https://doi.org/10.52326/ic-ecco.2022/BME.01



# EFFECTIVE MANAGEMENT OF MEDICAL TECHNOLOGIES FOR A FUNCTIONAL HEALTH SYSTEM

Gheorghe Gorceag [1], ORCID: 0000-0002-4470-8014
Victor Sontea [1], ORCID: 0000-0002-0372-8799
Artur Buzdugan [1], ORCID: 0000-0002-9226-004X
[1]Technical University of Moldova, Department of Microelectronics and Biomedical Engineering, National Center of Biomedical Engineering, Stefan cel Mare blv, 168, MD-2004, Chisinau, Republic of Moldova,
gorceag.gheorghe@gmail.com , victor.sontea@mib.utm.md, artur.buzdugan@mib.utm.md

***Abstract* – Medical devices are indispensable in performing the medical services, and their importance has become a priority at the institutional level as well as at the national level. In order to assure the proper functioning of the health system, it is necessary to provide medical devices, in accordance with the latest progress of medical technologies. However, qualified human resources and the implementation of effective management are vital for qualitative, safe, and efficient medical devices.**

***Keywords* – *medical devices, management of medical technologies, endowment, technology assessment, maintenance, periodical verification, the user.***

## I. INTRODUCTION

Good international practices demonstrate the need for the operative and continuous implementation of research results, and new innovative technologies with the potential to improve medical services offered to the population. Effective technologies associated with relevant health improvements create an ongoing challenge for health systems, as their most effective application requires increasing identification of financial and human resources for the health system. Obviously, the increasing costs of new technologies require the optimization of the evaluation and management of medical devices, but also of the available resources, and the most effective technologies must be promoted taking into account organizational, ethical, and societal issues in particular. Adequate management is an indispensable condition [1, 2] for ensuring a high level of safety, in some cases also security, but also the performance of medical devices. Respectively, ensuring the uninterrupted functionality of the health system, increasing the quality of medical services, and the degree of satisfaction of the beneficiary, are dependent on the technical-material basis, the professional competence of the personnel involved, as well as the quality, efficiency, and safety of medical devices. To improve the availability of innovative healthcare technologies such as medicines and certain medical devices to patients in the EU, Regulation (EU) 2021/2282 on Health Technology Assessment (HTAR) [3] was approved, which aims to help ensure efficient use of resources, to strengthen the quality of HTA in the EU, to reduce duplication of effort for national authorities and industry, will facilitate business predictability and ensure the long-term sustainability of EU HTA cooperation, as well as the approval in May 2022 of an implementation plan by - in the year 2025 [4].

Health technology assessment provides evidence-based and up-to-date information for policy-making on the use of technology in health services. Periodic health technology assessment thus acts as a mediating mechanism between policy, research and implementation domains, providing a problem-oriented systematic overview of research needed by both producers and users. This allows the adoption of a high quality and current standard in the medical service system.

## II. MEDICAL DEVICE ENDOWMENT AND TECHNOLOGICAL POTENTIAL

In order to implement the provisions of Law no. 92/2012 Regarding medical devices [5], the provisions of the Memorandum of Understanding between the Swiss Agency for Development and Cooperation and the Ministry of Health of the Republic of Moldova regarding the implementation of the project Development of the National Information System for Management of Medical

Devices (SIMDM) was approved, by order Ministry of Health no. 274 of 18.03.2013 [6], an Action Plan, according to which this SIMDM was implemented.

Responsible for the updating and management of SIMDM is currently the "Agency of Medicines and Medical Devices [7], which ensures the periodic verification of medical devices put into operation [8]. Currently, in the Medical Devices Management Information System of the Ministry of Health of the Republic of Moldova 41,273 medical devices of 3,893 models are registered. From the point of view of the quantitative endowment with medical devices, medical institutions are considered sufficiently equipped. But, from a technological point of view, the technological potential of endowment is physically and morally exceeded, taking into account the pace of development of medical technologies This obvious factor affects the quality and efficiency of medical services provided to the population.

The calculations show that the degree of endowment of public medical-sanitary institutions is 3.0 medical devices per bed, and the rate of medical devices older than 10 years, operated in public medical-sanitary institutions in the Republic of Moldova is below 40%.

The health system in the Republic of Moldova is provided with medical devices through purchases from the state budget, projects and donations. The basic mechanism being the public procurement carried out by the Center for Centralized Public Procurement in Health (CAPCS).

According to the accumulated data, more than 2000 names of medical devices are purchased annually through CAPCS, as a result of the organization and implementation of centralized public procurement procedures, according to table no. 1.

Table no. 1

| **Year** | **2020** | **2021** | **The first semester of 2022 / estimated for the 2022 year** |
|---|---|---|---|
| No. procedures carried out | 143 | 123 | 65/130 |

On the other hand, the provision of public medical and sanitary institutions with medical devices is also carried out through projects and donations. For example, through the projects: "Emergency Response to COVID-19", financed by the World Bank, and "Emergency Response to COVID-19", financed by the loan of the Development Bank of the Council of Europe (CEB), as well as through donations, the health system was equipped with medical devices such as:

- mobile digital radiology devices;
- ultrasonography;
- artificial respiration devices/ventilators;
- monitors for patients;
- oxygen concentrators;
- infusion/infusion pumps;
- electrocardiographs;
- pulse oximeters;
- laryngoscopes/video laryngoscopes;
- defibrillators;
- oxygen generators;
- Analyzers.

Thus, during the COVID-19 pandemic, in accordance with the medical device needs of the health system, public medical and sanitary institutions were equipped with approximately 10,000 units of medical devices, including over 1,000 medical beds. Some of the mentioned projects, as well as other projects in the form of grants, loans or technical projects, are currently underway, and respectively, the purchase and further equipping of medical devices (computed tomography, oxygen generators, analyzers, etc.) follow. Regardless of the way of equipping the health system with medical devices, the essential step that needs to be carried out initially is, of course, the assessment of needs and directly the assessment of medical technologies.

The needs of medical devices must be evaluated in accordance with the existing inventory of medical devices, the medical technologies used but also those applicable, the potential of human resources, as well as the best international practices in the field. In this sense, the primary role belongs to the Ministry of Health, which together with the public medical and sanitary institutions, carries out the continuous assessment of needs and launches the mobilization of financial resources. Human resources responsible for the use and maintenance of medical devices. The essential component in the effective use of medical devices are the users of medical devices, who in the sense of Law no. 102/2017 [5], represents - "medical and sanitary institution, regardless of the form of ownership and legal form of organization, as well as its staff involved in the use of medical devices, including clinical staff (doctors and nurses), paramedical staff (radiologists and physiotherapists) and support services staff" [5]. According to the Statistical Yearbook of the Republic of Moldova for 2020, 12,552 doctors and 23,584 medical personnel worked in the health system, of which 18,514 were nurses – all users of medical devices [5] International practices show us that people involved in the use of medical devices must possess the appropriate knowledge and skills. As a result of the research and study of the challenges of the health system at the national level, as well as international experiences, in art. 15, paragraph (7) of Law no. 102 regarding medical devices [5], for the first time (year 2017) for the Republic of Moldova, the obligation of users of medical devices to use medical

devices only after being instructed on how to use them was provided. Also, in the management of medical devices, responsibilities and obligations are also outlined for other people, namely:

- Managers of medical institutions;
- Staff of the procurement and supply subdivision within the medical institution;
- Staff of the finance/economy subdivision;
- The staff of the human resources subdivision.

One of the most important roles in the management of medical devices belongs, of course, to the personnel responsible for the maintenance of medical devices (medical bioengineers, technical engineers, technicians, mechanics, etc.). Starting from 2016 until now, annual evaluations have been carried out regarding the endowment of the health system with human resources (medical bioengineers, engineers, and technicians). Recent evaluations have shown that their total number is about 150, of which 50 are medical bioengineers. At the same time, the real need of the health system is over 300 medical bioengineers. For this purpose, the Department of Microelectronics and Biomedical Engineering of the TUM [10], and the National Center of Biomedical Engineering within the Technical University of Moldova [11], which are authorized by statute with such functions, play a special role in the periodic training and improvement of staff.

## CONCLUSIONS

In order to ensure the efficient functioning of the health system, only the endowments of medical devices and/or the allocation of financial resources are not sufficient. But, it is necessary to have qualified medical and technical personnel, as well as tools for managing resources and processes that ensure the efficient use of medical devices. In the same way, to increase the quality of medical services and patient satisfaction, it is necessary to ensure the process of periodic evaluation of the conformity of medical devices, which lesss to the use of qualitative, efficient, and safe medical devices.

## REFERENCES

[1] HTA 101: II. Fundamental Concepts https://www.nlm.nih.gov/nichsr/hta101/ta10104.html

[2] John C. O'Donnell, Sissi V. Pham, Chris L. Pashos, David W. Miller, Marilyn Dix Smith. Health Technology Assessment: Lessons Learned from Around the World—An Overviewvhe, International Society for Pharmacoeconomics and Outcomes Research (ISPOR) 1098-3015/09/S1 S1–S5

[3] Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (Text with EEA relevance) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021R2282

[4] Implementation rolling plan Regulation (EU) 2021/2282 of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU. file:///C:/Users/User/Downloads/hta_htar_rolling-plan_en.pdf

[5] The Law on Medical Devices no. 102 from June 09, 2017. Monitorul oficial of the Republic of Moldova, 2017, no. 244-251, 389. https://www.legis.md/cautare/getResults?doc_id=105695&lang=ro

[6] The Action Plan for the implementation of the Memorandum of Understanding between the Swiss Agency for Development and Cooperation and the Ministry of Health of the Republic of Moldova regarding the implementation of the project Development of the National Management Information System of Medical Deviceshttp://ms.gov.md/sites/default/files/legislatie/ord._274_din_18.03.13.pdf

[7] Medicines and Medical Devices Agency. https://amdm.gov.md/public/ro/news/sistemul-informational-de-management-al-dispozitivelor-medicale

[8] Government Decision no. 966 from 14.11.2017 for the approval of the Regulation on the Periodic Verification of Medical Devices Put into Operation and in Use. The Official Monitor of the Republic of Moldova, 2017, nr. 399-410, 1076. http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=372536

[9] Statistical Yearbook of the Republic of Moldova. https://statistica.gov.md/public/files/publicatii_electronice/Anuar_Statistic/2020/Anuar_statistic_editia_2020.pdf

[10] https://fcim.utm.md/departamentele-fcim/departamentul-mib/ national Center on Biomedical Engineering. https://fcim.utm.md/cercetari-stiintifice/centre-si-laboratoare-stiintifice/centrul-national-de-inginerie-biomedicala/