Republic of North Macedonia

Ministry of Health

NATIONAL PLAN FOR PATIENT SAFETY

2024-2030

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Acknowledgments

The National Patient Safety Plan of the Republic North Macedonia is based on a comprehensive assessment of the situation conducted in December 2022, with technical support from the WHO Office for Quality of Care and Patient Safety in Athens. The WHO Athens Office for Quality of Care and Patient Safety played a crucial role in both the assessment and the Plan's development, offering valuable expertise to ensure its alignment with best practices and international standards in the field of Quality of Care and Patient Safety.

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Abbreviations

AQAHI	Agency for Quality and Accreditation of Health Institutions
CME	Continuing Medical Education
CPH	Center for Public Health
CPS	Committee for Patient Safety
DCM	Doctors' Chamber of North Macedonia
EHD	E-health Directorate
HI	Health Institution
HIF	Health Insurance Fund
IOM	Institute of Occupational Medicine
IPH	Institute of Public Health
ITM	Institute of Transfusion Medicine
MALMED	Macedonian Agency for Medicines and Medical Devices
MMA	Macedonian Medical Association
MoH	Ministry of Health
PA	Patients' Associations
PHC	Primary Health Care
PRD	Protection and Rescue Directorate
QC	Quality Committee
RNM	Republic of North Macedonia
SSHI	State Sanitary and Health Inspectorate
UN	United Nations
WHO	World Health Organization

Introduction

Situation analysis (based on the Mission report: Health Care Quality and Patient Safety in the Republic of North Macedonia)

Patient safety is a health care discipline that emerged with the increasing complexity in healthcare systems and the resulting rise of adverse events in patients in the healthcare facilities. It aims to prevent and reduce the risks, errors and harm that occur during the provision of healthcare. A cornerstone of this discipline is the continuous improvement of care based on learning from errors and adverse events.

Patient safety is fundamental to deliver quality health services. Indeed, there is a clear consensus that healthcare across the world should be universal and of high quality, i.e., effective, safe and people-centered and health services must be timely, equitable, integrated and efficient.

The successful implementation of patient safety strategies requires many activities such as: clear policies, leadership capacity, data to implement safety improvements, reducing the risk of patient harm during their care, experienced and skilled healthcare workers, and effective involvement of patients in their care.

Why does patient harm occur?

A quality health system also recognizes the growing complexity of healthcare environments that increases the risk of adverse events. People are less likely to make mistakes when placed in an environment that reduces the risk of errors, where the protocols, tasks and processes they carry out are well designed. Therefore, focusing on a system that either facilitates or prevents harm is the beginning of improvement, and this can only take place in an open and transparent environment where a safety culture prevails. In such a culture, safety beliefs, values, and attitudes are highly prioritized and shared by most individuals within the workplace[1].

The Republic of North Macedonia, along with many other countries, faces the challenges in the field of patient safety and health care quality.

Therefore, as part of the two-year agreement with WHO (2022-2023), the Ministry of Health of the Republic of North Macedonia has recognized the patient safety and health quality as one of the work priorities. Accordingly, in December 2022, WHO supported the technical mission on patient safety and the role of the Agency for Quality and Accreditation of Health Institutions in North Macedonia in the patient safety and quality of care.

As part of this technical mission, the first of its kind, a national workshop on patient safety was organized to raise awareness among hospital management and relevant staff in the healthcare facilities about the importance of the concept of patient safety in the delivery of health care and to identify challenges to implementing patient safety practices and quality of care at the institutional level.

Seven domains of achievements in the field of patient safety were evaluated during the mission and based on the findings in these areas, the National Plan proposes goals and activities that would improve patient safety as part of overall quality and health protection across the country.

[1]Workplace Health and Safety Queensland. Understanding safety culture. Brisbane: The State of Queensland; 2013 (https://www.worksafe.qld.gov.au/__data/assets/pdf_file/0004/82705/understanding-safety-culture.pdf, accessed 26 July 2019)

National plan for patient safety

The development of the proposed National Plan is based on the recommendations of the mission conducted in December 2022 and aligns with the WHO Global Action Plan 2021-2030[2]. It was also developed in accordance with the Health Strategy of the Republic of North Macedonia 2021-2030[3], where the Agency for Quality and Accreditation of Health Institutions (AQAHI) was nominated as the leading institution and Secretariat of the National Plan.

The basic goals for the improvement of the system for patient safety and health care quality will be realized through the establishment of a **Committee for Patient Safety (CPS)**, which will have a permanent mandate as an advisory and regulatory body in the field of patient safety and health care quality of the Ministry of Health.

Vision

The Republic of North Macedonia will be an environment where no patient will experience harm from an adverse event and every patient will receive safe health care that will be timely, equitable, and available everywhere.

Mission

To implement policies, strategies and practices that are based on evidence, patient experience, appropriate system design, healthcare workforce and partnership in order to eliminate all sources of preventable risks and harm to patients and healthcare workers.

Main dimensions

The main dimensions for the advancement of the patient safety framework, consequently contributing to the improvement of the quality of care across the country are:

1. Adopting policies that will eliminate preventable harm in health care
2. Establishing stable health care systems
3. Safety of clinical processes
4. Involving the patient and their family in the care
5. Education, skills and safety for healthcare workers
6. Information, research and dealing with risks
7. Synergy, partnership and solidarity

For each of these domains, a group of objectives, activities, subjects in charge of the activities, a rough timeline and possible sources of financing have been developed in a period that is synchronized with the National Health Strategy of the Republic of North Macedonia, until 2030. These elements of the national plan are drawn from the existing results of research, accreditation standards related to the safety of patients, other legal regulations, the mission of international consultants conducted in December 2022, medical practice guides, WHO policy recommendations and other documents.

[2]Global patient safety action plan 2021–2030: towards eliminating avoidable harm in health care. Geneva: World Health Organization; 2021.
[3]Health Strategy of the Republic of North Macedonia 2021-2030. Web page http://zdravstvo.gov.mk/wp-content/uploads/2021/12/19.11.-SZ-posledna-Konechna-Natsrt-Strategija-MKD.pdf. Accessed on 01.02.2023

Considering the context of the current healthcare system and patient safety situation in the Republic of North Macedonia, four core priorities arise from the main dimensions of the national Plan: a) training of healthcare professionals, b) awareness and patient engagement, c) establishment of the Committee for Patient Safety, d) data infrastructure and IT-based systems to support patient safety interventions.

A part of the planned steps is to submit the plan to the Government of the Republic of North Macedonia and, once it is adopted, to start the implementation of activities and initiatives. Depending on the success of the planned programs, the plan can be used to further lead national efforts for patient safety and other elements of the health system, budget development for this very important area in health care, and harmonization with other health priorities.

The working group that focused on the preparation of the National Patient Safety Plan has made sure to define the interventions that need to be implemented throughout the in-patient health system, simultaneously expanding the scope to include primary health care, by planning synchronized, timely activities that also aim to provide sustainability of the system. Utilization of the established framework should allow the measurement of indicators throughout the whole process of health care.

Given the heterogeneity in the culture and awareness of patient safety, the intention is not to create a rigid framework, but to prioritize measures that are applicable and feasible, and to define indicators for monitoring activities, ensuring their relevance to patient safety interventions.

More challenges and limitations have been recognized in the process of designing the plan, including:

- This plan is focused on the safety of patients in public health care institutions at secondary and tertiary level, while primary health care is only planned for the offices that have an agreement with the Health Insurance Fund (HIF), and will be linked to ongoing Primary health care reform and accreditation of PHC institutions;

- Given the time restraints, it was not possible to include all structures of the health sector in the planning process, but focus was placed on those who directly have a legal mandate towards improving patient safety;

- Representatives of rural areas and representatives of patient associations were not included at this stage, but will be invited to the Committee for Patient Safety (CPS)

The table below outlines the activities planned for the implementation of the plan aimed at improving patient safety in both patient care and the health of healthcare workers.

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Objective	Activities	Responsible institutions	Timeframe	Source of funding
A. Establishing a Committee for Patient Safety*	A.1. Nominating members*	AQAHI Ministry of Health (MoH)	April/May 2024	No financial implications
	A.2. Defining the competencies of the Committee members*		May/June 2024	
	A.3. Establishing a Committee for Patient Safety*			
	A.4. Rules of Procedure of the Committee*			
B. Situational analysis of patient safety at the level of healthcare facility*	B.1. Development of a self-assessment questionnaire*	Committee for Patient Safety (CPS) AQAHI MoH	April/May 2024	MoH UN
	B.2. Self-assessment of the situation with the patient safety*			MoH UN
1. Policies that will eliminate preventable harm in health care				
Objective	**Activities**	**Responsible institutions**	**Timeframe**	**Source of funds**
1.1. Patient safety policy, strategy and action plan	1.1.1. To conduct research and analysis of patient safety indicators, to identify critical processes with the highest risk in terms of safety (safe surgery, safe birth, medication safety, blood and blood products, radiation, immunization, antimicrobial resistance, infection control)* 1.1.2. To adapt the WHO technical document on implementation of strategies and tools to the national context and to build capacities for patient safety	AQAHI MoH EHD	2024	AQAHI MoH UN
	1.1.3. Development of national protocols programs for patient safety, including safe surgery, safe birth, safe use of medicines and medical devices, radiation safety, immunization, blood and blood components, infection control and antimicrobial resistance (development of local guidelines and plans for reducing adverse events)*	AQAHI MoH DCM MMA	2024	AQAHI MoH UN
1.2. Resource mobilization and allocation	1.2.1. To conduct investigation on the causes of patient overload of some healthcare facilities or units therein and on complexity of the diseases being treated 1.2.2. To abide by the stratification of health care according to the levels of health care	AQAHI MoH EHD HI	2024-2025	AQAHI MoH EHD UN

1.3. Protective legal measures	1.3.1. Identifying all laws and by-laws related to patient safety 1.3.2. Harmonizing existing legal measures related to patient safety 1.3.3. Defining minimum standards for patient safety in the regulations for the establishment of healthcare facilities* 1.3.4. Mandatory training related to patient safety included in the training for licensing and relicensing of healthcare workers* 1.3.5. Introducing legal protective mechanisms for those reporting adverse events*	AQAHI MoH MALMED State Sanitary and Health Inspectorate (SSHI) ITM DCM MMA	2024-2025	No financial implications
1.4. Safety standards, regulation and accreditation	1.4.1. Implementation of the AQAHI Action Plan in the healthcare facilities (including revision and update of the Standards for accreditation and the revision of the Rulebook for Quality indicators)*	AQAHI	2024-2027	AQAHI
1.5. World Patient Safety Day, and challenges of global patient safety*	1.5.1. Conducting a national campaign for World Patient Safety Day* 1.5.2. Coordination with relevant institutions and patient associations to mark this day in accordance with the theme selected for each year*	AQAHI MoH PA	Every year	AQAHI
2. Establishing stable systems				
Objective	**Activities**	**Responsible institutions**	**Timeframe**	**Source of funds**
2.1. Transparency, openness and a culture of safety (not a culture of blame)*	2.1.1. Implementation of models of confidential investigation of mortality and critical cases* 2.1.2. Media activities to eliminate the culture of blame* 2.1.3. Cooperation with professional associations to strengthen open access and learning in the culture of safety*	AQAHI MALMED ITM MMA IPH	2025-2027	MoH AQAHI
2.2. Good management of the health system	2.2.1. Strengthening the role of the Commissions for monitoring and improving the quality of healthcare, which are established in each hospital based on the legal and improved regulations 2.2.2. To prepare annual reports on the revised quality indicators that are to be submitted to the Committee for Patient Safety	AQAHI in cooperation with healthcare facilities (part of the process of preparation for accreditation)	2024-2026	AQAHI HI
2.3. Leadership capacity in clinical and management functions	2.3.1. To designate one or more centers in the country for building leadership capacities in the field of patient safety, research and innovation (Centers of excellence for patient safety)	AQAHI MoH	2028-2030	No financial implications

2.4. Human factor for health system resilience	2.4.1. To conduct study/research on the ways to enhance the human factor in improving patient safety and reducing the risk of adverse events 2.4.2. Developing a curriculum (program) for training in the field of patient safety in the form of Continuing Medical Education (CME) 2.4.3. Introduce regular updates of occupational safety and health plans and regulations at the institutional level	AQAHI in cooperation with healthcare facilities (part of the process of preparation for accreditation) Institute for Occupational medicine (IOM)	2024-2026	AQAHI UN
2.5. Patient safety during emergencies and various disasters	2.5.1. Making recommendations and guidelines for updating the plans for dealing with mass accidents and adverse events 2.5.2. Developing guidelines for conducting system resilience simulation exercises to improve patient and employee safety 2.5.3. Creating a Plan for cooperation with the local community and healthcare facilities in terms of crisis, accidents and epidemics.	AQAHI in cooperation with healthcare facilities (part of the process of preparation for accreditation) PRD (Protection and Rescue Directorate) MoH	2026-2027	No financial implications

3. Safety of clinical processes

Objective	Activities	Responsible institutions	Timeframe	Source of funds
3.1. Safety of risky clinical procedures	3.1.1. Utilizing hospital's capacities (Quality Committees) to develop plans for strengthening key areas of preventable risks in each domain of clinical practice 3.1.2. Creating guidelines for developing local plans to improve patient safety (pharmacovigilance, hospital infections, safe surgery, thromboembolism, ulcers, miscommunication) and their dissemination 3.1.3. Development of a digital system for reporting and monitoring adverse events	AQAHI Committee for Patient Safety (CPS) HI Quality Committees	2024-2025	No financial implications
3.2. Global challenge to patient safety: medicines without harm	3.2.1. Emphasizing legal obligations – Raising awareness of the importance of reporting adverse drug reactions – Article 88 of the law (education, flyers, workshops, presentations)* 3.2.2. Familiarizing with the procedures for reporting side effects from drugs* 3.2.3. Strengthening the system by connecting the pharmacovigilance system with the existing system of the MoH and the e-health system My Appointment - for easier monitoring of adverse reactions	MALMED AQAHI MoH E-health Directorate HI PHC	2024-2026	No financial implications

	3.2.4. Monitoring new and updated drug safety information using the drug register tool as an official document – Emphasizing the importance of tracking changes and updated information in the summary report on characteristics of drugs published in the drug register 3.2.4.1. Raising awareness of the additional conditions that should be monitored and reported for the sake of patient safety (Off-label use of a drug, use during pregnancy and breastfeeding...)* 3.2.4.2. Training of the health workers on procedures dealing with medicines under additional special monitoring 3.2.4.3. Prevention of polypragmasia, i.e., polypharmacy – Developing an integrated information system for monitoring the therapy for each patient individually (together with PHC)			
3.3. Infection control and prevention and antimicrobial resistance*	3.3.1. Improvement of programs for control and prevention of intrahospital infections, through the existing hospital Commissions for control of infections through evidence based antibiotic stewardship programs* 3.3.2. Developing a plan for regular and continuous cooperation between relevant institutions for patient safety (networking)*	MoH SSHI AQAHI IPH EHD	2024-2025	No financial implications
3.4. Safety of medical devices, drugs, blood and vaccines	3.4.1. Establishing two-way connections of programs on safety of medical devices, drugs, vaccines and blood and blood products 3.4.2. Raising awareness of the reporting of adverse events from medical devices and the procedure for emergency safety corrective measure in the field – conducting trainings for healthcare workers and raising awareness of patients (information)*	MALMED EHD CPS	2026-2027	No financial implications
3.5. Patient safety in the primary health care and care transition*	3.5.1. Raising patients' awareness of the importance of reporting adverse events and possible complications across all levels of health care and care transition* 3.5.2. Developing guidelines and procedures for continuation of care during transition from one level to another* 3.5.3. Developing standardized patient records, and reconciliation of the hard copy with the electronic form of the records*	PHC MoH AQAHI CPH/IPH PA	2024-2026	No financial implications

4. Involving the patient and their family				
Objective	**Activities**	**Responsible institutions**	**Timeframe**	**Source of funds**
4.1. Joint development of policies and programs with patients*	4.1.1. Strengthening the role of patient associations in raising awareness of patient safety and reporting adverse events* 4.1.2. Introducing the practice of holding joint meetings between the Quality Commission and patient associations, through the representative member from the association in the Quality Commission*	AQAHI PA	continuously	No financial implications
4.2. Learning from patient experience to improve safety*	4.2.1. Establishing multiple platforms to share patient experiences* 4.2.2. Organizing joint meetings of patients with healthcare workers on the topic of Patient Safety (forums, workshops, meetings of professional associations, other events)*	AQAHI MoH PA	continuously	No financial implications
4.3. Patient advocacy for safety in clinical practice*	4.3.1. Analysis of opportunities/ manners of patient engagement that would prepare them as good advocates for patient safety*	AQAHI PA	continuously	No financial implications
4.4. Detecting the adverse event of a patient - victim	4.4.1. Evaluation of the adequacy of obtaining informed consent from patients for medical intervention (diagnostic, therapeutic) through research, analysis 4.4.2. Introduction of a confidential investigation of adverse events and measures to prevent their recurrence	AQAHI PA	continuously	No financial implications
4.5. Information and education of patients and their families*	4.5.1. Develop a media plan to raise patient awareness about safety in healthcare facilities* 4.5.2. Developing standardized electronic and printed information on patient safety available to patients (drugs, medical devices, blood, blood products, prevention of intrahospital infections, and other adverse events)* 4.5.3. Developing guidelines for updating the websites of the healthcare facilities for the purpose of better informing the patients	MALMED SSHI ITM HI AQAHI	continuously	No financial implications
5. Education, skills and safety of health workers				
Objective	**Activities**	**Responsible institutions**	**Timeframe**	**Source of funds**
5.1. Patient safety in education and Continuing Medical Education (CME) programs*	5.1.1. Complementing the CME Programs with a Module for patient safety (exploring the WHO Module)* 5.1.2. Development of a Module for patient safety for the managers of the HI and Quality Committees*	AQAHI MALMED MMA MoH Medical Simulation Center	continuously	AQAHI MoH UN

	5.1.3. Conducting workshops on “patient safety” with already developed plan and program, as part of CME*			
5.2. Centers of Excellence for patient safety education and training	5.2.1. To designate at least one center in the country that will be in charge of the activities for education and training in the field of patient safety 5.2.2. Providing training of professionals who would be in charge of the activities in the Center of Excellence (preferably, outside the healthcare facility)	MoH AQAHI MALMED ITM MMA DCM	2028-2030	AQAHI
5.3. Competencies for patient safety as a legal obligation	5.3.1. Defining the competencies for patient safety for each profile of employees in the healthcare facility 5.3.2. Ensuring a regular check of the competencies of the employees in the healthcare facility regarding their skills for ensuring better patient safety	AQAHI MoH HI All medical universities	2024-2026	HI
5.4. Linking the patient safety to the assessment system for healthcare workers*	5.4.1. In the process of two-way assessment of employees, a parameter related to patient safety should be introduced* 5.4.2. Establishing an internal mechanism for recognition and assessment of highly developed competencies for patient safety* 5.4.3. Engaging the best rated employees in the training process which will be held on a regular basis*	AQAHI MALMED EHD	2025-2026	No financial implications
5.5. Health workers’ safety	5.5.1. Evaluation of the obligations related to the Law on safety and health in the workplace	CPS IOM	2024-2030	No financial implications

6. Information, research and dealing with risks

Objective	Activities	Responsible institutions	Timeframe	Source of funds
6.1. Adverse event reporting system and learning systems*	6.1.1. Defining the list of reported adverse events* 6.1.2. Improving the existing adverse event reporting system (development of a reliable, effective and user-friendly electronic system)*	AQAHI EHD MALMED SSHI ITM	2024-2026	No financial implications
6.2. Patient safety monitoring systems	6.2.1. Conducting an initial analysis of the patient safety situation, and a comparative analysis of the same indicators after a defined period, with an analytical assessment of the effectiveness of the implemented measures 6.2.2. Development of the evaluation system of measures for improving patient safety	CPS AQAHI SSHI	2025-2026	MoH UN

	6.2.3. Pilot project in several hospital/clinical health facilities and comparison between accredited and non-accredited institutions, in terms of predefined indicators 6.2.4. Establishment of a system for early detection and reaction on detected intrahospital infections*			
6.3. Patient safety surveillance systems*	6.3.1. According to the surveillance, performing analytical assessment of the effectiveness and mapping the priority areas which require improvement of the measures* 6.3.2. Analysis of international experience and evidence and application in the local context* 6.3.3. Development of periodical and Annual reports*	CPS AQAHI	2026-2027	No financial implications
6.4. Digital technology for patient safety	6.4.1. Advancement of digital technology in the direction of improving patient safety and strengthening human capacities for its usage (practical trainings for using digital technology)	EHD AQAHI	2025-2027	EHD MoH AQAHI UN

7. Synergy, partnership and solidarity

Objective	Activities	Responsible institutions	Timeframe	Source of funds
7.1. Involvement of key factors	7.1.1. Conducting an analysis of the role of all relevant factors in improving patient safety* 7.1.2. Developing a Strategy for Patient Safety with clear and comprehensive guidelines for the engagement of each institution and individual profile	CPS MoH MALMED ITM AQAHI MMA	2024-2026	No financial implications
7.2. Patient safety information systems	7.2.1. Developing a plan for monitoring the global Action Plan that will result from the national guidelines that will also include the identification of barriers, with proposed solutions	AQAHI EHD MALMED SSHI ITM IPH	continuously	No financial implications
7.3. Patient safety networks and collaboration (national, regional and international)	7.3.1. Establishing national, regional and international networks for sharing experiences and good practices for improving patient safety (creating a platform on national level)*	CPS AQAHI MALMED SSHI ITM EHD	continuously	No financial implications

*Priority activities (quick, immediate activities that are expected to have a major effect on improving patient safety)

A.1. The members of the Committee for Patient Safety should be nominated by the following institutions:

- Agency for Quality and Accreditation of Health Institutions (2 representatives)
- Ministry of Health (2 representatives)
- Patient safety expert
- Health Insurance Fund of the Republic of North Macedonia
- Macedonian Agency for Medicines and Medical Devices
- State Sanitary and Health Inspectorate
- E-health Directorate
- Representatives of Committees for monitoring and improving the quality of health care
- Institute of Transfusion Medicine
- Institute of Occupational Medicine
- Institute of Public Health
- Macedonian Medical Association
- Doctors' Chamber of North Macedonia
- Nursing association representative
- Academic community (a representative from one of the Medical Faculties in the Republic of North Macedonia)
- Patient Associations

Strategies for the implementation of the National Patient Safety Plan (2024-2030):

The strategies to improve patient safety through implementation of the plan can be short-term and long-term. This strategic process of planning activities synchronizes patients' needs and health system opportunities.

Short-term interventions:

Four key interventions are identified that can be implemented within the first 12 months of adopting the plan, in order to improve patient safety.

The first intervention is the establishment of a Committee for Patient Safety to promote and monitor patient safety activities, including the implementation of the Action Plan, which will be comprised of people with different professional backgrounds – multiprofessional committee, with representatives of different health care levels and will be the advisory body of the Minister of Health. The main purpose of the Committee will be to define the priority of activities and efforts throughout all levels of healthcare and will synchronize the steps of different actors in the health system.

Members of the Committee should be representatives of all institutions that can in any way contribute to the realization of the set goals. The composition of this committee will include representatives of the Agency for Quality and Accreditation of Health Institutions, the Ministry of Health, the Macedonian Agency for Medicines and Medical Devices, the State Sanitary and Health Inspectorate, the Institute of Public Health, the Institute of Transfusion Medicine, the Quality Committees of all levels of hospital health care protection, primary health care representatives, patients' associations, the academic community and all relevant collaborative institutions and a national patient safety expert.

This step is the first one for launching all other system level changes related to the improvement of patient safety, including implementation of the Action plan for strengthening capacities of the Agency for quality and accreditation of health institutions.

The **second immediate intervention involves intensive training for key staff** throughout the health system at the local level with a previous Training of trainers Module. This team of multidisciplinary trainers will strengthen the team of health professionals and other profiles working with patients, through a series of training courses, in order to record and resolve adverse events, and especially implement measures to reduce the risk of adverse events. The preparation of a training program can include an international expert who has experience with the implementation of patient safety plans and quality of health care. One of the central points should be Infection control and prevention.

The **third short-term intervention focuses on the culture and awareness of patients' safety**, using tools based on evidence and information during the promotion of the culture, as well as awareness of patient safety, primarily of health workers and the general population, including the national campaigns on the 17th September (World Patient Safety Day).

The **fourth group of interventions refers to research**, in order to obtain information on the efficient implementation of the interventions (legal improvements in terms of confidentiality in adverse events reporting, trainings and competency improvement, safety of blood transfusions, identification of the weak points, anticipation of the economic effect following patient safety improvement, impact of

clinical guidelines on patient safety, defining the challenges in the process of implementation and modalities on how to overcome them).

Medium-term and long-term interventions:

The proposed medium-term and long-term strategies for plan implementation (one to 5 years) again cover four main areas.

The **first area is the development of national policies**, including the development of a national patient safety policy as part of the quality of health care, as well as defining standards, priorities, and a framework for implementing measures to improve patient safety.

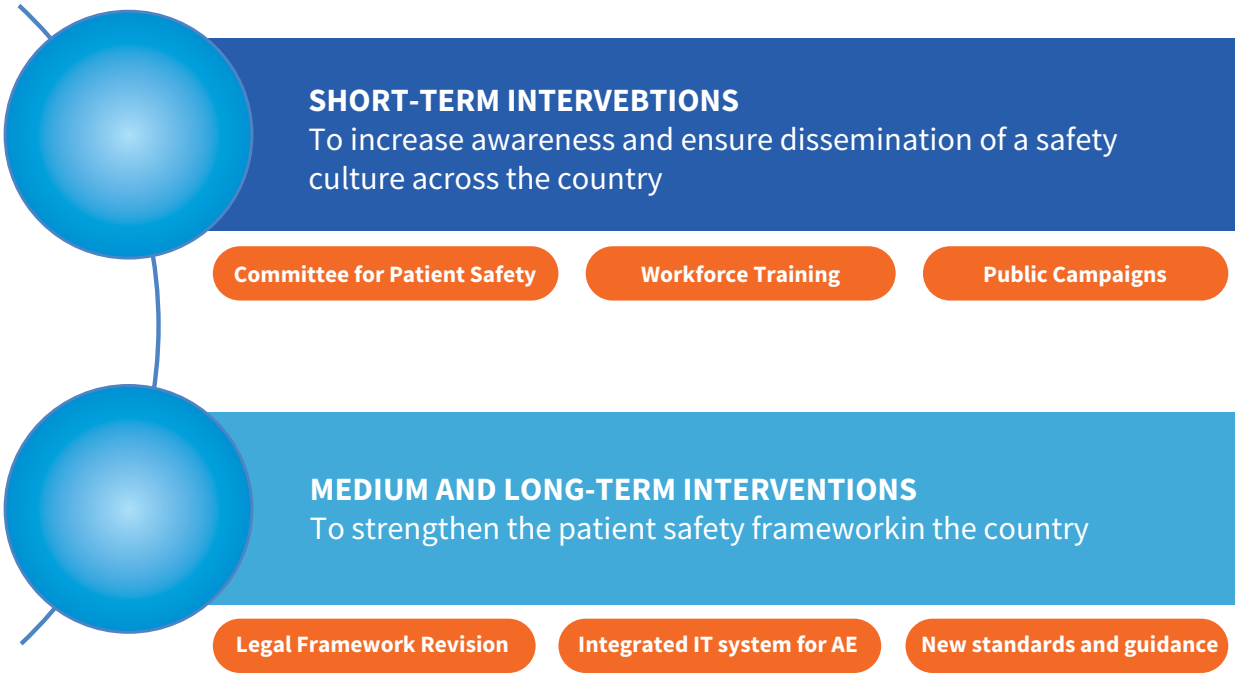
The **second area covers the processes in information technology, digitalization**, in terms of developing and supporting the infrastructure to report adverse effects, **and networking of all institutions involved in the patient safety system** - health institutions of each level and the institutions that collect and analyze the data on adverse events and which will prepare a report on the state of promotion measures for each subsequent period.

The **third area refers to training** in the field of patient safety in formal education, as part of the intersectoral cooperation with the faculties. This group of measures will take a step forward in ensuring the sustainability of the National Patient Safety Plan.

The **fourth area is the harmonization of all interventions**, by unifying initiatives to improve patient safety and the quality of health care at the regional and national level, monitoring and continuous assessment of the implementation and adoption of this plan across the country.

The summary of all interventions needed to improve patient safety are schematically presented in **Figure 1.**

Figure 1: National Plan for patient safety 2024 – 2030. Republic of North Macedonia: Roadmap for implementation



Monitoring key performance indicators

Based on the first annual report on the rates of the indicators provided below a baseline will be established, that will then serve as foundation for development of a plan with measurable performance indicators.

Domain	Key performance indicators measured once per year, and compared to both the baseline (a "delta analysis") and to the 2030 goal (a "progress" analysis)
1. Enacting of policies that will eliminate preventable damage in health care	- Revised Law on Health Protection, amendments made to Section X -Quality of Health Care** - Adopted Patient Safety Plan at a Session of the Government of the Republic of North Macedonia** - Completed assessment of the work of the hospital committees for monitoring and improving the quality of health care** - Developed program for continuous medical education in the field of patient safety -Consolidated accreditation standards and distributed to all relevant institutions** -Number of accredited health care facilities from hospitals and primary health care (95% of hospitals - HI and 50% of PHC institutions)** - An annual increase of at least 5-10% in reported adverse events (including adverse reactions to drugs, vaccines, blood transfusions and supplement derivatives) - A report on the National Campaign conducted annually on September 17th, based on the designated theme for each year. **
2. Establishing stable health care systems	- Having established a Committee for Patient Safety as an advisory body to the Minister of Health** - Developed standard operational plan for the hospital committees for monitoring and improving the quality of health care (QC) that will be applied in all institutions - Number of reports received with calculated quality indicators from quality committees from hospitals (of at least 95% of committees)** - Developed a plan for centralizing the reporting of unwanted events - 90% of institutions provide health care by monitoring and performing internal revisions of the communications process in the transition of health care delivery - Developed a feedback plan from the investigation of the reported adverse events
3. Safety of clinical processes	- number of Guidelines issued at the national level for the most relevant topics related to patient safety - established regular internal audit for the number and dissemination of issued Clinical guidelines

	- Defined list of processes that contain a higher level of risk in the health system and monitoring indicators** - Defined and standardized measures and procedures for reducing risks in healthcare institutions (30% reduction in urinary catheter infections, venous and arterial lines, respirator-related pneumonia, operative wound)** - Developed integrated IT-based system for events related to patient safety - At least 85% of health care facilities have established a regular internal audit i.e., a revision system for risk reduction procedures for adverse events** - 90% of institutions provide health care using control tools to monitor safe practice related to safe surgery, prevention of falls, prevention of decubitus, patient identification, medication safety** -100% of health facilities have plans to deal with mass accidents and unfortunate developments**
4. Including the patient and their family in the care	- Created model for patient involvement in defining national recommendations to improve patient safety - The number of appearances in the media dedicated to patient safety (an increase of at least 75%) - 90% of health care institutions with at least one action annually on raising awareness of patients and their families
5. Education, skills and safety of health care workers	- The number of workshops held on the topic of patient safety** - The number of workshops dedicated to measures for improvement of patient safety - 90% of health care institutions with at least one action for awareness of health care workers annually - Integrated concepts for patient safety in the formal curriculum of health care workers
6. Information, investigation and risk management	- Developed plan for evaluating patient safety conditions at hospital level with defined parameters - Developed form and methodology for patient safety evaluation in hospital HIs - Established digital system for reporting adverse events, available to all institutions involved in improving patient safety** - Percentage of reported adverse events per year - Conducted assessment of the condition of patient safety in primary health care - Analysis of anonymous research on patient satisfaction from service delivery across all levels of care - Analysis of the conducted anonymous research on the level of culture of safety for health care workers
7. Synergy, partnership and solidarity	- Number of joint intersectoral meetings - Number of meetings of the Committee for Patient Safety**

** Critical key performance indicators, directly related to patient safety

Evaluation of the National Patient Safety Plan:

The National Patient Safety Plan will be evaluated at least twice during the 2024-2030 period, using the Theory of Change. Questions that will be evaluated will be directly related to the seven domains of the National Patient Safety Plan, and the methods that will be used are document review, (semi)structured questionnaires, individual interviews and focus group discussions, field visits, and triangulation techniques.

It is recommended that the evaluation be carried out by independent experts with experience in the field of monitoring and evaluation of health care programs. This plan should be revised in 2027.

List of Annexes:

Annex 1: Report from the WHO Consultant Mission, December 2022

Annex 2: Law on Health Protection ("Official Gazette of the Republic of Macedonia" no. 43/12, 145/12, 87/13, 164/13, 39/14, 43/14, 132/14, 188/14, 10/15, 61/15, 154/15, 192/15, 17/16, 37/16 and 20/19 and Official Gazette of the Republic of North Macedonia" No. 101/19, 153/19, 180/19, 275/19, 77/21, 122 /21, 178/21, 150/22, 236/22, 199/23, 236/23, 263/23, 30/24, 74/24 and 170/24)

Annex 3: Rulebook on the types of health care quality indicators ("Official Gazette of the Republic of Macedonia" no. 127/12).

Annex 4: Accreditation Standards (AQAHI)

Annex 5: Health Strategy of RNM (2021-2030)

Annex 6: Health System – Action plan 2021-2030 (Program of the European Union for North Macedonia, EC ref. number: 2018/399662 (S317 – L4)

Annex 7: Law on medicines and medical devices ("Official Gazette of RM" No. 106/07, 88/10, 36/11, 54/11, 136/11, 11/12, 147/13, 164/13, 27/14, 43/14, 88/15, 154/15, 228/15, 53/16, 83/18, 113/18, 245/18 and "Official Gazette of RM" no. 28/21, 122/21 and 60/23).

Annex 8: Law on safety of blood supply ("Official Gazette of RM" No. 110/07, 164/13, 144/14 and 150/15).

Annex 9: Law on safety and health in the workplace, "Official Gazette of RM" No. 92/2007, 136/11, 23/13, 25/13, 137/13, 164/13, 158/14, 15/15, 129/15, 192/15 and 30/16 and Official Gazette of RM" No. 18/20).

Annex 10: Law on protection of the population from infectious diseases, "Official Gazette of RM" No. 66/04, 139/08, 99/09, 149/14, 150/15, and 37/16 and "Official Gazette of RM" No. 157/20) and Rulebook for closer criteria on intrahospital infections prevention and eliminating ("Official Gazette of RM" No. 25/08

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