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ANALYSIS OF MINISTRY OF HEALTH'S QUALITY CONTROL CAPACITY IN GOVERNANCE

SUPPORT TO THE MINISTRY OF HEALTH OF MONTENEGRO IN CREATING A QUALITY CONTROL SYSTEM

TECHNICAL NOTE

June 2023

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1 Background

The health system of Montenegro is based on a social health insurance system, with more than 95% of the population being covered by social health insurance. The switch to a fully tax-funded health insurance system happened in 2022. Additional funds come from the state budget, as well as out-of-pocket payments.

According to the Law on Health Care, The founder of a healthcare institution can be the state, municipality, domestic and foreign legal entity and natural person.

The state is the founder of the largest number of health institutions that provide health care for the population. Health care is provided in health institutions that make up the network of state health institutions and privately owned institutions.

The network of health institutions is organized in such a way as to provide citizens with health care according to the needs and capabilities of the health system, and in accordance with the principles of solidarity, accessibility and equality in the provision of health care.

Health care is provided on three levels.

In accordance with legal regulations, the state has established health institutions: 18 health centers, 7 general hospitals, 3 special hospitals, Clinical Center of Montenegro, Institute for Public Health, Institute for Emergency Medical Assistance, Institute for Blood Transfusion, Pharmacy of Montenegro "Montefarm" . The aforementioned institutions provide health care by level (primary, secondary and tertiary) in relation to the activity for which they were established.

The Ministry of Health is the creator of health policy, which enacts regulations, defines the concept, monitors implementation and carries out constant supervision.

The Health Insurance Fund of Montenegro is a state fund whose main activity is ensuring that the insured exercise their rights to health care and other rights from compulsory health insurance, i.e. financing the health care of citizens.

The rights, obligations and responsibility of the Fund are determined by the Law on Compulsory Health Insurance.

The Institute for Medicines and Medical Devices was established by the Law on Medicines, as an independent regulatory body of Montenegro in the field of drugs and medical devices and as a scientific research organization. The Institute is the legal successor and continues the work of the Agency for Medicines and Medical Devices, established by the Decision of the Government of Montenegro in 2008.

Recent independent analysis on the Montenegro health system concluded that one of the challenges for the health system is that data collection is fragmented, statistics are often not publicly available, and data are not sufficiently used for decision-making purposes. Hence, the Ministry of Health requested support to the EU in order to strengthen institutional capacity and address the lack of a quality control system in the health sector.

The present note builds on the results of Activity 1 to provide the Ministry of Health of Montenegro with an analysis of its quality control capacity in governance.

2 Health system in Montenegro

The health system of Montenegro is based on a social health insurance system, with more than 95% of the population being covered by social health insurance. The health system is largely centralized, without substantial involvement by local self-government in health service provision and planning1.

The Ministry of Health is the creator of health policy, which enacts regulations, determines the concept, monitors implementation and performs permanent supervision.

The Health Insurance Fund of Montenegro is a state fund whose main activity is to ensure that insured persons exercise their rights to health care and other rights from mandatory health insurance, that is, to finance the health care of citizens.

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The Institute for Public Health is the main body responsible for public health action and plays the role of national reference laboratory.

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Following the priorities of the WHO European Programme of Work 2020–2025, the Health Care Strategy 2022–2026 is currently being developed with three key objectives[3]:

1. moving towards universal health coverage (UHC),
2. protecting against health emergencies, and
3. promoting health and wellbeing.

Primary health care deserves great emphasis on the Master Plan for the Development of the Health System 2015–2020, but payment mechanisms linked to performance are not in place and the current model of primary and specialized care encourages people access to outpatient specialized care.

Primary care services are delivered by the "chosen doctors" (family medicine specialists, medical doctors, paediatricians, gynaecologists, general or emergency medicine specialists, internists, dentists or occupational medicine specialists). The chosen doctor acts gatekeeper to the health system, since access to publicly funded secondary care requires a referral from the chosen doctor. There are 18 primary health care centres (*dom zdravlja*) in Montenegro that deliver primary care services and other services provided by support centres (diagnostic and prevention centres, home visits and patient transport units, centres for lung diseases and tuberculosis, mental health centres, centres for children with special needs, day care centres, and primary level physical therapy units)[1].

People often bypass primary care through the emergency department of the clinical centre. The current model of primary care encourages referrals to specialist services, even for conditions that could be easily addressed in primary care. The lack of payment mechanisms in primary care and proper referral protocols is conducive to such inefficiency.

People in Montenegro face high out-of-pocket payments, representing 39% of current spending on health[1]. This suggests inefficiencies in the organization of health services delivery and in the use of public funds in the health system. Quality assurance systems and health technology assessment are underdeveloped and payment systems do not incentivize performance and quality of care[1].

3 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 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 format depicted in **Figure 1**.

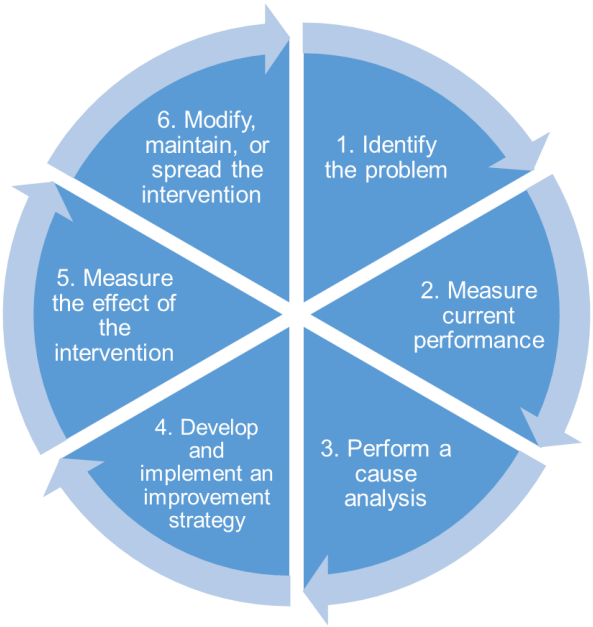

Figure 1. *Model of system to guide the process of quality improvement*

It is important to understand what one is trying to accomplish before determining how to do it. Applied to healthcare quality, this means that we 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[4]:

- 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 30%[5] of expenditure are due to:

- rework,
- overused, misused and underused procedures,
- defensive medicine.

Healthcare quality framework consists of several components, including:

- clinical governance,
- working environment,
- evidence-based practice,
- technology
- quality of care and patient safety competencies
- positive interpersonal behaviour,
- teamwork
- six dimensions of quality: safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity[6].

While promoting the quality and safety of the health system and ensuring greater prosperity and faster development in Montenegro, 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.

4 Governance and organization of quality of care in Montenegro

The organization chart of the Ministry of Health of Montenegro is depicted in **Figure 2**.

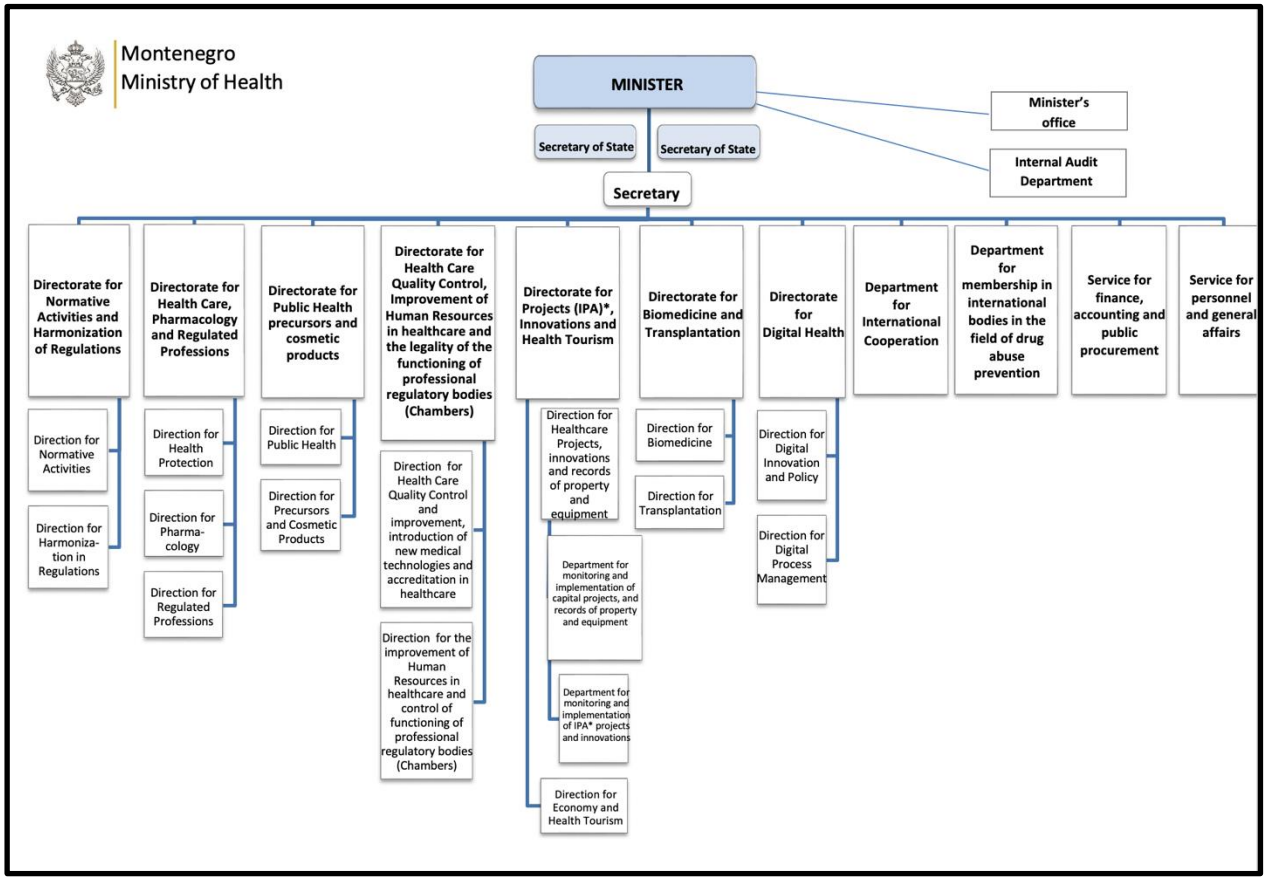

Figure 2. *Organizational chart of the Ministry of Health of Montenegro*

Quality of health care is managed at the *Directorate for Health Care Quality Control, Improvement of Human Resources in healthcare and the legality of the functioning of professional regulatory bodies (Chambers)*. This Directorate is composed by two Directions (**Figure 2**): *Direction for Control and Improvement of Quality of Health Care, introduction of new medical technologies and accreditation in health care* and *Direction for improvement of human resources in health care and control of the functioning of professional regulatory bodies (chambers)*. The Direction for Control and Improvement of the Quality of Health Care, the introduction of new medical technologies and accreditation in health care, employs a total of 4 full-time officers.

The *Direction for Health Care Quality Control and Improvement, the introduction of new medical technologies and accreditation in health care* performs tasks related to:

- strengthening capacities for quality management;
- strategic planning, implementation, monitoring and control of the quality and safety of health care;
- establishing an adverse event reporting system;
- examination and verification of patient satisfaction with the scope, quality and availability of health care services;
- surveying health care providers on satisfaction with participation in quality assurance and improvement;
- development of national guidelines for good clinical practice, clinical pathways, patient treatment pathways in hospitals;
- development of criteria for placing the patient on the waiting list and availability of waiting lists to the public (website of the Ministry of Health and health institutions);
- external verification of the quality of professional work of health institutions;
- systematic measurement of quality improvement and safety (monitoring, improvement and promotion of quality indicators and results of work in health institutions);
- cooperation with HEALTH NGOs in the part of quality, scope and availability of health services; handling complaints and citizens' initiatives relating to the quality, scope and availability of health services;
- implementation of procedures for granting, renewing and abolishing accreditation of health institutions; establishing accreditation standards;
- establishing a reference list of accreditation experts; issuing certificates and keeping a register of issued certificates of accreditation;
- monitoring existing and creating conditions for the application of new health technologies by establishing criteria, standards and guidelines for health technology assessment;
- assessment of the characteristics and impact (technical characteristics, safety, efficiency, effectiveness, benefit) of new medical technologies in health care facilities, as well as the social, legal, ethical influences of their application;
- introduction of new health technologies necessary to provide evidence-based healthcare on the quality, safety and efficacy of healthcare methods and procedures;
- development of guidelines for health technology assessment based on priorities and clear criteria for choosing medical technology in communication with national academic and scientific institutions and other tasks at the behest of the Directorate Manager and the Minister.

5 Main gaps identified

POLICY & STRATEGY

- National policy for the development of quality of care published developed in 2019, with action plan for 20219-2020, has not been implemented
- Patients' organisations are not involved in policymaking
- Measures to ensure dissemination of information about PS are not in the routine
- No consistent mechanisms of using guidelines or spreading best practices
- Lack of mechanisms for patient empowerment

GOVERNANCE

- No independent national body for quality of care and patient safety: the Ministry of Health is the competent authority but the capacity for governing is not sufficient and the work on quality improvement and patient safety is not consistent
- No participation processes in place: patients' associations and health services' users are not involved in decision-making
- 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: anecdotal evidence estimates zero convictions
- No independent national body with a power to effectively process patient complaints for medical professional and/or ethical misconduct

HUMAN RESOURCES

- Safety and quality improvement competencies are absent from the curriculum of students in various health disciplines
- 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: continuous education is funded by the Ministry of Health but without control
- Lack of medical doctors
- No trained professionals to deal with no-fault system and claims

FUNDING

- No financial incentives in place (or penalties) linked to quality of care and patient safety
- No budget for research in quality of care and patient safety and on health services research

6 SWOT analysis

STRENGTHS

- Ministry of Health is regulator in the field of quality of care and patient safety
- Healthcare Law has a chapter dedicated to quality of health care
- Existence of a Strategy for improving the quality of health care and patient safety for the period 2019-2023, and Action Plan for 2019-2020
- Examples of good practices at the institutional level: Institute for Medical Assistance and Kotor Health Centre for example
- Institute for Public Health, as reference laboratory, has experience in international accreditation
- Understanding of existing gaps and willingness to improve the current situation
- Political will to undergo reforms in the health sector

WEAKNESSES

- Lack of adequate capacity at the Ministry of Health competent authority for quality and patient safety regulation and development
- Weak national governance and policy: Commissions of Health care Quality receive no feedback from the Ministry of Health (actually those procedures are not even defined)
- Lack of communication with healthcare institutions and relevant partners such as the Chamber of Doctors
- No political agenda of any kind for the type of compensation scheme for medical injuries, either fault or no-fault based
- Ongoing training on quality of care and patient safety 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 quality of care and patient safety and for projects to improve and research on health services
- No incentives in place linked to quality of care and patient safety
- The provisions in the Healthcare Law are too vague and could to be strengthen
- Lack of administrative capacity and available financial resources for the implementation of planned Activities
- Inadequate system framework for monitoring training needs
- Insufficient management involvement to introduce quality assessment methods
- non-existence of plans for quality improvement at the level of healthcare institution

OPPORTUNITIES

- Support from the EU, WHO and other partners is available
- Working on improving the institutional communication and gaining back trust in MoH in providing regulatory framework, consistent supervision, and timely communication.
- Need to create a national independent body dedicated to quality of care and patient safety
- Revision and update of strategic objectives and action plan for quality and patient safety
- Develop multidisciplinary curriculum for quality of care and patient safety
- 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 quality of care and patient safety at the national and providers level through the legislation
- Establishment of clinical nationally accepted clinical guidelines
- Collection of data on the type and number of cases of avoidable events, compensations awarded, mechanisms to collect, process of data and its management
- Upgrading audits of providers in the domain of quality of care and patient safety
- The new Strategy for digitalisation of healthcare system has foreseen some of mentioned problems

THREATS

- Political instability in the country could hamper much needed reforms
- No participatory mechanisms in place and no involvement of patients' organizations in policy making
- No budget for research in quality of care and patient safety and on health services research

7 Priority recommendations

1. **Implement the *Strategy for improving the quality of health care and patient safety for the period 2019-2023*.** The country already has a strategy for quality of health care and patient safety – and an action plan for the first year – but was never implemented. With appropriate revisit and update, the strategy is a good starting point to initiate the much-needed improvement in quality of care.
2. **Enhance quality of care governance.** The implementation, monitoring and evaluation of a quality system demands a **dedicated group of professionals, educated and trained in quality of health care and fully committed to the improvement of quality of care in the health sector**. This would better be achieved by a **technical body, working outside the Ministry of Health structure**, staffed with skilled professionals and with a mandate to improve quality of care in all health system (public and private providers). Furthermore, that body would be less exposed to regular political changes in the Ministry of Health, with a stability that is desirable to relevant technical bodies.
3. **Invest in training of health care workers on quality of care.** No prioritization of quality of care is possible without appropriate training of health care staff in hospitals and health centres. A marked lack of knowledge in the field of quality and safety was witnessed. There is a lack of qualified staff both at the national level and among healthcare providers. The culture in the field of quality of care is very low and quality is not recognized as science-based. Training at all levels is urgently needed, as well as establishing education in the field of health professions at all faculties. Training in quality of care could be coordinated with the Chamber of Doctors for professionals already practicing (through continuous education programmes), but also with the Faculty of Medicine for medical students. Also nurses and other health care professionals should receive training in quality of care.

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