Governance of the Quality of Care model and the Patient Safety system - Slovenia

Phase 7

Support for improving quality of healthcare and patient safety in Slovenia

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AARC - Consortium

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ABBREVIATIONS

AQuAS	Catalan Agency for Health Quality and Evaluation
CRM	Clinical Risk Management
D	Deliverable
DDKM	Danish Healthcare Quality Programme
DPSA	Danish Patient Safety Authority
DPSD	Danish Patient Safety Database
EU	European Union
GRC	Centre for Clinical Risk Management and Patient Safety
HIIS	Health Insurance Institute of Slovenia
HIQA	Health Information and Quality Authority
HSA	Health and Safety Authority
HSE	Health and Safety Executive
HTA	Health Technology Assessment
IKAS	Danish Institute for Quality and Accreditation in Healthcare
IT	Information Technology
NHQRS	National Healthcare Quality Reporting System
NIJZ	National Institute of Public Health
NPSO	National Patient Safety Office
OECD	Organisation for Economic Cooperation and Development
PDSA	Plan-Do-Study-Act
PFF	Patient Insurance Association
PS	Patient Safety
PSC	Patient Safety Culture
QI	Quality Improvement
QoC	Quality of Care
RM	Risk Management
VBHC	Value-Based Health Care
WHO	World Health Organization

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EXECUTIVE SUMMARY

The aim of the document on the **Governance of the Quality of Care (QoC) model and the Patient Safety (PS) system - Slovenia** is to support the Ministry of Health (MoH) in developing a more detailed understanding of the current challenges in the governance of the QoC and PS system and propose concrete options for improving it. A realistic governance model will be prepared based on gap analysis and comparative analysis of European Union (EU) countries.

Governance sets norms, strategic vision, and direction, formulate high-level goals and policies of QoC, PS, and no-fault compensation, and oversees the management and organizational performance to ensure that all stakeholders, especially health care providers and national independent body for QoC and PS collecting, analysing, processing, and storing data to achieve the desired outcomes. Governance should ensure that stakeholders are acting prudently, ethically, and legally in the best interests of patients.

Clinical governance is an integrated component of corporate governance. **Clinical governance** is the system by which the governing body, managers, healthcare professionals, and staff share responsibility and accountability for the safety and QoC. Five key pillars of clinical governance for QoC and PS are established:

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

In D2: Report of a situation analysis of the national context of PS & patient RM, patient compensation, and QoC, the main gaps in regards to QoC, PS, and no-fault compensation model were identified, and recommendations on governance and organization of healthcare system in Slovenia were proposed. This process was carried out in consultation with the main key stakeholders. Furthermore, a comparative analysis of governance models for the QoC from 5 EU countries (Tuscany (Italy), Ireland, Catalonia (Spain), Australia, and Denmark) was conducted (Appendix A).

This document contains:

- The proposed model of clinical governance for Slovenia, with structures and standards at the national and local levels;
- A set of clinical governance standards to specify the actions that a government, independent public organ for quality and PS, health service organisation needs to take to develop and create systems for good clinical governance;
- A description of roles, responsibilities, and accountabilities to fully utilize the group's capacity and recognize where responsibilities can be shared across the health sector (appendix B);
- Explanation of the governance of each topic of the project of QoC, PS, the culture of PS, Clinical Risk Management (CRM), competencies for PS, and no-fault compensations.

1. INTRODUCTION

The delivery of health care is a complex activity. Healthcare in Slovenia is organized at different levels, from primary to tertiary care, and patients move between these services and sectors (1). Safety and quality risks exist at all points of the patient's journey through the system. Therefore, the healthcare system must organise to meet patients' needs and be thus patient and people centered.

People-centered care demands greater attention to broader aspects of patient care beyond bio-medical conditions and requires attention to psycho-social needs and other aspects of patient lives. To be successful for the patient and people-centered care, strong governance and management of quality and PS, jointly with a non-fault compensation system, must become a priority for the Slovenian healthcare system.

1.1. Short description of the project

The MoH is currently carrying out a project, funded by the EU through DG REFORM, whose main objective is to support the Slovenian MoH in capacity building to develop a National strategy on QoC, CRM, and PS, and a legal framework for a no-fault compensation model. The outcomes of the project that should, over the longer term, contribute towards improving the QoC and PS in Slovenia are:

- Improved knowledge of challenges and opportunities in QoC and PS
- Development and strengthened Patient Safety Culture (PSC) and CRM
- Improved strategic planning and governance of the QoC system
- A revised set of indicators for QoC for hospitals, specialist outpatient care, and primary care available, tested, and communicated
- Development and implementation of education programs in quality and safety
- Development of a no-fault compensation scheme reduced criminal prosecution and civil litigation
- Upgrade the level of healthcare providers, higher awareness and accountability of healthcare professionals, the reduced practice of defensive medicine, patient empowerment, and improved doctor-patient relationship
- Systematic improvement of the efficiency and effectiveness of healthcare

1.2. Aim

The aim of the document on *Governance of the Quality of Care model and the Patient Safety system* is to support the MoH in developing a more detailed understanding of the current challenges in the governance of the QoC and PS system and propose concrete options for improving it. A realistic governance model will be prepared based on gap analysis and comparative analysis of European Union (EU) countries.

Description and definition of governance in healthcare

Governance is more narrowly defined as stewardship. It refers to the wide range of functions carried out by governments as they seek to achieve national health policy objectives. In addition to improving overall levels of population health, objectives are likely to be framed in terms of equity, coverage, access, quality, and patient's rights. The national policy may also define the relative roles and responsibilities of the public, private and voluntary sectors - as well as civil society - in the provision and financing of health care (2). However, to achieve 'quality-led governance,' it is necessary to measure whether the system is delivering effective, safe, and patient-centered care and to promote the creation of European common quality standards in health care.

The governance system should set the parameters under which management and administrative systems will operate. Governance is about how power is distributed and shared, policies formulated, priorities set, and stakeholders accountable.

Referring to that, governance should set norms, strategic vision, and direction, formulate high-level goals and policies of quality, PS, and no-fault compensation, and oversee management and organizational performance to ensure that all stakeholders, especially health care providers and national independent body for QoC and PS also dealing with compensation claims, collecting, analysing, processing and storing data is achieving the desired outcomes. Governance should ensure that stakeholders are acting prudently, ethically, and legally in the best interests of patients.

In Slovenia, terms for governance and management are often used interchangeably. Thus governance (*upravljanje*) is utilized instead of management (*ravnanje*). In everyday practice, the word management is replaced by leadership (*vodenje*), but leadership is only part of management (3).

Leadership is the process in which one engages others to achieve a common goal (4)

Management is the process of accomplishing predetermined objectives through the effective use of resources (5)

In healthcare quality and PS, an example of inappropriate use is medication governance (*upravljanje z zdravili*) instead of medication management (*ravnaje z zdravili*).

1.3. Description of clinical governance

Clinical governance is an integrated component of corporate governance. **Clinical governance** is the system by which the governing body, managers, health care professionals, and staff share responsibility and accountability for the **safety and QoC**. It promotes an integrated approach to PS and QoC 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 (6).

Clinical governance is also the set of relationships and responsibilities established by a health service organisation between its MoH, the independent organ for quality and safety in healthcare, governing body, executive, healthcare professionals, patients, citizens, and other stakeholders to ensure good clinical outcomes. **Clinical governance aims** to ensure that patients and citizens receive safe and high-quality health care by describing the elements that are essential for health service organisations to achieve integrated corporate and clinical governance systems. Through these systems, organisations and individuals are accountable to patients and the community for continuously improving the safety and quality of their services (7).

There are five key pillars of clinical governance for QoC and PS:

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 (6). In D4: Report on the support for the preparation and implementation of a national plan and local action plans to improve PS and safety culture, there is a description of each pillar of clinical governance.

2. GAP ANALYSIS OF THE CURRENT GOVERNANCE MECHANISMS OR PRACTICES IN THE SLOVENE QUALITY OF HEALTHCARE SYSTEM AND CONSULTATION WITH NATIONAL STAKEHOLDERS

In Situation Analysis, the main gaps were identified and proposed recommendations were proposed on the governance and organization of the Health Care system in Slovenia regarding QoC system throughout consultation with national stakeholders.

In 2003, the representatives of stakeholders got together to establish a network and organisation for quality development in healthcare on the national level. Participants included the Medical Chamber of Slovenia, the Slovene Medical Association, the Chamber of Nurses, the Institute of Oncology, the Clinical Centre, the Health Sector Management Project, the Slovene Association of Healthcare Institutions, the General Hospital of Maribor, the General Hospital of Jesenice, the MoH, the Retirement and Disability Pension Insurance Fund, the insurance companies Generali and Vzajemna, and the Health Insurance Insistute of Slovenia (HIIS). As the parties could not agree on issues about financing, it has yet not been possible to establish a National independent body for Quality in Healthcare. Later, several other efforts to establish an independent national body for healthcare failed due to no political decision.

Since all the attempts to establish an independent national body for quality in healthcare were unsuccessful, a Department for Quality in Healthcare was established in 2004 (with one full-time and two part-time employees) to facilitate some of the most important activities – mainly to introduce QoC and PS in healthcare as part of the daily routine for healthcare staff. The competent authority is currently at the MoH.

An example of an organizational chart for quality and PS with a description of responsibility was provided in the documents on policy on quality in healthcare of 2006. This has been accomplished only in a few healthcare facilities. The accredited organisations now have the governance structure due to accreditation standards requirements.

The Medical Chamber, Nurses and Midwives Chamber, and Chamber of Pharmacy have the mandate from the MoH to regularly peer review with counseling and to analyse those adverse events where a patient complaint or requirement of the regulator is involved.

Competent chambers and other associations, healthcare providers, regional patients ombudsmans, etc. who have the mandate to process patients' complaints should be authorised and organised in a way to be able to provide in a standardised form the data from the complaint procedure to the independent body which may be established for all functions, namely QoC, PS and for processing of no-fault compensation claims.

Bellow, there is a list of the main identified gaps:

- No independent national body for QoC and PS as currently, MoH is the competent authority but the capacity for governing is not sufficient and the work on Quality Improvement (QI) and PS is not consistent;
- Patient representation in official roles and decision-making processes involved included for public discussion after the documents are prepared by the government and do not participate in the development of documents;
- No systemic nationwide data collection is in place on any type of adverse events;
- No statistical data collection on court cases from the indemnity and criminal cases;
- No partial or nationwide statistical data on the number, types, outcomes, or other data on complaint procedures, either at the level of healthcare providers, healthcare ombudsman,

health insurance, medical chamber, or any other body dealing with patients complaints; no feedback of data which may exist;
- No independent national body with the power to effectively process patient complaints about medical professional and/or ethical misconduct;
- Criminal prosecution of human errors with its widespread harmful influence on the PS system because of the culture of fear that prevents error reporting.

In this regard, following, the main recommendations are presented:
- Creation of an independent national body for QoC, PS, and no-fault compensation;
- Invite representatives of patient groups in preparation of relevant documents, and
- Authorization of an independent body to have access, to collect, keep, process, assess and analyse data on adverse events, civil and criminal court cases data, complaint procedures data, at different levels and competent bodies;
- Providing feedback data and analisys to policy/decision-makers and HC providers on QoC, PS, civil and criminal cases, and no-fault compensation.

3. COMPARATIVE ANALYSIS OF GOVERNANCE MODELS FOR THE QUALITY OF HEALTHCARE FROM OTHER EU COUNTRIES

This part describes a short overview of clinical governance in the 5 studied countries: Tuscany (Italy), Ireland, Catalonia (Spain), Australia, and Denmark. **CRM** is detailed in D3: Report on safety RM including the current status of the RM system available in Slovenia, the comparative analysis of RM systems of PS, the analytical framework for RM system for Slovenia, a and the SMART recommendations and action plan for the development of the system; and **PS** in D4: Report on the support for the preparation and implementation of a national plan and local action plans to improve PS and safety culture. A more extensive version is in appendix A. The entire study is a part of D3 and is an annex in pdf to this document (D7).

3.1. Governance structures

All analysed countries own governance structures (public organizations or institutions) responsible for overseeing QoC and PS issues (except for the Tuscany region, where institution focuses on CRM and PS).
Each of the analysed countries has a governance structure to their specific characteristics and all of them depend on their respectively MoH.
In **Tuscany**, the CRM and PS Centre is directly instituted by the Tuscany region council. This organization is also observed in **Catalonia**, where the different stakeholders for quality and PS governance (the PS department, the Alliance for PS, and the Agency for Quality and Sanitary Evaluation) are competencies of the local government.
In **Ireland and Denmark**, the directorates in QoC and PS directly depend on the MoH.
In **Australia**, the Commission on Safety and Quality in Health Care is an independent institution despite the funding of the Australian and territorial governments.

3.2. Plans and strategies

All analysed countries have one or more strategic plans specifically for Quality and PS.
- The development of the work plans ranges between 2 and 5 years.
- In **Ireland**, they have two separate plans: one for QI and another one for PS.
- There is a global framework for Safety and Quality in **Australia** and a specific 2-years work plan.
- In **Denmark**, the QoC and PS are addressed through a specific Quality Programme.

All the strategic plans pursue similar key objectives, even though each country shares the vision of those goals with a different approach. All plans emphasize:

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

3.3. Clinical Risk Management

In terms of **CRM**, the five studied countries follow the ISO 31000 Risk Management (RM) Standards, which clearly define the CRM process.

3.4. Reporting systems

Each country has established specific reporting systems: some countries have more standardized and systematized reporting based on gathering multiple quality indicators through medical records. In contrast, others use tools/platforms to register and report events manually and not systematically.

In **Tuscany**, a tool that allows front-line healthcare workers for voluntary reporting is used. Similarly, in **Catalonia**, a reporting system is used to inform about any type of incident related to PS in the public hospital network.

Ireland and **Australia** utilise monitoring indicators. For example, in Ireland, the National Healthcare Quality Reporting System (NHQRS) is based on 52 indicators for 5 key domains, while in Australia, indicators for reporting systems are classified into 5 indicators sets.

Regarding risk mitigation, countries are less specific in the procedures applied to compensate for risks. For example, only Ireland provides information about the general framework for risk mitigation.

In **Ireland**, a National Risk Assessment acts as a guide for risk. The Lead Government Department prioritizes and resources appropriate mitigation measures and monitors and reports internally the progress on mitigation. They establish a five-stage procedure for risk assessment.

3.5. Patient Safety

All analysed countries implement a PSC prioritizing education, training, and research on PS to healthcare professionals, making the special focus on Managers and Directors of healthcare facilities capacitation.

Particular strategies differ among countries, but they pursue these goals through initiatives like specific training programs, masters, forums, newsletters, etc.

- In **Tuscany** and **Ireland**, the promotion of a safety culture is supported through training programs, including certified master's courses taught by regional centres or the Executive Health Service to promote a new safety culture, with a special focus on manager training.
- In **Catalonia,** the Department of Health has implemented the Functional PS Units to promote PS in the healthcare facilities. These units work in the promotion and implementation of PS strategies and measures in their center.
- **Australia** also emphasizes the measurement of the PS process and, the Commission is developing a toolkit that includes a short, validated survey and an implementation guide for regular PS qualitative monitoring.

4. CLINICAL GOVERNANCE MODEL FOR THE SLOVENIAN QUALITY OF CARE AND PATIENT SAFETY SYSTEM

4.1. General view of the clinical governance model

Clinical governance recognises the following:

- Clinical governance is of equal importance to financial risk and other business governance.
- Decisions about other aspects of corporate governance can directly affect the safety and QoC, and decisions about clinical care can directly affect other aspects of corporate governance, such as financial performance and RM.
- At the national level Government is responsible for good governance in health care
- Governing bodies are ultimately responsible for good corporate (including clinical) governance.
- Governing bodies cannot govern clinical services well without the deep engagement of skilled clinicians working at all levels of the organisation.
- Clinicians, managers, and members of governing bodies have individual and collective responsibilities and accountabilities.

4.2. Proposed model of clinical governance in Slovenia

4.2.1. Structures

Governance can be structured at the clinical, organisational/institutional, and system levels.

For example, **clinical 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, PS incident reporting, and management systems. Finally, national efforts to enhance PS and QoC include **system-level governance**, such as mandatory reporting of adverse events, safety standards linked to accreditation, etc.

Structure at the national level

The situation analysis of quality and safety in the Slovenian healthcare system (D2 of this project) revealed many gaps and one of the most important was the lack of clinical governance. Currently, only the MoH is responsible for the national Quality and PS at the national level. The situation analysis highlighted the need to restructure this area in order to obtain more efficiency, transparency and accountability (D2).

The new governance model proposes to ensure the existence at the national level of two structures with different responsibility and accountability:
1. The Sector for Quality at the MoH.
2. Independent public organ for quality and PS, including no-fault compensation (has been proposed several years ago but still not created).

Structure at the healthcare organisational level

Structure at the healthcare organisational level started to evolve in 2006 (8).

The structure of a larger healthcare organisation is shown in figure 1.

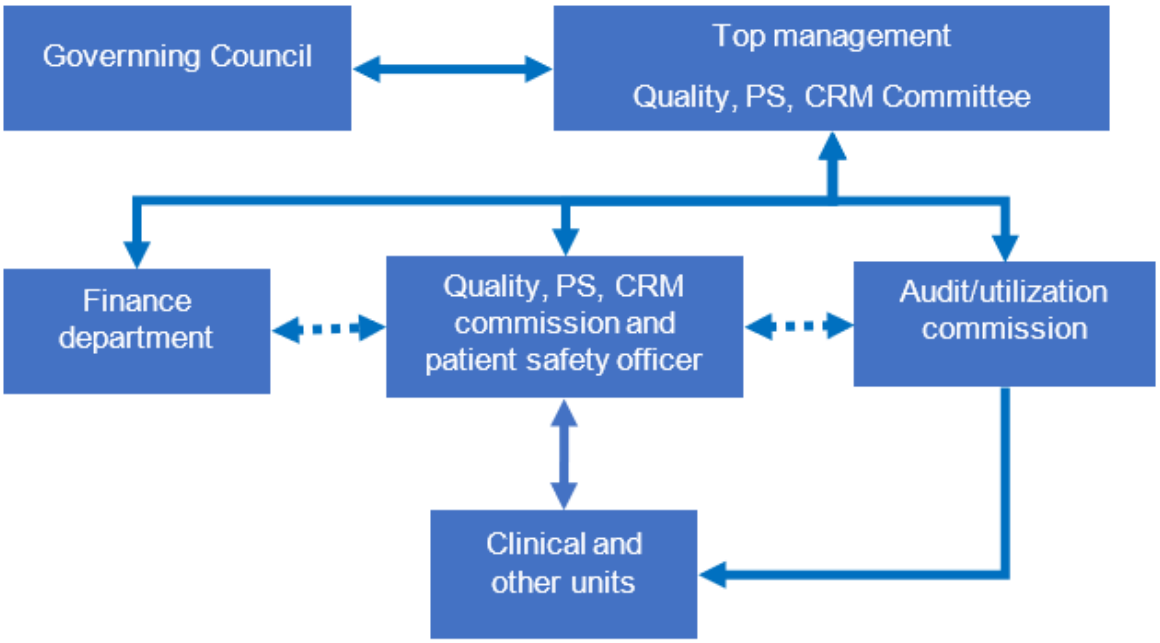

Figure 1. Structure of governance at a healthcare organisational level.

Smaller healthcare organizations can adapt the structure from figure 1 per their own capability, but a person should be responsible for the quality and PS governance.

4.2.2. Standards for clinical governance

In Slovenia, there are no clinical governance standards. Thus standards from the Australian Commission on Safety and Quality in Health Care (9), Organisation for Economic Cooperation and Development (OECD) (10), and content of D2 to D8: Revised set of quality indicators to be applied at all levels of healthcare, is proposed.

The clinical governance standards specify the actions that a government, independent public organ for quality and PS, health service organisation needs to take to develop and set up systems for good clinical governance.

1. *Governance, leadership, and culture* – integrated corporate and clinical governance systems are established and used to improve the safety and quality of health care for patients.
2. *PS and QI systems* – safety and quality systems are integrated with governance processes to actively manage and improve the safety and quality of health care for patients - Systems for measuring and monitoring progress.
3. *Clinical performance and effectiveness* – the workforce has the right qualifications, skills, and supervision to provide safe, high-quality health care to patients - Capacity-building to ensure the right skills and competencies.
4. *Safe environment for the delivery of care* – the environment promotes safe and high-quality health care for patients and staff.
5. *Partnering with patients and citizens* – systems are designed and used to support patients, carers, families, and citizens to be partners in healthcare planning, design, measurement, and evaluation. Elements under this component include clinical governance and QI systems to support partnering with citizens;

- clinical governance and QI systems to support partnering with citizens;
- partnering with patients in their care;
- fostering health literacy;
- partnering with citizens in organisational design and governance (figure 2).

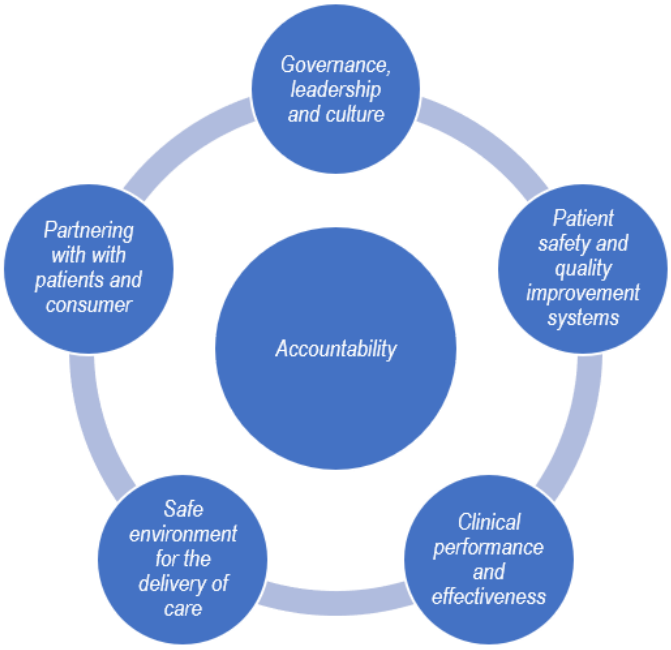

Figure 2. The framework of a model for clinical governance in Slovenia. Adapted from (9).

Proposed standards for clinical governance are in appendix B.

4.2.3. Roles and responsibilities for clinical governance

Roles and responsibilities are described to utilize the group's capacity fully and recognize where responsibilities can be shared across the health sector (Table 1). For the responsibilities, please also check the standards in Appendix B.

Table 1. Reasonability and accountabilities for clinical governance

Body	Responsibility	Accountable to
MoH	Provide leadership and direction of national efforts, including capacity building	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.	MoH
Professional bodies	Assist and support training, professional education, and settingof evidence-based tools and standards.	MoH and people
HIIS and other insurance entities	Fund and monitor incentive programmes and integrate measures for PS and QoC improvement in payment mechanisms - Value-Based Health Care (VBHC).	Government and insured people

Table 1. Reasonability and accountabilities for clinical governance (continue)

Body	Responsibility	Accountable to
Governing board (Sveti zavodov)	Establish policy and strategic framework, lead organizational culture, oversee management performance and ensure organisational accountability. Review institutional quality and PS improvement programmes and initiatives and engage the community in improving service delivery.	MoH and people
Committee for quality, PS, and CRM at healthcare facilities	Organization and operation of quality and PS policy, strategy, and action plan. Improve the culture of PS. Lead and coordinate the workforce and implement a system for delivery of quality and safe health care.	Institutional Governing board and MoH
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
Healthcare professionals	Work in clinical teams and with patients to deliver and continuously improve safety, high-QoC. They maintain their skills and performance and get support from their colleagues and their organization.	Committee at healthcare facility and patients

4.3. Decision making based on data (evidence based policy)

Ensuring and improving quality and safe health care are priority activities in all health systems. Following and introducing internationally accepted quality principles is the simplest way to provide quality health care: the best possible care with the best possible outcomes that people receive when they need it. Such a level of service represents the optimal use of available resources and should therefore represent the main objective of the operation of all parts and thus the whole system, from the regulator, through the payer, to the individual contractor: the regulator through strategic and regulatory changes, the payer with a fair funding system to encourage quality and safe treatment methods and operators using all resources optimally and rationally. Quality and safety assurance and improvements in a health organisation are based on equal cooperation and the interplay of the knowledge of all employees in the management of processes for the coordinated functioning of individual articles within the business. This will bring the results closer to the expectations of users and participants in the health system. Empowered citizen with smartphones and health apps is becoming the active operator of their health data and an increasingly important link in the health care chain.

Effective governance needs appropriate tools and a legal base. The Health Care Databases Act entered into force in August 2000. The list of databases and registers is defined as an annex, which facilitates the possible amendment of the lists. The annex includes 40 records and 35 registers. Each collection has a defined purpose, reports, data reporter, controllerd data delivery meth,od and data retention time. The legal base is established (11).

On the other hand, Slovenia has made substantial efforts to strengthen its health information infrastructure through its national e-health project. The e-prescription system is widely used by all healthcare providers and has improved interoperability and transparency. The e-registry of

patient data and patient summaries is being implemented, as is the registry of health care providers, making for easier exchange of information between providers. Other e-health initiatives are being rolled out, such as an e-referral system, which is soon expected to replace paper referrals completely; the e-booking system, which started in late 2016; and the zVem patient portal (enabling patients to see their own medical data) which launched in January 2017.
The collection, analysis, and use of large data is a necessity for greater transparency, reliability, quality, knowledge,e and disease control. There is a need for interopeand rability, greater interconnection for the transfer of databases in decision-making.

The future direction should be through the implementation of VBHC promotion of evidence-based medicine, patients' engagement, IT upgrades, and the use data analytics for transparent payment methods of health care services. The health status and the changes incurred by the interventions can be estimated by measuring outcomes. To this end, systematic measurement of outcomes is the basis of every change, every investment, regardless of the level of change and the country. The aim of collecting outcomes data is to improve the value of clinical treatment for the patient, which can only be achieved by comparing transparent data on outcomes between teams and health care providers, sharing good practices, and improving the treatment processes. The comparison should base on a statistical analysis that considers all relevant control variables, demographic, social, and clinical, at the benchmark's level: health care provider, hospital, region, and country.

Governance of data collection, data analysis, and information promotion should be top–down, from Mog to HIIS, National Institute of Public Health (NIJZ,) and providers based on produced manuel on quality indicators. The selection of clinical conditions should use the following criteria to determine the choice: high volumes, high burden (including social),and planned healthcare. For sure long-term care, cardiology, neurology, psychiatry and oncology as the main specialities, baring in mind the main problem, accessibility, and long waiting lists.

Based on the existing administrative data analysis of the services provided for patients with selected diagnoses, a standard patient pathway in the current system and the deviations must be observed. The analysis should consider many variables to ensure the proper comparison, such as the number of visits, coding of services, ratios of services, and differences among the healthcare providers. The results could represent the base for the definition of the package of services for each patient at the first visit and subsequent control visits referred from the primary level. For each package, the selection of indicators on outcomes should base on internationally defined minimum sets of outcomes and instruments determined for their collection to measure outcomes for selected groups of patients. Implementing the tools requires translation, validation, and IT support. All financial and human investment will be "repaid" with a decrease of "waste" in the health care system and better population health. The last but not the least important step is organising data collection, control, analysis, and reporting to the providers. Outsourcing can be helpful for these purposes, especially for highly specialised procedures, such as IT support and statistical analysis services.

In 2022 selection of priority specialities should be defined and the process should start with a selection of 1% of the yearly budget for each speciality: half would be deduced from the actual budget, the other half as additional funds as a motivation for frontrunnerthe s. In next four y,ears the bonuses should increase by 1% each year to reach a 5% increaseInAt the beginning bonuses would be for the voluntary collection and monitoring of selected indicators, from 2024

on the bonuses will be available for thpaynt package for all health care providers. For those health care providers who would not accept the new model, the additional 2,5% of the five years cycles would not be paid.

4.4. Process for policy, standards and tools for implementation

Policies, processes, and procedures form a system for maintaining compliance. Every organization faces liability issues and risks. These can result in lawsuits, fines, a damaged reputation, and more. In an era of increasing regulatory scrutiny, healthcare organizations need well-defined policies, processes, and procedures working in synchrony to mitigate risk and protect their organization from the unknown. In the health care system, there is a need to describe the necessary policies and procedures required to successfully implement the initiative, program, or intervention, usually like a set of documents describing an organization's policies/rules for operation and the procedures necessafulfillfulfil those policies.
Four basic reasons justify the need for writing policies and procedures:

- Operational needs — Policies and procedures ensure that fundamental organizational processes are performed in a consistent way that meets the organization's needs.
- Risk Management — Established policies and procedures are a control activity needed to manage risk.
- Continuous improvement — Procedures can improve processes by implementing a Model for improvement with Plan-Do-Study-Act (PDSA) approach by building important internal communication practices (12).
- Compliance — Well-defined and documented processes (i.e., procedures, training materials) along with records that demonstrate process capability can demonstrate an effective internal control system compliant with regulations and standards (13).

In Slovenia, it is important to facilitate the process of preparing and implementing the clinical guidelines and clinical pathways. The proper publications are already published (14,15).

Clinical guidelines, professional standards, and protocols
Clinical guidelines are recommendations on the best care for specific clinical conditions, considering the available evidence of the most successful approaches. Views are systematically formulated to healthcare professionals and patients to make decisions regarding appropriate healthcare in specific clinical circumstances. Clinical guidelines do not replace the healthcare professionals' knowledge and experience but are a tool for making decisions about the most appropriate measures for an individual patient, as they offer an answer to what and why.
Clinical guidelines are the basis for the development of treatment standards and can make an important contribution to the development of clinical pathways, the education, and training of healthcare professional,s and the information to patients about the expected course of medical care. Professional standards and reading protocols are recommendations adopted by the competent professional body of each medical profession to achieve an optimal level of regulation in a particular field and provide an answer to what and how.
The development of clinical guidelines and professional standards is the domain of the profession.

Clinical pathways
Clinical pathways are a tool to capture the different aspects of the treatment of each patient group in a single document. They shall record the plan and pathways of implementation of clinical guidelines and standards when dealing with a group of patients with a specific medical condition or method of treatment in a medical institution while allowing for adaptation to the actual needs of the individual patient. Clinical pathways provide healthcare professionals and colleagues with a guide to patient health care, but they are also important for patients as they offer an answer to questions about what, who, and when.

The use of clinical pathways also enables better traceability of patient care and thus better planning, management, and management of clinical, professional elements, as well as administrative elements of the health organization. Clinical pathways are primarily a local tool adapted to the specific circumstances and working culture of each health institution and are publicly available on the foundations' websites. The Clinical Pathways Handbook provides a tool for healthcare providers in the process of designing them.

Slovenian healthcare professionals' organizations (Medical chamber, other chambers) are preparing standards, some of which are already produced, which need to be definitively coordinated among stakeholders to ensure their official approval. The coordination and standards implementation should be the responsibility of the MoH.

4.5. Participation and partnership with stakeholders

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 (6). 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 QoC and PS program to build trust and legitimacy (healthcare professionals, patients, management, and governing boards of healthcare providing organisations, payers, healthcare industry, etc.). In addition, collaboration occurs between organisations with different roles (regulatory, care delivery, insurance) and between other sectors of healthcare (primary care, hospital care, rehabilitation, etc.)

Patients' participation is fundamental for safe care. The World Health Organization (WHO) (16) 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 (17). 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 healthcare workers, patients provide helpful Information. Moreover, they tend to report suspected adverse effects earlier than professionals, decreasing the delays in seeking treatment (18).

Figure 3 demonstrates the main stakeholders that shall be inin within this participatory approach.

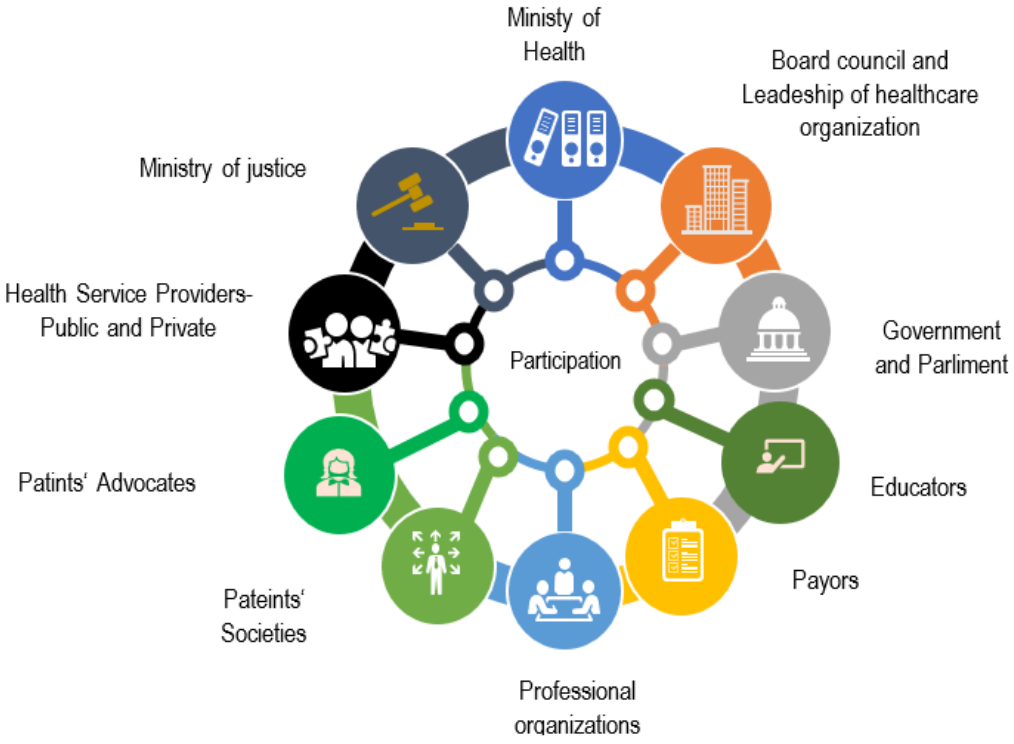

Figure 3. Participation of main stakeholders in clinical governance. Prosunt©

4.6. Transparency and accountability

Transparency

Transparency refers to the **measurement of QoC and PS**, **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 QoC and PS is **public reporting of 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 a **»no-fault« scheme** for patient compensation are known in countries with no-fault plans 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 of 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 (19).

Transparency is not only about accumulating knowledge on incidents and near incidents and healthcare quality. 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

clinical history because a patient journey through the healthcare system can be easily accessible.

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 refers to explanation and sanction. It is a relationship where people have to inform and justify their actions to others and be mandated and sanctioned. Accountability is a necessary complement to governance functions emphasizing learning and transparency in QoC and 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 that have contributed 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 (20).

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 (21). Secondly, emphasizing accountability of healthcare-providing organisations is fundamental to ensuring reporting of safety incidents (22).

4.7. Monitoring and audits

A clinical audit is a systematic and critical review of the system of care (structure, process, outcome, patterns of behaviour) and is essential for comparing performance against evidence-based standards and policies. Clinical audit measures compliance of treatment, interventions of care offered to the patient, and effectiveness of patient care. In Slovenia, there is no independent national audit commission. A clinical audit is organized as internal by healthcare organisations audit their practice; external audits by professional chambers managed as peer reviews with counselling. An international accreditation program also looks to comply with accreditation standards.

A proper (independent) audit is missing in the case of errors and violations ending in patient harm because there is no independent commission to analyse such adverse events.

There is also no national audit of a specific disease or specific specialty.

In this project, the implementation of strategies for QoC, PS and clinical governance standards for clinical governance should also be audited by an Independent organ for quality and PS and an independent national audit commission.

There are two publications in the Slovenian language. One is for audit of clinical practice (12), and the other for investigation of errors (23).

4.8. Governance of Quality of healthcare

Effective governance is increasingly recognised as pivotal to improvements in healthcare quality, including patient experiences and the safety and effectiveness of care (24).

The broader governance literature abounds with descriptions of the boards' role in setting strategy, assessing organisational performance, and stakeholder engagement. Detailed articulation of healthcare quality taskwork is more commonly found in normative literature and includes the following tasks:

- Evaluating and improving healthcare quality performance;
- Setting and oversight of strategic quality priorities;
- Promoting leadership and culture;
- Ensuring effective systems and processes are in place to maintain and improve quality (25).

Effective Governance for Quality and PS in Canadian Healthcare Organizations identified several interdependent drivers that enable boards to fulfill their responsibilities for quality and PS (26) (figure 4).

Figure 4. The Frame of Quality Governance. Adapted from to Canadian Patient Safety Institute (26)

A similar framewoek is provided by NHS United Kingdom (27).

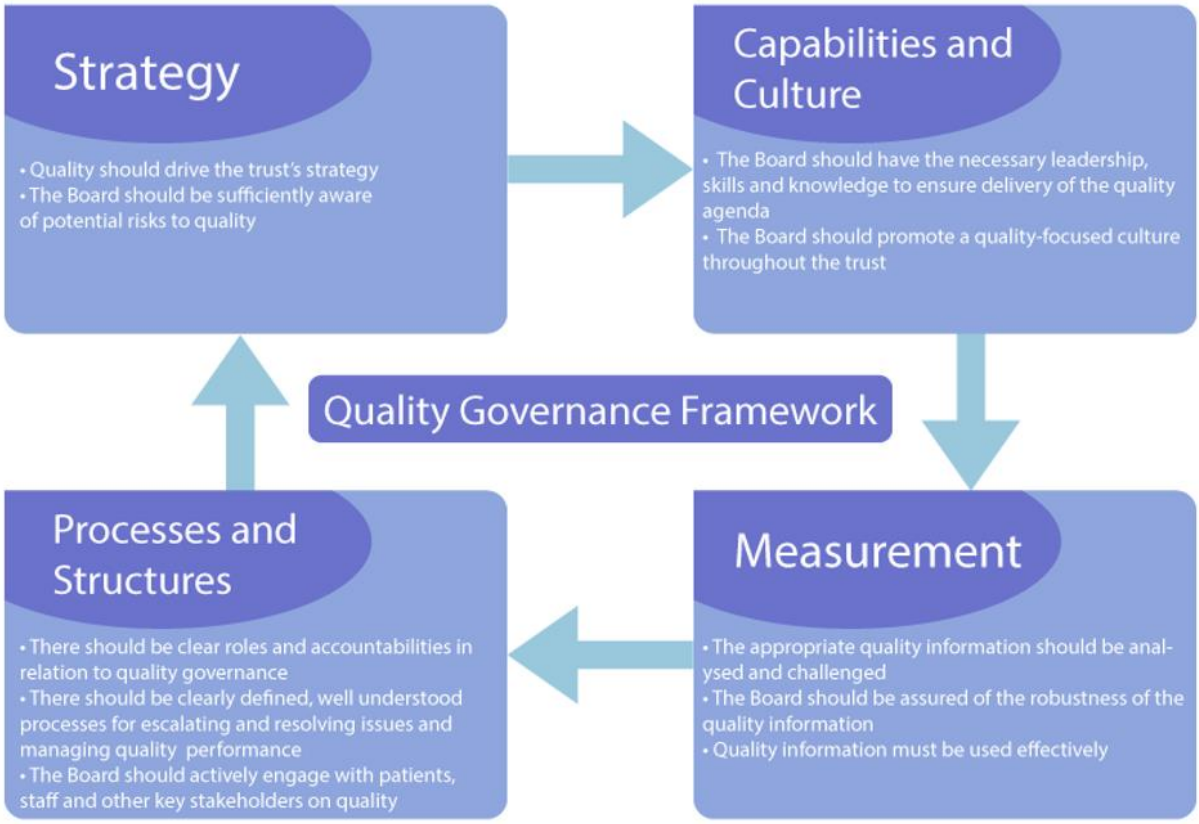

Figure 5. The Quality Governance Framework. Adapted from Quality governance NHS (27).

4.8.1. Governance of Quality of health care at the national level

QoC is a strategic choice and part of the strategic decision making at the societal, political, organisational, and managerial levels.

MoH, the National independent body for QoC and PS, is accountable for the governance of quality of health care on a national level. They shall define quality governance and give shape to what it means to govern for quality across the healthcare system. They shall offer support to provider boards in achieving and delivering this quality governance They shall identify and provide links to further publications, documents, and concepts that provide detail on supporting aspects of quality governance.

Their responsibilities for quality are:

- to ensure that the essential standards of quality and safety are at a minimum being met by every service that the system delivers
- to ensure that the health care institutions are striving for continuous QI and outcomes in every service
- to ensure that every member of staff that has contact with patients or whose actions directly impact patient care, is motivated and enabled to deliver effective, safe, and person-centred care.

MoH has a responsibility to provide governance, leadership, and direction of national efforts.

The national independent body for quality and PS has a responsibility to support the 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.

Besides Moh and the National independent body for quality and PS, the important role in health care quality governance have also HIIS and professional bodies. HIIS is responsible for funding and monitoring incentive programmes and integrating measures for PS and QoC improvement in payment mechanisms- VBHC. Professional bodies assist and support training, professional education, and setting evidence-based tools and standards.

4.8.2. Governance of Quality of healthcare at providers' and stakeholders' level

While QoC is predominantly expressed at the level of the interaction between health providers and service users, it takes place within a much broader context, including the larger health system. At each level of the health system and in the different steps of the QI process, stakeholder and community engagement is crucial and will be shaped according to national, district, and facility strategies to improve QoC.

Stakeholder and community engagement is often defined in terms of the degree to which engagement takes place: it can fall anywhere along a continuum ranging from passive involvement through public dissemination of information to active participation and shared decision-making.

For QI initiatives to be effective, meaningful, and sustainable, stakeholder and community engagement is crucial across the start-up and implementation phases and across the healthcare system at the national, district, and facility levels

Policymakers and planners need to conduct a careful stakeholder mapping and analysis to ensure that the right individuals and organizations are contributing commitment, knowledge, and resources to QI initiatives.

The stakeholder analysis will have facilitated the identification of core stakeholders that need to be actively involved in the QI initiative. This next step helps identify the forums in which these stakeholders can be engaged and through which governance mechanisms be enabled.

Developing a capacity strengthening plan for stakeholders and communities and separately for health professionals, facilitating partnerships, and consolidating of stakeholder engagement strategy are required steps.

After having defined the governance structure and QI team composition and procedures, the next step is to conduct a collaborative quality assessment to identify gaps and improvement aims. Such reviews provide an opportunity to collect, aggregate, and compare data on all dimensions of QoC and to develop a comprehensive operational plan.

Society and managers are responsible for the care system as a whole and must apply system-oriented, rather than sector-oriented, thinking. Employees are responsible for ensuring the continuity of client services in their work, and managers and employees share the responsibility of achieving the organisational goals and quality standards. The clients are responsible for acting as responsible service users and providing the required information to obtain care. Communication was strongly emphasised in the data, and it necessitates cross-professional and organisational boundaries, professional and political boundaries, and boundaries between the professional and the client (28, 29).

4.8.2.1 Healthcare providers governance of health care quality

Governing board (Sveti zavodov) is responsible for establishing policy and strategic framework, leading organizational culture, overseeing management performance and ensuring organisational accountability; reviewing institutional quality and PS improvement programmes and initiatives and engaging the community in improving service delivery. It has been shown that clinical participation on the hospital board and the focus on quality in hospital board roles can have a beneficial effect (30).

Committee for quality, PS, and CRM at healthcare facilities is responsible for the organization and operation of quality and PS policy, strategy, and action plan; to improve the culture of PS; and responsible for leading and coordinating the workforce and implementing a system for delivery of quality and safe health care.

Commission for quality, PS, and CRM at the healthcare facility (an execution body at the facility level) is responsible for carrying out quality care practices and standards and reporting the relevant health data for continuous QI.

Clinicians are responsible for working in clinical teams and with patients to deliver and continuously improve safety, high-QoC. They maintain their skills and performance and are getting support from their colleagues and their organization.

4.9. Governance of clinical risk management and patient safety

4.9.1. Clinical risk governance

Safety is critically dependent on healthcare leaders and government bodies as well as the positions they take on establishing safety for patients, families, and the healthcare workforce.

MoH, the National independent body for QoC and PS, and healthcare service providers' governing bodies are accountable for CRM.

For strong PS governance and, therefore also for clinical risk governance, it should be required from the government to consider key findings of the OECD study (10):

1. Requirements for **aligning clinical risk governance with overall health system governance and financing** align its components and functions
2. **Inclusion into all healthcare settings**
3. Enforcement of **people-centeredness** in safety governance
4. Fostering a **culture of openness and trust** among health professionals and regulators
5. Enabling **continuous learning** from both harm and success
6. **Incorporating other policy areas**, notably data privacy/security policies, and workforce preparedness

Health service provider governing bodies are accountable for CRM and must ensure that a local RM policy, framework, and any other supporting documentation is developed and includes:

- Defined processes to identify, assess, treat, monitor, review, record, and report clinical risks
- Risk review frequency requirements
- Supervision requirements for the governing council and/or dedicated risk and audit sub-committee
- Risk ownership and acceptance decisions for risks at each risk level are specified in the local policy
- Risk identification and continuous monitoring of the risk profile occurs on an ongoing basis
- RM requirements are formally communicated to staff across the organization
- Processes are in place to build staff awareness and risk understanding through education and training

4.9.2. Patient safety governance

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 (10).

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 (31).

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 (32).

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.

Currently, only the MoH is responsible for the national Quality and PS at the national level. This has proved to be inefficient, as shown in the situational analysis (D2, pp 34-35).

OECD health systems frequently use governance functions to define roles and responsibilities in PS clearly. The results of the survey of 2019 on system-level safety governance in OECD countries as reported by countries' authorities were also described (10).

4.10. Governance of no-fault compensation

4.10.1. Governance of no-fault compensation scheme at the national - governmental level

Governance of the no-fault compensation scheme as part of the PS should be a comprehensive system that refers to structures and processes that are designed to ensure accountability, transparency, responsiveness, the rule of law, stability, equity, and inclusiveness empowerment, and broad-based participation through stakeholders.

Governance while introducing a no-fault compensation scheme should also represent the norms, values, and rules of the game through which all other general public affairs are managed in a transparent, participatory, inclusive, and responsive manner.

Therefore the governance should be subtle and may not be easily observable. In a broad sense, introducing a no-fault compensation mechanism and its governance is about the culture and institutional environment in which citizens and healthcare stakeholders should interact among themselves and participate in it. It is more than the organs of the government.

Often there is a tendency to equate governance with **management**, the latter primarily referring to the planning, implementation, and monitoring functions to achieve results. Management encompasses processes, structures, and arrangements designed to mobilize and transform the available physical, human, and financial resources to achieve concrete outcomes. Management of no-fault compensation should therefore refer to individuals or groups of people who are given the authority to achieve the desired results in the field of PS from reducing unwanted consequences in terms of quality of life of injured persons and any additional individual or public costs in the case of adverse events.

A National Independent body for QoC and PS should be established as a public company, which also administers the no-fault compensation scheme.

4.10.2. Barriers or risks to the successful implementation of a no-fault compensation scheme

After adopting a legal framework for no-fault compensation claims, there could be some obstacles that could lower or even stop the successful implementation of a newly designed system or even stop it. A strong commitment to introduce governance on all levels and implement the scheme is essential:

1. Legislation for a no-fault compensation scheme was adopted but a national independent body for QoC and PS was not established; All three observed countries in the comparative analysis have established independent public bodies to process compensation claims; Danish patient Insurance Association in Denmark, Patient Insurance Association (PFF) in Sweeden and Accident Compensation Association in New Zealand; therefore strong political and commitment to govern the scheme is essential;
2. Lack of medical, legal, and financial expertise in this very specific field; the boost for learning from good practices will be essential; trained and qualified panel;
3. No sufficient political and financial support for the work of the independent national body
4. No political will to change legislation in the field of tort law in decriminalising all except gross negligence medical behaviour;
5. Resistance from some parts of the public and some politicians on the areas that may be argued as the negative sides of no-fault compensation

4.10.3. Governance and management (operational level) of no-fault compensation scheme at the level of healthcare providers and other stakeholders

1. Structure and management at the level of healthcare providers
2. Structure and management at the level of the patient ombudsman
3. Structure and management at the professional representative bodies (chambers, associations)
4. Structure and management at the health insurance

4.11. Barriers to the implementation of clinical governance

The barriers to clinical governance implementation are numerous and can be efficiently confronted if known in advance. Examples are lack of understanding, fear, no clear vision, notion that there is nothing new, lack of time, lack of resources, lack of support, poor Information, poor leadership, ineffective communication, etc.

The barriers can originate from internal and external sources, which can affect the organization, teams, and individuals (33) (table 2).

Table 2. Some possible barriers to clinical governance.

Internal sources	External source
Individual	***Individual***
Lack of competencies	Lack of peer support
Lack of understanding	Lack of human resource
Lack of confidence	Lack of time
Resistance to change	
Ineffective communication	
Lack of Information	
Organisation	***Organisation***
Poor organisational culture	Political pressure
Management and leadership style	Increased demands on already overstretched service
Ineffective communication	Increased performance targets
Lack of financial and human resources	Public expectation
	Litigation

5. POLICY BRIEFING FOR PROPOSING GOVERNANCE MODEL

Main points of the **clinical governance model for quality and PS in the Slovenian healthcare**:

1. Structure at the level of the MoH – capacity for QoC and PS and no-fault compensation governance
2. Establishing an independent national body for quality and PS
3. Creating a national audit commission for quality and PS, including avoidable adverse events investigation
4. Implementing and auditing standards for clinical governance
5. Implementing the strategic plan for quality and PS
6. Implementing transparency and accountability

Principal topics for **clinical governance in healthcare organisations**:

1. Structure at the healthcare organisation as proposed in figure 1
2. Compliance with clinical governance standards
3. Implementation of strategies and action plans for quality and PS improvement
4. Implementation of internal audits
5. Implementing transparency and accountability
6. Participation and partnership with stakeholders

Main points of the **no-fault compensation structure**:

1. Governance activities and structure to introduce, regulate and monitor the no-fault compensation model
2. Establishing an independent national body (may be the same as under point no.2 in the first paragraph) for tackling adverse events and processing no-fault compensation claims
3. Structure at the level of an independent body
4. Structure at the level of MoH, Ministry of Justice and at the level of health care providers, professional chambers, and patient ombudsman at the national and local level

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7. APPENDICES

7.1. Appendix A: The study of five countries

Tuscany (Italy)

The Department of Health provides Information (in the foreground, opportunities, rankings and events) and regional indications (authorization and accreditation) aimed at supporting the activities to improve the services and health of citizens together.

Governance structure. Centre for CRM and PS (**GRC *Centre-Centro Gestione Rischio Clinico e Sicurezza del Paziente*)** is a clinical governance structure instituted in 2003 by the Tuscan regional council. The GRC enrolls professionals of different disciplines (public health, CRM, industrial design, human factors, organization studies, communication science, law, psychology, international relations) and since the beginning of the activity, is connected to a scientific committee.

GRC promotes a safety culture through the active and cross-disciplinary learning from adverse events and errors. The GRC aims to construct a shared vision for safety through the sharing of experiences and the development of collaborative projects for PS. The centre proposes standards for the operational contexts and supports the effective measurement of critical process and measures. The GRC has organized a series of initiatives to involve citizens in PS's policy and practice. The GRC centre Management and WHO Collaborating Centre aims to develop and promote practices for safety, awareness-raising and the analysis of adverse events for the constant improvement of care delivery.

Key objectives. The GRC aims to construct a **shared vision for safety** by sharing experiences and developing collaborative projects for **PS**. The centre proposes standards for the operational contexts and supports the effective measurement of critical processes and measures.
The GRC has organized a series of **initiatives to involve citizens in PS's policy and practice**. The GRC centre Management and WHO Collaborating Centre (GRC *Centre-Centro Gestione Rischio Clinico e Sicurezza del Paziente*) aim to develop and promoting practices for safety, awareness-raising and the analysis of adverse events for the constant improvement of care delivery.

The main activities are:

- Building a transparent and branched system of quality and safety governance
- Supporting the self-assessment by professionals and, therefore the processes of accreditation and continuous improvement
- Promoting the appropriateness and adoption of evidence-based technical professional tools at all levels
- Enhancing the user experience in improving services
- Encouraging, disseminating and supporting the culture of reporting and transparency
- Incident reporting systems
- Monitoring indicators
- 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
- Establishing CRM system
- Measuring safety culture
- Training programmes

Ireland

Governance structure. There is a **Quality and PS Directorate** established in order to ensure that high quality safe services are designed and delivered to patients and clients. This directorate is committed to a multi-agency approach, and it is focused on the development and implementation of safe and quality healthcare.
Governance for Quality involves having the necessary structures, processes, standards, and oversight to deliver safe, person-centred, and effective services. Good governance supports **strong relationships between frontline staff, service users, and leaders.**

In Ireland, Quality in healthcare is defined by the four domains set out in the **Health Information and Quality Authority (HIQA) National Standards for Safer Better Healthcare** (Health Information and Quality Authority, 2012): **person-centred**, **effective**, **safe and better health** and **well-being**.

Key objectives. The overall goal of the Health and Safety Executive (HSE) Quality and PS Enablement Programme as outlined in the HSE **Code of Governance** (2015) is underpinned by four key objectives:

- Services must subscribe to a set of **clear quality standards** that are based on international best practices
- Services must be **safe** and there must be a robust level of both QI and quality assurance
- Services must be **relevant** to the needs of the population

Patients must be appropriately **empowered** to interact with the service delivery system.
In 2016, the HSE launched the **Framework for Improving Quality in Health Service** which outlines six critical success factors:

- Leadership for Quality
- Personal and Family Engagement
- Staff Engagement
- Use of improvement methods
- Measurement for Quality
- Governance for Quality

The **governing board leads the organization using authority to direct and control provided by the owner and the legal act of formation** (where applicable). They set initial direction and have the authority to act in the service user and services best interest. Governing boards function at arm's length from the operational organization. They **focus on the big picture, future-oriented and act as a single entity**.

There are a **number of key policy documents and resources applicable to boards** and executives within healthcare in Ireland. When services do not have boards the CEO/General Manager and executive team take on this responsibility. There are different types of boards within HSE funded healthcare services which operate within the HSE Performance Accountability Frameworks. These include **Hospital Group Boards, Voluntary Healthcare Provider Board of Directors, Advisory Boards.**

The National Quality Improvement Team

Programmes of the National QI Team are:

- Sustainable QI Programme
- School of QI Programme
- QI Connections Programme
- Evidence for Improvement Programme
- Partnering with people who use health services Programme
- Global Health Programme
- Clinical Directorate Programme

The National Patient Safety Office (NPSO) has a health indicator framework named the NHQRS. The primary objective of the NHQRS is to provide publicly available Information on the QoC. This in turn should inform and support decision-making by patients, policy makers and service providers.
The NHQRS has produced an annual report that is published on the Department of Health website. In the 2020 report, there are 52 indicators from 11 data sources.
Clinical risk assessment and mitigation. A National Risk Assessment for Ireland produced by the Government of Ireland acts as a guideline regarding risk.

Patient safety. The **Health and Safety Authority (HSA)** is responsible for administering and enforcing health and safety at work in Ireland. 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 on PS. The Commission recommends:

- All bodies responsible for healthcare workers' training and continuing development should review their curricula to ensure that both technical and human factors in relation to PS and QoC are incorporated into their education modules.
- Specific education and training requirements and supports for healthcare managers.
- The organizations should measure, monitor and evaluate safety and health performance.

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 address these issues in a positive way.

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 in order to contribute to the improvement of the health of the citizens and to the sustainability of the health system of Catalonia.

Incident reporting. In 2012, a PS model in the Quality and Bioethics Promotion Service was established. The aim is to collect incidents that allow them to be analysed and solutions sought to reduce the ir number and frequency to increase PS.

The system used to report these incidents is TPSC-CloudTM , (**the online platform** of the PS Company), which began to be implemented in Catalonia at the end of 2013. In this system all types of incidents related to PS can be reported voluntarily, confidentially, anonymously and not punitively.
CRM follows the ISO 31000 RM Standard.

PSC and PS have been promoted since 2008 through the Department of Health and, especially since 2012, the “Functional Patient Safety Units” have been implemented in health centres with the following strategy:

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

Australia

Governance structure and organization of QoC and PS The **Australian Commission on Safety and Quality in Health Care** to lead and coordinate national improvements in health care safety and Quality of health care. The Commission commenced as an independent statutory authority on 1 July 2011, funded jointly by the Australian Government and state and territory governments.

Key objectives of the Commission include **developing national safety and quality standards**, developing clinical care standards to improve the implementation of evidence-based health care, coordinating work in specific areas to improve outcomes for patients, and providing Information, publications and resources about safety and Quality. The Commission works in four priority areas: 1) PS, 2) Partnering with patients, consumers and communities, 3) Quality, cost and value, 4) Supporting health professionals to provide care that is informed, supported and organized to deliver safe and high-quality care.

Department of Health and Wellbeing (DHW) has used the Safety Learning System (SLS) since 2011. This is an incident management system that allows healthcare staff to report incidents and near misses

Their **key objectives** are to have SLS reviewed, escalated where appropriate, analysed, and investigated to prevent their occurrence in the future. The SLS is a "state-wide" system that allows healthcare professionals access to report incidents in all South Australia public health services and related agencies such as ambulance service.

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. Leaders of a health service organization have a responsibility to the community for continuous improvement of the safety and quality of their services, and ensuring that they are patient-centred, safe and effective.

Indicators for Reporting Systems are classified in five indicators sets:
- Patient experience question set
- Sentinel events
- Clinical incidents
- Hospital-acquired complications
- Avoidable hospital readmissions

CRM follows the Australian/New Zealand Standard AS/NZS ISO 31000:2018 RM.
Measurement of PSC enables the identification of strengths and areas for improvement.

Denmark

Governance. The **Danish Patient Safety Authority (DPSA)** supervises authorized healthcare professionals and organizations in the Danish healthcare system. The board issues i.e., authorizations and advices on, for example, infectious diseases, and collects and disseminates knowledge about PS, among other things, from the **Danish Patient Safety Database** (DPSD).
The DPSA performs a number of tasks that are part of their vision to **strengthen PS**. These tasks include to:

- **Supervise** authorized health professionals and health organizations
- Offer **advice about communicable diseases**, health conditions relevant to issuing driving licenses and conducting inquests, etc.
- Issue **registrations** in 17 different healthcare professions to both Danish and foreign healthcare professionals
- Issue **permissions to practice independently** as a medical doctor, dentist or chiropractor
- Issue **specialist registrations** in the 38 medical specialties and specialist registrations in the two dental specialties
- Handle the **central administration of the reporting system for adverse events** in the health service and contribute to using knowledge about adverse events and knowledge from patient and compensation cases in a preventive way
- Give advice about the right to medical assistance in other countries pursuant to Danish legislation, EU regulation and other international agreements.

In 2001, a study named Danish Adverse Event Study found out that 9% of discharged patients had experienced an adverse event. From that moment, they start to act on PS by implementing a **Reporting System** that could teach how to do it.
CRM follows the ISO 31000 RM Standard.
PSC. The Danish PSC Questionnaire was developed based on an extensive development process with field testing and validation. Individual units and organizations e.g. nursing homes and hospitaldepartments have worked with measuring and improving PSC as part of QI.

The Danish Institute for Quality and Accreditation in Healthcare (IKAS), develops, plans and runs the Danish accreditation programme for healthcare providers, called the **Danish Healthcare Quality Programme** (DDKM, referring to the name of the programme in Danish).

IKAS is an independent institution financed partially by public means, while private clients cover the costs related to their accreditation. It was established in 2005 and is **supervised by a board of directors**, including representatives from the Danish Health Authority, Danish Regions, the Ministry of Interior and Health, Local Government Denmark, The Association of Danish Pharmacies, and The Danish Chamber of Commerce, representing private hospitals.

7.2. Appendix B: Clinical governance standard

A systematic approach to quality and PS improvement identifies those accountable for specific actions. The government has ultimate responsibility for a high QoC and PS. Safe and high-quality care requires the vigilance and cooperation of the whole healthcare workforce and other stakeholders.

Authorisation of an independent body to have access, to collect, keep, process, assess and analyse data on adverse events, civil and criminal court cases data, complaint procedures data, at different levels and competent bodies

Governance, leadership and culture

Item	Standards
1 MoH and government	1.1 National legislation on quality and PS. 1.2 Quality and patient policy, safety strategy and programmes. 1.3 No -fault compensation for patients after avoidable adverse events. 1.4 Decriminalisation of human errors with the establishment of a just Culture. 1.5 Patient representation in official roles and decision-making processes are involved in public discussion after the documents are prepared by the government and participating in the development of documents. 1.6 Creation of an independent national body for QoC, PS and no-fault compensation. 1.7 Requirements for external accreditation, inspections, audits of QoC and PS structure, processes and outcomes. 1.8 Specifying yearly budget for QoC and PS. 1.9 Provide financial incentives and/or penalties applied to promote and ensure safety QoC and PS.
2 Independent public organ for quality and PS	2.1 National QoC and PS standards and indicators. 2.2 Establishment of national set of clinical indicators and indicators supporting safety standards. 2.3 Routine public reporting of quality and PSI and performance. 2.4 Ongoing training on QoC and PS as part of professional development of health care personnel. 2.5 Safety and QoC competencies built into students' curriculum in various health disciplines. 2.6 Leadership and management development to promote PSC. 2.7 Reports on QoC and PS to MoH. 2.8 Running sentinel events system. 2.9 Monitoring and audit quality and PS, including RM at the national level (structures, processes, outcomes). 2.10 Support to the development of clinical guidelines and facilitate their implementation into practice. 2.11 Support Health Technology Assessment (HTA), healthcare standards system and accreditation. 2.12 Support QoC and PS improvement projects and research. 2.13 Reports on quality and PS with recommendations to MoH and stakeholders.

Leaders at all levels in the organisation set up and use clinical governance systems to improve PS and quality of health care.

Item	Standards
3 Governance, leadership and culture	3.1 The governing body: a. Provides leadership to develop a culture of safety and quality improvement, and satisfies itself that this culture exists within the organisation. b. Provides leadership to ensure partnering with patients, carers and consumers. c. Sets policy, priorities, and strategic directions for comprehensive PS framework safe and high-quality clinical care and communicates these effectively to the workforce and the community. d. Endorses the organisation's clinical governance framework. e. Ensures that roles and responsibilities are clearly defined for the the governing body, management, clinicians and the workforce f. Monitors the action taken as a result of analyses of clinical incidents. g. Reviews reports and monitors the organisation's progress on safety and quality performance.
4 Organisational Leadership - Quality committee	4.1 The health service organisation establishes and maintains a clinical governance model, and uses the processes within the model to drive improvements in safety and quality. 4.2 The health service organisation implements and monitors strategies to meet the organisation's safety and quality targets 4.3 The health service organisation considers the safety and quality of health care for patients in its business decision-making
5 Clinical leadership	5.1 Clinical leaders support clinicians to: a. Understand and perform their delegated safety and quality roles and responsibilities b. Operate within the clinical governance model

PS and quality systems

Safety and quality systems are integrated with governance processes to enable rganisations to actively manage and improve the safety and quality of health care for patients.

Item	Standards
6 Policies and procedures	6.1 The health service organisation uses: a. Establish, review, and maintain the currency and effectiveness of policies, procedures and protocols b. Monitor and take action to improve adherence to policies, procedures and protocols c. Review compliance with legislation, regulation and jurisdictional requirements d. Internal monitor QoC and PS for continuous improvementincluding quality indicators

PS and quality systems (continue)

Item	Standards
7 Measurement and quality improvement	7.1 The health service organisation uses organisation-wide quality improvement systems that: a. Identify safety and quality measures (indicators), and monitor and report performance and outcomes b. Identify areas for improvement in safety and quality c. Implement and monitor safety and QI strategies

	d. Involve consumers and the workforce in the review of safety and quality performance and systems 7.2 The health service organisation ensures that timely reports on safety and quality systems and performance are provided to: a. The governing body b. The workforce c. Consumers and the local community d. Independent public organ for quality and PS e other stakeholders
8 RM	8.1 The health service organisation: a. Identifies and documents organisational risks, including clininical risks b. Regularly reviews and acts to improve the effectiveness of the RM system c. Reports on risks to the workforce and consumers d. Plans for and manages internal and external emergencies and disasters
9 Incident management systems and open disclosure	9.1The health service organisation has organisation-wide incident management and investigation systems, and: a. Supports the workforce to recognise and report incidents b. Supports patients, carers and families to communicate concerns or incidents c. Involves the workforce and consumers in the review of incidents d. Provides timely feedback on the analysis of incidents to the governing body, the workforce and consumers e. Uses the Information from the analysis of incidents to improve safety and quality f. Incorporates risks identified in the analysis of incidents into the RM system g. Regularly reviews and acts to improve the effectiveness of the incident management and investigation systems 9.2 Healthcare organisation separetes system for incident reports from other patients compolains 9.3 The health service organisation: a. Uses an open disclosure program b. Monitors and acts to improve the effectiveness of open disclosure processes

PS and quality systems (continue)

Item	Standards
10 Feedback and complaints management	10.1 The health service organisation: a. Has processes to seek regular feedback from patients, carers and families about their experiences and outcomes of care b. Has processes to regularly seek feedback from the workforce on their understanding and use of the safety and quality systems c. Uses this Information to improve safety and quality systems 10.2 The health service organisation has an organisation-wide complaints management system, and: a. Encourages and supports patients, carers and families, and the workforce to report complaints b. Involves the workforce and consumers in the review of complaints c. Resolves complaints in a timely way

	d. Provides timely feedback to the governing body, the workforce and consumers on the analysis of complaints and actions taken e. Uses Information from the analysis of complaints to inform improvements in safety and quality systems f. Records the risks identified from the analysis of complaints in the RM system g. Regularly reviews and acts to improve the effectiveness of the complaints management system
11 Diversity and high-risk groups	11.1 The health service organisation: a. Identifies groups of patients using its services who are at higher risk of harm b. Incorporates Information on the diversity of its consumers and higher risk groups into the planning and delivery of care

Clinical performance and effectiveness

Item	Standards
12 Safety and quality training	12.1 The health service organisation provides orientation that describes roles and responsibilities for safety and quality for: a. Members of the governing body b. Clinicians, and any other employed, contracted, locum, agency, student or volunteer members of the organisation 12.2 The health service organisation uses its training systems to: a. Assess the competency and training needs of its workforce b. Implement a mandatory training program to meet its requirements arising from these standards c. Provide access to training to meet its safety and quality training needs d. Monitor the workforce's participation in training 12.3 The health service organisation has strategies to improve the cultural awareness and cultural competency of the workforce

Clinical performance and effectiveness (continue)

Item	Standards
13 Performance management	13.1 The health service organisation has valid and reliable performance review processes that: a. Require members of the workforce to take part in a review of their performance regularly b. Identify needs for training and development in safety and quality c. Incorporate Information on training requirements into the organisation's training system d. Contracts include safety requirements collaboration for QoC and PS improvement
14 Credentialing and scope of clinical practice	14.1 The health service organisation has processes to: a. Define the scope of clinical practice for clinicians, considering the clinical service capacity of the organisation and clinical services plan b. Monitor clinicians' practices to ensure that they are operating within their designated scope of clinical practice c. Review the scope of clinical practice of clinicians periodically and whenever a new clinical service, procedure or technology is introduced or substantially altered 14.2 The health service organisation:

	a. Conducts processes to ensure that clinicians are credentialed, where relevant b. Monitors and improves the effectiveness of the credentialing process
15 Safety and quality roles and responsibilities	15.1 The health service organisation has processes to: a. Support the workforce to understand and perform their roles and responsibilities for safety and quality b. Assign safety and quality roles and responsibilities to the workforce, including locums and agency staff 15.2 The health service organisation provides supervision for clinicians to ensure that they can safely fulfill their designated roles
16 Evidence-based care	16.1 The health service organisation has processes that: a. Provide clinicians with ready access to best-practice guidelines, integrated care pathways, clinical pathways and decision support tools relevant to their clinical practice b. Support clinicians to use the best available evidence.
17 Variation in clinical practice and health outcomes	17.1 The health service organisation has systems to: a. Monitor variation in practice against expected health outcomes b. Provide feedback to clinicians on variation in practice and health outcomes c. Review performance against external measures d. Support clinicians to participate in clinical review of their practice e. Use Information on unwarranted clinical variation to inform improvements in safety and quality systems f. Record the risks identified from unwarranted clinical variation in the RM system

Clinical governance and QI systems to support partnering with consumers

Systems are designed and used to support patients, carers, families and consumers to be partners in healthcare planning, design, measurement and evaluation.

Item	Standards
18 Integrating clinical governance	18.1 Clinicians use the safety and quality systems from the Clinical Governance Standard when: a. Implementing policies and procedures for partnering with consumers b. Managing risks associated with partnering with consumers c. Identifying training requirements for partnering with consumers
19 Applying quality improvement systems	19.1 The health service organisation applies the QI system in the Clinical Governance Standard when: a. Monitoring processes for partnering with consumers b. Implementing strategies to improve processes for partnering with consumers c. Reporting on partnering with consumers

Partnering with patients in their own care

Systems that are based on partnering with patients in their own care are used to support the delivery of care. Patients are partners in their own care to the extent that they choose.

Item	Standards
20 Healthcare rights and informed consent	20.1 The health service organisation uses a charter of rights that is: a. Consistent with the Slovenian Act on Patients' Rights b. Easily accessible for patients, carers, families and consumers 20.2 The health service organisation ensures that its informed consent processes comply with legislation and best practice

21 Sharing decisions and planning care	21.1 The health service organisation has processes for clinicians to partner with patients and/or their substitute decision-maker to plan, communicate, set goals, and make decisions about their current and future care 21.2 The health service organisation supports the workforce to form partnerships with patients and carers so that patients can be actively involved in their own care

Health literacy

Item	Standards
22 Communication that supports effective partnerships	22.1 Where Information for patients, carers, families and consumers about health and health services is developed internally, the organisation involves consumers in its development and review 22.2 The health service organisation supports clinicians to communicate with patients, carers, families and consumers about health and health care so that: a. Information is provided in a way that meets the needs of patients, carers, families and consumers b. Information provided is easy to understand and use c. The clinical needs of patients are addressed while they are in the health service organisation d. Information needs for ongoing care are provided on discharge

Partnering with consumers in organisational design and governance

Consumers are partners in the design and governance of the organisation.

Item	Standards
23 Partnerships in healthcare governance planning, design, measurement and evaluation	23.1 The health service organisation: a. Involves consumers in partnerships in the governance of, and to design, measure and evaluate health care b. Has processes so that the consumers involved in these partnerships reflect the diversity of consumers who use the service or, where relevant, the diversity of the local community 23.2 The health service organisation provides orientation, support and education to consumers who are partnering in the governance, design, measurement and evaluation of the organisation