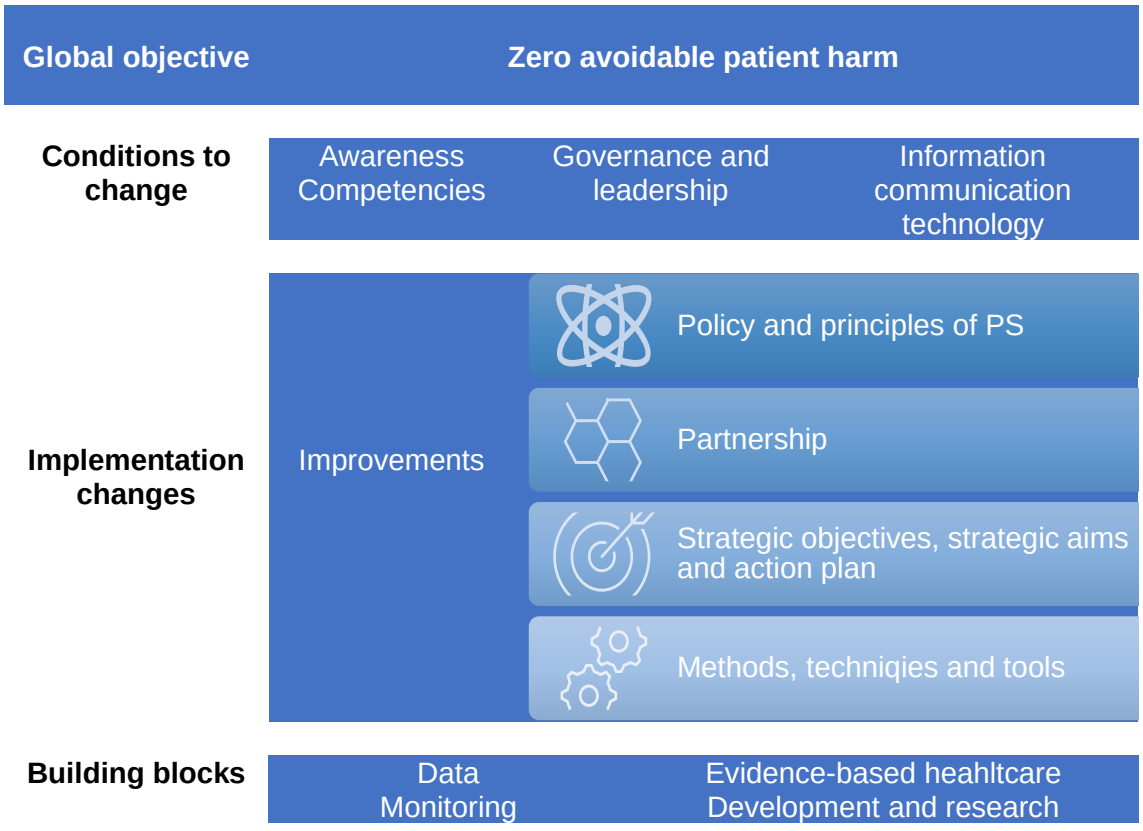

Figure 2. A pathway towards zero avoidable harm

Source: Prosunt©

PS is a task or set of technical measures and a way of thinking about everything we do - what we do right, what can go wrong, what we do when it goes wrong, and how we set up systems to prevent errors. Thus, PS is strongly linked to PSC, organizational and national culture, systemic view of healthcare and its organization.

Most errors have their roots in systems and processes, where many latent conditions await to occur. Active errors thus occur in such systems and processes. However, some safety

problems relate to substandard individual performance, unjustified violations or risky behaviour, or rarely due to intentional harm to the patient (2,3).

Traditionally, the scientific and/or technical knowledge originates from policymakers, health system leaders, health care professionals, academics, and managers, but the interest originates from citizens, civil society, and patient advocates. Developing and implementing a plan demands scientific and/or technical knowledge. It likewise must have the buy-in and positive emotional drive of those who recall that too many past patients and families have experienced loss and severe harm due to flawed healthcare. Hence, combining the top-down and bottom-up approaches is the right thing to do. The bottom-up approach implies input from personnel and patients, partnership with management, and compliance. Top-down methods produce legislation and guidelines from higher authorities and top management, providing personnel with tasks delegated by management.

PS is a framework of organized activities that create structures, processes, and culture patterns of behaviours in health care that consistently and sustainably lower risk, reduce the occurrence of avoidable harm, make the error less likely and reduce its impact when it does occur (4).

Several elements are necessary to implement a comprehensive PS framework into all levels of healthcare (figure 2, and figure 3).

Figure 3. Necessary elements for a comprehensive patient safety system

Source: Prosunt©

Mission, vision goals and values are shown in figure 4.

a) Mission

Delivery of policies, governance, strategy, action planning, and system design based on science and partnership to eliminate avoidable harm and risks to patients and healthcare workers.

b) Vision

Nobody is harmed in health care due to avoidable adverse events.
Every patient receives safe and respectful care, each time, everywhere.

c) Goal

Attain highest possible reduction of avoidable harm due to unsafe care.

d) Values

Values shape attitudes of responsible stakeholders towards PS.

Excellence - high-level performance in everyday work and services is cherished
Honesty- words and actions that build trust are valued
Respect - each patient who seeks care and each person who care for him/her is respected
Empathy – understanding and sharing the feelings of another is valued
Kindness - the approach to patients, staff and stakeholders is considerate and kind is respectful of their values
Humility – is virtue of excellence; it is not humiliation but appreciation of one's competencies and shortcomings and enables the ongoing cooperation

Figure 4. Mission, vision, goal and values

Source: OWG for patient safety

4.2. Policy and principles of patient safety

The **purpose** of the national and local policy on PS is to improve PS, staff safety and reduce risk to patients and staff through an environment that encourages strategy arrangement of PS taking into consideration **system, organization of care and clinical strategies to improve PS.**

At the heart of successful policy implementation is empowered stakeholders across the system, who should be enthusiastic partners interested in the policy's success. There may be a case for mandatory adherence to standards in some circumstances. Various forms of sanctions may affect licensing[1], clinical privileges, accreditation, or funding, and there may be recourse to legal mechanisms, including fines or other activities through the legal systems. The policy should be officially adopted, and decide how the policy will interface with existing health system policy and legislation.

The policy framework is based on a continuous improvement and knowledge exchange model to support the development of effective, adaptable and evidence-based policies at different levels across the Slovenian healthcare system.

Hopefully, the policy framework on PS and strategies will encourage government, regulators, payors, researchers, private and public healthcare delivery organizations, front-line care providers, health managers, leaders, patients and their families, and the broader Slovenian public.

Patient care should be safe across the country, and efforts are made to prevent, respond to and learn from a PS incident and act proactively to avoid patient harm.

If healthcare is not safe, then this is not the care (5)

People in Slovenia need policies that support PS at the level of the government and healthcare organizations. Policies must include PS competencies, adherence to accreditation standards and strong governance. In addition, a shift in mindset and culture is necessary to approach zero avoidable harm successfully.

[1] Licensing in this context is in Slovenia named »Verification of Healthcare facilities«; licensing in Slovenia means to grant permission to an individual to practice their profession in their field of expertise.

The policy applies both to public and private healthcare. It provides a clear roadmap and outlines “how” the policy will come to reality. PS policy formulates guidelines for approaching PS to reach high reliability and resilient state of national healthcare. It forms the external framework for implementing a PSS and is the foundation of a PS strategy (figure 5).

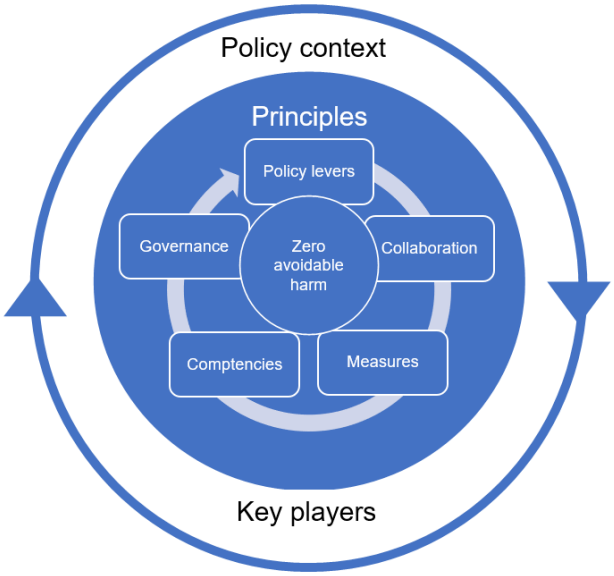

Figure 5. A framework for the national patient safety policy

Source: adapted from Canadian Patient Safety Institute (12)

The **policy context** refers to the systemic political, economic, and social factors influencing the policy process (6, 22,32).

Central to successful policy on PS are empowered and enthusiastic people and organizations interested in the policy's success. A **wide range of players** influence and are influenced by the policy process to improve PS. The actors include government, educators, researchers, regulators, payors and professional associations, accreditation bodies, health authorities, non-governmental organizations, informal and family caregivers, healthcare providers, health leaders, employers, patients, patient advisors, and the public.

Policy levers are mechanisms accessible to decision-makers to influence system changes (7)

4.2.1. Principles of national policy

The principles take into consideration:

a) Patients and families are partners in safe care and empowered

Health care is predominantly service and is always co-produced with the users. Patients must be informed, involved, and treated as full partners in their care. Patients, families, and communities have significant contributions to PS. They should participate in policy development and give their comments when the policy is ready for acceptance at the regulator or parliamentary level.

b) Collaborative working

All PS interventions need to be carefully designed, and collaboration among key stakeholders nationally and internationally is a prerequisite for successful PS improvement.

c) Collection, analyzing, and sharing of data to generate learning

Competent authorities and organizations have mechanisms for measuring and monitoring safety.

Reporting systems that gather data about patient harm and incidents from the point of care are widespread worldwide. Slovenia introduced the first reporting system in 2002 for sentinel events. The system was upgraded in 2019 in the project of EC but has not yet been implemented. Nevertheless, reporting can catch a relatively small percentage of errors. Other possible sources of such data are malpractice claims, data for no-fault compensation, patient-reported experience, and outcome measures, patient complaints, patient-reported incidents, clinical audits, medical record reviews, surveys, adverse event audits, and safety surveillance data for blood products, medicines, vaccines, and medical devices and transplantation services.

The primary aim of data collection on PS and CRM is not on statistics of the frequency of errors but the designing solutions for preventable patient harm. When there are significant volumes of data, most of the time and resources are spent storing them. Much less time is spent analysing and sharing data for learning to reliably and steadily improve PS. There are also problems with data quality and reliability. While it is always of interest to use such data to provide information on patterns and trends in the types of harm that occur, the focus must be firmly on their capability to make future care safer.

d) Translation of evidence into actionable and measurable improvement and standards

An area of weakness in PS is the slow translation of evidence of effectiveness into routine practice. Therefore, during framing actions to improve PS, it is important to fully understand the process of change and utilize the established body of knowledge on improvement science to achieve the desired outcome.

e) Found policies and action on the nature of the care setting

PS policies and solutions are adapted to the local context and levels of healthcare organisations and other providers. It is not simply translated into healthcare facilities. There is still paternalistic behavior towards patients in Slovenia and a culture of fear among providers regarding error reporting (2).

f) Relying upon both scientific expertise and patient experience to improve safety

Technical development of PS involves planning, design, and strategic investment. However, advocacy, awareness-raising, political commitment, persuasion, and local situations are necessary for successful implementation into daily practice. Drawing and delivering a plan involves scientific and technical expertise. It also should have the buy-in and positive emotional drive of those who remember that many past patients have suffered loss and severe harm due to flawed health care (4).

g) Improving safety culture in the design and delivery of health care

Encouraging and engaged leadership promotes a culture of safety. A caring and just culture are established at all levels of Slovenian healthcare. The health workforce is engaged and supported. Developing a safety culture is essential to any sustainable efforts toward PS improvement. Policy and legislative interventions can offer a conducive environment for a flourishing safety culture. The safety culture must intertwine with the overall organizational philosophy and culture. The essential preconditions for safety culture are leadership commitment, transparency, accountability, respectful communication, learning from errors and best practices, just culture, and psychologically safe working conditions (8-11).

h) Legislation

The government can enact legislation changes to the Slovenian healthcare system to support and mandate PS. Comprehensive quality and PS laws have to be established, including establishing an independent national quality and PS body, the role of the government, MoH, payors, healthcare organizations, and public and private providers of healthcare, mandatory education on PS and QI, obligatory reporting of avoidable patient harm and near misses and learning from them, disclosure and apology protection, of human errors, no-fault compensation, protection of documents produced during an analysis of errors, etc.

Measures of success need monitoring if systems are in place to consistently measure and report safety, the rates and scale of harm, using shared definitions across the healthcare system.

i) Professional regulation

Professional regulators have the legal mandate to impose restrictions and conditions for practice and to set out standards for professional conduct and practice. The safety competencies framework must be developed and integrated into graduate and postgraduate educational institutions and staff training by healthcare organizations or their partners.

Measures of success demand professional associations, chambers, and regulatory bodies to include PS competency standards in their professional standards of practice. All professional licensing requirements include PS practice standards. PS competency standards are incorporated into professional development tools and strategies.

j) Standards

Accreditation is a critical driver for PS and QI. However, national standards for PS have to be developed.

Measures of success require organizational practices to promote and enforce PS by incorporating national and accreditation safety standards and can be measured through accreditation practices.

k) Patient Safety indicators

National Patient Safety Indicators (PSI) have to be further developed and expanded.

Measures of success are that reports on improving PSI are publicly available.

l) Organizational policies

Improving safety requires an organizational culture that empowers and prioritizes PS. The significance of culture needs to be brought to the forefront of safety activities. By organizations, we mean health service delivery organizations including, but not limited to, health authorities, primary care, hospitals, public and private long-term care facilities, home care, private practitioners, specialist ambulatory services, pharmacies, rehabilitation services, palliative care institutions, and hospices. Various organizational factors drive PS and QI: governing board, top and middle management, and front line staff.

Measures of success mean that healthcare organizations are reinforced by boards and senior leadership to accept policies that support a just and open culture of safety, support transparency, and reporting, and involve patients and families at every level.

m) Public engagement

Systems must be created to actively and meaningfully engage the public through different avenues such as advisory committees and public forums. Investment in the structures and

skills required for engagement can influence set and institutionalize a culture of quality within a health system. Tragedies raise public awareness about PS, primarily through social media. Raising public awareness of PS needs goal setting, coordination, and effective communication strategies using social media, podcasts, videos, media releases, and presentations.

Measures of success demand that PS awareness increase among Slovenians. PS is a priority and value across health systems (12).

Example of the national policy statement. PS is the national priority and value. The strategy described in this document will be applied by 2031 and aims to zero patient harm. The policy supports the delivery of PS strategies and actions to avoid preventable adverse events. The policy is available to all providers.

Executing the strategies and action plans is obligatory in all healthcare facilities and providers, public and private. The responsibilities for implementation are established in the strategy and action plans.

In developing a policy and strategy for PS that is based on the recent WHO publication (4), seven dimensions of quality are likewise to be considered as these domains are usually tightly coupled.

Safe. Does the delivery of health services utilize the safest means possible and reduce avoidable harm?

Effective. Is care appropriate for the population's health needs and consistent with knowledge and evidence for achieving the best possible health outcomes?

People-centered. Is the experience of care positive through the eyes of patients and families?

Is there a sense of trust among communities in the QoC available?

Do patients, families, and communities feel empowered as partners in designing and refining health services?

Timely. Are waiting times for treatment acceptable to the population and sufficiently short to avoid unnecessary harm?

Equitable. Are there barriers to or disparities in factors related to age, sex, gender, race, ethnicity, geographical location, religion, socioeconomic status, linguistic or political affiliation?

Integrated Are there gaps in patient care between clinical settings? Do components across the health sector communicate to maintain a seamless transition of patient care?

Efficient. Are resources allocated and used in the best possible manner to achieve outcomes? (13,14).

4.2.2. Policy in healthcare organizations

Healthcare facilities are expected to implement policy, strategy, and action plans based on the national policy and strategy for PS. We emphasized that this is not a simple translation of the national policy and strategy to local healthcare facilities. Different healthcare organisations and providers should use a flexible approach to help them reach the main goal of zero avoidable harm.

There can be challenges with the implementation of the policy levers. For instance, policy implementation depends heavily on front-line staff and managers in organizations. However, front-line staff and managers often do not have the available time, training, or human resource

capacity (e.g., staffing, psychological safety) to make and sustain necessary workplace changes to support PS (15).

An example of the policy statement in a healthcare organization - not exhaustive. PS is the crucial system to improve patients' outcomes, patient, staff, and visitors' safety. This system of internal control and accountability of the top management fulfills their responsibility and accountability. Governing board realizes its responsibility of stewardship. PS strategy is fully embedded at every level of the organisation and ensures compliance with the current science of PS.

Policy involves:

- Statement of the attitude of the organization to PS
- Safety training includes team communication and the use of standardized protocols
- Measurements of PSC and PSI
- Support for harmed patients and their families
- Promotion of safety culture, especially just culture with support to the staff
- Development of a robust approach of consistent usage of appropriate PS methods, techniques, and tools
- Identification of resources available to support the implementation
- Definition of the roles and responsibilities at all levels of the healthcare organization
- Outlining the process to be adopted at all organizational levels about PS reporting, analysing and learning
- A formal communication to staff across their organization is in place
- Involving patients' families in care planning
- Information technology to support patient care

Healthcare facilities can use the PS framework to comprehensively introduce PS into their daily work (figure 6).

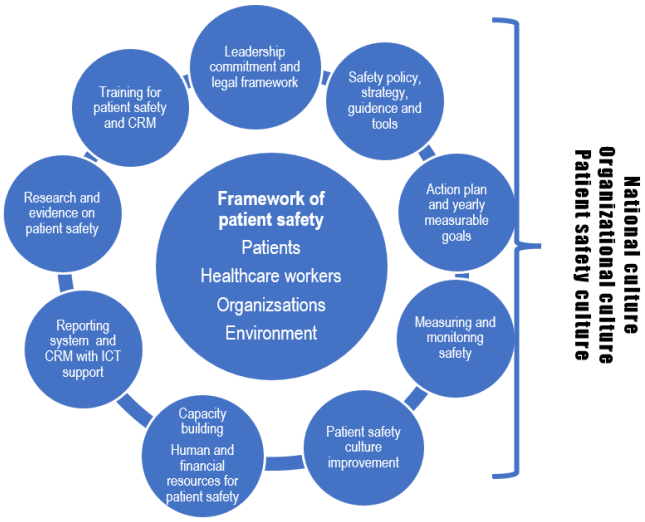

Figure 6. Components of patient safety framework and a journey to a successful patient safety management system

Source: Prosunt©

Suppose a safety management system is not used. In that case, decisions on hazards and associated clinical risk assessment controls may not be given the correct priority needed to ensure that the organization and all patients and employees are protected (16).

Figure 7 displays sustainable and nonsustainable improvements of the PSS.

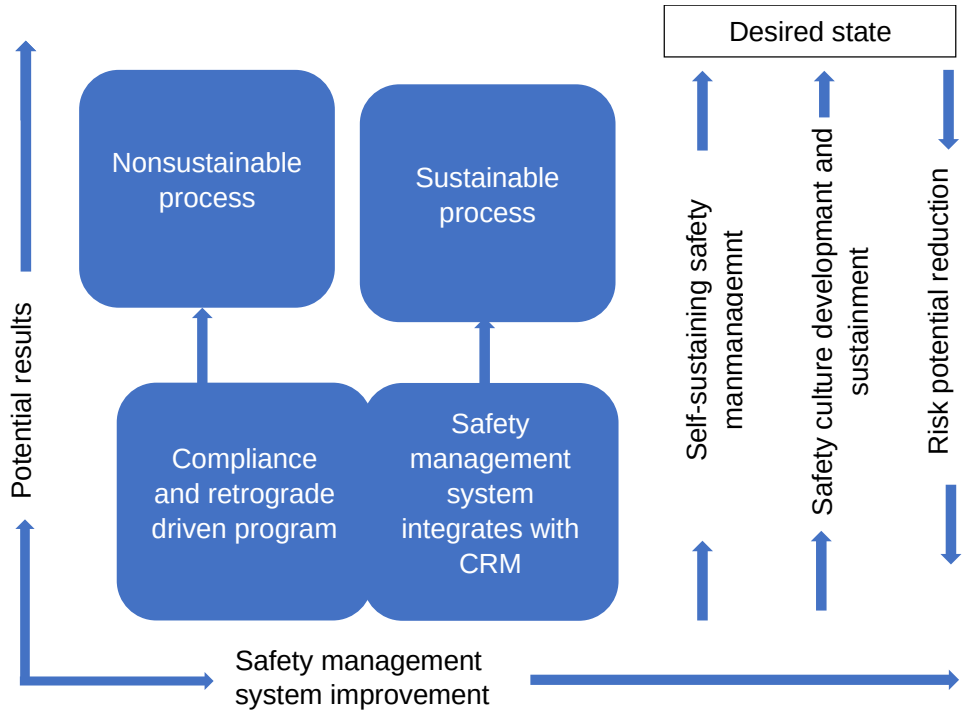

Figure 7. Successful patient safety system

Source: adapted from (17)

Processes are unstable if only compliance with standard and retrograde analysis of preventable harm is conducted. CRM and safety management systems can produce sustainable and robust processes to approach a desirable state.

5. CLINICAL AND SAFETY GOVERNANCE

Clinical governance is an integrated component of corporate governance. **Clinical governance** is the system by which the governing body, managers, clinicians, and staff share responsibility and accountability for the safety and QoC. It promotes an integrated approach to PS improvement. It attempts to bring all PS and quality activities under one umbrella, combining administrative and clinical elements and providing a framework for PS and quality accountability. A key feature of clinical governance is to monitor and improve professional performance. Governance is key to achieving policy goals and directly affects the health system's capacity to overcome challenges. (18)

Safety governance refers to the approaches taken to minimise the risk of patient harm across an entity or system. It typically comprises steering and rule-making functions such as policies, regulations, and standards (19).

PS governance describes an extensive range of steering and rule-making related functions carried out by governments and decision-makers at the **national level** and leaders at the level of **healthcare facilities and professional bodies** as they seek to accomplish PS. Governance implemented by leadership can significantly contribute to establishing a PSC that is increasingly recognised as one of the essential elements for ensuring PS (20).

PSC of trust and openness must be established for knowledge to be shared and accumulated in a **blame-free environment** that encourages collaboration and learning while welcoming the involvement of patients (21).

PS governance functions are defined as specific interventions, programmes, or initiatives to ensure safe care for patients. For instance, national safety standards, strategies to influence PSC, external accreditation, ongoing training as part of professional development, defining roles and responsibilities within the health system, establishing systems for measurement and monitoring, ensuring key accountabilities, building capacity and skills of the health workforce, and involving stakeholders in formal decision-making processes are to all part of PS governance. Later in this document, strategic goals and action plans prescribe PS governance functions.

Governance can be structured at the clinical, organisational/institutional, and system levels. For example, c**linical governance is optimally initiated and managed at the clinical level, such as** catheter insertion bundles, surgical safety lists, etc. On the **organisational level**, governance is often aimed at a particular clinical area or patient type but implemented across a health care organisation or institution, for example, clinical incident reporting, and management systems. Finally, national efforts to enhance PS include system-level governance, such as mandatory reporting of adverse events, safety standards linked to accreditation, and the National independent body responsible for PS.

Currently, only the Ministry of Health is responsible for the national quality and PS at the national level. This has proved to be inefficient, as shown in the situational analysis.

OECD health systems frequently use governance functions to clearly define roles and responsibilities in PS. The results of the survey of 2019 on system-level safety governance in OECD countries as reported by countries' authorities were also described (19).

Table 1 shows the results for Slovenia.

Clearly defined roles and responsibilities			
1.1 National patient safety legislation	**1.2 National Quality and Safety Agency**	**1.3 National safety standard**	**1.4 National patient safety programme**
Currently no national-level legislation on safety and quality, but safety is to a certain extent embedded in other legislation, e.g. the Patients' Rights Act, etc.	PS unit within the Ministry of Health	National safety standards exist	The last national safety strategy was adopted for 2010-2015.
Systems for measuring and monitoring progress			
2.1 Establishment of national set of indicators supporting safety standards	**2.2 Internal monitoring of PS for continuous improvement**	**2.3 External accreditation, Inspections, audits of PS processes and outcomes**	
A national set of psi exists and will be updated over the next two years	Health providers organise PS meetings and perform internal supervision	External accreditation, inspections or audits of PS processes and outcomes are not mandatory	
Key accountabilities			
3.1 Provider financial incentives and/or penalties applied to promote and ensure safety	**3.2 Routine public reporting of PSI and performance**	**3.3 Contract and/or commissioning arrangement include safety requirements**	
Health providers are incentivised to fund training and PS days	Reports are published only at the level of providers	Safety is included in contracts.	
Capacity-building to ensure the right skills and competencies			
4.1 Safety competencies built into the curriculum of students in various health disciplines	**4.2 Ongoing training as part of professional development of health care personnel**	**4.3 Leadership and management development to promote PSC**	
Safety competencies built into the curriculum for students in various health disciplines	Ongoing training as part of professional development and health care personnel	Leadership and management development to promote PSC	
Involvement of key stakeholders			
5.1 System report by the agency responsible for PS to the government	**5.2 Healthcare-providing organisations integrating clinical governance with corporate governance**	**5.3 Patient representation in official roles and decision-making processes**	
No, there is no single system report.	Healthcare-providing organisation integrating clinical and corporate governance	Yes, patients are represented in official roles and decision-making processes	

Table 1. The results of the OECD survey on patient safety governance, 2019

In phase 2 of situational, the MoH was asked to explain their responses and confirm that with the relevant documents because there were some controversies between the report to OECD and real-life situations. Details are in deliverable 2. We decided that in the proposal for strategic objectives, strategies, and action plan, the work on PS will be considered by comparing each strategy to the current situation and then acting accordingly for Slovenia.

A new **National independent body for quality and PS** is on the **political agenda** of the present government that would take the bulk of the responsibility for further developing quality and PS and take care of sustainability.

At the level of stakeholders, the structure and governance will differ according to their roles in the system of PS and quality.

It is essential to ensure that governance is clearly defined in the organizational structure. Roles and responsibilities are adequately described to fully utilize the group's capacity and recognize where responsibilities can be shared across the health sector (table 2).

Body	Responsibility	Accountable to
Ministry of health	Provide leadership and direction of national efforts.	Government and people
National independent body for quality and PS	Support development and implementation of national policy, strategy, action plans, development, and adaptation of tools. Monitor and evaluate progress, identify gaps in quality, coordinate and align inputs of multiple stakeholders to policy and strategy etc.	To a founder
National PS and clinical audit commission	Auditing health care facilities, public and private, on clinical quality and PS. It can be part of the National independent body for quality and PS	Ministry of Health
Professional bodies	Assist and support training, professional education, and setting evidence-based tools and standards.	Ministry of health and people
HIIS and other insurance entities	Fund and monitor incentive programmes and integrate measures for PS improvement in payment mechanisms.	Government and insured people
Governing board (Sveti zavodov)	Review institutional quality and PS improvement programmes and initiatives and engage the community in improving service delivery.	Ministry of health and people
Committee for quality, PS, CRM at healthcare facilities	Organization and operation of quality and PS policy, strategy, and action plan. Improve the culture of PS	Institutional Governing board and Ministry of health
Commission for quality, PS, CRM at healthcare facility	Carry out quality care practices and standards, and report the relevant health data for continuous QI. This is an execution body at the facility level.	Committee at healthcare facility

Table 2. Examples of patient safety roles and responsibilities

The strongest reported alignments of functions are found in health systems with a centralised approach to decision-making.

For strong patient safety governance, it should be required from the government consider the key findings of OECD study (19):

- Requirements for aligning PS governance with overall health system governance and financing align its individual components and functions
- Inclusion into all healthcare settings
- Enforcement people-centeredness in safety governance
- Fostering a culture of openness and trust among health professionals and regulators

- Enabling continuous learning from both harm and success
- Incorporating other policy areas, notably data privacy/security policies and workforce preparedness

An example of clinical governance for a healthcare organization is summarized in figure 8.

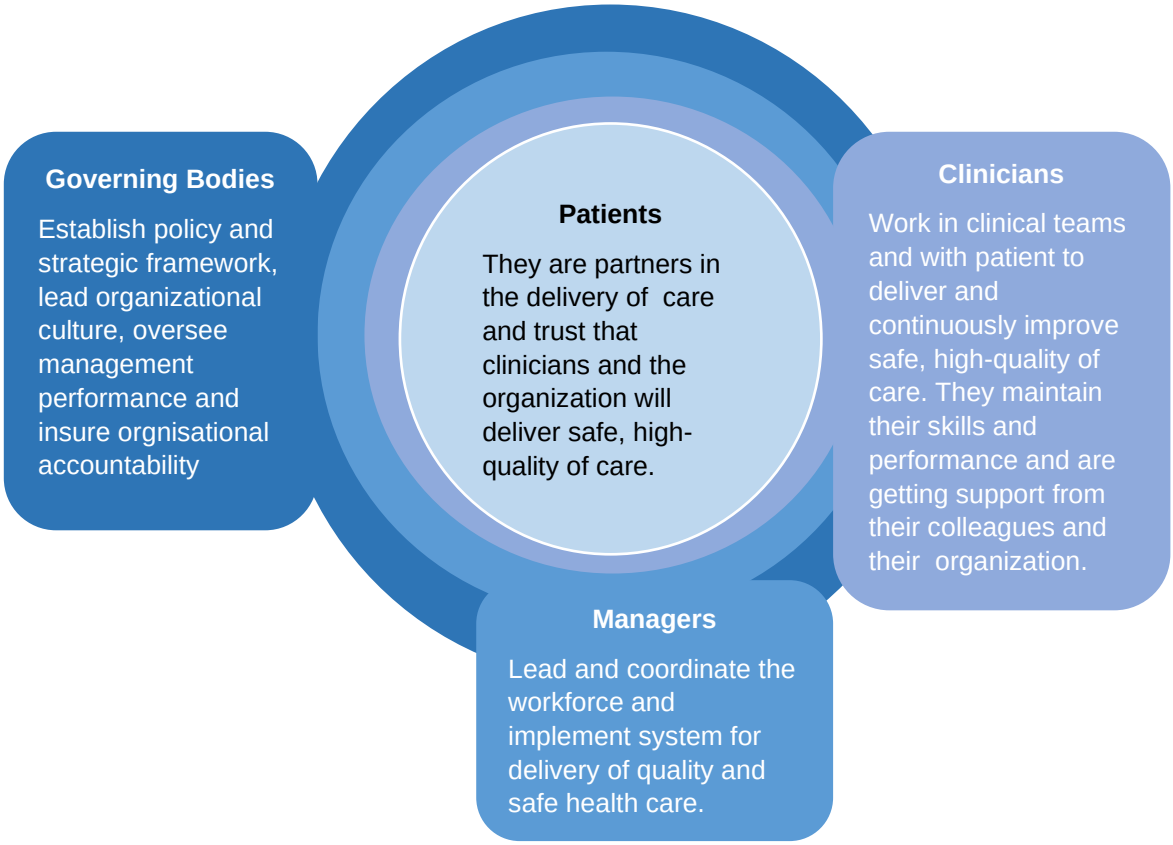

Figure 8. Model of clinical governance

Source: adapted from Australian commission on safety and quality in health care (23)

5.1. Approaches to the governance of patient safety

TAPIC framework defines five mutually exclusive pillars of health care governance; transparency, accountability, participation, integrity, and capacity. Elaborating the TAPIC framework and applying it to PS produces **five pillars of governance**:

1. Encouraging transparency and information sharing
2. Ensuring accountability
3. Promoting participation
4. Upholding integrity through effective leadership facilitating a culture of safety
5. Building capacity

Transparency enables information and knowledge sharing to evoke learning. **Accountability** builds trust and enhances compliance. **Participation** contributes to legitimacy, which is key for trust and efficacy. **Integrity** supports good management and safety culture, and **capacity** building strengthens the resilience of health care systems (18).

a) Transparency

Transparency refers to **PS measurement**, **access to data and decisions**, enhanced by the supervisory body, inspectorates, regular reporting, legislation, or performance assessment. It

seeks to understand institutions, and identify illegal acts and incompetence. Transparency in PS is **public reporting of safety indicators**, **incident reporting** to induce collective learning, and information sharing to avoid safety problems. Transparency is crucial to identify the strengths and weaknesses of health care systems and is opposite to the culture of silence that is also influenced by the criminalization of human errors in Slovenia. In the cases of avoidable patient harm, **open disclosure** increases trust in health care. Positive examples of reporting errors in the context of a **»no-fault« scheme** for patient compensation are known in countries with no-fault schemes for patient compensation due to avoidable adverse events. Such systems benefit patients and communities and can contribute to cultural transformation, remove barriers to reporting harm, and facilitate open discussions with patients. They also encompass pooling information to generate new knowledge for preventing adverse events. The result is better reporting errors and near misses and, therefore, better data collection, encouraging good clinical practice and reducing defensive medicine. The databases are widely used to identify safety problems and publicly share knowledge and experiences on safe care practices. Open disclosure of errors increases trust in health care. Physicians who disclose adverse events due to errors are less likely to be sued (24).

Transparency is not only about accumulating knowledge on incidents and near incidents. It also refers to **sharing data** and patient information to prevent safety problems from happening due to poor communication. Improving **interoperability of data systems** between service providers is especially important for patients with a long or complex medical history because a patient journey through the healthcare system can be easily accessible.

b) Accountability

Accountability can help uphold **public trust** in health care by establishing responsibilities, minimum standards, and compliance. Accountability is a relationship where people have to inform and explain their actions to others. Accountability in TAPIC refers to explanation and sanction. It is a relationship where people have to tell and justify their actions to others and be mandated and sanctioned. Accountability is a necessary complement to governance functions emphasizing learning and transparency in PS. In the absence of accountability, adverse event reporting is not expected to yield considerable improvement. Healthcare-providing organisations are accountable for **correcting systematic weaknesses** and issues contributing to avoidable patient harm.

Accountability can be clinical, professional, legal, financial, political, or ethical, depending on how it is enforced. It can be promoted by safety governance functions, such as national safety standards, external accreditation, high-level progress reports, financial incentives, contracting arrangements, or choice mechanisms that enable users to choose health care providers.

The most stringent way to ensure accountability is through **national regulations setting out responsibilities and sanctions.** For example, there are ‘’no-pay”’ rules for avoidable patient harm and payments linked to clinical outcomes (25).

Making **PS reporting publicly available** is expected to increase accountability.

A **‘just culture’** is an essential concept in the discussion of accountability in safety. Firstly, ‘just culture’ considers broader systemic issues when investigating PS incidents, which enables healthcare professionals to learn from safety incidents without fear of retribution (26). Secondly, emphasising accountability of healthcare-providing organisations is fundamental to ensuring reporting of safety incidents (27).

c) Participation

Participation is a crucial element of governance, referring to the inclusion of all affected actors in decision-making to maximise efficacy. It enables information gathering **from different stakeholders**, thereby facilitating more effective policies and ensuring legitimacy and

ownership needed for successful implementation (18). Participation can involve **patient representation in official roles and decision-making processe**s, reviewing safety by governing boards of healthcare organisations, system reports by a national body responsible for PS to the government, or patient-reported incident monitoring.

Numerous stakeholders must be an essential part of the PS program to build trust and legitimacy (health care professionals, patients, management, and governing boards of healthcare providing organisations, payers, health care industry, etc.). In addition, collaboration occurs between organisations with different roles (regulatory, care delivery, insurance) and between different sectors of healthcare (primary care, hospital care, rehabilitation, etc.) (28).

Patients' participation is fundamental for safe care. The World Health Organization (29) has recommended involving patients in safety through technical tools, patients' rights legislation, and other empowerment policies, such as educational campaigns. There is increasing evidence that organisations that encourage the inclusion of patients are less prone to risks (30). For instance, studies have shown an increase in staff hand hygiene after campaigns encouraging patients to ask their doctors and nurses whether they had cleaned their hands before direct contact. While reporting different information than health care workers, patients provide helpful information. Moreover, they tend to report suspected adverse effects earlier than professionals, decreasing the delays in seeking treatment (31).

The OECD work on PS has suggested that empowering patients to be active participants in treatment situations could reduce safety lapses by up to 15% (33).

d) Integrity

Integrity is the parallel to solid leadership and crucial in health care governance to ensure consistency of action. Governance functions associated with integrity include **defining the roles and responsibilities of PS in national legislation,** setting up **national quality and safety agencies**, and encouraging leadership, which promotes PSC (28).

Leadership is the indispensable component of all PS governance functions. The role of leadership in PS goes beyond defining roles as responsibilities through legislation. Leadership has a crucial stake in promoting an organisational culture characterised by a spirit of collegiality, collaboration, openness, and respect that are inherent to PSC. Poor communication and ineffective teamwork are the root cause of most sentinel events, while teamwork is associated with better patient outcomes. Leadership has the power to facilitate a blame-free culture reinforced by legislation. If **blame culture** prevails, information sharing and collective learning are undermined (34). On the other hand, leadership can promote just culture and be supportive by emphasising collective learning and trust. Blame free environment is thought to increase incident reporting.

e) Capacity

Capacity-building activities are challenged by resource constraints but contributing to PS is to be seen as an i**nvestment to decrease expenses stemming from avoidable patient harm**. Capacity in PS can include embedding safety into **students' curricula** and integrating **safety training as part of professional development** for health care professionals. Capacity building can also take a broader approach within the organisation by shifting the focus on safety training from technical skill-building towards emphasising teamwork, QI and organisational change. Embedding safety curricula into educational programmes is a governance function that produces results in the long term. **Continuous staff training** is fundamental to keep medical staff up with the latest developments. This does not only concern front-line professionals because **competencies for leadership are important**. **Training**

governing board members on quality and including clinicians in boards has shown to positively affect the governance and quality of health care (35).

While developing skills is essential, they cannot be put into practice without resources. Practice analyses suggest that professionals often attempt to meet regulatory standards but fail to overcome systemic constraints such as lack of staff or competing interests like delivering care to several patients simultaneously. **A high workload and a stressful working environment contribute to staff burnout**, which has been associated with a higher **likelihood of adverse events** and a decrease in the reporting of near misses (36).

Information technology can help to build capacities for maintaining and improving safety. There are increasing opportunities to leverage health information technology to capture and prevent errors, patient identification errors, and poor data accessibility (37).

5.2. Partnership

Collaboration at both the strategic and the operational levels is indorsed. There are four main actors with different roles in PS in Slovenia. The essential roles in seven strategic objectives for PS implementation are seen in figure 9.

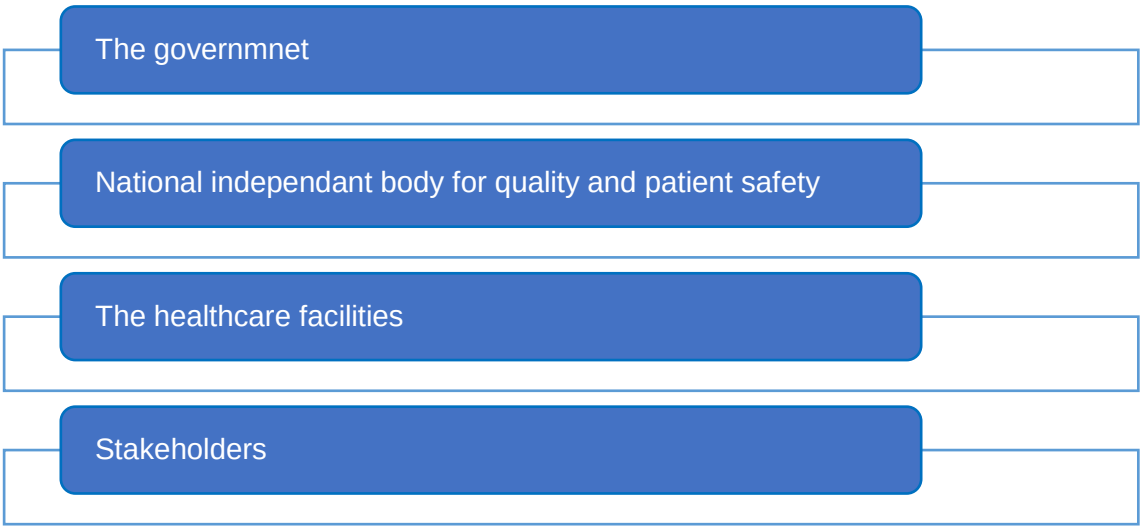

Figure 9. Main actors in patient safety in Slovenia.

a) Top-level

- National government
- Parliament
- Ministry of Health as the national regulatory body
- National specialized agencies, e.g., implementation bodies, public health institutions, accreditation agencies,
- Other ministries directly or indirectly involved in health include the ministry of education, science and sport, ministry of finance, ministry of labor, family, social affairs and equal opportunities, ministry of Justice
- Health insurance institute of Slovenia

b) Development and implementation institution

- National independent body for quality and PS

c) Healthcare facilities, public and private

- Tertiary and secondary care facilities and health care organizations
- Primary health care facilities and service providers
- Long term care facilities and service providers
- Palliative care service providers
- Specialized outpatient clinics and diagnostic service providers
- Substance abuse facilities and dementia care facilities
- Community-based and home-based care
- Individual care providers
- Community pharmacies
- Rehabilitation centres

d) Stakeholders

- Patient, civil society
- Professional chambers and associations
- Educational institutions

e) International partners

- Inter-governmental organizations, e.g., European Commission, OECD
- National and international non-governmental and professional organizations
- International and independent standard-setting bodies/ accreditation agencies
- Academic institutions and other international and national training and capacity building institutions, private and public
- Research institutions and educational institutions, public and private
- National and international consortium/ associations and chambers of health care providers
- National and international civil society organizations, including patient organizations
- Community groups and organizations
- Media
- United Nations and other multilateral organizations
- Development partners, donors and funding agencies

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6. STRATEGIC OBJECTIVES, STRATEGIES AND ACTION PLAN FOR 2022-2031

WHO prepared the global action plan 2021-2030, "Towards eliminating avoidable harm in health care," discussed with the Member States [2] through regional committees and consultations and provided strategic direction on action for countries. The global PS action plan provides a framework for countries to develop their respective national strategies and action plans on PS. It comprises seven strategic objectives (figure 10) and 35 strategies that are the foundation of the WHO global action plan. Seventy-Fourth World Health Assembly (WHA) adopted this global action plan in May 2021 with a vision of "a world in which no one is harmed in health care, and every patient receives safe and respectful care, every time, everywhere". The Global Patient Safety Action Plan, 2021–2030, draws its mandate from WHA resolutionWHA72.6 on "Global action on PS".

Situational analysis in Slovenia, results of workshops and description of 5 countries are also considered. Slovenia will develop priorities for action plans in short-term, medium and long-term timeframes from this framework.

1	2	3	4	5	6	7
Policies to eliminate avoidable harm	High-reliability systems	Safety of clinical processes	Patient and family engagement	Health worker education, skills	Information, research, risk management	Synergies, partnerships and solidarity

Figure 10. Seven strategic objectives

Zero avoidable harm

1 Make zero avoidable harm to patients a state of mind and a rule of engagement in the planning and delivering health care everywhere.

High-reliability system

2 Build high-reliability health systems and health organizations that protect patients daily from harm.

Safe clinical processes

3 Assure the safety of every clinical process.

Engagement and empowerment of patients and families

4 Engage and empower patients and families to help and support the journey to safer health care.

[2] Argentina, Australia,**Austria**, Bangladesh, Brazil, Canada, Chile, China, Ecuador, **Finland, Germany**, Guinea-Bissau, ndia,Indonesia, Israel, **Italy**, Jamaica, Japan, Kenya, Liberia,Namibia, New Zealand, Norway, Oman, Philippines,**Poland**, Republic of Korea, Russian Federation, **Spain**, SriLanka, Sudan, Thailand, Tonga, Tunisia, Turkey, United Kingdom of Great Britain and Northern Ireland, UnitedStates of America, and Uruguay.

Education of healthcare workers

5 

Inspire, educate and skill health workers to contribute to the design and delivery of safe care systems.

A constant flow of information

6 

Ensure a constant flow of information and knowledge to drive the mitigation of risk, the reduction in levels of avoidable harm, and improvement in the safety of care.

Synergy, solidarity and partnership for patient safety

7 

Develop and sustain multisectoral and multinational synergy, partnership and solidarity to improve PS and QoC.

Each strategic objective has several actions for the **government**, the **National independent body for quality and PS**, **healthcare facilities**, and **stakeholder**s. This is only slightly adapted from WHO global PS framework and thus helps Slovenian efforts to establish a long awaiting comprehensive PSS. The WHO framework will serve for many years as a base for the prioritisation of strategies and action plans and the efforts that have already been done in Slovenia.

6.1. Strategic objective 1 – Zero avoidable harm

Zero avoidable harm might be an unrealistic goal, however, reduction of harm is possible. Instead, zero avoidable harm should be expressed as a **state of mind and engagement in providing health care.** A mindset and attitude of zero harm and a frame of reference for planning and delivering health care would be a shift from the current status quo. This framework can make enormous reductions in death, disability, and physical and psychological injury from unsafe care.

1 

Make zero avoidable harm to patients a state of mind and a rule of engagement in the planning and delivery of health care everywhere.

Strategy 1.1 Develop a comprehensive patient safety policy, strategy, institutional framework and implementation plan for the Slovenian health system and all its components	
Actions for government	A. Recognize PS as a health priority in health sector policies and programmes, making it an essential component for strengthening health care systems.
	B. Launch a national PS programme reinforced by a PS policy, strategy, institutional framework and action plan within the health care context, including overall health priorities and goals; current levels and sources of avoidable risks and harm; resources available; and both public and private sector service providers and institutions.
	C. Work in collaboration with other states, civil society organizations, patient organizations, professional bodies, academic and research institutions, industry and other relevant stakeholders to promote, prioritize and embed PS in all health policies and strategies.

	D. Chart the existing national health policy and strategy, including primary health care, QoC and health workforce, to create maximum opportunities for synergies with the PS policy framework.
	E. Incorporate implementation with safety-critical technical programmes such as surgical safety, medication safety, blood safety, radiation safety, immunization safety, medical device safety, infection prevention and control and antimicrobial resistance into a national PS programme.
	F. Adapt scientifically based PS technical guidance, implementation strategies and tools to the national context and build capacity in PS.
	G. Create a national PS charter that includes institutional standards and patients' and health care providers' rights and responsibilities.
	H. Establish a comprehensive communication programme to raise and maintain public and professional awareness of PS and secure maximum engagement in special international initiatives and campaigns.
Actions for National independent body for quality and PS	A. Provide high-level advocacy and guidance regional and national levels to create a vision for eliminating avoidable harm in health care.
	B. Identify PS as a key strategic priority in national strategies and interventions.
	C. Develop, disseminate and support the implementation of guidance for formulating national PS policy, strategy, framework and implementation plans.
Actions for health care facilities	A. State a clear public commitment that the organisation is working to orientate culture and practices towards zero avoidable harm; this can be reinforced by adding patient representatives as board members and by creating a patient council to advise on safety matters.
	B. Align and implement processes and practices at the facility level with PS guidelines, protocols and standard operating procedures.
	C. Review progress on PS performance at the organization's main board meetings and at all other key governing board meeting (Svet zavoda).
Actions for stakeholders	A. Advocate for PS to be a strategic priority for health care organizations.
	B. Engage with professional organizations and patient organizations in the development and implementation of the PS goals, objectives and values.
	C. Participate in, support and facilitate PS programmes at local, national and global level.

Strategy 1.2 Mobilize and allocate adequate resources for patient safety implementation throughout every level of the health care system	
Actions for government	A. Allocate adequate human resources and sustainable finances for the action plan of a national PS plan integrated within the financial structure of the health system through mechanisms such as a specific budget, health insurance or other mechanisms.
	B. Construct an annual budget and human resource plan for a national PS action plan.
	C. Take steps to limit inappropriate hospitals through optimal resource planning, primary health gatekeeping, scientific layout and process design, and other evidence-based interventions.
	D. Ensure sufficient funding to deliver needs-based safe staffing and establish effective human resource planning systems to ensure an adequate supply of health workers to meet patient and population needs.

	E. Explore whether the system of funding of health care in the country can be adjusted to fairly reward health organizations that achieve good performance on PS.
Actions for National independent body for quality and PS	A. Help creating institutional structures and define responsibility and provide adequate financial and human resources for PS activities at regional and country levels.
	B. Mobilize, allocate and provide guidance on assessing and obtaining adequate resources for PS campaigns, initiatives, programmes and consultations, and for cooperation and technical support.
	C. Provide guidance and recommendation for policies and tools to improve PS.
Actions for health care facilities	A. Include activities for PS implementation in the organization's overall operational plan, including annual budget and human resource plan.
	B. Assign adequate financial resources for PS implementation at the organizational level.
	C. Provide an adequate level of staffing with an appropriate skills mix; develop information systems based on reliable real-time data, agreed metrics, benchmarking and best practices to inform evidence-based planning.
	D. Ensure optimal staffing, infrastructure, layout and process flow to limit overcrowding in health care facilities.
Actions for stakeholders	A. Advocate for adequate human and financial resources to tackle the most serious PS problems.
	B. Engage the private sector to help it to define its role in improving PS.
	C. Publicize PS solutions to get public support.

Strategy 1.3 Use selective legislation to facilitate the delivery of safe patient care and the protection of patients and health workers from avoidable harm.	
Actions for government	A. Review and adjust legislation governing the country's health system to facilitate the formulation and implementation of PS policies, practices and behavioural norms.
	B. Develop legislation to protect health workers from retaliation or punitive action in the case of human error or of reporting an adverse event; introduce mandatory licensing schemes for health care providers that incorporate PS aspects; recognize PS as a human right incorporating access to safe medicines, medical devices, blood products, and essential health services.
	C. Establish legislation on quality and PS.
Actions for National independent body for quality and PS	A. Create a repository of policy, legal and regulatory best practices.
	B. Provide technical support to develop and amend laws and regulations for improving PS.
Actions for health care facilities	A. Influence opportunities through adequate national legislation to strengthen measures to protect patients and health workers from avoidable harm and to systematically improve PS.
	B. Advocate to law makers and national government for new legislation where this could make it easier to meet PS goals and standards.

Actions for stakeholders	A. Coordinate professional organisations, civil society, patient and community groups, and other PS interests to identify scope for new legislation then advocate to lawmakers and national government for enactment of such measures.
	B. Partner with patient-led organizations to raise public awareness of the impact that safe staffing has on patients, families and communities.

Strategy 1.4 Align all health care regulatory, accreditation, and inspectorial activities with the goal of improving performance on patient safety	
Actions for government	A. Define and incorporate PS standards in regulatory requirements for health care facilities.
	B. Include and/or augment PS as a key component of accreditation standards and award criteria.
	C. Include PS in health system performance assessment.
	D. Mandate PS dimensions in licensing and re-licensing schemes for health professionals.
Actions for National independent body for quality and PS	A. Provide technical support and expert guidance for healthcare providers to build PS strengthening measures into the national health care licensing, regulation and accreditation systems.
	B. Develop normative guidance on PS standards.
Actions for health care facilities	A. Implement the licensing, regulatory and accreditation requirements for PS in all service areas.
	B. Communicate to all staff on a regular basis about PS licensing, regulatory, and accreditation systems.
	C. Incorporate a culture of continuous improvement of PS utilizing principles of QI.
	D. Feed information back to national government on the ways in which licensing, regulatory and accreditation systems could be improved to better facilitate the achievement of higher standards of PS and patient engagement.
Actions for stakeholders	A. Adequately address PS requirements in international accreditation standards and programmes.
	B. Convene researchers and research bodies to create an evidence-base (including commissioning new research where necessary) on the effectiveness of licensing, regulatory and accreditation systems in improving PS.
	C. Bring together experts, public and private, health system leaders and civil society to establish the best ways to help patients and families to interpret and, use, and contribute to PS performance information produced from the processes of licensing, regulation and accreditation of health care providers.

Strategy 1.5 Create maximum awareness of World Patient Safety Day and Global Patient Safety Challenges, as a way of maintaining a high public and political profile for patient safety.	
Actions for government	A. Participate in designing the World Patient Safety Day global campaign annually.
	B. Adapt, develop and launch national campaigns aligned with the theme of World Patient Safety Day each year.

	C. Mark World Patient Safety Day annually on 17 September through organizing activities and events (for example, lighting up iconic landmarks in orange) and educating the public on the importance of PS.
	D. Engage all related stakeholders and initiate sustained action on the theme of World Patient Safety Day.
	E. Restate the government's commitment to PS and showcase its achievements and progress towards reaching national milestones on World Patient Safety Day.
	F. Use World Patient Safety Day every year on 17 September to restate the government's and national health system's commitment to achieving the highest standard of safe care and to educate the public on the importance of PS.
	G. Adopt and implement annual World Patient Safety Day goals and other theme-specific technical products.
	H. Monitor and evaluate the outcome and impact of World Patient Safety Day.
	I. Commit to prioritize and take action to achieve the goals of Global Patient Safety Challenges with required leadership, coordination, expert advisory structures, and monitoring and evaluation.
Actions for National independent body for quality and PS	A. Develop a global campaign each year for World Patient Safety Day, including the selection of a theme, key messages, production of communication materials, and collation and dissemination of success stories.
	B. Launch a set of annual World Patient Safety Day goals linked with the annual theme for focused action.
	C. Launch events for World Patient Safety Day and coordinate action through WHO regions, Member States, professional organizations and civil society organizations.
	D. Evaluate the impact of World Patient Safety Day.
	E. Design WHO Global Patient Safety Challenges based on lessons from previous challenges.
	F. Develop implementation tools and provide technical support to Ministry of Health, healthcare facilities and stakeholders delivering the goals and tasks of the Global Patient Safety Challenges.
	G. Develop monitoring and evaluation tools for assessing the progress of and possible improvements to the WHO Global Patient Safety Challenges and World Patient Safety Day.
Actions for health care facilities	A. Observe and celebrate World Patient Safety Day every year.
	B. Adapt and develop local campaigns aligned with the national campaign and the theme of World Patient Safety Day each year.
	C. Showcase the PS work and achievements at the point of care over the previous year as part of the World Patient Safety Day communications.
	D. Implement annual World Patient Safety Day goals
	E. Implement the actions required by the Global Patient Safety Challenges at health care service delivery level.
Actions for stakeholders	A. Help to shape and amplify the messages of World Patient Safety Day every year through networks and partners.
	B. Support the implementation of annual World Patient Safety Day goals.
	C. Collaborate in implementation of existing WHO Global Patient Safety Challenges.
	D. Participate in the design of new Global Patient Safety Challenges.

6.2. Strategic objective 2 – High-reliability systems

Knowledge of high-reliability health systems and health organizations is needed to protect patients from harm. The concept of high reliability has emerged from **resilience,** which is an organization's capacity and capability to persistently maintain a safe state of operating and recover quickly and restore this state when something goes wrong. Such organizations can foresee problems, use data to monitor processes and work conditions, respond to signals in the expectation of challenges, and learn from successes and failures forwards.

High-reliability organizations operate in complex, high-hazard domains for extended periods without serious accidents or catastrophic failures. Most studies have been in the industry and operating situations outside health care. High-reliability is attractive for health care because of the high complexity and risks that can have disastrous dimensions. Sometimes people think that a high-reliability organization means only successfully standardizing of processes, but that is not enough. High reliability is better described as persistent mindfulness within a health organisation. The most important priorities are the culture of the organization and the culture of PS, which is not only a motto but a defined condition at all levels of the health organization.

Prerequisites for a high-reliability organization is:

- Leadership engagement
- Safety culture
- Robust process improvement

Five characteristics of a high-reliability organization

1. **Preoccupation with failure.** High-reliability organizations are prominent because they treat **every minor gap** as a potential symptom of a vital system weakness that could have significant consequences. **Everybody is aware** of and thinking about the **possibility of failure**. People understand that new threats regularly arise from situations no one envisioned could occur. All personnel actively think about what could go wrong and are attentive to minor signs of potential problems. The **absence of errors or accidents leads not to complacency** but to an increased sense of vigilance for the subsequent possible failure. Near misses are viewed as opportunities to learn about system issues and potential improvements rather than as evidence of safety.

   NEVER satisfied that they have not had an accident for many months or years and always alert to the SMALLEST SIGNAL that a new threat to safety may be developing.

2. **Reluctance to simplify**. People in a high-reliability organization understand that the **work is complex and dynamic**. However, there is an unwillingness to respond to the complexity of processes, technologies, and delivery environments by adopting a simplified view of them to stay focused on a small number of key tasks.
   It is being able to identify the subtle differences among threats.

3. **Sensitivity to operations**. In high-reliability organizations, there is a strong emphasis on **senior management being aware of what is happening on the front-line of delivery**. This **situational awareness** is crucial to maintaining solid defenses against untoward events, especially those with high impact. Situational awareness means that people cultivate an understanding of the context of the current state of their work about the unit or organizational form—i.e., what is going on around them—and how the current state might support or threaten safety.

Recognize the earliest indicators of threats to organizational performance and ensure that all workers who are most intimately involved in operations consistently report any deviations from expected performance (SPEAK UP CULTURE).

4. **Commitment to resilience**. People assume **the system is at risk for failure**, and they practice performing rapid assessments of and responses to challenging situations. Teams cultivate **situation assessment** and **cross-monitoring** to identify potential safety threats quickly and either act before safety problems, cause harm, or mitigate the seriousness of the safety event.

   Recognize that despite all their best efforts and past safety successes, errors will occur, and safety will be threatened but in essence, a high-reliability organisation is not that it is error-free but that errors don't disable it. In healthcare, that means that error will not reach a patient and thus will not harm him.

5. **Deference to expertise.** People closest to work are most knowledgeable about the work. Thus, people know that the person with the most significant knowledge of the situation might not be the person with the highest status and seniority in a crisis or emergency. Deference to local and situation expertise leads to an attitude of inquiry and de-emphasis on hierarchy in favor of learning as much as possible about potential safety threats. As a result, all staff members are comfortable speaking up about potential safety problems.

   Mechanisms in place to identify the individuals with the greatest expertise relevant to managing the new situation and will place decision-making authority in the hands of that person or group

PS I and PS II. Both approaches are needed if a transformational change is to be achieved in PS. The contributing factors thought to have played a part in the origin of an incident in one care setting could be the same factors that permit excellence in another. Those responsible for improving and sustaining safety in organizations must **invest in learning mechanisms responsive to cues from the good and bad.** However, less strategic attention has been given to building high-reliability organisation in healthcare. Therefore, it must be one of the seven strategic objectives.

Safety Culture and Leadership. When culture is mentioned about PS, most people's thoughts will turn to the concept of the no-blame culture. **Since errors are unintentionally provoked by poorly designed systems, blaming and punishing an individual is unfair and misguided.** A culture based on blame and **retribution will ultimately be unsafe because individuals will be afraid to admit their mistakes and hide them**. If a culture of blame and fear is predominant in a health organization, it is pretty impossible to have a meaningful PS program. Unfortunately, this approach is still prevailing in Slovenia. Simply stated, **true PSC** means using data, openness, transparency, and being fully patient-centered. To strengthen the leadership and PSC, true transparency to both providers and patients at every system level is required. Transparency means sharing information but also reducing the hierarchical approach.

Developing and sustaining a solid patient safety-orientated culture requires strong leadership at all levels: Ministries of Health, healthcare facilities, and in every clinical team. Thus, there is a need for a **new generation of PS leaders** who are skilled and passionate: to create

conditions, organizational and team cultures for safer care and to ensure that all systems and procedures comply with the highest standards; and to guide and motivate staff.

Human Factors/ergonomics (HFE). Today, the description 'human factors' is used interchangeably with the older term "ergonomics". HFE is concerned with understanding the **interactions between humans and other system elements**. The human factors or ergonomics profession applies theory, principles, data, and methods from relevant fields to design for human well-being and overall system performance. HFE explores a problem by looking at the people within a system, their interactions with each other and the system, and then redesigning the tasks, interfaces, and system. It uses a systems analysis approach where humans will be defined as stakeholders within the system. Incorporating essential elements of human factors or ergonomics across all health care contexts is one of the keys to achieving the strategic objectives of this plan. These elements include person-centred approach, participatory approach, design-driven approach, systems approach, and continuous learning and refinement.

Transformational leadership. The key areas of transformational leadership that will determine the effectiveness of the strategic objectives include: the regular and consistent communication of vision with patient-centred, harm-free, safe services as the vital purpose of all health care; making the vision, guiding principles, strategic objectives through which the business of PS is conducted; identifying and addressing the issues in the design, organization, and delivery of services which will have the major impact on the safety and resilience of services; creating a sense of "team" with clinical leaders, listening and acting upon their concerns and ideas.

2 Build high-reliability health systems and health organizations that protect patients daily from harm.

Strategy 2.1 Develop and sustain a culture of openness and transparency that promotes learning, not blame and retribution, within each organization providing patient care.	
Actions for government	A. Implement administrative and legal protection for those reporting adverse events or raising worries about the safety of services.
	B. Ensure the protection mechanism is based on learnings from PS failures and articulates around refining the work system, rather than punishing individuals, and is widely available and known to all stakeholders.
	C. Define clear-cut boundaries and distinctions between errors and negligence in order to establish a just culture and facilitate appropriate corrective actions. This was also on of the strategic goals of the National health quality and safety strategy (210-2015).
	D. Adopt global approaches for the establishment of safety culture across the health system, including Building competencies in methods for culture change.
Actions for National independent body for quality and PS	A. Advocate and promote the importance of just culture and safety culture concepts for PS improvements within health care systems.
	B. Develop and disseminate guidance on establishing a safety culture, including PSC surveys, and other technical resources and tools.
	C. Provide technical support to healthcare facilities to establish a safety culture adapted to the local context, in all health care organizations and at all levels.

Actions for health care facilities	A. Create and endorse a non-punitive policy for responding to and learning from adverse events, while clarifying the circumstances where individual accountability will apply.
	B. Develop a system for rapidly implementing recommendations from analyses of adverse events and through proactive risk management.
	C. Conduct a regular survey of the organization's PSC identify gaps and introduce innovative approaches to building safety culture, in line with international experience and best practice.
	D. Reduce hierarchical structures, attitudes, and behaviour throughout the organization, promoting a speak-up culture.
	E. Promote transparency with patients; ensure that patients have access to their speak-up records and that full informed consent is practiced.
	F. Create open and respectful rights-based organizational cultures.
Actions for stakeholders	A. Work with professional bodies to strengthen openness and learning in clinical culture.
	B. Encourage membres of the public to contribute to establishment of a safety culture in the Health system by reporting to PSS and learning from publicly reported safety data.
	C. Engage patients and families and seek their advice in building a safety culture and a just culture in health care.

Strategy 2.2 Develop and operate effectively a good governance framework within each component of the health care system	
Actions for government	A. Appoint National independent body for quality and PS for receiving, analyzing, synthesizing, and publicly reporting information on the safety of health care in the country and commenting upon progress.
	B. Designate a national PS officer, team, agency or centre, appropriate to the national context and responsible for the coordination of PS implementation within the country.
	C. Establish a national PS multidisciplinary advisory committee, including representation from health workers, patients and thepublic, to advise on executing and monitoring the action plan, including resource allocation.
	D. Establish arrangements to strengthen organizational structures for PS at the national and local levels of health care planning and provision.
	E. Map the existing organizational structures related to PS, including all allied clinical areas, health programmes and QI in the health system, and develop an optimal governance structure for PS following principles of quality management.
	F. Define roles and responsibilities within the institutional framework, with a clear demarcation of authority and responsibilities, channels of reporting and communication, and conflict resolution.
	G. Create a statutory requirement and accountability mechanism for all health care organizations to operate transparently, ensure mínimum safety standards and publicly share reports on PS.
	H Establish a national governance mechanism for PS with the participation of, national professional associations, standard-setting agencies.

Actions for National independent body for quality and PS	A. Establish a national governance mechanism for PS with the participation of EU, WHO national professional associations, standard-setting agencies, patient organizations and research institutes, with elements of accountability and mandatory reporting on issues vital to PS.
	B. Appoint or designate a person for PS within National independent body for quality and PS within all functional levels of Slovenian healthcare.
Actions for health care facilities	A. Designate an officer or a team responsible for PS and CRM in each health care facility to minimize patient harm, manage risks and improve PS.
	B. Establish a PS committee at the organizational level, including PS and clinical leadership, to adapt and implement national PS priorities aligned with local priorities.
	C. Establish a clear specification of roles and responsibilities to identify, mitigate and eliminate risks to patients and staff.
	D. Design and implement effective clinical governance structure to fully engage point of care providers in the organization' PS policies and programmes.
Actions for stakeholders	A. Bring together all key stakeholders – national professional associations, academic experts, researchers, civil society organizations to pool experience and knowledge, nominate patient representatives, and generate ideas about how to build institutional governance mechanisms for PS within health care systems.

Strategy 2.3 Develop clinical and managerial leadership capacity and capability at all levels to ensure a strong and visible focus on eliminating avoidable harm in health care	
Actions for government	A. Designate one or more centres in the country to develop capacity in PS leadership, research and innovation.
	B. Establish a leadership capacity development programme in PS for clinical and managerial leaders and multi-tiered levels of workforce education and training that could influence decisions and configuration at institutions.
	C. Establish a PS leader group for early career professionals in existint health care positions.
Actions for National independent body for quality and PS	A. Develop a leadership competency framework with implementation guidance and accompanying tools, and provide technical support for implementation.
	B. Design training courses and programmes, including in e-learning format, for building leadership capacity in PS for different categories of health professionals.
Actions for health care facilities	A. Appoint or designate a senior officer in the organization to a PS leadership position.
	B. Designate PS leadership roles in every clinical service and traint, develop and support existing staff to fill them.
	C. Make a leaders' succession plan to ensure continuity, sustainability and cultural consistency of the PS programmes in each clinical service.
Actions for stakeholders	A. Convene wide-ranging discussions amongst stakeholders to identify priorities for leadership development in PS.
	B. Participate in PS leadership development and training programmes bringing in the perspective of stakeholders.
	C. Promote implementation of the training programmes at national and local levels.

Strategy 2.4 Bring a strong human factors/ergonomics perspective and input to strengthening the resilience of health organizations and clinical practices	
Actions for government	A. Work with partners nationally and externally to incorporate PS elements in guidance documents, policies, strategies and action plans (preparedness, response, recovery, routine).
	B. Provide normative guidance to ensure the safe and effective functioning of health care systems in terms of PS, health worker safety and safe working environament.
	C. Ensure that all licensing, regulatory and accreditation requirements for PS involve principles of and training on human factors.
	E. Establish and enforce norms for fire safety, electrical safety and structural safety in health care facilities.
Actions for National independent body for quality and PS	A. Establish an expert group to report on the ways in which human factor-related principles and training could drive sustained improvements in PS.
	B. Incorporate expertise on human factors into the design, purchase, deployment, use and evaluation of equipment, devices and information technology, as well as in the design of tasks and procedures.
	C. Develop or facilitate availability of training programmes on human factors for health care providers and managers.
	D Provide technical support on inclusion of PS elements into national policies, strategies and plans.
Actions for health care facilities	A. Identify the risks associated within the context of emergencies, disease outbreaks and settings of extreme adversity that have the potential to cause patient and health worker harm.
	B. Prepare a risk mitigation plan in line with the government's guidance.
	C. Test the resilience of the plan by regular simulation exercises and strengthen it accordingly.
Actions for stakeholders	A. Provide support and expertise for incorporation of PS elements in national policies, strategies, plans and normative guidance.
	B. Work with civil society organizations to mobilize the public, raise awareness and engage communities on the importance of patient and health worker safety and a safe working enviornment.
	C. Identify and facilitate opportunities for widening multisectoral collaboration, support and prioritization of safety in health care

Strategy 2.5 Incorporate PS elements within the context of emergencies, disease outbreaks and settings of extreme activity	
Actions for government	A. Ensure representation of PS focal points in coordination mechanisms, including all health system actors (leadership, service delivery, finance, supply chain management, health workforce, health information system) from related sectors (developmental or humanitarian).
	B. Ensure incorporation of PS elements in national policies, strategies and plans (preparedness, response, recovery, routine).

Actions for National independent body for quality and PS	A. Maintain a risk register of all known and potential threats to the safe and effective functioning of health care systems
	B. Develop mitigation strategies for identified risks.
	C. Test the resilience of the plan by regular rehearsal exercises and strengthen them accordingly.
Actions for health care facilities	A. Identify the risks associated within the context of emergencies, disease outbreaks and settings of extreme adversity that have the potential to cause patient and health worker harm.
	B. Prepare a risk mitigation plan in line with the government's guidance.
	C. Test the resilience of the plan by regular simulation exercises and strengthen it accordingly.
Actions for stakeholders	A. Provide support and expertise for incorporation of PS elements in national policies, strategies, plans and normative guidance.
	B. Work with civil society organizations to mobilize the public, raise awareness and engage communities on the importance of patient and health worker safety and a safe working environament.
	C. Identify and facilitate opportunities for widening multisectorial collaboration, support and prioritization of safety in health care

6.3. Strategic objective 3 – Safe clinical processes

When patients look for help from a health care system, they enter a series of care processes that are often significantly interrelated. The number and scope of clinical processes and procedures are enormous and vary from relatively simple, such as prescribing medicine, to much more complex, such as major heart surgery.

A high proportion of PS incidents that occur in health care systems worldwide is because of flaws in the design or operation of clinical processes.

Herein are mentioned some errors as an example of patient harm. Patients' conditions are often misdiagnosed owing to clinical misjudgments. When the correct test was not carried out, test results were lost, miscommunication between different parts of the same health care system, etc. In surgery, the wrong procedure is performed, the wrong blood group or component is transfused, or the wrong prosthesis is inserted, or the wrong patient is operated on. Patients die or are harmed due to failure to deliver care in a way that protects them from acquiring serious infection. Mothers and babies die during or after birth because of unsafe practices, failure to take the right action at the right time, or shortages of staff or equipment. Large numbers of PS incidents occur because of errors in the prescribing, ordering, storage, dispensing, preparation and administration of medicines and/or failure to monitor.

A more comprehensive approach to PS is essential for Slovenia, which is nowadays fragmented mainly because of the attitude that the culpability for an error lies in the hands of the first-line practitioner. The legislative environment is likewise unproductive and the main obstacle to PS improvement.

The design and operation of safe clinical processes mean overcoming the challenges of their diversity and complexity. For example, more than 4,000 medical and surgical procedures can be performed. For doctors and nurses managing clinical processes, the amount of information they need to guide them is increasing all time. Nearly 7,000 papers are published and listed in

the main clinical science database every day. Therefore, it is challenging for the busy individual clinician to be up to date with the best evidence.

Unfortunately, many generic features of clinical processes determine whether they risk delivering an unsafe outcome. For instance, incorrect identification is responsible for medication errors and wrong-site, wrong-patient surgery. In addition, the packaging and labeling of medicines contribute to medication errors and death in many clinical areas.

The key clinical areas where adverse outcomes consistently occur because of failures in care safety are studies showing that patient falls account for an important proportion of avoidable harm. They occur in hospitals and health care facilities and at patients' homes. Consequences of falls have grave concerns: fractured hips, brain bleeds, and sometimes death. Successful solutions have involved more cohesive teamwork, good monitoring data, creating the right culture, critical review of environmental hazards, and vigorously enforcing best practice protocols for making the prevention of falls a priority.

There are, however, some good practices in Slovenia like immunization of children, blood transfusion, transplantation programme, infant mortality with an established perinatal system and organisation of care for infants and children, and safe surgery checklist, to mention only a few of them. But unfortunately, a comprehensive system of spreading these good practices is missing.

3 Assure the safety of every clinical process.

Strategy 3.1 Identify all risk prone clinical procedures and mitigate their risks, taking account of national and local priorities	
Actions for government	A. Set out the policy systems and processes that are required to ensure that risks are managed consistently across Slovenian healthcare governance and develop a system for monitoring and controlling CRM system at the providers level.
Actions for National independant body for quality and PS	A. Review evidence to identify risk-prone clinical procedures in collaboration with professional bodies, experts, academia, and patient and family representatives, and other relevant stakeholders and partners.
	B. Establish a range of clinically led PS improvement programmes each year consistent with the national PS plan and strategy (see strategy 1.1) that target systemic themes (patient identification, diagnostic safety); patient groups (dementia patients, paediatric patients); health care settings (primary care, nursing homes); sources of harm (venous thromboembolism, sepsis and patient falls); clinical practice domains (surgical care, obstetric services, critical care, emergency medical services, radiotherapy); and mental health and public health programmes (immunization, reproductive health, maternal health).
	C. Create expert groups to identify, assess, map and widely communicate the information on key areas and sources of avoidable risk and harm in each domain of clinical practice.
	D. Create and regularly updated database of knowledge and tools to enable organizationsand health care professionals to mitigate the risks and manage harm associated with clinical processes.
	E Develop assessment tools and guidance to identify and mitigate these risks, for example in the areas of diagnostic safety, patient falls, and hospital-associated venous thromboembolism.

	F. Develop PS improvement programmes that target systemic themes, patient groups, different health care settings, sources of harm, clinical domains and public health programmes.
	G. Provide guidance and leadership support to annual PS improvement programmes, evaluate them, and disseminate lessons learned with overall safety and QI programmes in the health sector.
	H. Develop standards criteria and indicators for the evaluation CRM system, including the implementation of policy, strategy, tools, number and quality of HFMEA projects and implement regular evaluation of CRM system.
	I. Collate and disseminate best practices and success stories and develop trainings for healthcare facilities and stakeholders.
Actions for health care facilities	A. Designate or appoint clinical risk managers or PS officers in large health care facilities. Incorporate it into existing risk management, quality and PS structure.
	B. Establish a healthcare risk unit at a healthcare organization that can be part of the quality and PS unit.
	C. Establish a clinical leadership group within the organization to adapt and drive forward the annual national PS improvement priorities together with local priorities for clinical services.
	D. Specify a system for information communication from different sources such as audit committee, CRM committee, PS committee, drug and therapeutic committee, utility committee, infection prevention committee, accreditation reports etc.
	E. Establish or upgrade and maintain a risk registry
	F. Formulate a CRM programme.
	G. Identify key clinical service areas requiring focused PS improvement based on national and local health priorities, criticality of delivered services, and safety incidents reported.
	H. Identify all risk-prone clinical procedures within the spectrum of care delivered to patients by the organization and develop a Package of actions for risk mitigation.
	I Apply basic principles for quality management and utilize improvement science methods for improving clinical services and outcomes.
	J. Implement CRM activities to improve patient care, for example to address venous thromboembolism, falls and pressure ulcers, patient identification and communication during transitions of care.
	K Promote the wider use of validated standard operating procedures in all clinical areas in consultation with clinicians.
Actions for stakeholder	A. Encourage and facilitate professional organizations to systematically identify the sources of risk and harm in each area of clinical care, and to formulate PS solutions for different health care settings and share their expertise.
	B. Collaborate with National independent body to develop or revise national guidelines for CRM.
	C. Support health care providers in prioritizing clinical safety programmes based on context, burden and feasibility.
	D. Advocate inclusion of, incorporate and prioritize PS components in national and International public health programmes.

	E. Form collaborative working arrangements with private sector partners to identify and mitigate risks inherent to their products and services.

Strategy 3.2 Implement a programme to transform the safety of medication management and use based on the third WHO Global Patient Safety Challenge: *Medication Without Harm*	
Action for government	A . Designate a national coordinator to spearhead the third WHO Global Patient Safety Challenge: Medication Without Harm.
	B. Encourage reporting of adverse drug (medication) events (ADEs) and medication errors.
Actions for National independent body for quality and PS	A. Create and implement a communications and advocacy strategy and promote the global Know, Check, Ask campaign and the 5 Moments for Medication Safety tool.
	B. Convene national experts, health sytems leaders and practitioners in multidisciplinary task teams to produce guidance and action plans for each of the four domains (patients and the public, medicines, health care professionals, systems and practices of medication) of the third WHO Global Patient Safety Challenge: Medication Without Harm.
	C. Advocate and support assessment and identification of the burden of medication related harm due to unsafe medication practices, and actively pursue efforts to improve medication safety.
	D. Develop and disseminate technical materials, including PS solutions, technical reports, measurement tools and methodologies (such as medication safety assessment tools), and a monitoring and evaluation framework to monitor progress and evaluate the impact of the Challenge.
	E. Empower patients and families to co-design patient materials that address health literacy and support patient empowerment.
	F. Support healthcare facilities to establish and strengthen mechanisms for medication error reporting, address medication safety culture, strengthen the role of the multi-professional team in medication safety and promote learning from errors.
	E. Co-design and implement measures to improve patient medication literacy. Ensure patients are aware of and have access to medication safety tools that allows the patient to focus on key points in the medication process to mitigate risks.
	G. Set out research priorities on the burden of medication-related harm and the effectiveness of interventions to address medication safety.
Actions for health care facilities	A. Establish a leadership group within the organization to implement the third WHO Global Patient Safety Challenge: Medication Without Harm, to undertake assessment and to agree early actions, taking account of national guidance and priorities.
	B. Designate an officer or a team responsible for medication safety in each health care facility; raise awareness about medication risks and implement safety practices in every clinical service within the organization.
	C. Ensure that safety of traditional and complementary medication use is included in programmes to address medication safety.
	D. Put mechanisms in place, including the use of tools and technologies, to enhance patient awareness and knowledge about the medicines and medication use process, including patients' roles in managing their own medications safely.

	E. Identify medication-related errors and harm through the organization's PS incident reporting and learning system, investigate their root causes, and take action to ensure that learning is prioritized.
	F. Take early action to protect patients from harm arising from high-risk situations, polypharmacy and transitions of care.
	G. Monitor progress in reducing medication-related harm within the organization's services, using the existing pharmacovigilance system where appropriate. Alert national authorities to any apparently new source of medication-related harm.
	G. Encourage all patients served by the organization to download the WHO mobile phone app MedSafe (part of the 5 Moments for Medication Safety tool), which allows the patient to focus on key points in the medication process to mitigate risk.
Actions for stakeholders	A. Ensure that patients, families and civil society organizations are closely involved in all aspects development of tools to help patients protect themselves from harm.
	B. Fully engage all stakeholders in implementing the developmnet, including educational and research institutions, regulatory authorities, health professional societies, pharmacy bodies, patient advocacy groups, donors and the pharmaceutical industry

Strategy 3.3. Put in place rigorous and evidence-based measures for infection prevention and control to minimize the occurrence of health care-associated infections and antimicrobial resistance	
Action for the government	A. Aligned with the national PS policy and programme, establish a national IPC policy and programme with clearly defined objectives, functions and activities in accordance with national priorities for the purpose of preventing health care-associated infections and combating antimicrobial resistance through good IPC practices.
	B. Adapt technical guidance and implementation strategies to the national context and build capacity for IPC core components.
	C. Encourage routine public reporting requirements for health care-associated infections, antimicrobial resistance and other adverse events from health care facilities (including hospitals and long-term care facilities) to local and national governments.
	D. Establish systems for the surveillance of health care-associated infections and antimicrobial resistance in order to monitor IPC practices and assess progress and improvement over time against established national targets and best practices..
	E. Establish and ensure appropriate health care laboratory testing capability and capacity at local, national and global levels to improve detection of and response to multidrugresistant organisms in health care settings.
	F. Ensure connectivity and coordinated efforts with water, sanitation and hygiene, antimicrobial resistance and health emergency departments.
	G. Provide adequate regulatory provision, resources and guidance on handling and disposal of infectious waste.
Actions for National independent body for quality and PS	A. Provide leadership, connectivity and coordination to support successful programmes of IPC and other related PS programmes across the diversity of health care settings in the country.
	B. Build infection prevention and control (IPC) programmes to provide safety for patients, health workers and visitors (refer to WHO core components for IPC: implementation tools and resources, 2018).

	C. Provide guidance and recommendations on best practices and policies to prevent health care-associated infections and address antimicrobial resistance in health care.
Actions for health care facilities	A. Implement IPC requirements in health care facilities.
	B. Designate an officer responsible in each health care facility to coordinate PS efforts and implement IPC practices to prevent health care-associated infections and to combat antimicrobial resistance.
	C. Implement IPC, antibiotic stewardship and comprehensive waste management education and training for all health workers by using team- and task-based strategies that include bedside and simulation training.
	D. Perform routine, regular surveillance of health care-associated infection (including antimicrobial resistance) to guide interventions and detect outbreaks, with rapid feedback of results (including reporting to national networks) to health workers, stakeholders and public health authorities.
	E. Encourage and implement use of diagnostic tests to strengthen early and accurate pathogen identification and antimicrobial resistance results to guide the most effective and safest patient treatment using the right drugs, doses and duration of treatment.
	F. Implement multimodal IPC strategies; audit the compliance with IPC standards and feedback results to the leadership of the organization and staff.
	G. Ensure a clean and hygienic environment that incorporates a water, sanitation and hygiene infrastructure, with availability of appropriate IPC materials and equipment.
	H. Implement evidence-based processes for the segregation, transportation and disposal of infectious waste.
Actions for stakeholders	A. Maintain networks and groups with expertise and research involvement in the area of IPC to assist in producing guidelines and advising on their application in different health care settings and contexts.
	B. Link the work of all relevant programmes and professional organizations to national IPC programmes.
	C. Raise awareness on the importance of preventing health care-associated infections and combating antimicrobial resistance in health care at the local, national and global levels.
	D. Advocate allocation of dedicated resources to establish and sustain programmes related to IPC, health care-associated infections and antimicrobial resistance at local, national and global levels.
	E. Encourage accountability, public reporting of data and transparency to make progress towards preventing health care-associated infections and antimicrobial resistance in health care.

Strategy 3.4 Assure the safety of medical devices, medicines, blood and blood products, vaccines and other medical products	
Actions for government	A. Provide adequate policy, legal and regulatory provisions to ensure that these programmes can be implemented safely and effectively to fulfil their purpose.
	B. Establish bidirectional linkages of programmes for the safety of medical devices, medicines, blood and blood products, vaccines and other medical products with PS programmes.

	C. Establish a national blood programme supported by a blood policy and legislative framework.
	D. Develop normative guidance for ensuring the safety of medical products.
	E. Surveillance programmes for medical products.
	F. Promote coordination amongst multisectoral stakeholders to prevent the proliferation of substandard and falsified medical products.
Actions for National independent body for quality and PS	A. Promote and support observing and celebrating World Blood Donor Day on 14 June annually.
Actions for health care facilities	A. Use only authorized medical devices that meet the prescribed safety standards.
	B. Introduce mechanisms for the regular maintenance and calibration of all critical equipment.
	C. Ensure that the operating manual and safety instructions of equipment are always available at the point of use and that new staff receive induction training on appropriate use as well as training during device upgrade.
	D. Adopt standard operating procedures for transfusion services and participate in an external quality assessment programme and a hemovigilance programme.
	E. Adopt standard operating procedures and safety protocols for immunization services.
Actions for stakeholders	A. Maintain mutually agreed international safety and quality standards for medical devices, blood and blood products, medicines and vaccines.
	B. Engage with industry leaders to improve products and devices in their respective fields.

Strategy 3.5 Assure the safety of patients in all settings, including in mental health settings and care homes, with a focus on primary care and transitions of care	
Actions for government	A. Implement integrated information infrastructures to enable free flow of information across all health care settings.
	B. Develop and implement referral pathways for primary care.
	C. Introduce and strengthen PS elements in service delivery, licensing and accreditation of primary care, and hospice and home-based care services.
	D. Extend PSS interventions such as reporting and learning systems, integration of digital technologies, safety culture and patient engagement across the care continuum, including primary care.
Actions for National independent body for quality and PS	A. Develop tools and guidance for improving PS across the continuity of care, for example in primary care settings, including preventive and promotive care, and safe communication during transitions of care.
	B. Establish standardized and clear handover procedures and protocols within and between health care facilities and home-based care.

	B. Provide technical support to build country capacity in implementing PS strategies and interventions across the care continuum.
	C. Develop guidance and tools on PS in home-based care.
Actions for health care facilities	A. Standardize formats for patient records in primary and ambulatory care, supported by electronic health records.
	B. Implement standard operating procedures and establish clear channels for communication with different care providers across care transition, for example, from a primary care setting to a outpatient specialty service and hospital setting for patient referral.
	C. Include primary and ambulatory care services in PS incident reporting and learning system.
	D. Implement diagnostic and treatment pathways for primary care services, similar to the hospital services.
	E. Implement uniform handover procedures across health care facilities.
Actions for stakeholders	A. Provide support in adapting and implementing PS strategies and interventions across the care continuum, including primary care and transitions of care.
	B. Build the capacity of primary care organizations to provide safer care.
	C. Promote PS research in areas and different settings across the care continuum, including primary care and transitions of care.
	D. Include and strengthen PS elements in international technical support programmes across the care continuum, including primary care and transitions of care.

6.4. Strategic objective 4 – Engagement and empowerment of patients and families

Patients, families, and other informal caregivers bring **insights from their care experiences** that cannot be substituted for by clinicians, managers, or researchers. Patients, families, and caregivers can serve as attentive observers of a patient's condition and alert healthcare providers when new needs arise. With the proper information, the patient and family can help be the system's eyes and ears. They can experience a breakdown in communication, teamwork and propose solutions. **Slovenia** does not have a strong patient voice campaigning for improvements in PS. Patient advocates are established by law but represent individual patient when they complain about possible errors in their care. Patients and families engagement calls for the healthcare system to be democratized.

WHO recommends five interlinked strategies that need to be implemented:

- Engaging and empowering people and communities
- Strengthening governance and accountability
- Reorienting the model of care
- Coordinating services within and across sectors
- Creating an enabling environment

Patient and family engagement needs to be made an integral part of PS: as a partner of health care practice, by building it into each health care organizational and governance structure, by having it a subject of community and national oversight, and by giving it an equal seat at the table in global PS leadership and planning. This would empower the voice and experience of patients and families to have a powerful and beneficial influence on international and national policies through bedside and clinic practices; all strategies would be seen through the patient's lens.

Identifying and training patient advocates and champions is vital to increase patient and family engagement. It is necessary to identify, grow, and incentivize health care leaders with those **values**. Such leaders champion patient participation in their governance structures, in their strategic priorities, and in their budgets. Their moral imperative is to integrate patient and citizen roles into their organisation's work and produce a culture of safety and respect that encourages active listening to patients' voices within their organization. This works both ways. A safer culture for patients will usually also be safer for health workers.

Most importantly, **patients need to be given the information they need to manage their care** and take charge of their safety to the greatest extent possible. Health care institutions, supported by national and international entities, should commit to policies to promote transparency to patients, including fully informed consent, patient access to medical records, and full disclosure if their care harms patients. Patients should be able to escalate concerns within a health care organization and be actively encouraged to submit reports to PS reporting systems. These reports should be given full standing as incident reports and not sidelined into a separate category as patient "complaints."

A shift in emphasis to **view PS as a fundamental human right** that should prioritize patient engagement is an important principle on which to base strategies.

4 Engage and empower patients and families to help and support the journey to safer health care.

Strategy 4.1 Engage patients, families and civil society organizations in co-development of policies, plans, strategies, programmes and guidelines to make healthcare safer	
Actions for government	A. Develop a national PS rights charter or bill with legal standing, to include concepts such as patient rights to safety, respect, autonomy, reliable care, information and transparency; and promote the concept of safe, respectful care as a human right.
	B. Embed the WHO Framework on Integrated People-centred Health Services in the design and delivery of safe health services.
	C. Create formal mechanisms to include patients and families in national governance mechanisms, working groups, task forces and committees that plan and take action to improve PS in the country.
	D. Create alliances with existing patient and civil society organizations on PS.
	E. Embed patient and family engagement standards in accreditation and evaluation.
	F. Include goals related to patient and family engagement as key components of short- and long-term strategic plans
Actions for National independent body for quality and PS	A. Ensure involvement of patients, families, PS advocates and champions, Patients for PS network members, and patients' and civil society organizations in national activities for co-developing policy, strategies, guidance and tools related to PS.
	B. Develop action frameworks, principles for engagement and implementation tools for patient and family engagement for PS that countries and institutions can adopt at different levels.

	C. Provide advocacy to healthcare facilities for establishing policy and developing tools on patient and family engagement, including guidance on informed consent.
	D. Involve Patients for Patient Safety network members, patients and families with experience of avoidable harm, and patients' and civil society organizations in implementation of the national action plan, and in its monitoring and accountability mechanisms.
	E. Create a model PS rights charter or showcase existing ones; offer a rationale for PS as a human right and guidance on developing and implementing charters.
Actions for health care facilities	A. Involve patient or family representatives with experience of avoidable harm in health care in designing strategies and defining actions to reduce the likelihood of a recurrence.
	B. Appoint patient and family representatives to be part of the organization's boards and committees.
	C. Rearrange the care processes and wherever necessary reorient them to make services patient centred and based on the cardinal principle of "what is important for patients and families".
	D. Create patient and family advisory councils that are focused on PS.
	E. Develop procedures around the provisions of the national charter or bill, including non-discrimination, patient autonomy, informed consent and shared decision-making, emergency response, access to medical records and full disclosure of adverse events.
	F. Develop institutional standards for patient and family engagement, and develop a practice of improvement based on patient experience.
Actions for stakeholder	A. Conduct research to identify behaviours that constitute and support patient and family engagement – by patients, families, clinicians, administrators and other health professionals, within various health care settings.
Strategy 4.2 Learn from the experience of patients and families exposed to unsafe care to improve understanding of the nature of harm and foster the development of more effective solutions	
Actions for government	A. Establish platforms, networks and events to bring together PS advocates, champions, patients and patient organizations to share their experience of avoidable harm or unsafe care and best practices in patient and family engagement.
	B. Create mechanisms and strengthen platforms for sharing health care experiences of patients and families, including patient reporting on outcomes and experiences, that highlight PS problems and point to solutions for PS improvement.
	C. Ensure that the patient and family experience of harm informs the design of all PS programmatic areas (for example, policy, education and training, research and information).
Actions for National independent body for quality and PS	A. Provide advocacy to healthcare facilities to create mechanisms to learn from patient experience of safe and unsafe care, including patient reporting on experiences and outcomes.
	B. Develop tools and guidance to collect, collate and analyse patient-reported experiences and outcomes of unsafe care for PS improvement.

	C. Create and maintain a global collection of stories from patients and families with experiences of safe and unsafe care, avoidable harm and effective change, and disseminate those experiences to raise awareness of the importance of prioritizing PS within broader health system strengthening efforts.
Actions for health care facilities	A. Create a culture and organizational framework whereby the encounters and experiences of patients and families with avoidable harm, told by themselves, are an integral part of all PS work within the organization's services.
	B. Include a patient and family experience, told by themselves, as a regular agenda item on the organization's main board meeting in order to give health care leaders a deep insight into the realities of the impact of unsafe care.
	C. Create PS reporting mechanisms that encourage patients and families to report and, by collecting, collating and analysing patient-reported experiences and outcomes of unsafe care, demonstrate actions for learning and improvement.
Actions for stakeholders	A. Organize national and local workshops, symposia and events to share the experiences and expectations of patients and families, especially those who have suffered avoidable harm.
	B. Ensure that professional associations and specialist societies invite patients and family members with PS experiences to their annual conferences and scientific events.

Strategy 4.3 Build the capacity of patient advocates and champions in patient safety	
Actions for government	A. Support and empower the development of networks of patient advocates and champions, and collaborate with the WHO Patients for Patient Safety programme.
	B. Establish, train and support a panel of patient and family advocates for PS to act as speakers at national and local conferences.
	C. Support capacity-building of PS advocates and champions at national and local levels.
	D. Share the findings of PS reporting and learning systems with patient advocates and champions.
Actions for National independent body for quality and PS	A. Strengthen the WHO Patients for Patient Safety programme and expand the Patients for Patient Safety global network.
	B. Provide advocacy and guidance to support the establishment of Patients for Patient Safety programmes and patient organizations at national levels.
	C. Develop educational and technical resources, including e-learning programmes, guidance and tools, for PS advocates and champions.
	D. Facilitate relationships between civil society organizations, patient advocates and government agencies.
Actions for health care facilities	A. Conduct a wide-ranging review to assess the involvement of patients in the improvement of safety in health care within the organization.
	B. Institute measures to fully engage with patients and families to enhance their opportunities to contribute to processes to improve PS.
	C. Develop a strategy for involving PS advocates and champions as educators.

Actions for stakeholders	A. Use networks and collaborations to identify, recruit and train patient advocates and champions for PS to serve as patient representatives in government and health care settings.
	B. Develop and disseminate patient information materials on different aspects of PS and participate in public awareness campaigns.
	C. Work with the government to support the development of the national Patients for Patient Safety programme.

Strategy 4.4 Establish the principle and practice of openness and transparency throughout health care, including through patient safety incident disclosure to patients and families	
Actions for government	A. Develop national guidance for informed consent, for patient access to their medical records, and for a patient and family to escalate care concerns if they perceive a patient to be deteriorating.
	B. Develop a guidance framework and procedures for enabling health care providers to disclose to patients and families the adverse events that have caused (or could have caused) inadvertent harm.
	C. Consider introducing legislation on disclosure policies to inform patients and families where guidance has not been effective.
Actions for National independent body for quality and PS	A. Collect, collate and disseminate model disclosure policies and procedures to inform patients and families of PS incidents that caused (or could have caused) inadvertent harm.
	B. Recommend policies on transparency, patient information and full disclosure, including references for sample policies and advice on implementation.
	C. Encourage healthcare facilities to introduce policies promoting transparency, including open disclosure policies, as part of the national PS policy, as a way of demonstrating their commitment to a positive PSC in their health systems.
	D. Provide guidance on best practice in designing and operating open disclosure policies and legislation.
Actions for health care facilities	A. Develop institutional policies for robust informed consent, for patient access to their medical records, and for emergency escalation systems that can be triggered by patients and families.
	B. Develop and implement disclosure policies and procedures to inform patients and families of PS incidents that caused (or could have caused) inadvertent harm.
	C. Ensure that patients, families and health workers are given ongoing psychological and other support in the aftermath of a serious PS incident.
Actions for stakeholders	A. Raise awareness about safety reporting systems, the right to access medical records, the right to informed consent and the right to an emergency response, including other PS avenues available to patients.
	B. Raise awareness of civil society organizations, patients and families and seek the full support of professional bodies and their members for a policy of open disclosure of PS incidents to patients and family members.
	C. Organize a flow of information from stakeholders about the practical experience of the open disclosure policy and other transparency initiatives and suggestions for improvement.

Actions for stakeholders	D. Raise awareness of civil society organizations, patients and families about the positive purpose of the open disclosure policy and their entitlements under it.

Strategy 4.5 Provide information and education to patients and families for their involvement in selfcare and empower them for shared decision-making	
Actions for government	A. Incorporate activities to enhance public education, including in schools and communities, and increase awareness of PS in the national PS plan.
	B. Include patient and family engagement in the PS education curriculum, and develop a specific curriculum for school-aged children.
	C. Develop mechanisms for providing information and education to patients and families to enable them to partner with health care organizations and with other stakeholders.
	D. Develop and disseminate public service announcements with clear messages about what patient and family engagement is and why it is important.
	E. Integrate patient and family engagement into the health care professionals curriculum, and develop standardized patient and family engagement competencies.
	F. Promote use of digital technologies, including smartphones, in improving awareness about PS and enhancing patient and family engagement.
Actions for National independent body for quality and PS	A. Develop, collate and disseminate information and educational materials and tools for enhancing the health literacy of patients and families and enabling their involvement in self-care and shared decision-making, including mobile applications, fact sheets and videos; make these resources readily available and encourage their use.
	B. Include patient and family engagement in national PS curriculum, and develop a specific curriculum for school-aged children.
	C. Advocate engagement of patients and families as educators in PS education and training activities.
Actions for healthcare facilities	A. Educate patients and families about their health and health care, support patients in managing their own health, and train families to deliver care, especially in responding to patients' needs in a home care environment.
	B. Develop patient information materials on clinical procedures, including safety risks, to empower patients when seeking information from health workers.
	C. Implement communication mechanisms that help clinicians understand patient perspectives and concerns.
	D. Structure care processes to support information sharing, care planning, self-management and shared decision-making, and implement patient-centred tools for patients and clinicians to support shared decision-making.
Actions for stakeholders	A. Increase the use of peer education for patients and families, support patients in managing their own health and encourage them to take an active role.
	B. Include patient and family engagement and safety in educational curricula and training courses.
	C. Develop and disseminate patient information and education materials on PS.

6.5. Strategic objective 5 – Education of healthcare workers

All health professionals are devoted to keeping their patients safe. However, the majority believe they are doing so by practicing within the ethical code of practice and attaining new technical knowledge of their specialty or professional group. Even legislation can support the permanent vigilance of human beings as a means of avoiding error. Only a few think beyond this to fully value the scope of the risks involved in delivering health care and the scale of preventable harm that rises daily within every health care system in the world. **Errors do not occur because of any lack of compassion** on health professionals. Traditionally, undergraduate, postgraduate, and continuing education programmes emphasize **evidence-based practices and standards that are disease or clinical condition-oriented.** The systems aspects of safety problems are often missing, and programmes provide no training on human factors or ergonomics.

Health worker safety and PS are inseparably interconnected. Health and safety risks to health workers can lead to risks for patients, patient harm and adverse patient events. **Violence against health workers, burnout and musculoskeletal disorders** are all widespread occupational health problems in health care facilities, many of which also face **acute shortages of competent health workers**. **Health worker absenteeism and attrition,** resulting in **suboptimal care outcomes**, are aggravated by health workers' poor physical and mental health. **Physically and psychologically sound health workers are less predisposed to make errors,** contributing to safer care. The safety of health workers is therefore, directly impacts the safety of patients.

Healthcare practice means that every individual clinical encounter is embedded into a broader system of care delivery that can affect the patient’s safety at any specific moment.

All health workers, managers, and leaders must comprehend the nature and importance of risk and how harm is generated, the core concepts of PS science, how the causes of unsafe care are appropriately investigated and understood, and the actions necessary to ensure that care and the individual processes that make it up are as safe as is possible.

One health care school in Slovenia was an additional center to evaluate a Multiprofessional PS Curriculum Guide. Regrettably, practical teaching was done only for a few nursing students at the postgraduate level.

There are **multiple barriers to ensuring that PS is a major component of education** and training programmes, like the absence of buy-in from stakeholders, weaknesses in educational coordination and planning, limited leadership interest, and insufficient senior medical and nursing champions.

Furthermore, several factors have **hindered PS education** such as **unfamiliarity of educators or trainers to teach PS**, reluctance by academic institutions **to teach knowledge outside clinical disciplines** to health care students because of existing full curricula; failure of education to keep pace with technological and system advances for safe care. **Training in non-technical skills is primarily focused on listening to and communicating with the patient.**

It can be concluded that the **education and training of health professionals** have been **underused and undervalued** as a vital tool to address the challenges of achieving improved PS as it is understood today.

In many countries, like in Slovenia, the overall responsibility rests with ministries of education and not ministries of health. **Professional bodies and membership associations such as**

medical and nursing colleges may set and monitor educational standards that then drive curriculum design. The educational providers themselves are also important policy-makers, whether in universities or in free-standing schools and institutes. Leverage from these disparate bodies to achieve change is essential and currently lacking.

Traditionally, the education of health care professionals gives little attention to the importance of PS. There is no professional ethos that a practitioner's responsibilities must extend beyond the care of individual patients to ensure that their **service as a whole is safe**. There is little consideration of the nature of risk in health care and the importance of strengthening systems and there is minimal emphasis on the importance of teamwork and communication in protecting patients from harm.

Looking at best practices within health care and other high-risk industries, it is clear that **new fundamental approaches, including interprofessional and multidisciplinary approaches, are needed** if education and training play the fundamental role they should in improving PS.

5 Inspire, educate and skill health workers to contribute to the design and delivery of safe care systems.

Strategy 5.1 incorporates patient safety within all health professional undergraduate and postgraduate education curricula and broader professional development and training programmes, emphasizing an interprofessional approach.	
Actions for government	A. Reach an agreement with stakeholders responsible for standards and curriculum setting to incorporate PS in professional education and continuing professional development.
	B. Introduce the WHO Patient safety curriculum guide at national level and adopt key approaches and principles within the local context.
	C. Develop and offer specialized courses on PS for in-service training of health care professionals of different categories and at multiple levels.
	D. Include health and safety skills pertaining to personal safety in education curricula and training programmes with an interprofessional learning approach.
Actions for National independent body for quality and PS	A. Review and expand the WHO *Patient safety curriculum guide* with a focus on a competency based and interprofessional approach to education.
	B. Develop and promote PS courses and trainings, including in e-learning format.
	C. Establish a national repository of educational and training resources on PS and disseminate at different levels.
	D. Develop a training of trainers' programme for PS educational faculty and training specialists.
	E. Facilitate the design of PS education and training programmes at national levels for all categories of health workers.
Actions for health care facilities	A. Include PS in induction and orientation programmes as well as on-the-job trainings for staff.

Actions for health care facilities	B. Introduce and implement specialized trainings on PS for all professional staff, with an emphasis on team- and task-based strategies that include bedside and simulation training, with certification of satisfactory completion.
	C. Provide advanced training on PS and QI competencies for those with managerial and leadership roles.
	D. Encourage staff to take online and on-site courses on PS as part of continuing professional development.
	E. Design specialized training programmes for staff working in high-risk areas such as intensive care and emergency departments.
Actions for stakeholders	A. Convene a forum for representatives of educational institutions, professional organizations and bodies, scientific societies and experts from industry to advise government on the design, content and delivery of PS education and training programmes and support their implementation.

Strategy 5.2 Identify and develop centres of excellence for patient safety education and training.	
Actions for government	A. Designate one national quality and PS centres, public or private, in the country to provide leadership in PS education and training.
	B. Establish a national network of PS centres and allied agencies to support professional education and training in PS.
	C. Advance the use of simulation methods throughout the professional education and training in PS by identifying and designating centres to lead the development and implementation process.
Actions for National independent body for quality and PS	A. Identify centres of excellence in quality and PS education and training, ensuring equal geographical representation, and establish strategic collaborations.
	B. Develop a national and global network of centres of excellence in quality and PS education and training to share best practices and innovations, and support capacity development at national level.
	C. Promote establishment of national networks of centres of excellence in quality and PS education and training and advocate their representation in the global network.
Actions for health care facilities	A. Work closely with national quality and PS centres and the network, as applicable, to provide training opportunities in PS within the organization.
	B. Share feedback on best practices and innovations within the organization with the national quality and PS centres and the network, as applicable, to ensure information sharing and wider application.
	C. Identify staff members for the training of trainers' programme for quality and PS and facilitate their training and competency development.
Actions for stakeholders	A. Bring together all relevant stakeholders at individual and organizational levels to advise on and support quality and PS education and training at all levels.
	B. Agree upon the roles and responsibilities of stakeholders, covering different functions in education and training, such as the training of trainers' function, course and curriculum design, teaching and training methods, and development of simulation techniques.

Strategy 5.3 Ensure that patient safety core competencies are part of the regulatory requirements for all health professionals.	
Actions for government	A. Work with licensing, regulatory and accreditation bodies to ensure linkages between individual and organizational performance and PS improvements in both the public and private sectors.
	B. Define PS core competencies for each category of health care professional and specialist clinical role for PS improvements. Competencies should include non-technical skills such as teamwork and communication.
Actions for National independent body for quality and PS	A. Specify a set of PS competencies for different health professionals
	B. Work with national professional licensing, accreditation and regulatory bodies to adopt a common global standard for PS competencies and their assessment
Actions for health care facilities	A. Conduct a periodic assessment of PS competencies among health professionals.
	B. Incorporate PS competencies in the scope of practice and job descriptions of health care professionals.
	C. Link PS competencies to service standards.
Actions for stakeholders	A. Convene experts, researchers, educators and civil society organizations to discuss and agree upon initiatives to advance the routine use of PS competencies.

Strategy 5.4 Link commitment to patient safety with appraisal systems for health care professionals and managers.	
Actions for government	A. Ensure that performance assessments of health professionals are linked to participation in PS programmes and initiatives.
	B. Explore mechanisms, such as incentives and markers of esteem, that recognize exceptional achievement by individual staff members in improving PS.
Actions for National independent body for quality and PS	A. Develop a global standard, tools and methods for performance assessment of individuals, health professionals and teams involved in PS work.
Actions for health care facilities	A. Establish an internal appraisal system to monitor competencies in understanding sources of harm and participation in development of solutions and identifying evidence of achieving gains in PS in clinical services.
	B. Incorporate team-based aspects of PS performance into assessments.
	C. Recognize particularly those who have identified sources of risk and implemented successful measures to combat them.
Actions for stakeholders	A. Bring together the evidence and experience of all relevant stakeholders to provide advice on defining excellence in PS work by individual health professionals and teams and advise on the best assessment methods and tools.

Strategy 5.5 Design care settings, environments and practices to provide safe working conditions for all staff	
Actions for government	A. Support and endorse the WHO charter Health worker safety: a priority for PS by signing up to it and supporting its implementation.

Actions for government	B. Develop and implement national programmes for the occupational health and safety of health workers in line with national policies and provide adequate resources for sustainability of programmes.
	C. Adopt and implement relevant policies and mechanisms to prevent and eliminate violence in the health sector in accordance with national laws.
	D. Provide access to mental well-being and social support services for health workers, including advice on work–life balance and risk assessment and mitigation.
	E. Develop norms, standards and guidance for design of care settings and environments to ensure health worker safety.
	F. Collate and disseminate best practices on PS and health worker safety for policy, legislative and regulatory frameworks.
	G. Work with Member States and all relevant stakeholders to strengthen the occupational health and safety of health workers, with special focus on responders in emergency preparedness and response.
	H. Develop linkages of PS programmes with health, safety and environment and occupational health and human resource strengthening programmes at national and subnational levels.
Actions for National independent body for quality and PS	A. Advocate the development and implementation of adequate policy and regulatory frameworks for health worker safety and PS at international, national and subnational levels.
	B. Promote the national reporting, benchmarking and learning system for work-related adverse events concerning health workers and patients.
Actions for health care facilities	A. Ensure appropriate and fair duration of eployments, working hours and rest breaks, as well as minimizing the administrative burden on health workers.
	B. Ensure vaccination of all at-risk health workers against vaccine-preventable infections.
	C. Provide functioning and ergonomically designed equipment and workstations to minimize musculoskeletal injuries and falls.
	D. Maintain levels of personal protective equipment for health workers for the expected workload but store appropriate supplies to respond to emergencies.
	E. Implement measures to protect health workers from physical and mental violence, including incivility, bullying, harassment and discrimination.
	F. Proactively assess all care settings to identify and mitigate hazards and risks to safety of patients and health workers using the national framework as a guide.
Actions for stakeholders	A. Engage professional bodies, the medical device industry and experts and researchers to provide advice to the government on actions to keep health workers safe in all respects.

6.6. Strategic objective 6 – A constant flow of information

Despite decades of work in PS, the capacity and capability in different nations' to decrease risk, avoid harm, and improve health care safety remain severely constrained by the absence of high-quality information systems. There are many different sources of data: incident reporting systems, complaints, malpractice claims, patient-reported outcomes, avoidable

deaths, case note trigger tools, clinical care audits, organizational culture surveys, and significant event audits. Most of the data were developed for other purposes except for PS incidents. They can only be seen as proxy indicators of PS, albeit some are very helpful in functioning in that way.

Therefore, present data sources are fragmented and unrelated and fall well short of the comprehensive, integrated information systems needed within PS programmes.

Role of reporting and learning systems. Several PS programmes have raised very high expectations about the potential impact of incident reporting and learning systems. Preferably, all occurrences in a health service that have caused, or could have caused harm, would be quickly documented and thoroughly reviewed and investigated. The resulting action would lead to the **redesign of care processes, products, procedures, and changes to individuals and teams' working practices and styles**. Such actions would typically lead to a measurable and sustained reduction of risk for future patients. Some types of harm would be eliminated. *Nevertheless, very few health systems or health facilities can approach this ideal level of performance in capturing and learning from incidents of avoidable harm.*

A reporting system should aim to be resourced appropriately.

If too many PS incidents are being reported to handle realistically or even look at, let alone review, this lets down those taking time to file these reports conscientiously.

Obstacles to reporting in **Slovenia** are described in the document of situational analysis.

Measurement. Measurements of PS should be grounded on the data collected regularly for operating and managing health care systems. It should also be reinforced by governance activities that strengthen the information infrastructure so that PS can be measured. Most of the discussion about PS data is about its reactive use. Much less attention is given to initiatives that use such data for proactive learning and implementing CRM.

Principles for measuring PS are :

- The measurement aims to collect and disseminate knowledge that results in action and improvement.
- Effective measurement requires the full involvement of patients, families, and communities within and across the health system.
- Safety measurement must advance equity.
- Selected measures must enlighten an integrated view of the health system across the continuum of care and the **entire path of the patient's health journey** (figure 11).
- Data should be collected and **analysed in real-time** to proactively identify and prevent harm as often as possible.
- Measurement systems, evidence, and practices must continuously evolve and adapt.
- The burden of measures collected and analysed must be reduced.
- Stakeholders must intentionally foster a safe and just culture to optimise the value of measurement fully.

https://www.salzburgglobal.org/multi-year-series/health/pageId/8526 (accessed 20th November 2020)

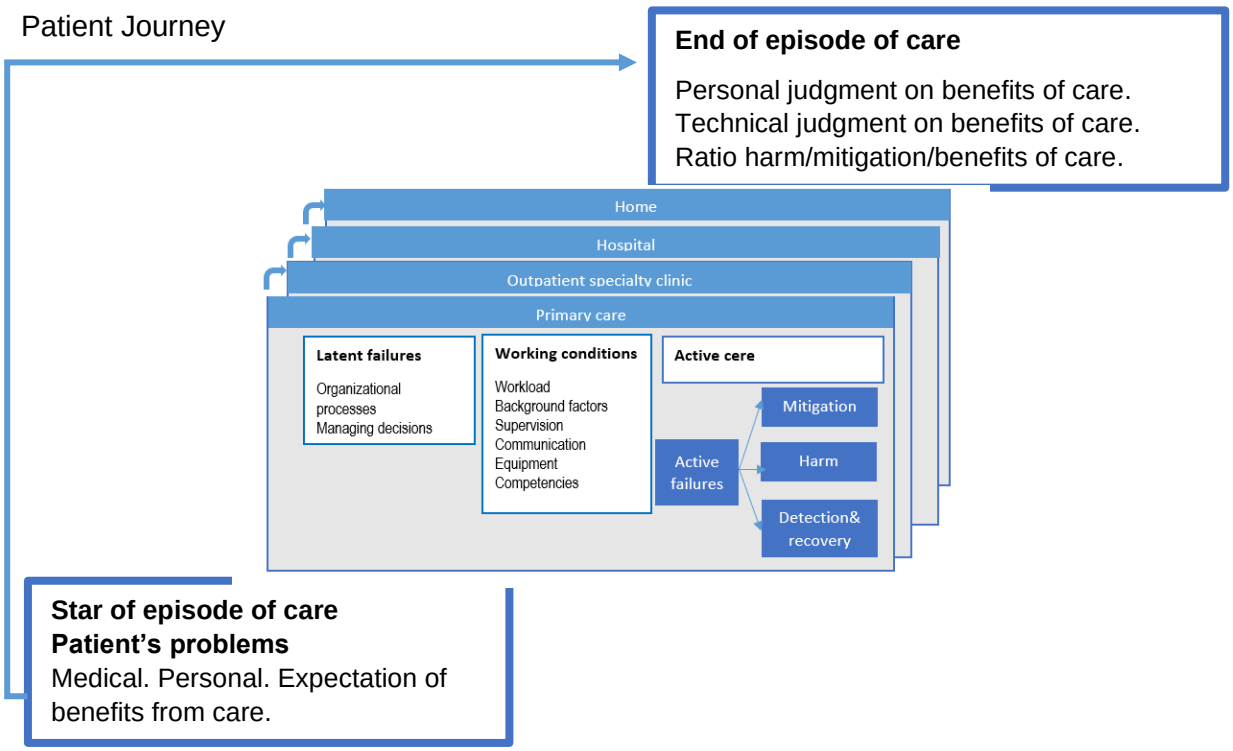

Figure 11. Patient journey. At each healthcare facility there is a possibility of preventable harm

Source adapted from McCarthy et al., 2016.

There is no doubt that commitment is needed to progress analytical capability to improve PS. In doing so, health care organizations should seek to move from the purely descriptive or diagnostic phases of working – from what happened? and why did it happen?– to predictive (what is likely to happen?) and prescriptive (what can we make happen?) capabilities which is a proactive approach considered in CRM. **CRM** is going in this direction to find problems in advance.

The change models are developed through improvement science, which can support teams to articulate the aim of the project and structure plans for developing and testing changes, monitor the impact of the changes, and sustain success.

Research. One of the major strategic goals of PS research is to produce new knowledge that improves the capability of health care systems and the health organizations and practitioners that involve them in reducing the harm associated with health care. Ideally, the outcomes of research studies would be generalizable to other healthcare systems worldwide. As a result, an active field of research sprung up with considerable resources allocated to this discipline. Research showed the **extent and causation of harm to patients** in various clinical specialties (e.g., anesthetics), in treatment areas (e.g., medication), in demographic groups (e.g., neonates) and settings (e.g., operating rooms). As a result, problems with an established pattern of harm have been re-conceptualized.

Technological and other solutions to reduce risk and the safety concepts and interventions from different disciplines have been applied to healthcare.

There have been attempts worldwide to translate this research into practice to improve care safety and decrease the relatively high burden of harm. New methodological work is needed in some key areas, including:

- Greater use of theory and logic models
- A more robust understanding of the relationship between the endpoints of the research that may not have a guaranteed relationship with actual harm
- A better description of interventions and their proposed mechanisms of effect and pathways to implementation
- Improved explanation of desired and unintended outcomes
- More detailed description and measurement of context and of how this influences intervention effectiveness

Researchers should be alert to the challenges which can arise when *unconventional concepts and definitions are used to improve the quality and value of this work*. It will be beneficial to use ***agreed terminology*****,** develop a core set of PS outcome measures and produce more PS reporting checklists. Careful alignment to the WHO International Classification for PS (this has been translated into **Slovenian** language, but used not at all and many and new nonconventional euphemisms are in use nationwide) will support the global sharing of data for priority setting, exchange of solutions for common challenges and maximize opportunities to learn from rare events. The most significant research need for the coming decade is for trials to formally evaluate the **effectiveness of the policy**, public health actions, or clinical interventions aimed at improving PS. Most interventions are likely to be complex, non-pharmacological interventions in PS. The development of trials will require ambition and cooperation amongst investigators seldom previously seen in PS research.

There is a great paucity of research on almost any area of PS in **Slovenia** and the scale and nature of in-hospital harm care, primary care, mental health services, and vulnerable groups of patients (such as older adults and disabled people) are unknown.

Digital infrastructures can be used to develop risk prediction models, augmented by artificial intelligence-based analytical approaches, to identify those at greatest risk of harm from PS incidents. Developments in health information technology also offer opportunities to support care delivery and self-management through, for example, professional or patient-facing computerized decision support. The move to digital infrastructures is not without risks, such as biased algorithms and data breaches that can involve entire populations. These technologies will be limited to well-resourced health systems in the immediate future.

The translation of research into improvements in PS does not begin and end with presenting the research findings to policy-makers and practitioners. The **implementation** of new practices nearly always involves a process of organizational development, including aspects of professional attitudes and culture. It must be a priority to focus research programmes on problems and apply definitive solutions if health care is to be made safer. Much closer relationships with policymakers will be indispensable to moving from the current “push” model of knowledge translation to a “pull” model in which researchers respond faster to the needs of decision-makers.

6 Ensure a constant flow of information and knowledge to drive the mitigation of risk, the reduction in levels of avoidable harm, and improvement in the safety of care.

Strategy 6.1 Establish or strengthen patient safety incident reporting and learning systems	
Actions for government	A. Establish or strengthen existing mechanisms for PS incident reporting and learning in both the public and private health care sectors and make improvements where necessary to the system (refer to WHO PS incident reporting and learning systems: technical report and guidance, 2020; and WHO Minimal information model for PS incident reporting and learning systems: user guide, 2016) or conclude SenSy.
	B. Place emphasis on the need to investigate incidents, learn lessons and develop clear actions to mitigate the root cause of incidents that are reported.
	C. Support and facilitate timely access to data for research and development purposes.
Actions for National independent body for quality and PS	A. Develop implementation tools and guidance to support healthcare facilities in establishing reporting and learning systems.
	B. Establish a system of safety alerts for the health care system to draw attention to and advise action on PS incidents that highlight risks with systemwide implications.
	C. Disseminate WHO or other reporting and learning guidance and tools.
	D. Develop linkages with safety reporting and learning programmes across relevant international sites.
	E. Provide technical support to healthcare facilities in establishing and strengthening PS incident reporting and learning systems.
	F. Create a national network of reporting and learning systems with the purpose of sharing knowledge about PS incidents and sources of avoidable harm that could affect multiple countries and health facilities, including the dissemination of lessons learned.
Actions for health care facilities	A. Appraise the functionality of the current PS incident reporting system aligned with WHO or other PS incident reporting and learning systems: technical report and guidance, 2020, WHO Minimal information model for PS incident reporting and learning systems: user guide, 2016, and any national guidance.
	B. Create user-friendly, confidential, and effective reporting mechanisms.
	C. Use the reporting and learning system to identify PS priorities to be addressed by improvement activities.
	D. Establish (if none present) or adjust the reporting and learning system to an appropriate scale according to the capacity of the organization to capture, analyse and investigate incidents; support increased capacity where there are clear benefits in reducing severe harm and death.
	E. Engage and support all the organization's staff in the reporting and learning effort by feeding back what has been learned and what actions have been taken to improve safety.
Actions for stakeholders	A. Raise awareness of the importance of reporting PS incidents and disseminating lessons learned, including the need to promote health organizational cultures and professional values to achieve this.

Strategy 6.2 Create a patient safety information system based on all sources of data related to risks and harm inherent in the delivery of health care and integrated with existing health management information systems	
Actions for government	A. Strengthen synergies and data-sharing channels between sources of PS information for timely action and intervention, such as incident reporting systems (including patient reports), malpractice claims, patient-reported experiences and outcome measures, clinical care audits, medical record reviews, surveys, significant event audits, burden of harm studies, and safety surveillance data for blood products, medicines, vaccines, medical devices and organ transplant procedures.
	B. Deliver annual report on PS performance of the health system of the country, including the frequency, nature and burden of avoidable harm in health care, and implement plans to reduce it to parliment and office of ombudsman of human rights.
	C. Develop a set of indicators for PS aligned with global PS targets.
	D. These indicators should be comparable between health care facilities as well as at national level.
	E. Design accountability mechanisms, informed by rigorous evaluation, to ensure that progress is made in reducing harm and improving PS throughout the health care system.
Actions for National independent body for quality and PS	A. Monitor PS practices and assess progress and improvement over time and against best practice and best performance benchmarks.
	B. Include yearly global PS targets.
	C. Create a repository of PS indicators.
	D. Develop and disseminate PS assessment tools for various health care settings.
	E. Publish an annual report on PS performance of the health system of the country, including the frequency, nature and burden of avoidable harm in health care, and implement plans to reduce it.
Actions for health care facilities	A. Identify and track the sources of avoidable harm across the organization and in each clinical service.
	B. Implement PSI and use these to track progress and monitor trends.
	C. Evaluate the impact of improvement programmes with an emphasis on sustaining the benefits over time.
Actions for stakeholders	A. Raise awareness of the importance of reporting PS incidents and disseminating lessons learned, including the need to promote health organizational cultures and professional values to achieve this.

Strategy 6.3 Establish, synergize and scale up patient safety surveillance systems to ascertain the magnitude and causes of harm in health care	
Actions for government	A. Establish systems for PS surveillance to monitor PS practices and assess progress and improvement over time and against best practice and best performance benchmarks.
	B. Establish core laboratory capacity at national and subnational levels to quickly detect and respond to emerging infections and other PS risks.

Actions for government	C. Institute an independent investigation mechanism in cases of severe harm and death.
	D. Conduct baseline and concurrent surveys to establish burden of harm due to unsafe care.
Actions for National independent body for quality and PS	A. Conduct a baseline study on the national burden of avoidable harm in health care and assess progress and improvement over time.
	B. Support healthcare facilities in developing, implementing and strengthening PS surveillance systems, including laboratory networks, for identifying emerging PS risks.
	C. Develop normative guidance on learning and improvement methodology for PS.
Actions for health care facilities	A. Participate in the PS surveillance system at national and local levels.
	B. Support governments and health care facilities in establishing and operationalizing safety surveillance systems.
	C. Produce benchmark analyses to compare the organization's performance in dealing with avoidable harm against best practices elsewhere in the country and in the world.
Actions for stakeholders	A. Bring together expertise and experience in improvement science both in other fields of health care and outside the health sector; make these resources available to advise on national and local programmes.
	B. Support establishing laboratory systems and networks at local, national and global levels to quickly detect and respond to emerging infections and PS risks.

Strategy 6.4 Develop active and funded patient safety research programmes, especially translational research	
Actions for government	A. Map, analyse and prioritize areas where research could yield substantial gains of knowledge about avoidable harm and its reduction in the country's health care system.
	B. Ensure that there is sufficient capacity, skills and resources to meet the country's need for PS research.
	C. Incorporate international research evidence, if applicable in the local context, in policy and implementation programmes for PS; facilitate its translation in point of care practices.
	D. Establish or incorporate safety risk assessment in existing health technology assessment programmes for medical procedures, medicines, devices and information technology products.
Actions for National independent body for quality and PS	A. Maintain an up-to-date research strategy identifying PS research priorities.
	B. Mobilize resources to promote and support PS research.
	C. Promote and support PS research in specific areas such as PS in primary care, mental health, people with disabilities, and ageing populations.
	D. Promote and provide support to build research capacity in PS.
Actions for health care facilities	A. Provide a conducive environment for research exploring the causes of avoidable harm and the development of effective interventions to improve PS.

Actions for health care facilities	B. Base the design of PS improvement programmes in each clinical service on the priorities apparent from local data and use available research evidence on effective solutions and safest practices to improve the system.
	C. Partner with researchers on measurement and improvement research.
Actions for stakeholders	D. Arrange research funding bodies, researchers and research partners to advance the agenda of PS research.
	E. Ensure that patients and families play a substantive role in setting research priorities, study design, conduct of studies, advocacy for funding and research governance.

Strategy 6.5 Develop and implement digital solutions to improve the safety of health care.	
Actions for government	A. Develop a national strategy and required tools or harmonize the existing relevant strategy to bring the benefits of digitization, including harnessing artificial intelligence and big data, to efforts to improve the safety of health care in the country, aligned with a national digital health strategy (refer to the WHO Global Strategy on Digital Health 2020–2025).
	B. Promote and support digitization of health care processes such as medical records, electronic prescribing and clinical decision support systems.
	C. Invest resources in digitalization of end user health services, such as telemedicine and telediagnosis, as well as public health services, such as health promotion, disease surveillance and prevention.
	D. Establish mechanisms for assessing and ensuring the safety of health informatics technology solutions before they are deployed for use in the health sector.
	E. Continuously monitor the safety aspects of health informatics technology products used in clinical and diagnostic processes.
	F. Provide regulatory or legal means to use health care data for timely analytical purposes without compromising the privacy, confidentiality and ethical standard of care of individual patients and citizens.
Actions for National independent body for quality and PS	A. Explore digital approaches for identifying and communicating sources of avoidable harm and risk that are in health care systems globally.
	B. Identify and list areas where digital technology can help make health care safer.
	C. Evolve a policy framework, practice areas and ethical and regulatory considerations in the use of digital technologies to enhance PS.
	D. Develop a database and taxonomy of the patient harms potentially associated with digital technologies.
	E. Develop digital tools and applications for helping care providers to deliver safer care.
Actions for health care facilities	A. Implement new and proven technologies to improve the safety of care at scale.
	B. Provide feedback on information and experience of using digital technology in the organization's PS programme to those responsible for the national strategy.
Actions for stakeholders	A. Develop existing and new digital technologies to enhance the identification and analysis of risk, avoidable harm and PS incidents.

Actions for stakeholders	B. Connect technology innovators to health system and clinical leaders to explore new, more effective ways to identify risk and potential harm and discover new routes to improve PS with active involvement of industry and the private sector.
	C. Promote and fund innovative use of digital technology for PS improvement.

6.7. Strategic objective 7 – Synergy, partnership and solidarity

In **Slovenia**, clinical programmes operate in **isolation with inadequate interaction**, integration or any requires linkages with the elements of the comprehensive system of PS. The lack of independent national institutionalization of PS in different programmes and practice areas has been the missing link. Not only in hospitals but at all levels of healthcare, PS is a significant part of health care delivery at all levels.

It is essential to develop mechanisms to i**ntegrate and apply PS strategies in all health programmes, and clinical risk areas**. This will potentially reduce avoidable harm and mitigate the risk of such harm related to health care procedures, products, and devices. Key areas in the **Slovenian** healthcare system within the scope for action include medication safety, surgical safety, infection control, sepsis management, diagnostic safety, environmental hygiene and infrastructure, injection safety, blood safety and radiation safety, and many others in each specialty and each healthcare facility.

It is vital to work in synergy with partnerships such as inter-governmental bodies, professional organisations, civil society, patients' organizations, universities, private centers, experts, and PS advocates and champions to improve PS.

It is indispensable to increase and **distribute good PS practices** and learning at all levels, build partnerships and create networks across the nation, across European Union and the world. All cooperative initiatives and partnerships should be based on mutual respect and trust, clear communication, and a shared vision of the desired outcome. Robust and interconnected harmonization, co-planning, and co-production could be the foundation of such PS partnerships. All PS partnerships should be multidisciplinary and multisectoral in composition.

There is a great value in having **networks that stimulate dialogue**, share adaptable strategies of low-cost interventions, and promote continuous learning and key lessons learned and not as is the culture in Slovenia to stick only to a top-down approach.

The key objectives of these networks are to:

- Encourage leadership commitment
- Gather evidence from a variety of standpoints
- Increase knowledge transfer and technical capacity across borders
- Institutionalize PS for sustainability
- Boost the sharing and application of best practices

7 

Develop and sustain multisectoral and multinational synergy, partnership and solidarity to improve PS and QoC.

Strategy 7.1 Fully engage all stakeholders that have the potential to have a positive impact on patient safety.	
Actions for government	A. Conduct an analysis of stakeholders at national and subnational levels, including individuals and organizations, representing the public and private sectors, with the potential to be engaged in action on PS.
	B. Define the roles and responsibilities of all stakeholders in promoting or advancing PS within the country's health system.
	C. Establish clear and comprehensive coordination mechanisms for stakeholder engagement in action on PS.
	D. Mobilize the widest possible range of political commitment to and international solidarity for PS and foster national and international annual PS. conferences
Actions for National independent body for quality and PS	A. Identify key stakeholders at global, regional and national levels that have roles and responsibilities in PS, as well as those with a potential to contribute and have a positive impact.
	B. Provide high-level advocacy, strategic leadership and guidance to all stakeholders to prioritize PS in strategic planning.
	C. Establish networks of experts and representatives, such as civil society organizations, patient organizations, professional organizations, academic and research institutions, the private sector and industry.
Actions for health care facilities	A. Map stakeholders for the population served, including patients, families and local community leaders, local chapters of professional organizations, and training providers, and engage them in the organization's PS programmes and initiatives.
Actions for stakeholders	A. Reduce the incidence of working in silos and promote a unified movement on PS through the networks of professional organizations and industry representing different sectors of health care.

Strategy 7.2 Promote a common understanding and shared commitment among all stakeholders to successfully deliver the Patient Safety Action Plan	
Actions for government	A. Create a clear narrative that accurately reflects the goals, principles and objectives of the national PS action Plan and is aligned with national PS policies, strategies and plans within the broader health care context of the country.
Actions for National independent body for quality and PS	A. Monitor implementation of the national action plan, including identification of major barriers and proposing solutions.
	B. Expand and coordinate the expertise of the WHO collaborating centres, centres in EU countries for PS and non-state actors in to ensure inclusion of PS in the national action plans and accelerate implementation of the national action plan.
Actions for health care facilities	A. Match the goals and objectives of the national action plan to the respective institutional plans, within the local context, and engage all staff, patients and families in implementation.
Actions for stakeholders	A. Develop a clear and compelling narrative within the PS stakeholder community that explains the national action plan to all relevant audiences and advocates its implementation.

Strategy 7.3 Establish networks and convene consultative meetings to foster collaboration and partnership in patient safety.	
Actions for government	A. Establish national and subnational PS networks for sharing and disseminating PS best practices and ensuring mutual learning to reduce patient harm.
	B. Arrange partners and stakeholders for consultative meetings to develop sustainable mechanisms for implementing the global action plan and the national PS policy and strategy.
	C. Engage partners and innovators from non-health sectors to promote creativity in finding new solutions to reduce avoidable harm and death in health care, including industry and the private sector.
Actions for National independent body for quality and PS	A. Strengthen the national PS network and expand subgroups on specific PS subject areas.
	B. Expand and strengthen thematic and regional networks on PS.
	C. Advocate creation of national and subnational PS networks to engage all partners in action on PS.
	D. Convene global, regional and national consultations for joint action on PS and collective ownership.
Actions for health care facilities	A. Set up an in-house training to train individuals within the organization for proactive engagement in promotion and delivery of safe care within the organization.
	B. Participate in PS networks for exchanging experiences and resources and improving PS practices in day-to-day clinical care.
Actions for stakeholders	A. Participate in global, national and local initiatives, meetings and consultations related to implementation of the global action plan.

Strategy 7.4 Promote cross geographical and multisectoral initiatives to advance action on patient safety	
Actions for government	A. Establish innovative intergovernmental collaborative models with strategically prioritized action on PS and participate in international collaborative PS initiatives.
	B. Consider participating in the annual Global Ministerial Summits on PS.
	C. Mobilize the widest possible range of political commitment to and international solidarity for PS.
	D. Promote long-term strategic initiatives for alignment and synergy in action on PS among WHO Member States, European Union, Group of 20 (G20), and OECD.
Actions for National independent body for quality and PS	A. Encourage clinical and health care management leaders to seek out examples of best PS practice in other countries and adopt the approaches within the national health system.
	B. Share and disseminate best practices and encourage mutual learning to reduce patient harm through regional and international collaboration.
	C. Establish formal collaborative mechanisms with common objectives around PS, nationally and internationally.

Actions for National independent body for quality and PS	D. Advocate prioritization of PS in the strategic agendas of collaborative mechanisms and initiatives, in line with the national PS Action Plan, to ensure timely action and sustainability.
	E. Promote and support global PS initiatives, including observing World Patient Safety Day annually.
	F. Foster national and international annual PS conferences.
Actions for health care facilities	A. Participate in national and international collaborative initiatives to seek out best PS practices and performance and incorporate them into the design of services and programmes within the organization.
	B. Identify opportunities for inter-organizational collaborative initiatives and set up schemes to allow the organization's staff to exchange problem-solving and improvement ideas across different systems and settings.
Actions for stakeholders	A. Use established international networks and initiatives between professional organizations and medical societies, research groups and patient associations in different countries to strategically prioritize PS and express solidarity in support of the goals, principles and objectives of the global action plan.

Strategy 7.5 Work closely with technical programmes to ensure alignment in patient safety action	
Actions for government	A. Review the range and scope of all technical health programmes within the country and identify the need for and potential benefit from alignment with PS action.
	B. Embed PS objectives and actions within technical programmes, in line with the local context.
Actions for National independan body for quality and PS	A. Develop clear insights into sources and levels of avoidable harm in services delivered through other health programmes and identify synergies and the scope for collaborative action, in line with the global action plan.
	B. Foster strategic cooperation and develop linkages with safety programmes, such as injection safety, radiation safety, IPC, blood safety, immunization safety, and water, sanitation and hygiene; clinical programmes, such as maternal health, noncommunicable diseases, and communicable diseases; and broader health system programmes, such as health workforce, occupational health, information and research, and QoC, to ensure alignment and effectiveness of interventions.
	C. Ensure joint resource mobilization strategies at all levels for action on PS across all healthcare programmes.
Actions for health care facilities	A. Ensure that PS is incorporated within all health programmes that the organization is responsible for, especially those that have not traditionally explicitly recognized avoidable harm as a problem.
Actions for stakeholders	A. Promote strategic prioritization of PS in discussion with donors and mobilize resources for joint action on PS.

7. IMPLEMENTATION

Delays in translating quality and PS strategies into daily practice are substantial. Implementation science can promote the faster introduction of PS strategies and action plans into clinical practice, thus improving health services' quality

Implementation science involves understanding behaviour, developing strategies to change behaviour, and engaging stakeholders.

When implementing the national strategy and action plan for quality and PS, one can consider target stakeholders, help with the adoption (by leadership and staff of healthcare organisations, provide the agreement on resources, provide education, start incrementally), and make documentation available to staff and conduct training how to implement with step by step approach, ensure that staff understand their responsibility to sustain implemented changes,

Previous attempts to implement national policy and strategies for quality and PS introduction to healthcare services failed mainly due to a lack of governance and implementation strategy.

The earlier project of EC in Slovenia showed that there are many challenges in developing a culture of quality and safety. First, the entire **expert, political, and general public must be aware** of the significance of investing in a culture of quality and safety. Culture must become an integral part of sustainable development and not be a political category or just a trend but should be a fundamental paradigm in society generating progress.

The steps to be taken are:

- Introduction of a system for managing avoidable adverse events, near misses and CRM
- Concern for safety should be an essential part of the vision and a fundamental value of all stakeholders in healthcare
- Mutual trust, respect, and inclusion should be established in institutions and between them, regardless of the type and level of operations
- The management of institutions must create and support a culture of safety and fairness in institutions
- Critical approaches to improving safety culture must be determined, such as timely recognition, notifying, treatment, and taking measures related to risks and avoidable adverse events
- The possibility of introducing a no-fault compensation system
- Integrate a generative approach to ensuring PS at a micro, meso, and macro level
- Measures should be taken to establish a plan for comprehensive, integrated management of quality in healthcare

Prioritization, feasibility, and application speed will vary according to the present situation in PS. Achieving full implementation at the national level will be a long-term agenda. Therefore, with the help of the assessment of the situation provided in Deliverable 2 found areas of progress that can be strengthened and the new opportunities and practice gaps.

Regulation, accreditation, leadership, safety culture, and public reporting can drive PS improvement. ***An independent national body for healthcare quality and PS is a prerequisite to applying policy and strategy, sustaining further development in PS, and pulling together all the fragmented attempts to improve it.*** All these interventions must be accompanied by downstream PS improvement interventions such as training, capacity

building, reporting and learning systems, teamwork and communication, patient engagement, as well as solutions to high-risk clinical care processes.

Possible steps in the implementation of PS management system are seen in figure 12 and 13.

Some of the positive features of such PSMS are:

- The structured system is integrated with all other management processes and does not just become a stand-alone program
- Leadership team and employees are aligned regarding objectives and goals
- Time-saving by using a structured map or template to ensure continuous improvement
- Information from the experience of other organizations using a similar process that can include benchmarks to show achievements and progress
- A way for everyone in the organization to know the status of the system that can encourage discussion, corrective action, and problem solving
- Assistance in discussing with regualtors and payors that you are managing patient safet and CRM and that formalized process in is in place
- Internal and external auditors (for example an accreditation agency) with the same criteria for reviewing the process

The success of PS management system is increased if the sequences of a safety management system are defined (figure 12).

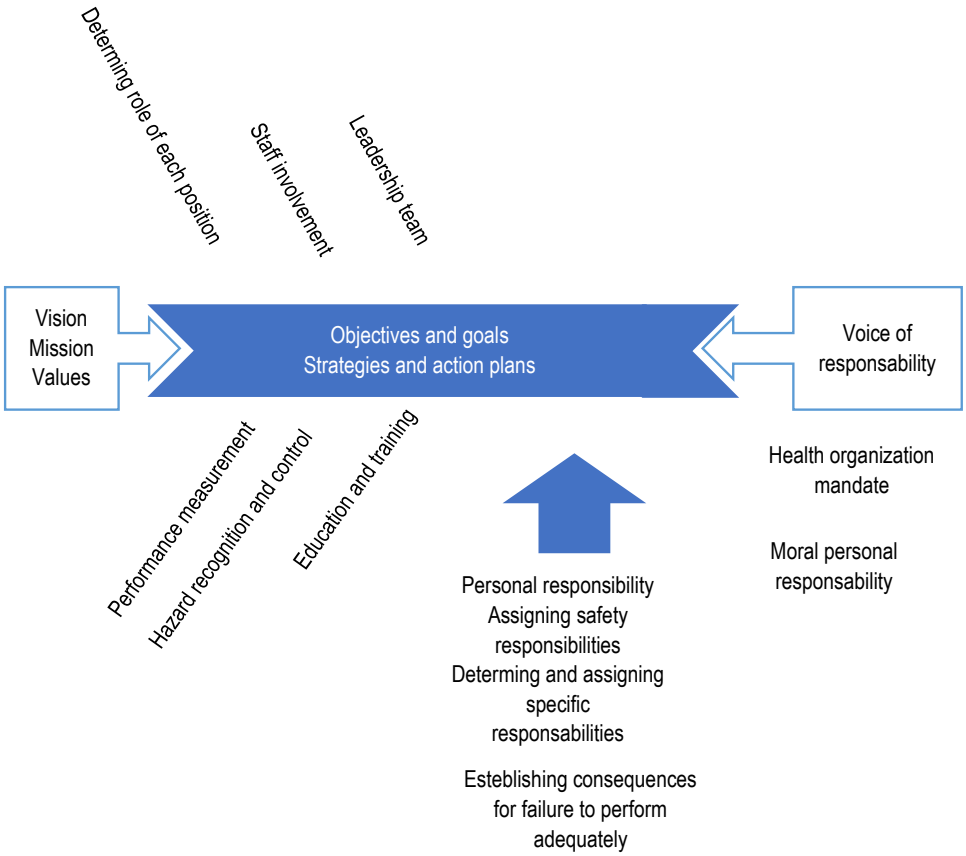

Figure 12. A possible sequence of patient safety management Systems

Source: Prosunt©

Problems may arise if PSMS:

- Is a stand-alone system
- Has only a few projects and programs and is not implemented as a process
- Not monitored, it allows a false sense of security
- It is only relatively well documented and not working in the daily routine at the frontline
- Is perceived as too time-consuming
- Is not customized to the different healthcare organisations

Implementation will require **effective partnerships** as PS is everyone's responsibility. All must contribute to applying this action plan at the national level, individually and through partnerships in leadership, policy and governance, coordination, resource mobilization, patient, family and community engagement, promotion and advocacy, and evidence-based practice.

Our suggestion is to launch **severe national campaigns** to promote political, stakeholder and public awareness and support. The proposed audience are government, especially the Ministry of Health, the Ministry of education, the Ministry of justice parliament, the national council, the Health Insurance Institute of Slovenia, the Medical council, National Institute of Public Health, Slovenian healthcare professional societies, all professional chambers, faculties of medicine, pharmacy, healthcare, representative of patients and other interested parties.

Figure 13 shows a frame for upstream and downstream actions. All partners and stakeholders are accountable for moving through key milestones in applying the action plan. Success should be demonstrated and be measurable. Implementation is outside the scope of any single national entity or stakeholder group and will require effective partnerships.

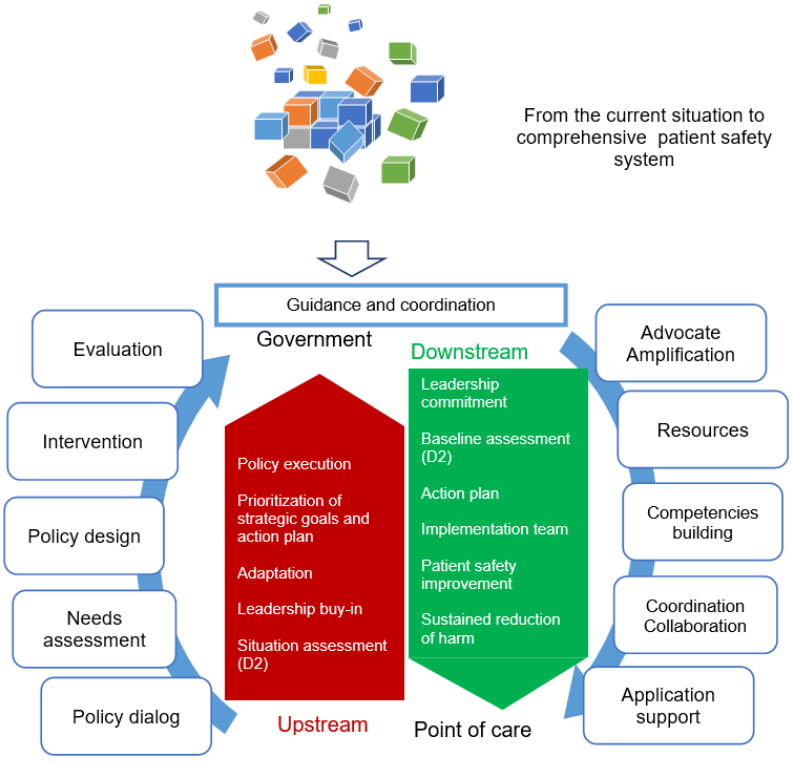

Figure 13. The system for implementation of the national patient safety strategy and action plan

Source: adapted from WHO, 2021

The obligation for the government is shown in the upstream flow and that for healthcare organizations and other healthcare providers as downstream flow.

There are **five essential milestones and recommendations for implementing** the national PS strategic goals and action plans

Milestone 1 - Situational analysis

In Deliverable 2, assessment of significant risks and barriers to improvement in the existing PS at all levels, mapping the current policy, standards, legal and regulatory environment, and institutional mechanisms was accomplished.

Milestone 2 – Strong commitment from political and organizational leadership

Information on the burden of patient harm and economic impact, extrapolated from the studies in developed nations, media coverage of stories of patients experiencing avoidable harm can trigger a public discourse encouraging political leaders to take action for safer health care. Inspiring health leaders to participate in international platforms in the European Union and the Global Ministerial Summits on PS could help gather momentum and seek commitment. There is a necessity for **strong political statement** that PS is a priority and one of the first values of national healthcare.

Milestone 3 – Establish a sustainable mechanism for implementation

Establish a **sustainable mechanism** for implementing PS **policies, strategies and plans**. A designated **national independent body** is needed to coordinate and oversee nationwide implementation at government, healthcare facilities, and stakeholders. The current capacity **for quality and PS** at the Ministry of Health is inadequate and is not independent of political influences. An independent national body, coordination and optimization of structures for PS at the national, healthcare facility and stakeholder level is the key to success.

Milestone 4 – Relate to national context and priorities

A **comprehensive programme for PS** that will flow from national to health facility and clinical team level is to be constructed. A consultative process involving all concerned stakeholders, including the non-governmental and private sectors, will shape an action plan.

Some of the criteria for prioritizing could be:

- Key essential and critical action to reduce the highest risks for patients
- Interventions that are relatively easy to implement and make high impacts on avoidable harm
- PS interventions and solutions are consistent with existing national health priorities
- PS interventions contribute to better health system performance and improved health outcomes
- Interventions that are systemic in nature benefit large numbers of patients and will ensure sustainable improvements

Based on the prioritization and estimated implementation timelines, identify processes and outcomes to be achieved in **the short-term (2022-2023, 2 years), medium-term (2024-2026, 5 years) and long-term (2017-2031, 10 years).**

Milestone 5 – Decide upon and design the model of change for implementation

A **strong change management strategy** should be in place to ensure a **holistic approach** to PS policy interventions and strategic initiatives, together with the engagement of key stakeholders with a clear vision and sustainable implementation. Some best practices are:

- The incremental approach to improvement. Start with small-scale implementation with a quick turn-around
- Recognize and **reward teams** for their good work
- Use a **project management approach** to implement planned actions. Assign roles and responsibilities to all stakeholders, define timelines, and designate a key person for coordinating and monitoring implementation
- Develop a **system of mentorship and coaching**. Identify best practices and role models (individual and organizational) that could inspire and initiate improvements
- **Break the silos**. Be in constant touch and cooperation with other related programmes and stakeholder
- Use **public and private sector to implement solutions**, projects for improvement and education in quality and PS context and tools

Success should be celebrated and promoted to raise political, stakeholder and public awareness and support. Mobilizing patients, families, and communities to plan and implement solutions and actions is critical to success.

8. INDICATORS TO JUDGE IMPLEMENTATION AT NATIONAL AND HEALTH CARE FACILITY LEVELS

The outcome indicators are aligned with the seven strategic objectives of the national strategic goals and action plans. Indicators are categorized into “key” and “advanced” to limit the burden of collecting data and allow flexibility. The ten **core indicators** proposed are fundamental to measuring the progress on implementing this national strategic goal and action plans. The National independent body for quality and PS will monitor all the key indicators. Progress on achieving these indicators will be communicated to the Ministry of Health. **The government of Slovenia will transparently report to the WHA through successive biennial progress reports as mandated by resolution WHA72.6. (2019).**

The set of **progressive indicators** is proposed to measure additional aspects of PS actions. National independent bodies for quality and PS will select the most appropriate indicators based on context, capacity, and specific PS priorities. Progress measured based on core and advanced indicators could be made publicly available at the national level and contribute to annual reporting on PS improvements. The National independent body for quality and PS will develop detailed guidance on monitoring and reporting as part of an implementation toolkit for the action plan. This toolkit will provide information on definitions, sources of data, methods and the process of reporting and analysis.

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8.1. Core indicators and targets to judge implementation at national and health care facility levels

8.1.1. Indicators for strategic objective 1

1 Make zero avoidable harm to patients a state of mind and a rule of engagement in the planning and delivery of health care everywhere.

1.1 Indicator	**Targets for each Category**	**Data source**
The number of hospitals, primary care settings (public, concessionaires, private), nursing homes (DSO), rehabilitation centres, community pharmacies) have developed a plan for implementing patient safety policy and strategies and action plans.	*Percentage* 2022 –Establish a baseline 2023 – 30% 2026 – 50% 2031 - 90%	National health, patient safety information systems

8.1.2. Indicators for strategic objective 2

2 

Build high-reliability health systems and health organizations that protect patients daily from harm.

2.1 Indicator	**Targets for each category**	**Data source**
Number of hospitals, primary care settings (public, concessionaires, private), nursing homes (DSO), rehabilitation centres, community pharmacies) have implemented a system for reporting of never events (or sentinel events)	*Percantage* 2022 - Establish a baseline 2023 – 30% 2026 – 50% 2031 – 90%	National health, patient safety information systems

8.1.3. Indicators for strategic objective 3

3 

Assure the safety of every clinical process.

3.1 Indicator	**Targets for each Category**	**Data source**
Education in health care-associated infections at hospitals, and nursing homes (DSO). **3.2 Indicator** Reduction in medication-related harm (adver se drug events) in hospitals, primary care settings (public, concessionaires, private), nursing homes (DSO), rehabilitation centres, community pharmacies).	*Percantage* 2022 - Establish a baseline 2023 - 20% 2026 - 50% 2031 - 80%	National health, patient safety information systems

8.1.4. Indicators for strategic objective 4

4 

Engage and empower patients and families to help and support the journey to safer health care.

4.1 Indicator	**Targets**	**Data source**
Number of hospitals that have a patient representative on the Governing board (Svet zavoda).	*Percentage* 2022- Baseline established 2023-20% 2026-30% 2031 -70%	Yearly hospital report o National independent body for quality and patient safety

8.1.5. Indicators for strategic objective 5

5 

Inspire, educate and skill health workers to contribute to the design and delivery of safe care systems.

5.1 Indicator Incorporation of patient safety curriculum in education programmes for undergraduate and postgraduate medical, nursing and healthcare students	**Targets** 2022 - Baseline established for undergraduate and postgraduate medical, nursing schools and healthcare students 2023- 50% 2025 - 100%	**Data source** Yearly hospital report to National independent body for quality and patient safety
5.2 Indicator Incorporation of patient safety curriculum for healthcare professionals in hospitals, primary care settings (public, concessionaires, private), nursing homes (DSO), rehabilitation centres, community pharmacies)	**Targets for each category** 2022 - Baseline established 2023-30% 2026-50 2027- 70% 2031-80%	**Data source** Yearly hospital report to National independent body for quality and patient safety
5.3 Indicator Signed up for implementation of the WHO Health Worker Safety Charter	**Targets** 2022 – Signed charter	**Data source** Report to WHO by the government

8.1.6. Indicators for strategic objective 6

6 

Ensure a constant flow of information and knowledge to drive the mitigation of risk, the reduction in levels of avoidable harm, and improvement in the safety of care.

6.1 Indicator Number of hospitals, primary care settings (public, concessionaires, private), nursing homes (DSO), rehabilitation centres, community pharmacies) participating in a patient safety incident reporting and learning system	**Targets for each category** *Percentage* 2022 - Baseline established 2023-30% 2026-60% 2031-90%	**Data source** Yearly reports to national patient safety incident reporting and learning system
6.2 Indicator Number of hospitals, primary care settings (public, concessionaires, private), nursing homes (DSO), rehabilitation centres, community pharmacies) that publish an annual report on patient safety	**Targets for each category** *Percentage* 2022 - Baseline established 2023-30% 2026-60% 2031-90%	**Data source** Yearly reports to national patient safety incident reporting and learning system

8.1.7. Indicators for strategic objective 7

7 Develop and sustain multisectoral and multinational synergy, partnership and solidarity to improve PS and QoC.

7.1 Indicator	Target	Data source
Establishing a national patient safety network	2022 - Baseline established 2023 -100%	Government report

8.2. Progressive indicators and targets to judge implementation at national and health care facility levels

These will be drawn after prioritizing with Slovenian stakeholders by the National independent body for quality and patient safety based on the context, capacity, and specific patient safety priorities.

8.3. Indicators for a healthcare organization/providers of healthcare

PS indicators are of no benefit unless they are routinely measured and communicated throughout organisation. *Lagging indicators* provide the outcome (outcome indicators). They show what was accomplished but can not predict future results—measurement of the system and conditions to predict future performance can be achieved by *leading indicators* (figure 14).

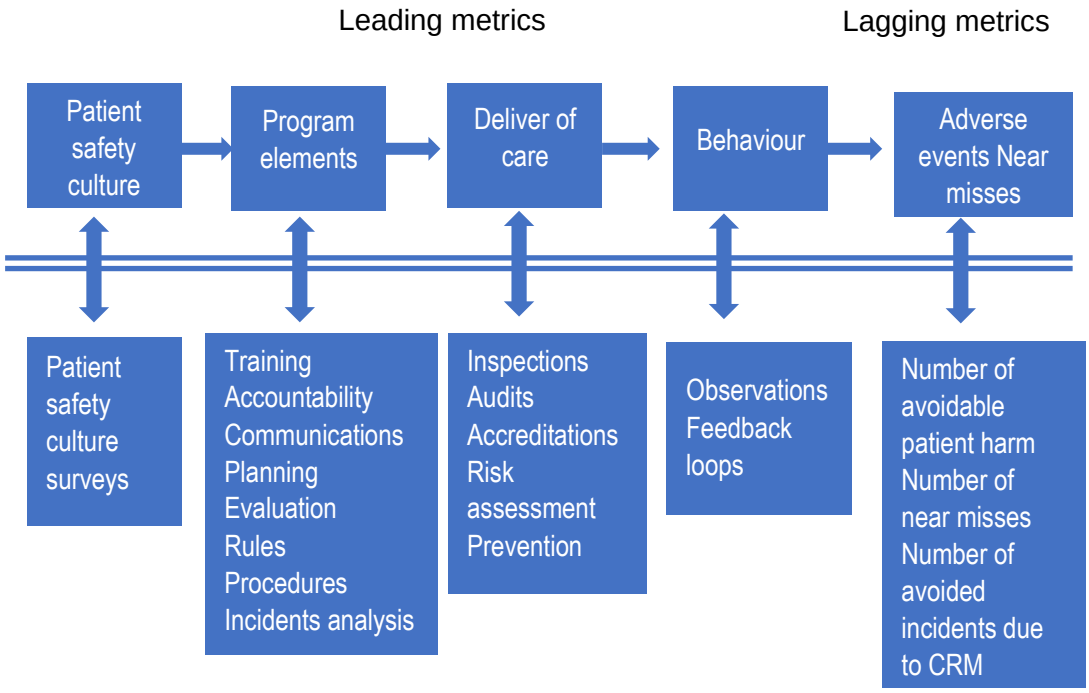

Figure 14. Metrics for continuous improvement

Source: adapted from the Improvement Academy, 2017 https://www.yhahsn.org.uk/ (accessed 15 December 2021).

Implementation of PS strategy and action plans can practically follow SMART recommendations:

a) Specific

The objective of PS strategies is to improve PS and patient outcomes with specific action plans for each of four main actors in the PSS: government, national independent body, providers of healthcare, and stakeholders. The tasks are to be followed precisely as stated in each strategy and action plan using indicators specific for each strategic goal.

b) Measurable

Strategic goals and action plan realization must be continuously monitored and measured as stated by each strategic goal indicator. Based on the results of monitoring, corrective actions are introduced.

c) Achievable

A plan to reach these goals has to be in place. When setting the goals, consider financial and human resources. Prepare a SWOT analysis to determine if the objective is achievable. Understand challenges and threats to goal attainment to identify solutions.

d) Relevant

The goals described in the section on indicators must be accepted by the top and middle management and be explained to all staff. Emphasize why the goals are worthwhile and that are in alignment with the PSS and that are applicable not only for accreditation and certification but predominantly for patients and staff safety. The unit for quality and PS should have control over the goals.

e) Time-bound

Each indicator has a target date so that there is a deadline to focus on. The intermediate monitoring goals have to be checked against the prepared set of intermediate goals.

9. TOOLS FOR PATIENT SAFETY IMPROVEMENT

In previous years, some tools for PS improvements have been developed in Slovenia. A noncomprehensive list of PS tools are provided in appendix C.

9.1. Suggested readings for strategies and action plans

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65. Morris ZS et al.The answer is 17 years, what is the question: understanding time lags in translational research. J Roy Soc Med. 2011;104:510–20.
66. Alberts B et al. Rescuing US biomedical research from its systemic flaws. Proc Natl Acad Sci. 2014;111:5773–5777.
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10. APPENDICES PART 1

10.1. Appendix A - Study of foreign countries

This appendix describes PS in 5 of the studied countries. CRM governance and processes were described in Phase 3 of this project

a) Tuscany (Italy)

The plan for QoC and PS. This undertakes to guarantee a structured path of **quality, safety and process improvement** in compliance with national and regional guidelines. The improvement actions that will arise from this path will be consistent with the general company processes, in particular with the planning and management control processes and budget objectives, quality, permanent staff training, insertion of newly acquired personnel, diagnostic paths, prevention of risks / unwanted events.

The strategic lines and actions on which the plan is committed are:

- Build a **clear and branched system of quality** and **safety governance**
- Support the **self-assessment by professionals** and therefore the processes of accreditation and **continuous improvement**
- Promote the **appropriateness** and adoption of **evidence-based** technical professional tools at all levels
- Enhance the **user experience** in improving services
- Encourage, disseminate and support the **culture of reporting** and transparency
- Oversee adverse events, promote their analysis and monitor the resulting **improvement actions**
- Supporting operators at all levels through **continuous training** and coherent enhancement and **evaluation systems**
- Analyze, reorganize, standardize and monitor corporate macro processes with a view to **quality and safety**

Incident-reporting systems (IRS) are tools that allow front-line healthcare workers to voluntary report adverse events and near misses. The WHO has released guidelines that outline the basic principles of designing and implementing successful IRS in healthcare organizations.

A written survey was administered with an assisted self-assessment technique to a representative sample of healthcare workers in Italian hospitals with and without IRS. Data were collected using two different 16-item questionnaires. The questionnaires targeted two issues:

1. Workers' experience of PS incidents
2. Workers’ expectations on incident reporting

0% of respondents confirmed involvement in a PS incident, but only 40% utilized an IRS to report the event formally. The data indicate that information regarding PS incidents is not communicated throughout the entire organization. So, the conclusion is that research findings are consistent with the available evidence on healthcare workers' experience of PS incidents.

Training program based on ergonomics and human factors for clinical risk managers, the CRM team, facilitators and healthcare workers has been designed in order to prepare the human resources for this effort.

CRM regional centre organized 3 editions of the **course** for CRM teams members, with the aim to train those who promote **PS** initiative at the agency level. A master course for certified

CRM was organized together with the most authoritative academic institutions in Tuscany. Training programs have been delivered for facilitators and for operators, beginning from high risk clinical areas.

The main objective of the training program is to promote a **new safety culture** based on the cognitive approach to the human error and the systemic approach to clinical risk and PS. In order to create reporting culture where the operators feel free to talk about their errors without being blamed, the training courses have been based on the discussion of adverse events presented by participants.

All the operators of the clinical areas where adverse events are more relevant (emergency department, orthopaedics, intensive care unit, surgery,…) have been involved in a basic course about CRM.

The CRM centre also designed and is delivering a **training program for the forensic medical doctors** and the operators of the **offices for public relations** with the citizens. It will also be activated the simulation laboratories for emergency teams and an aesthesia and critical care teams to foster the **communication skills** and the ability of the team to manage the unexpected.

b) Ireland

The plan for QoC and PS. National QI Team working in partnership to lead innovation and lasting QI to achieve better and safer care

Aims

1. Partner with people who use and work in our health and social care services to achieve measurable and sustainable improvements in quality
2. Proactively enable a culture of person centredness within our health and social care services that continually improve QoC, practice and experience
3. Promote learning and development through education, research and continual evaluation of improvement work
4. Make connections between those interested in and trained in QI

The National QI Team has **7 programmes of work** to support front-line teams in improving quality:

1. Sustainable QI Programme
2. School of QI Programme
3. QI Connections Programme
4. Evidence for Improvement Programme
5. Partnering with people who use health services Programme
6. Global Health Programme
7. Clinical Directorate Programme

Reporting System & Monitoring indicators. The National Patient Safety Office (NPSO) has a health indicator framework named the National Healthcare Quality Reporting System (NHQRS). Since 2014 the NHQRS has produced an annual report that is published on the Department of Health website. In this 2020 report, there are a total of 52 indicators, from 11 data sources, across five key domains:

Domain	Datasource
1. Helping people to stay health and well	▪ Immunisation rates ▪ Cancer screening rates
2. Supporting people with long term conditions	▪ Ambulatory care sensitive conditions
3. Helping people when they are being treated and cared for in our health services	▪ Cancel survival rates ▪ Cancer surgery ▪ Acute hospital care
4. Supporting people to have positive experiences of healthcare	▪ National In-Patient Experience Survey ▪ National Maternity Experience Survey
5. Treating and caring for people in a safe environment	▪ Healthcare-associated infection rates ▪ Antibiotic consumption rates ▪ Medication Safety

Safety culture. The **HSA has the overall responsibility for administering and enforcing health and safety at work**. They promote the benefits of creating a **positive safety culture** and **defend that directors and officers** of undertakings who authorize and direct work activities are responsible for ensuring good safety and health as part of their corporate governance role. Regarding PS, the Commission on PS and Quality Assurance strongly supports the prioritization of **education, training, and research**. The Commission recommends **training and continuous professional development** to all **bodies responsible for the training and continuing development of healthcare workers** should r**eview their curricula to ensure that both technical and human factors concerning PS and QoC are incorporated** into their education modules. Education and training suites and modules on PS need to be developed and implemented in collaboration with professional training bodies, the HSE and the Health Research Board (HRB).

c) Catalonia (Spain)

Governance. The **Health Department of the Government of Catalonia** has its own **PS department** and the **Alliance for PS in Catalonia.** Within the framework of the Alliance, multicentre projects in PS have been promoted and various initiatives have been carried out, making it possible to achieve quite significant results in the areas that have been improved. Their key objectives is to **promote PS** through the development and **improvement of systems** for the detection and prevention of healthcare safety problems and the coordination of the different initiatives and contribute to the involvement of citizens, professionals, centres and the administration so that society can positively address these issues.

There is the Catalan Agency for Health Quality and Evaluation **(AQuAS)**. This is the agency that promotes the evaluation of technologies and health services and the analysis of the social impact of research, among others. The key objective and mission of AQuAS is to generate knowledge through the evaluation and analysis of data for decision-making to contribute to the improvement of the health of the citizens and to the sustainability of the health system of Catalonia.

The plan for QoC and PS. The **mission** of the Strategic plan for PS in Catalonia 2014 - 2018 is to facilitate personalized, comprehensive and quality care, which reduces patients to suffer an unnecessary risk related to health care to an acceptable minimum. The **vision** of this plan is commitment, patient orientation and the desire for continuous improvement with safe healthcare for all citizens.

The **strategic lines** are: promotion of Safety Culture for patients, promotion of best practices through specific projects about PS, evaluation and improvement of PS strategy, communication about PS with all healthcare stakeholders, training to all healthcare stakeholders and participation of patients in QoC and PS improvement.

Reporting System & Monitoring indicators. The system used to report incidents is TPSC-Cloud™ , (the **online platform** of the PS Company), which began to be implemented at the end of 2013. In this system, all incidents related to PS can be reported, voluntarily, confidentially, anonymous, **and not punitively**.

The principal functionalities of this system are:

Notification: allows notification in a structured way, based on different types of questionnaires depending on the type of incident being reported (medication, falls, etc.).
Analysis and reporting: allows to analyze incidents to identify risks in a systematic way and prevent errors.
Management: allows proactive management through tools (risk matrix, cause-effect analysis, barrier analysis, process analysis, AMFE (modal analysis of falls and their effects)) integrated in the platform.
Improvement actions: allows to define, plan and monitor improvement actions, preventive measures or changes in the organization.

Safety culture. The patient's safety culture is based on learning from adverse events, developing preventive strategies to prevent their occurrence and recognizing and accompanying those who have suffered unnecessary and involuntary harm resulting from the health care received.

This is the reason why the culture of PS has been promoted since 2008 through the Department of Health and, specially since 2012, the “Functional Patient Safety Units” have been implemented in health centres with the following strategy:

1. Create a quality and PS **committee**
2. Identify those responsible and leaders who must **drive, promote and implement** the PS strategy in the centres
3. Identify and prioritize **areas of greatest risk** in health centres
4. Implement an **incident notification system**
5. **PS training** for healthcare professionals
6. **Dissemination of PS** through the News PS newsletter and the PS channel
7. Evaluate the **PS strategy** by implementing the dashboard in acute care and primary care hospitals
8. **Involve patients and citizens** by transmitting useful and interesting information about their safety as patients and how to make their care safer
9. Establish **communication forums** by conducting PS Conferences (14 conferences to date).

d) Australia

The **National Safety and Quality Health Service (NSQHS) Standards** provide a nationally consistent statement of the level of care consumers can expect from health service organizations. The Commission developed the NSQHS Standards in collaboration with the Australian Government, states and territories, private sector providers, clinical experts, patients and carers.

The primary **aims of the NSQHS Standards** are to **protect the public from harm** and to improve the quality of health service provision. The **eight NSQHS Standards** provide a nationally consistent statement about the level of care consumers can expect from health services.

1. Clinical Governance
2. Partnering with Consumers
3. Preventing and Controlling Infections
4. Medication Safety
5. Comprehensive Care
6. Communicating for Safety
7. Blood Management
8. Recognizing and Responding to Acute Deterioration

Safety and Quality Work Plan 2017-2019
This plan identifies the priorities to improve the safety and QoC provided to consumers. It identifies 6 priority areas:

1) PS
2) Partnering with patients, consumers and community
3) Quality cost and value
4) Supporting health professionals to provide safe and high quality care
5) SLS

Communication strategy to support safety and quality.

Australian Safety and Quality Framework for Health Care
Australian Health Ministers endorsed the Australian Safety and Quality Framework for Health Care in 2010. The Framework describes a **vision for safe and high-quality care** for all Australians and sets out the actions needed to achieve this vision. The Framework specifies three core principles for safe and high-quality care: **care is consumer centred**, **driven by information**, and **organized for safety**. This Framework is used as the basis for strategic and operational safety and quality plans, providing a mechanism for refocusing current safety and QI activities and designing goals for health service improvement.

Reporting System & Monitoring indicators. Indicators for Reporting Systems are classified in five indicators sets:

1. **Patient experience question set**: the Australian Hospital Patient Experience Question Set (AHPEQS) is a questionary with response options.
2. **Sentinel events**: A sentinel event is a particular type of serious incident that is preventable and has caused serious harm to, or death of, a patient. In Australia, reporting of sentinel events, against a nationally endorsed and agreed sentinel event list (supported by all Australian Health Ministers in 2002), has been mandatory since 2007. Since 2017, public hospitals have received no Australian Government funding for an episode of care in which a patient experiences or suffers from a sentinel event.
3. **Clinical incidents**: Australia has implemented a mandated reporting system where clinical incidents, their causes and any relevant contextual information are systematically recorded in a central repository. The data is then analysed and deployed to improve deficient processes where relevant, share lessons across related settings, improve PS, and prevent similar incidents from happening again.
4. **Hospital-acquired complications**: Hospital-acquired complications (HACs) are a sub-set of adverse healthcare events that have been identified as originating

during the patient's hospital stay and are not present when the patient is admitted. A HAC refers to a complication for which clinical risk mitigation strategies may reduce (but not necessarily eliminate) the risk of that complication occurring.

5. **Avoidable hospital readmissions**: avoidable hospital readmissions are costly, and rates remain relatively steady. However, action is being taken to improve data collection which can be used to inform local QI.

Safety culture. The Commission uses the term 'patient safety culture' to focus on the aspects of culture that relate to PS. Positive PSC have **strong leadership** that drive and **prioritize safety.** Commitment from leaders and managers is important, their actions and attitudes influence the perceptions, attitudes and behaviors of the wider workforce. Other important aspects of positive PS culture include:

- Shared perceptions of the importance of safety
- Constructive communication
- Mutual trust
- A workforce that is engaged and constantly aware that things can go wrong
- Acknowledgment at all levels that mistakes occur
- Ability to recognize, respond to, give feedback about, and learn from, adverse events.

Measurement process. Measurement of PS culture enables the i**dentification of strengths and areas for improvement.** This information can be used to develop appropriate interventions. PS culture measures can also be used to evaluate new safety programs by comparing results before and after implementation. It can be measured through surveys of hospital staff, qualitative measurement (focus groups, interviews), ethnographic investigation or a combination of these. **Surveys of hospital staff are the most common way of measuring PS culture**. Hospital staff are often the first to notice unsafe practice patterns and the conditions that increase or decrease the likelihood of such practice.

PS culture forms one component of a comprehensive measurement and improvement system; it should be **measured alongside other safety and quality indicators, such as complications acquired while in hospital, accreditation outcomes, mortality, patient-reported measures,** and serious in-hospital incidents.

e) Denmark

The plan for QoC and PS. The **Danish Healthcare Quality Programme (DDKM)**

Denmark has developed and implemented national **QoC and PS** initiatives in the health-care system in terms of **national clinical guidelines**, **performance and outcome measurement integrated in clinical databases**, measurement of **patient experiences**, **reporting of adverse events**, **national handling of patient complaints**, national **accreditation and public disclosure of all data on the QoC**. At the national, regional, local and hospital level, it is mandatory to participate in quality initiatives and use data and results for quality management, QI, transparency in health care, and accountability.

The **DDKM,** developed and run by the **IKAS**, is a method to generate continuous quality development across the entire healthcare sector in Denmark: providing standards for good quality and methods to measure and control this quality. The DDKM aims to include all Danish publicly financed healthcare services and operates on a cross-sectoral basis. The programme is a result of a collaboration between central government and the regions, thereby covering the public healthcare sector in full. Also, municipalities, private hospitals, and pharmacies have signed agreements to become a part of the programme.

The objectives of the **Danish Healthcare Quality Programme** are:

- To **avoid errors** causing loss of lives, quality of life and resources;
- To ensure that **knowledge** achieved via research and experience is utilised in all branches of the healthcare sector;
- **To document** work performed;
- To achieve the **same high quality across geographical boundaries** and sectors;
- To **generate coherence in citizens' pathways across sector**s – e.g. in the transition from hospital to local healthcare;
- To render **quality** within the healthcare sector more **visible**;
- To **avoid that all institutions must invent their own quality assurance system**
- To strive towards **excellence** – at all times.

They also have the Digital Health Strategy 2018-2022, from which among the main goals it includes: improve PS, high-quality treatment and a more efficient health service

Reporting System & Monitoring indicators.

In 2001, a study named *Danish Adverse Event Study* found out that 9% of discharged patients had experienced an adverse event. They start to act on PS by implementing a Reporting System that could teach how to do it from that moment. The reporting system for adverse events is an important tool for ensuring knowledge about what is going wrong in the healthcare system. Since the reporting system was established, there has been a great deal of focus on the system and reporting itself. A culture of reporting has been created in all sectors and among healthcare professionals, patients and relatives. But at the same time, it has become clear that the reporting system is too bureaucratic and that there is too much focus on reporting and too little focus on acting and improving the systems as a result of the reports. To optimize the system, they have established eight recommendations for an optimized reporting system that can support improvements in the healthcare system for the benefit of PS. The eight recommendations can be summarized under the following headings:

The original spirit of the reporting system must be preserved

The perspective and reactions to unintended events can be divided into individual and system perspectives. The reporting system is thought of and should still be too anchored in a **system perspective** alone. This is entirely in line with the available knowledge that in the vast majority of cases, inappropriate systems are the cause of unintended events - and not the negligence or negligence of individuals.

The reporting system must be considered together with the quality program

Incidents cannot stand alone and **reporting itself does not lead to improvements**, there is a need to think about the reporting system and a national quality program. **Adverse events should not be prevented in a different context, but should be used everywhere to motivate improvements in the quality Health system** established and where each unit Works systematically towards local goals related to the overall quality goals.

It must be reported the importance and anchor the system locally

The working group recommends that healthcare professionals report what is important in the future - in contrast to now, where you are obliged to report all unintended events. It must also be made **easier to report**, and the reports must be used locally as far as possible.

The reporting system must support a legitimate and transparent healthcare system

The reporting system must **contribute to a transparent public system**. There are international experiences about the **publication of anonymous incidents**, which the working

group recommends that you study and possibly pilot tests. Finally, plans must be established to ensure that the **reporter receives feedback** on improving the system after reporting.

Safety culture. The Patient Safety Strategy for 2019-2024 promoted by HSE specifies ways to improve PSC by implementing a new way of organizational learning that actively promotes, captures, shares, spreads, and implements learning to improve PS at every level of organization. The **Danish Act on Patient Safety** was introduced in 2004. However, already in 2002, the importance of a supportive culture for a high level of PS, and the active role of the line management in creating such a culture, was emphasized. The Danish Society for Patient Safety has emphasised the importance of PS culture as a lever for better PS. They have addressed the issue of cultural changes in their improvement projects.

Measurement process. The **Danish Patient Safety Culture Questionnaire** was developed based on an extensive development process with **field testing and validation.** It has different stages: developmental, testing, validation, and general use. Individual units and organizations e.g. nursing homes and hospital departments have worked with **measuring and improving PSC as part of QI.** Also, PS culture was used as an outcome measure in a large in-situ simulation intervention study across hospitals. In two of the five Danish regions accountable for hospital care, pilots of a PS culture measurement have been made to **qualify the political strategical decision** of a regional measure and plan the execution of the measurement and follow-up activities, respectively. Measurement has been performed across all hospitals in the Capital Region of Copenhagen. It involved answers from more than 15,000 health care professionals. It was motivated by a serious breach in PS. The **measurement was called PLUS**, it was performed, and results were fed back to the hospitals in 2019.

10.2. Appendix B – Identifying relevant existing national documents

Legislation

- Korošec D.Zakon o pacientovih pravicah with comentary. Ljubljana: GV založba, 2009.
- Robida A. Criminalization of human errors in healthcare (Kriminalizacija človeških napak v zdravstvu). ISIS. 2012;2:17-23.

Human errors in the Slovenian judicial system are considered recklesness and despite relatively rare punishment of healthcare professionals have an effect on error reporting and learning.

Opportunities for improvement: Introduction of just culture.

Policy, governance and strategic goals

- Robida A (ed). National policy for the development of quality in healthcare. Ljubljana: MoH, 2006.

The policy described six dimensions of quality, a framework of national systems of quality in healthcare, national values and priorities, a proposal for national independent agency for quality, the introduction of accreditation, ISO 9001 or IST-TS CEN/TS 15224 and ISO 15189 for medical laboratories, guidelines for the systematic implementation of quality in healthcare in the Republic of Slovenia as presented in the document “Healthcare Reform 2003”.

An important chapter on the development of the national system of quality in healthcare explained patient-centredness, the process of continuous QI, organisation of QI and responsibilities. Key issues in the continuous QI system were defined such as outcome indicators and other quality indicators, clinical practice guidelines, clinical pathways, standards, health technology assessment, information technology, patient view and change management.

Conditions for the implementation of a QI system depicted the roles of government, regional and local levels, professional associations, education, motivation, resources and public accountability.

Emphasis was also on research of quality and PS, European, WHO and international cooperation.

The chapter on PS and PS incidence described the importance of leadership in PS development and PS incidence reporting.

Finally, setting up structures at the national and organisational level, providers' level of activities, framework of the national institute for quality in healthcare, and barriers to implementation were explicitly defined.

Opportunities for improvement: 15 years have passed since the publication of this document and there are many requirements in the policy that were not fulfilled. Reasons for this are mainly a lack of political will to implement the requirements, criminalization of human errors and no independent national body responsible for the implementation.

- Simčič B. (ed) National strategy for quality and PS development (2010-2015). Ljubljana. MoH, 2010. (in Slovene).

In the National strategy for QoC and PS (2010 – 2015), vision, mission and values were defined. The MoH, or envisioned independent national body for QoC and PS was obliged to set up programs based on this strategy for each year with target goals for different levels of healthcare and different disciplines. There were four strategic goals with action plans with what to do, who, how, when and responsibility but many were either not reached or partially (Deliverable 2 – situational analysis).

Opportunities for improvement: Reevaluation of strategic goals and added new ones in accordance with the development of quality and PS in the developed countries.

Methods and tools

- Poldrugovac M, Simčič B (eds): Manual of quality indicators. Ljubljana: Ministry of Healt, 2010 (in Slovene).

Opportunities for improvement: Updated indicators and ICT support.

- Robida A. Introduction of quality improvement into hospitals (Uvajanje izboljševanja kakovosti v bolnišnice). Ljubljana: Ministry of Health, 2006.
- Robida A. Pot do odlične zdravstvene prakse (Pathway to health care excellence). Ljubljana: GV založba, 2009.
- WHO: Konceptualni okvir za mednarodno klasifikacijo za varnost pacientov (Conceptual framework for the international classification for patient safety. Geneva: WHO, 2009.
  Translated into Slovenian in 2019 by Center for quality and patient safety improvement-Prosunt.
- Robida A. Sistematična analiza globljih vzrokov za napake in njihovopreprečevanje(Manual for root cause analysis- RCA). Bled: Prosunt, 2013.

Opportunities for improvement: development of new methods and tools according to gaps identified in the Delivery 2 – situational analysis

Patient safety, patient safety culture and clinical risk management

- Robida A. Hospital Survey on Patient Safety Culture in Slovenia: a psychometric evaluation. International Journal for Quality in Health Care 2013a; 0.1093/intqhc/mzt040
- Robida A. Perception of patient safety culture in Slovenian acute general hospitals. Zdrav Vestn 2013b; 82: 648–60.
- Klemenc-Ketis Z., et al. The safety attitudes questionnaire – ambulatory version: psychometric properties of the Slovenian version for the out-of-hours primary care setting. BMC Health Serv Res 2017; 17: 36.

Opportunities for improvement: If we want to see any improvement in PSC it should be measured periodically and with instrumets that have already been used, valedated and psychometrically evaluated.

- Robida, A. Opozorilni nevarni dogodki (Engl. Sentinel events). Zdravstveni vestnik, 2004; 73 : 681–687.

The system of sentinel events was supposed to be upgraded in 2009 but there was no political will to do so.

Opportunities for improvement: Upgrade the system of sentinel events and revise the SenSy

Education

- Robida, A et al. Nacional survey on education for competencies for quality and PS 2016 . Working group at MoH. Utrip. 2016; 24: 14-16.
- Robida A. Ocena več poklicnega kurikuluma o varnosti pacientov študentov VŠZNJ in študentov šestih regij SZO. Evaluation of a multi-professional curriculum on patient safety by students of the College of Nursing Jesenice and students of six regions of the World Health Organization. Conference paper Jesenice : College of nursing Jesenice, 2014, 150-155.
- Robida A. Kakovost in varnost (Quality and safety) . V: Rozman R et al. (eds). Management v zdravstvenih organizacijah (Management in healthcare organizatioins). Ljubljana ; GV Založba, 2019.

Opportunities for improvement: Development of comptency requirement for patient safety and multi-professional curricula on quality and patient safety.

10.3. Appendix C - A non-comprehensive list of tools for patient safety, patient safety culture and clinical risk management

There are many tools for quality, PS, PSC improvement and CRM. Healthcare facilities are already using some of these tools. Here are examples of some tools:

- Model of improvement with PDSA cycle
- Lean six sigma
- Incident reporting system
- Global PS trigger tool
- CRM – HFMEA tool
- Audit system and accreditation
- ISO 9001
- ISO 31000
- Analysis of safety incidents and implementing corrective actions

- Statistical tools, including SPC
- Measurement of PS, PSC and CRM indicators
- Tools for indicator measurement
- Patient handover
- Prevention of HAI
- Various checklists
- Clinical guidelines
- Clinical pathways
- SOPs
- Various checklists
- PSC measurement
- PREMs, PROMs, PRIMs, PaRIS
- Training systems for acquiring competencies for quality, PS and CRM
- Mortality and morbidity conferences
- Top management walkarounds
- Simulation of adverse events
- Safety huddles
- Informed consent
- Disclosure of an adverse event to patient/family
- Psychologic safety for healthcare professionals

PART 2: Proposal for the Slovenian Patient Safety Culture

1. INTRODUCTION AND CONTEXT OF PATIENT SAFETY CULTURE

PS today still measures what goes wrong PS-I. Even CRM that proactively establishes what can go wrong is not enough to protect patients and staff from avoidable adverse events. Policymakers focus on risk mitigation, learning-based health systems, and health care environment design that considers human factors. A culture of PS is an essential component of these efforts. Many EU countries have contributed to the importance of PSC for patient and staff safety improvement (Austria, Belgium, Czech Republic, Denmark, Finland, Ireland, Luxembourg, Malta, the Netherlands, Portugal, Romania, Slovenia, Spain, Sweden) (1).

> Safety culture is the foundation upon which healthcare can reduce avoidable patient harm (1).

PSC influences healthcare facilities and individuals' approaches to safer care. The development of a solid PSC is not an easy task. It involves collaboration in several domains that must be aligned to improve patients and staff safety. The improvement and sustaining of PSC necessitate a multidisciplinary approach that requires understanding the work environment, perception about safety, compliance, and management of PSS.

The work from the OECD developed for the 5th Patient Safety Ministerial Summit in Montreux, in 2020, notes that **political leadership and safety culture** are key elements for reducing harm, noting that effective PS governance can only be sustained if a culture that prioritizes safety is adopted at all levels of health care governance (2).

The **term safety culture** has been used in high-risk industries, including aviation, energy, and health care. Safety culture is predisposed by organizational culture and the latter by national culture. National values, beliefs, norms, practices and assumptions may directly influence healthcare workers' perceptions of the organization around them and the behavioral preferences within their organization concerning safety. Safety management practices and leadership characteristics depend on characteristics of the organization's and national cultures (3). Predominant socially accepted values at the national level create a context that can discourage individual behavior. The three elements of safety culture, the **normative** (management), the **pragmatic** (behavioral), the **anthropological** (values, beliefs, assumptions, and attitudes), form an interactive framework (4).

The purpose of the **normative component** of safety culture is to make a safe environment for patients and healthcare staff and raise needed behaviors to decrease avoidable adverse events. The normative feature is implemented through **policies, programs, practices and leadership strategies**. It is designed to transfer knowledge and motivate healthcare workers. The level to which normative control can be effective is limited and moderated by the values, beliefs, assumptions, and attitudes that members of an organization or groups share within the organization—the **anthropologic component** of safety culture. The values, beliefs, assumptions, and attitudes shared by members of the organization do not exist within the vacuum of an organization's margins. The context of **national culture** is partially included in the values, norms, attitudes, practices and beliefs people share as members of the greater national context.

Figure 15 shows a model of the interrelation of national and organisational safety culture. It is essential to recognize that, as anthropological and normative cultural attitudes vary, worker perceptions and interpretations of behavioral expectations and behavioral tendencies vary.

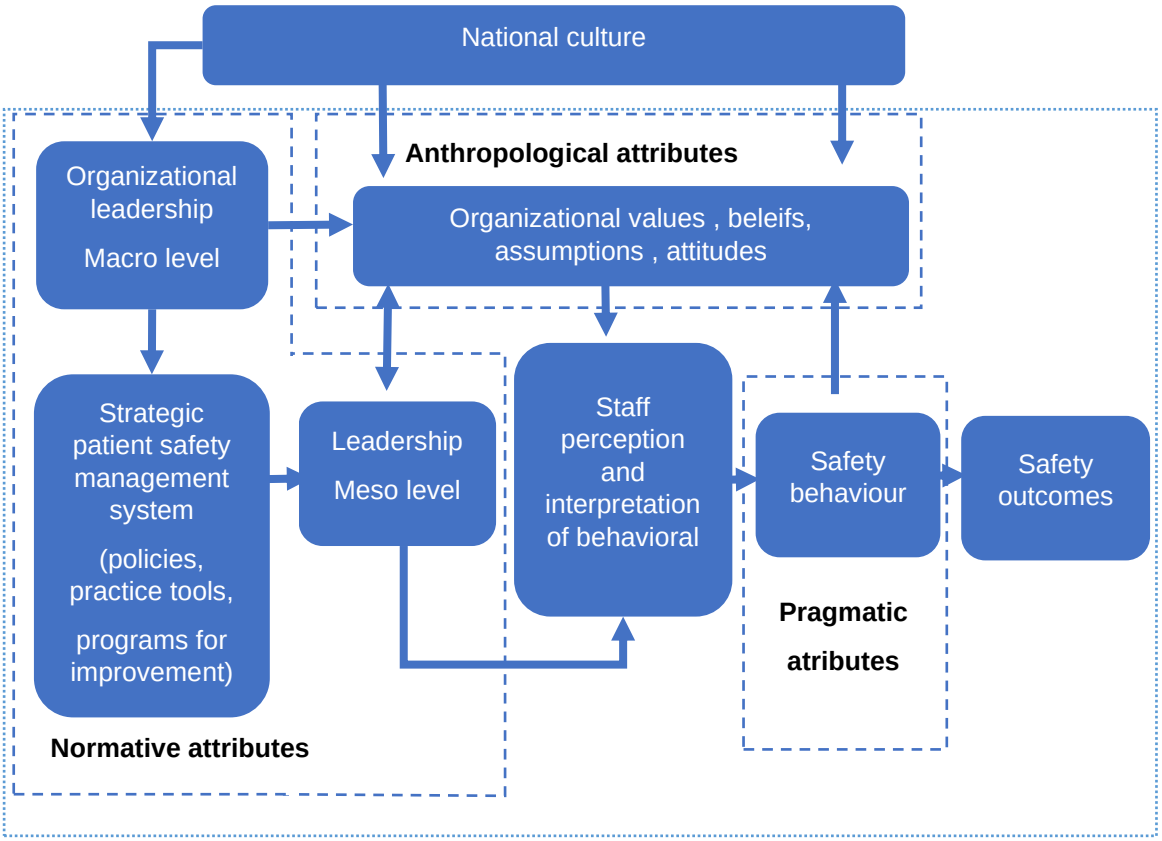

Figure 15. National culture's influence on safety culture model. National culture influences an organization's anthropological, cultural attributes and normative cultural attributes. Safety outcomes depend on all three components: anthropological, normative, and pragmatic attributes

Source: adapted from (3).

Deficient PSC has been associated with poor patient and staffing outcomes and should be addressed at all levels of health system governance. The general drivers of adverse events are shared across settings and include inadequate organisational culture: lack of communication and information, lack of skills/knowledge and misaligned incentives.

Research has shown a positive link between PSC and patient outcome, patient experience, staff safety, behaviour and productivity, and less burnout of healthcare workers (5-9). In organizations, safety culture can create norms that employees refer to when deciding how to behave in a particular situation. In this way, safety culture can affect safety behaviors and lead to positive outcomes (10). Normative strategies need to account for fundamental differences in healthcare worker perceptions and behavioral tendencies to facilitate the desired behaviors across cultures. The effective normative strategies are most likely culturally contextualized, and that alignment between chosen strategies and existing values is vital to a thriving safety culture (3).

2. PATIENT SAFETY CULTURE

The mission statement includes safety. Positive safety is the core value and people have defined and shared responsibilities. Safety is part of each professional discipline, teamwork and individual attitude. Leadership actively seeks safety improvement, and safety is seen as a benefit for anyone.

PSC is a way to **improve PS outcomes** and health system performance. It can be a cure for PS issues and adverse events. Measures of PSC in evaluation activities at all levels of health can safeguard a comprehensive view of the status of PS by linking culture, documented adverse events, and overall health outcomes. PSC can be realized if individuals at all health system levels **work together** to ensure that care is provided in a **learning system** with **continuous improvement, accountability, and PS**.

Culture change **cannot be mandated by strategy** but with the systematic approach to elements of a **PSS.** A positive safety culture can be developed if everyone in healthcare is trained to do their job safely, proactively look for hazards, and report incidents and near misses. Thus we will be approaching a level of safety that is behaviour driven. Managers must actively demonstrate all the components of positive safety culture regularly to encourage everyone to participate in achieving safety toward zero avoidable harm (figure 16).

2.1. Components of patient safety culture

Culture of knowledge and system thinking. Leadership is up to date with the development of PS science.

Culture of reporting. Organisational culture encourages reporting rather than blaming and shaming. A safety culture depends on an organization's willingness to learn from failure.

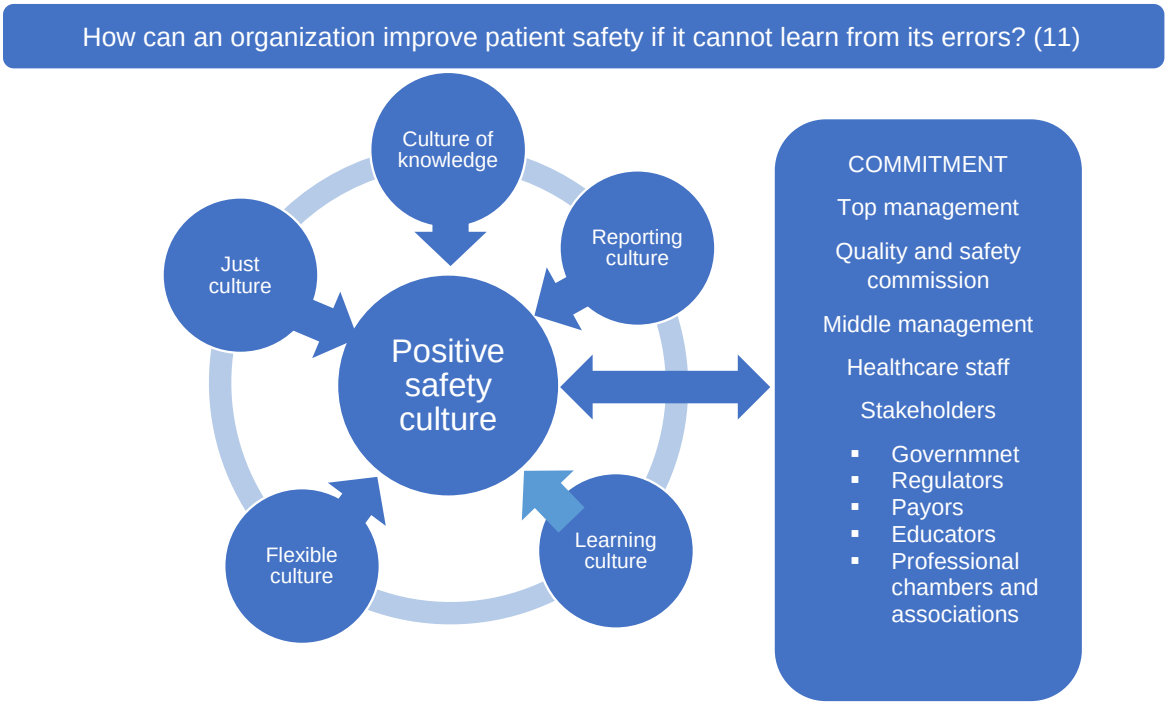

Figure 16. Five positive interconnecting components of positive safety culture

Source: adapted from (11).

Safety culture requires a solid event reporting program. Organizations' event reporting programs depend on staff members voluntarily completing an event report about a near miss, unsafe condition, or patient injury. Unfortunately, many events are not reported for a variety of reasons. The barriers to event reporting are well documented (table 3) (12,13). If the organization suspects underreporting of events, it should **find out why the staff is hesitant to report** and help them overcome the obstacles.

Questions to be asked are:

- Do the staff clearly understand the types of events the organization expects to see reported?
- Does the organization **encourage staff to report** near misses and close calls to take steps to address the unsafe conditions?
- Do staff **trust that the organization views** PS incidents as system failures?
- Does the organization provide **feedback** about event reports, so staff knows that the information they report is taken seriously?

Actions to overcome barriers for not reporting:

- **Define event**s to be reported and identify roles of stakeholders
- Choose an **event reporting system** based on ease of use and results
- Ensure that all potential reporters understand **why and how to report** events
- Cultivate an **atmosphere** that **encourages reporting**
- **Analyze data** and respond accordingly **to improve** clinical and operational processes
- Ensure that all stakeholders receive timely and comprehensive **feedback** (table 3)

Barriers	Actions
Someone has already reported the event	Use reporting systems that can identify duplications.
Lack of time to complete an event report form	Design event report forms for ease of completion (e.g., explore ways to auto-populate some fields with data from other sources, such as the admission, discharge, and transfer system).
Lack of understanding of the importance of reporting	Require education about event reporting at orientation and annually after that; establish reporting as a performance expectation in job
Unclear policies and procedures for reporting; lack of availability of event report forms (or computer access for electronic systems)	Create clear, specific policies and procedures for event reporting; provide easy access to forms and systems to support reporting.
A belief that reporting does not contribute to improvement; lack of feedback on action taken as a result of the event report	Communicate to staff information about changes and improvements made due to reported events; explicitly recognize the positive effect reporting has on PS.
Reluctance to "tell on" another healthcare worker; fear of punishments and lawsuits	Clarify that individuals are not punished for errors that result from system failures; establish a just and fair approach to evaluate accountability for PS incidents.
Lack of involvement by physicians and other providers in the event reporting system	Include physicians and other providers in event reporting system development and educational programs; create the expectation that physicians and other providers will participate in event reporting.

Table 3. Reporting barriers and strategies to overcome them.

Flexible culture. Participative leadership and management and adaptation to a particular situation.

Just culture. The staff knows that there will be a just approach and is aware of the boundary between acceptable and unacceptable behaviour. It is not an entirely blame-free approach and certain violations deserve disciplinary or legal actions. Nurses and doctors are among the most trusted people in **Slovenian** society (14).

Patients trust clinicians to support them when they are most vulnerable. Patients rely on clinicians to maintain high professional behaviour and competence standards. Additionally, patients trust that there are mechanisms to hold clinicians accountable if they are deliberately malicious or reckless and to ensure they are competent.

Blame is a natural and easy response to error. It allows the cause of errors to be ascribed to individual incompetence, carelessness or recklessness and asserts that the problem is the individual. **Blame** relies on two myths. First, the **perfection myth**: if we try hard, we will not make any errors. Second, the **punishment myth**: if we punish people when they make errors, they will not make them again. Such myths are prevailing and are making **PS improvement almost impossible**. In the **sporadic cases** where people are deliberately malicious, knowingly and inappropriately depart from good practice, or are unfit to practice, action should be taken to protect patients. In most situations, however, where an unintended or unexpected error occurs, the chosen action must be the most likely to reduce the chances that the error is repeated - a **systemic approach to PS** (15,16).

A **fair approach** to PS incidents holds problematic individuals accountable for unacceptable behavior. It draws a **line between acceptable and unacceptable behavior** by differentiating the problematic individuals from the sound, skilled people who were set up to fail from system errors they could not foresee (17).

In rare cases, malicious actions or impaired judgment from drug or alcohol use could contribute to a PS event. A healthcare professional who deliberately intended to cause harm to a patient exhibits behavior that is punishable regardless of the outcome of the behavior (18).

Over the last several decades, healthcare organizations have been encouraged to shift from a punitive culture to a "just culture," first coined in 2001 by Marx (19). A fair and just culture **recognizes that individuals are human, fallible, and capable of making errors**, especially when the systems that they work in are flawed. These i**ndividuals should not be held responsible for errors that are symptomatic of an imperfect system that needs fixin**g. By contrast, a "**shame and blame" environment drives error reporting underground** because people feel singled out for safety issues that may have deeper causes. Without the information provided by event reporting, organizations cannot learn from errors.

Culture of learning. The prerequisites for improving patient and staff safety are analyzing avoidable adverse events and near misses, psychological safety, disclosure and apologizing to patient/family, CRM, improvement science, and patient-centered care. In Slovenia, there is the criminalization of human errors. It has become a judicial practice in recent years (20).

The criminalization of human errors is the worst approach to PS because doctors hide errors, ascribe them to complications, and practice defensive medicine. It is not about the small number of legal procedures but of the attitude of courts towards PS (20).

Fundamental to safety culture is a healthcare facilitys' motivation to examine its weaknesses and use the findings to improve care delivery. The term "high-reliability organization" has been used to describe organizations from high-risk industries, such as healthcare, that attain and maintain a high level of safety by demonstrating preparedness to learn and change before accidents occur. They approach safety systematically, even at the expense of production or efficiency. They look for, identify, and fix problems before harm can occur using event reporting programs and other means. When accidents do occur, high-reliability organizations investigate them to identify and address the underlying system faults that contributed to the problem (21).

A learning culture is linked with a reporting culture and a fair and just culture to support a safety culture, many attributes of a learning culture.

Positive PSC is characterized by a '**collective mindfulness'** about PS issues, mutual trust among staff, shared responsibility for safe care delivery, and confidence in organizational-level safety initiatives (22).

Positive PSC have **strong leadership** that drives and prioritize safety. Commitment from leaders and managers is essential. Their actions and attitudes influence the wider workforce's perceptions, attitudes, and behaviours.

Other important aspects of positive PSC include:

- Shared perceptions of the importance of safety
- Constructive communication
- Mutual trust
- A workforce that is engaged and constantly aware that things can go wrong
- Acknowledgment at all levels that errors occur
- Ability to recognize, respond to, give feedback about, and learn from adverse events

One of the many definitions of PS is written in appendix A. For the practical purpose, the **attributes of an organization that contribute to a safety culture**, which shape clinician and staff behavior daily, are more important than a definition of PS:

- Staff and leaders value transparency, accountability, and mutual respect
- Safety is everyone's priority
- Behaviors that undermine a culture of safety are unacceptable
- Staff recognizes that systems can fail and are, therefore, mindful of identifying hazardous conditions and close calls before a patient is harmed
- Staff report errors because they know the information can be used to address system flaws that contribute to PS events
- Staff creates a learning organization by learning from PS events to improve continuously (23)

What can be assessed to find out what is an organization's safety culture is:

- Leadership support of the safe practice
- Systems, procedures and processes exist that normalise or protect PS
- Resources for safety (staffing, equipment, training, finance)
- The quality of interpersonal relationships (teamwork, collaboration within and across units)

- Communication, particularly about safety, includes perceptions of reporting and speaking up
- A focus on learning from errors, responding and improving systems
- Individual staff characteristics and perceptions of their effect on work (such as job satisfaction, stress)
- General awareness of PS as being a value and priority
- Other means of prioritising safety (such as through rewards and incentives)
- Actual safety issues witnessed/reported (24)

2.2. Features of patient safety culture

The critical influences for PS and good PSC are:

- Staff who feel psychologically safe
- Valuing and respecting diversity
- A compelling vision
- Good leadership at all levels
- A sense of teamwork
- Openness and support for learning

Psychological safety needs the work settings for staff to work at their best and adapt as the environment requires. **The staff must feel supported** within a compassionate and inclusive environment. Psychological safety operates at the level of the group, not the individual, with each individual knowing they will be treated fairly and empathically by the group if things go wrong or they speak up to stop problems from occurring. It means staff does not feel the need to behave defensively to protect themselves and instead opens the space in which they can learn (25).

Diversity. Team psychological safety is represented by a climate of inclusivity, trust, and respect, where people can prosper as themselves. Valuing diversity plays a critical role. Recognizing how beneficial differences in age, gender, ethnicity, power or diversity of thought is vital for teamwork, communication, and performance. These differences motivate learning and creativity if employed in the right way. Leading collectively through the team increases the voice of even the most minor influential roles and enhances safety. Working in a deficit-based manner can destabilise, humiliate or discriminate against those who are different, lead to fear, and decrease team psychological safety and workplace learning.

Compelling vision. Before leadership can practice well, there needs to be a vision of what leadership wishes to achieve. A good understanding of why the staff is doing something and where it wants to get to encompasses the successful system: the vision needs to be explicit, not dependant on the assumption. Organisations that highlight the importance of long-term thinking and strategy and have high aspirations for the teams encourage pride and positivity in the workplace (26).

Open to learning. The system must focus on changing rather than punitive actions to develop a learning culture. An organisation that recognizes and recovers from errors as quickly as possible will be alert to learning and continuous improvement possibilities.

2.3. Leadership and patient safety culture

Leadership and teamwork. Policymakers and health care leaders can act as catalysts for improving PSC and implementing policies to improve **CRM** and thus contribute to better PSC. Insufficient management has been found to contribute to adverse events. For example, inadequate support for error reporting, a lack of response to staff reports safety vulnerabilities or leaving staff burnout unaddressed (27).

Compassionate leadership creates psychological safety and encourages team members to pay attention to each other, develop mutual understanding, and empathize and support each other. The way leadership is practiced through the organisation is critical to its success. Clinical leadership is significant to safety. Furthermore, feeling part of a team protects individuals against the demands of the organisation they work for. If they have clarity about their role in the team, they are less likely to burn out and more likely to operate safely.

Leaders in healthcare facilities can be seen as a governing body, top and middle management, nurse and physician leaders. Responsibility to PSC on leadership and management is vital for establishing and maintaining a safe environment and producing high-quality health care services. Leaders play a crucial role in driving an organization's safety culture by setting examples, promoting communication, creating and enabling atmospheres for raising concerns, and leveraging rewards and punishments (28).

Without sustained leadership support for a safety culture up to 80% of initiatives that require people to change behaviors fail in the absence of effective leadership to manage the changes (29).

Failure to create a prominent safety culture contributes to many types of adverse events. In addition, without a safety culture, staff may be insufficiently motivated to report events that could be used to identify and address the causes of PS problems.

When leaders set the right attitude for a safe culture, staff trust them and listen to their concerns. In such an atmosphere, staff members are unafraid to speak up about unsafe conditions and hazards. They understand the importance of event reporting because the information is used to improve PS. The staff knows that event reporting can make a positive difference in the QoC provided at their organization.

A necessary consequence of a strong safety culture is its effect on staff morale. If staff feel engaged and productive at the workplace, staff is also more likely to find meaning in work (30).

Leaders are role models and must demonstrate the type of behavior they expect from staff to support safety culture. One strategy used to indicate a commitment to safety and engage senior managers and staff is PS rounds, often referred to as leadership **walkarounds** (31,32). The concept involves leaders, such as the chief executive officer and other senior executives, governing board members, vice presidents, and key clinical managers, visiting various hospital areas and asking providers and frontline staff specific questions about PS regularly. Walkarounds offer leaders insight into barriers that prevent staff from delivering safe patient care. In addition, this information help leaders identify improvement priorities. Leaders demonstrate their commitment to the organization's PSC by their readiness to provide funds

to improve PS by offering team training programs to promote quality and PS competencies, cooperation, and collaboration.

Examples of **disruptive behaviour** are shaming others for negative outcomes, refusal to comply with known and generally accepted standards of care, failure to work collaboratively or cooperatively with other members of an interdisciplinary team, not returning calls promptly etc. The organization is expected to hold all staff accountable for adhering to the code. Permitting exceptions and unequal treatment creates mistrust and undermines the organization's ability to achieve a safety culture. In addition, the intimidating behavior can suppress staff willingness to report errors and unsafe conditions if staff are afraid of retaliation for reporting (21,33). The summary of leadership actions to advance PSC is shown in figure 3.

2.4. The importance of individual behaviours

At its center, a positive culture requires **kindness and civility**. The importance of individuals' day-to-day behaviour about safety is increasingly recognised. Civility is seen as friendly and safe, but we start to see its importance when it is missing. Studies have shown that safety is compromised where people are rude and disrespectful (35).

If people are rude, we need to understand their context and why but not judge. **Most incivility arises from ignorance not evil**. In many instances, the person may not know that their actions are hurtful. Most people are rude only rarely and when they are it is for a reason. To shift from incivility to a kinder culture, everyone needs to counter the rudeness by role modeling the correct behaviour, rewarding good behaviour, and dealing with bad behaviour.

High-performing teams promote a culture of honesty, authenticity and safe conflict. The behaviours that counter incivility are often small; smile and say hello in the hallway, say thank you, recognise what people do, listen with intent (36).

2.5. Actions to support patient safety culture

Developing a PSC requires **local systems** to:

- Use **existing culture metrics** and **create new for a different kind of healthcare** to understand the safety culture and focus on staff perceptions of the fairness and effectiveness of incident management
- Focus on the development and maintenance of a just culture
- Embed the safety culture principles within and across local system organisations and align those efforts with work to ensure organisations adhere to the well-led framework

Table 4 suggests actions for leadership.

	Actions for leadership to improve patient safety and patient safety culture
1	Present a transparent, nonpunitive approach to reporting and learning from adverse events, near misses and unsafe conditions. Create an environment where people can speak up about errors without fear of punishment.
2	Create clear, just, and transparent risk-based processes for recognizing and differentiating human error and error arising from poorly designed systems from unsafe or reckless actions that are blamable.
3	Promote just culture and trust within the organization, adopt and model appropriate leadership behaviours and support efforts to eradicate intimidating behaviours.
4	Institute, implement and communicate to all team members the policies that support safety culture and the reporting of adverse events, near misses and unsafe conditions.
5	Appreciate care team members who report adverse events and near misses, detect unsafe conditions, or have good proposals for safety improvements. Team members are supported and encouraged to grow and develop. Identify and address organizational barriers to event reporting.
6	Establish an organizational baseline measure on safety culture performance using the surveys (SOPS,SAQ). Repeat organizational safety culture assessment every 24 months to review progress and sustain improvement.
7	Respectful behaviour and the absence of intimidation or discrimination.
8	In response to information obtained from safety assessments and/or surveys, develop and implement unit-based quality and safety improvement initiatives designed to improve safety culture.
9	Implant safety culture team training into QI projects and organizational processes to strengthen safety systems.
10	Use CRM in the areas such as medication management and electronic health records strengths and vulnerabilities and prioritize their improvement.
11	Model expected behavior within a safety culture. Enforce a code of conduct that defines appropriate behavior to support a safety culture and unacceptable behavior that can undermine it.
12	Implement PS, CRM strategy and action plans and introduce PS tools with collaboration projects among public and private institutions.

Table 4. Action for leadership (34)

3. MEASUREMENT OF PATIENT SAFETY CULTURE

Change to safety culture does not occur because policies and procedures to support it are in place. **Culture change takes time to become rooted within a healthcare organisation**. The attitudes and beliefs that support the elements of a safety culture must penetrate the organization and be adopted by everyone—including those who may have been initially reluctant to embrace change.

Health care systems require measures that assess their capacity and ability to deliver safe care. Without measurement, one cannot improve (37). Measures of PSC are used to understand the presence or absence of safe organisational environments. Instead of ascribing blame for failures to individuals, health systems now focus on improving the systemic and organisational characteristics that are necessary for ensuring PS. PSC forms one component of a comprehensive measurement and improvement system. It should be measured alongside other safety and quality indicators.

Measurement of PSC is vital because it helps health care organisations **identify strengths, weaknesses and gaps, and areas for improvement.** Measurement recognizes the type of environment and the conditions conducive to good PS and is vital for a proactive management approach to health care improvement. It becomes virtually impossible to detect and reinforce beneficial trends that enhance PS without measurement PSC. **Systematic measurement of PSC and follow-up evaluation** of the results is essential for learning, improvement, benchmarking, and comparison. Measurement of PSC enables the identification of strengths and areas for improvement. This information can be used to develop appropriate interventions. PSC measures can also be used to evaluate new safety programs by comparing results before and after implementation.

Armutlu et al. (38) proposed evidence-based PS bundle practices for senior healthcare leadership to establish and sustain high-quality health care delivery and PSC.

Measurement of PSC is understood to be a **leading indicator of PS**. It is a critical component of safe, reliable health care and is not an end in itself but a means for improvement. (2). Safety measurement must be considered as part of a feedback loop and thus contribute to organisational and individual learning and improvement. Follow-up evaluation of the results is central for learning, improvement, benchmarking, and comparison. Unfortunately, in Slovenia, the measurement of PSC initiated in 2011 was not act upon and not repeated due to the regulator's unwillingness to support the measurement (46).

PSC can be measured through a psychological approach with surveys of healthcare staff, qualitative measurement (focus groups, interviews) and ethnographic investigation (39), and experience-based approach (40), or a combination of these. Experienced based approach shows five levels of PSC (Figure 4).

3.1. Tools for measurement of PSC

Psychological approach with surveys of health care staff are the **most common way** of measuring PSC. This is because healthcare staff are often the first to notice unsafe practice patterns and the conditions that increase or decrease the likelihood of such practice.

A review by the European Union Network for Patient Safety in 2010 identified 19 tools specific to measuring PSC in use in EU member countries. In EU member states the most common

tools are: the HSPSC developed by the Agency for Healthcare Research and Quality (AHRQ), the Manchester Safety Framework (MaPSaF) and the Safety Attitudes Questionnaire (SAQ) (41).

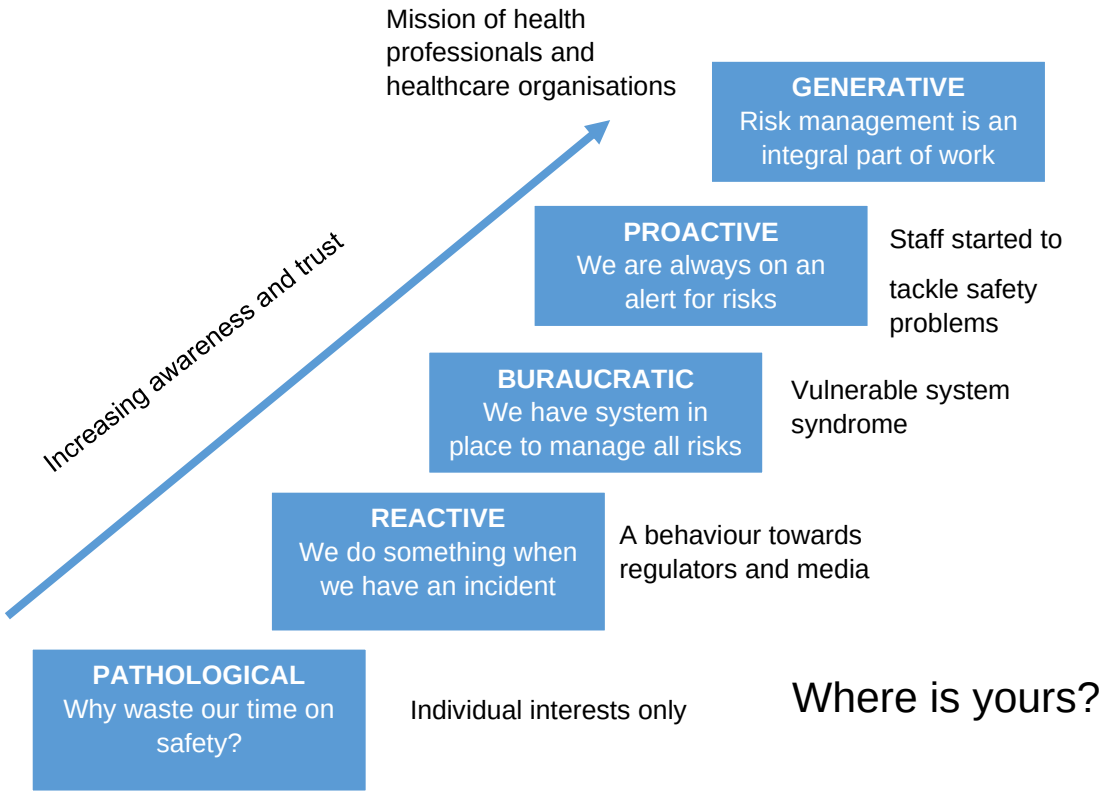

Figure 17. Experience-based approach to safety culture

Source: adapted from (40)

AHRQ developed a set of surveys to assess PSC in hospitals, primary care, nursing homes, community pharmacies and ambulatory surgery centres (42). The Hospital Survey on Patient Safety Culture (HSPSC) is used in over 90 countries and has been translated into 40 languages (44), including **Slovenian** (45). The HSPSC questionnaire consists of 42 items addressing 7 unit-level, 3 hospital-level aspects of safety culture and 4 outcome variables, of which 2 (overall PS grade and the number of events reported in the last 12 months) were single-item measures. An analysis of the HSPSC found that the tool was psychometrically sound at the individual, unit, and hospital levels and demonstrated high levels of reliability and validity (43). Waterson et al. (44) recently conducted a systemic review of 62 international studies using the HSPSC. The HSPSC tool's strengths are that it permits large-scale comparisons and identifies changes over time.

In **Slovenia** it was used in 2011 in 16 of 26 public hospitals (46) and 2019 in 5 psychiatric hospitals (47). The HSPSC tool was translated into Slovenian and psychometrically evaluated with exploratory and confirmatory factor analysis. Each of the 16 studied hospitals received a full report with recommendations for improvement.

Results of HSPSC dimensions in 2011 are shown in figure 18.

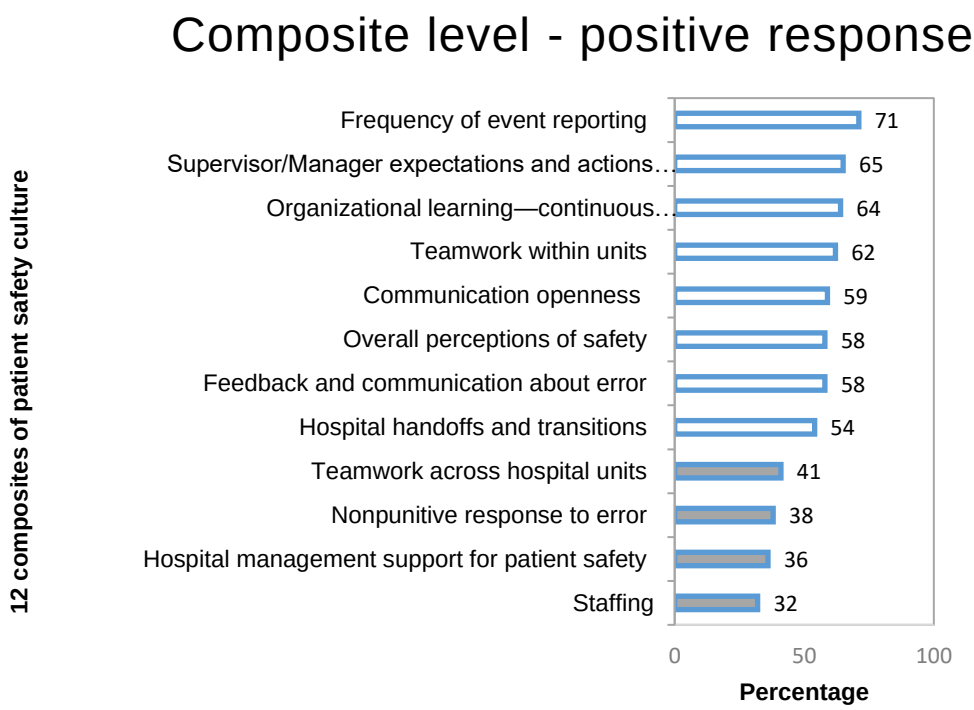

Figure 18. Results on 12 dimensions of patient safety culture in the acute general hospital in Slovenia. Gray bars represent dimensions with less than 50% positive scores

Source: (46).

In 2010 there was an obligatory requirement from MoH to include the measurement results of the perception of PS into sets of clinical indicators. However, none of the providers fulfilled this requirement.

In 2019 an electronic survey among the hospitals' leaders was conducted with the current opinion of hospital leaders before starting the national measurement of safety culture. 35 questionnaires from a total of 19 hospitals were included in the analysis. The responders were Assistant Nursing Directors (28.6%), Directors (25%), Medical Directors (22.9%), Quality Authorized Persons (11, 4%), and others (5,9%) as e.g., authorized person for waiting lists. The survey results showed relatively high self-esteem of management in their efforts to develop a culture of safety. However, since only management participated in the assessment, there is a danger of a "discrepancy between words and actions." Such a discrepancy about the opinions of the management and first lin staff was confirmed in the previous study (48). Therefore, the leaders emphasize that crucial actions to be addressed are developing a culture of safety in their institution and national learning to improve the situation in the institutions.

While a significant number of countries currently use the HSPSC, AHRQ has developed a new version of the tool incorporating substantial changes. In 2019, AHRQ released a new version, of HSPSC which includes only 40 survey items. Another psychometric evaluation will be needed to use the improved version in Slovenia.

Another frequently used survey tool is the Safety Attitudes Questionnaire (SAQ) (49). The generic version of the survey includes 36 items across six dimensions, teamwork climate, safety climate, stress recognition, job satisfaction, perceptions of management and work conditions. The SAQ and HSPSC have several overlying domains. There are also many other

tools for measuring PS like Manchester Patient Safety Framework (MaPSaF), Safety Climate SCORE, Canadian patient climate survey, Safety Climate Survey Safety Climate Scale, Patient Safety Climate in Healthcare Organisations survey, Modified Stanford Instrument and others. There is no single tool currently available that measures all major dimensions of safety and quality in healthcare (24).

The tool was also used in primary care (50, 51 52). The short form of SAQ was used (49). It was conducted at the primary health level in Slovenia's largest primary health centre and 211 leaders were invited to the electronically conducted survey. The response rate was 73%. The results of this research suggested that the Slovenian-language version of the SAQ - Short form with six factors could be a reliable and valid tool for measuring the safety culture in the primary health care workers with leadership roles. The Slovenian version differed from the original SAQ - Short form and most other translated versions. However, the data were from one health centre only and therefore, firm conclusions could not be drawn on its external validity (52).

Not all tools measure the exact same dimensions. The dimensions of the most frequently used tool are shown in table 2. Common dimensions of all three tools are in italics. The dimensions present in two tools are underlined.

Although survey tools to measure PSC are widespread, issues of reliability and validity remain. Analysis from the OECD (53) has discussed the cyclical nature of behaviour change and safety culture, noting that safety culture is influenced by safety standards, protocols and other systems that are formed in response to undesirable behaviours and poor outcomes (normative cultural attributes). For this reason, it is important to consider measures of PSC in the context of other measures, including outcomes and PSI, as well as in the context of long-term improvement. These mechanisms influence new behaviours—thus creating a new culture, which result in changing outcomes and different response options for policymakers and health care leadership (OECD, 2020[2]). This was also shown in a repeated study of PSC in one hospital in Slovenia two years after the implementation of different methods and tools of PS (54).

3.2. Patient safety culture measurement and use in EC and OECD countries

A study of de Bienassis et al. (1) revealed that ten countries indicated that PSC is measured at the national level (Austria, Belgium, Israel, Norway, Spain Sweden, Malta, Portugal, England (UK) and Wales (UK). Seven reporting countries (Austria, Belgium, Canada, Israel, Portugal, Spain, and Slovenia) indicated a national program responsible for PSC monitoring.

The most commonly used tools in OECD countries are HSPSC (Australia, Belgium, Chile, Czech Republic, Finland, Iceland, Israel, Japan, Luxembourg, The Netherlands, Portugal, Slovenia, Spain, Sweden, United States); SAQ (Australia, Denmark, Iceland, Malta, Norway, Slovenia, Spain, Sweden); MaPSaF (Australia, the Netherlands, Sweden, United Kingdom).

Currently, **governance approaches** are not common mechanisms for implementing PSC measurement or improvement initiatives. However, in some cases, they have been implemented. In Norway, the Ministry of health and care services requires that at least 60% of

clinical units in all hospital trusts have a "mature safety climate", according to a specified definition.

Several OECD countries are currently developing concrete plans to expand activities related to PSC measurement (Australia, Finland, Ireland, Slovenia, Sweden, Turkey, United Kingdom) (1).

Table 5 displays the dimension of usually used PSC instruments.

HSPSC	SAQ	MaPSaF
Domains		
1. *Teamwork within units*	*1. Teamwork Climate*	1. Commitment to overall continuous improvement
2. Supervisor/manager expectations and actions	2. Safety Climate	2. Priority is given to safety
promoting safety	3. Stress Recognition	3. System errors and individual responsibility
3. Organisational learning – continuous improvement	4. Job Satisfaction	4. Recording incidents and best practice
4. Management support for PS	5. Perceptions of Management	5. Evaluating incidents and best practices
5. Overall perceptions of PS	6. Work Conditions	6. Learning and effecting change
6. Feedback and communication about error		7. Communication about safety issues
7. Communication openness		8. Personnel management and safety issues
8. Frequency of events reported		9. Staff training and education
9. *Teamwork across units*		10. *Team working*
10. Staffing		
11. Handoffs and transitions		
12. Non-punitive response to errors		
Population		
All hospital personnel	All hospital personnel	Health care staff
Number of items		
42 closed items; Likert Scales	36 closed items, 5-point Likert Scale	5-point scale; qualitative (from 'pathological' to 'generative')

Table 5. The Dimensions of usual PSC instruments adapted from OECD, 2020

Common dimensions of all three tools are in italics. The dimensions present in the two tools are underlined.

Slovenia launched SenSys project in January 2018, a program to establish the national PS incident system reporting, initiated with the technical support provided by the European Commission's Structural Reform Support Service and the Danish Patient Safety Authority but has not yet been implemented.

The project includes three main objectives:

- Preparation of the legal basis for the system
- Implementation of a web-based reporting system
- Reporting and learning platform, and the development of a PSC indicator

Slovenia has indicated that a national study of PSC is planned for 2020, however, due to several reasons, including Covid-19 pandemic the plan has not yet been fulfilled (55).

Appropriate translated and validated tools specific to countries and settings are important to PSC comparability across countries and national settings. Therefore, tools should be translated and psychometrically evaluated to capture the intended meaning of the questions and validated to ensure that the items apply to the setting in which they are being administered.

4. INTERVENTIONS FOR SAFETY CULTURE IMPROVEMENT

With the **persistent challenge of errors**, policymakers and practitioners need guidance regarding how to achieve improvement. Using only some tools for PS improvement is inadequate. Reinforcement of safety culture necessitates interventions that simultaneously enable, enact, and elaborate it. An extensive collection of interventions may be pooled to reduce errors (56). A conceptual framework proposes that existing interventions target one of **three aspects of safety culture—enabling, enacting, or elaborating**. Enabling refers to leader actions and external influences that emphasize safety. These enabling activities influence frontline workers' perceptions of safety climate and promote the enactment of safety culture. Enacting includes frontline actions to rise and resolve threats to safety, and elaborating means systematically reflecting on and learning from performance (57). The interrelationships among interventions that enable, enact, and elaborate culture of safety to reduce hospital errors is presented in figure 6.

Safety culture is the key mechanism **enabling** enacting and frontline providers' interpretations of leaders' safety, commitment, and organizational practices. Creating a safety culture and their perceptions of it influence frontline staff behaviors. **Enacting** a safety culture that reduces errors means frontline health care providers consistently translate safety policies and guidelines into routine practice. **Elaborating** a safety culture is the systematic process of exposing and translating prior experience to spread and refine manager and frontline employee safety-oriented behaviors and practices that have been previously enabled and enacted. Elaboration refers to the evolutionary expansion of these behaviors and practices, preferably characterized by increasing tolerance for them and growing capabilities for addressing complications that may accompany them.

A **practical example** of the cultural approach model: in a microsystem, the goal is to improve teamwork (enacting). Teamwork can be enabled through leader support and organizational practices, such as adequate staffing to allow for training and other exercises during work hours. The success of teamwork can then be elaborated by disseminating the plan to other groups and refining the intervention over time.

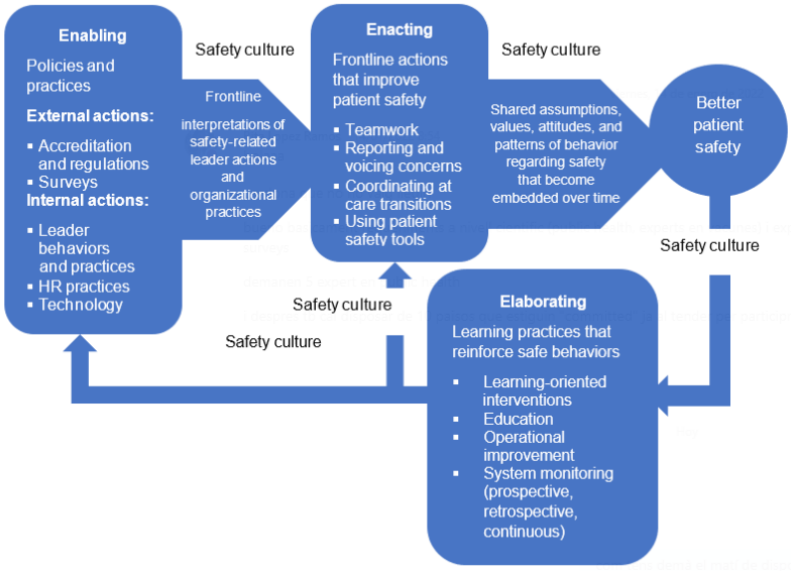

Figure 19. A cultural approach to patient safety. The arrows in this model indicate that climate and culture are dynamic processes. HR, human resources

Source: adapted from (57)

5. STRATEGIC GOALS FOR PSC IMPROVEMENT

In 2019 as a part of Sen Sy project, a document was issued with instructions for preparing an action plan for developing a safety culture among healthcare service providers (58).

A new term was also constructed, " safety deviations," translating into Slovenian language "varnostni odklon." The term "deviation" can mean a positive or negative event. It is supposed to describe a PS incident that harms or could harm a person in this context. Among many used in Slovenia, it is another euphemism for naming an error. Using euphemisms is not in the context of PSC but rather in the organizational culture avoiding the term "error" that has a very negative connotation.

The conclusion of this report (58) was that there is a need for new impetus, as activities have been gradually terminated, national measurements have not been carried out, standardised instruments have not been sufficient for multiple situations in health care institutions, and the activities have also not been adjusted to educational establishments. Reasons for these failures were not given. Plans for measuring safety culture in 2020 were not carried out. The plan are now incorporated in the strategy for PSC.

The strategic goal and action plan for each key stakeholder is described in Strategic objective 2 described in partr I above . It takes into consideration the finding of the previous EC project (58) and Emergency Care Research Institute (59).

2		Build just culture, culture of reporting, flexible culture and culture of learning

5.1. Practical recommendation for safety culture improvement at the national level

In Slovenia, work on safety culture was at its peak in 2010 and 2011. Due to the Ministry of Health's decision to fund the PSC program, no further activities were performed. There was no national governance of the program. As mentioned in the previous project, the national evaluations of PSC have not been carried out, and not all levels of healthcare experience even the base measurement of PSC (55). Currently, two validated and reliable instruments exist in Slovenia. Internationally there has been some adjustment of the instruments. This should also be implemented into the Slovenian situation.

PSIs at healthcare facilities should be expanded and supplemented with outcome measures and structural and environmental measures that assess the PSC of health delivery systems. It is imperative to understand what the PSC is in a given health care environment to understand why the culture is that way and to be able to act on it effectively. Key PS measurements are the measurement of PSC collected from providers, PSI and outcome indicators.

There is significant potential for patients to provide meaningful feedback on their safety experiences in health care settings, including their experiences of safety culture and its domains. To develop a more comprehensive approach to assessing PS across healthcare levels, several OECD and EC countries also use information reported by patients themselves (PROMs, PPREMs PaRIS)

Sen Sy project describes the importance of PSC among the providers (58).

Some of the extracted findings of importance for the current project are:

- Safety culture is not based on the system but is more dependant on individual
- It is interesting that safety culture looks high by a self-evaluated survey by management (52)
- Indicators for the change in the safety culture in institutions are not established as though recommendations were provided for hospitals that participated in the survey with HSPS instruments (47,48)
- Some institutions have experience assessing safety culture, but this is not regular practice; they recommend using a standardized questionnaire; they recognize the usefulness of the data on measuring safety culture for their institution and at a national level
- The significance of introducing an obligation to cooperate in a national study on safety culture
- The significance of training related to PS and safety culture for everyone is highlighted – for both key employees of institutions and patients
- The importance of establishing a complete structure for the system of working on safety, personnel reinforcements by healthcare providers, partial unburdening of key persons, and a clear and sufficient design at a national level for implementing current initiatives for realizing common objectives of PS is necessary

This part of the SenSy project concluded that it would be reasonable to assess safety culture using the same instruments in other types of institutions (in community healthcare centres, health resorts, and in healthcare providers providing training and education). However, the same instrument can be used only in institutions of the same type due to different contexts and different levels of caring for patients.

Recommended tasks to be performed are:

1. Establish just culture at the national level
    a. Decriminalization of human errors
    b. Non-fault compensation for preventable harm to the patient
    c. Accountability for reckless behaviour
2. Measure perception of PSC
    a. Upgrade existing questionnaire for hospital survey of perception of PS and perform a pilot study to evaluate psychometric characteristics (46,47)
    b. Use SAQ for primary outpatient services (52) and ambulatory specialty services
    c. Adept and pilot study the AHRQ questionnaire for community pharmacies
    d. Adept and pilot study the AHRQ questionnaire for nursing homes (DSO)

The recommended translation procedure and psychometric analysis should be used (43).

3. Promote PSC at all levels of healthcare
4. Use **Strategic objective 2 - High-reliability system and PSC** and action plans described above

5.2. Practical recommendation for safety culture improvement at providers' level

Top management constantly communicates and emphasizes vision, mission, and strategic goals to promote quality and PS awareness in the ideal safety culture. Awareness is created through specific activities that are consistently performed daily, without exception, weekly and monthly. The performance is monitored and measured and acted upon. One of the best

methods is creating an internal network to spread quality and PS solutions in the entire organisation.

To start with an activity-based management system, it is necessary to look at existing safety management and decide which activities add value to the process and which activities currently do not add any value. Once all current safety activities are listed the decision can be made to remove, modify or replace them. Examples of indicators of some activities are number of avoidable patient harm, percentage of disclosure of avoidable harm to the patient/ family, number of patient complaints, number of processes examined with HFMEA method, rate of solutions for near misses, number of projects for improvement, number of yearly safety goals accomplished, the average length of time feedback was provided to employees for reports on patient incidents and, suggestions for improvement, number of times safety meetings were conducted in a unit, percentage of employees receiving yearly safety training, etc.

An example of activity-based management system overview is presented in figure 20. The management of a unit has decided that the handover of patients is necessary to improve as data showed that some vital information was lost during shift changes that harm patients. They are conducting weekly and monthly meetings to see the progress of change. Walkarounds were performed by top management monthly. All the information about the activities was recorded. Instead of handover, any other problem with quality and PS can be addressed similarly.

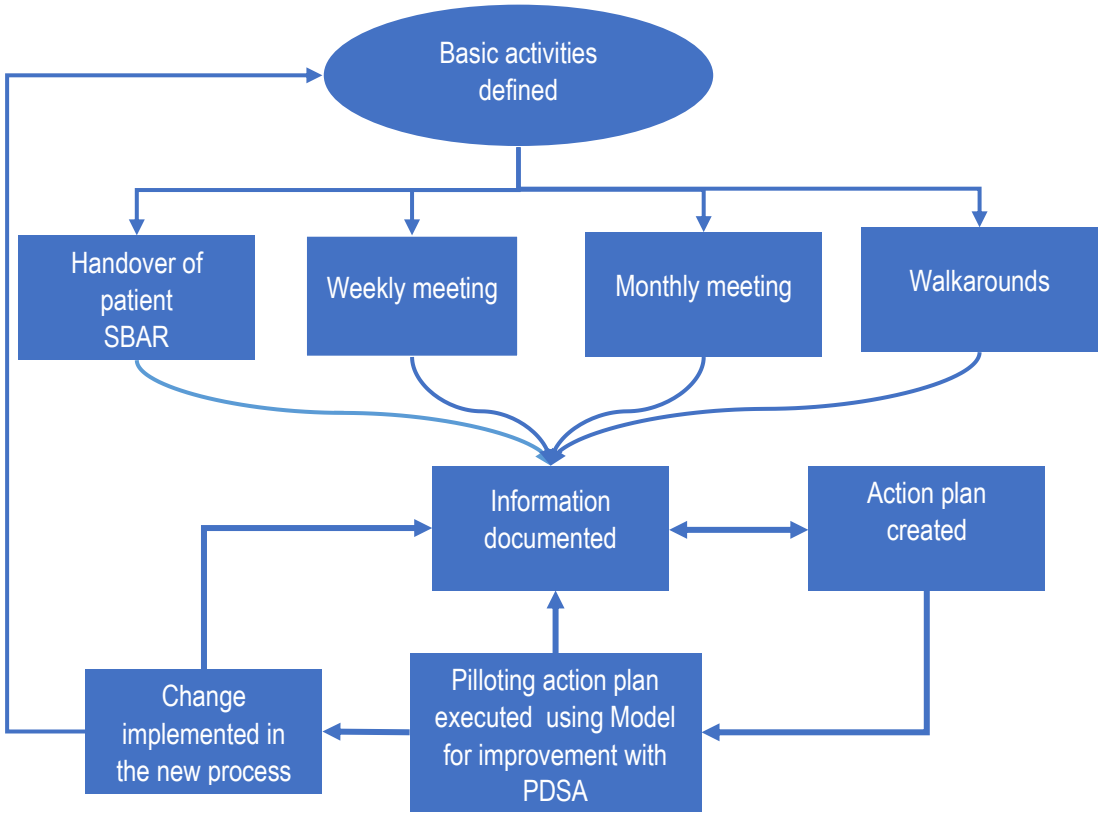

Figure 20. An example of four activities for improvement in a unit. SBAR, situation, background, assessment, request; PDSA, plan, do, study, act

Source: Prosunt©

Developing and sustaining PSC requires a multidisciplinary approach in setting vision, mission, policy, governance, partnership, strategic objectives, action plans, structure, processes and expected outcomes. Safety culture affects safety performance- prevention of avoidable harm

to the patient, staff and visitors. It is prudent to understand that safety **is not a separate activity of health care** but incorporated in all doing of healthcare facilities.

When assessing the current situation, the first step is to understand what you want to accomplish or what has been mandated. Then, you can answer the following questions:

The first step is to **assess the current PSC**.

Choices of cultural change:

1. Not to change anything with maintaining **status quo** and matching PSS to current PSC
2. Enabling change due to internal pressure like financial problems if there will be no payment for avoidable adverse events or pressure from the staff, governing boards, patients and civil society:
   - Plan change
   - Determine the desired culture
   - Establish a strategy for change
3. Mandatory change due to crisis because of severe incidents or external pressure like legal requirements, no payment for avoidable patient harm and other regulatory requirements:
   - Mandated change
   - Determine characteristics of mandated
   - Match safety desired mandated
4. Use **Strategic objective 2 - High-reliability system and PSC** and action plans described above
5. Recommended tasks for senior leaders of healthcare organisations:
   - Respectful behaviour and the absence of intimidation or discrimination
   - Team members are supported and encouraged to grow and develop
   - Promote just culture
   - Model expected behavior within a safety culture
   - Enforce a code of conduct that defines appropriate behavior to support a safety culture and unacceptable behavior that can undermine it
   - Create an environment where people can speak up about errors without fear of punishment
   - Use the information to identify the system flaws that contribute to mistakes
   - Apply a fair and consistent approach to evaluate the actions of staff involved in PS incidents
   - Support event reporting of near misses, unsafe conditions, and adverse events
   - Identify and address organizational barriers to event reporting
   - Cultivate an organization-wide willingness to examine system weaknesses and use the findings to improve care delivery
   - Promote collaboration across ranks and disciplines to seek solutions to identified safety problems
   - Periodically assess an organization's safety culture to track changes and improvements over time

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PART 3: Competencies for patient safety

1. INTRODUCTION

Health care is changing rapidly. New technologies, advances in care delivery, and scientific discoveries are happening at rates that make it challenging for teaching and learning practices across the continuum to keep up. New demands and advances in health care, including quality and PS, require healthcare professionals to acquire new competencies (1).

The future of healthcare depends on delivering exceptional quality and outcomes cost-effectively. Reaching this future depends on shared quality priorities, investment, and active engagement throughout healthcare.

All health professionals should possess competencies to deliver patient-centered care as members of an interdisciplinary team, emphasizing evidence-based practice, quality and safety improvement approaches, and informatics (2).

Education systems play a key role in shaping the culture of quality and safety in healthcare. In addition, they are central to creating professional competencies that become a part of the students' professional culture (3,4).

Education in healthcare traditionally focused on integrating clinical learning and basic science. However, as healthcare is a **sociotechnical domain**, it is not enough for healthcare professionals to obtain and further develop technical competencies and competencies in QI and PS. Thus QI and PS are also social processes that influence behaviour (5,6).

There is a need for healthcare professionals to have essential quality and safety knowledge and skills by identifying five key competencies that all healthcare professionals should possess: providing patient-centered care, working in interdisciplinary teams, using evidence-based practice, applying QI, and using informatics (2).

1.1. Background

The setting of health services delivery needs to undergo a significant transformation from a disease-centered care delivery system toward value-based and people-centered models of care. Over the past few decades, the adoption of evidence-based medicine, involving guidance by expert panels with an emphasis on specialisation and technical knowledge, has helped improve healthcare quality. However, it has also contributed to the segmentation of care by specialties and professions (7).

People-centered care demands greater attention to broader aspects of patient care that extend well beyond bio-medical conditions and require attention to psycho-social needs and other aspects of patient lives. Expanding the scope of care into psycho-social spheres requires specific interpersonal skills, such as patient-centered communication or interprofessional collaboration. It also gives rise to new ethically challenging issues. If unaddressed, these emerging demands may contribute to more significant tensions in a workplace and higher worker attrition rates (8). This also adds to the strain in the increasing rate of burn-out across all categories of health professionals (9).

All health professionals should be educated to deliver patient-centered care as members of an interdisciplinary team, emphasizing evidence-based practice, quality and PS improvement approaches, and informatics (2).

Situational analysis and research in Slovenia have shown that undergraduate and postgraduate education and training are not part of the curriculum of medical faculties. It is somewhat better in faculties for healthcare and faculty of pharmacy (10). Some progress has been made to embed basic quality and safety competencies in health professions education, but this does not address the need for a workforce with specific expertise in healthcare quality methods and techniques. Healthcare professionals and other staff are unfamiliar with science-based QI and PS approaches.

Currently, there are not enough qualified professionals - teachers to implement programs to improve the quality and safety of patients. We are experiencing shortages in both secondary schools of healthcare, healthcare faculties, and medical schools and inside healthcare organisations. Therefore, it is one of the reasons why it is unrealistic to expect that we will achieve improvements in a relatively short period. “Teach the teacher” for the quality and safety of healthcare is a priority. The competencies of clinical mentors require at least a level of training professional for healthcare professionals. A clinical mentor uses practical methods, techniques and tools to improve the quality and safety of patients in their daily work. However, teachers' competencies at healthcare faculties and medical schools must be at the level of the expert for the formal teaching of students. In addition to the professional level, they also achieve research visibility in the quality of healthcare and PS.

1.2. Brief theories

A generally accepted definition of competence is not agreed upon. The simplest definition would describe competencies as an individual's ability to do the job properly (11). Competencies include mastering concepts, knowledge, skills, social relationships, and attitudes. When we talk about competencies in the workplace, we mean professional, special, and personal competencies and values as an integral part of employees' competencies.

Professional competence are described as the ability to perform a particular professional function, consisting of a repertoire of professional practice (12-18).

Competencies can be divided into intellectual, interpersonal, adaptable, and goal-oriented. A competent medical professional carries out a medical practice by focusing on the patient, most often in a multi-professional healthcare team. A healthcare team operates by persuing ethical principles and uses evidence-based delivery of health care, and methods and tools for improving quality with support from the information technology.

Dreyfus et al. (19) described different levels of competencies

1. **Novice:** Behavior is at the level of rules and instructions they get. They feel responsible for only following these rules and instructions. The behaviuour is adapted to rules and instructions (knowledge of terminology and basic principles and concepts and personal projects to improve quality and PS).
2. **Advanced Beginner:** They get work experience understanding the environment and the context. They feel responsible only for following rules and instructions (Practical use of knowledge by participating in projects to improve quality and safety at work).

3. **Competent**: behaviour is at the level of rules and at the same time understanding of the context and the environment; they can follow guidelines in certain circumstances. According to the situation, they can use the best tools to improve quality and safety. (Active deployment and work on improvements in patient quality and safety in their work unit from start to finish and evaluation of their project by a proficient o ran expert).
4. **Proficient:** behaviour in certain circumstances is based on knowledge and acquired experience and skills. They can study the problem from several different perspectives (involved in projects to improve the quality and organisation and operate in a group responsible for the systemic development of quality and PS in a healthcare organisationn).
5. **Expert and master:** behaviour is at the level of 'intuition', which is a reflection of a deeper understanding of the field (not just rules and guidelines) and lessons learned; the latter are such as to enable intuitive decision-making based on experience-based associations acquired in certain circumstances (spreading knowledge through staff training and spreading improvements in quality and safety throughout the healthcare organisation, in this category are also teachers of quality and PS improvement, including publishing quality and safety research and assisting with complex problems within their own or outside of their organisation).

1.3. Objectives

Slovenia needs resilient and resourceful health workers equipped with biomedical competencies, competencies in QI and PS and self-awareness and interpersonal skills to help them work safely in a changing, complex, and stressful workplace.

This chapter aims to describe competencies for healthcare professionals and others working in healthcare in the domain of PS. The other required competencies by health professionals working in people-centered health are only briefly mentioned.

2. HEALTHCARE QUALITY COMPETENCY FRAMEWORK

Health professionals operate in a system where their roles and functions are defined mainly by their professional categories. For this reason, competency frameworks are usually produced and endorsed by professional bodies and are used to enforce professional and regulatory standards. However, with the proliferation of new models of care delivery and the emergence of new roles and functions, there is a need for a more flexible and inclusive competency framework that will help health professionals gauge their skills in the context of a broader healthcare team setting.

In today's multi-disciplinary workplace, all care team members share the common goals and values of people-centered care. A common competency framework encompassing all the major categories of health professionals envisages major domains or areas of focus necessary for people-centered care. It is mainly targeted by multi-disciplinary teams managing complex "whole person" care.

The domains of competencies for healthcare professionals are patient focus, practice focus, management and organisational focus, population social focus, and education and research.

Patient-centredness or patient focus refers to competencies in handling ethically complex issues and understanding the professional standards of conduct and knowledge of the legal and regulatory context in which these standards are to be interpreted. This area requires more attention to developing professional competencies as technological advances and emphasis on people-centered and personalised care raise new challenges and push the boundaries of ethical and moral standards.

Management and organisation focus recognizes that healthcare is no longer a solo operation and demands professionals with considerable skills and knowledge to develop and implement complex work processes and collaborate with diverse and multi-disciplinary teams.

Practice focus encompasses evidence-based healthcare practice, including professional standards and ethics.

Social and population focus is an area that is expected to grow with the expansion of people-centred care, which demands much greater knowledge and skills in handling difficult social issues and better understanding of the community, environment and other aspects affecting the health and well-being of the patients and their families.

Education and research are not part of direct patient care but are critical competency areas for ensuring quality and safety in all aspects of healthcare, which requires continuous discovery, evaluation and improvement. Health professionals would be expected to have some competencies in all these domains. Over the course of a career, some may choose to specialise and achieve higher competency levels in one or more of these domains (7).
There is a growing recognition of the importance of common functions and skills, such as teamwork and PS QI communication (20).

The competencies framework describes the knowledge and skills required for developing and leading a successful healthcare quality and PS program. All healthcare quality professionals should meet at least the operational level of capability in all eight dimensions (figure 21) (21).

Achieving proper quality-driven healthcare as soon as possible requires higher performance from quality professionals and the entire healthcare workforce. In addition, quality-driven healthcare requires collective intention, shared competency standards, collaborative effort, and sustained commitment.

Healthcare leaders need to commit now to training their workforce to meet the new demands of healthcare quality so they can leverage these professionals as key drivers of more excellent value.
Competency-based training should be leveraged as a business and growth strategy.

Figure 21. Eight domains of the healthcare competency framework

Source: adapted from (21)

The competencies framework describes the knowledge and skills required for developing and **leading** a successful **healthcare quality program**. All **healthcare quality professionals** should meet at least the foundational level of capability in all eight domains. Because different quality professionals often specialize in certain areas, it's unlikely and unnecessary for a single professional to possess all competencies at an advanced level. Instead, the spectrum of foundational, proficient and advanced capabilities should be represented across each organization's quality workforce, both within and outside the quality department, and through services provided by consultants or other vendors. It's also important to recognize that a wide variety of healthcare professionals is conducting quality work.

In 2016 a group of Slovenian experts proposed five levels of competencies for quality and PS because it is unnecessary for a single professional and staff to have all competencies at an executive level. However, this was not implemented.

- **Novice or first level:** this group consists of all healthcare professionals, co-workers and non-healthcare staff - requires knowledge, skills and professional behaviour - knowledge of terminology and basic principles and concepts and projects for the improvement of quality and PS.

- **Advanced beginner or second level:** practical use of knowledge by participating in projects to improve quality and safety at work. In this group are physicians, residents and other health care professionals and co-workers being in practice for 4 years and providing direct health care to patients under supervision.
- **Competent or third level**: active deployment and work on improvements in patient quality and safety in their work unit from start to finish and evaluate their project by a proficient person. This group consists of physicians after residency and other healthcare professionals in practice for more than 4 years.
- **Proficient or fourth level:** this group is involved in projects to improve the quality and organistaion and are responsible for the systemic development of quality and PS in a healthcare facility. They also serve as mentors and managers responsible qamd accountable for the operation of units and departments.
- **Expert and master or fifth level:** this group has a deeper understanding of the field (not just rules and guidelines) and lessons learned. They are responsible for spreading knowledge through staff training and spreading improvements in quality and safety throughout the healthcare organisation, in this category are also teachers of quality and PS improvement, including publishing quality and safety research and assisting with complex problems within their own or outside of their organisation (22).

3. COMPETENCIES FOR PATIENT SAFETY

One of the core competencies shown in figure 21 is PS. The objectives of PS competencies are to:

- Identify the key knowledge, skills, and attitudes related to PS for all healthcare workers
- Develop a framework that will act as leverage for training, educating, and assessing healthcare professionals in PS
- Help make PS competencies easy for everyone to understand and apply in postsecondary, postgraduate, and continuing professional development settings

As PS is a global problem, the competencies for PS are universal. Here is a description of competencies and requirements for different levels of the competency ladder. There are 6 domains of PS competencies described as knowledge, skills, and attitudes (figure 22).

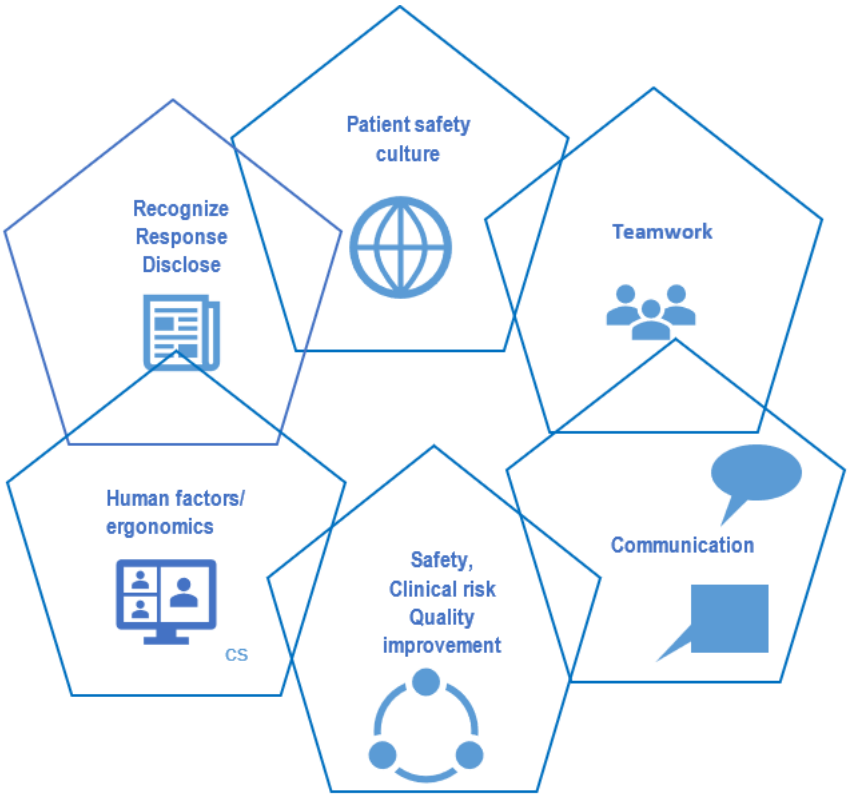

Figure 22. Six domains of patient safety
Source: adapted from (23)

3.1. KSA for patient safety

1. Competencies for patient safety culture	1. Contribute to the establishment and maintenance of a just culture 2. Advocate for improved PSC 3. Contribute to the continuous improvement of safety culture

The safety culture determines what actions and behaviours are acceptable and the level of priority that all individuals place on quality, safety, and risk issues. The shared nature of a PSC

means that it is bigger than the individual healthcare providers who work within the organization. PSC improvement involves recognizing the importance of ongoing collaboration and the commitment to advocate for change. Often changes in culture occur following a sentinel event or as a part of a broader PS improvement initiative. While it is difficult for individuals to change the culture on their own, changes in collective attitudes, actions and ethical values aimed at goals to continuously minimize patient harm are essential in helping to move organizations forward. PSC is described in Part 2 of this document.

Each competency is supported by the following related knowledge (K), skills (S), and attitudes (A) – the requirements that permit a competency to be placed into practice.

PSC improvement involves recognizing the importance of ongoing collaboration and the commitment to advocate for change—value and respect patients, families, and colleagues in respectful, non-judgemental and culturally safe ways.

Persons who enhance PSC

a) Knowledge

1. State the elements that contribute to a culture of PS, conceptual models of safety culture, and safety culture assessment methods
2. Examine how a poor PSC can negatively impact PS and patient outcomes
3. Analyze how PSC relates to PS improvement concepts, such as high-reliability organizations
4. Describe how PSC is related to other concepts, such as leadership, engagement, teamwork and communication
5. Describe how individuals improve the PSC at an individual, team, organization and system level
6. Describe attributes of effective leadership for quality, safety and risk
7. Recognize how engagement with patients and families contributes to patient safe

b) Skills

1. Enact PS principles and systems in daily practice
2. Demonstrate leadership skills to champion PSC improvement
3. Employ strategies to improve the safety culture within their area of influence
4. Partner with patients and families in respectful and meaningful ways

c) Attitude

1. Demonstrate a willingness to collaborate with others, including patients and families, to contribute to a positive PSC
2. Embrace strategies that promote PSC
3. Value and respect patients, families, and colleagues in respectful, non-judgemental and culturally safe ways
4. Commit to reporting and learning from PS incidents
5. Demonstrate openness to change

2. Teamwork	1. Meaningfully partner with patients and families, enabling them to be key members of their interprofessional teams 2. Respect the professional, patient, and family roles and responsibilities within the interprofessional team and integrate this diversity seamlessly into service delivery 3. Be vigilant of interprofessional team dynamics to optimize PS, QoC, and health outcomes 4. Demonstrate shared authority, leadership, and decision-making 5. Communicate respectfully and responsively 6. Work effectively with all interprofessional team members to promote understanding, manage differences, and resolve conflict

Organizational and system enablers facilitate interprofessional teamwork. Team members and leaders at all levels promote collaboration, partnerships with patients and family, cultural safety, team effectiveness, and QI initiatives. Patients and their families are key partners on the team, engaged in decision-making and appropriately directing their care.

High-performing interprofessional teams demonstrate capabilities and competencies that are essential to efficient, effective, and safe collaborative practice.

Healthcare providers who work effectively in teams for patient safety

a) Knowledge

1. State the roles and responsibilities of each team member, including decision-making, supervision and support, and the expectations and requirements for individual contribution
2. Identify the relevant competencies, experience and scopes of practice of interprofessional team members, including overlaps and gaps in the team's capabilities
3. Describe the team's role within the healthcare system
4. Define team dynamics
5. Recognize key safety issues and priorities inherent in interprofessional team practice and relevant to the patient population
6. Outline the rationale for and implementation of an interprofessional team's processes, policies and procedures
7. Describe the resources and administrative skills required to achieve the interprofessional team's objectives
8. Identify levels of authority and the importance of relevant expertise as a basis for leadership in a given situation
9. State the impact of information and communication technology on an interprofessional team's function and dynamics
10. Describe how to proactively address provider or system performance concerns involving risk to interprofessional team members, including patients and/or family, to optimize PS

b) Skills

1. Demonstrate empathy and professionalism
2. Establish partnerships with patients/families
3. Integrate patient's beliefs and values respectfully
4. Discuss options with a patient using language that they understand
5. Advocate on behalf of a patient

6. Demonstrate with confidence and respect one's professional roles and responsibilities
7. Access unique skills and knowledge of other interprofessional team members to address the needs of patients
8. Apply standardized team processes and protocols to ensure consistency and shared understanding
9. Give and receive clear and accurate feedback
10. Manage PS incidents appropriately
11. Monitor, evaluate and take action to improve the performance of the interprofessional team
12. Exercise decision-making authority in a situationally appropriate manner
13. Set clear parameters for independent decision-making
14. Provide consultation, support, and delegate tasks appropriately
15. Advocate for solutions to address concerns involving risk to team members
16. Use a shared vocabulary to facilitate effective communication within the team
17. Seek clarification when language or jargon makes comprehension unclear
18. Use appropriate shared documentation to facilitate continuity of care
19. Apply a variety of evidence-informed communication tools and techniques
20. Engage in respectful communication that fosters team development
21. Actively participate in teams
22. Respect the perspectives of others
23. Employ strategies to prevent, manage and resolve conflict

c) Attitudes

1. Value and respect the contributions of patients and their families as partners in their care
2. Commit to fulfilling individual responsibilities in the team environment
3. Respect all team members, including their histories, feelings, values, and beliefs
4. Seek and value constructive feedback
5. Embrace a culture where team functioning is viewed as an important element of continuous QI
6. Accept the team as an evidence-informed community of practice that learns with, from, and about one another
7. Foster an environment where responsibility for care and accountability for outcomes are appropriately shared
8. Foster an environment where the team works to provide the best possible patient outcomes
9. Commit to advocating for resources and systems that support the needs of individual team members
10. Acknowledge the value of, and foster shared leaders

3. Communication	1. Demonstrate effective verbal and non-verbal communication skills to promote PS. 2. Demonstrate effective clinical documentation for PS. 3. Communicate to prevent high-risk PS threats. 4. Employ healthcare technology to provide safe patient care.

This domain focuses on processes where healthcare providers and leaders share and receive information to develop positive interpersonal relationships within clinical situations, within and across organizations, and support active patient engagement and safe, effective patient care. Communication practices include written, oral and technological communications. Online communication tools and information channels are important methods to raise awareness of

threats to PS. Through effective communication, healthcare providers and healthcare leaders share safety knowledge and improve their understanding of patient and family perspectives. One of the most important goals of effective communication is to establish partnerships with patients and their families as members of their healthcare team and when they are engaged as safety and quality teams partners. Patient and family members' perspectives about their care are continuously evolving, are grounded within a sense of trust and comfort with the care processes, and are influenced by social context and community values. Effective communication benefits patients and healthcare providers build trust and is a precondition of obtaining patient consent. Clear and consistent information enables patients to understand the risks, benefits and possible outcomes of investigations and treatments, to participate as full partners in their care and shared decision-making.

Effective communication benefits patients and healthcare providers, build trust and is a precondition of obtaining patient consent.

Healthcare providers who communicate effectively for patient safety

a) Knowledge

1. Describe models of effective communication, which include concepts of patient engagement, cultural humility, and diversity, with considerations of power differential
2. Assess patient and family competence related to issues of health literacy
3. Assess patient and family capacity to make healthcare decisions

b) Skills

1. Demonstrate respect, empathy, humility and non-judgemental active listening
2. Protect privacy and confidentiality
3. Obtain informed consent
4. Ensure clear communication between all healthcare providers during transitions in care
5. Engage patients and families in all transitions in care (including discharge) to ensure safe continuity of care
6. Effectively communicate (close the loop)
7. Modify communication approaches, including interpretive services, to ensure clear understanding
8. Provide the correct type and amount of information disclosing and reporting PS incidents and use jargon-free language to convey complex information

c) Attitudes

1. Have courage and will to speak up
2. Respect and value individuals' contributions and create opportunities for expression
3. Seek and value ways to improve communication
4. Advocate for robust system communication processes related to healthcare risk, and in the aftermath

4. Safety, Clinical risk Quality improvement	1. Anticipate, identify, reduce and mitigate hazardous and routine situations and settings in which safety problems may arise 2. Systematically identify, implement, and evaluate QI interventions for PS 3. Sustain QI and safety practices at a local and system level

Acting on safety risks is a broad concept that encompasses identifying, assessing, reducing, and mitigating safety risks to patients and healthcare providers. This is well described in Phase 3 of the project.

Healthcare providers work in complex environments and are vulnerable to service delivery pressures, systems failures, and fallibility. Healthcare leaders and providers must be accountable in their daily work, mitigating ongoing risk within specific care contexts at the local level and from a proactive preventative systems design perspective. To detect PS threats, act on risk and improve quality in complex dynamic situations, healthcare providers require competence in system-based activities as well as clinical practice. These competencies can include teamwork, task management, situational awareness, and knowledge of HFMEA method and other QI methods. By learning and applying these skills, healthcare providers can help to improve outcomes for patients and their families by preventing or mitigating patient and provider safety incidents. Healthcare providers collect and monitor performance data to assess risk and improve outcomes. They also apply their knowledge to proactively prevent PS incidents through engagement
in quality and safety improvement activities. Achieving highly reliable healthcare service for patients and families depends on healthcare providers knowing when to escalate care concerns and what processes to employ for real-time early detection of safety and patient deterioration. Healthcare leaders and managers are accountable for fostering learning organizations that provide adequate resources and infrastructure to support healthcare providers in clinical work and QI, quality assurance and PS efforts. Organizations have strategic plans prioritizing PS through safety and quality vision/mission statements and goals. Safe environment programs in organizations support healthcare provider health and safety by protecting their teams from physical and psychological injury and burnout, all known to impact PS negatively.

Healthcare providers collect and monitor performance data to assess risk and improve outcomes

Healthcare providers who act on safety risk and quality improvement

a) Knowledge

1. Describe human and system design factors related to safety risk and QI
2. Outline QI methodologies and quality assurance practices
3. Outline patient and family engagement approaches related to safety risk and QI
4. Describe potential safety threats to patients/families and healthcare providers
5. Describe high-risk situations that require reliable fail-safe processes
6. Describe when standardization of approaches and processes is required
7. Describe the impact of cultural diversity on healthcare risk and PS

b) Skills

1. Anticipate, recognize and act on risk at the individual patient, unit and system level of care
2. Report risks and the potential for harm
3. Monitor, track and evaluate system failures
4. Demonstrate awareness of how cognitive biases can influence safety
5. Develop personal practices to mitigate individual-level factors that influence safety
6. Exercise vigilance on safety issues

c) Attitudes

1. Discuss and report near-misses openly
2. Foster a blame-free practice environment
3. Commit to being transparent in the team and practice environment
4. Advocate for PS
5. Speak up and listen up
6. Commit to protecting civility in all interpersonal relationships
7. Commit to self-reflection and be personally accountable while acknowledging one's fallibility and vulnerability in the healthcare system

5. Human factors/ergonomics 	1. Describe the individual and environmental factors that affect human performance. 2. Apply critical thinking techniques to enhance safe decision outcomes. 3. Discuss the impact of the human/technology interface on PS. 4. Recognize that human factors are a diverse set of system elements that must be considered in an integrated manner to improve PS and prevent and mitigate hazards.

Human factors are a scientific discipline that studies how people interact with systems, tools, processes, and devices. It incorporates how users' psychological, social, physical, biological, and safety characteristics affect these interactions. Optimizing the human and environmental factors that support the best human performance is an essential safety competency for all healthcare providers. Understanding individual human factors (patients, family and healthcare providers) and the ambient or environmental factors that shape decisions help recognize and mitigate prejudices and biases and improve decision-making. The ability of healthcare providers to optimize PS depends on an understanding of their performance and the performance of others within a given practice environment, including how to involve patients and their families. Complex, ongoing interactions between individual providers and patients, together with the technological characteristics of the healthcare environment, significantly shape individual and system performance and the safety of patient care. Critical thinking, which involves situational awareness and insight into the cognitive biases that affect decision-making, is influenced by various human and organizational factors. In terms of individual factors, human performance is significantly shaped by knowledge, skill and experience, personality attributes and attitudes toward risk tolerance. The well-being of individual practitioners about work-life balance, fatigue, and other personal health factors constitutes another key element of performance. Systems-based thinking in healthcare can help further understand the relationships between the various aspects of complex work environments in terms of environmental factors. The relationships between policies and procedures, resource allocation and work cultures are intertwined with local, regional, national and international organizational structures. It is essential that health providers know these relationships and how their interactions with patients impact these relationships. Finally, the interface between individual practitioners and patients and the technological attributes of healthcare environments have a critical effect on individual and system capacities in delivering safe care. The key to identifying effective interventions lies in aligning interventions to causal factors.
Interventions should avoid always resorting to person-based solutions (e.g. remedial training, policy/ procedure reinforcement which imposes actions on the individuals). Instead, system-level changes (e.g. automating a safety check, forcing functions, changing culture) should be considered to address poorly designed systems. An established framework in human factors engineering for framing the design and analysis of healthcare research is the Systems Engineering Initiative for Patient Safety (SEIPS). This model of work systems and PS is noted

in Appendix 2. It depicts the healthcare work system as a sociotechnical, human-centered system with six interacting elements that influence system performance:
1. Person
2. Tasks
3. Tools and technologies
4. Organization
5. Internal environment
6. External environment.

Optimizing the human and environmental factors that support the best human performance is an essential safety competency for all healthcare providers.

Healthcare providers who optimize human and environmental factors for patient safety

a) Knowledge

1. Recognize the effect of individual characteristics, including gender, age, personality, cultural background and risk tolerance/aversion on interactions and actions
2. Understand the effect of environmental factors such as light and sound, surge conditions, work interruptions, and technology on the safety of care and healthcare provider safety
3. Relate the theory and practice of ergonomics, human factors engineering, system design, technology and workflow to safe system functioning
4. Integrate knowledge of critical thinking, including situational awareness, and an awareness of cognitive biases in decision-making to clinical care processes and personal practice
5. Understand systems thinking (unit, service, organization/ local, regional, provincial, national and international)

b) Skills

1. Execute self-monitoring and self-care to optimize a safe level of performance
2. Identify the normalization of deviance and unsafe workarounds related to human performance and culture
3. Identify cognitive, psychological, emotional and cultural biases that influence effective decision-making
4. Demonstrate situational awareness
5. Apply systems-level thinking to the development and execution of clinical care processes and clinical practice

c) Attitudes

1. Appreciate that human performance is affected by one's behaviour within a system constructed by types of tasks being completed, tools and technology used and by organizational factors such as culture and politics
2. Accept that certain factors may affect one's well-being, including work-life balance, sleep deprivation/sleep debt, and physical and emotional health issues, which may interfere with a safe level of performance
3. Accept the fallibility of human performance

6. Recognize, Response Disclose 	1. Recognize PS incidents 2. Engage with patients and families affected by PS incidents to meet their needs 3. Disclose PS incidents 4. Learn from PS incidents 5. Professionally and constructively cope with the emotional stress of being involved in a PS incident 6. Those informal leadership roles support patients, families, and health providers involved in a PS incident

The human impact of a PS incident on the patient, their family, the healthcare providers directly involved, and the ramifications on the system itself, including the economic burden, are significant.
Disclosure is an ethical, professional and legal obligation in many countries. Patients and their families, governments, regulatory licensing authorities expect health providers to be knowledgeable and accountable for their actions and responses to PS incidents. Open, honest, and empathetic disclosure and appropriate apologies benefit patients and families, health providers, and organizations. Patients and families impacted by a PS incident want to know the extent of harm, the facts about how it happened, and what measures can be undertaken to prevent the harm in the future.
Many patients and families want to be involved in seeing these improvements put into action, and/or to be informed when these new safety measures are in place.
Healthcare providers can recognize PS incidents and take responsibility to respond in a timely way with empathy and compassion to meet urgent clinical, emotional, and information needs and provide follow-up as required of their patients.
Healthcare providers report these incidents to their leaders, team members and colleagues, and support these individuals as needed. Healthcare providers recognize the importance of culturally sensitive disclosure by exploring and acknowledging the patient's values, beliefs, and wishes. Patients and/or their families are promptly told about the occurrence of harm. A commitment is made to provide the factual reasons for what happened as soon as known and on time to the patient and/or their family. To mitigate harm, the healthcare provider and team effectively address the patient's immediate clinical needs and plan with the patient and/or their family for further ongoing care. An appropriate apology is provided.
Healthcare providers report PS incidents, including near misses to their organization and contribute to incident analyses, recognizing these as learning opportunities to contribute to the system redesign and patient engagement and improve team and personal performance. The patient and/or family is provided with a follow-up about the improvement on time. The patient and/or family may be invited to participate in helping to design, test and/or implement the improvement to prevent similar harm to other patients in the future. Being involved in a safety incident where a patient has suffered harm, whether it is preventable or not, can be highly stressful and can have a significant impact on one's personal, family and professional life. Patients and their families are provided with supports and access to resources to assist them through this stressful period. Healthcare providers reflect and recognize if they or their team can provide the best clinical care because of the stress related to the safety incident. Healthcare providers use healthy and constructive coping strategies and readily seek emotional support. They help their team and colleagues cope emotionally with incidents, including drawing on available support systems.

Open, honest, and empathetic disclosure and appropriate apologies benefit patients and families, health providers, and organizations.

Healthcare providers who effectively recognize, respond to and disclose patient safety incidents

a) Knowledge

1. Define the different types of PS incidents and recognize them in their professional practice
2. Describe the ethical importance and foundation of disclosure
3. Recall the relevant regulatory and organizational policies and related legislation
4. Describe professional accountabilities of individual health providers, interprofessional teams, and organizations for disclosure and reporting
5. Determine the threshold for disclosure when a patient has suffered any degree of harm when there is a potential for future harm, or there will be a change in care or monitoring due to increased risk
6. Recognize the importance of reporting near misses and when might patients and organizations benefit from learning of these instances
7. Describe disclosure as a process with initial (early) and post-analysis stages, often requiring multiple conversations at each stage
8. List possible roles in the initial (early) and post-analysis stages of disclosure
9. Describe the importance of a genuine apology
10. Document PS incidents and disclosure in the patient's health record
11. Contrast how disclosure of harm and reporting aligns with improving the QoC
12. Recognize that all healthcare team members are responsible for contributing to a just culture and culture of safety and that for those in leadership roles, there is a responsibility for *establishing* a just culture and culture of safety

b) Skills

1. Provide honest, timely, factual communications about the occurrence and reasons for a PS incident as they become known
2. Differentiate between a clinical outcome related to the natural progression of a medical condition, a recognized unavoidable complication related to the inherent risk of treatment, and avoidable harm
3. Partner with patients and/or families to meet their clinical, emotional and information needs
4. Support their leaders and team in disclosure communications
5. Demonstrate personal learning from incidents and implement practice improvements
6. Employ healthy strategies to cope with the stress from a PS incident
7. Demonstrate emotional support for their team and other health providers affected by the PS incident
8. Effectively coach individuals and teams to plan and prepare for disclosure and debrief afterward when in a formal leadership role
9. Demonstrate how to apologize depending on the type of incident appropriately
10. Demonstrate openness, empathy and compassion when communicating and providing an apology
11. Achieving cultural humility and disclosure through exploration and acknowledgment of the patient's and/or family's values, beliefs, and wishes
12. Find disclosure information and when and how to seek advice and help
13. Employ healthy strategies for individuals and teams to cope with the stress of being involved in PS incidents
14. Differentiate between a clinical outcome related to the natural progression of a disease, a recognized unavoidable complication associated with the inherent risk of treatment, and avoidable harm from a PS incident

c) Attitudes

1. Apply moral-ethical reasoning and critical analysis about how PS incidents happen
2. Commit to maintaining honesty and trust in the patient–health professional relationship

3. Accept the personal obligation to disclose PS incidents according to codes of ethics, professionalism, organization and regulatory policies, and legislation
4. Demonstrate support for each other when participating in team disclosure communications
5. Demonstrate a willingness to report PS incidents, including near misses, and fully participate in incident analysis and QI activities
6. Partner with patients and/or families in QI activities
7. Self-reflect and constructively learn from PS incidents to prevent their recurrence
8. Demonstrate constructive coping strategies to deal with the stress of a PS incident and provide emotional support to team members and colleagues

3.2. Suggested readings for domains of patient safety

3.2.1. Patient safety culture

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3.2.3. Communication

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3.2.5. Optimize Human and System Factors

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3.2.6. Recognize, Respond to and Disclose Patient Safety Incidents

1. Gallagher TH eta al. Patients' and physicians' attitudes regarding the disclosure of medical errors. JAMA. 2003; 289 :1001–1007.
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4. EDUCATION OF HEALTHCARE PROFESSIONALS ON PATIENT SAFETY

The list of competencies on PS serves as a guide for developing PS multi-professional curricula for undergraduate students of health care secondary schools, faculties and higher education for healthcare professionals, medical and pharmaceutical faculties and professionals already working in healthcare.

Common language and adoption of core competencies are a nust doe successful improvement of PS. Any collective movement by the health professions to reform education must begin with **defining a shared language** that will enable the professions to communicate and collaborate.

Standard terms can facilitate the development of new curricula, with departments and programs having a more remarkable ability to coordinate related courses and training activities. A lack of consensus around language and terms related to the five competencies may be hampering their implementation. It may also be undermining attempts to define a core set of competencies across the professions and to integrate these competencies into oversight processes.

4.1. Recommendations

Recommendation 1: **NIBQPS** should support an interdisciplinary effort focused on developing a common language, with the ultimate aim of achieving consensus across the health professions on a core set of competencies that includes patient-centered care, interdisciplinary teams, evidence-based practice, QI, and informatics.

Recommendation 2: **NIBQPS** should provide a forum and support for a series of meetings involving the spectrum of educational organizations and private facilities across and within the disciplines. Participants in these meetings would develop strategies for incorporating core competencies into curricula based on definitions shared across the professions. These meetings would actively solicit the input of health professions associations and the education community. A possible list of undergraduate studies participants includes medical faculties, pharmacy and healthcare faculty, Ministry of Education, Science and Sport, professional chambers and associations, and National agency for quality in Slovenian higher education (NAKVIS). **Faculties** should be encouraged to expand their efforts by opening their doors to other students, faculty, and clinicians. Emphasis should be given to all healthcare professionals, although approaches will differ depending upon which is targeted at any given time. In light of the evidence, faculty shortages and lack of preparedness are barriers to integrating the core competencies.

NIBQPS establishes curricula for PS with relevant experts and assigns coordinators to supervise and validate content. The system for implementing PS competencies includes evaluation in the form of pre and post-training evaluation. Train the trainers methodologies, fostering the knowledge and its transmission through each organization can also be developed.

At present, it makes sense to prioritize developing quality workforce competencies where the need is most pressing: in the healthcare workplace. However, longer-term, aligning undergraduate and graduate healthcare quality education with best practices in the quality field will produce students who are better prepared to meet the rigor of the quality work.

Recommendation 3: MoH should identify key experts on PS to develop and teach curricula for health care professionals who already work in healthcare and require obligatory evaluation of competencies for all.

Recommendation 4: Building upon previous efforts, accreditation bodies should move forward expeditiously to revise their standards so that programs are required to demonstrate through process and outcome measures that will prove competencies of healthcare professionals

Recommendation 5: All **professional chambers** should move toward requiring licensed health professionals to demonstrate periodically their ability to deliver patient care as defined by the six PS competencies identified by the committees through direct measures of competence in the field of PS.

Recommendation 6: All **professional chambers** should require their certificate holders to maintain their competence throughout their careers by periodically demonstrating their ability to deliver patient care that reflects the six competencies, among other requirements. This is similar to granting clinical privileges to healthcare professionals by standards of the accreditation bodies.

Recommendation 7: Educational and practice organizations, should take the lead in developing learning centers, representing partnerships between practice and education. In Slovenia, one such private center provides education on PS and QI, but the interests of healthcare organisations and professional societies are relatively poor.

Recommendation 8: **NIBQPS** organise an interdisciplinary summit every 2 years. Conferences should be held involving health care leaders in education, oversight processes, practice, and other areas. This summit should focus on reviewing progress against explicit targets and setting goals for the next phase concerning the six competencies and other areas necessary to prepare professionals for the 21stcentury health system.

There are many **barriers** to incorporating the six PS competencies into the practice environment, where medical residents and new graduates in nursing, pharmacy, and allied health obtain initial real-life training that leaves an essential imprint on their future practice.

Further, studies have shown that new graduates and residents become disheartened and cynical if there is too much disconnect between what is learned in school and the initial practice norms encountered.

In addition to the barriers of time constraints, oversight restrictions, resistance from the professions, and absence of a political will, the overall health care financing system is a large impediment to integrating the core competencies into practice. Therefore, steps should be taken to explore alternative ways of paying for acquiring competencies.

It would be necessary to convince institutions to add new topics to an already overcrowded curriculum, modify teaching methods to cover the new topics, and make a considerable investment in associated new infrastructure – especially ICT.

Traditional curricula in the health professions also lack PS education, raising questions about maintaining the status quo. In addition, students have often been trained in knowledge apart from both skills and attitudes.

5. CONCLUSION

The staging of these recommendations is important. **The first step is** to articulate common terms so that shared definitions can inform interdisciplinary discussions about core competencies described above. Once the disciplines have agreed **on a core set of competencies**, **public and private oversight bodies** can consider how to incorporate such competencies into their processes and support those who have already moved toward adopting curricula for PS. The development of common language and definition of core competencies should happen as rapidly as possible and by no later than 2023.

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7. APPENDICES PART 3

7.1. Appendix A – Glossary

Term	Definition
Competency framework	An organized and structured representation of a set of interrelated and purposeful competencies.
Domains of competence	Broad distinguishable areas of competence constitute a general descriptive framework for a profession in the aggregate.
Competency list	The delineation of the specific competencies within a competency framework.
Competence	The array of abilities (knowledge, skills, attitudes (KSA)) across multiple domains or aspects of performance in a certain context. Statements about competence require descriptive qualifiers to define the relevant abilities, context, and stage of training. Competence is multi-dimensional and dynamic. It changes with time, experience, and setting.
Competency	An observable ability of a health professional, integrating multiple components such as knowledge, skills, values, and attitudes. Since competencies are observable, they can be measured and assessed to ensure their acquisition.

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