



Situation analysis

National context of quality of care, patient safety and clinical risk management and patient compensation

Support for improving quality of healthcare and patient safety in Slovenia

**RFS REFORM/SC2020/021
AARC - Consortium**

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ABBREVIATIONS

AEZQ	German Agency for Quality in Medicine
CHF	Congestive Heart Failure
COPD	Chronic diseases is used in Pulmonary Disease
CRM	Clinical Risk Management
CRPD	Central Registry of Patient Data
EBM	Evidence-Based Medicine
EC	European Commission
EHR	Electronic Health Record
EU	European Union
GA	General Agreement
GIN	International Guidelines Network
HAG	Health at a Glance
HAI	Healthcare Associated Infections
HCQI	OECD Health Statistics
HFMEA	Healthcare Failure Mode and Effect Analysis
HIIS	Health Insurance Institute of Slovenia
HRQoL	Health-Related Quality of Life
HTA	Health Technology Assessment
ICHOM	International Consortium for Health Outcomes Measurement
ICT	Information Communication Technology
MCS	Medical Chamber of Slovenia
MoH	Ministry of Health
NGO	Non-governmental Organization
NIPH	National Institute of Public Health
OECD	Organization for Economic Cooperation and Development
OWG	Operating Working Group
PaRIS	Patient Reported Indicator Surveys
PATH	Performance Assessment Tool for Quality Improvement in Hospitals
PREMs	Patient-Reported Experience Measures
PROMs	Patient-Reported Outcome Measures
PS	Patient Safety
QALYs	Quality-Adjusted Life Years
QI	Quality improvement
QoC	Quality of Care
SIGN	Scottish Intercollegiate Guidelines Network
WHO	World Health Organization

1. INTRODUCTION AND OBJECTIVES

The Ministry of Health of Slovenia (MoH) is currently carrying out a project, funded by the European Union (EU) through DG REFORM, whose main objective is to **support the Slovenian MoH in capacity building to develop a National strategy on Quality of Care (QoC), Clinical Risk Management (CRM) and Patient Safety (PS), and a legal framework of 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 PS culture and CRM
- Improved strategic planning and governance of the QoC system
- Revised set of indicators for QoC for hospitals, specialist outpatient care and primary care available, tested and communicated
- Development and implementation of education programmes in quality and safety
- Development of no-fault compensation scheme, reduced criminal prosecution and civil litigation
- Upgrade the level of healthcare providers, higher awareness and accountability of healthcare professionals, reduced practice of defensive medicine, patient empowerment, improved doctor-patient relationship
- Systematic improvement of the efficiency and effectiveness of healthcare

For the successful conduction of this project is previewed the elaboration of an initial situation analysis (Phase 2 of the project) that aims, through an identification and analysis of the available information, to obtain the current national context situation in Slovenia in regards with:

- **QoC**
- **CRM and PS**
- **No-fault compensation model**



Quality of care



Patient safety
and risk
management



Patient
compensation

2. CONTEXT

2.1 Overview of the Slovenian Healthcare system

a) Health System in Slovenia

Since 1992, Slovenia has a Bismarck-type social insurance system. The system is based on a single insurer for statutory health insurance. This is regulated by national legislation and administered by the Health Insurance Institute of Slovenia. The insurance is based on employment status or dependence status (assigned to minors, unemployed spouses, registered unemployed people and individuals without source of income)¹.

The regulatory role rests with the Ministry of Health. The Ministry is supported by the Health Council, an advisory body that advises on policy, as well as health technology assessment (HTA) and the introduction of new therapeutic and diagnostic procedures. The Health Ministry is the owner, manager and investor of all public hospitals and national institutes. Also, the Health Ministry is the granting authority of practice authorizations for medical specialists.

b) Financing

Slovenia's health system is mainly funded through compulsory health insurance, with the remainder coming from voluntary health insurance and direct out-of-pocket payments.

Mainly Slovenia financing system flows from four sources:

- Taxes (mostly used for financing national and local government: Ministry of Health and Health Municipalities)
- Compulsory health insurance contributions (Financing by the Health Insurance Institute of Slovenia)
- Co-payments (Private health insurers -for co-payment coverage)
- Direct payments for services not covered

Compulsory health insurance contributions accounted for 68.1% of the health expenditure in 2014. Health services in Slovenia are purchased by the Health Insurance Institute of Slovenia and voluntary health insurance companies².

c) Organization

Mainly, Slovenia has a social health insurance system based on a single public insurer, providing universal compulsory health insurance. The Health Insurance Institute of Slovenia provides universal compulsory health insurance. This health insurance is complementary with co-payments. Three private companies (Adriatic-Slovenica, Triglav and Vzajemna) provide voluntary health insurance, which is mainly used by patients to cover co-payments. Health services are delivered by public providers (health care centres network at primary level and hospitals and outpatient clinics at secondary level), as well as private providers that hold a "concession" to provide publicly funded services. Health-related nongovernmental organizations (NGOs) coexist with the health system.

¹ Albrecht, T. et al. Health Systems in Transition: Slovenia (Vol. 18 No. 3 2016). Slov. Heal. Syst. Rev. 18, (2016).

² Williams, J. M. J. England - Organization and financing of public health services in Europe - NCBI Bookshelf. (2018).

The main organizations that operate in the administrative, constitution and configuration of the health system of Slovenia (see figure 1) are:

- Parliamentary Committee on Health:
 - Social consensus on all laws and legal matters in relation to health issues
- Ministry of Health:
 - Prepare health care and health protection legislation
 - Supervise implementation
 - Ensure regulation
 - Monitors public health
 - Develops and implements health promotion programmes
 - Promotes people's health education
 - Supervises the production, trade and supply of medicines and medicinal products
 - Implementing international agreements
- Agency for Medicinal Products and Medical Devices of the Republic of Slovenia
 - Performs administrative, expert and inspection tasks in the fields of medicinal products and medical devices
 - Acts as the official control laboratory
- Health Council
 - Special advisory body to the Health minister
- National Institute of Public Health of Slovenia
 - Central institution in the field of public health
 - Responsible for a number of public health functions, research and education and training in public health
- National Laboratory for Health, Environment and Food
 - Carries out a number of functions ranging from microbiological tests for the needs of health care providers to the isolation of pathogens for epidemiological surveillance and the preparation and coordination of monitoring programmes at national level
- Health Insurance Institute of Slovenia
 - Adopts the financial plans and policies that regulate the rights and benefits of the insured and proposes the level of contribution rates to the National Assembly on a regular basis
- Local government
 - Responsible for the management of the primary health care network in their territory
- Unions and professional associations
 - Supervisory and administrative functions; both are responsible for specialization, licensing, the development and issuing of a code of medical ethics and supervision over professional practice
- Other voluntary organizations

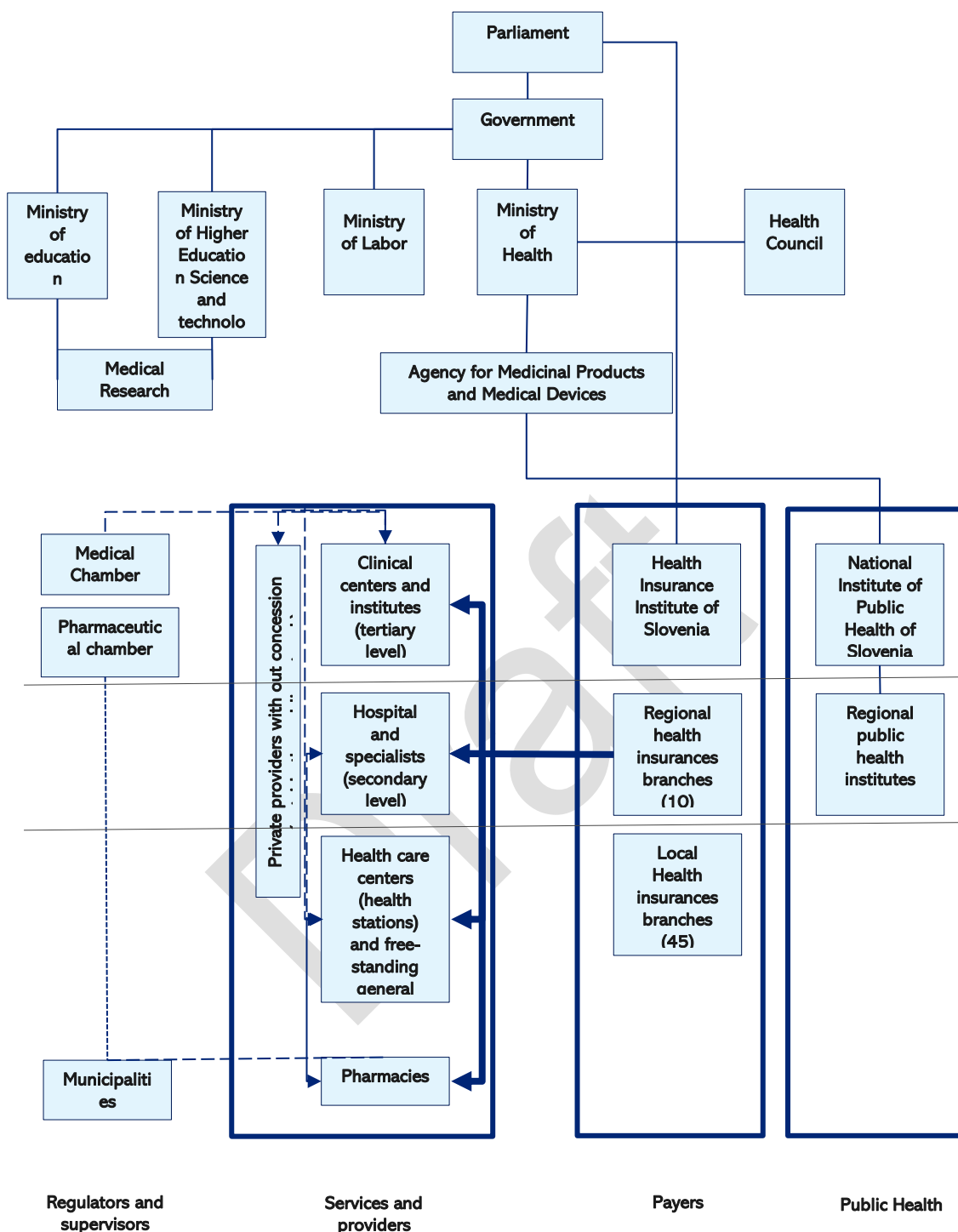


Figure 1. Organization of the Slovene Health Care system

d) Value system concerning solidarity

In Slovenia, compulsory health insurance contributions are the largest source of revenue for health system financing. They are regulated in the Healthcare and Health Insurance Act (1992) and have remained largely unchanged since 2002. Contribution rates, which are employment based and levied on gross income, vary by category and group of insured individuals. For regular employees, 13.45% of gross income is collected per insured person split between employers (6.56% for illness and injury out of work; 0.53%

for injuries at work and occupational diseases) and employees (6.36%). The contribution rates are the same for self-employed, yet their contribution base is equal to the gross pension base, but cannot be lower than 60% of last known average annual wage³. For pensioners, the Pension and Disability Insurance Institute pays contribution at 5.96% contribution rate from pension to HIIS. The unemployed or those not registered as employed are covered by state or local budgets.

The universality of insurance in Slovenia is high. The centralised compulsory health insurance system entitles virtually all persons with permanent residence in Slovenia – insured persons and their dependants – to all health services and benefits covered by the scheme.

At the end of 2020, there were 3,345, or 0.14%, uninsured persons (3,979 at the end of 2015, 4,083 at the end of 2016, 3,773 at the end of 2017, 3,430 at the end of 2018 and 3,050 at the end of 2019)⁴. These numbers include also temporarily uninsured persons waiting for a new status (e.g., students waiting for employment). Main reason is unregulated permanent residence, which is a condition for the inclusion in compulsory insurance scheme. Also, there were 15,892 persons with unpaid contributions, meaning that their rights to healthcare services were on hold and that they only had access to emergency medical services. This group is dominated by sole proprietors.

Complementary health insurance, which in Slovenia covers co-payments up to the full price of health services and medicines, is concluded by 95% of persons liable for co-payments (73% of total population). The reason for the high insurance is mainly in the high risk of co-payments as well as high absolute amounts of co-payments.

In order to assess the accessibility of healthcare, it is necessary to look at the basic benefit package, namely scope and depth of the coverage. The scope of the rights basket in Slovenia is very wide and includes certain services, often excluded in other EU countries: dental services for adults, physiotherapy, orthodontic treatment for children, hearing aids, nutritional supplements, speech therapy, rehabilitation of alcohol and drug addicts, treatment of injuries due to extreme sports, non-emergency ambulance services.

In spite of wide scope, the depth of the coverage is low: some of these services are only 10% covered by compulsory health insurance; the remaining 90% is covered by complementary health insurance. Wide scope of coverage in combination with complementary health insurance results in low out-of-pocket expenditures in Slovenia. If we took into account only public financing, namely compulsory health insurance, the accessibility to healthcare services would be importantly reduced and would be higher than in EU only in the field of dental care⁵. The accessibility is high, but only if the individual has a complementary health insurance.

As mentioned, out-of-pocket expenditures are relatively low in international comparisons. They amounted to 13.2% of the total health expenditure in Slovenia⁶. In 2019, direct OOP payments amounted to €259.3 *per capita*. In 2018, out-of-pocket

³ Health Care and Health Insurance Act

⁴ HIIS, Letno poročilo za leto 2021 [Annual Report for year 2020]. HIIS, Ljubljana, 2021. Available from: [http://api.zzzs.si/ZZZS/info/egradiva.nsf/0/a998991f0f548b4bc125868c0040ba61/\\$FILE/Letno%20poro%20%202020.pdf](http://api.zzzs.si/ZZZS/info/egradiva.nsf/0/a998991f0f548b4bc125868c0040ba61/$FILE/Letno%20poro%20%202020.pdf)

⁵ Zver E., Nagode M., Srakar A. Dostopnost do zdravstvenega varstva in dolgotrajne oskrbe [Access to health care and long-term care]. In: Gabrijelčič Blenkuš M, Kofol Bric T, Zaletel M, Hočevar Grom A, Lesnik T, (eds). Neenakosti v zdravju: izziv prihodnosti v medsektorskem povezovanju [Inequities in Health: a future challenge in intersectoral cooperation]. Ljubljana: National Institute for Public Health, 2021 (in press). [Inequities in health: future challenge in intersectoral cooperation]. Ljubljana: National Institute for Public Health, 2021.

⁶ OECD/EU, Health at a Glance: Europe 2020: State of Health in the EU Cycle, OECD Publishing, Paris, 2020. Available at: <https://doi.org/10.1787/82129230-en>.

expenditures were mostly used for medicines and medical devices (56%), followed by expenditures for ambulatory services (27%, out of which 11% is used for alternative medicine), 10% for dental care, 3% for long-term care and 4% for hospital care⁷.

The unmet needs in Slovenia increased sharply in 2017 to 3.5% and were at 2.9% in 2019⁸. This increase, however, was due to changes in the survey questions used as a basis to calculate the indicator. In the last ten years, the major challenge has been long waiting lists that thwart timely access to healthcare. Waiting times are the cause of much public debate in Slovenia and probably the major source of patient dissatisfaction with the healthcare system. The waiting lists have been consistently lengthening in spite of measures taken by decision-makers, such as occasional additional financing, penalties for referrals that do not follow the set criteria, and incentivising additional productivity⁹.

Insight into the factors and decisions that cause health inequalities is important for finding solutions and taking action to reduce inequalities. The authors of the recent study¹⁰ presented an analysis of inequalities in self-assessed health in Slovenia between the group of people with the highest and the group of people with the lowest household incomes. The analysis breaks down the health gap between the two groups in terms of the relative contribution of five important areas of life: healthcare (23%), income and social security (42%), housing and the environment (11%), social and human capital (17%), and employment and working conditions (8%).

The same study⁶ further elaborated the contribution of healthcare to self-assessed health status in Slovenia, which generally contributes 23% to the above-mentioned health gap. Differences in respondents' answers to questions about waiting for examination with GP and waiting in a GP's waiting room, self-assessment of the quality of services provided and costs related to a doctor's visit are considered as healthcare factors. Each of the four factors in healthcare system contributes more or less equal share to the health gap. In contrast, on average in EU countries, the lower contribution of healthcare to the gap in self-assessed health is almost entirely (92%) attributed to self-assessed quality of service.

e) Cultural accessibility

The accessibility to healthcare and inclusion into health insurance is often hampered due to cultural issues. The qualitative Research (11) identified the problems of vulnerable and uninsured in the following population categories: "Roma children", "middle-aged population due to alcoholism", "temporary or season workers who do not apply into health Insurance", "pensioners without complementary health Insurance", "immigrants, mostly women due to lack of information and administrative difficulties", "young older than 26 years", "workers, for whom the employers do not pay social contributions", "self-

⁷ SORS, Izdatki in viri financiranja zdravstvenega varstva v Sloveniji [Expenditures and Sources of Financing Health Care in Slovenia]. Statistical Office of Republic of Slovenia, Ljubljana, 2020. Available at: <https://www.stat.si/StatWeb/news/Index/8916>

⁸ Eurostat, 'Database', 2021. Available at: <https://ec.europa.eu/eurostat/data/database> (accessed 02 June 2021).

⁹ Prevolnik Rupel, V., Kuhar, M., Marušič, D., Decision-making in Slovenian outpatient care: can financial incentives reduce patient waiting lists? Medical Writing, 2021 (in press).

¹⁰ Yang, L., Kofol Bric, T., Pet osnovnih pogojev za enakost v zdravju [Five basic conditions for equality in health]. In: Gabrijelčič Blenkuš M, Kofol Bric T, Zaletel M, Hočevar Grom A, Lesnik T, (eds). Neenakosti v zdravju: izziv prihodnosti v medsektorskem povezovanju [Inequities in Health: a future challenge in intersectoral cooperation]. Ljubljana: National Institute for Public Health, 2021 (in press). [Inequities in health: future challenge in intersectoral cooperation]. Ljubljana: National Institute for Public Health, 2021.

¹¹ Huber I, Lipovec Čebtron U., Pistotnik S. Neenakosti in ranljivosti v zdravju v Sloveniji: kvalitativna raziskava v 25 okoljih. [Inequalities and vulnerabilities in health in Slovenia qualitative research in 25 environments]. Ljubljana: National Institute for Public Health, 2020. Available at: https://www.nijz.si/sites/www.nijz.si/files/publikacije-datoteke/neenakosti_ranljivosti.pdf

employed”, “farmers”, “users of illicit drugs”, “prisoners relieved from prison” and other vulnerable categories.

Most often the vulnerability of Roma community was brought to the attention as well as people with mental health problems, especially in young and children. A special group of homeless was mentioned as well in the interviews, where their vulnerability is not only in healthcare field, but is complex and multi-dimensional.

2.2 Quality of Care

Achieving high quality in the provision of healthcare services represents a basic factor in meeting the healthcare needs of the individuals. Quality is the principal point in the transformation of the healthcare system. A fundamental change in the way care is delivered and financed requires addressing every feature of quality, including:

- Understanding the gaps and variation from best practices and evidence based care and service
- Leveraging data, tools, and information technology to lead quality improvement
- Creating a culture of service excellence, safety, high reliability, and value
- Leading and governing toward population health
- Engaging with all key stakeholders, such as accrediting bodies, policy makers, payers, purchasers, providers, and consumers

Several systems exist to guide the process of quality improvement. At their core, all of these systems are approaches to complex problem solving. All the models discussed were initially developed for industries outside of healthcare. Their adoption in and adaptation to the field of healthcare quality improvement demonstrate the field's willingness to learn from the success of others. Although these models have different names, they have certain core commonalities. Most share the following basic format:

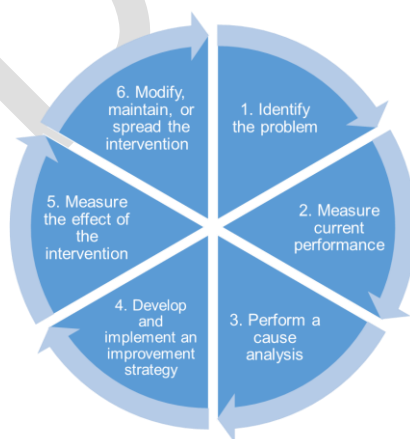


Figure 2: Model of system to guide the process of quality improvement

It is important to understand what one is trying to accomplish before determining how to do it. Applied to healthcare quality, the phrase highlights the need to understand the purpose behind the effort—the goal—at the individual, departmental, and organizational level before deciding what improvement process or approach to adopt. The following approaches, are the ones most applied:

- Model for improvement with the Plan-Do-Study-Act (PDSA) cycle

- Lean
- Six Sigma

Poor quality leads to increased expenditure. Foreign research suggests that 20 to 30¹² percent are due to rework, overused, misused, underused procedures, and defensive medicine.

Healthcare quality framework consists of clinical governance, management of the environment, evidence based practice, technical, QoC and PS competencies and positive interpersonal behaviour, teamwork and six dimensions of quality.¹³

While promoting the quality and safety of the health system and ensuring greater prosperity and faster development in Slovenia, it will be necessary to ensure more appropriate investment in health. Considering all the successful steps of upgrading the healthcare system, investments in staff, knowledge and innovation will be needed to find a balance between the wishes and real health needs of citizens.

2.3 Patient Safety

One of the most critical problems in healthcare is **PS**. A sense of safety is one of the patients' essential needs, a fundamental human right. Every contact of a patient with a process of care can comprise an intrinsic risk. The challenge for health systems and all facilities providing healthcare is to maintain heightened mindfulness to detect safety risks and address all sources of potential harm. The subject of PS I, a system defined as freedom from unacceptable harm, uses both retroactive and proactive approaches. A retroactive method is used after a preventable adverse event or near-miss has occurred. The proactive method looks at critical points in the system, helping prevent avoidable adverse events. Another recently recognized system is Safety-II, the approach where as much as possible goes well.

PS is a discipline in the healthcare professions that applies safety science methods toward achieving a trustworthy system of healthcare delivery. PS practice is an aspect of healthcare systems that minimizes the incidence and impact of adverse events and maximizes recovery from such events. The occurrence of adverse events due to unsafe care is most likely one of the 10 leading causes of death and disability in the world. In high-income nations, it is estimated that one in every 10 patients is harmed while receiving hospital care. In Organization for Economic Cooperation and Development (OECD) countries, 15% of total hospital activity and expense is a direct result of adverse events. Extrapolation of this number to the Slovenian situation reveals that around 35.000 patients are harmed due to adverse events in hospitals each year, and around two to three died each day. Approximately 50% of adverse events are preventable.

PS is recognized as a fundamental problem of healthcare in the EU, and elsewhere. Nevertheless, PS and CRM continue to be substantial challenges in implanting safety policies and practices. A **comprehensive system of PS** with all necessary components has been expressed by researchers and practitioners over the years.

The attitude to PS has changed over the last twenty years from a "blame and shame" or punitive culture to a systemic and just culture approach to the problem. It has slowly

¹² Leebov V, Ersoz CJ. The healthcare management guide continuous quality improvement. Lincoln: Authers choice press, 2003.

¹³ Robida A (ed). National policy for the development of quality in healthcare. Ljubljana: Ministry of Health, 2006.

moved from only retrograde analysis with special tools to a proactive approach with CRM.

To this day, healthcare systems and facilities provide quite variable degrees of performance in PS. This can be seen across the world and within countries. Errors provoked by flawed systems are common and keep causing harm to individuals. These problems are not unique to anyone's health system. However, for many years, they have shown to be mostly intractable. No one would argue that any harm caused to a recipient of healthcare must be tolerated. Basing every thought in every strategy, every step in the design of every program, every decision in every clinical encounter, every opportunity to learn when something goes wrong, on this approach would produce a new paradigm in healthcare.

2.4 Clinical Risk Management

Most human activities lead to some safety risks. CRM is about being aware of the potential of things that can adversely affect service/function (risks) and putting in place actions (controls) to ensure that the likelihood of them occurring is reduced so far as is reasonably practicable. A **risk** is something that **could happen**. An **incident** is something that **has happened**.

CRM is a specific form of RM focusing on clinical processes, directly and indirectly related to the patient. A uniform process for managing CRM is useful. CRM is a proactive system specifically concerned with improving the quality and safety of healthcare services by identifying the circumstances and opportunities that put patients at risk of harm and then acting to prevent or control those risks.

The **purpose of situational analysis in the domain of PS** is to look into the development of PS and CRM in Slovenia with the goal of developing a comprehensive PS system and CRM and closing gaps between the current situation and good practice based on scientific evidence in later phases of the project.

2.5 No-fault compensation model

Slovenian judicial system requires patients injured by medical negligence and in cases of avoidable medical injury to seek compensation through lawsuits, an approach that has significant drawbacks related to fairness, cost, and impact on medical care. Several countries, especially Nordic ones, New Zealand, France, Austria, etc. have replaced, in most cases, litigation with administrative compensation systems for patients who experience an avoidable medical injury. So called "no-fault" systems, such schemes enable patients to file claims for compensation without using an attorney. A governmental or governmental regulated adjudicating organization uses neutral medical experts to evaluate claims of injury and does not require patients to prove that healthcare providers were negligent in order to receive compensation. Information from claims is used to analyse opportunities for patient safety improvement. Although the systems in those countries differ, most of them have successfully limited liability costs while improving injured patients' access to compensation.

The costs of litigation may be large and may increase to a level that may place a drain on precious health-care resources and surely affect the way medicine is practised.

A change to a no-fault legal compensation system would lead to reduced costs, improved patient care and satisfaction in terms of QoC and PS.

First initiatives tackling new ways to compensate an injured patient, called no-fault compensation schemes in the Nordic countries date back to the 1980s and 1990s.

At that time there was no specific compensation scheme in place designed for the healthcare sector in Slovenia except civil litigation. Civil law was/is a legal ground to compensate only a fault based damage of an individual patient. There was no model in place to compensate a damage induced by preventable adverse events except for those, where major negligence was judicially proved. And that is still a case today.

In 1999 The Law on Medical Services (1 Zakon o zdravniški službi, available at: [Zakon o zdravniški službi \(ZZdrS\) \(pisrs.si\)](#)) was introduced which demanded from all medical doctors to buy fault-based insurance against malpractice with the insurance companies.

2.6 Quality of Care and Patient Safety in Slovenia

Movement for QoC and PS started in Slovenia in the late nineties of the twentieth century. The activities are shown in the brief history of their development (Appendix A).

The termination of the sole strategy for quality and safety in 2015 leaves Slovenia without a valid blueprint on a national level. The five years National Strategy for Health Quality and Safety launched in 2010 aimed for the systematic development of continuous improvements in healthcare.

During the time of the use of the strategy, most hospitals and many other healthcare providers accredited their management systems using one of the international standards. The financial incentives for the accreditation of healthcare providers and for monitoring quality indicators appeared later, in 2016, excluded from the contracts between the Health Insurance Institute of Slovenia (HIIS) and healthcare providers. Practical implementation of other definite measures suggested by the National Strategy has been rather sluggish. Several attempts to redesign the strategy have not been successful. However, there are several objectives in quality set in the Resolution on the National Healthcare Plan 2016-2015. Those include, for example, clear definition of the competencies and responsibilities of each stakeholder in improving quality and safety, and increasing capacity by ensuring human and financial resources, and strengthening training in quality, safety, and patient communication. The National Healthcare Plan also foresees an update of the set of quality indicators currently collected and of the adverse event reporting system. Furthermore, it aims at establishing a national PREMS framework. Since the adoption of the Resolution of the National Healthcare Plan introduced in 2016 a project began to develop a new adverse event reporting system. A standardized patient experience measurement in outpatient consultation has been introduced, while the survey of patient experiences in acute inpatient care has been updated. There has been experiments conducted to introduce Patient-Reported Outcome Measures (PROMs) into the healthcare system on a project basis (National tenders in 2010 and 2011), however, the PROMs were abandoned due to pressure from the healthcare providers.

The competent authority was and still is at the MoH, and this had many influences on the state of QoC and PS in Slovenia, mainly too slow development and not enough emphasis on comprehensive systemic development and especially sustainability of the executed work. There are many reasons for this which will be described in this paper.

To improve anything, it is necessary to firstly find where the problems and gaps are compared to the science of quality and PS, and practical experience of other nations.

In the later phases of the project, all the achievements and relevant work in the past and at the current work will be taken into consideration to develop an up-to-date comprehensive system of quality and PS and its sustainability.

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3. METHODOLOGY

3.1 Compilation of information

A desk review on legislation and existing documents on national policy, strategy, action plans, tools, and governance at the MoH and some of the healthcare facilities was carried out. The relevant recent recommendations, directives, and EC, OECD, and World Health Organization (WHO) studies have been evaluated. Significant Slovenian studies in peer-reviewed journals have also been examined. Relevant healthcare legislation has been examined using keywords in Slovene – quality (kakovost), PS (varnost pacientov), clinical guideline (klinične smernice), clinical pathway (klinične poti), quality indicators (kazalniki kakovosti), and accreditation (akreditacija) of healthcare facilities and indemnity/compensation (odškodnina/kompenzacija).

A workshop was conducted with Operating Working Groups (OWGs) and interviews were held with key stakeholders.

The collection of information from the MoH and other stakeholders during a workshop and through interviews was an essential first step to find the problems and opportunities for improvement in legislation, QoC, PS, CRM and a general opinion on introducing a no-fault compensation model.

3.2 Workshops

A workshop with OWGs was conducted in Slovenian on 28th May 2021 at the MoH. MoH state secretary announced the commitment to the improvement of QoC and PS. After that, short presentations of three topics were presented by four of the everis Slovenian experts - QoC, PS, CRM and no-fault compensation. The framework for situational analysis was confirmed.

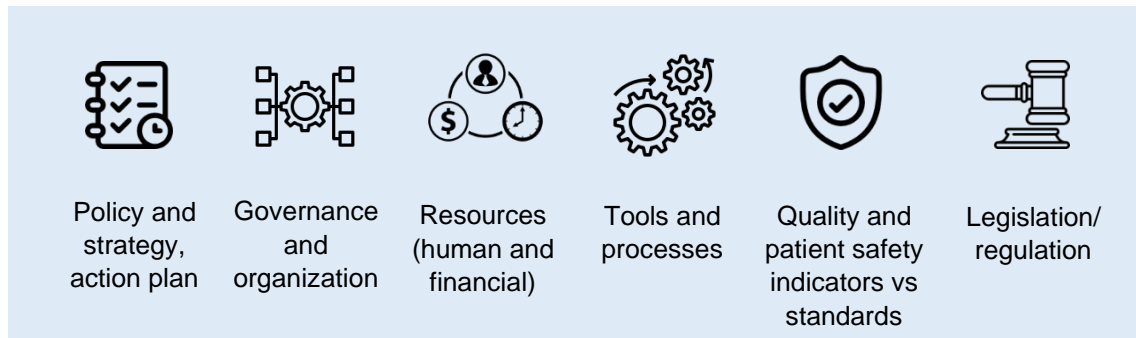
Next, each of the three OWG separately discussed the problems they would like to solve in short-term, medium-term, and long-term periods. It turned out that they would like to tackle everything in these three domains in the short term and some in the medium term. Thus the impression of all four experts was that QoC, PS, CRM, no-fault compensation and accompanying legislation were of great concern and that the governance of these domains should be strengthened. Concerns of the OWGs will be taken into consideration in the next phases of the project.

3.3 Interviews

Interviews with the representative of the MoH, National Institute of Public Health (NIPH), The Association of Health Institutions, Community health centre Ljubljana, Slovene Chamber of Pharmacy, Nurses and midwives Chamber - Association, National Committee for Healthcare Associated Infections (HAI), Patients' rights representative, Non-governmental Organization (NGO) - representative of patients, Slovene Medical Chamber, HIIS and Psychiatric Clinic Idrija were conducted at the MoH in person and with some stakeholders on-line on 16th and 23rd June 2021. The stakeholders gave their opinion on the problems, expectations and governance of quality and patient safety and no-fault compensation.

3.4 Structured analysis of the information

The proposed scheme to carry out an analysis of the current situation regarding **QoC, CRM and PS, and no fault compensation model** in Slovenia includes the following axes that will be analysed from the perspective of **QoC, CRM and PS, and no fault compensation model**:



Each of the previous axes will present an **executive summary** which includes the main identified gaps and main recommendations followed by an **explanation in detail** of the proper topic.

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3.5 SWOT Analysis



Strengths

- MoH is regulator in the field of QoC and PS
- The National reporting system for Sentinel Events
- Retention of accreditation system and ISO 9001 certification
- Perinatology information system
- National quality indicators methodology
- Model for chronic disease management in primary care
- Projects like PREMs, PROMs, PaRIS and SenSy



Weaknesses (1/2)

- Political influence/agenda - with every change of the government political plan, it has changed with different emphases on quality and PS priorities, awareness and commitment of the MoH
- Requirements of the Resolution on the National Healthcare Plan (2016-2025) have not been accomplished, apart from rare requirements
- Lack of adequate capacity at the MoH competent authority for quality and PS regulation and development
- No national governance and policy, healthcare providers are left to themselves
- No coordination of implementation – implementation of policy 2006 and the strategy 2010-2015 were scarcely implemented and has not been updated
- There are no core competencies for patients as stated in Council Recommendation 2009/C 151/0
- No political agenda of any kind for the type of compensation scheme for medical injuries, either fault or no-fault based
- Ongoing training on QoC, PS and CRM as part of the professional development of healthcare personnel is sporadic and no curricula are available
- No comprehensive regulated requirements for education for graduate, postgraduate, and healthcare employees for quality and safety
- No budget for research in QoC and PS and for projects to improve and research on health services, for training in PS and CRM at healthcare facilities



Weaknesses (2/2)

- No incentives or penalties linked to QoC and PS
- No job systematization for healthcare providers with the task of HAI management and prevention
- No benchmark among healthcare providers
- No standardized capacity for quality management at the healthcare providers' level
- Missing many QoC and PS tools
- No adequate information communication technology (ICT)
- The national upgrading of OECD Indicators is not followed
- Non appropriate management of indicators at local levels
- No good healthcare providers' competencies for QoC and PS
- Problems with HAI in many facilities, including primary care and nursing homes
- Noticeable differences in the assessment provided by the Nursing and midwives chamber among institutions accredited ISO 9001 or certified and those that are not
- Accessibility is a problem as the worst quality and PS is inaccessibility of healthcare providers especially at the level specialist care leading to worsening of the disease and even deaths of some patients while on the waiting lists
- Problem with informed consent in dental care
- Significant unjustified variability among healthcare providers regarding results of care
- Passive funding of healthcare providers – funded on activity volume and not also on quality and safety of care
- No political position or legal opinion on current Criminal Code which contains in its provisions several different criminal offences healthcare professionals may commit
- No exact data on type, the number of cases and amount of compensation paid in claims per year; no firm data on trends
- Lack of proper capacity and reluctance at the MoH for developing no-fault compensation scheme
- No data and no studies on a type and extend, quantity of defensive medicine and what are health and medical, economic and legal consequences and implications due to defensive medicine
- Lack of law on QoC and PS



Opportunities (1/2)

- Need to create a national independent body for QoC and PS
- Develop and upgrade the national quality and PS system in healthcare, including pharmacy - a common platform for the whole country
- Development of strategic objectives and action plan for quality and PS
- As quality and safety is a technical issue, establish that it doesn't depend on political agendas
- Inclusion of primary healthcare in the system of quality and PS
- Make requirements for education for quality and PS mandatory
- Develop multidisciplinary curriculum for QoC, PS and CRM
- Possibility to have better communication of the information to the patient from physicians health professionals
- Following four global aims of healthcare: improving the health of populations, reducing per capita costs of healthcare and improving the experience of care and satisfaction of healthcare personnel
- Improvement financial and human resources for QoC and PS at the national and providers level through the legislation
- Establishment of clinical indicators for dental care
- Develop missing tools and educate providers for using them by creating collaborative projects with providers
- Focusing on patients' journey and experience through healthcare system – coordination and integration
- Develop clinical national audits
- Creation of core national QoC and PS standards
- Arrangement of a no-fault system for patient compensation for avoidable adverse events. Collection of data on the type and number of cases of avoidable events, compensations awarded, mechanisms to collect, process of data and its management
- Design a new no-fault based compensation model, necessity to change several regulations including the Criminal for not considering human errors in healthcare as a criminal act
- More outstanding commitment of top management to quality and safety
- Upgrading audits of providers in the domain of QoC and PS
- Quality and safety management at the mid-level of the management in healthcare facilities
- Greater decision-making powers of the committee for HAI and not just the role of consultative body of the MoH



Opportunities (2/2)

- Action by the MoH for not meeting the nonconformities after an audit committee for HAI controls
- Monitoring outcomes of patients' healthcare
- No-fault compensation for patients experiencing avoidable adverse events
- Establishment of clinical indicators for mental health
- Amendment of the regulations including the Criminal Code in terms of decriminalization of human error
- Establish a law for quality and PS
- Design a draft Law on no-fault compensation in healthcare



Threats

- The same data for indicators are collected at two institutions (NIPH and the MoH)
- Clinical quality indicators for reference clinics - there is no feedback and that also affects nurses' motivation to collect these indicators In addition to delay in feedback nurses are questioning the aims of indicators as they should be a basis for quality and PS improvement and no or too late feedback the QI are not possible
- Communication of national committee for HAI with the MoH – rarely is there feedback on the committee proposal and findings of supervision of healthcare facilities
- Culture of fear for adverse events and near misses reporting with consequential error hiding, ascribing all adverse events to complications, and defensive medicine
- Accountability for different responsibilities for QoC and PS are not required for example, accountability for feedback on reference clinic indicators is not checked
- No funding for QoC and PS for projects to improve and research on health services, and for training in PS and CRM at healthcare facilities and at the national level
- Patients' organisations are not involved in policymaking
- No consistent mechanisms of using guidelines or spreading best practices

4. RESULTS

In order to accomplish the stated objectives, the current situation analysis will be carried out regarding **three dimensions**:



Quality of care



Patient safety
and risk
management



Patient
compensation

4.1 Policy and strategy (including mission, vision and principles)



Executive Summary

Main identified gaps:

- National policy for the development of QoC published in 2006 has not been updated
- National strategy for QoC and PS (2010 – 2015) has not been modernised
- Requirements of the Resolution on the National Healthcare Plan (2016 – 2025) have not been accomplished, apart from rare requirements (page 15)
- There is no PS strategy because the strategy for QoC and PS expired in 2016
- Patients' organisations are not involved in policymaking
- Measures to ensure dissemination of information about PS are not in the routine
- There are no core competencies for patients as stated in Council Recommendation 2009/C 151/0
- Reports in the national system for preventable adverse events and near misses face many obstacles and SenSy project has not yet been implemented
- Proper mechanisms to encourage reporting by health professionals do not work as there is significant underreporting
- No consistent mechanisms of using guidelines or spreading best practices
- National strategy and policy/Resolution on the National Healthcare plan 2016-2025 lacks of comprehensive IT supported data collection on avoidable and non-avoidable adverse events, managing and processing of data, use of data
- Lack of a policy for just and proper compensation scheme
- Lack of legal basis for no-fault claims
- Lack of mechanisms for patient empowerment

Main recommendations (1/2):

- Upgrade the National policy for the development of QoC and PS
- Develop a National strategy for QoC and PS, creating a new document with the modernization of previous work with present-day requirements
- Fulfilment of the requirements of the Resolution on the National healthcare plan 2016 – 2025
- Develop of PS and CRM strategy by developing a multidisciplinary curriculum of PS in phase 3 and 4 of the project by researching the relevant literature and experience at the domestic level
- Inclusion of a no-fault compensation scheme to the Government strategy and policy, patient empowerment mechanisms to ease claims procedures on several levels

Main recommendations (2/2):

- Adequate change of a Criminal Law in terms of decriminalisation, changes to Law on medical services and other legislation and bylaws

a) National policies

a.1. National policy for quality of care

National policy for the development of quality in healthcare was published in 2006. The content of the policy was based on international and national documents and publications. Its objectives were:

- **Objective 1:** Setting up structures at the healthcare organisational level with an example of such a structure
- **Objective 2:** Describing providers' and main stakeholders' activities and responsibilities
- **Objective 3:** Structures at the national level with recommended organisational chart of the National independent body for quality in healthcare

A table with gaps in fulfilment of requirements of the National policy is presented below:

The requirements fulfilled	No	Partially
Objective 2 was accomplished only partially, and the activities of stakeholders were dependant on their enthusiasm. Audit of the accomplishment of the activities.		Partially*
Objective 3 structures at the national level with recommended organisational chart of the National independent body for Quality in Healthcare	No	
Six dimensions of quality, including PS, were declared to be followed by all stakeholders		Partially*
Responsibilities for PS at a different levels of healthcare.		Partially*
Introduction of reporting and training on the basis of PS incidents focusing on the analysis of systemic causes of these incidents and not on the individual, except in the case of suspicion negligence or criminal offence.		Partially**
A proactive approach for reducing PS incidents with the help of applying risk management	No	
Management of the register of PS incidents and sentinel events, suggesting and implementation of measures for improvement.		Partially
Information for professionals and the public of achievements in quality and PS.	No	
Measurement of performance of QoC and PS and developing responsible teams, individuals, departments, activities and the entire healthcare organisations.		Partially*

Table 1. Gaps in fulfilment of requirements of the National policy¹⁴

a.2. National strategy for quality of care and patient safety

¹⁴ *Accomplished only at the accredited facilities and facilities with ISO 9001: 2015.

**Analysis of adverse events is conducted according to the Health Services Act by peers and according to their internal by-laws. The root cause analysis is rarely done and only in a few facilities.

Regarding the National strategy for QoC and PS (2010 – 2015), vision, mission and values were defined, and the MoH, or envisioned independent national body for QoC and PS was obliged to set up programs based on this strategy for each year with target goals for different levels of healthcare and different disciplines. There were four strategic goals with action plans with what to do, who, how, when and responsibility:

1. Development of systematic QoC and PS management.

- i. Establishment of a national independent body for QoC and PS in healthcare
- ii. Launch and implementation of internationally recognized quality management systems
- iii. Increase the activities of the committees, commissions and quality PS officers in healthcare facilities
- iv. Implementation of annual QoC and PS programmes
- v. Development of information technology in healthcare

2. Development of a culture of safety and quality.

- i. Development of a partnership among participants in healthcare with patient-centred processes

3. The establishment of a quality education and training system and PS

4. Developing systems to improve the effectiveness and efficiency of healthcare (23).

Below it is presented a table where the gaps in fulfilment of requirements of the National strategy for quality and PS are exposed:

The requirements fulfilled	No	Partially
Development of systematic quality and safety management		Partially*
Establishment of a national independent body for quality and safety in healthcare	No	
Launch and implementation of internationally recognized quality management systems		Partially*
Increase the activities of the committees, commissions and quality PS officers in healthcare facilities		Partially*
Implementation of annual quality and safety programmes	No	
Development of information technology in healthcare		Partially**
Development of a culture of quality and safety		Partially***
Development of a partnership among participants in healthcare with patient-centred processes	No	
The establishment of a quality education and training system and PS		Partially****
Developing systems to improve the effectiveness and efficiency of healthcare		Partially*

Table 2. Gaps in fulfilment of requirements of the National strategy for quality and PS¹⁵

¹⁵ *Accomplished only at the accredited facilities and facilities with ISO 9001:2015.

a.3. National healthcare plan

Regarding the resolution of the National Healthcare Plan (2016-2025), in chapter 6.3.4 titled: *Total Quality management and continuous QoC and PS improvement (25)*, the main activity regarding QoC and PS is the provision of a system of comprehensive quality in healthcare with indicators and reports accessible to a wide range of users – both healthcare providers, patients, and the payer. This will enable monitoring of the quality of individual healthcare providers and ensure accessibility to key quality indicators of individual healthcare providers to patients. At the same time, monitor patient satisfaction will also be monitored.

8 main actions are envisioned:

1. Legislative changes to determine the conditions and authorities to ensure continuous improvement of the QoC and PS of healthcare and patient-centeredness and regulation of the authorities of individual health institutions to control the quality
2. Updating and public access to the set of quality indicators to be monitored at the national level, including patient satisfaction
3. Modernisation of the monitoring system and the implementation of sentinel events and other adverse events
4. Adoption of a national strategy for the effective use of antimicrobials and the management of antimicrobial resistance in human and veterinary medicine
5. Establishment of a system for quality, safety, and patient/family - centeredness education on patients and family supporting research in this field
6. Adoption of the National Strategy for the Prevention and Control of Healthcare-Associated Infections
7. Education of communication in healthcare, with a focus on communicating with a patient
8. Provision of human and financial resources for the development of a quality system and its control System

There is also envisioned the development of a model for healthcare providers' payment by performance on the basis of selected quality indicators by preparing the by-laws based on Healthcare and Health Insurance Act and specified in the yearly General Agreement (GA) act.

With the following activities and actions, there will be a contribution to a working system of QoC and PS of healthcare (see table 3).

Unfortunately, the milestones were not reached with the exception of updating sentinel events and other events reporting in the project of EC. However, it was not implemented in practice.

*** No national system for CRM and register for PS. Partially accomplished at the accredited facilities and facilities with ISO 9001:2015*

****Initial survey using HSOPS in 80% hospitals and SAQ in primary care were performed in 2011 and 2018 respectively. The survey were not repeated, except once in 2 hospitals.*

*****There is no national comprehensive system for undergraduate educational facilities and professionals to accomplish curriculum in PS (19). There are some nursing conferences about PS and a short basic education for young physician for preparation of the state exam.*

Below are presented the specific goals of the resolution on the National healthcare plan:

Indicator of efficiency	Background value	Background year	Target value in the year 2025	Source of data	Milestone
1. Legislation changes	0	2015	1	MoH	2017
2. Strategies published on the MoH web page	0		2		2017
3. Quality indicators update	1		3		2016
4. The report on updating of sentinel events system monitoring*	0		1		2016
5. The report on carried out education on quality and patient	0		5		2025
6. The report on carried out education on communication in healthcare			3		2025
7. The report on human and financial resources for development system of Quality posted on the MoH webpage	0		1		2018

Table 3. Specific goals of the resolution on the National healthcare plan¹⁶

Apart from the adoption of a national strategy for the effective use of antimicrobials and the management of antimicrobial resistance in human and veterinary medicine (Strategy 2019-2024), and partially on adverse event reporting, all other activities were not fulfilled. The milestone for some is in 2025.

The recommendation regarding the national strategy for QoC and PS is based on an update of quality indicators: updating PS incidents reporting (realize SenSy project) and human and financial resources for quality and PS. These requirements are tasks of the present project and will be incorporated into the final report.

Below it will be presented a table with the fulfilment of the recommendations of Council Recommendation 2009/C 151/01 on PS, including the prevention and control of Healthcare Associated Infections (HAI as reported by self-evaluation by MoH).

Recommendation	Fulfilment		
	No	Partially	Yes
1. PS strategies			x
2. Competent authority			x

¹⁶ Items under # 1-3, and 7 were not accomplished

*Item 4 was partially accomplished but it is not yet in the system.

Recommendation	Fulfilment		
	No	Partially	Yes
3. Specific measures to prevent medication errors, HAI and complications during or after surgical intervention			x
4. ICT tools to support PS	x		
5. Measures to involve patient organisations in policy making	x		
6. Measures to ensure dissemination of information about PS to patients		x	
7. Core competencies for patients	x		
8. Reporting and learning systems in place			x
9. Reporting and learning systems fulfilling criteria as defined by the Recommendation		x	
10. Mechanisms to encourage reporting by health professionals		x	
11. Multidisciplinary training on PS in hospitals			x
12. PS embedded in the education and training of health professionals			x
13. Measures to inform health professionals about PS standards, guidelines or best practices			x

Table 4. Fulfilment of recommendations^{*17}

Figure 3 shows implementation by countries in the year 2014 (35).

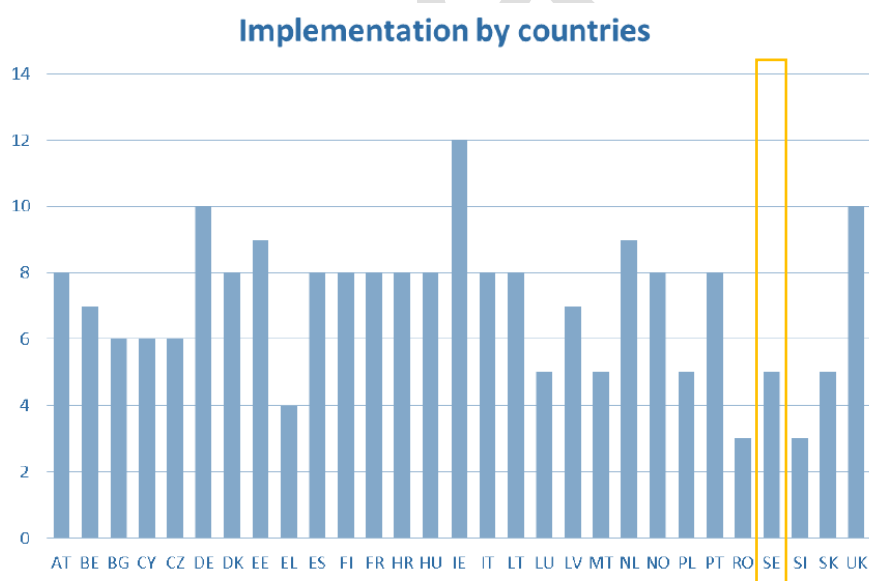


Figure 3. Implementation by countries of the 13 measures of PS

Source: Report from the commission to the council, 2014

b) Comments of everis team on the responses of MoH

Recommendation 1: there is no patient safety strategy. The strategy for quality and patient safety expired in 2016.

¹⁷ *The responses in this table were provided from MoH on 30th June 2021.

Recommendation 4: standardized ICT tools for patient safety are not available, as though the ICT for HFMEA was developed in the research and tested in one hospital. It had not been implemented in the healthcare system (35).

Recommendation 5: patients' organisations are not involved in policymaking.

Recommendation 6: measures to ensure dissemination of information about patient safety to patients is not the routine.

Recommendation 7: there are no core competencies for patients.

Recommendation 8: currently, only the national system for sentinel events is in place but the reports are rare due to many obstacles. SenSy project has not yet been implemented.

Recommendation 9: reporting and learning systems fulfilling criteria as defined by the recommendation depends on the will and commitment of each healthcare facility.

Recommendation 10: proper mechanisms to encourage reporting by health professionals do not work as there is significant underreporting.

Recommendations 11 and 12: multidisciplinary training on patient safety in hospitals depends on the free will of healthcare faculties, medical faculties and faculty of pharmacy to implement quality and patient safety in their curricula. There is also no use of a multidisciplinary WHO curriculum. The situation is better in faculties of healthcare than in medical faculties where there are no curricula on patient safety. There is an elementary few hours course on quality and patient safety for young physicians in training.

Recommendation 13: there is no patient safety standards, no consistent mechanism of using guidelines, or spreading best practices.

There were, to our knowledge, two surveys from OECD (2016 and 2019) in which the MoH took part.

Besides the responses provided in the table of Appendix B MoH had commented on some items to OECD regarding QoC. The everis experts commented on the answers from MoH and requested documents to prove the evidence. Most of the documents were not received. And the gaps regarding OECD 2016 are described in the Appendix B.

Web pages were provided by MoH for electronic documents on the Family Medicine Model Practices and national quality indicators (Appendix B).

c) Compensation claim procedures

Since there is a fault based insurance in place the complainants aim, in most cases, to prove a doctors guilt in order to get the legal basis for civil procedure and to be compensated for their damage. Chambers, especially the medical chamber are under heavy pressure from patients and public to play a "role of a judge" for civil lawsuits and also criminal cases.

Chambers have developed their rules i.e. bylaws on the basis of legal provisions in order to process complaints for alleged misconduct and/or breach of ethical rules of profession, against healthcare professionals.

The number of damage claims in healthcare is increasing over time, which is consequently causing a more frequent practice of defensive medicine and in most cases a more negative relationship between doctors or other healthcare professionals and patients.

The classical system of fault based compensation is unfavourable for parties to the dispute. Procedure render proving fault and causal relationship may be more difficult, while judicial proceedings are lengthy and litigation costs are generally high.

As long as medicine continues to foster a "blame and shame culture", underpinned by fear of litigation and by doctors themselves, mistakes will keep on happening. Both doctors and patients have colluded to create an impossible expectation of perfection, which makes it impossible to admit mistakes, let alone learn from them and prevent them from happening again.

Competent authorities for processing complaints struggle to get adequate health professionals to process complaints. The whole procedure is usually lengthy, processing complaint is not based on contradictory principles and many complainants think they are biased.

There is no statistical data available on the type and quantity of complaints as well as results of procedures.

4.2 Governance and organization



Executive Summary

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 QI and PS is not consistent
- Patient representation in official roles and decision-making processes are involved for public discussion after the documents are prepared by the government and not participating in the development of documents
- No systemic nationwide data collection in place on any type for adverse events
- No statistical data collection on court cases from the indemnity and criminal cases
- No independent national body with a power to effectively process patient complaints for medical professional and/or ethical misconduct

Main recommendations:

- Creation of independent national body for QoC, PS and no-fault compensation
- Invite representatives of patient groups in preparation of relevant documents and not only after they are published for public discussion
- 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

Slovenia's responses on PS governance function to OECD survey 2019, the requests from everis for documents/results, and MoH comments are provided in Appendix C. Some answers on requests from everis team were left empty, and only few documents/results confirming the responses from MoH were received.

National Policy for the Development of Quality in Healthcare envisioned establishing governance at the national and providers' levels, including the responsibility and accountability of each actor.

a) Governance

a.1. Governance at the national level

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 Adriatic and Vzajemna, and the HIIS. As the parties could not agree on issues pertaining to 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.

Competent authority. 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.

a.2. Governance at the healthcare providers level

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.

a.3. Governance at chambers with privileges for peer review

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

a.4. Governance at chambers, associations and other competent authorities for complaint procedures

Competent chambers and other associations, healthcare providers, regional patients ombudsmans etc. who have a 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 established for all functions, namely QoC, PS and for processing of no-fault compensation claims.

4.3 Resources (human and financial)



Executive summary

Main identified gaps:

Human:

- Safety and QI competencies built into the curriculum of students in various health disciplines are not present apart from some healthcare faculties
- There is no use of a multidisciplinary WHO curriculum on patient safety
- Ongoing training as part of the professional development of healthcare personnel is sporadic and no curricula are available
- Lack of medical doctors
- National Human Resources Plan is missing
- No trained professionals to deal with no-fault system and claims

Financial:

- No incentives or penalties linked to QoC and PS
- No budget for research in PS and QOC and for projects to improve and research on health services, for training in PS and CRM at healthcare facilities and for the functioning of the PS committee or PS officers as there are not full-time positions
- No financial sources envisaged to form a budget of app. 10 to 15M.EUR/year to process and compensate patients claims

Main recommendations:

Human:

- Develop multi-professional curriculum for the acquisition of competencies of PS at undergraduate and postgraduate schools of medicine and healthcare faculties and schools by continuously meet clear goals and timelines
- Develop a National Human Resources plan
- Obligatory professional development in the field of QI and PS with content prepared in advance
- Training of professionals (jurists, medical doctors and supportive staff) for dealing with compensation claims

Financial:

- Create incentives or penalties linked to QoC and PS
- Improve financial and human resources for PS and QoC at the national and providers level through the legislation
- Connect quality indicators with healthcare services purchasing
- A need to envisage sufficient budget for establishment and functioning of an independent body; a systemic funding needed

a) Resources

a.1. Human resources and appropriate institutions for education of health professionals

Despite a steady increase in the number of physicians, partly driven by migration from neighbouring countries, Slovenia has one of the lowest physician densities in the EU. In 2018, Slovenia ranked a modest 17th among the twenty-one Member States with 326 physicians per 100,000. In terms of the numbers of nurses (383 per 100,000) medical technician (645 per 100,000) and graduate midwife, Slovenia ranked in the first third

among the EU countries and in terms of the number of dentists (72.5 per 100,000 inhabitants) just below the EU average. There are high geographical variations among the number of medical staff: while the number of physicians is highest in Central Slovenia statistical region (463 per 100,000), it is lowest in the Coastal-Karst region (136 per 100,000)¹⁸.

In 2020, the number of general practitioners and paediatricians still lagged behind most EU countries, leading to problems of access and over-referrals to specialist care in some parts of the country. Nurse density was slightly above the EU average. Slovenia tried to solve the lack of medical doctors by opening second medical faculty Maribor in 2003. Also, provision has been made for foreign doctors to practice in Slovenia. Still, the issue of lack of physician has not been solved, especially in some defined specializations, such as primary care and anaesthesiology. Due to these difficulties, the question of task-shifting has been analysed and the scope of practice for community nurses has been widened to optimize patient-centred care. The model practices were introduced, described in the processes, unfortunately the evaluation of their introduction has never been conducted.

The gap of health professionals, especially medical doctors, with no national strategic plan on human resources represents a great risk in providing high quality and safety services in the future, especially if the healthcare decisions makers will insist in increasing productivity and efficiency in assuring the accessibility to healthcare services defined in benefit basket.

a.2. Payment mechanisms

The total budget for health services is divided among the healthcare providers through the negotiation process with main stakeholders, being HIIS on behalf of the patients, MoH on behalf of the Government and the healthcare providers of healthcare services. When the allocation of the funds is agreed, the defined models are applied for fund allocation. This procedure clearly defines healthcare provider budgets as well as the healthcare services they have to provide and which will be paid for by compulsory health insurance. In contrast, there are no pre-defined limits for private health expenditure. The GA with special agreements for different groups of healthcare providers are the key products of the first phase of contracting processes, which create the fundament for direct contracting negotiations between the HIIS and each healthcare provider.

The second stage of purchasing of health services involves HIIS and the specific healthcare provider within the public healthcare network. Definition of the GA includes special agreements for various groups of healthcare providers, on basis of which the contracts between the HIIS and each healthcare provider are concluded. The contracts specify the type and volume of services, but also the prices, methods of payments and other important elements, such as supervision and quality monitoring. Except for some of the programs (outpatient care, surgeries, dialysis services and the transplantation program), the reimbursement of provided services is prospectively defined and capped in way that healthcare services exceeding the negotiated amount are not paid by the HIIS. If a healthcare provider produces fewer services than determined by the contract, he/she is reimbursed according to the provided services. Voluntary health insurance companies do not participate in the negotiation process to define the GA and special agreements for different groups of healthcare providers but are mandated to reimburse the total value of the provided health services covered by complementary health insurance according to the annual plan negotiated in the GA. The relative value of voluntary health insurance coverage for different health services is defined by law.

¹⁸ NIPH. Zdravstveni statistični letopis za leto 2019 [Yearbook in Health Care for 2019] [Internet]. National Institute for Public Health. Available from: <https://www.nijz.si/sl/publikacije/zdravstveni-statisticni-letopis-2019>

Payment mechanisms used in Slovenia differ according to the health service category. In primary healthcare, a combination of capitation and fee-for-service is used. The planned income of the family medicine in the amount of 132,000 EUR at the annual level is divided into the capitation income (approximately 50%) and fee-for-service income (approximately 50%).

The capitation income is defined according to the number and age structure of the registered persons. Doctors with an above-average number of registered persons (more than 29,231 capitation coefficients per year) receive more funds than family physicians with a below average number of persons registered. Capitation is paid in a flat rate.

The other half of the income - the service part - depends on the services provided. Although the program of services is planned (27,488 coefficients per family physician per year), however, to obtain the whole service part of the revenue, it is sufficient to perform half of the planned services (13,000 coefficients). The acute care services (coefficients – relative prices) are listed in a catalogue. One coefficient is worth around 2.5 EUR, depending on the value of the total annual budget for family physicians¹⁹.

Outpatient care is paid on a fee-for-service basis. The payment is based on the planned (and realized) number of “points”, which historically reflect the estimated costs of the provided services. Each specialty has a defined set of services (short visit, expanded visit, ultrasound etc.) and each service is assigned a cost weight expressed in the number of points. These points reflect the labour costs (medical doctor specialist, nurse, administrative and laboratory staff), material costs, depreciation, and a separate informatization costs.

Acute inpatient care is paid on DRG basis and non-acute inpatient care on bed day of stay.

The payment methods used in Slovenia are based on the main guidelines of the developed health systems at all three levels, from primary to tertiary care. Unfortunately, there were no systematic incentives implemented to promote integration, improve accessibility and quality of healthcare services and awards for higher quality of service provided at the level of providers or individual healthcare worker.

a.3. Equity in fund allocation among levels

Equality and fair distribution of funds for healthcare is systemically conditioned. According to the legally regulated system of distribution of funds through the system of GA and the final arbitration decision of the Government (regulator), the values underlying the distribution of funds are respected by the partners. Strategic procurement and involvement of national patient-centered priority programs is limited, mainly due to the will to preserve historical ways and subtle but strong opposition to changes.

Most care is delivered by state-owned healthcare providers (hospitals and primary healthcare centres), who employ more than 83% of the total health workforce. Public healthcare providers (hospitals and healthcare centres) are members of the Association of public providers of healthcare. This Association represents the interests of organizations employed in these healthcare provider institutions and is one of the partners in negotiations on health services programs and their implementation.

Slovenia operates a typical gate-keeping system, in which patients need a referral for an outpatient (or ambulatory) specialist or hospital consultation. Although the primary care

¹⁹ Prevolnik Rupel V, Rotar Pavlič D. Suggesting changes to the payment system. In Švab I, Homar V (eds). Support for the development of the primary care system in Hungary. Ljubljana: Institute for development of Family medicine; 2021. 454 p.

system is strong, particularly since 2011 when the government upgraded family medicine practices and increased the emphasis on prevention and care coordination, service organization and delivery overall are highly fragmented.

Primary healthcare services within the public network are paid for by a combination of capitation and FFS, while outpatient specialised care is paid by FFS only. Payment for acute inpatient care is covered (in theory) by fixed allocations and DRG, whereas payment for non-acute inpatient care is calculated by the number of bed days per hospitalization. The volume of these programs is prospectively determined and the payment for the respective services is hence constrained. However, in practice, hospitals are allocated budgets according to available resources and historical volumes and they usually continue to treat patients after having reached the nominal DRG-based budget cap.

Secondary care services are provided by specialists' offices in hospitals, private specialists with concessions and ambulances, located in health centres on the primary level. Based on Eurostat data²⁰ there were 6.6 consultations of a medical doctor (in private practice or as outpatient) per inhabitant in 2018, with minimum of 2.06 visits in Cyprus and maximum of 10.88 visits per person in Slovakia. In Slovenia, 4.3 of the contacts per inhabitant were at primary and 2.3 were at secondary level.

From a strategic purchasing perspective, the role of HIIS is not as efficient as it could be. There is no systematic use of HTA, its application is strongest in the area of pharmaceuticals, and less regulated in other health technologies²¹.

In Slovenia, the payment of services was linked to the quality of services provided by measuring the results and effectiveness of the health services provided only in 2010, when the National Tender for hip replacement, hernia, varicose vein, and carpal tunnel release has been launched with a need of reporting PROMs. Unfortunately, despite promising results, the process has been abolished by HIIS in 2011²². In 2011, a broad set of quality indicators was set out and included in the contracts with HIIS with the expectation that hospitals would monitor and publish their performance. However, data limitations and the lack of external verification have impeded the reliability of the approach.

The outpatient payment methods regulated by Healthcare and Health Insurance Act and GA are not connected with any quality or safety indicators, healthcare providers are not monitored and paid for better provision of services, only productivity is expected²³.

Until 2012, patients' experiences were annually surveyed by the MoH. In general, satisfaction scores were high, the highest cumulative scores were in two privately owned specialized hospitals that provide public healthcare services²⁴. In 2008, the 'Decree on officiation with users in public healthcare'²⁵ was published. The Decree includes a requirement for all health service providers to measure patients' satisfaction monthly. According to the regulation, hospitals must report the feedback from users, which is to

²⁰ Eurostat. Databrowser. Available at:

https://ec.europa.eu/eurostat/databrowser/view/hlth_hc_phys/default/table?lang=en

²¹ Prevolnik Rupel V. Current Implementation of HTA in Healthcare System in Slovenia. *Int J Technol Assess Health Care*. 2017;33:360-364. DOI: 10.1017/S0266462317000083.

²² Prevolnik Rupel V, Erker R, Divjak M. Comparing Quality of Life of General Population and Orthopedic Patients in Slovenia. *Value in Health Regional Issues*, 2020; 22: 93-98. DOI: 10.1016/j.vhri.2020.07.575

²³ Prevolnik Rupel, V., Kuhar, M., Marušič, D., Decision-making in Slovenian outpatient care: can financial incentives reduce patient waiting lists? *Medical Writing*, 2021 (in press).

²⁴ MoH. Nacionalna anketa o izkušnjah odraslih pacientov v akutni bolnišnični obravnavi 2012. [National Survey on Patients' experience in acute hospital care in 2012]. MoH, Ljubljana, 2012. Available at: https://www.sb-brezice.si/pdf/Nacionalna_anketa.pdf

²⁵ Uredba o poslovanju z uporabniki v javnem zdravstvu [Decree on officiation with users in public health care]. Official Gazette of the Republic of Slovenia, No 15/2008, No 55/2017. Available at: <http://www.pisrs.si/Pis.web/pregledPredpisa?id=URED4943>

be evaluated and reported in annual reports of hospitals. The average scores, which were reported, are also high, with a general complaint about long waiting times. Additionally, a report on the protection of patients' rights is prepared on annual basis. Most of the recorded patients' contacts with patients' ombudsmen were requests for advice or informal support²⁶.

Tertiary activity is defined in the GA:

- 1) Tertiary activity ensures the implementation of the highest expert level of healthcare, research, development, and application of new knowledge in the field of national pathology and the transfer of knowledge and skills to health professionals and healthcare associates at all levels and the development of guidelines for the whole country
- 2) Tertiary activity also ensures issuing of opinions by competent clinics or institutes regarding the procedures for exercising the right to examination, and treatment abroad

According to this definition of tertiary activity, in addition to the provision of demanding services, the development and transfer of knowledge is also emphasized. Tertiary institutions with a concentration of professional, pedagogical and research potential are best suited for monitoring the development of medicine and health systems, acquiring new knowledge and skills in other countries and transferring them to other health professionals in Slovenia, developing clinical guidelines and clinical pathways, conducting undergraduate and postgraduate classes in clinical subjects, developing and testing new diagnostic and treatment methods and carrying out research activities.

In recent years, there have been slight deviations in the implementation of the content of tertiary activity. Due to the concern for maintaining the volume of funds, a significant part (in 2019: 78.3%) is used for expensive services. Due to the coverage of health services from compulsory and complementary insurance, the entire healthcare providers' budget is transferred into acute hospital treatment. An important reason lies in the stagnation in the development of the DRG and the delay in conducting national cost analysis, which is not available even 17 years after the introduction of the DRG system. Still, it should be mentioned that in the last ten years, for many very expensive services, such as transplants, price (weight) has been set.

The first part of the DRG introduction was completed seven years after their introduction with a reallocation of funds triggered by the introduction of the DRG. This meant that the same DRG group had a uniform price throughout the country, with tertiary activities having additional add-ons to the average weight of each tertiary institution. Thus, the prices of the same cases differ between secondary and tertiary institutions, as well as between individual tertiary institutions.

The GA defines the planned value of health programs for each year. In 2017 and 2021, the indicative value of the entire agreed program (compulsory and complementary health insurance) distributed by levels indicates a partial prioritization of the primary level. Between 2017 and 2021, the share of planned funds for primary healthcare increased (Table 5). Also, the growth rate of funds for

²⁶ GRS. Državno poročilo o stanju varstva pacientovih pravic za leto 2019 [National report on the state of patient rights for year 2019]. Government of the Republic of Slovenia, Ljubljana, 2 July 2020. Available at: <https://www.gov.si/assets/ministrstva/MZ/DOKUMENTI/Drzavno-porocilo-o-stanju-varstva-pacientovih-pravic-za-leto-2019.pdf>

primary care was higher than in specialist outpatient and hospital secondary and tertiary activities.

	2017	Share	2021	Share	2021/2017
Primary healthcare	494,397,145	26.0	664,941,681	26.4	134.5
Specialist outpatient and hospital and tertiary care	1,213,050,137	63.7	1,585.503,764	62.8	130.7
Spas	28,215,142	1.5	44,016,975	1.7	156.0
Pharmacy	44,710,299	2.4	55,710,168	2.2	124.6
Long-term care	124,222,151	6.5	173,173,687	6.9	139.4
SKUPAJ	1,904,594,874	100.0	2,523,346,275	100.0	132.5

Table 5: Planned funds by levels of care in EUR, 2017 and 2021

Source: General Agreement 2017 and 2021²⁷

To cushion the impact of COVID-19 epidemics, 2018 and 2019 can be compared. The comparison shows the growth of planned funds in 2019 at the primary and secondary level except in the community service and acute hospital level. In all activities of the primary, secondary and tertiary levels, the service plan was exceeded, which is largely due to the built-in incentives in the payment system. The highest increase in achieved visits between 2018 and 2019 was noticed at the primary level with 2.47%²⁸.

Some quality and safety measures have been introduced in GA, but without any connection with the appropriateness of fund allocations between the three levels. Production for clinical pathways is the yearly obligation of hospitals, but no monitoring is provided. The obligatory accreditation process for hospitals was removed from GA in 2016 to become voluntary without financial consequences.

a.4. Comprehensiveness and availability of equipment for well-equipped service

Investment in medical equipment is the responsibility of the owner of the particular healthcare facility. For investments in new technology, the Health Council at the MoH approves costs, based on national priorities, scientific justification, and the economic sustainability of the proposed programme. In 2003, the MoH and the HIIS introduced a centralized procedure for purchasing medical equipment, devices, and aids. This measure aimed to increase transparency in terms of spending public money, and to reduce prices. Consequently, the MoH assured equitable geographical distribution of equipment. There is no estimation of national needs regarding medical equipment, nor has there been any activity in terms of preparing a national plan on investments in healthcare.

All public tenders for major pieces of medical technology are prepared and conducted by the MoH itself. National funds within the Ministry's budget are set aside for these investments. Minor investments are funded by healthcare providers themselves. Primary healthcare offers basic diagnostic and imaging tools, such as radiology and ultrasound devices. More specialized procedures are available at the secondary care level.

²⁷ HIIS. GA for years 2017 and 2021. HIIS, Ljubljana, 2017 and 2021. Available at: <https://www.zzs.si/?id=126&detail=F6C0DA6F659694F6C12586EF00234EDE> and <https://www.zzs.si/?id=126&detail=82D005B0A48C9A75C1258164002781BA>

²⁸ HIIS. Poslovno poročilo za leto 2019 [Business Report for year 2019]. HIIS, 2020. Available at: <https://www.zzs.si/novica/obvezno-zdravstveno-zavarovanje-v-letu-2019-obravnavajava-in-javna-objava-poslovnega-porocila-zzs-za-letu-2019-ljubljana-27-2-2020/>

The number of magnetic resonance imaging (MRI), computed tomography (CT) and positron emission tomography (PET) scanners has risen since the mid-2000s but is still low²⁹.

According to data for 2017, Slovenia has 24 MRI and 30 CT devices available within the public health network. Compared to EU countries, Slovenia has a significantly lower number of CZT and NMI devices. In 2017, the number of MRI devices per 1,000,000 population in Slovenia was 11.6 or 4.2 less than in the EU (15.4), and the number of CT devices per 1,000,000 population was 15.0 or 9.1 less than in the EU (24.1). In terms of the number of MRI devices per million inhabitants, Slovenia reaches about 75% of the EU-28 average, and in terms of the number of CT machines it reaches about 65% of the EU-28 average^{30,31}.

There are not many data available on investments in equipment in public health institutions. According to the published article³², the difference between spent and calculated depreciation in all public health institutions 2018 is expected to be EUR 37.9 million (EUR 34.5 million in 2017). The write-off rate of equipment is estimated to 82.3%, in hospitals only 82.8%. Such a high percentage is attributed to inadequate financing of services, which forced contractors to use funds to cover depreciation costs due to liquidity problems, preferring to cover to cover labour costs and material costs, because the funds received were not sufficient. At the end of 2020, the share of written-down value of the equipment was 80.8%³³ (Table 3). Currently, a preparation of draft legislation on investment in healthcare for 2021-2031 is underway. Its aim is to modernize and increase the sustainability of the public healthcare system by investing €1,943.3 million in new education and treatment facilities, equipment, and human resources³⁴.

	2016	2017	2018
Hospitals	494,397,145	664,941,681	134.5
Primary health centres	1,213,050,137	1,585,503,764	130.7
Other institutions	28,215,142	44,016,975	156.0
All	1,904,594,874	2,523,346,275	132.5

Table 6. Degree of written-off equipment

Source: Jevševar T, Novis, 2019

Since the structure - inputs - represents one of the three pillars of the quality of the healthcare system, lack of equipment can influence the quality and safety of healthcare services provided.

²⁹ Albreht T, Pribaković Brinovec R, Jošar D, Poldrugovac M, Kostnapfel T, Zaletel M, Panteli D, Maresso A. Slovenia: Health system review. Health Systems in Transition, 2016; 18(3):1–207. Available from: https://www.euro.who.int/__data/assets/pdf_file/0018/312147/HiT-Slovenia_rev3.pdf

³⁰ HIIS, Poslovno poročilo za leto 2019 [Business Report for year 2020]. HIIS, Ljubljana, 2020. Available from: <https://www.zzzs.si/zzzs-api/e-gradiva/podrobnosti/?detail=968A5DF3E47B29B4C125851C0035369D&cHash=81f1d95852d9352d860ff680978c2b68>

³¹ OECD (2019), Health at a Glance 2019: OECD Indicators, OECD Publishing, Paris, <https://doi.org/10.1787/4dd50c09-en>.

³² Jevševar T, (Non) investment as a development lag, Novis 7/8, 2019

³³ Ferlič Žgajnar, B., Zdravstveni zavodi izboljšali likvidnost [Healthcare institutions have improved their liquidity situation], Delo, 11.03.2021a. Available at: <https://www.delo.si/novice/slovenija/zdravstveni-zavodi-izboljsali-likvidnost/>

³⁴ Ferlič Žgajnar, B., Dve milijardi za zdravljenje zdravstva [Two billion to heal healthcare], Delo, 05.06.2021. Available at: <https://www.delo.si/novice/slovenija/dve-milijardi-za-zdravljenje-zdravstva/>.

a.5. Competence and empathy of health professionals

The competences of all health profiles are defined in a List of professions in healthcare³⁵. The competences of some health professionals are further defined by documents prepared by chambers of health professionals³⁶. National competences have been adjusted to European regulations and competence descriptions.

Empathy is mentioned in Recommendations for care at home (as well as in introduction on webpages of some healthcare institutions), but is not systematically measured or mentioned in strategic documents at the national level.

The research of the empathy among healthcare workers is sporadic and limited to the research performed by students. A study in 2016 used Hogan's scale to measure empathy among healthcare workers. The study found that the healthcare workers, contrary to the expectations, have a low empathy score (33.55± 6.39 out of maximum 64 points). The research showed that healthcare workers with higher education had higher score. Furthermore, the healthcare workers in long-term care had higher score than those working in healthcare institutions.

Another research (37) among the employees in one of the primary healthcare centres showed, that only 49% of the participants agreed that empathy and communication are important in their profession. The sample in the research was small, non-random, and unrepresentative. Results of the survey among the nurses in anaesthesiology department in intensive care in University Clinical Centre Maribor³⁸ showed that 73% of nurses use communication with empathy, 21% uses it only occasionally and the remaining 7% do not use it.

Technology has made a significant contribution to reducing the level of empathy of health professionals, which can be seen as problematic especially in COVID-19 pandemic, but is also important to highlight that not only the Technology but also the attitude of healthcare professionals is relevant in the level of empathy. Long-distance treatments and patients monitoring came at the expense of changing the way doctors and nurses communicate with their patients. Less opportunities for direct contact with the patient hinder the ability to develop relationships with patients, monitor their nonverbal communication, and obtain feedback on the interaction.

a.6. Measures for engagement, motivation of healthcare workers, rewards, sanctions – cost and savings estimate

All medical staff in public healthcare are public workers and are paid according to public sector salary system act³⁹. The group marked "E" are workers in healthcare, who are divided into 4 groups: physicians and dentists, pharmaceutical workers, nurses, healthcare workers and co-workers. The basic salary of a civil servant is determined by the salary grade of the position or title to which the civil servant is assigned or which

³⁵ Seznam poklicev v zdravstveni dejavnosti (UL 82/2004, 110/2004, 40/2006)

³⁶ MoH, Nurses and Midwives Association of Slovenia. Poklicne kompetence in aktivnosti izvajalcev v dejavnosti zdravstvene nege. [Professional competencies and activities of practitioners in nursing care]. Ljubljana, 2019. Available at: https://www.zbornica-zveza.si/sites/default/files/doc_attachments/dokument_kpa_vzbn_16.5._2019_sprejete.pdf

³⁷ Železnik, H. Komunikacija in pomen empatije v zdravstveni negi [Communication and empathy in nursing care]. University of Maribor, Maribor, 2016. Available at: file:///C:/Users/IERUser/Desktop/VS_Zeleznik_Helena_2016.pdf

³⁸ Knuplež, U. Pomen empatije pri obravnavi pacienta v enoti intenzivne terapije [Use of empathy in patient care in intensive care unit]. University of Maribor, Maribor, 2015. Available at: <https://core.ac.uk/download/pdf/67594372.pdf>

³⁹ Public Sector Salary System Act [Zakon o sistemu plač v javnem sektorju]. Official Gazette of the Republic of Slovenia No. 108/09 and updates. Available at: <http://www.pisrs.si/Pis.web/pregledPredpisa?id=ZAKO3328>

he/she acquired through promotion. Each civil servant, also medical and healthcare staff, have right to wage supplements, for example for work in special circumstances (night shifts, radiation etc.). Since the salary system includes all civil servants, it is very difficult, or maybe impossible, to get very creative, motivate and/or financially reward individuals for their outstanding results. On the other hand, the financial sanctions are, similarly, impossible for less effective workers in healthcare. Levelling the wages of all healthcare workers is non-motivating; employers' hands are to a large degree tight. Introducing new measures and incentivizing healthcare providers to follow them is possible, though, at the level of provider (organizational level), which is essential for many healthcare providers, especially those, who work as sole proprietors as specialists (dentists), and have concession for work in public sector (who are paid by HIIS). For such small healthcare providers, the changes at organizational level impact their income and salaries. For large healthcare providers, such changes would impact the income of the hospital or healthcare centre and their annual financial results, which will further impact the position of the institution, but will leave the salaries of the employees largely unaffected. Introducing quality and safety principles in healthcare can be included into payment system at organizational level. Currently, as the indicators are not fully implemented in a sense of feedback loop⁴⁰ and improvements in the system; as the indicators are not calculated and analysed taking into account case-mix variables; as the data collection and reporting is not monitored and improved with the healthcare providers; as the system of digital support for indicators' collecting is not in place and as indicators are still defined at the level of inputs and outputs (and not outcomes), it is still too early to introduce the payment according to the quality even at the organizational level.

4.4 Tools and processes



Executive Summary

Main identified gaps (1/2):

- PS reporting and learning processes and tools in progress (SenSy needs more revision and plan for its implementation)
- No processes and tools for analysing adverse events due to errors or violations and near misses
- No national standardized information technology support for PS and CRM
- ICT tools for PS are not available as though the ICT for Healthcare Failure Mode and Effect Analysis (HFMEA) was developed in the research and tested in one but not implemented in the healthcare system
- Rare support for psychological safety and care of second victims
- The accreditations system set up in 2004 and endorsed by Medical Council but not implemented due to political issues
- The penalty was abolished from MoH at the time of change in the government and most of healthcare facilities stayed on the path of accreditation and some were left out

⁴⁰ Berwick DM, James B, Coye MJ. Connections between quality measurement and improvement. *Medical Care*, 2003, 41(1 Suppl):I-30–I-38

Main identified gaps (2/2):

- The contracting and/or commissioning arrangements include safety requirements stipulated in the yearly GA act but there are no audits to confirm these requirements
- The last measurement of safety culture in 16 of 26 hospitals was performed in 2011 and in 5 psychiatric hospitals in 2019. There is no evidence that leadership and management promote PS culture
- PREMs was not psychometrically evaluated and thus cannot be generalized and it is not clear how each entity of healthcare tried to improve patient experience after receiving the results
- Almost no research or projects to improve PS and QoC, apart from some international projects like PREMs, PROMs and Patient-Reported Indicator Surveys (PaRIS) and projects financed by EC
- No common platform where the projects could be accessible for engaging public
- No independent peer review of HSPA about QoC and PS. Outcome indicators for certain diseases only were presented
- Yearly national plans to celebrate 17th September-world PS day has not reached all healthcare facilities to raise awareness of PS among professionals, politicians and the general public

Main recommendations:

- Involvement of all healthcare providers by requirements for mandatory accreditation
- Developing online national reporting of indicators and auditing the QoC and PS requirements as the incentives at all levels of healthcare prepared by HIIS and stakeholders
- Prepare for measurement of PS culture and tools to improve it
- Usage of the already psychometrically evaluated questionnaires and adapted other well evaluated international questionnaires for other entities of healthcare
- Develop missing tools and educate providers for using them by creating collaborative projects with providers

The accreditation system was not implemented. When the new minister international accreditation scheme was accomplished, there was a penalty of 0,3% yearly budget for healthcare facilities if they had not started preparation for being accredited. The penalty was abolished from MoH at the time of acchange in government.

Some of the accredited healthcare facilities use specific tools for PS improvements, such as PS walk around, PS briefs, reporting systems developed by themselves, sentinel events reporting to MoH, and structured patients' handovers.

a) Availabilities

a.1. Implementing an integrated approach

The Resolution on the National Health Plan⁴¹ “seeks to strengthen primary care and provide greater access to comprehensive and quality treatment through better care integration and a more adequate professional skill-mix across care levels”. The upgrading of family medicine practices in 2011 was an innovative government initiative to improve care coordination and the management of chronic diseases. Upgraded

⁴¹ Resolution on the National Health Care Plan 2016-2025 »Together for Health« [Resolucija o nacionalnem planu zdravstvenega varstva 2016–2025 »Skupaj za družbo zdravja«]. Official Gazette of the Republic of Slovenia, No. 25/16. Available from: <http://pisrs.si/Pis.web/pregledPredpisa?id=RESO102>

primary healthcare teams or 'model practices' include a designated nurse who has a part time responsibility to screen for chronic disease risk factors, preventive counselling and care coordination. Additionally the nurse received specific training including screening for chronic disease risk factors and preventive counselling for patients aged 30 and over, as well as the care coordination of all registered patients with a stable chronic disease. Following the asthma and chronic obstructive pulmonary disease (COPD) modules⁴², training was expanded to include the arterial hypertension, coronary disease, diabetes⁴³, and osteoporosis and prevention modules⁴⁴. The purpose of family medicine "Model practices" operation is to improve the quality of work with an active approach in the promotion of health, screening for the most current health problems of the adult population and systematic management and monitoring of patients with stable chronic diseases. The new way of increased the accessibility of the whole population to high-quality and safe healthcare.

By 2014, about half of all primary care provision was in such 'model practices' and by 2018 most practices included an additional nurse. Annual costs for model practices are estimated to 13 million EUR, the effects of their functioning have not been evaluated yet.

The primary healthcare system represents a main base of the Slovenian healthcare system, nearly 4 out of 5 problems can be solved at the primary level, the fifth one with appropriate integration with secondary and tertiary healthcare levels.

Implemented "model practice" can represent a solid base for further integration in provision of healthcare services.

a.2. Availability of standards and norms

Standard is a statement of the expected quality level, it clearly defines the necessary inputs for service delivery: how things should be developed, implemented, and what will be the results. For the realization of any health activity, there are three steps according to which work needs to be done: input – resources, how to accomplish goals - processes and the knowledge what we expect - results.

The state, via legislative and executive bodies (ministries, state agencies and offices), has administrative and regulatory functions. The state can pass laws and by-laws, along with implementing standards and other mechanisms to assure the prevention of communicable diseases, a health-friendly environment and protection and health in the workplace.

Healthcare and health Insurance Act⁴⁵ stipulates in Article 26 that the HIIS is competent to define standards and norms (in agreement with the MoH) which are later the subject of discussion between the partners. So far, HIIS has neglected these assigned duties by law.

Significant attempts have been made to improve the situation, for example through a programme for the standardization of equipment as well as by the introduction of technical guidelines. The MoH is trying to implement standards for medical premises and

⁴² Poplas-Susič T, Švab I, Klančar D, Petek D, Vodopivec-Jamšek V, Bulc M, et al.. Screening and registering patients with asthma and COPD in Slovenian primary care: first results. *Slovenian Journal of Public Health*. 2015;54:161–167. DOI: 10.1515/sjph-2015-0023

⁴³ Petek D, Mlakar M. QoC for patients with diabetes mellitus type 2 in 'model practices' in Slovenia—first results. *Slovenian Journal of Public Health*. 2016;55:179–184. DOI: 10.1515/sjph-2016-0023

⁴⁴ Petek Šter M, Šter B. Pomen izobraževanja diplomiranih medicinskih sester v referenčnih ambulantah: primer arterijske hipertenzije. *Obzornik zdravstvene nege*. 2015;49:52–59. DOI: 10.14528/snr.2015.49.1.46

⁴⁵ Health Care and Health Insurance Act [Zakon o zdravstvenem varstvu in zdravstvenem zavarovanju], Official Gazette of the Republic of Slovenia, No 9/1992, No 72/2006. Available at: <http://www.uradni-list.si/1/objava.jsp?urlid=200672&stevilka=3075>

equipment as well as measures for the assessment of new methods of treatment (e.g. medical effectiveness, economic efficiency, social aspects). However, these processes have not been completed yet. However, a special committee appointed by the MoH must still approve the premises to ensure that they conform to spatial and construction standards. There are national standards for physical infrastructure (i.e. premises that need to be modernized). However, there are fewer standards regarding equipment and types of appliances to be used by various clinical and hospital departments. Such decisions are predominantly based on empirical and practical experience, and partly also on foreign approved standards.

Since 2015, the Medical Chamber has been responsible for setting the standards for postgraduate training for dental specializations and for continuous medical education. Doctor of Dental Medicine have to undergo similar procedures as medical doctors in order to obtain their dental specialty training.

Patient Rights Act Article 4⁴⁶ sets important general limitations to the patient rights, among other things stating that their realization must take into account the right to healthcare services (social rights to healthcare), as determined in other laws and regulations, and modern medical doctrine and standards (e.g. physicians have the right to refuse treatment if it is not medically necessary).

a.3. Availability of and access to health-related information

Health-related information are plentiful, collected by registries, located either with the providers of healthcare or with NIPH. The health-related information captures the health status of the population and reports on health status, equality of access and equality of health according to various variables are regularly reported and published. A lot of the data is publicly accessed and published by Statistical Office of Slovenia or NIPH, however, the data is mostly published with a delay of two or three years.

Much less data is available that describe Health-Related Quality of Life (HRQoL) in connection to treatments and procedures. Cancer registries are a service for the systematic collection, storage, analysis, interpretation and presentation of data on cancer patients, their disease and treatment in Slovenia. Cancer reporting is mandatory and legal. More detailed information can be ordered by doctors, researchers and the public using a special form.

Registries are a valuable source of information on patients and their treatments but include mostly clinical data without HRQoL and PROMs. The data in the registries lack external evaluation procedures and could be underutilized. The applications to obtain the data from the registries are limited and technically less user-friendly. The Cancer Registry is one of the oldest population registries in Europe. It was established in 1950 at the Ljubljana Oncology Institute as a special service for collecting and processing data on all new cases of cancer (incidence) and on the survival of cancer patients. The Cancer Registry of the Republic of Slovenia has been a regular member of the International Association of Cancer Registries since its establishment in 1968, and from the very beginning also of the European Cancer Registry Association⁴⁷.

The Healthcare 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

⁴⁶ Patient Rights Act [Zakon o pacientovih pravicah], Official Gazette of the Republic of Slovenia, No 15/08, 55/17 in 177/20. Available at: http://pisrs.si/Pis_web/pregledPredpisa?id=ZAKO4281

⁴⁷ Institute of Oncology Ljubljana. Register raka Republike Slovenije in drugi registry [Cancer Registry of the Republic of Slovenia and other registries] [Internet]. Onkološki Inštitut, 2021. Available from: <https://www.onko-i.si/rrs>

purpose, reports, data reporter, controller, and data delivery method and data retention time⁴⁸.

The endoprosthesis registry contains extended information about the patient, the provider of healthcare, the prosthesis, the operation, or the reoperation. The collection is managed for: monitoring the survival (time from insertion to removal) of inserted hip and knee endoprosthesis, ensuring quality control of endoprosthesis operations, enabling rapid detection of lower quality endoprostheses, indirect reduction of costs of primary and revision hip and knee endoprostheses and as a basis for clinical and epidemiological studies and expert analyses. The registry manager is hospital Valdoltra, which prepares an annual report based on data sent on an ongoing basis by all healthcare providers and other legal and natural persons, regardless of the concession, who perform the arthroplasty medical activity⁴⁹.

a.4. Availability of implementation strategies and research on health service delivery

There are two types of implementation strategies; passive strategies, which include the use of educational materials, posters, toolkits and visual aids, or active strategies, which include interactive workshops, academic detailing, audit and feedback and reminders⁵⁰. The evidence suggests that passive strategies may have modest beneficial effects, but do not necessarily lead to sustained behaviour change. In contrast, active multifaceted strategies appear to have the greatest impact⁵¹. In addition to the type of strategy used, both the individual practitioner and the organization perspectives should be considered in the implementation strategy.

The effectiveness of implementation strategies is rarely ever tested specifically for the allied health therapy group. When considering implementation of evidence informed interventions in allied health a multi-pronged approach appears to be more successful⁵².

In Slovenia, the propensity to prepare strategies is extremely high, some of which are constitutionally or legally conditioned, such as the umbrella strategy of the healthcare system adopted in 2016⁵³. The strategy stipulates the implementation of the obligations prescribed by the Constitution and laws regarding the provision of access to adequate, high-quality and safe public healthcare to all residents. Ensuring adequate healthcare interferes with the field of healthcare, as well as with all other essential areas of state activity: taxes, economic activity, social, environmental and other policies. Activities in these areas should direct society and the state to create conditions and conditions conducive to a healthy lifestyle of the population. The measures are aimed at ensuring quality and financially sustainable care for the population and reducing inequalities in the field of health and the provision of services. One of the means to achieve this is investment in research, planning and development of human resources, information

⁴⁸ Healthcare Databases Act [Zakon o zbirkah podatkov s področja zdravstvenega varstva]. Official Gazette of the Republic of Slovenia, No 61/2010. Available from: <http://pisrs.si/Pis.web/pregledPredpisa?id=ZAKO1419>

⁴⁹ Orthopedic Hospital Valdoltra. Register Endoprotetike Slovenije [Registry of Endoprosthetic of the Republic of Slovenia] [Internet]. Ortopedska bolnišnica Valdoltra, 2021. Available from: <https://www.ob-valdoltra.si/si/raziskovalna-dejavnost/register-endoprotetike-slovenije>

⁵⁰ Comisso I, Lucchini A, Bambi S, Giusti GD, Manici M. Nursing in critical care setting: an overview from basic to sensitive outcomes. Springer, 2018.

⁵¹ Grimshaw JM, Russell IT. Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations. *Lancet*. 1993;342(8883):1317–22.

⁵² Goorts, K., Dizon, J. & Milanese, S. The effectiveness of implementation strategies for promoting evidence informed interventions in allied healthcare: a systematic review. *BMC Health Serv Res* 21, 241 (2021). <https://doi.org/10.1186/s12913-021-06190-0>

⁵³ Resolucija o nacionalnem planu zdravstvenega varstva 2016–2025 »Skupaj za družbo zdravja« Resolution on the National Health Care Plan 2016–2025 (ReNPZV16–25). Official Gazette of Republic of Slovenia No. 25/2016. Available at: <http://pisrs.si/Pis.web/pregledPredpisa?id=RESO102>

system. The resolution is in line with the EU's commitments and the Health 2020 strategy⁵⁴.

In addition to the umbrella strategy, a number of strategies are adopted at the level of the Government or Parliament, primarily in the field of public health with elaborated action plans, monitoring and appropriate upgrading of strategies for new periods. As an example, we can cite the Resolution on the National Program on Nutrition and Physical Activity for Health 2015-2025⁵⁵.

There are, unfortunately, several strategies which are not updated after their expiration, e.g. National Strategy for Health Quality and Safety⁵⁶ expired in 2015. Furthermore, there are strategies prepared in different groups, associations, chambers, but not approved at the level of Government and consequently, not implemented. The example is Strategy of development of primary care in Slovenia by 2020⁵⁷, prepared by Slovenian Medical Association, Slovenian Family Medicine Society.

The implemented strategies are never evaluated, even if fully implemented. Therefore, evaluation of the implemented measures does not serve as a foundation for further decision-making and does not even serve as a feedback loop for the actors in the strategies in the strategies' lifetime. Although the action plans and indicators for carrying out the strategies are set, they are often vague and inappropriate, followed only for administrative reasons.

Other systemic and targeted research on health services delivery is rare. One of the last was carried out under the WHO in 2016. Health in Transition, supported by The European Observatory on Health Systems and Policies, is prepared every 5 years and describes state and trends in healthcare system in the covered period.

On annual basis, HIIS published own business reports, which includes HIIS data on the implementation of compulsory health insurance and realization of rights from compulsory health insurance, available capacities of the health system, implementation and evaluation of health programs, new accounting models in healthcare, the establishment of several sets of indicators for the quality of the provision of health services, the reduction of administrative burdens for insured persons and providers of health services and informatization.

Individual master and doctoral thesis in the field of healthcare are prepared, some focused on quality and safety. Most measure patient satisfaction with treatment or health status of certain patient population.

a.5. Health Technology Assessment (HTA)

⁵⁴ WHO. Zdravje 2020: Temeljna evropska izhodišča za vsevladno in vsedružbeno akcijo za zdravje in blagostanje [Health 2020: A European policy framework and strategy for the 21st century]. WHO, Copenhagen, 2013. Available at: https://www.nijz.si/sites/www.nijz.si/files/uploaded/health_2020_svn.pdf

⁵⁵ Resolucija o nacionalnem programu o prehrani in telesni dejavnosti za zdravje 2015–2025 [Resolution on the National Programme on Nutrition and Physical Activity for Health 2015–2025]. Official Gazette of Republic of Slovenia No. 58/2015. Available at: <http://www.pisrs.si/Pis.web/pregledPredpisa?id=RESO101>

⁵⁶ Kiauta, M., Poldrugovac, M., Rems, M., Robida, A., Simčič, B. Nacionalna strategija kakovosti in varnosti v zdravstvu (2010-2015) [National Strategy of Quality and Safety in Healthcare]. MoH, Ljubljana, 2010. Available at: <https://core.ac.uk/download/pdf/52484025.pdf>

⁵⁷ Poplas Susič T, Švab I, Kersnik J, Klančič D, Živčec Kalan G, Klemenc D, Završnik J, Kerstin Petrič V, Prevolnik Rupel V. Predlog nacionalne strategije razvoja osnovne zdravstvene dejavnosti v Sloveniji do leta 2020 [Draft National Strategy of development of primary healthcare in Slovenia by 2020]. Slovenian Medical Association, Slovenian Family Medicine Society, Ljubljana, 2013. Available at: https://drmed.org/wp-content/uploads/2014/06/Strategija_DM-8.-4.-2013.pdf

HTA framework in Slovenia has not been established at the national level. The need to formalize HTA for all health technologies has been known and various initiatives have been present in the system to introduce it. The most developed level of HTA is present in the area of pharmaceuticals, while with other health technologies, HTA process is much more unclear, irregular and unsystematic⁵⁸. HTA in pharmaceuticals is conducted by HHS. HHS passed the Rules on inclusion of medicines in the list⁵⁹, which define the types of the analysis that can be used, timelines, and decision criteria that are to be followed in the assessment process. The criteria, according to which the pharmaceuticals are evaluated, are clinical effectiveness, safety and cost-effectiveness. Adaptation of the study results to Slovenian setting is demanded and the analysis should use Slovenian data as much as possible.

Consulting body to HHS, called Pharmaceutical Reimbursement Commission, makes recommendations on the placement of the pharmaceuticals on the positive or intermediate list. These are based on the presented relative therapeutic value and incremental cost-effectiveness ratio of the drug. The latter must be expressed in marginal costs per quality-adjusted life-year (QALY). The threshold for the acceptance of the pharmaceuticals into the public financing is set to 25,000 EUR. The Pharmaceutical Reimbursement Commission members are physicians and clinical pharmacists as well as other experts with systemic knowledge in the field of drugs. Their recommendations are independent.

Other healthcare technologies, especially healthcare services programmes, are introduced through Health Council. Health Council is the highest advisory body to the Minister of Health. It gives recommendations on introducing new technologies to the Minister, who makes the final decision on their introduction. Upon his decision, the suggestion is made to the HHS for its public financing and HHS can make a decision to reimburse the use of new technology or not. The recommendations to the Minister of Health are based on the criteria defined in Procedures on handling the applications for new healthcare programs⁶⁰. The protocol is quite complex and long and consists of several questions on the technology, its safety, target population, clinical effectiveness, costs, and organizational issues. Cost-effectiveness is not included in the protocol.

a.6. Clinical decision making

Clinical decision making has three integrated phases: 1) diagnosis, 2) assessment of severity, and 3) management. Appropriate clinical decision making considers the need to make a precise diagnosis as well as the costs associated with inappropriate or indiscriminate use of diagnostic tests. It also assesses the risk for an adverse outcome because of inappropriate management, and the costs and possible harmful effects of therapeutic interventions.

The aim of evidence-based medicine (EBM) is to ensure that decision making in healthcare incorporates the best available evidence. Clinical decision making (including prescribing decisions) involves the judicious use of evidence, considering both clinical

⁵⁸ Prevolnik Rupel V. Current Implementation of HTA in Healthcare System in Slovenia. *Int J Technol Assess Health Care*. 2017;33:360-364. DOI: 10.1017/S0266462317000083.

⁵⁹ Rules on inclusion of medicines on the list [Pravilnik o razvrščanju zdravil na listo]. *Official Gazette of the Republic of Slovenia*, No 35/2013, 3 April 2013. Available from: <http://www.pisrs.si/Pis.web/pregledPredpisa?id=PRAV11493>

HHS. Decision on incremental cost effectiveness ratio. Ljubljana: Zavod za zdravstveno zavarovanje Slovenije; 2013. Available from: [http://www.zzs.si/zzs/info/egradiva.nsf/0/de161d25a238859cc1257c1d0026d7f9/\\$FILE/Podpisan%20sklep%20ICER.pdf](http://www.zzs.si/zzs/info/egradiva.nsf/0/de161d25a238859cc1257c1d0026d7f9/$FILE/Podpisan%20sklep%20ICER.pdf)

⁶⁰ MoH of Republic of Slovenia. Postopek obravnave vlog za nove zdravstvene programe [Procedures on handling the applications for new health care programmes]. Ljubljana: MoH; 2015. Available from: <https://www.gov.si/assets/ministrstva/MZ/DOKUMENTI/O-ministrstvu/Zdravstveni-svet/Postopek-obrnave-vlog-za-nove-zdravstvene-programe.pdf>

expertise and the needs and wishes of individual patients⁶¹. The EBM movement has now developed a large repository of high-quality evidence synthesized into the form of guidelines, and in many healthcare systems this is becoming linked into systems to both support and incentivize evidence-informed decision making. There is further research required to determine the optimal approach to teaching current and future decision makers how human beings make decisions. Until such research has been performed, clinical decision makers should familiarize themselves with the different processes involved in decision making, and the biases that can affect their decisions.

EBM employs systematic searching, evaluation and use of current research findings as the basis for clinical decision-making. However, there are some problems and uncertainties hindering introduction and spreading of the use of the method in clinical practice. Physicians often have no time for literature searching and for use of the method in practice. For certain questions in clinical practice there are no answers in medical literature. Most of the evidence in medical literature are only available in English. Introduction of the method is hampered also by the fact that clinical decision-making is complex and does not allow procedures prescribed in advance. Rigidity and universality of decisions resulting from the evidence may appear impersonal and may affect the relationship between the physician and the patient⁶². The beneficial effect of the guidelines on the quality of procedures and outcomes of care has been scientifically confirmed. We also know that their success depends on a number of factors, which in particular affect the validity and reliability of individual advice in the guidelines, as well as their acceptability as a whole⁶³.

The implementation of clinical decision-making and EBM is based on implementation of clinical guidelines and pathways. In 2003 a Manual for clinical guidelines⁶⁴ has been prepared and first two clinical guidelines designed and implemented: the management of colorectal carcinoma as a base for screening program SVIT and primary prevention of cardiovascular disease as a base for national prevention program against cardiovascular diseases.

Guidelines serve as an aid to clinical decision-making, but they cannot replace it. The guidelines also do not provide answers to all clinical questions and do not guarantee a positive outcome of care in each individual case. The final decision on the specific type and method of medical treatment will always depend on the condition, circumstances and wishes of the individual patient and the clinical judgment of the team(s) caring for the patient⁶⁵. Designing, evaluating, putting into practice, and updating guidelines is not easy. It requires a large investment of energy for all members of working groups, reviewers, organizers, and providers of healthcare, as well as cultural and behavioural shifts in society. Trainings in the form of workshops, reminders and personal contacts are needed for successful implementation. The most successful way to implement the key recommendations of the guidelines in everyday clinical practice is very likely having carefully and systematically designed clinical pathways^{66,67}. The practice of introducing

⁶¹ Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. *BMJ*. 1996;312:71–72.

⁶² Čuk A. Na izsledkih temelječa medicina: klinična uporaba in kritike [Evidence-based medicine: clinical use and critics]. *Zdravniški vestnik*, 2003; 72(12): 695-699. Available at: <http://dlib.si/details/URN:NBN:SI:DOC-YPKMZNOW>

⁶³ Geršak K., Fras Z., Rems M. Ali vemo kaj je dobra klinična smernica? *Zdrav Vestn* 2016; 85: 6–14

⁶⁴ Fras Z, Robida A, Brubnjak-Jevtič V, Rems M, Jug B, Kersnik J, et al. Priročnik za smernice [Slovene Guidelines Manual]. Ljubljana: Ministrstvo za zdravje, 2003: p. 1–32. Available at: http://www.mz.gov.si/si/delovna_podrocja/zdravstveno_varstvo/kakovost_in_organizacija_zdravstvenega_varstva.

⁶⁵ Fras Z. Smernice in priporočila–kaj potrebuje zdravnik za kakovostno klinično prakso. In: Fras Z, Poredoš P, eds. *Zbornik prispevkov*. Ljubljana: Medicinska fakulteta; 2009. p. 17–27.

⁶⁶ Campbell J, Hotchkiss R, Bradshaw N, Porteous M. Integrated care pathways. *BMJ* 1998; 316: 133–7.

⁶⁷ Yazbeck AM, Robida A. Metodološka priporočila za oblikovanje in uvajanje kliničnih poti. Ljubljana: Ministrstvo za zdravje; 2006.

clinical guidelines by adopting international ones seems easy and practical, but are unfortunately, very seldom integrated in the organizational structure and financing of the healthcare system. In Slovenian education system, Faculty of Health Sciences Maribor offers subjects Integrated care of chronic patients and advanced comprehensive assessment of health status and clinical decision-making.

a.7. Availability of guidelines

In Slovenia, care pathways serve as a tool for organizing the care of patients at the level of individual healthcare provider organizations. The GA in 2015 required each general hospital to have a least 14 care pathways established by 2015⁶⁸. According to a survey performed in 2009, most hospital healthcare workers estimated that care pathways were used for 20–40% of admitted patients⁶⁹. There are only a few implemented nationally agreed care pathways.

The manual for designing national clinical guidelines has been published⁷⁰ as a base for first two national guidelines on management of colorectal carcinoma and primary prevention of cardiovascular diseases. The manual reflected some already existing models for the preparation of guidelines, such as Scottish Intercollegiate Guidelines Network (SIGN), German Agency for Quality in Medicine (Arztlichen Zentralstelle Qualitätssicherung (AEZQ)), and International Guidelines Network (GIN).

There are several guidelines prepared and promoted for different services, but the process of preparation, evaluation, and implementation in the included healthcare system and financing system is not in place.

Two examples are the guidelines for acute coronary syndrome, which are related to the national network of primary centres able to perform percutaneous coronary interventions at very short notice in emergency situations (usually situated within hospitals)⁷¹ and implemented telemedicine care programme for stroke⁷².

a.8. Continuity (availability of medical information, medical record keeping)

Clinical documentation was developed to track a patient's condition and communicate the author's actions and thoughts to other members of the care team. Over time, other stakeholders have placed additional requirements on the clinical documentation process for purposes other than direct care of the patient. More recently, new information technologies, such as electronic health record (EHR) systems, have led to further changes in the clinical documentation process. Although computers and EHRs can facilitate and even improve clinical documentation, their use can also add complexities and new challenges and, in the eyes of some, an increase in inappropriate or even fraudulent documentation. At the same time, many physicians and other healthcare professionals have argued that the quality of the systems being used for clinical documentation is inadequate.

EHRs should be leveraged for what they can do to improve care and documentation, including effectively displaying prior information that shows historical information in rich context; supporting critical thinking; enabling efficient and effective documentation; and

⁶⁸ HIIS et al. Splošni Dogovor za leto 2015 [GA for year 2015]. Ljubljana: Zavod za zdravstveno zavarovanje Slovenije; 2013. Available from: <https://www.zzs.si/?id=126&detail=2EC3F2AC07922434C1257E7C0040094A>

⁶⁹ Kiauta M et al. (2010). National strategy for quality and safety in health care 2010–2015. Ljubljana, MoH.

⁷⁰ Fras Z, Robida A, Brubnjak-Jevtič V, Rems M, Jug B, Kersnik J, et al. Priročnik za smernice [Slovene Guidelines Manual]. Ljubljana: Ministrstvo za zdravje, 2003: p. 1–32. Available at: http://www.mz.gov.si/si/delovna_podrocja/zdravstveno_varstvo/kakovost_in_organizacija_zdravstvenega_varstva.

⁷¹ Radšel, P., Čerček, M., Gričar, M., Kompara, G., Poklukar, J., Prosen, G., Noč, M. Akutni koronarni sindrom: smernice za obravnavo v Sloveniji v letu 2014 [Acute Coronary Syndrom: guidelines for treatment in Slovenia in year 2014]. Društvo latros, društvo za napredek v medicini, Ljubljana, 2014, 28 pgs.

⁷² MoH (2015b). Guidelines for the telemedicine care programme for stroke. Ljubljana, MoH

supporting appropriate and secure sharing of useful and usable information with others, including patients, families, and caregivers. These features are unlikely to be optimized as long as the format and content of clinical documentation are primarily based on coding and other regulatory requirements. Furthermore, under these circumstances, EHRs lose much of their potential to improve care and documentation and instead are relegated to doing nothing that could not be done with paper records—only less efficiently⁷³.

The growing complexity of care with more professionals involved is a threat to the delivery of coherent and consistent care. Maintaining continuity of care demands excellent exchange of relevant information between professionals and EHR which have the potential to fulfil that role⁷⁴.

Telemedicine advances in electronic communications have enabled patients to be diagnosed and treated by health professionals long-distance. A systematic review, including 76 countries globally, was conducted to analyse the use of telemedicine in the delivery of cross-border healthcare⁷⁵. Most countries described services delivering a combination of types of telemedicine; most represented specialties were telepathology, telesurgery, Emergency and trauma telemedicine and teleradiology. A main driver for the development of cross-border telemedicine is the need to improve access to specialist services in low- and middle-income countries and in underserved rural areas in high income countries. Factors that hinder or support implementation clustered into four main themes: 1) legal factors; 2) sustainability factors; 3) cultural factors; and 4) contextual factors.

A qualitative study of a teleradiology clinic in Barcelona, offering services to hospitals in European countries, was undertaken to identify the challenges faced in providing such a service⁷⁶. It identified the need for a clear legal framework to govern such services, especially in relation to areas such as liability and comparability of clinical governance arrangements. For example, patients in Sweden benefit from a no-fault compensation scheme when treated by domestic healthcare providers but this does not extend to healthcare providers established abroad. In some other areas, there is a European legal framework, such as data transfer.

In the 1990s, Slovenia was among the leading EU countries in the field of healthcare informatization - a healthcare was introduced and several links between hospitals (e.g. tele-radiology) was established. All E-health projects were in majority of cases focused to connecting professionals among themselves, forgetting about the end users. Only recently, this focus is shifted and starts to include professional staff with end users via online and mobile platforms.

E-prescription computerized issuing prescriptions, which can be now used in digital form. Because the original solution was already well-established, digitization was all the easier. In the case of e-procurement, we faced the challenge of connecting many service healthcare providers on the one hand (several thousand public institutions and other healthcare providers), where the state of Slovenia made a mistake in allowing

⁷³ Kuhn T, Basch P, Barr M, Yackel T for the Medical Informatics Committee of the American College of Physicians Clinical Documentation in the 21st Century: Executive Summary of a Policy Position Paper From the American College of Physicians. Position Paper. *Annals of Internal Medicine*, 2015. doi: 10.7326/M14-2128

⁷⁴ Schers H, van den Hoogen H, Grol R, van den Bosch W. Continuity of care through medical records--an explorative study on GPs' management considerations. *Fam Pract*. 2006;23(3):349-52. doi: 10.1093/fampra/cml002.

⁷⁵ Saliba V, Legido-Quigley H, Hallik R, Aaviksoo A, Car J, McKee M. Telemedicine across borders: a systematic review of factors that hinder or support implementation. *Int J Med Inform*. 2012;81(12):793-809. doi: 10.1016/j.ijmedinf.2012.08.003.

⁷⁶ Legido-Quigley H, Doering N, McKee M. Challenges facing teleradiology services across borders in the EU: a qualitative study. *Health Policy and Technology*, 2014; 3(3):160-6, doi:10.1016/j.hlpt.2014.04.001. 2014

uncoordinated informatization. Namely, the contractors were able to decide on certain solutions themselves, which caused incompatibility problems. Until the structure of e-procurement is unified with the legal basis and other legal acts, of course, any information approach to solving this problem is wrong.

Slovenia is known for well qualified human resources in informatization and communication technology. Shortcomings are more present in investing in hardware and software in this area.

One of the major dangers in the field of increasing focus on the end user is the professionalism of equipment developers, with a flood of different solutions and applications; on the contrary, end users (patients) with own healthcare issues lack knowledge or ability to make rational judgments, which can be dangerous for the patients. However, patients' inputs are required: the collection, analysis and use of "big data" is a necessity for greater transparency, reliability, and quality, knowledge and disease control. Greater connectivity of databases is needed for information support in decision-making. An empowered citizen with a smartphone and health apps is becoming an active controller of their health data and an increasingly important link in the healthcare treatment chain.

Over the past two decades, several attempts have been made to modernize Slovenia's data collection, including efforts to develop a uniform and standardized health information system, eHealth solutions and standard classifications, leading to new streamlined data collection systems at NIPH, HIIS and MoH. A national eHealth project (e-Health) (2010-2015) implemented new applications to improve service quality and capture additional data. These include a central registry of patient data (CRPD), zVEM Patient Portal, electronic prescriptions, appointments and triage, and teleradiology and telemonitoring for stroke patients. This project also introduced a "uniform information model" involving standardized classifications and data standards, code lists and definitions of selected variables, and using the interoperable "backbone"⁷⁷.

4.5 Quality and patient safety indicators vs standards



Executive Summary

⁷⁷ Albrecht et al. Slovenia: Health system review. Health Systems in Transition, 2021 (in press).

Main identified gaps:

- No updates of national quality indicators that were created in 2010. The comparison of indicators with national standards is not possible as there are none
- No national systemic and systematic, regular audits of clinical services
- Not all healthcare facilities are accredited or certified because these external evaluations are voluntary
- A small number of indicators for PS and non-official feedback from the competent authority to providers
- No common national platform where the public can see indicators
- No national clinical standards for QoC, PS and CRM

Main recommendations:

- Creation of core national QoC and PS standards
- Develop clinical national audits
- Make accreditation and certification obligatory
- Updating QoC and PS indicators with relevant stakeholders and national governance for all levels of healthcare
- Encourage providers for PS and outcomes improvements with collecting indicators in their own specialty grounded on evidence-based medicine and evidence-based healthcare

There is a paucity of PS indicators for primary care, except for chronic diseases and obligatory national indicators. In community pharmacy or nursing homes no national indicators exist although providers are collecting some indicators of their own interest (32-33).

a) Indicators**a.1. Review of the existing quality standards and indicators**

Slovenia introduced healthcare quality indicators in 2010. The chosen indicators were selected from a number of sources, such as OECD Healthcare Quality Indicators project and WHO Performance Assessment Tool for Quality Improvement in Hospitals. Additionally, some indicators were proposed and developed by the MoH and the Medical Chamber. The results are published every year in a special report on quality indicators and are publicly accessible on the MoH webpage; the last report covers year 2019⁷⁸. Altogether, out of all 73 indicators, there are 30 more relevant indicators; one in patient-centered care, four in promotion, prevention and primary care (hospital admissions), seven in communicable diseases, 12 in healthcare efficiency, five in PS and an indicator for hand hygiene. PROMs have been launched in 2009 and 2010 in National Tender, but later on not systematically introduced⁷⁹.

a.2. Patient-centred indicators

The share of exclusively breastfed new-borns has decreased significantly, by almost 17 percentage points, in the last decade. In 2019, the share of exclusively breastfed healthy new-borns in Slovenian maternity hospitals was thus only 69.9%. The differences between hospitals are large; they range from 16% of exclusively breastfed new-borns in

⁷⁸ Petek Šter M, Šter B. Pomen izobraževanja diplomiranih medicinskih sester v referenčnih ambulantah: primer arterijske hipertenzije. Obzornik zdravstvene nege. 2015;49:52–59. DOI: 10.14528/snr.2015.49.1.46

⁷⁹ Prevolnik Rupel V, Erker R, Divjak M. Comparing Quality of Life of General Population and Orthopedic Patients in Slovenia. Value in Health Regional Issues, 2020; 22: 93-98. DOI: 10.1016/j.vhri.2020.07.575

Postojna to 96% in Ptuj, while the shares in most of the hospitals range between 60 and 80%.

a.3. Promotion, prevention and primary care indicators

Hospital admission rate due to COPD, heart failure, asthma and arterial hypertension. These indicators reflect the quality of primary care. In 2019, the hospital admission rate for asthma was 32.7 and has been declining since 2016. The hospital admission rate for COPD was 113.1, heart failure 285.9 and arterial hypertension 47.9. In all chronic disease a general downward trend can be noticed in the last decade.

a.4. Communicable diseases

The indicators on communicable diseases report proportions of vaccinated children against measles, diphtheria, tetanus, whooping cough and hepatitis B. Vaccination against these diseases has been relatively high at the national level for several years in a row, higher than 90% (except for hepatitis B), there are no major deviations. This provides good protection against the spread of the aforementioned infectious diseases in Slovenia. The vaccination of elderly aged 65 years and more reached 12.9%, which is among the lowest levels in EU.

Further indicators in this category report incidence rates of measles, whooping cough and chronic hepatitis B. While the incidence rate in measles and chronic hepatitis B are low, the incidence rate for whooping cough was relatively high in 2017 and 2018, above 10%. Among the possible causes relatively rapid decline in immunity after vaccination, change in the causative agent, and lower performance of a newer (acellular) whooping cough vaccine are mentioned. Therefore, many countries have introduced boosting doses in adolescence, booster doses at least once in adulthood and vaccination of pregnant women.

a.5. Healthcare efficiency

The pressure ulcer quality indicator shows the rate of hospital ulcers. The differences in the percentage of ulcers acquired differ widely among hospital and ranges from 0 to 23%.

Further indicator in this category refer to waiting times for computer tomography – the legal framework for monitoring waiting times was established in 2008 by the Patient Rights Act⁸⁰ and the Regulation on maximum waiting times for individual health rights⁸¹. On 1 May 2011, National Institute for Public Health published data on the waiting lists for selected healthcare services for the first time. There were 24,819 patients waiting for 60 defined services. The list of 60 services was slightly changed on 1 September 2012, and then there were no further changes until 1 May 2016, when one more service was added to the list. In August 2018, the whole operational system of reporting was replaced, and at the same time, the list of services, their coding and the reporting methodology have been completely changed. For example, data on physiotherapy treatment are no longer monitored and 58 services from previous system now correspond to 400 new services. The service code translator has not yet been officially published; however, the data could potentially be compared if it existed.

Between 1 January 2015 and 1 January 2020, the number of patients waiting for first visit increased by 54.1%. There were total of 403,811 patients on waiting lists on 1 January 2020, among them 165,201 or 40.9 % waited longer than allowed. 71.3 % of all

⁸⁰ Patients' Rights Act [Zakon o pacientovih pravicah]. Official Gazette of the Republic of Slovenia, No. 15/08, 55/17 and 177/20. Available from: <http://pisrs.si/Pis.web/pregledPredpisa?id=ZAKO4281>

⁸¹ Rules on the referral of patients, the management of waiting lists, and the maximum permissible waiting times [Pravilnik o naročanju in upravljanju čakalnih seznamov ter najdaljših dopustnih čakalnih dobah]. Official Gazette of the Republic of Slovenia, No 3/2018 and 201/2020. Available from: <http://www.pisrs.si/Pis.web/pregledPredpisa?id=PRAV13238>

patients were waiting for outpatient specialist services and the rest were waiting for diagnostic procedures or day care. The estimated financial value for provision of services for all patients on waiting list was 120.4 mio EUR, and the estimated value of service provision for patients waiting longer than allowed was 44.7 mio EUR⁸².

A series of indicators on efficiency of the surgical processes include utilization of operating theatres for hospital and outpatient procedures, share of cancelled procedures, average length of stay for selected procedures (cholecystectomy, pneumonia, hip replacement etc.), indicators connected to diabetes (hospital admissions because of diabetes, amputations due to diabetes), indicators connected to new-borns. The first one is injuries in vaginal delivery: in 2019 a total of 17 cases of third- or fourth degree of such injuries were reported during childbirth. The share of Caesarean sections has increased significantly in the last decade but remains below EU average. Both the proportion of elective and emergency Caesarean sections increased. In 2019, the proportion of Caesarean sections at the gestational age of 37 was 17.2 percent, lowest in general hospital Jesenice (9.1%) and highest at 30.5%, in Trbovlje.

Very important indicators are post-surgical deep vein thrombosis and lung embolism. The rate of cases of pulmonary embolism per 100,000 admissions due to hip or knee endoprosthesis has been decreasing constantly in the last decade while the data on the lung embolism are less clear, stills showing a slight decreasing trend. The use of antimicrobials is monitored as well.

a.6. Patient and personnel safety

Patient and personnel safety report data on the injuries caused by sharp objects, falls, foreign bodies in the body after the surgery, methicillin resistant *Staphylococcus aureus* (MRSA) and post-surgical sepsis. Hand hygiene has been improving but can improve further: overall consistency of hand hygiene has reached 77.5% in 2019.

a.7. Proposal of indicators on quality and integration of care (from referral to discharge), effectiveness, appropriateness, and responsiveness

Integrated health systems are widely considered to provide superior performance in terms of quality and safety because of effective communication and standardized protocols, although these outcomes have not been fully demonstrated⁸³.

Despite the growing enthusiasm for integration, information related to implementing and evaluating integration-related initiatives is dispersed and not easily accessible. There is little guidance for planners and decision-makers on how to plan and implement integrated health systems. With evidence-informed decision-making as an expectation in healthcare management and policy⁸⁴, there is a need to seek out and apply current knowledge on health systems integration to advance effective service delivery.

The National Strategy for Health Quality and Safety (2010–2015)⁸⁵ aims at systematic development of continuous improvements in healthcare. Strategic objectives are the development of quality management systems, the development of a clinical culture of safety and quality within the health sector, the development and implementation of

⁸² Simčič B, Kuhar M, Marušič D. Nedopustno čakajoči - dosežen je novi rekord! Razsežnosti problema pravočasne zdravstvene obravnave [Number of waiting above permissible waiting time – a new record is set! Viewpoints on the problem of timely health services]. Dnevnik. 2018; 68:14-15. Available from: <https://www.dnevnik.si/1042842229>

⁸³ Gillies RR, Chenok KE, Shortell SM, Pawlson G, Wimbush JJ. The Impact of Health Plan Delivery System Organization on Clinical Quality and Patient Satisfaction. *Health Services Research*. 2006; 41:1181–99.

⁸⁴ Cookson R. Evidence-Based Policy Making in Health Care: What It Is and What It Isn't. *Journal of Health Services Research & Policy*. 2005; 10:118–21.

⁸⁵ Kiauta, M., Poldrugovac, M., Rems, M., Robida, A., Simčič, B. Nacionalna strategija kakovosti in varnosti v zdravstvu (2010-2015) [National Strategy of Quality and Safety in Healthcare]. MoH, Ljubljana, 2010. Available at: <https://core.ac.uk/download/pdf/52484025.pdf>

education programmes in quality and safety and systematic improvement of the efficiency and effectiveness of healthcare.

Although most hospitals are accredited by international accreditation organisations, implementation of other recommendations under the National Strategy for Health Quality (2010–15) has lagged plans. In particular, systems for internal monitoring of PS, QoC and uptake of evidence-based clinical guidelines were not set up in a uniform and structured manner. In 2011, a broad set of quality indicators was set out with the expectation that hospitals would monitor and publish their performance. The healthcare providers' obligation for reporting is a part of the contracts between HIF and healthcare providers. However, data limitations and the lack of external verification have impeded the reliability of the approach. Similarly, safety indicators (patients' falls and methicillin-resistant *Staphylococcus aureus* infection rates) are not reliable. Current efforts to establish an Agency for Health Quality and Safety may help to overcome these challenges and improve quality assurance. There are also concerns that the wide range of specialised services offered by relatively small regional hospitals may undermine QoC, PS and efficiency simply because healthcare providers will tend to perform only a few procedures of a specific type per year.

Appropriateness indicators measure how well services meet clients' needs. An appropriateness indicator could be proportion of clients receiving the services that they are assessed as needing. Appropriateness indicators also seek to identify the extent of any underservicing or overservicing⁸⁶. Other services have few measurable standards of service need; for example, the appropriate number of medical treatments available for particular populations is not known. However, data on differences in service levels can indicate where further work could identify possible underservicing or overservicing.

The WHO developed and proposed the concept of responsiveness, defining it as aspects of the way individuals are treated and the environment in which they are treated during health system interactions. The concept covers a set of non-clinical and non-financial dimensions of QoC that reflect respect for human dignity and interpersonal aspects of the care process, which Donabedian⁸⁷ describes as "the vehicle by which technical care is implemented and on which its success depends". Eight dimensions (or domains) are collectively described as goals for health-care processes and systems: (i) dignity, (ii) autonomy, (iii) confidentiality, (iv) communication, (v) prompt attention, (vi) quality (of) basic amenities, (vii) access to social support networks during treatment (social support), and (viii) choice (of healthcare providers).

Classification of indicators of QoC starting from the Donabedian-triangle of structure, process and outcome can use four operational levels: macro, meso, micro and nano. The nano-level is seen as the single patient-provider-interaction level, whereas the micro-level contains indicators of quality that occur in the (interdisciplinary) collaboration between healthcare providers. The meso-level is the place where policies and organisations operate that support these collaborations. Healthcare system characteristics as indicators for quality are observed at the macro-level.

There are many quality indicators that are developed at an international level and can be adapted to any national environment. Development of indicators is hence not a problem anymore; a bigger problem is how to choose them in order to measure the priorities relevant for the country. The introduction of the indicators is always a long and expensive process, starting from their planning, preparation (translation, validation, informatization) and use (collection, cleaning, analysis).

⁸⁶ Renwick, M., Sadkowsky, K. (1991). Variations in Surgery Rates in Australia, Canberra: Australian Institute of Health.

⁸⁷ Donabedian, A. (1988). "The quality of care: How can it be assessed?". *JAMA*, **260** (12): 1743–8. doi:10.1001/jama.1988.03410120089033

There are many global/international initiatives identified that measure various components of quality in healthcare. A systematic overview⁸⁸ has been prepared by WHO in 2018 which tried to identify the domains that each initiative covers. Performance domain included three QoC subdomains: effectiveness, safety and people-centeredness. While almost all of the 20 identified global frameworks included effectiveness indicators, only 14 included safety and 12 people-centeredness. Eight frameworks cover all three quality domains, out of those 2 are disease specific. The remaining six are shortly presented below.

b) Tools

b.1. Global Reference List of WHO 100 Core Health Indicators

Global Reference List of WHO 100 Core Health Indicators framework was established in 2015 by WHO. A standard set of 100 indicators prioritized by the global community to provide concise information on health situations and trends, reflecting indicators of relevance for country, regional and global reporting across the full spectrum of global health priorities relating to the MDG agenda, as well as to new and emerging priorities such as NCDs, universal health coverage and other key issues in the post-2015 development agenda. The main objectives are: to guide monitoring of health results nationally and globally; to reduce excessive and duplicative reporting requirements; to enhance efficiency of data collection investments in countries; to enhance the availability and quality of data on results; and to improve transparency and accountability. The Global Reference List presents the indicators according to multiple dimensions. First, each indicator belongs to one of four domains: health status, risk factors, service coverage and health systems. Second, each indicator is further categorized into subdomains. The third dimension presents the indicators according to levels of the results chain. The indicators might be used by countries wanting to monitor, evaluate and diagnose the performances and quality of healthcare systems. The indicators can be found at: <https://www.who.int/healthinfo/indicators/2018/>.

The following tools affect Slovenia since it is important to propose a new set of quality and safety indicators.

b.2. Health Facility and Community Data Toolkit

This toolkit was established by WHO in 2014. The aim of this toolkit is to provide an overview of best practices, innovations, tools and methods available to countries in support of strengthening the components of a health facility information system. The materials are presented according to an organizing framework for the key components of a country health facility information system, namely: governance (an overarching component), data collection and management, data quality and analysis, and data dissemination and use. Within each section, key action steps are identified for countries and examples of available tools and resources are provided to support country action. A checklist of key items and attributes is also provided designed to facilitate the monitoring of progress towards defined standards (also available as a separate spreadsheet). The checklist should be completed in a collaborative process by all stakeholders, including data producers and data users. This is a toolkit to monitor and evaluate the service availability and readiness, which are the important component of system level healthcare quality and performance. Significant portion of the indicators can also be used to monitor the QoC. The indicators can be found at: https://www.who.int/healthinfo/facility_information_systems/

b.3. Performance Assessment Tool for Quality Improvement in Hospitals (PATH)

⁸⁸ Global efforts in measuring QoC. Geneva: WHO; 2018 (WHO/HIS/SDS/2018.1). Licence: CC BY-NC-SA 3.0 IGO

WHO EURO established PATH in 2004. This tool is a performance assessment system designed by the WHO to support hospitals in defining quality improvement strategies, questioning their own results and translating them into actions for improvement. The PATH system takes a more comprehensive approach to hospital performance within a framework comprising six dimensions: clinical effectiveness, efficiency, staff orientation, responsive governance, safety and patient centeredness. For each dimension, indicators were selected based on their importance and usefulness, potential impact and burden of data collection. Starting with performance measurement, PATH encourages hospitals to learn about their strengths and weaknesses and initiate improvement activities that ultimately help them to fulfil their mission. PATH provides hospitals with a set of indicators with descriptive sheets, a feedback report, a newsletter, a website (www.pathqualityproject.eu) and E-Forum. It presents the indicators and methodology to measure quality of hospital care. The indicators can be found at: http://www.pathqualityproject.eu/requirement_for_performance_measurement.html

b.4. OECD Health Statistics (HCQI)

Established by OECD in 1991, an online database offers a comprehensive source of comparable statistics on health and health systems across OECD countries. It includes a wide range of datasets covering health expenditure and financing; health status; non-medical determinants of health; healthcare resources; health workforce migration; healthcare utilization; healthcare quality indicators; pharmaceutical market; long-term care resources and utilization; social protection; demographic references; and economic references. It also includes metadata on the complete list of indicators, their definition, national sources, and methodologies. The most recent dataset on healthcare quality indicators in 2016 included 57 indicators under seven dimensions: primary care, prescribing in primary care, acute care, mental healthcare, PS, cancer care, and patient experience. While most of the health statistics contained in the OECD health database is updated annually, the dataset on healthcare quality indicators is only updated once every two years. The indicators can be found at: <http://www.oecd.org/els/health-systems/health-data.htm>

b.5. Health at a Glance – OECD Indicators (OECD HAG)

Established in 2001 by OECD, Health at a Glance publishes key data on health status and health systems performance in OECD countries, candidate countries and key emerging economies. It was initially published every two years, but since 2010, the OECD-wide edition alternates with a European edition and an Asia/Pacific edition (see the next two items). Based on the OECD conceptual framework for health system performance assessment, the latest version of HAG in 2015 presents key data and indicators on health status, non-medical determinants of health, health workforce, healthcare activities, access to care, QoC, health expenditure and financing, the pharmaceutical sector, and ageing and long-term care. A statistical annex provides additional information on the demographic and economic context within which health and long-term care systems operate. The indicators can be found at: http://www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance2015_health_glance-2015-en;jsessionid=49un8n3jgoh4o.x-oecd-live-03

b.6. International Consortium for Health Outcomes Measurement (ICHOM)

ICHOM was founded as a non-profit organization by leaders at Harvard Business School, Boston Consulting Group and the Karolinska Institute, to unlock the potential of value-based healthcare by measuring and reporting patient outcomes in a standardized way. ICHOM define global standard sets of outcome measures that really matter to patients for the most relevant medical conditions and drive the adoption and reporting of these measures worldwide by healthcare institutions. The systematic measurement of standard sets of outcomes, will, for the first time, allow global outcome comparisons. This

will catalyse a new wave of learning for healthcare professionals and transform healthcare systems worldwide, improving healthcare quality, supporting informed decision-making and reducing healthcare costs. Since 2012, ICHOM has created standard sets of outcomes that matter most to patients for 39 medical conditions and population sub-groups (plus 5 additional in progress) being treated. ICHOM recommends “Standard Sets,” by condition or population sub-group, of essential standardized patient-reported outcomes, clinical outcomes, and case-mix factors. This will enable global outcome comparisons to identify where the best outcomes are being achieved and then learn from the processes that they have in place. The indicators can be found at: <http://www.ichom.org/>

Additionally, it is worth mentioning PaRIS initiative by OECD. In PaRIS initiative countries work together on developing, standardising, and implementing a new generation of indicators that measure the outcomes and experiences of healthcare that matter most to people.

The International Survey of People Living with Chronic Conditions is the first of its kind to assess the outcomes and experiences of patients managed in primary care across countries. The PaRIS survey aims to fill a critical gap in primary healthcare, by asking about aspects like access to healthcare & waiting times, as well as quality of life, pain, physical functioning & psychological well-being.

In Slovenia, some indicators should or could be placed into GA to increase accessibility. These indicators are:

- Proportion of registered patients per individual doctor from socially deprived areas (number of all registered patients from socially deprived areas/number of all registered patients)
- Proportion of referrals to the secondary level (number of all referrals/number of all examinations), adjusted by the average age of identified persons
- Proportion of the first visits performed in relation to the national average of the first visits per standardized team (number of performed first visits/national average number of performed first visits)
- Proportion of first visits performed in all visits per standardized team (number of performed first visits/number of all performed visits)
- Proportion of readmissions due to the same procedure (orthopaedic surgery and cardiac interventions) within three months after discharge
- Proportion of prospective cases in relation to all cases of relevant specialties (number of prospective cases/numbers of treated patients within a specialty where there are prospective cases)
- The relationship between the patients waiting and the patients treated for a particular procedure

In currently planned National Tender to increase accessibility, for each of the procedures the quality indicators have been defined which are aligned with OECD and ICHOM recommendations. In orthopaedics, the indicators are planned to be connected to the registries, which will enable the use of case-mix variables.

b.7. Waste in Healthcare

There are some relevant indicators related to the health of the population and in consequence, to QoC and PS as there is a study that reflects that if the Health sector were a country, it would be the fifth largest pollution emitter on the planet. This is why how we manage waste in healthcare is of great importance.

Hospitals are energy and resources intensive consuming facilities that have a significant environmental impact (energy consumption, waste disposal, etc.). Many countries are developing specific strategies (controlling the use of hazardous substances; reducing energy consumption; re-using; recovering; re-cycling, etc.) to promote and integrate environmental sustainability into the routine functioning of hospitals^{89,90}. “Improving environmental sustainability can also be a cost saving exercise and strengthen healthcare systems and institutions”⁹¹. The review of EU reforms did not bring out effective measures regarding these topics, same in Slovenia.

On the other hand, as health systems evolve, they must become more resilient and adapted to rapidly changing environments and needs. Therefore, it is necessary to highlight the importance of reducing wasteful spending, and the potential gains resulting from an efficient and sustainable health system.

Wasteful spending occurs when patients receive unnecessary tests or treatments or when care could have been provided with fewer and less costly resources. Evidence from various countries suggests that up to one-fifth of health spending is wasteful and could be reallocated to better use. For example, too many hospital admissions reflect failures in the management of health problems in the community and consume over 37 million bed days each year across the EU.

A mix of policy levers can support this goal, including: 1) ensuring value for money in the selection and coverage, procurement and pricing of pharmaceuticals through HTA; 2) exploiting the potential savings from generics and biosimilars; 3) encouraging rational prescribing; and 4) improving patient adherence.

The digital transformation of health and care, a key component of the EU’s Digital Single Market, offers tremendous potential for improving the prevention, detection and management of chronic diseases, as well as improving health system management and research⁹².

A special attention should be given to avoidable hospital admissions. Potentially avoidable hospitalisations can be reduced by strengthening primary care. Hospitalisations for chronic conditions, such as asthma, COPD and diabetes, provide an indication of the quality of primary care as these hospitalisations may be prevented if well-managed in primary care.

Asthma, COPD and congestive heart failure (CHF) are three widely prevalent long-term conditions. Common to all three conditions is the fact that the evidence base for effective treatment is well established and much of it can be delivered at a primary care level. A high-performing primary care system, where accessible and high quality services are provided, can reduce acute deterioration in people living with asthma, COPD or CHF and reduce unnecessary admissions to hospital. Slovenia’s performance in asthma and COPD hospitalization is relatively good; the performance have also improved in congestive heart failure where Slovenia was found to be below OECD average in 2017.

⁸⁹ McGain F, Naylor C. Environmental sustainability in hospitals - a systematic review and research agenda. *J Health Serv Res Policy*. 2014 Oct;19(4):245-52. doi: 10.1177/1355819614534836.

⁹⁰ Global Green and Health Hospitals. Annual Report 2016. Available at: https://www.greenhospitals.net/wp-content/uploads/2017/03/Web_2016_GGHH_Annual_Report.pdf

⁹¹ IFMSA. Policy Statement Environmentally Sustainable Healthcare Facilities. International Federation of Medical Students’ Associations. Ohrid, FYR Macedonia, 2015. Available at: http://ifmsa.org/wp-content/uploads/2015/05/2015AM_PS_Environmentally-Sustainable-Healthcare-Facilities.pdf

⁹² OECD/EU (2018), Health at a Glance: Europe 2018: State of Health in the EU Cycle, OECD Publishing, Paris/EU, Brussels, https://doi.org/10.1787/health_glance_eur-2018-en.

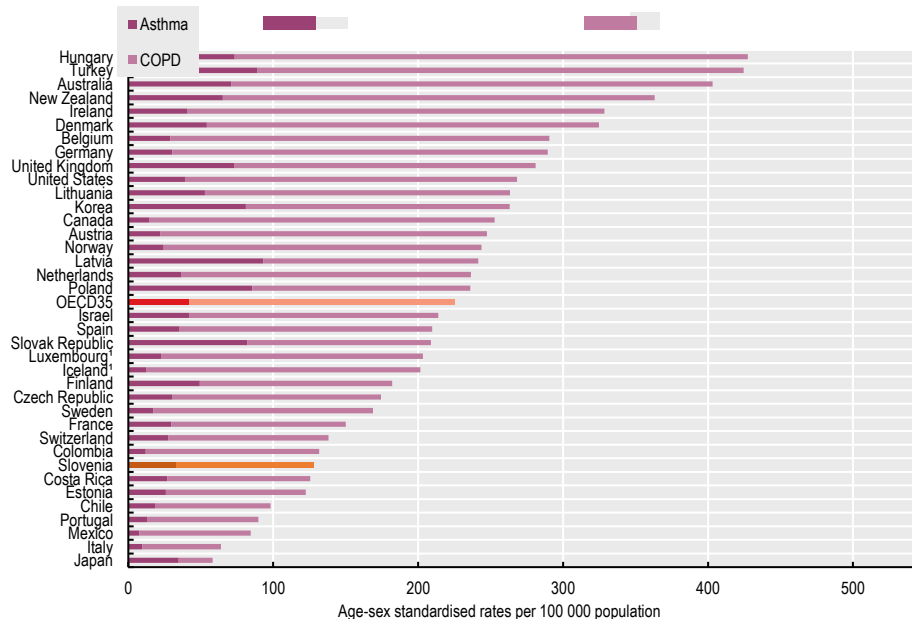


Figure 4. Asthma and COPD hospital admission in adults, 2017 (or nearest year)

Source: OECD (2019), "Asthma and COPD hospital admission in adults, 2017 (or nearest year)", in *Quality and outcomes of care*, OECD Publishing, Paris, <https://doi.org/10.1787/e1a68f0a-en>.

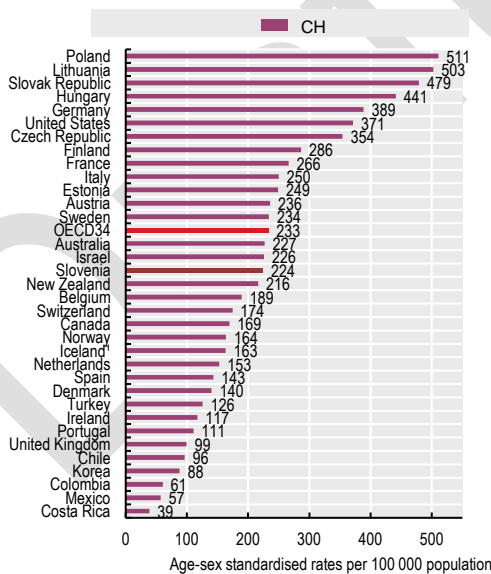


Figure 5. CHF hospital admission in adults, 2017 (or nearest year)

Source: OECD (2019), "CHF hospital admission in adults, 2017 (or nearest year)", in *Quality and outcomes of care*, OECD Publishing, Paris, <https://doi.org/10.1787/e1a68f0a-en>.

b.8. Health-related Quality of Life

Measuring HRQoL is not systematic in Slovenia. Generic as well as disease-specific instruments are well spread in Slovenia and are used by many clinicians in various

clinical areas, e.g. orthopaedics⁹³, celiac disease⁹⁴ and diabetes⁹⁵. There are many more studies performed in various clinical areas by students of Medical Faculty each year, though on a smaller scale. HRQoL is being incorporated into decision making processes in evaluation of new technologies via the calculation of quality-adjusted life years (QALYs). The calculation of QALYs is explicitly included in the evaluation of medicines but is also welcome in the evaluation of other health technologies with The Health Council. For none of the technologies the instrument for the estimation of HRQoL is specified; any of the instruments can generally be used.

Practically, there are not many generic instruments that are currently in use. Most widely used generic HRQoL instrument is EQ-5D (in 3L and 5L versions as well as youth Y version). All versions are translated into Slovenian language and respective value sets for EQ-5D defined health states are available^{96,97,98}.

HRQoL is a part of patient reported outcomes (PROMs), which have been widely discussed in Slovenia, but have not been developed and implemented. PROMs have been launched in 2009 and 2010 in National Tender, but have later not been systematically introduced⁹⁹. As the international initiatives, such as ICHOM and OECD Paris Initiative have developed in the meantime, it is expected that the local development of PROMs will follow both these initiatives and developed standard sets in various disease fields. However, due to the past experience, the full cooperation of healthcare providers is needed in addition to full informatization of the selected indicators. ICT support will make the collecting procedure easier, data validity higher and rate of missing data lower. It will ensure that the data entered in correct as some information (such as patient ID or date) can be automatically controlled.

The current initiative at MoH tries to incorporate the PROMs into the existing registries, described previously, which would enable the analysis of the data taking into the account case-mixed variables and furthermore, benchmarking of the results and changes among the healthcare providers. Based on transparency and positive situation, such initiative can lead to positive motivation, improvements in care pathways and sharing of good practices among the healthcare providers.

4.6 Legislation/regulation



Executive Summary

⁹³ Drobnič M, Kolar M, Verdonk P, Vannini F, Robinson D, Altschuler N, Shabshin N, Kon E. Complex Osteochondral Lesions of the Talus Treated With a Novel Bi-Phasic Aragonite-based Implant. *J Foot Ankle Surg.* 2021 Mar-Apr;60(2):391-395. doi: 10.1053/j.jfas.2020.06.028. Epub 2020 Sep 5. PMID: 33246791.

⁹⁴ Turk, E., Mičetić-Turk, D., Šikić-Pogačar, M. et al. Health related QoL in celiac disease patients in Slovenia. *Health Qual Life Outcomes* 18, 356 (2020). <https://doi.org/10.1186/s12955-020-01612-9>

⁹⁵ Turk, E., Prevolnik Rupel, V., Tapajner, A., Isola, A. Reliability and Validity of the Audit on Diabetes-Dependent Quality of Life (ADDQoL) and EQ-5D in Elderly Slovenian Diabetes Mellitus Type 2 Patients. *Health* 6(8), 2014. Available at: https://www.scirp.org/html/8-8202782_44018.htm

⁹⁶ Prevolnik Rupel, V., Ogorevc, M., IMPACT HTA HRQoL Group. et al. EQ-5D-Y Value Set for Slovenia. *PharmacoEconomics* 39, 463–471 (2021). <https://doi.org/10.1007/s40273-020-00994-4>

⁹⁷ Prevolnik Rupel, V., Srakar, A., Rand, K. Valuation of EQ-5D-3L Health States in Slovenia: VAS based and TTO based value sets. *Zdrav Var*, 2020; 59(1): 8-17.

⁹⁸ Prevolnik Rupel V, Ogorevc M. Crosswalk EQ-5D-5L Value Set for Slovenia. *Zdr Varst.* 2020 Jun 25;59(3):189-194. doi: 10.2478/sjph-2020-0024. PMID: 32952720; PMCID: PMC7478094.

⁹⁹ Prevolnik Rupel V, Erker R, Divjak M. Comparing Quality of Life of General Population and Orthopedic Patients in Slovenia. *Value in Health Regional Issues*, 2020; 22: 93-98. DOI: 10.1016/j.vhri.2020.07.575

Main identified gaps:

- No specific law on QoC and PS in healthcare although a draft was prepared some years ago with the request of a patients' association
- Many legal requirements were missing in different legislation documents
- Criminalization of human errors instead of implementing a just culture
- No specific law on no-fault compensation but a draft proposal was created a couple of years ago and sent to the MoH

Main recommendations:

- Develop a comprehensive and specific law on QoC and PS by updating the already existing draft
- Requirements regarding QoC and PS must be supervised by an independent national body
- Create a competent authority with the involvement of stakeholders
- Decriminalization of human errors and establishing just culture by collaborating with the Ministry of Justice
- Developed a comprehensive law on no-fault compensation by significant update on current draft. Consequently, changes to Criminal Law, Medical Services Act, Health Services Act, Law on Patients Rights, Law on Pharmacy etc.

a.1. Compensation

Currently a general compensation scheme for no-fault preventable adverse events does not exist in Slovenian legislation. There is only a no-fault compensation scheme for damages caused by an obligatory vaccination (Communicable Diseases Act).

Usually, compensation for damages in medicine is treated as a contractual liability event. The liability event caused by an error in treatment (e.g. patient's (victim's) deterioration of health, victim's death, severe disability etc.) can result in pecuniary or non-pecuniary damages. Only those encroachments on legal goods which are determined as such in Article 179 of the Civil Code are legally recognized non-pecuniary damages.

In the late 1990s The Law on Medical Services was introduced which aim was also to enforce mandatory insurance for medical malpractice for all practicing medical doctors. There is no link to be found in the law between insurance, QoC, data collection of adverse events, feedback to the MoH, insurers and health services providers. Today compensation is still based on proven guilty of malpractice. The burden of proof stands on the plaintiffs themselves.

Current fault system:

1. Regulation of liability for damages in healthcare is based on the system of culpable liability.
2. The legal basis on which a certain individual is entitled to compensation for damages is the provisions of the Civil Code. According to the first paragraph of Article 131 any person that inflicts damage on another shall be obliged to reimburse it, unless it is proved that the damage was incurred without the culpability of the former.
3. Common general assumptions for liability for damages, which must be expressed cumulatively, are unlawfulness, which can be expressed as unlawful conduct or the unlawfulness of the consequences of certain actions, a causal link, damages and in the case of culpable liability also fault or culpability.
4. With regard to liability for damages that a patient suffers during medical treatment, it is also necessary to take into account the provision set out in Article

147(1) of the Civil Code which stipulates that regarding the damage inflicted on a third person by an employee during work or in connection with work, the legal or natural person for whom an employee was working at the time the damage was inflicted, shall be liable, unless it is shown that the employee acted as was necessary under the given circumstances. The injured party has the right to demand compensation for the damage directly from the employee, if the damage was caused intentionally. Whoever has reimbursed the injured party for the damage caused by the employee intentionally or through gross negligence, has the right to demand reimbursement of the amount paid from the employee.

5. Legally relevant damages are according to article 132 of the Civil Code a reduction in the value of property (ordinary damage), prevention of the appreciation of property (lost profits), the infliction of physical or mental distress or fear on another person, and damage to the reputation of a legal person (non-pecuniary damage).
6. A medical error is a behaviour that does not comply with the rules of the profession, which determine how a doctor should act during a certain treatment. Acting contrary to the rules of the profession is a key presumption of liability for damages caused by medical malpractice. As the patient is the subject of treatment, his/her will must be respected.
7. Civil Code also treats the patient-physician relationship as a non-business tort relationship, as a civil tort, because any unjustified interference with the body's integrity (life and health of the patient) means damage for which the perpetrator is liable for. To define an act as a civil tort it must be unlawful, which is excluded if the affected person consents to it. Therefore, it is considered that a medical procedure performed *lege artis*, with the consent of the patient, cannot be the basis for compensation claims, even if the desired and expected success has not been achieved and the patient's health may have worsened. On the basis of a non-business compensation relationship, liability can be enforced in cases where the patient did not consent to the procedure (emergency medical care) or in cases where the duty to explain was inadequately fulfilled and the patient's consent was invalid due to insufficient information.
8. Compensation for damages resulting from certain (specific) cases is regulated in Slovenia within so called state reimbursement schemes, which do not represent a classic system of state liability for damages, because the liability of the state is based on a legal norm, which also determines the scope of its guarantee.
9. The basis for the claim for damages therefore exists:
 - a. When the deterioration of health is the result of the doctor's incorrect or unprofessional conduct;
 - b. When the doctor's conduct was professionally impeccable, but he/she did not have the patient's consent for it.
- 10.

Current fault based system doesn't really satisfy anyone. Current regulation of liability in healthcare, which the injured party asserts in the context of civil (court) proceedings, has a number of shortcomings that are becoming increasingly apparent with the increase in the number of lawsuits filed against healthcare providers and sometimes even against healthcare professionals at the same time. The trend of increasing litigation has also been observed in Slovenia in recent years, which is why the reform of the regulation of liability in healthcare is (urgently) necessary in our country as well.

The problems of the classical fault compensation in healthcare can be roughly grouped into individual problem sets, which are intertwined and complementary:

- Costs and length of the procedure
- Difficulty of proving guilt and liability
- Consequences in causing defensive medicine

The criminalization of human errors does not improve patient safety incident reporting and stimulates patient safety improvements.

Excessive penalization of human errors in healthcare has the following negative consequences:

- Healthcare professionals often choose to cover up their own mistakes for fear of severe penalties, which means that mistakes are not analysed, which makes it impossible to learn from them
- Because of the tag “scapegoat” healthcare professionals are numb, anxious, alienated, depressed, confused, have sleeping disorders and workplace dissatisfaction - in the society of accusation they feel ashamed, guilty and full of doubts about their own abilities
- "The method of accusation, which is traditionally and stubbornly used in the medical profession to reduce adverse events due to errors, is the most unsuccessful way to prevent them"
- Simple human mistakes that are not the result of reckless or negligent conduct are too often taken as a sufficient ground for conviction
- The emergence of defensive medicine and the concealment of errors, which prevents the development of medical science
- Mistrust between the patient and the doctor

Criminal law stipulates a health professionals criminal offences as they can be seen from the Appendix D.

a.2. Insurance scheme for medical malpractice – fault based

It was fully introduced in the year of 2000. Office based/private doctors were obliged to insure themselves, while employed doctors in primary care units and in hospitals were insured by their employers. There are no data on the type and number of compensation cases and amounts of claims covered. Legal requirement was to adjust insurance scheme in a way that medical specialists of a different specialities may be grouped to several different premium classes depending on a speciality risk factor. On a level of all practicing doctors in Slovenia an average premium for the damages (excluding general civil liability) is about € 200 per medical doctor per year. Including civil liability it is about € 350 per year. An average liability sum is app € 200.000 for individual medical practices and up to 5 million for hospitals. As mentioned, there are no firm or source of reliable data on the number of compensation cases per year and average liability sum being paid. Some so called large cases are reported in the media but the extent of the issue cannot be concluded drawing upon them. Again to emphasize, only fault caused injuries are covered with this scheme.

a.3. Proposal for introducing no-fault compensation

A conference on the no-fault compensation was organised in Ljubljana in June 2004 by medical profession, with international speakers. Later in the year the first formal initiative was addressed to the Ministry of Health (MoH) to assess the possibilities for introducing no-fault compensation scheme in Slovenia. In 2019 a new initiative and a draft proposal of compensation scheme was addressed to the MoH by the Medical Chamber.

The Ministry of justice prefers to keep the existing system of indemnification unchanged, as the judicial case-law shows that courts take into account all circumstances on which the fulfilment of the presumptions of liability for damages depend in each specific case. However, if we opted for a system of no-fault liability, we could follow the regulation from the act by regulating the compensation for damage sustained as a result of the erasure from the register of permanent residents. In this case, it would be expedient for this not to be an administrative procedure, but a prescribed internal procedure within a hospital or a body within the MoH (or HIIS). No-fault liability systems are support systems, which means that they are primarily aimed at increasing patient safety in order for them to receive compensation even in the event of an error that is not the result of a medical error. These systems are also complemented by the possibility of enforcing compensation through courts (judicial system), as we cannot restrict an individual's right to judicial protection if he or she considers that the damage was unlawful. Namely, the restriction of the possibility of judicial protection means an interference with the right to a fair trial, which derives from Article 6 of the European Convention for the Protection of Human Rights and Fundamental Freedoms. Thus, States parties to the Convention cannot introduce a no-fault compensation system without maintaining the possibility for filing an action for damages under the traditional compensation system and without the possibility of judicial review of the decision of the administrative body that decided the scope of compensation in the no-fault system, as this would violate the Convention.

Financing: No-fault compensation system requires adequate and permanent financing method for damages paid and for administrative costs of the procedures and appropriate trained human resources. It is estimated that an amount between 10 to 15 million Euros would be sufficient for the first year. It is not possible to be firm on prediction for several years in advance.

1. Health Services Act

The QoC and PS is mentioned a few times without a definition of the terms and without specific requirements of clinical indicators reporting. Supervision regarding QoC and PS is divided among several institutions: Medical Chamber, Nursing chamber for peer review and counselling with their own rules, MoH for the supervision of legislation, HIIS regarding contracts and GA rules and other rules, Healthcare inspectorate for same specific requirements like HAI, and so-called systemic inspection that combines inspection from chambers, HIIS and MoH. In this law, there is no requirement for establishing a comprehensive system of QoC and PS.

2. Healthcare and Health Insurance Act

National contact point for cross-border healthcare (article 77 b) according to Directive 2011/24/EU for providing information to a patient published on HIIS internet pages (e-mail and contact and a telephone number is provided). Among the requirements is information about standards and guidelines for QoC and PS to be fulfilled by healthcare providers in the Republic of Slovenia and information on which healthcare providers are in compliance with standards and guidelines.

Providers of healthcare in the Republic of Slovenia withdraw information to citizens/patients about waiting times, QoC and PS for each healthcare service.

There is no mention of what kind of standards and guidelines are necessary to follow and who is going to audit the healthcare providers.

3. Medical Practitioners Act, Medical Services Act

Physicians have to, after the first six months of practical work, pass the state exam on the basics of QoC and PS in healthcare. This is very basic, just to get the awareness of the importance of this domain. Physicians have to assure quality with the mean of continuous professional development, but there are no prescribed competencies of quality to be proved.

4. Patients' Rights Act and Patients' Rights Act with commentary

There is one article stating that patients have the right to appropriate, quality healthcare and safety. The waiting times and informed consent are also described. In chapter V procedure for requesting infringements of patient's rights is explained. Patient's right to receive the apology and explanation in case of violations on his/her rights is also described. However, disclosure of reasons for an adverse event due to error or professional violations and apology is not part of professional practice due to a culture of fear and criminalization of human error (36). It is of note that these procedures can only occur in the case of a patient's complaint. In the healthcare system in Slovenia, no guidelines and no training exist to help healthcare providers exercise their moral duty and legislative obligations (26).

5. General agreements and annexes

Each year, representatives of contractors (chambers, associations), the MoH and the HIIS negotiate and agree on the total range of health service programmes and the necessary funds to pay for the programme at the national level.

The GA is the result of partnership negotiations, which is the legal basis for contracting with public health institutions and private individuals. The objective of negotiations is in the responsible setting of "ceilings" of public funds for health and accountable use of funds, which are collected jointly and solidary on the basis of compulsory contributions of all insured persons in Slovenia.

The GA defines, taking into account global economic opportunities, the overall scope of health service programmes, priority areas, the necessary capacities and elements for the evaluation of services.

The GA acts from 2011 to 2020 were examined to look into QoC and PS requirements.

Quality indicators must be monitored by healthcare providers on a monthly basis from the 1st of January 2011. They must also be published on their own websites every three months. The report shall provide the healthcare providers with information on the values of the quality indicators and the plans and measures for improvement. The following lists were part of the GA acts:

- List of criteria and notes to determine the appropriateness of admissions of patients over 19 years of age
- List of criteria and notes to determine the appropriateness of admissions of patients under 19 years of age, excluding new-borns
- List of 73 quality indicators

In paediatrics, psychiatry, gynaecology, perinatology, cardiology, traumatology, abdominal and thoracic surgery, ophthalmology, urology, and neurology methodology of Medical Chamber is used, until 2018, where the program in Medical Chamber of Slovenia (MCS) was abolished.

MoH requires hospitals in their annual reports the implementation of the obligations under the GA regarding QoC and PS. They have to report mandatory indicators and prepare annually two clinical pathways.

The mandatory quality indicators have been reported with some delays from 2010. The last report is from 2019. Not all indicators are reported and no data quality is controlled.

Below the general agreement acts is presented:

Items ¹⁰⁰	GA 11	GA 12	GA 13	GA 14	GA 15	GA 16	GA 17	GA 18	GA 19	GA 20
Introduction of Quality system based on national policy ¹⁰¹	1	1	1	1	1	1	0	0	0	0
Development of a system of quality and PS ¹⁰²	0	1	1	1	1	0	0	0	0	0
PS ¹⁰³¹⁰⁴	1	1	1	1	1	1	1	1	1	1
Clinical guidelines ¹⁰⁵	0	0	0	0	0	0	0	0	0	0
Clinical pathways ¹⁰⁶	1	1	1	1	1	1	1	1	1	1
Indicators ¹⁰⁷	1	1	1	1	1	1	1	1	0 ⁴	0 ⁴
Accreditation		1	1	1	1	1	1	1	0	0
Internal control at all levels of healthcare	1	1	1	1	1	1	1	1	1	1
Waiting lists	1	1	1	1	1	1	1	1	1	1
Appropriateness of hospitalization	1	1	1	1	1	1	1	1	1	1

Table 7. General agreement acts

6. Legislation based on EU Directives regarding quality and PS

Below some Acts are presented:

- Act Regulating the Obtaining and Transplantation of Human Body Parts for the Purposes of Medical Treatment. Uradni list RS, št. 56/15
- Act on quality and safety of human tissues and cells, for the Purposes for medical treatment., Uradni list RS, št. 61/07 in 56/15

¹⁰⁰ GA, GA; 1, the item is present; 0, the item is not present

¹⁰¹ Robida A (ed). National policy for the developing of quality in healthcare. Ljubljana:Ministry of health 2006

¹⁰² Based on National strategy for quality and patient safety 20110-2015. Ministra of Health: National strategy for qulaity and patient safety in healthcare. Ljubljana: Ministry of Health, 2010

¹⁰³ Poldrugovac M, Simčič B (eds): Manual of quality indicators. Ljubljana: Ministry of Healt, 2010

¹⁰⁴ Robida A (ed). Introducing quality improvement to hospitals. Ljubljana: Ministry of Health, 2006

¹⁰⁵ Fras et al. Slovenian guidelines manual. Ljubljana: Ministry of Health, 2003

¹⁰⁶ Yazbeck AM, RobidaA (eds).Methodological recommendations for clinical pathway development and implementation. Ljubljana: Ministry of Health, 2006

¹⁰⁷ Quality indicators developed at Medical Chamber of Slovenia for peediatrics, psychiatry, perinatology,cardiology, traumatology, abdominal and torhacic surgery, ophthalmology, urlology, neurology.

- Blood Supply Act. Uradni list RS, št. 104/0

The healthcare providers follow these acts and they can also be a stimulus to arrange other areas of QoC and PS.

7. Management of prevention programs

There is also a good system for quality improvement in some of preventive programs, like prevention of breast cancer, cervical cancer, and colorectal cancer.

- MoH. National Cancer management Programme 2017–2021. Ljubljana: MoH, 2017

It is of interest how programmes for early detection of carcinomas are well structured and regularly monitor quality indicators.

Draft

5. STRATEGIC CONCLUSIONS

In strategic conclusions, we propose a list of measures derived from the current situation analysis to validate them before forming them into recommendations for their systematic implementation into the Slovenian healthcare system.

There is a need for fine-tuning the legislation to assure universal coverage, starting with the regulation of permanent residence.

Basic benefits package must be redefined or appropriately additionally financed since nowadays it is too wide and already unsustainable with worrying projections already by 2025.

Updated and unsustainable “Siamese” twins of compulsory and voluntary complementary insurance must be politically revised.

Innovative measures should be undertaken to tackle waiting lists times and incentivize productivity.

Promotions of further analyses in health inequalities is needed for their reduction across sectors.

5.1 Governance and organization

The new National Strategy for Health Quality and Safety should be launched and implemented through a realistic action plan.

There is a need for a public, non-profit, independent, and autonomous organization (“body”) to systematically perform all tasks related to the management of the productivity, efficiency, effectiveness, quality, and safety dimensions of the healthcare system through evaluation and standardization of all healthcare services and technologies – current and potential. It may also include a function of processing compensation claims.

There is a need to empower primary care, promote the shift from inpatient to outpatient care, and double the percentage of prospective programs in the next three years with outcome-oriented incentives.

Governance for QoC and PS should be improved at healthcare facilities, especially those that are not accredited. The MoH is owner public secondary and tertiary care and municipalities are owners of primary care. They influence the business and clinical function of healthcare facilities through the public Board Council (Svet zavoda). There is need for board members to control QoC, PS and CRM development at each organisation they are responsible for.

5.2 Resources (human and financial)

a) Resources

a.1. Human resources and appropriate institutions for the education of health professionals

A national human resource strategy should be launched to increase the number of students at medical faculties by one-third. Accordingly, the planning of all other healthcare workers should follow with a priority focus on current and future gaps across specializations.

There is an immediate need to incentivize students and increase the attractiveness of the occupation of a family physician.

Human resources are also needed for governance of QoS and PS at all healthcare facility levels, including training for the relevant competencies.

a.2. Payment mechanisms

The negotiation process needs to be changed, since it has been shown that it is time-consuming, non-transparent, especially regarding the role of MoH as a partner, chairman of the arbitration, and final decision-maker.

Payment methods at all levels should promote quality and safety for service provision, appropriate incentives must be embedded in the system.

The payment methods should be patient-centred; the referral letter as the only integration tool should be upgraded.

a.3. Equity in fund allocation among levels

Strategic procurement must become unique and uniform in the fund allocation in a patient-centered system.

The primary healthcare level must be further prioritized; empowerment is crucial.

The SPP (Slovenian DRG) needs complete refreshment.

There is a need to upgrade or at least update the payment method for tertiary activity.

Systematic use of HTA is needed.

In all payment methods, quality or safety must overcome productivity.

The surveys on patients' experiences, patients' satisfaction, and protection of patients' rights have to be revisited.

a.4. Comprehensive and availability of equipment for well-equipped service

The prepared legislation on investment in healthcare for 2021-2031 is not based on analyses or evidence.

A situation analysis of national needs regarding medical equipment is needed as a base for much-needed national interventions in equipment since the density of some high-value equipment is low and the write-off rate of equipment is extremely high.

a.5. Competence and empathy of health professionals

There is a need for strategic implementation of programs oriented toward the importance of empathy and potential learning dimensions of empathy of healthcare workers in all healthcare institutions and competencies for QoS and PS

a.6. Measures for engagement, motivation of healthcare workers, rewards, sanctions – cost and savings estimate

The salary system should be completely renewed if the promotion of effectiveness, quality, creativity, and patient-centeredness are to be promoted.

Introducing quality and safety principles in healthcare must be included in the payment system at the organizational level.

5.3 Tools and processes

a) Availabilities

a.1. Implementing an integrated approach

All implemented promotions of integration of services must be analysed for the preparation of further tools for achieving higher levels of integrated care, QoS and PS.

a.2. Availability of standards and norms

The legislative obligation of HISS should be completed: standards and norms must be defined in a participative approach with stakeholders.

The initiated process of implementation of standards for medical premises and equipment, measures for the assessment of new methods of treatment must be completed.

a.3. Availability of and access to health-related information

The delay in health-related information on the health status of the population, reports on health status, equality of access, and equality of health according to various variables should be shortened.

The volume and content of data on HRQoL in connection to treatments and procedures should include HRQoL and PROMs and not only clinical data. They should be transparent and publicly available.

The endoprosthesis registry needs implementation in planning, rewording, and organization of orthopaedic services.

a.4. Availability of implementation strategies and research on health service delivery

The propensity to prepare strategies should be balanced with the needed implementation followed by a necessary evaluation as a foundation for further decision-making solutions. Nevertheless, the first step should be a political agreement on an "umbrella" healthcare strategy.

The accepted action plans with proposed indicators should be appropriate and shall surpass administrative reasons.

a.5. HTA

An HTA framework in Slovenia must be systematically established for all health technologies. Clearer instructions on the preference-based tools and definition of benefits and the analyses submitted should be set.

a.6. Clinical decision making

There is a need for further promotion of international clinical guidelines and national clinical pathways starting in the education system up to organizational structure and financing system of healthcare service provision.

a.7. Availability of guidelines

The process of preparation, evaluation and implementation of guidelines should be promoted and interlinked with the payment methods.

The successful process of clinical pathways implementation should be finalised with financial incentives for successful healthcare providers, their implementation shall be incentivized through non-financial and financial tools.

a.8. Continuity (availability of medical information, medical record keeping)

HER should be leveraged to improve the quality and effectiveness of care, the accuracy of documentation, promote continuity of care and exchange of relevant information.

There is a need for a national strategy on telemedicine, informatization, and communication technology in the healthcare system to restart a successful process at the beginning of the millennium positioning Slovenia on leading positions in the EU regarding several successful IT solutions.

5.4 Quality and patient safety indicators

a. Indicators

a.1. Review of the existing quality standards and indicators

There is a need to review the list of quality indicators to assure the international, national and local benchmarking and avoid overlapping.

The annual analyses should be performed by an independent organization and publicly pre-sented after external verification.

PROMs must be launched and systematically implemented in payment methods. They should be analysed periodically, upgraded regularly, reported back to the healthcare providers by programs to enable the possibility of benchmarking and exchange of good practices.

The service code translator has not been officially published.

a.2. Proposal of indicators on quality and integration of care (from referral to discharge), effectiveness, appropriateness, and responsiveness

Promotion and implementation of integrated health systems can provide a superior performance rate, increase quality and safety as a result of more effective communication and standardized protocols.

The systems for internal monitoring of PS, QoC, and uptake of evidence-based clinical guidelines should be set up in a uniform and structured manner in all hospitals.

Classification of indicators of QoC should be revised starting from the Donabedian-triangle of structure, process and outcome can use four operational levels: macro, meso, micro, and nano.

Development of indicators should be started with the list of relevant priorities; the selection should be from developed international indicators.

The process of introduction of the indicators is long and expensive, starting from their planning, preparation (translation, validation, informatization), and use (collection, cleaning, analysis).

The selection of indicators should be from Global Reference List of WHO 100 Core Health Indicators, Health Facility and Community Data Toolkit, PATH, HCQI, Health at a Glance - OECD Indicators (OECD HAG), ICHOM and PaRIS and other.

The set of indicators placed in the GA should be revised.

The defined quality indicators in the currently planned National Tender should be used at the level of all services, not only for the purposes of the tender.

a.3. Waste in Healthcare

The strategy on waste in the healthcare system is a need in the strategic orientation toward “green” Slovenia in “green” EU. “Green” should be included in public tendering processes in all healthcare institutions.

Information technology for collecting data, analysing, interpreting, and corrective actions in the domain of quality should be in place. The introduction of indicators should be fully supported by ICT!

Urgent national, regional, and local actions are needed to reduce wasteful spending in healthcare to reduce harm for patients, reduce adverse events, and avoidable hospital admissions.

As an obligation in the GA for hospital providers, inappropriate admissions to hospitals from primary level and outpatient specialty services should be measured and audited.

a.4. Health-related Quality of Life

Measuring HRQoL should become systematic and promote positive motivation, improvements in care pathways, and sharing of good practices among the healthcare providers.

Information technology for collecting data, analysing interpretation, and corrective actions in the domain of quality should be in place. The introduction of indicators should be fully informatised.

5.5 Legislation

There are several laws and bylaws to be tackled and prepared to implement strategic conclusions. Majority of health legislation is at least 20 or even 30 years old. Significant part is quite outdated. It was amended in between so many times that in the “legal jungle” even some frequent users may feel a little bit lost.

6. REFERENCES

1. Hollnagel E. Safety-II in practice. Developing the resilience potentials, Abingdon: Rutledge, 2018.
2. Slawomirski L, Auraaen A, Klazinga N. The Economics of PS in Primary and Ambulatory Care: Flying blind. Paris: OECD; 2018
3. de Vries EN, Ramrattan MA, Smorenburg SM, Gouma DJ, Boermeester MA. The incidence and nature of in-hospital adverse events: a systematic review. Qual Saf Healthcare. 2008;17(3):216–23.
4. WHO. Global PS Action Plan 2021–2030. Towards Zero Patient Harm in Healthcare. Working document, 2021.
5. Briner M et al. Assessing hospitals' CRM: Development of a monitoring instrument. BMC Health Services Research 2010, 10:337. <http://www.biomedcentral.com/1472-6963/10/337>
6. Robida A (ed). National policy for the development of quality in healthcare. Ljubljana: MoH, 2006.
7. Institute of Medicine Medicare: A Strategy for Quality Assurance. Washington DC. National Academy Press, 1990; Vol.
8. Shaw, D.C., Kalo, Y. A Background for National Quality Policies in Health Systems. WHO, 2002.
9. Hindle, D. Accreditation in Slovenia. A background paper. MoH, Ljubljana, 2003
10. Shaw DC, Kalo YA .Background for National Quality Policies in Health Systems. WHO, 2002.
11. Hindle, D. Accreditation in Slovenia. A background paper. MoH, Ljubljana, 2003.
12. Institute of Medicine. Crossing the Quality Chasm. Washington DC. National Academy Press, 2001.
13. Kersnik, J. Kakovost v sistemu zdravstvenega varstva v Republiki Sloveniji. (Engl. Quality in the Slovene National Health System. Regional WHO Office, Copenhagen, 2001) Pregled stanja in bodoče usmeritve. Regionalni urad SZO, Kopenhagen, 2001.
14. Nacionalni program zdravstvenega varstva Republike Slovenije – zdravje za vse do leta 2004. (Engl. National Healthcare Program of the Republic of Slovenia - Health for All until 2004) Uradni list RS, št 49-2333/2000.
15. MoH. Zdravstvena reforma: osnutek. (Engl. Healthcare Reform: Draft), Ljubljana, 2003.
16. Fras, Z., Robida, A., Brubnjak, JV. et al. Priročnik za smernice (Engl. Clinical Guidelines Handbook). Ministrstvo za zdravje, Ljubljana, 2003. <http://www.mz.gov.si>
17. Robida, A. Opozorilni nevarni dogodki (Engl. Sentinel events). Zdravstveni vestnik, 2004; 73 : 681–687.
18. MoH. Celjski primer.Ljubljana: Ministr of health, 2003 (Engl. The Case of Celje Hospital).<http://www.mz.gov.si>
19. Yazbeck, A. Introducing Clinical Pathways in the Slovene Hospital (Clinical) Setting: Professional cultures and changes in organisational behavior. Master's Thesis, University of Ljubljana: Faculty of Economics, 2004.
20. Robida A, ed. Accreditation standards for hospitals. Ljubljana: MoH, 2004.
21. Robida A, ed.Manual for self-assessment for hospitals. Ljubljana: MoH, 2004.
22. Robida A, ed. Program for self-assessment and external assessment- accreditation in **healthcare**. Ljubljana Ministry of Health,2004

23. Simčič B. (ed) National strategy for quality and PS development (2010-2015). Ljubljana. MoH, 2010. (in Slovene).
24. Robida, A. Nacional survey on education for competencies for quality and PS 2016 . Working group at MoH. Utrip. 2016; 24: 14-16.
25. Resolucija o nacionalnem planu zdravstvenega varstva 2016–2025 »Skupaj za družbo zdravja« (Uradni list RS, št. 25/16)
26. Korošec D. Zakon o pacientovih pravicah with comentary. Ljubljana: GV založba, 2009.
27. Direktiva 2011/24/EU Evropskega parlamenta in Sveta z dne 9. marca 2011 o uveljavljanju pravic pacientov pri čezmejnem zdravstvenem varstvu.
28. Ministrstvo za zdravje. Model vzpostavitve sistema akreditacije zdravstvenih ustanov v Sloveniji. Ljubljana: Ministrstvo za zdravje, 2010.
29. Council Recommendation (2009 C 151/01) of 9 June 2009 on PS, including the prevention and control of healthcare-associated infections (OJ C 151, 3.7.2009).
30. OECD. Health Systems Characteristics Survey 2016, Slovenia
<https://qdd.oecd.org/subject.aspx?Subject=hsc> (accessed 4.3.2021)
31. OECD. System governance towards improved PS, 2019.
<https://www.oecd.org/health/system-governance-towards-improved-patient-safety-2abdd834-en.htm> (accessed 4.3.2021).
32. Svetovna zdravstvena organizacija. Obvladovanje kakovosti v osnovnem zdravstvu-Slovenija. Copenhagen: WHO Regional Office for Europe, 2008.
33. Šuklar S. Quality indicators in primary healthcare. Izzivi prihodnosti. 2019; 4:15-36.
34. Report from the commission to the council. The Commission's Second Report to the Council on the implementation of Council Recommendation 2009/C 151/01 on PS, including the prevention and control of HAI. Brussels, 19.6.2014
COM(2014) 371 final.
35. Prijatelj V, et al. A model for risk assessment in healthcare using a Healthcare failure method and effect analysis. Zdrav Var :2013; 52: 316-331.
36. Robida A. Kriminalizacija človeških napak v zdravstvu. ISIS. 2012;2:17-23.

7. APPENDIX

7.1 Appendix A - A brief history of quality and patient safety development in Slovenia

Year	Context	Year of update
<2000	<ul style="list-style-type: none"> Perinatology information system, 1987 (1) Šorli J, Kersnik J. Quality in healthcare: a proposed national policy. Copenhagen: WHO, 1996 (3) 	<p>Yes</p> <p>Updated 2006</p>
2002	<ul style="list-style-type: none"> The national reporting system for Sentinel Events (4) 	<p>Proposal for update rejected by MoH</p> <p>Updated in SenSy project of EC in 2018-2020</p>
2003	<ul style="list-style-type: none"> Proposal for establishment of a National independent body for Healthcare Quality and PS (6) 	No
2004	<ul style="list-style-type: none"> Generic standards for Hospital Accreditation (7) Manual for Self-Assessment (7) Program for Self-Assessment and Accreditation (7) 	<p>Not implemented</p> <p>Not implemented</p> <p>Not implemented</p>
2005	<ul style="list-style-type: none"> Luxemburg Declaration on PS- Slovene Translation (9) 	-
2006	<ul style="list-style-type: none"> National Policy for the Development of Quality in Healthcare (10) Implementation of Quality Improvement in Hospitals (11) Pledge of Slovenia and WHO regarding HAI (13) Six national quality indicators (14) National Survey of Patient Experience in Hospital (15) 	<p>No</p> <p>No</p> <p>-</p> <p>Updated in 2010 and not after that</p> <p>Cancelled in 2012</p>
2008	<ul style="list-style-type: none"> Quality and safety of healthcare provision: The role of middle management (16) 	Study
2010	<ul style="list-style-type: none"> National Strategy for Quality and PS 2010-2015 (20) Quality Indicators Manual (73 Indicators) (21) Multiprofessional PS curriculum guide (22) Results of Quality Indicators (23) 	<p>No</p> <p>No</p> <p>Implemented into only one faculty of healthcare</p> <p>Published each year (2010-2019)</p>
2011	<ul style="list-style-type: none"> International Accreditation of healthcare facilities - 2019 +ISO 9001) (24) 	In the system; not all facilities are accredited
2013	<ul style="list-style-type: none"> Perception of PS culture (21 of 26 Hospitals) (25) Root causes manual for errors in healthcare (26) 	<p>Yes, no repeated study</p> <p>Manual</p>
2014	<ul style="list-style-type: none"> Attitude and knowledge of nursing clinical mentors about PS (27) 	Study
2016	<ul style="list-style-type: none"> National Survey on Quality education (28) Competencies for Quality Improvement (29) Draft for Quality and PS law- Internal document MoH 	<p>Study</p> <p>Study</p> <p>Cancelled</p>

Year	Context	Year of update
2017	<ul style="list-style-type: none"> SAQ primary care (30) 	Study
2019	<ul style="list-style-type: none"> SenSy project-EC (31) Health System Performance Assessment for Slovenia 	Not implemented
2020	<ul style="list-style-type: none"> PREMs – outpatient specialty services 	Not psychometrically evaluated

HAI, healthcare-associated infections; HIIS; MC Medical chamber; MoH, MoH; PREMS, Patient Reported Experience Measures; WHO; SAQ, safety attitude questionnaire, Yes, was updated, NO, was not updated; – not relevant.

References to the Appendix A

- ¹Verdenikl, Pajntar M. National perinatal information system and quality assessment. Zdrav Vestn 2002; Standards 71: 761–3.
- ²Pajntar M, Leskošek B. Results of project: »Quality healthcare in Slovenia. Zdrav Vestn 2002; 71: 765–71
- ³Šorli J, Kersnik J. Quality in healthcare: a proposed national policy. Copenhagen: WHO, 1996.
- ⁴Robida A. Sentinel Events. Zdrav Vestn 2004; 73: 681–7.
- ⁵Fras Z, et al. Slovene guidelines manual Ljubljana: MoH 2003
- ⁶Heijnen S. Proposal for the Slovene Quality of care institute. Ljubljana: Health sector management project, 2003
- ⁷Robida A. Generic standards for Hospital Accreditation. Manual for Self-Assessment. Program for Self-Assessment and Accreditation. Ljubljana: MoH 2004
- ⁸World health organisation. Standards for Health Promotion in Hospitals. Geneva: WHO, 2004
- ⁹Luxemburg Declaration on PS- Slovene Translation, 2005
<https://www.prosunt.si/prosunt-2-2-2/project/luksemburska-deklaracija-o-varnosti-pacientov/>
- ¹⁰Robida A. National Policy for the Development of Quality in Healthcare. Ljubljana: MoH, 2006
- ¹¹Robida A. Implementation of Quality Improvement to Hospitals. Ljubljana: MoH, 2006
- ¹²Yazbeck AM, Robida A. Manual for Development and Implementation of Clinical Pathways. Ljubljana: MoH, 2006
- ¹³MoH. Pledge of Slovenia and WHO regarding HAI. Ljubljana: MoH, 2006
- ¹⁴Robida A. Six national quality indicators in Generic standards for Hospital Accreditation. Ljubljana: MoH, 2006
- ¹⁵MoH. National Survey of Patient Experience in Hospital. Ljubljana: MoH, 2006
- ¹⁶Skela-savič B, Robida A. Quality and safety of healthcare provision: The role of middle management. Obzor Zdrav Neg. 2012;46:9-35.
- ¹⁷Act on Patients Rights. Uradni list RS, št. 15/08 in 55/1
- ¹⁸Robida A. Pathway to Clinical Excellence. Bled: Prosunt, 2009
- ¹⁹MoH. Clinical Pathway Manual (updated version from 2006). Ljubljana: MoH, 2009

- ²⁰ MoH. National Strategy for Quality and PS 2010-2015. Ljubljana: MoH, 2010
- ²¹ MoH. Quality Indicators Manual (73 Indicators). Ljubljana: MoH
- ²² World Health Organisation. Multiprofessional PS curriculum guide. Geneva: World Health Organisation, 2011.
- ²³ MoH. Results of Quality Indicators. <https://www.gov.si/teme/kakovost-zdravstvenega-varstva/> (Access 7th, Decemeber, 2020)
- ²⁴ Simčič B et al. Accreditation – an external assessment of quality and safety of healthcare treatments in healthcare institutions. Bilt - Ekon Organ Inform Zdrav 2011; 27(2): 113-122
- ²⁵ Robida A. Perception of PS culture in Slovenian acute general hospitals. Zdrav Vestn 2013; 82: 648–60
- ²⁶ Robida A. Root causes manual for errors in healthcare. Bled: Prosunt, 2013
- ²⁷ Robida A. Attitude and knowledge of nursing clinical mentors about PS. Obzor Zdrav Neg. 2014; 48: 220–226.
- ²⁸ Robida A, et al. National Survey on education for quality and PS. ISIS. November 2016; 38-40.
- ²⁹ Robida A. et al. Competencies for quality, safety and patient centredness. Bled: Prosunt, 2016. <https://www.prosunt.si/content/uploads/2018/09/Kompetenca-kakovost-varnost.pdf> (Access 7th December, 2020)
- ³⁰ Klemenc-Ketis Z., et al. The safety attitudes questionnaire – ambulatory version: psychometric properties of the Slovenian version for the out-of-hours primary care setting. BMC Health Serv Res 2017; 17: 36.
- ³¹ SenSy project-EC. <https://www.gov.si/zbirke/projekti-in-programi/projekt-sensys/> (Access 7th December, 2020)

7.2 Appendix B – OECD: Healthcare System Characteristics Survey 2016 in Slovenia

Item	2016 MoH response	Comments from MoH
65. National legislation in QoC	Yes	Not a long-term decision yet.
66. Is there an organisation with responsibility for national policy on healthcare quality in your country?	Yes MoH	Yes, the MoH is responsible for the establishment of an integrated management system for QoC and PS. However, we must not ignore the management of healthcare institutions and their role.
67. Are there national standards for healthcare quality in your country:	Yes	Yes, they are for some specific disease or medical conditions, but further development is needed in this area.
- Hospital	Yes	However, there is a problem with understanding and interpreting which standards are meant.
- Primary care	Yes	
- Technologies	Yes	
68. Do these standards apply equally to public	Yes	Guidelines and standards are a good basis for comparable medical treatment in different institutions. The use of guidelines and standards represents a safe quality for the institute. From a

and private healthcare providers?		strictly formal point of view, the use of guidelines and standards in an individual institution is a decision of the leaders, or individual healthcare workers or the team.
69. How is compliance with these standards assessed in your country? - Accreditation scheme - Inspectorate function - Clinical audit - Other	Yes No Yes Yes- medical devices;	Certification is mandatory for some areas in healthcare (pharmacies) and voluntary for others. The role of listed activities is clear and we support it to fulfil their role.
70. Is there a set of national metrics available to monitor compliance with the standards in your country?	Yes No national metrics, metrics of accreditation organization are used in accredited facilities	There is a lot of openness in this area. It is certainly a tool for quality improvement, but there are often gaps in implementation that are unacceptable.
71. Are these metrics publicly reported at the healthcare provider level at least annually?	No Accreditation results are not publicly available; MoH has a list of accredited facilities	Rule of principle: what is funded by public money must be available to the public.

Table. Responses: OECD. Health Systems Characteristics Survey 2016, Slovenia

The answers in the third column are also opinions of what should be there but is still not. This is more about expectations than the current situation. Nevertheless, this will help everis team to include it into the project as much as possible if this is in alignment with the term of references.

Item 65: MOH: Not a long-term decision yet

Comments of experts: there is no comprehensive QoC and PS legislation

Q67Comments from MoH: *There are no national standards set for healthcare quality yet, however the hospitals as well as some other healthcare providers are accredited according to the international standards (ISO, DNV, JCI). There are standards related to medical devices, in line with EU regulation. The organization responsible is the Agency of the Republic of Slovenia for Medicinal Products and Medical Devices. There is a national recommendation issued by MoH for healthcare providers to get accredited by one of the recognized international accreditation organizations. In 2011 the MoH has initiated the introduction of "Family Medicine Model Practices", aimed at ensuring the work on the primary level with appropriate staffing, content and financial structure and consequently better quality and cost-effectiveness of the healthcare. To this end 32 quality indicators have been monitored and the special healthcare providers database has been set up. In hospital sector Slovenia established the system of **compulsory** recording and gathering of quality indicators. In accordance with the Manual on quality indicators, the healthcare providers currently collect data on 74 quality indicators that are analysed and 6-10 of them are published on hospitals' websites. Quality indicators, quality systems, the results of accreditation and newly introduced clinical pathways are*

reported in annual reports. At the end of 2015, the Council for quality and safety in healthcare has been established at the MoH and in 2016 four priority areas will be discussed in project subgroups: revision of the existing set of quality indicators and methodology, regulation and institutionalisation of quality and safety, training in the field of quality and safety at undergraduate and postgraduate level and setting up an information contact point for patients/citizens. (Source: SPC draft report for Slovenia2016)

1. Comment from everis team

In response to OECD MoH claimed that there are national standards for quality of hospital care, primary care and technologies. Herein standards of quality are meant, but no national standards exist.

The international accreditation and ISO standards are generic standards and not disease-specific standards for each level and type of service like primary care, outpatient specialty care, hospital care, nursing care, pharmaceutical care, rehabilitation care, preventive care etc. Some professional groups have standards for their profession, but these are not national standards.

Request of everis team to MoH: Please list all standards if they exist (for instance: SVIT, DORA, ZORA, transplantation, blood, model practice in family medicine - referenčne ambulante etc.).

No standards were received from MoH.

In 2011 the MoH has initiated the introduction of "Family Medicine Model Practices", aimed at ensuring the work on the primary level with appropriate staffing, content and financial structure and consequently better quality and cost-effectiveness of the healthcare. To this end 32 quality indicators have been monitored and the special healthcare providers database has been set up.

2. Comment from everis

Please provide the document "Family Medicine Model Practices", 32 quality indicators and **results** of these monitoring from the year when they had been implemented to the year 2019.

The address of the web page was provided: <https://www.gov.si/teme/mreza-javne-zdravstvene-sluzbe/>

In the document "Učinkovitost dela ambulant družinske medicine za področje nalog diplomirane medicinske sestre (Efficiency of the work of family medicine in the field of the duties of graduate nurse) the quality indicators were presented, showing many variations among healthcare providers. The statistical calculation did not use statistical process control, thus it is not known what were the causes for such immense variations among healthcare providers.

The recommendations for improvement were described but their realization is not known.

There were complaints from the primary care sector that the feedback to their own outpatient clinic is not provided on a timely basis.

In hospital sector Slovenia established the system of compulsory recording and gathering of quality indicators. In accordance with the Manual on quality indicators, the healthcare providers currently collect data on 73 quality indicators that are analysed and 6-10 of them are published on hospitals' websites. Quality indicators, quality systems, accreditation results, and newly introduced clinical pathways are reported in annual reports.

3. Comment from everis team

Please provide:

- The summary of data showing how many indicators were not reported for each year
- The data of improvements from the beginning of the implementation to the last reported year, if this statistics exists
- What system of improvement provider of healthcare use to improve quality (Model of improvement, Lean, Six sigma, Lean six sigma, other)
- Why are not all indicators publicly available
- Are there any other communication channels with patient's organization to regularly inform them on all relevant standards?

No answers were received about how many indicators were not reported, data about possible improvement over time, about models used for improvements. The data up to year 2019 can be found on: <https://www.gov.si teme/kakovost-zdravstvenega-varstva/>

Q68Comments from MoH: *The recommendations directed to all healthcare providers; however a financial incentive to be accredited is provided to public and private healthcare providers who offers public services and have contractual relationship with the HIIS.*

4. Comments from everis team

There is no financial incentives for accredited facilities. At the start of the international accreditation program there was a financial penalty if facilities did not started the process of accreditation.

At the end of 2015, the Council for quality and safety in healthcare has been established at the MoH and in 2016 four priority areas were discussed in project subgroups: revision of the existing set of quality indicators and methodology, regulation and institutionalization of quality and safety, training in the field of quality and safety at undergraduate and postgraduate level and set up an information contact point for patients/citizens. (Source: SPC draft report for Slovenia-2016)

5. Comments from everis team

Please state the reason why, to our knowledge, was the Council for quality and safety abolished

No answers why the Council was abolished were received from MoH.

7.3 Appendix C – OECD survey on patient safety governance functions, 2019

Name and surname: *MoH*

Please provide evidence where your answer is YES

CAPACITY

1. How many people is fulltime engaged in quality and PS at MoH.

The MoH has now established a sector for quality within the Directorate for the development of healthcare. The staff is still being supplemented.

However, efforts to improve quality in healthcare are carried out in an integrated manner within all constituent units of the MoH

2. What are their competencies
 - a. Formal training:
 - b. Informal training:
 - c. Other

3. What are their responsibilities:

The MoH is committed to employment be people with practical work experience in the field of:

- *carrying out healthcare of patients*
- *quality and safety assurance*
- *participation in international working groups and projects in the field of quality and safety in healthcare*
- *development and implementation of systemic measures in the field of quality and safety*
- *quality evaluation and introduction of innovations for quality in healthcare*

At present, however, the situation is not yet satisfactory. Delegation of tasks is done by leaders at different levels and by state secretaries. It is crucial that the leaders know the area of work well.

The MoH has committed itself to a competency model, taking into account both formal and informal education of candidates for individual positions. At present, there are still some discrepancies regarding the adherence to the competency model.

4. What are their tasks:

Due to the small number of employees, each employee covers several areas of work. Otherwise, all tasks within the MoH can be classified as tasks for improving the quality and safety in healthcare.

5. Fulfilment of the recommendations of Council Recommendation 2009/C 151/01 on **PS, including the prevention and control of HAI**. This has been answered above.
6. OECD Health Systems Characteristics Survey 2016 Slovenia is presented in Appendix B
7. PS governance functions

Responses from MoH of Republic of Slovenia to OECD at 2019 survey

1. Clearly defined national/system-wide roles and responsibilities

Item	2019 MoH response	Documents/results needed from team everis	Comments
1.1 National legislation on quality and safety	No In Slovenia, patients have the legal right to adequate quality care and safe medical treatment through the Patients Right Act, as well as embedded in other legislation, e.g. The Contagious Diseases Act and the Health Services Act. Slovenia is currently amending the Patients Right Act to also include PS monitoring.	a. Describe what is in both act that are mentioned herein regarding quality and PS improvement and is implemented in healthcare organizations? b. Do you think that this legislation is adequate to overall requirements for PS, CRM and quality in every healthcare settings	Is a base that represents a great deal of added value. Of course, in many ways it is not enough.
1.2 National quality and safety agency	No PS unit within the MoH	Describe the context of the unit, personnel, and their competencies, when it was established, and what deliverable it produces since its establishment	Now the direction is to go into a special body The sector at the Ministry has already been established.
1.3 National safety standards	No		
1.4 National PS program	No		

Comments from everis: Item 1.1. In the text it is written that there is no special law on PS and QOC and the contents in different legislations is far from being comprehensive in sense of QI, PS, PSC and CRM. Item 1.3 and 1.4 were not answered.

2. Systems for measuring and monitoring progress

Item	2019 MoH response	Documents/results needed from team everis	Comments
2.1 National set of indicators supporting safety standards have been established	Yes A national set of PS indicators exists and will be updated over the next two years	a. Provide the indicator's manual b. When were indicators updated? What actions have been done for of quality and PS sector at MoH to improve quality after receiving the results from healthcare organisations?	Recently, measures have been linked to the COVID-19 epidemic and the curbing of the spread of the virus. The introduction of systemic measures has not yet been implemented as necessary.
2.2 Internal monitoring of PS for continuous improvement	Yes Healthcare providers organise PS meetings and perform internal supervision	Please send us evidence that these meetings are in place in all facilities (hospital care, primary care, community pharmacies, nursing homes, rehabilitation centres) Was any audit performed by MoH?	The MoH carried out an assessment of the situation and, on this basis, planned to introduce a renovation of the existing system.
2.3 External accreditation, inspection or audit PS processes and outcomes	Yes External accreditation, inspections or audits of PS processes and outcomes are not mandatory	Provide the reason for not externally auditing as a mandatory procedure evaluated PS processes and outcomes at hospital care, primary care, community pharmacies, nursing homes, rehabilitation centres	Internal and external controls, audits and evaluations are extremely useful procedures. The added value of external controls is also the dissemination of examples of good practice

Comments from everis: Item 2.2 – no answer regarding audit from MoH, item 2.3 MoH agreed that this is useful but it is not clear if audit from MoM are regularly conducted.

3. Key accountabilities

Item	2019 MoH response	Documents/results needed from team everis	Comments
3.1 Healthcare provider financial incentives and/or penalties applied to promote and ensure safety	Yes Healthcare providers are incentivized to fund training and PS day	<p>a. Describe and provide evidence of the incentive for PS promotions. Do you have any reports from healthcare providers</p> <p>b. Describe and provide evidence on how was world PS day celebrated at the national level in 2019 and 2020</p>	<p>In 2019, we were very active in the commemoration, and in 2020, a public statement was prepared. We are now preparing the program for 2021.</p> <p>https://www.gov.si/novice/2020-09-17-ob-svetovnem-dnevu-varnosti-pacientov-varni-zdravstveni-delavci-varni-pacienti/</p> <p>https://www.gov.si/novice/2019-09-16-17-september-svetovni-dan-varnosti-pacientov-in-razvoja-kulture-varnosti-v-zdravstvenih-zavodih-govorite-o-varnosti-pacientov/</p>
3.2 Routine public reporting of PS indicators and performance	Yes Reports are published only at the level of healthcare providers	<p>a. Please provide evidence that PS indicators were published at the healthcare providers level (hospital care, primary care, community pharmacies, nursing homes, rehabilitation centres</p>	<p>The hand hygiene indicator is published by healthcare providers.</p> <p>https://www.gov.si teme/kakovost-zdravstvenega-varstva/</p>
3.3 Contracting and/or commissioning arrangements include safety requirements	Yes Safety is included in contracts	<p>a. Provide an anonymized sample contract</p> <p>If this is written in General agreements who is auditing that this is really occurring.</p>	<p>Documentation in the framework of public procurement is publicly published on the portal.</p> <p>The basis for the implementation of inspections is the Health Services Act.</p> <p>The audit of the Court of Auditors</p>

Comments from everis: Item 3.1a was not answered, 3.2 only few PS indicators are published (these are indicators required in the Manual or quality indicators, 3.3 the requirements are in the GA but are not audit.

4. Capacity building to ensure the right skills and competencies

Item	2019 MoH response	Documents/results needed from team everis	Comments
4.1 Safety competencies built into the curriculum of students in various health disciplines	Yes Safety competencies built into the curriculum for students in various health disciplines	a. Provide curricula for PS for both medical faculties, nursing faculties, faculty of pharmacy etc.	We already had a meeting with the deans of the faculties.
4.2 Ongoing training as part of professional development of healthcare personnel	Yes Ongoing training as part of professional development and healthcare person	a. Provide documents on the content for continuous professional development for all healthcare professions b. Is this training mandatory or voluntary on the discretion of each healthcare worker	We already had a meeting with the deans of the faculties. We will ask them for documents regarding the implementation of the content, but some of the content is also publicly published.
4.3 Leadership and management development to promote a PS culture	Yes Leadership and management development to promote PS culture	a. Describe and provide evidence of how leadership and management are developed for the promotion of PS	They are appointed authorized persons for quality management ...

Comments from everis: 4.1 no actions apart from the meeting with the deans, 4.2 a,b no documents provided, 4.3 in the accredited healthcare facilities there is a structure of quality commissions but the response from MoH did not tackle leadership involvement to promote PS.

5. Involvement of key stakeholders

Item	2019 MoH response	Documents/results needed from team everis	Comments
5.1 System report by the agency responsible for PS to government (e.g. minister)	No No, there is no single system report		
5.2 Healthcare-providing organisations integrating clinical governance with corporate governance	Yes Healthcare-providing organisation integrating clinical and corporate governance	a. Provide documents on how clinical governance is incorporated into corporate governance	These are internal acts, the institutions are autonomous
5.3 Patient representation in official roles and decision-making processes	Yes Yes, patients are represented in official roles and decision-making processes	a. Provide evidence on how patient representation is officially involved in decision-making processes.	The key documents are in public discussion patient representatives are members of working groups

Comments from everis: 5.2 Institutions prepare internal regulations regarding their functioning and it is accepted or rejected by MoH- from the MoH response it is not clear if item 5.2 is fulfilled. 5.3 Not in place.

Additional information

1. PS culture measurement

Describe models for PS culture measurement for hospital, primary healthcare, outpatient specialty care, community pharmacies, and nursing homes.

Level	Name the model	Last year of measurement	Provide the model and the results when it was measured for the last time
Hospital			In 2019, we made an assessment of the situation. This is not a priority this year. Certainly, however, several challenges await us in measuring the culture of safety and the safety of patients and medical staff.
Primary care			
Outpatient specialty services			
Community pharmacies			
Nursing homes			

Comments from everis: The answer from MoH is not in compliance with the question. No model was described. The assessment of the situation was not provided.

2. Patient experience measurement

Level	Name the model	Last year measurement	of	Provide the model and the results when it was measured for the last time
Hospital				In 2019, we made an assessment of the situation. This is not a priority this year. Certainly, however, several challenges await us in measuring the culture of safety and the safety of patients and medical staff.
Primary care				
Outpatient specialty services				
Community pharmacies				
Nursing homes				

Comments from everis: As mentioned in the text, PREMs has not been psychometrically evaluated and the objective of the PREMs are mainly not national data but data for each facility in order to improve patient experience.

3. What project has been done at MoH regarding patients safety, clinical risk management and quality improvement

Level	Name the project, results and implementation at national and healthcare providers' level	Last year of measurement	Provide the model and the results when it was measured for the last time
National level	PREMs and PROMS, HSPA		
Hospitals			
Primary care	PaRIS		
Outpatient specialty services			
Community pharmacies	seamless care		
Nursing homes			

Several projects are underway in this area. Some take place without a special financial basis, or as part of formal education to obtain a level of education. Subsequently, projects to directly improve quality and safety in the clinical setting, funded under tertiary funding, were under way. Mention should be made of long-term care projects and SRSS projects PREMs and PROMS, HSPA and SenSys,

and a network of healthcare providers. Then there are the ARRS projects, namely the Target Research Programs (CRP). However, we do not have a common platform for the effective dissemination of findings.

Comments from everis: No direct projects for QI and PS were explicitly mentioned or provided and no answers for columns 3 and 4.

4. Patient reporting experience, outcomes, incidents reporting etc.

Name of the project	Implemented Yes/No		Last year of measurement and the results	Comments
National level	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	PREMs	
Hospitals	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	PREMs	
Primary care	Yes <input type="checkbox"/>	No <input type="checkbox"/>	PaRIS	In progress
Outpatient specialty services	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>		
Community pharmacies				

5. Quality

Please describe the state responsibility for quality improvement for the following activities:

First, explain the current situation for each of the below items and then defining responsibility.

Items	Comments from MoH
<ul style="list-style-type: none"> Structure for quality and PS at the national level (independent agency or institution) 	Special body , currently sector at MoH Posebno telo, trenutno sektor
<ul style="list-style-type: none"> Policy, strategy and action plans for quality and PS 	In progress
<ul style="list-style-type: none"> Systemic improvement goals 	In progress
<ul style="list-style-type: none"> Clinical guidelines development 	Important
<ul style="list-style-type: none"> Clinical pathway development 	Important
<ul style="list-style-type: none"> Clinical indicators development for each specialty and each profession (physician, nurses, pharmacists etc.) 	Important
<ul style="list-style-type: none"> Statistical methods for measuring quality and PS (descriptive and inferential) 	Important
<ul style="list-style-type: none"> Implantation of quality tools into the everyday practice of healthcare providers 	Important
<ul style="list-style-type: none"> Development and implementing ICT to help collect, analyse, and report quality and PS data 	Required
<ul style="list-style-type: none"> Development of capacity for quality and PS at healthcare providers level 	Required
<ul style="list-style-type: none"> Training healthcare staff on quality and PS 	Required
<ul style="list-style-type: none"> Curricula on quality and PS at undergraduate and post graduate level 	Important
<ul style="list-style-type: none"> Implementing projects with the use of quality improvement models like Model for improvement, Lean Six sigma for quality and PS improvement 	Models are different, new ones always come. It is important to get to know everyone...
<ul style="list-style-type: none"> Decreasing waste (money, time, other resources) 	Important
<ul style="list-style-type: none"> Following six principles of quality published at MoH in 2006 	Importantly, efforts are underway
<ul style="list-style-type: none"> Developing policy and strategy for quality and PS 	Importantly, efforts are underway
<ul style="list-style-type: none"> Removing barriers and financial incentivize healthcare providers for quality and PS improvement 	Importantly, efforts are underway
<ul style="list-style-type: none"> Research agenda and financing for quality and PS improvement 	Importantly, efforts are underway
Items	Comments from MoH

<ul style="list-style-type: none"> Yearly summit of healthcare providers, payors, regulators, educators 	Importantly, efforts are underway
<ul style="list-style-type: none"> Auditing all the above activities 	Currently, the priority was to respond to COVID-19
<ul style="list-style-type: none"> Dedicated yearly budget for quality and PS improvement 	In part, consent is required for all
<ul style="list-style-type: none"> Human resources plan – macro, mezzo, micro level 	In progress
<ul style="list-style-type: none"> National plan for investments in HCI 	Efforts are underway, in effect
<ul style="list-style-type: none"> Measuring quality indicators 	Efforts are underway, in effect
<ul style="list-style-type: none"> Monitoring QoC with public reports 	Efforts are underway, in effect
<ul style="list-style-type: none"> Research on QoC 	They are running, not yet established enough
<ul style="list-style-type: none"> PROM and PREM 	The measurement is running
<ul style="list-style-type: none"> HTA 	Efforts for implementation

6. Patient safety

Please describe the state responsibility for quality improvement for the following activities:

First, explain the current situation for each of the below items and then defining responsibility.

Items	Comments from MoH
<ul style="list-style-type: none"> Establishing a system of PS, policy strategy, action plan, tools, integration with quality and CRM 	Efforts are taking place locally at individual contractors
<ul style="list-style-type: none"> Any research or other source data on epidemiology of PS in Slovenia 	A wish without a plan of realization
<ul style="list-style-type: none"> Development of learning organization 	Efforts are taking place locally at individual contractors
<ul style="list-style-type: none"> Implementing just culture 	Efforts are taking place locally at individual contractors
<ul style="list-style-type: none"> Implementing psychological safety for healthcare staff 	Efforts are underway
<ul style="list-style-type: none"> Implementing a system for PS incidents reporting (adverse events, near misses, errors that did not cause harm) 	Efforts are underway
<ul style="list-style-type: none"> System of analysing PS incidents – root cause analysis 	Efforts are underway
Items	Comments from MoH

<ul style="list-style-type: none"> Implementing learning system from errors 	Efforts are underway
<ul style="list-style-type: none"> Measuring PS culture 	There is no plan
<ul style="list-style-type: none"> Measuring PS indicators 	There is no plan
<ul style="list-style-type: none"> Monitoring PS 	Partially
<ul style="list-style-type: none"> Developing yearly goals for PS 	Partially
<ul style="list-style-type: none"> Celebrating global PS day 	Yes
<ul style="list-style-type: none"> Establishing activities for yearly PS week 	Yes
<ul style="list-style-type: none"> System for CRM 	Not national, sometimes local
<ul style="list-style-type: none"> Tools for PS improvement 	They are enforced locally by interested healthcare providers
<ul style="list-style-type: none"> Safety of healthcare staff 	Safety at Work
<ul style="list-style-type: none"> Patient engagement 	Health literacy and patient commitment need to be raised
<ul style="list-style-type: none"> Disclosure an adverse event to a patient/family 	Efforts are underway
<ul style="list-style-type: none"> Capacity for PS improvement 	Efforts are being made locally by individual healthcare providers - in the field of infection prevention

Comments from everis: Many contents of the responses for quality and PS from MoH are either in the form of importance or efforts and not what has been required, namely the current situation for each item and then defining responsibility

Down here are additional comments from MoH.

Care quality and PS are fundamental aspects of effective healthcare services. However, there is no overarching legal framework in Slovenia for the governance, monitoring and evaluation of healthcare quality and PS, including the lack of an adequate legal framework and of quality assurances mechanism, as well as of a robust system for health system performance assessment. Care quality and PS management are core strategic challenges of the health system also identified in the Resolution on the National Healthcare Plan 2016–2025, adopted by the National Assembly of the Republic of Slovenia. It is also relevant to address this challenge appropriately in the light of the implementation of the Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare and the Council recommendation on PS, including the prevention and control of infections associated with healthcare (2009/C 151/01).

This project builds upon previous SRSP support concerning PS and health systems performance assessment (HSPA).

The expected outcome of the current project on PS (to be concluded at the end of 2019) is a clear design for a functioning system for monitoring and implementing measures for sentinel and other adverse events in Slovenia. It will be important though that new solutions are piloted before the full roll-out of the new system. The pilot implementation would build upon and complement the on-going Sensys project with the implementation at the level of healthcare providers at primary, secondary, tertiary level and in social protection institutions. For the project on HSPA, which will finish with a first HSPA report for Slovenia, it will be important to advance further on the legal framework surrounding the HSPA, as well as designing quality assurance frameworks enabling healthcare provider of care to make visible progress in care quality.

As part of the SenSys, all the necessary elements for piloting will be established (a legal basis, a development of the web application VAR-NET¹⁰⁸ and a guide to operators for developing action plans for the improvement of safety culture). In addition, the necessary discussions were held with key stakeholders at national level (May 2018), hospital directors (September 2018) and also selected local-level healthcare providers, including municipality representatives to ensure the necessary support and capacity for the pilot implementation of the project (which will include the use of web application, ICPS-SI application, support in the preparation of an action plan for measuring and improving safety culture of selected operators, measuring safety culture, etc.).

7.4 Appendix D – Criminal Code

Criminal Code:

Injuries caused by the doctors in Slovenia are treated as “general” criminal offences against life and body as well as crimes against public health under Criminal Code.

Chapter Fifteen (CRIMINAL OFFENCES AGAINST LIFE AND BODY) stipulates:

Manslaughter

Article 115

(1) Whoever takes the life of another person shall be sentenced to imprisonment for between five and fifteen years.

(2) If two or more persons associate to commit an act referred to in the preceding paragraph, they shall be sentenced to imprisonment for between ten and fifteen years.

Murder

Article 116

Whoever murders another person

(1) in a horrific or treacherous manner;

(2) due to actions taken regarding official acts to protect public security or in a pre-trial criminal procedure, or due to the decisions of state prosecutors, or due to the proceedings and decisions of judges, or due to a criminal complaint or testimony in court proceedings;

(3) due to a violation of equality;

(4) out of desire to murder, out of a self-serving interest, in order to commit or to conceal another criminal offence, out of unscrupulous vengeance, or for other base motives; or

¹⁰⁸ A working title

(5) by an act committed within a criminal organisation;
shall be sentenced to imprisonment for at least fifteen years.

Negligent homicide

Article 118

Whoever causes the death of another person by negligence shall be sentenced to imprisonment for between six months and five years.

Slight bodily injury

Article 122

(1) Whoever inflicts bodily harm on another person resulting in the temporary weakness or impairment of an organ or part of his or her body, his or her temporary inability to work, the impairment of his or her outlook on life or temporary damage to his or her health, shall be punished by a fine or imprisonment for up to one year.

(2) If the injury referred to in the preceding paragraph has been inflicted by means of a weapon, dangerous implement or any other implement capable of causing serious bodily harm or severe damage to health, the perpetrator shall be sentenced to imprisonment for up to three years.

(3) The Court may issue a judicial admonition to the perpetrator referred to in the preceding paragraph, particularly if his or her conduct is provoked by indecent or brutal behaviour on the part of the injured person.

(4) Prosecution of a criminal offence referred to in paragraph one of this Article shall be initiated upon a proposal

Serious bodily injury

Article 123

(1) Whoever inflicts bodily harm on another person or damages his or her health to such an extent that this might place the life of the injured person in danger or cause the destruction or permanent serious impairment of an organ or part of the body, the temporary serious weakness of a vital part or organ of the body, the temporary loss of his or her ability to work, a permanent or serious temporary reduction of his or her ability to work, his or her temporary disfigurement, or serious temporary or less severe but permanent damage to the health of the injured person, shall be sentenced to imprisonment for between six months and five years.

(2) If the injury referred to in the preceding paragraph results in the death of the injured person, the perpetrator shall be sentenced to imprisonment for between one and ten years.

(3) Whoever commits an act referred to in paragraph one of this Article by negligence shall be sentenced to imprisonment for up to two years.

(4) A perpetrator who commits an act referred to in paragraph one or two of this Article through no guilt of his or her own and in the sudden heat of passion provoked by assault or grave insult from the injured person shall be sentenced to imprisonment for up to three years.

Particularly severe bodily injury

Article 124

(1) Whoever inflicts bodily harm on another or damages his or her health so severely that this results in a risk to the life of the injured person, the destruction or substantial permanent impairment of any vital part or organ of the body, permanent loss of his or her

ability to work, or serious permanent damage to his or her health, shall be sentenced to imprisonment for between one and ten years.

(2) If the injury referred to in the preceding paragraph results in the death of the injured person, the perpetrator shall be sentenced to imprisonment for between three and fifteen years.

(3) Whoever commits an act referred to in paragraph one of this Article by negligence shall be sentenced to imprisonment for up to three years.

(4) A perpetrator who commits an act referred to in paragraph one or two of this Article through no guilt of his or her own and in the sudden heat of passion provoked by assault or grave insult from the injured person shall be sentenced to imprisonment for between six months and five years.

Chapter Twenty (CRIMES AGAINST PUBLIC HEALTH) of Criminal Code includes the criminal offence of Negligent medical treatment and healing activity:

Failure to Render Medical Aid

Article 178

A doctor or any other medical employee who breaches the terms of his professional duty by failing to render aid to a patient or any person whose life is in danger shall be sentenced to imprisonment for not more than one year.

(2) The act referred to in the preceding paragraph is not unlawful if the doctor abandons a certain method of treatment, procedure or medical procedure at the explicit written request of the patient or another person capable of deciding on himself and refuses help even after being instructed on the necessity for help; about the possible consequences of the refusal and also after the doctor tried again to persuade her to change her decision.

Negligent medical treatment and healing activity

Article 179

(1) A physician who in the performance of a medical activity fails to act in conformity with the code of professional conduct, thereby causing substantial impairment of a patient's health, shall be sentenced to imprisonment for up to three years.

(2) The same punishment shall be imposed on:

(a) healthcare professionals who in the performance of their duties fail to act in conformity with the code of professional conduct out of negligence, thus causing substantial impairment of a patient's health, or

(b) healers who in the performance of their duties make an inappropriate choice or use a healing system or method that causes substantial impairment of a patient's health.

(3) If an act referred to in paragraph one or two results in the death of a person, the perpetrator shall be sentenced to imprisonment for between one and eight years.

The crime of negligent medical treatment and healing activity is a normative peculiarity. Comparative legal and historical analysis shows that a comparable crime is known only in neighbouring Croatia - Article 179 of the Criminal Code is therefore most likely a remnant of the criminal legislation of the Republic of Yugoslavia.

In our opinion Article 179 would not be problematic if the practice of Slovenian courts and the opinion of the legal profession showed a unified understanding of this criminal offense. However, a more detailed analysis of the negligent medical treatment and healing activity raises doubts as to the compliance with the fundamental principles of criminal law, such as the principle of legal certainty (*lex certa*) and predictability. The problem of the current regulation, which is reflected in the case law, is the legal

unpredictability and excessive expansion of the field of criminality, which significantly reduces the preventive purpose of criminal law and at the same time leads to the concealing of errors. The latter prevents their analysis or learning, thus inhibiting the development of medical science and preventing safer and more professional medical treatment.

Civil Code:

Article 131

(1) Any person that inflicts damage on another shall be obliged to provide recompense for it, unless it is proved that the damage was incurred without the culpability of the former.

(2) Persons shall be liable for material damage and activities that result in major risk of damage to the environment, irrespective of culpability.

(3) Persons shall also be liable for damage irrespective of culpability in other cases defined by an Act.

Article 179

(1) Just monetary compensation independent of the reimbursement of material damage shall pertain to the injured party for physical distress suffered, for mental distress suffered owing to a reduction in life activities, disfigurement, the defamation of good name or reputation, the curtailment of freedom or a personal right, or the death of a close associate, and for fear, if the circumstances of the case, particularly the level and duration of distress and fear, so justify, even if there was no material damage.

(2) The amount of compensation for non-material damage shall depend on the importance of the good affected and the purpose of the compensation, and may not support tendencies that are not compatible with the nature and purpose thereof.

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