

## ACTIVITY REPORT

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**Title:** Support to the Ministry of Health of Montenegro in creating a quality control system

**Partner institution:** Ministry of Health of Montenegro

Activity code and title: Activity 1: Analysis of MoH's quality control capacity in governance

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## Executive Summary

Montenegro's health system faces a number of challenges. 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. 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.

Although the country has a *Strategy for improving the quality of health care and patient safety for the period 2019-2023, with action Plan for 2019-2020*, it was not implemented to date. Most recommendations and challenges identified in that document are still valid. In order to adequately prioritize quality of health care, Montenegro lacks a dedicated body, staffed with skilled and trained professionals, and independent from the Ministry of Health.

Currently, the Directorate for Quality of Health care is one of the Directorates in the Ministry of Health, but with no capacity to adequately enhance a quality control system in the country. Also, training for health care professionals on quality of care is much needed.

# 1 Introduction

## 1.1 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.

The Ministry of Health, the Health Insurance Fund and public and private health care institutions are responsible for health care service delivery. The Health Insurance Fund is responsible for the implementation of health policy related to health insurance. For the implementation of pharmaceutical policy, the state has set up the Agency for Medicines and Medical Devices (CALIMS). 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 medicines and medical devices and as a scientific research organization. The Institute is a 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.

Health care providers in the public sector include 18 health centres, 7 general hospitals, 3 specialized hospitals, the Clinical Centre of Montenegro, the Institute for Public Health, the network of emergency services the Institute for Emergency medical care of Montenegro, the Blood Transfusion Institute, and the Pharmacies of Montenegro "Montefarm". Healthcare activities are performed at the primary, secondary and tertiary levels of healthcare.

Citizens receive health care at the primary level through a selected team of medical doctors or a selected medical doctor for adults, children and women.

Health activity at the secondary level of health care includes specialist-consultative, consultative and hospital health care, which are also provided at the tertiary level of health care, in addition to providing highly specialized care by performing the most complex forms of specialist-consultative, consultative and hospital health care, as well as educational, scientific and research work that is carried out in cooperation with health faculties.

Health institutions are: clinic, laboratory, pharmacy, health care institution, polyclinic, health center, hospital, institute, natural spa, clinic, clinical-hospital center, clinical center, institute Health institution of the Pharmacy of Montenegro "Montefarm"

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.

## 1.2 Expected results

As mentioned in the terms of reference (ToR) the expected results for this activity is a technical note, which includes:

- a state-of-play of the health governance framework (people, providers, policy-makers, transparency and accountability)
- a detailed SWOT analysis of the Ministry of Health's quality control capacities with a focus on governance.
- recommendations for improvement.

## 2 Methodology

A methodologic note with an approach was proposed to the Ministry of Health of Montenegro before the mission. The first activity of this mission aimed at providing the Ministry of Health of Montenegro a set of recommendations and guidelines to improve quality-of-care system. More specifically, this activity's objective is to provide the Ministry of Health with an overview of the current situation regarding quality control capacities focused on one of the two critical components of the health system: governance.

In order to better identify current problems in establishing a quality control framework, relevant stakeholders played an important role. Therefore, a number of meetings with relevant stakeholders were scheduled in order to better understand the current situation regarding quality control in the health system in Montenegro. Additionally, a survey (**Annexe 2**) was delivered by the Ministry of Health to several institutions (hospitals and health centres) in the public sector, with the objective of understanding their views and needs on quality control.

For this activity, a number of important issues were addressed, including:

- leadership, governance and organizational models of quality-of-care,
- policies and decision-making process on health,
- goals, priorities and interventions for quality-of-care improvement,
- Regulations and legislation,
- Institutional mechanisms, tools and processes,
- stakeholder involvement.

## 3 Results and deliverables (Outputs)

The main aim of the onsite mission was to provide the Ministry of Health of Montenegro a set of recommendations and guidelines to improve quality-of-care system.

In **Annexe 3** is a detailed agenda (updated several times during the mission) with the discussed content linked to the purpose as part of the proposed methodology. Persons involved besides Socieux+ are also mentioned in the agenda.

This chapter briefly outlines the outputs of the onsite activities. More information on each dimension analysed during the onsite mission can be found in the technical note (**Annexe 1**) which is the main output of this activity. The proposed steps in the methodology are used to describe the outputs.

### **1. The health system as a starting point**

Understanding the health system in Montenegro was one of the main concerns during Activity 1. The founder of a healthcare institution can be the state, municipality, domestic and foreign legal entity and natural person. The founder of a healthcare institution can be the state, municipality, domestic and foreign legal entity and natural person.

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.

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

Healthcare activities are performed at the primary, secondary and tertiary levels of healthcare.

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As it happens in other European countries, Montenegro faces important challenges in retaining health care workers in the public sector, either by draining to the private sector, which pays better salaries, or by migration to EU countries, particularly Germany (Golubović, 2021; European Observatory on Health Systems and Policies, 2022).

Although Montenegro has switched to a fully tax-funded health insurance system in 2022, with a population coverage close to 100% thanks to broad eligibility to health benefits, out-of-pocket payments (OOP) are high, accounting for 39% of current health spending in 2019, and close to 10% of households reported catastrophic health spending in 2017 (European Observatory on Health Systems and Policies, 2022).

The high level of OOP coexists with a relatively high share of government spending on health (11% of government budget), which suggests inefficiencies in the organization of health services delivery and in the use of public funds in the health system. The majority of public funding goes to hospitals and the current model of primary and specialized care encourages people access to outpatient specialized care. Quality assurance systems and health technology assessment are underdeveloped and payment systems do not incentivize performance and quality of care (European Observatory on Health Systems and Policies, 2022).

## **2. The governance of quality control in health care**

The Health Care Act (Annexe 4) has a set of articles dedicated to the quality of health care (Part VIII). The law establishes that The process of monitoring and evaluating the quality of health care services consists of the control of (1) compliance with the prescribed operating conditions of health institutions; (2) application of adopted standards in healthcare; (3) reduction of unwanted, unnecessary and inappropriate processes and (4) undertaken measures of professional training and education of healthcare workers. This process is carried out internally and externally. At the internal level, the process of checking professional work and quality is carried out by the Health Care Quality Control Commission, appointed by the director of the institution - while the external quality control is carried out by the Health Care Quality Control Commission appointed by the Ministry, whose members, in accordance with the Law, are prominent health professionals workers, representatives of the competent chamber and health faculty

The Health Care act is relatively vague regarding the understanding of quality of care, and the on-site mission revealed that not only those Commissions deal mostly with complaints from citizens (regarding waiting lists or complaints about the service) but also that no international indicators on quality of care are used, monitored or evaluated within the institutions. Additionally, those Commissions receive no feedback from the Ministry of Health about the reports they submit.

### 3. The strategy for improving the quality of care and patient safety 2019-2023

Despite important red flags identified regarding the governance of quality of care, Montenegro has a *Strategy for improving the quality of health care and patient safety for the period 2019-2023 (Annexe 5)*. The document also includes an action plan for 2019-20, with appropriate activities, indicators and roles for each stakeholder. The document is very complete and identifies the main problems in governance and barriers to successfully implement a quality control system in the country. Published in 2019, the Strategy is clear about the strategic goals and priorities, namely:

- establishing a national body for quality in health care,
- introducing a health technology assessment,
- establishing international accreditation in health care,
- strengthening capacity for quality management,
- measuring quality and safety improvement through monitoring security.

Unfortunately, the Strategy was not implemented to date – understandably because of the COVID-19 pandemic – and its recommendations are still valid and supported by the on-site mission.

## 4 Outcomes and impact of activities

The main focus of this activity was to analyze the Ministry of Health’s quality control capacity in governance. For that purpose, an analysis of relevant documents coupled with questionnaires to health care institutions, meetings (**Annexe 6**) with relevant stakeholders and field visits was used as adequate methodology. Strengthening the Ministry’s quality control capacity in governance demands a strong commitment with quality of care and courage to invest in important reforms to transform the current situation. The main outcome of this activity was the technical note prepared in the scope of the on-site mission, with a detailed analysis a detailed SWOT analysis of the Ministry of Health’s quality control capacities with a focus on governance, as well as recommendations for improvement.

The real impact of this activity will only be seen at the end of the action, when the Ministry of Health will be expected to develop a quality control system in health and can develop a quality-of-care measurement framework. However, due to the survey sent to health care institutions by the Ministry of Health, a timid impact was already noticeable: those institutions were surprised with the request and answered promptly to the survey. Commissions at health care institutions were not used to communicate with the Ministry about quality of care, which shows that a better organizational structure and governance is needed to improve communication and feedback from the Directorate for Quality of Health Care to the health institutions.



## 5 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 is provided through continuous medical education for which MoH has yearly budget but due to small percentage of realisation of training Ministry of finance has decreased the budget considerably. MoH is currently working on monitoring of this process and developing performance indicators which can improve expected results. 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. MNE does not have the Chamber of nurses and other health care professionals and therefore organizing education and training for these professionals is more difficult as their education/training cannot be properly validated and accredited.

## 6 Conclusions

The health system in Montenegro faces great challenges: population ageing and the increasing burden of non-transmissible diseases are major drivers of healthcare utilization and will demand sound health policy in the upcoming years. Among the many challenges that lay on, quality of health care is one that deserves attention for the enormous contribution that can give to population health but also to tackle inequities and promote overall efficiency in the health system.

The country has some work to do regarding the prioritization of quality of health care: no body of the Ministry of Health is devoted to implementing, monitoring and evaluating quality of health care in the health system. However, the necessary instruments, such as a Strategy and Action Plan already exist. In order to develop a quality control system, the Ministry of Health needs to be committed to improve training of quality of health care and address the main red flags identified. Strengthening quality of health care can be pivotal to Montenegro successfully achieve its health policy goals.

## 7 References

Golubović V. How migration, human capital and the labour market interact in Montenegro. European Training Foundation; 2021.

European Observatory on Health Systems and Policies. Health Systems in Action: Montenegro. 2022 Edition. The Health Systems in Action Series. EOHSP; WHO Europe; 2022.

## 8 Annexes

**Annexe 1** - *Technical note: Analysis of Ministry Of Health's Quality Control Capacity In Governance*

**Annexe 2** - *Survey on Quality, Patient Safety, Clinical Risk Management and Legislation*

**Annexe 3** - *2023-08 MNE\_Act 1\_Agenda (final)*

**Annexe 4** - *Law on Health Care Montenegrin*

**Annexe 5** - *Law on Health Care in English*

**Annexe 6** - *Strategy for improving the quality of health care and patient safety for the period 2019-2023, and Action Plan for 2019-2020 in Montenegrin*

**Annexe 7** - *Strategy for improving the quality of health care and patient safety for the period 2019-2023, and Action Plan for 2019-2020 in English*

**Annexe 8** - *Contact list*

## About SOCIEUX+

The EU promotes and maintains dialogue on Social Protection and inclusive employment policies with an increasing number of Partner Countries. The European consensus on development, entitled 'Our world, our dignity, our future', has confirmed this effort. A significant number of cooperation initiatives in these fields are funded by geographic or thematic instruments of the EU in different Partner Countries. Those initiatives are highly structured and address the medium- to long-term needs of Partner Countries. However, short-term and peer-to-peer cooperation are essential to complement these and the EU's international cooperation agenda. The EU Expert Facility on Employment, Labour and Social Protection (SOCIEUX+) responds to this need.

The [SOCIEUX+](#) Facility was established and funded by the EU through the European Commission's Directorate for International Partnerships (DG INTPA). The Facility is co-funded by France, Spain, and Belgium. It is implemented by a partnership composed of Expertise France (the partnership lead), Fundación Internacional y para Iberoamérica de Administración y Políticas Públicas (FIIAPP) from Spain, Belgian International Cooperation on Social Protection (BELINCOSOC), and the Belgian Development Agency (Enabel).

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The Facility is an expansion of Social Protection EU Expertise in Development Cooperation (SOCIEUX), established in 2013.

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