THE PEOPLE`S ADVOCATE OMBUDSMAN

THEMATIC REPORT
ASSESSMENT OF THE INSURANCE LEVEL OF THE PATIENT'S RIGHT TO SAFETY AND QUALITY OF MEDICAL EQUIPMENT

CHISINAU, 2019

CONTENTS

ABBREVIATIONS

AMDM – Medicines and Medical Devices Agency

AOAM - Compulsory Health Insurance

CNAM – National Health Insurance Company

FAOAM - Mandatory Health Insurance Fund

MOLDAC – National Accreditation Centre from Republic of Moldova

CMAC - Center for Applied Metrology and Certification

IMSP – Public Medical-Sanitary Institutions

IMS – Medical-Sanitary Institutions

INS – National Institute of Standardization

INM– National Institute of Metrology

MDM – Medical Device Management

EU – European Union

OHCHR - Office of the United Nations High Commissioner for Human Rights

WHO – World Health Organization

SDC – Swiss Agency for Development and Cooperation

MBMES – Moldovan Biomedical Engineering Society

SIMDM – Management Information System of Medical Equipment

PERINAT and REPEMOL – the projects of the Swiss Agency for Development and Cooperation

DM - Medical device

MSMPS - Ministry of Health, Labor and Social Protection

CONTEXT

In accordance with the provisions of Article 1 of the Law on the People's Advocate (Ombudsman) number 52 of 03.04.2014, the People's Advocate ensures the protection of all human rights and freedoms by the public authorities, by the organizations and companies, no matter of the type of property and the legal organizational form, by the non-commercial organizations and by decision makers at all levels and contributes to the protection of the human rights and freedoms through the prevention of their violation, through monitoring and reporting on the modality of protection of the fundamental human rights and freedoms, through the application of the procedures provided by the present Law.

The right to health and access to health services has been declared by the People's Advocate as one of the priorities of his activity for the coming years.

The data from the study „Perceptions on human rights in the Republic of Moldova", prepared in 2016 by the People's Advocate Office in common with the Office of the United Nations High Commissioner for Human Rights, shows that 61% of respondents thought that the right to health is the most current and important law, which requires increased attention from society in Moldova[1].

In the next similar study in 2018, as in 2016, the right to health remains to be considered the main right that requires the attention of the society, only that the share of respondents who expressed this opinion in 2018 was higher (**71,6% compared to 61%)**.

The health of the population, which is a value and a precondition for economic prosperity, is one of the main priorities of each state, and the health policy provides for the right of everyone to access high quality healthcare.

In accordance with the principles of the World Health Organization, an important function of the health care system is its response to the expectations and needs of the population, which will be addressed in a fair and equitable manner in the context of human rights to life and health. Thus, the right to health is the right of every person to have access to and use the services of the institutions, the goods and conditions necessary to reach the optimum state of health.

[1] http://ombudsman.md/wp-content/uploads/2018/10/ro-raport_do_final_pentru_tipar_1.pdf

Ensuring the right to health necessarily includes guaranteeing access, equity, quality and continuity of medical care to each individual.

The legislation in force establishes the responsibility of the state to protect the health, prosperity and security of the citizens, and the public health system assumes social responsibility for the general health and the most efficient use of the resources to achieve the general sanitary objectives.

The European Charter of Patients' Rights, endorsed and recognized by the European Economic and Social Committee in 2005, lists 14 fundamental rights of the patient, among which is the right of access to medical services. This right is also found in the legislation of the Republic of Moldova.

Although, at the national level, there is a sufficient normative framework for respecting and protecting patient rights, over the last few years, the People's Advocate Office has repeatedly warned about the existence of system deficiencies and irregularities detected.[2] The non-resolution of these problems continues to present a danger to the plenary realization of the right to health of the population. The problems that generate alarming violations of the right to health care with a severe impact on access, quality and continuity of medical services are found mainly in: ensuring equity in health; coverage with funds from compulsory health insurance; conducting the accreditation procedure in health, etc.

Based on those invoked in the requests received from the People's Advocate on the medical assistance offered, but also in the audience of the citizens, we find in the most frequent cases that the dissatisfaction of the addressees refers to the insufficient quality and safety of the healthcare services; the outdated infrastructure of medical institutions and the unsatisfactory technical state of medical institutions; insufficient technical-material endowment.

In 2017, the People's Advocate Office presented the results of a study referring to the quality of the services offered through Pre-Hospital Emergency Medical Assistance. In the study, the authors focused on the exaggerated wear and deplorable endowment of the vehicles in the emergency service, where the equipment for the strictly necessary in the provision of emergency medical assistance was missing. This study has been discussed with the central authorities and, as a result, we appreciate the fact that in the course of 2018 the modernization of this service was initiated (new ambulances and resuscitation equipment were purchased).

[2] Report on the observance of human rights in the Republic of Moldova in 2015. http://ombudsman.md/ro/content/dreptul-la- ocrotirea-sanatatii-fragment-din-raportul-privind-respectarea-drepturilor-omului

In recent years, the public opinion in our country has been marked more and more often by media reports about the serious harm to the life and health of patients, due to the non-conforming equipment of the hospital institutions. At the same time, the People's Advocate received verbal and written requests regarding citizens' concerns about non-compliance with safety in the context of the medical act, in particular, on the use of outdated medical devices, which has generated or can have serious consequences for both medical workers and for patients.

Given the strong impact of the quality of medical devices on the efficacy and safety of the medical act, this subject was established as a priority for monitoring by the team of the People's Advocate Office.

In some cases, the People's Advocate was notified ex officio, for example, in the case of the use by a medical institution of outdated medical devices, which presented a danger to the patients' health. The case was examined in terms of compliance with the necessary conditions for accrediting the institution and the compliance of the existing medical equipment in the medical institutions of Moldova.

During the examination of the case, the People's Advocate found some deficiencies in ensuring the periodic checks and metrology of the medical devices by the medical institutions. The expenses for performing this procedure are for the medical institutions, which are obliged to plan the necessary financial resources in the annual budget of the institution. However, the financial resources available are limited, which is why, as a matter of priority, expenses are planned for the purchase of consumables. At the same time, many managers of the public medical-sanitary institutions also invoked the presence of deficiencies in the implementation of the specified normative acts, such as the insufficiency of the time required for verification. Often, verification requires a longer period of time, which requires removing the device from the institution. Accordingly, some institutions remain uninsured with important equipment, such as anesthesia devices. Such situations delay the activity of the institution.

We note that the EFC (Enterprise with Foreign Capital) „Trans-Standart" LLC (Limited Liability Company) at that time was the only accredited profile institution for conformity assessment. Moreover, this institution was accredited for periodically checking ten types of medical devices, covering only 15% of the types of medical devices used in medical institutions in the country[3]. For the accreditation of other deposits, the institutions are required

[3] http://ombudsman.md/wp-content/uploads/2018/10/raport-ombudsman_2016.pdf

to identify possibilities abroad (e.g. in Kiev, Ukraine), which requires high expenses and excessive time in retaining the activity of the institution.

During the discussions with medical managers / workers were mentioned also the serious problems faced by the medical institutions due to the high degree of wear of the equipment received through humanitarian aid and the lack of an opportunity to check it metrologically. Through this evaluation we set out to identify the systemic problems faced by the medical institutions on the maintenance of the medical equipment, which, consequently, affects the quality of the medical record and the patient's safety.

At the same time, the report clarifies the organizational problems and gaps that exist at the institutional level and comes with some recommendations for improving the management of medical equipment and devices in hospital institutions.

PURPOSE AND OBJECTIVES

As the purpose of this report we have proposed the assessment of the level of assurance of the patient's right to safe and quality medical services performed with the application of the equipment / devices in the hospital medical institutions, in order to elaborate recommendations to improve the quality of the medical act and to adjust to the procedures and standards for effective institutional management and observance of the patient's right.

In order to reach the proposed goal, the following objectives have been set:

1. Assessment of the normative framework in force and of the national system of control and monitoring of the quality of the medical equipment through the prism of the international standards and the recommendations of the international bodies on the observance of the patient's right to safety and the assurance of quality standards;
2. Assessment of the conformity of the medical devices and equipment of the hospital institutions in the country;
3. Consultation of the opinions of the managers of the hospital institutions on the management process of the medical devices and their criticality at the institution level;

4. Developing reliable recommendations for ensuring the right to quality and safety of the patient in the context of the medical act and adopting an effective quality management style in the hospital institutions in the country.

METHODOLOGY

In order to analyze the real situation on the safety and quality of the medical equipment and devices within the hospital institutions, we conducted a combined research, having both the qualitative and the quantitative component.

First, from the Medicines and Medical Devices Agency (AMDM) was requested the report of assessment of medical devices and equipment elaborated within the „REPEMOL" project, financed by the Swiss Agency for Development and Cooperation (SDC).

Also, data were requested from 71 hospital medical-sanitary institutions in the country by applying the questionnaire of the managers of the hospital institutions to verify the following aspects:

- The presence and the number of the staff trained to work with the respective medical equipment (with the annexation of the confirmatory materials of the training);
- The presence of the technical specialist (bioengineer) who monitors the work of the equipment in the institution.
- Presentation / explanation of the metrological verification procedure of the equipment in the institution (who monitors and how is monitored the work of the equipment, how to identify their working errors, where to check, how to plan the checks, how to plan and cover the expenses for the metrological verification of the equipment).
- How is ensured the access of patients to information on the state of the equipment used in diagnosis and treatment?

During the monitoring process there were subjected to assessment the sections of major importance within the hospital institutions, where the medical act is initiated to save the life and health of the patient, such as: emergency departments, intensive care and resuscitation departments, operating rooms, diagnostic units.

Subsequently, the team of the People's Advocate Office performed national monitoring visits to randomly selected hospital institutions.

The data from the Institutional Reports on the status of medical devices and equipment in the hospitals subject to monitoring were analyzed.

Also, information was accumulated by applying a questionnaire for the managers of the hospital institutions (*annex 2*), including, with open questions for collecting personal opinions about the problems encountered in organizing the equipment management process.

CHAPTER I
INTERNATIONAL AND NATIONAL STANDARDS ON THE OBSERVANCE OF PATIENT'S RIGHT TO SAFETY AND QUALITY STANDARDS

The right to health is one of the fundamental human rights. Article 25 of the Universal Declaration of Human Rights expresses the right to a standard of living that ensures health and explicitly access to medical care.

Article 36 of the Constitution of the Republic of Moldova, referring to the right to health care, stipulates both the guarantee of this right and the obligation of the state to ensure the minimum medical assistance. Currently, the right to health is approached through the international provisions, focusing on the rights of the patient, which are stipulated in the European Charter of Patients' Rights, which states 14 patient rights. These rights are important in the relationships between citizens and their health system.

From a legal point of view, the rights of the patient are defined in the legislation of the Republic of Moldova as rights derived from the fundamental human rights to life and health, which include social rights related to *accessibility, quality and equity* in obtaining healthcare, as well as individual rights on the respect of the patient as a human being, of his dignity and integrity, achieved through the use of health services.

It is also important to note that by ratifying the Convention on Human Rights and Biomedicine, the Republic of Moldova has once again made a commitment *„to take appropriate measures in order to ensure equitable access to good quality health services"*.

The right to health is provided in a series of international treaties, such as: the International Covenant on Economic, Social and Cultural Rights[4], Article 12; International Convention on the Elimination of All Forms of Racial Discrimination, Article 5 e) iv); Convention on the Elimination of All Forms of Discrimination against Women, Articles 11 (f), 12, 14, 2), b); Convention on the Rights of the Child, Article 24; Convention on the Rights of Persons with Disabilities, Article 25; Revised European Social Charter, Articles 11 and 13.

The UN Committee for Economic, Social and Cultural Rights approved (in 2000)

he General Comment number 14 on the right of any person to enjoy the best

[4] United Nations General Assembly Resolution 2200A [XXI]. December 16,1966. http://www2.ohchr.org/english/law/CDESC.htm

physical and mental health, which can be achieved. The Committee states that the right to health is the right of the person to have access to the use of the services of a number of institutions, of the goods and of the conditions necessary to reach the highest level of his or her health.

Assessment of the degree of observance of the right to health is made from the perspective of the 4 indissoluble elements: *availability*, which implies that the state is obliged to make available a sufficient number of institutions, goods, services and programs in the health system; **accessibility,** the goods and services in the field of health, available to the state, must be accessible to each person; **acceptability**, this means that all health goods and services must comply with the principles of medical ethics and cultural criteria, so that the particularities of all categories of persons are taken into account; **quality**, health goods and services must be scientifically and medically acceptable and of high quality.

The assessment in question reflects, in particular, the degree of realization of the patient's right to respect the quality and safety standards of the patient.

1.1 Right to observance of quality standards

The right to observance of quality standards implies that every individual has the right of access to high quality medical services based on clearly established criteria and with respect to precise standards.

The right to quality medical services requires that the institutions and health professionals offer satisfactory levels of technical performance, comfort and inter-human relations. This involves specifying and respecting precise quality standards, established through a public and periodically assessed and reviewed advisory procedure.

The health care system is based on the principle of the responsibility of the authorities and the medical-sanitary units for the accessibility, the opportunity, the quality and the volume of the medical-sanitary benefits, for the quality of the professional training and the improvement of the qualification of the medical-sanitary and pharmaceutical personnel.

The patient has the right to information on the quality of the services provided. The realization of the patient's social rights is ensured by exercising control over the quality of the health services provided and accredited in the manner established by the legislation[5].

Each healthcare provider is obliged to ensure the quality of the services offered. This obligation is closely linked to the following patient's rights: right to observance of quality standards, right to timely treatment, right to safety, right to innovation, right to avoid suffering and unjustified pain, right to personalized treatment.

The way in which hospital managers approach the concept of quality differs greatly depending on the experience and the training of each one. The purpose of the revision of the quality standards is to continuously improve the quality of the services provided and the ways of producing these services. In this sense, a good quality management consists in the planning, the practical application, the control and the revision of the measures necessary to model the services and processes so that they permanently correspond to all the needs of the main actors involved (clients, suppliers, financers).

The concept of quality encompasses at least three fundamental dimensions:

1. **Professional quality** – presupposes that medical and healthcare workers are held responsible for professional incompetence and non-compliance with professional obligations. In the case of the unsatisfactory state of health as a result of inadequate medical care, the medical workers must take into account and respect the right of the patient to request the carrying out, in the established way, of a professional expertise, as well as to repair the moral and material damage that has been brought to him or her[6].

   Professional quality is a factor that can be used as a criterion for assessing the quality of work provided by the medical staff. The quality of the services provided by the medical-sanitary and pharmaceutical institutions and enterprises is subject to periodic assessment and accreditation procedures in accordance with the legislation in force[7].

2. **Patient expectations** refer to the quality of the medical act (patient satisfaction).

   Typically, patients do not possess the ability or knowledge necessary to assess the technical competence of the healthcare provider or the way infection control measures have been used, but they know how they feel, how they have been treated, and whether their expectations have been met.

[5] Law on patient rights and responsibilities number 263 of 27.10.2005, Article 5, Article 8.
[6] Law on health protection number 411 of 28.03.1995, Article 4, Article 14, Article 36
[7] Law on health assessment and accreditation number 552 of 11.10.2001.

Obviously, patient satisfaction assessment is the way in which the provider meets patients' values and expectations. At the same time, the realization of the patient's social rights is ensured by exercising control over the quality of the health services granted and accredited in the manner established by the legislation[8].

3. **Total quality management** - the most efficient and productive way of using the resources within the limits set by the authorities / buyers (efficiency).

Total quality management is an organizational model that involves general participation for the planning and implementation of a continuous quality improvement process that exceeds customer expectations. This model starts from the premise that 90% of the problems are problems related to the process and not to the staff. Three principles govern the concept of total quality: customer focus, continuous quality improvement, teamwork.

The legislation in force describes the obligation of the doctor ***to ensure the quality of medical services.*** Among the general principles of the practice of the medical profession are the competence, professional responsibility of the doctor and his or her endowment with high ethical-moral qualities, as well as respecting the „do not harm" principle.

In order to ensure the quality of the medical act, there are developed the National clinical protocols, based on the International Guidelines based on evidence of clinical and economic effectiveness. They are tools for clinical decision making, being developed on particular fields.

In the exercise of his or her profession, the medical and pharmaceutical worker gives priority to the patient's interests, which prevail over any other interests[9].

1.2. Right to safety

According to the European Commission, patient safety is the absence of injury or of the potential for injury of the patient, in relation to the health system. Safety means that hospital premises, surroundings and equipment do not endanger or risk patients, staff and visitors. At the same time, the concept of patient safety is based on two pillars: the right to life and physical and mental integrity and the right to health protection.

[8] Law on patient rights and responsibilities, number 263 of 27.10.2005 (Article 5, 8 paragraph (8), letter (e)).
[9] Deontological code of the medical worker and the pharmacist, approved by the Decision of the Government of the Republic of Moldova number 192 of 24.03.2017

In the medical institutions a multitude of components interact - staff, patients, infrastructure, technology, drug suppliers and consumables.

Each patient has the right to be protected from harm caused by the inadequate functioning of health services, medical malpractice and errors, and must be guaranteed the right to access to services and treatments that meet safety standards.

Patient safety is based on providing adequate quality of services, being considered an absolute minimum standard, necessary for medical services. Therefore, this right can be attached to one of the four principles of modern non-harmful medical ethics / bioethics („do not harm").

Patient safety refers, in particular, to the following aspects: safety of medical services, safety of medical equipment and technologies, safety of blood and blood products, safety of medicines and vaccines, safety of the environment (including radiation and biological safety), control of nosocomial infections, etc.

In carrying out his or her professional duties, the doctor is not entitled to subject the patient to an unjustified risk, even with his or her consent. The patient or his or her legal representatives will be obliged to be informed by the doctor about possible risks which the medical intervention entails, respecting the right to decide and, possibly, to refuse the intervention[10].

It is unanimously accepted that many errors can be prevented and therefore require the introduction of essential changes in the way medical services are provided, in order to meet the major patient safety objective.

Patient safety is vital for maintaining and developing the medical system. Without ensuring proper care for each patient, the dangers associated with the spread and aggravation of the diseases detected will increase significantly.

Thus, the medical and pharmaceutical worker must show maximum vigilance in the provision of professional service and in avoiding the foreseeable complications in the patient in his or her care. The possibility of medical errors and occupational risk should be considered by each doctor. The position adopted by medical and pharmaceutical workers towards professional (occupational) errors must have as an essential criterion the good of the patient[11].

[10] Law on the exercise of the profession of doctor number 264 of 27.10.2005, Article 17, Article 18.

[11] Deontological code of the medical worker and the pharmacist, approved by the Government Decision number 192 of 24.03.2017, chapter VIII.

1.3 Quality and safety of medical devices in performing the medical act

Medical devices are an essential component of the medical act and must be maintained in good functional condition, to allow the medical institution to deliver high quality medical services. The medical device sector contributes to saving lives by offering innovative solutions for diagnosing, preventing, monitoring and treating various diseases.

Medical device - is any instrument, apparatus, equipment, material or other article, used separately or in combination, including the software necessary for its proper operation, intended by the manufacturer to be used for humans for the purpose of:

- diagnosing, preventing, monitoring, treating or ameliorating of a disease;
- diagnosing, preventing, monitoring, treating, ameliorating or compensating of an injury or disability;
- investigation, replacement or modification of the anatomy or of a physiological process;
- conception control.

All medical devices require maintenance, the purpose of which is to ensure their service life, avoiding their early use.

Maintenance of medical devices includes preventive and corrective maintenance (repairs). ***Corrective maintenance –*** is the set of activities performed after the failure of the device, which consist in locating and diagnosing the faults and in interventions to restore the proper functioning of this device; ***Preventive maintenance –*** is the set of activities that consists of checks, cleaning, replacing of consumables, tests, etc. systematically performed in order to prevent the probability of failure and degradation of the device and to maintain its functional status.

Maintenance must be planned and implemented in such a way as to ensure that medical devices are inspected periodically, to prevent possible problems, which could lead to major malfunctions.

It is recommended that the result of each maintenance procedure be recorded by the users, so that this data to be used for the subsequent improvement of this process[12].

[12] Guide on the establishment criteria, roles and responsibilities of the biomedical engineering departments / sections within the public medical-sanitary institutions, elaborated within the JICA project, February 2017

At the same time, in order to confirm that the medical devices used during the medical act are safe and qualitative, they must be checked periodically, and medical institutions and biomedical engineers must ensure the implementation of these periodic checks according to the previously prepared schedule.

It is well known that the equipment must be replaced with its physical and moral wear. Once it is worn out, its efficiency decreases and the cost of maintenance increases significantly. Used medical devices have a high failure rate, which is why they need to be disposed of in a timely manner, in order to avoid wasting the financial resources of the medical institution, which can be used to purchase new and better devices, to replace outdated technologies.

In such conditions, the efficient use of the available budget of the medical-sanitary institution is extremely important. The timely renewal of the inventory of medical devices is indispensable, but with it must also be taken into account the maintenance costs throughout the life cycle of these devices, not just the investment for their purchase. Therefore, efficient management of the budget of the medical institution can ensure and guarantee the durability of the acquired medical devices, which ultimately influences the quality of the medical act.

Medical devices are a category of means of the institution that need special maintenance. In the medical system of our country there is the perception that the medical devices can be maintained jointly with the other technical equipment of another destination by the technical personnel, without corresponding studies in the field of biomedical engineering. This vision does not correspond to reality and is inconsistent with modern medical technologies. Contemporary medical devices require adequate technical maintenance by a competent engineering staff, in order to give medical professionals, the opportunity to make the most of the capabilities of these medical devices.

Currently, in the Republic of Moldova, the procurement of medical devices by public medical-sanitary institutions takes place through the Center for Centralized Health Procurement[13]. The Center, as the central procurement authority, plans and conducts public procurement procedures for medicines, other medical products and medical devices, awards public procurement contracts, as well as assesses and supervises the execution of public procurement contracts for

[13] Decision of the Government of the Republic of Moldova „On the Center for Centralized Public Procurement in Health", number 1128 of 10.10.2016;

for medicines, other medicinal products and medical devices for the needs of the health system on the account of the means of the state budget, the budgets of the administrative-territorial units, the financial means of the public institutions, the means of the funds of the compulsory health insurance and of the external loans related to the direct or guaranteed state debts.

One component of medical device management is the vigilance system, whose main purpose is to improve the health and safety of patients, users and other people by reducing the likelihood of repairing the incidents.

This aim can be achieved by assessing the reported incidents, by disseminating information that could be used to prevent incidents from recurring or to mitigate the consequences of such incidents.

Incident – is any malfunction or deterioration in the characteristics and / or performance of a device, including deficiency in labeling or instructions for use, which, directly or indirectly, may lead to or have resulted in the death of a patient, user or other persons or the serious deterioration of their state of health;

Users – are all medical-sanitary institutions, regardless of the ownership and organizational-legal form, including their personnel involved in the use and maintenance of medical devices, such as clinical staff (doctors and nurses), paramedical staff (radiologists and physiotherapists) and support service staff. The responsibility for reporting the incidents involving the medical devices lies with the medical staff, the medical-sanitary institutions, other users, the manufacturer or its representative in the Republic of Moldova.

The incidents are reported to the – Medicines and Medical Devices Agency within 2 working days, according to Article 16 of the Law number 102 of 09.06.2017 on medical devices. In the event of an incident involving the medical devices, the medical and biomedical staff must make the necessary contribution in the process of reporting the incident by the medical institution. In most European Union countries, the field of medical device use is regulated in strict compliance with European Directives by adjusting the national legislation and approving the related standards to those recognized at European level. The degree of endowment of the medical institutions in the countries of Europe is on average of 5-15 medical devices in a bed and in charge of the management of the medical devices is the Department of biomedical engineering, which is part of the structure of the medical institutions identical to the clinical and auxiliary sections.

Modification of the legislation of the Republic of Moldova on medical devices was determined by the provisions of the Decision of the Government of the Republic of Moldova „On the approval of the National Action Plan for the implementation of the Association Agreement Republic of Moldova-European Union" number 808 / 2014.

Currently, the legal and institutional framework for the control and supervision of medical devices made available on the market and in use, as well as for the supervision of the activities of marketing, distribution and provision of services in the field of medical devices is established in the Law on medical devices number 102 of June 9, 2017.

Until the date of entry into force of this law, periodic checks of medical devices were carried out by „Trans-Standart" LLC, the Conformity Assessment Body, the only accredited institution of profile[14]. It has been accredited for periodic verification of only 10 types of medical devices, covering about 15% of the types of medical devices used in medical institutions in the country. By these actions was initiated the transition from metrological verification of medical devices to periodic verification - a new concept of verification and corresponding to the needs of the health system of the Republic of Moldova.

The law on medical devices establishes the procedure for the assessment and registration of medical devices imported into the country. Also, the act provides for the immediate recognition of the quality of the equipment certified by the European Community. At the same time, for the devices produced in other states, the registration procedure has been simplified. Also, according to the document, the medical equipment and devices used will be periodically checked.

In this context, we reflected some notions:

Metrological verification – is the method of legal metrological control, by which it is ascertained and confirmed that a means of measurement meets the requirements provided in the legal metrology regulations.

Periodic metrological verification – is the verification of a measuring means, performed periodically, at specified time intervals, according to a procedure established by applicable legal metrology regulations.

Testing – represents a technical operation for determining one or more characteristics of a product, in accordance with a specific procedure; it is found that namely the attempt, or

[14] Order of the Minister of Health number 1399 of 09.12.2014;

periodic testing by tests is that technical operation that can guarantee the appropriate level of performance and safety of medical devices.

Thus, in order to ensure the use of safe, harmless and qualitative medical devices, the adequate periodic verification of the medical devices put into operation and in use is extremely important for increasing the safety of patients and users.

In parallel with the verifications carried out, the process of managing medical devices is monitored through the Management Information System of Medical Equipment (SIMDM). This is a database managed by the Medicines and Medical Devices Agency and completed and updated annually by public health institutions.

By the Government Decision number 966 of November 14, 2017 was approved the *Regulation on the periodic verification of the medical devices put into operation and in use*. That regulation includes the following aspects:

a) assessment of the defining parameters of *security*, through examination and testing;
b) assessment of the defining parameters of *performance*, through examination and testing;
c) verification of compliance with the set of acceptability criteria for the medical device (required values, accessories, etc.);
d) issuing a test report containing the results obtained after the examinations and tests and based on it, issuing *a periodic verification bulletin*.

In addition to regulating the mechanism of periodic verification of medical devices put into operation and in use, the Regulation provides for the *Nomenclature of types of medical devices and the frequency of their verification*. It also provides that periodic verification of medical devices put into operation and in use is carried out by accredited and recognized testing laboratories in the field of medical devices, independent of manufacturers, users and persons providing the maintenance of medical devices.

According to this Regulation, accredited structures must carry out, every two years, the verification of medical devices and issue a periodic verification bulletin. The bulletin must include the results of the examinations and the conclusion on the use of medical devices. Among medical devices to be tested are: anesthesia devices, of artificial respiration, incubators for newborns, electrocardiographs, ultrasonographers, patient monitors, infusion pumps and others.

At the same time, it is important to mention the *Regulation on the system of surveillance of medical devices*, approved by the Order of the Ministry of Health, Labor and Social Protection number 211 of 21.03.2018. The purpose of this Regulation is to improve the protection of the health and safety of patients and users by assessing reported incidents and, where appropriate, by determining information that could be used to prevent their recurrence or to mitigate the consequences of such incidents.

The regulation on the system of surveillance of medical devices aims to establish a system of vigilance for all medical institutions of the country. These, together with the maintenance services and periodic checks of the medical devices will guarantee the safety of the patient and the user, which leads directly to the increase of the quality of the medical document.

The specific procedures for periodic verification of medical devices are approved by the Order of the Ministry of Health, Labor and Social Protection number 30 of January 12, 2018.

The Inspection Body for carrying out periodic checks of medical devices has been recognized the Center of Applied Metrology and Certification based on the Order of the Ministry of Health, Labor and Social Protection number 660 of 25.05.2018, in accordance with the provisions of Government Decision 966 / 2017.

Competent authorities in the field of medical device verification

- ***Ministry of Health, Labor and Social Protection***

- recognizes accredited bodies to carry out medical device checks;
- publishes the list of recognized bodies;
- approves by institutional act and publishes in the Official Gazette of the Republic of Moldova the specific verification procedures which will determine the minimum set of methods from the harmonized European standards, adopted as Moldovan standards, for the types of medical devices, according to the annex.

- ***Medicines and Medical Devices Agency***

- develops and submits for approval to the Ministry of Health, Labor and Social Protection the specific verification procedures which will determine the minimum set of methods from the harmonized European standards, adopted as Moldovan standards, for the types of medical devices.

➢ ***Recognized inspection bodies***

- organize the verification of medical devices according to the specific verification procedures, approved by the Ministry of Health, Labor and Social Protection;
- issue, after the verification of the medical devices, the periodic verification bulletin for the users;
- report quarterly to the Agency on the results of the verification of medical devices.

➢ ***Users who manage medical devices***

- designate a person responsible for keeping track of medical devices;
- ensure the planning of the verification of the medical devices according to the Regulation approved by the Government Decision number 966 / 2017;
- subject to verification the types of medical devices, following the procedure of purchasing verification services;
- update the information on the verifications of the medical devices in the medical device management information system.

The Medicines and Medical Devices Agency has an important role in the continuous supervision of the functioning of the medical devices. According to the *Regulation on the surveillance system of medical devices*[15], the Agency records and assesses any information on incidents related to the malfunctioning or deterioration of a medical device, as well as any case that may lead to or lead to the death or severe deterioration of the health of a patient or user.

Also, the Regulation stipulates the obligation of the manufacturer or his authorized representative, the importer, the distributor, the medical staff, the patients, the medical-sanitary institutions or other users to report to the Agency on the mentioned incidents.

The information on the mentioned incidents is transmitted to the Agency by three methods:

1) online on the Agency's website with the completion of the necessary fields;
2) official letter to the Agency with the corresponding report in Annex 1 and / or Annex 2 of this completed Regulation;
3) through the Management Information System of Medical Equipment (hereinafter referred to as SIMDM) which provided the way of reporting the incidents involving the medical devices.

[15] Order of the Ministry of Health, Labor and Social Protection number 211 of 21.03.2018

In order to avoid the occurrence of incidents, there must be appointed a person within the medical-sanitary institutions who is responsible for the surveillance of the medical devices, who together with the technical personnel, the medical personnel and the users must take corrective actions.

We appreciate the efforts of the State in the development of the new concept of medical device verification, which is an important step for the health system of the Republic of Moldova, and the efficient implementation of the new provisions will help to increase the quality of medical services, by ensuring the high level of performance and safety parameters of medical devices.

Classification of hospitals and their financing

The health system can be characterized by the functions it performs: *supervision, provision of services, financing and insurance with resources* (workforce, knowledge, etc.). The source of funding is important in determining the role of the state in the health system and its development. In this regard, it is important that all revenues collected in the health system are accounted for and the public health sector realistically and strictly defines its financial capacity to provide medical services. Most of the medical services in Moldova are provided by the public sector.

With the implementation of the AOAM (Compulsory Health Insurance) system, most of the public expenditures for health care are administered by CNAM (National Health Insurance Company), an institution that manages the financial mechanism based on FAOAM (Mandatory Health Insurance Fund). CNAM is responsible for organizing, conducting and directing the AOAM process, the formation of the financial funds to cover the costs of treatment and prophylaxis of diseases and conditions included in the AOAM's Single Program. Also, CNAM is responsible for the quality control of the medical assistance granted and the implementation of the normative framework related to the medical insurance.

The totality of the financial means accumulates in the unique account of the CNAM, being subsequently distributed according to the legal norms to several funds. These are subsequently structured on programs and subprograms, having established certain performance indicators which monitoring is also the responsibility of the CNAM.

The year 2019 should be a crucial one for the health field, given the reforms that are announced - the reform of hospitals, the reform of primary health care and the continuation of the public health reform. However, the budget allocated to the health field is declining and will constitute in

2019 - 8.4% of the total state budget expenditures.[16] According to the Law of the state budget for the year 2019, allocations of over MDL 4 billion are foreseen in the field of health care. It is the lowest weight in at least the last two years - 9.8% (in 2017) and 9.6% (in 2018).

Healthcare	**07**	**4316216,3**
Medical products, machinery and equipment	071	44350,0
Outpatient services	072	39416,5
Hospital services	073	269341,4
Public health services	074	707375,2
Scientific research applied in the field of health protection	075	36393,4
Other health services not assigned to other groups	076	3219339,

Source: Annex number 4 of the Law on the state budget for the year 2019

In the Republic of Moldova, the health care system includes the following components: emergency medical care; primary health care; hospital medical care; public health centers; HR (human resources). In its turn, hospital medical care includes 71 public hospitals:

- 16 republican hospitals
- 10 departmental
- 10 municipal hospitals
- 35 district hospitals

Hospitals are an extremely important, sensitive and strategic element of the health system in any country. Within the health system, hospitals occupy a special place, being the sector with the highest consumption of resources. The mission of any hospital is to provide the specific medical services needed to solve the patients' health problems (**effectiveness**), in the best (**quality**) and economical (**efficiency**) way possible.

The health system in the Republic of Moldova is organized in accordance with the principles of universal access to basic medical services and equity, as well as solidarity in the financing of health care, being financed both by the state and individually by each person within the compulsory insurance of healthcare.

[16] http://sanatateinfo.md/News/Item/8163

Public medical-sanitary institutions (IMSP) at district and municipal level provide hospital medical care services for the administrative territorial unit, being founded by the local public authorities.

The tertiary level IMSP provides specialized and highly specialized healthcare for the entire population of the Republic of Moldova. Most of the tertiary institutions are located in Chisinau municipality, being founded by the Ministry of Health, Labor and Social Protection.

CHAPTER II
SITUATION OF MEDICAL DEVICES IN HOSPITAL INSTITUTIONS - DATA OBTAINED

Information was disseminated in the media sources on the assessment of medical devices and equipment, within the „Repemol" project, funded by the Swiss Agency for Development and Cooperation (SDC), but its results were not known to the general public, without publication.

For these reasons, the People's Advocate requested from the AMDM (Medicines and Medical Devices Agency) the mentioned assessment report, which also was not possible to obtain.

The information presented in this report will only contain the data accumulated by the PAO (People's Advocate Office) team during 2018. We also mention that some medical institutions refused to participate in the proposed assessment due to the lack of staff able to answer the questions in the grid (lack of bioengineering specialist), and the manager did not want to delegate this activity to another specialist. For these reasons, we will not present data from all institutions initially included in the study.

2.1. Endowment of Emergency Receiving Units

The role of Emergency Receiving Units (UPU) within a medical institution is paramount, they function as a first contact of the medical care where the patients are examined and treated / stabilized according to their health status. Thus, a large part of the medical cases is solved in the UPU and there is no need for the patient's hospitalization. This fact contributes both to a rapid recovery of the patient and to the correct management of the funds for hospitalization.

Patients can go to UPU independently or they are brought by ambulance. UPU specialists are trained to assess the condition of patients and to sort them according to the severity of the case in patients requiring immediate resuscitation, in patients with major emergencies, with minor emergencies.

The UPU monitoring carried out by the PAO team aimed to verify compliance with the Organization, Operation and Practice Standard within the Emergency Receiving Units, approved by the Order of the Ministry of Health number 424 on June 2, 2017[17]. Annex 7 of this order describes the mandatory conditions (premises, endowment, equipment, medicines) required to be provided by UPU.

[17] http://old.ms.gov.md/public/info/Ghid/standarte/functionaresipractica/

It is very important for UPU to be endowed with the devices / equipment needed to maintain vital parameters.

According to the information gathered during the monitoring visits, it was found that part of the emergency reception units, during 2014-2017, were opened with the support of the Moldovan-Swiss project REPEMOL – *Regionalization of Pediatric Emergency and Intensive Care Services in the Republic of Moldova,* being purchased medical equipment and devices both for the provision of emergency reception units and for resuscitation rooms. These are defibrillators, electrocardiography devices, mobile oxygen, laryngoscopes, etc. To create the units, the hospital managers had to identify space, equip the department with equipment, as well as recruit medical staff. Although the purpose of the project was to improve pediatric health care, the reforms, equipment and emergency training carried out within REPEMOL have contributed, including to the improvement of emergency services at hospital and pre-hospital level for children and adults. In total, were reorganized 12 emergency reception units and five pediatric intensive care units in the country and they received modern endowments. In addition, medical staff were trained in accordance with European standards.

Within this project, four emergency departments were set up: within the Balti Municipal Clinical Hospital, the Cahul District Hospital, the Institute of Mother and Child and the Municipal Hospital „Valentin Ignatenco".

For example, at the end of 2017 at the Institute of Neurology and Neurosurgery was inaugurated the Emergency Receipts Unit (UPU) section, which was renovated according to European standards and its emergency medical services were improved. The section was endowed with the most modern furniture and high-performance medical equipment, such as: portable artificial ventilation device with multiple ventilation regimes, cardiorespiratory monitors, emergency and intensive care stretcher, medical aspirator, bed for resuscitation, digital pulse oximeter, automatic hematology analyzer, etc. Thus, all the necessary conditions have been created to provide qualitative emergency medical services to patients with neurological and neurosurgical emergency. The renovation of the section was made possible by the investment project „Endowment of the Emergency Reception Unit with medical performance equipment", financed by the Embassy of the Czech Republic in the Republic of Moldova in the amount of – MDL 314 874.84 and of the Investment project financed from the fund for the development and modernization of public providers of medical services, CNAM (National Health Insurance Company) in the value of – MDL 1 800 000.00.

Based on the overall analysis of the situation on the provision of UPU units with the devices needed to provide emergency medical care, we observe that about one third of the hospital institutions report deficiency of some necessary equipment, compulsory according to the UPU endowment standard.

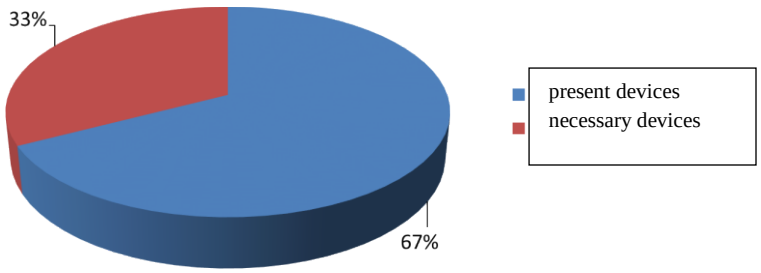

Figure 2.1 Endowment of Emergency Receiving Units
in accordance with the Order of the Ministry of Health 424 of June 02, 2017 (%)

According to the Standard - each UPU bed / patient level 3 and level 2 must be equipped with a ventilator for controlled / assisted ventilation and a high pressure oxygen delivery system for the operation of the fans and, if necessary, a compressed air system.

From the information presented by the institutions it appears that not all UPUs are properly equipped. In 5 out of 15 institutions there is a lack of an adequate medical gas insurance system, which is one third of the total number of institutions in which this system must be. This indicates a serious problem of ensuring the quality of the patient's medical act in an emergency situation.

Even if the presence of fans with controlled ventilation is found, in many institutions included in the study is determined a high degree of wear. The institutions informed us that these devices are not metrologically verified.

Of major importance in determining the condition of the patient in a medical emergency is the determination of blood gas, acid-base balance, electrolytes, hemoglobin, blood glucose, lactate, which influences medical decisions and tactics. To this end, all emergency reception units must be endowed with special devices for determining these parameters. All institutions note insufficient insurance with this device, the existing number being much smaller than the necessary.

For example, all Level 3 UPUs report the presence of only one blood gas measuring device, acid-base balance, electrolytes, hemoglobin, blood glucose, lactate. Three institutions indicated the lack of such a device, which raises doubts about the quality of the medical act granted to the patient in medical emergencies.

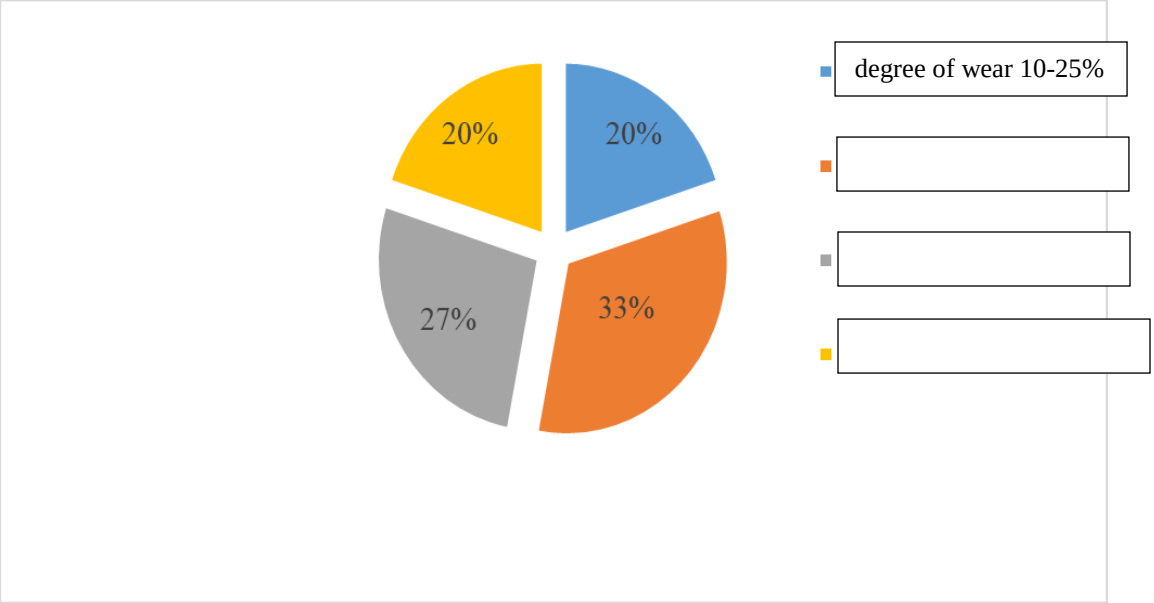

Figure 2.2. Degree of wear of the fan (ventilator) for controlled / assisted ventilation in level 3 and 2 UPU (%)

Some of the institutions also indicated some problems in providing oxygen cylinders with a pressure gauge. In 30% of the institutions included in the study there is insufficient endowment with such cylinders. At the same time, in about 72 percent of the institutions are noted cylinders with operating time of more than 50%.

According to the approved standard, must be provided the equipment for monitoring the vital parameters of the patient in critical condition from the considerations 1 / place - the red area and 1 to 2 places the yellow area.

In 30 percent of the institutions included in the assessment, insufficient staffing was found with such monitors, the number of existing ones is lower than the one provided in the standard. At the same time, we notice a high degree of wear -35% of the institutions have some monitors with a degree of wear 100%.

In order to ensure efficient medical interventions, the standard recommends that 2 infusomats per bed / patient be provided. Four institutions (27%) reported the lack of such devices in the UPU. At the same time, in about 1/3 of the institutions there is a wear of more than 85% of these devices.

In one institution, infusomats from 1987-1988 have been implemented. The institutions informed us that these devices are not metrologically verified.

Cardiac emergencies are very common cases with addressing to the UPU. For this reason, it is important to provide the necessary equipment, including the *defibrillator.*

In two of the institutions with UPU level 3, there is an insufficient number of defibrillators, and in 4 cases, even if the presence of these devices is reported, they reach 100% wear. The institutions informed us that these devices are not metrologically verified. Unfortunately, this situation indicates a high risk of possible harm to the patient and low quality of the medical care provided to the patient in cardiac emergency.

In 5 institutions it was found that the general anesthesia devices for rapid interventions have a degree of wear from 55 to 100%, and in 5 institutions an insufficient number of these devices was found. The institutions informed us that these devices are not metrologically verified.

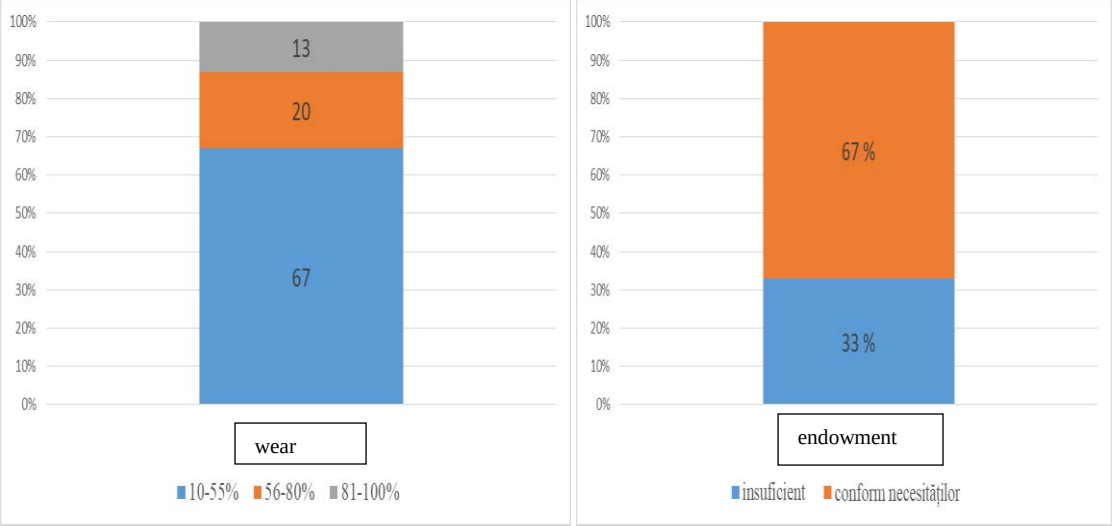

Figure 2.3. Endowment and the degree of wear of general anesthesia devices for rapid interventions in level 3 and 2 UPUs (%)

The UPU must be endowed with sufficient power sources for the activity of all connected devices. Moreover, it is important that these units are equipped with generators, which will be included automatically in case of disconnection of the electric current from the permanent source (accidents, power failure, etc.). Three institutions reported the lack of such equipment, and in other three institutions

its wear reaches 80 to 100%. It is regrettable and alarming the lack of the generator in a Level 3 UPU.

In many UPUs (47%) there is also a problem in providing sufficient vacuum cleaners. Even if they exist in all UPUs, the degree of they wear reported by medical institutions is alarming. In more than half of the UPUs verified (8 institutions) these devices have marked a degree of wear from 70 to 100%, are frequently encountered devices with the year of production 1987-1988. It is important to note that these devices are not metrologically verified.

UPUs must be equipped with devices for endoscopic emergency procedures, such as *laryngoscopes* and *bronchoscopes*. It is very alarming that six institutions reported the lack of both the bronchoscope and the laryngoscope, of which 3 institutions are of level 3, where the quality of the emergency medical act is expected to be at the highest level. It is also regrettable that many of the equipment present in other level 3 and 2 UPUs are also with a high degree of wear. Five institutions indicated a degree of wear from 60 to 80%. The institutions informed us that these devices are not metrologically verified.

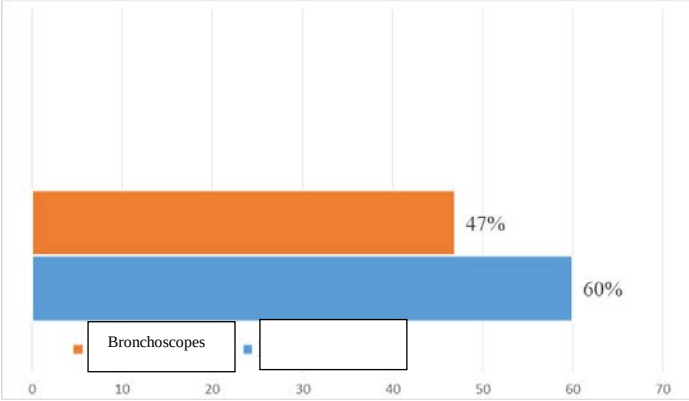

Figure 2.4. Level 3 and 2 UPUs insurance with laryngoscopes and bronchoscopes (%)

From the reports presented by the institutions were found certain problems with ensuring the urgent conduct of laboratory analyzes. Five institutions reported the total lack of such a device, and where it was present it was impossible to properly assess the wear. Because some institutions outsource this service it was not possible to determine its quality.

According to the standard, level 2 and 3 UPUs must have diagnostic equipment, such as Roentgen, USG, CT (Computed tomography).

In most cases these are common with other sections of the hospital, such as, for example, the consultative or imaging section. From these considerations we will describe the situation of these equipment in the compartment dedicated to these subdivisions of the hospital institutions in the following paragraphs.

2.2. Condition of the diagnostic equipment used in hospital institutions

- **Imaging equipment for diagnosis**

Functional diagnostics section in small hospitals requires ultraviolet and ultrasound equipment. X-ray equipment is foremost and essential, and ultrasound equipment can be added, depending on the financial resources available.

X-ray diagnostic equipment

The use of these equipment is based on the WHO recommendations „Basic Radiological System (BRS)" and „International Health Imaging System" (WHIS -RAD)[18].

The X-ray equipment can be mobile or stationary in a premise. Stationary equipment is very important. Most small hospitals do not require mobile equipment, but depending on the funds available, the institution can purchase the mobile unit to facilitate the necessary procedures, including for orthopedic procedures during an operation.

From the reports of the medical institutions included in our study, we observe that all institutions confirm the presence of Roentgen devices. However, in 6 institutions (40%) these devices have a very high degree of wear, reaching the values of 75-100%.

In the report of some hospitals we identified that the Roentgen devices have the year of production 1989, 1990 and 2002, that is with absolute wear. The figure below shows the status of all Roentgen devices reported by institutions at the time of assessment, noting that they are more per institution. Thus, out of the total number of reported devices (34 devices) 65% have a wear from 75 to 100%, indicating a risk of harm for patients and staff working with these devices.

[18] The World Health Imaging System for Radiography – the WHIS –RAD. Technical specifications. WHO, 1995. Available on: http://apps.who.int/iris/bitstream/handle/10665/60643/WHO_RAD_TS_95.1.pdf?sequence=1&isAllowed=y

At the same time, for some institutions it was difficult to correctly determine the degree of wear, because, even if the appliance is purchased relatively recently, its operation is very frequent, this being the only appliance available. In this case, the wear of the device doubles.

Even though institutions report that these devices are checked metrologically every year, it is frequently mentioned the importance of replacing them with similar devices.

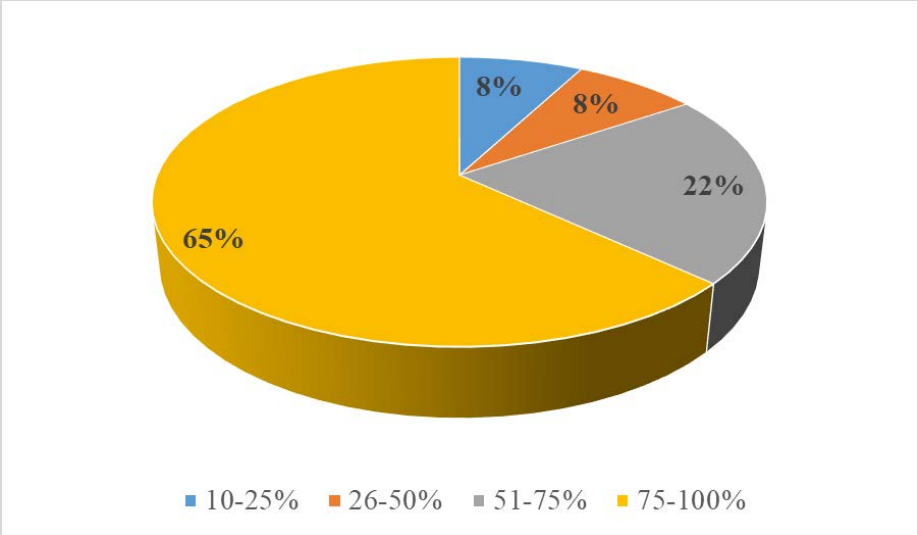

Figure 2.5. Wear of Roentgen devices in medical institutions (%)

It is important to mention a case found in a municipal institution included in the study, where a Roentgen apparatus is received through humanitarian aid from a partner from abroad. The device is on the balance of the institution, but it is defective and needs spare parts, which are not on the market of the Republic of Moldova. The institution's administration has identified a possible agency that could repair this device, but the price for replacing the required part is too high, which causes the institution to refuse this repair. Respectively, the entire workload of the patient investigation is transferred to the existing devices, even if they already have a high degree of wear.

Computed Tomography Devices

Only 33% of the medical institutions were able to confirm the presence of the computed tomograph, although this device is very important in establishing a precise and rapid diagnosis, which subsequently influences the correctness of the prescribed treatment, the quality of the medical record and the patient's safety, respectively.

In the absence thereof, the institution must present a contract for outsourcing services. Most institutions have such contracts signed, including for situations when their own tomograph may fail.

Ultrasonography equipment

Several varieties of ultrasonography equipment with different capacities are available. The minimum specifications for the general use of the ultrasound unit is provided by WHO in a technical report of a scientific group[19]. This minimum of specifications must be met or even exceeded, especially the technical requirements for resolution, as poor quality images generate inaccuracies in diagnosis. WHO publication[20] contains information on ultrasound unit testing at the time of delivery, continuous quality assurance and essential maintenance.

Three of the institutions included in the study reported that they do not have a functional ultrasonography device at the moment. However, in some institutions where these devices are present (32 devices have been reported) a high degree of wear is determined. USG devices with 60% to 100% wear are reported in 60% of institutions. *For example*, there are devices with the production year 2001 and 2003, which calls into question the quality and accuracy of the diagnostic procedure. In a level 3 institution, out of 7 USG devices currently available 5 have the 2003-2006 production year and 2 devices are produced in 2009-2011.

Respectively, the degree of wear of all exceeds the limit for operation, inducing a wear that varies between 50 and 100%. At the same time, as we have noticed in other cases, the degree of wear of these devices is inaccurate, because in some institutions, where there are not enough USG devices, the exploitation of the existing devices is excessive, which conditions the faster process of wear of these devices.

[19] Future Use of new imaging technologies in developing countries Report of a WHO Scientific Group Technical Report Series, 723. World Health Organization, Geneva, 1984. Available on: http://apps.who.int/iris/handle/10665/40297

[20] Manual of Diagnostic Ultrasound. Vol.1, 2nd edition, ed. by Lutz, H. BuscariniEl.WHO, 2011.
Available on: http://apps.who.int/iris/bitstream/handle/10665/43881/9789241547451_eng.pdf?sequence=1

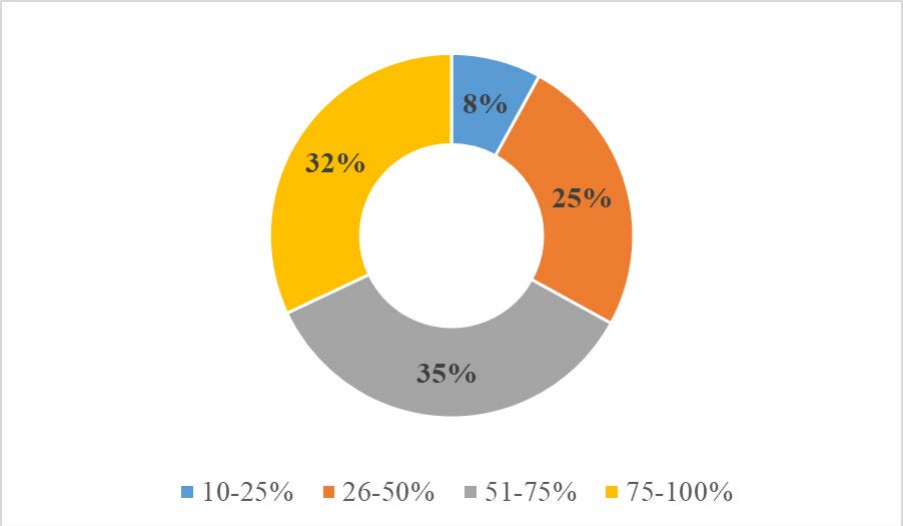

Figure 2.6. Wear of USG devices in medical institutions (%)

- **Basic electro-medical equipment**

Electrocardiograph

The institutions included in the study indicated a great diversity of types of electrocardiographs, these being with 3, 6 or 12 channels. Of the total number of ECG devices reported (52 devices) there is a large number of those with excessive wear. Over 65% of ECG devices have a wear degree over 70%. ECG devices with 1990 and 1991 production years were identified, indicating the technical and moral overcoming of these devices.

Portable electrocardiograph (is a single channel electrograph unit with a paper device)

About 25 percent of the institutions included in the study reported the absence of such a device, although this is very important in the case of medical emergencies in non-transportable patients.

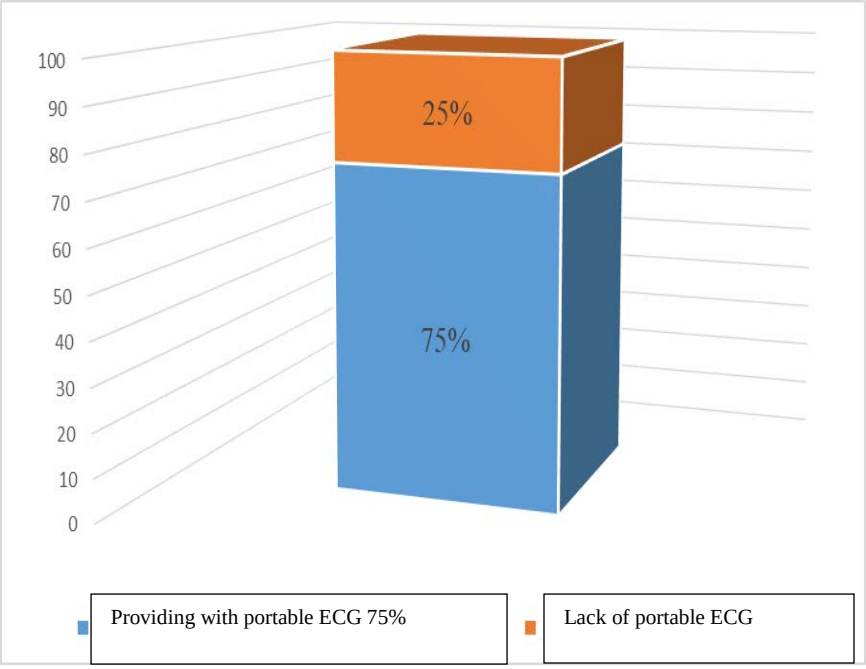

Figure 2.7. Situation with ECG devices in medical institutions (%)

- **Endoscopic diagnostic equipment**

The institutions included in the study also provided answers on the endoscopic equipment used in the diagnostic sections - bronchoscopes and laryngoscopes with video camera. Only 7 republican level and municipal level institutions reported the presence of these devices in the diagnostic units. However, we have been confirmed that these devices are not metrologically verified, and their degree of wear is difficult to assess due to the frequency of use of this equipment.

2.3. Medical devices used in the Resuscitation and Intensive Care sections and for the treatment (surgical sections)

Intensive care (IC) includes: diagnosis, prevention and treatment in the short, medium or long term of all acute deficiencies of vital functions. Specific treatment measures are recommended for patients whose life is threatened immediately, but whose prognosis is potentially favorable. The intensive care unit is currently considered the „hospital's hospital", with a well

standardized managerial and professional profile. The Intensive Care sections of the hospitals operate in specially designed spaces that allow efficient isolation of the compartment with beds from the rest of the circuits (including by the UPU, the operating unit, the transfusion point or the central sterilization station), but with the easy access to the UPU, operating unit, imaging service, being separate from the access reserved for visitors. If the Intensive Care section is located upstairs, it must have a lift for beds. It is recommended that the access provided for beds (stretches), staff and materials be distinct from the access reserved for visitors. The route between Intensive Care and other structures related to the operation of the department is recommended to be as short as possible to allow the rapid transfer of patients.

In case the sanitary unit with beds is multi-pavilion, and the surgical sections operate in different pavilions or one of the surgical profiles operates in a building different from the building in which the Intensive Care section is organized, Intensive Care compartments can be organized in the building where the respective surgical profile section / sections are operating.

Patients cared for in Intensive Care require specialized care and prolonged use of methods of filling these functions and organs, such as hemodynamic support, ventilator support, extra-renal clearance, etc. These patients require, including prolonged use of the methods of supervision and substitution of these organ functions.

Intensive Care sections are classified according to the complexity of the activity in 3 categories[21].

1. **Category I Intensive Care sections** (baseline competence) - re the sections capable of performing the initial stabilization of critically ill patients with limited possibilities of providing long-term intensive care.
2. **Category II Intensive Care sections** (medium competence) - are the sections capable of providing high specialized care for a large category of patients, but do not have resources for certain categories of patients (cardiothoracic surgery, transplantology, neurosurgery, polytrauma, major liver surgery), but may have prior transfer protocols for patients with specific problems.
3. **Category III Intensive Care sections** (extended competence) – are the sections that provide specific medical services for a special category of situations that require intensive therapy (cardiac surgery, major neurosurgery, organ transplant, polytrauma, major liver surgery), permanently have

[21] Order of the Ministry of Health number 27 of 13.01.2017 „For the approval of the Standard of organization, functioning and practice within the Intensive Care Sections (ICS)";
Available on http://old.ms.md/_files/15333-Standard%2520Management%2520ATI.pdf

teams of doctors and super-specialized assistants (nurses), and special support services with continuous activity to ensure the necessary level of care for complex critical cases.
The inclusion of the existing Intensive Care sections in one of the three categories is based on the assessment respecting the competence dictated by hospitals and the legal provisions on the organization of emergency medical assistance.

Each of these sections must have structural features (number of beds, technical equipment) corresponding to the activity carried out.
According to international and national standards, a range of requirements are determined for the devices used in these sections, namely:

DC defibrillator (external)

This instrument must have a synchronizer of up to 400 J, with the capacity indicated by the footage, analog or digital. An electrograph monitor is required to use a synchronizer, if not built into it. Although portable units containing a monitor and defibrillator are practically available to most manufacturers. A rechargeable battery source must also be available for internal options. Battery defibrillators must contain the option of the compensation load. Battery replacement needs to be promptly performed, as batteries usually have limited longevity. Pediatric paddles also need to be available.

In the assessment carried out most institutions reported that they are sufficiently equipped with defibrillators in the Intensive Care R (RTI) sections and surgical blocks. However, we were informed that these devices are not metrologically verified, although some have an operating period of 25-30 years and raise doubts about the efficiency and quality of the medical act granted with their help.

General anesthesia unit

General anesthesia devices present a pressing problem for many of the medical institutions included in the study.

For example, a municipal level hospital informed us that they had on balance 25 anesthesia devices, produced between 1985-2012. These are not metrologically verified. The manager mentions that he or she knows that such devices must be changed they have an

operating period of more than 10 years, but he or she cannot afford this purchase due to financial restrictions.

Medical gas insurance system

The medical gas insurance system must contain a high voltage alarm for operating and electrical problems and must be portable, if possible. Many institutions report that these systems are of high wear (installation year 1989, 2009). Some parts of these systems are not metrologically checked (e.g. compressors and generator), only the manometer is checked annually.

A similar problem is also identified in the provision of artificial respiration devices (life support). Many institutions (72%) declared to us the presence of technically and morally outdated appliances, with an operating term of up to 25 years. These devices are not metrologically verified.

The same municipal hospital mentions that out of 16 devices present in the RTI (Intensive care R) section and the operating block, only 4 devices are lucrative, being purchased in the last years, if the respective institution requires 11 units of such equipment.

Absorption pump

According to the Standards mentioned above, two absorption pumps are required: one portable and the other stationary.

The institutions included in the study have reported to us, for the most part, the presence of such pumps, but with a high degree of wear. About 52% of the institutions indicated that they have pumps in the sections with a degree of wear of over 80%. At the same time, they mentioned that at national level there is no possibility of metrological control of these devices.

Coagulation measuring device (diathermy)

A standard coagulation device must be obtained, hand-operated or with a foot switch, with variable electricity control. Only a few (5 institutions) at the republican and municipal level, included in the study, were able to confirm the presence of such a device. These devices are not subject to metrological control.

Monitors for monitoring vital parameters - 1 device per bed / patient

Most institutions (80%) reported to us an insufficient number of such monitors, which does not cover the number of RTI (Intensive care R) beds in the institution. Some institutions report coverage of 50 or even 45%, which means that practically every second bed with a serious patient, which requires monitoring, is not equipped with such a system. This fact is very alarming, with reference to the possibility of ensuring the quality of the medical act within the institutions. A large number of institutions (63%) indicate that although the number of monitors seems to be sufficient, they have a high degree of wear and do not meet the needs of a qualitative medical act.

For example, in the figure below we present the situation regarding the monitors for the monitoring of the patient from a republican hospital institution (level 3) – Institute of Mother and Child, where there are 64 such devices, spread over different sections within Intensive Care. It should be mentioned that out of the 2 existing monitors for premature, one has the degree of wear 100%, and the other - over 88%.

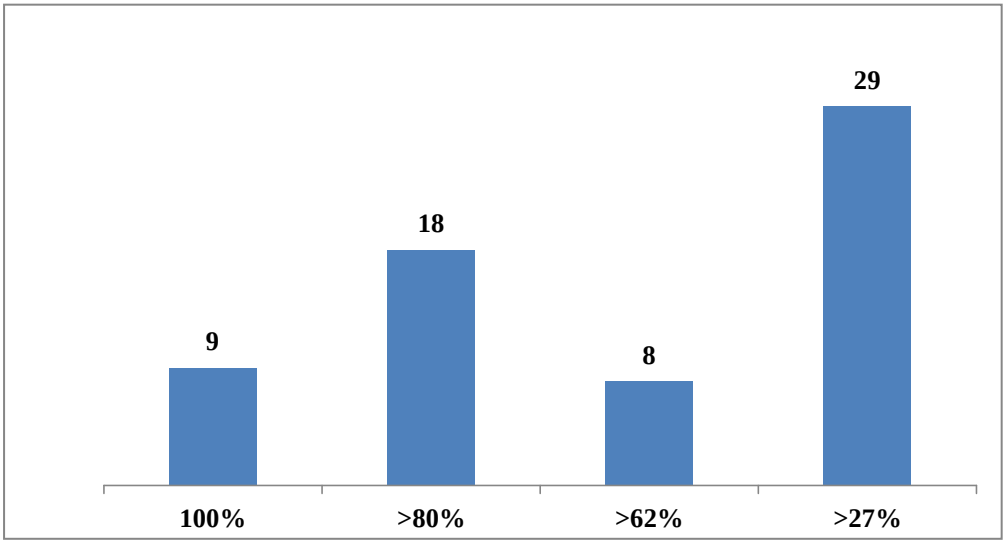

Figure 2.8. Situation on the wearing of the monitors for the monitoring of the patient from a republican hospital institution of the study (level 3), %

The institutions reported that the patient monitoring monitors are not metrologically verified, although some managers mentioned that they would like this to be possible because they have doubts about the quality of the activity of some devices they have in the institution. At the same time, they mentioned that they do not have information where this verification could be done in our country.

Endoscopic treatment equipment

Some republican and municipal level institutions have confirmed the presence of the laparoscope, but they indicate a high degree of wear - from 65 to 100%. Insufficient provision was also made with other endoscopic devices, among which the most common is the fibrogastroscope (46%). Difficulties with repairing these devices are reported in many of the institutions included in the study. According to the managers of medical institutions, the repair of these devices seems to be a problem, the cause being the lack of spare parts, the problem of procurement, etc.

Thus, overall, doing a general analysis of the situation regarding the provision of RTI (Intensive care R) sections with the necessary equipment, according to the standards, we can find that about 28% of the required devices, according to the approved standard, are missing.

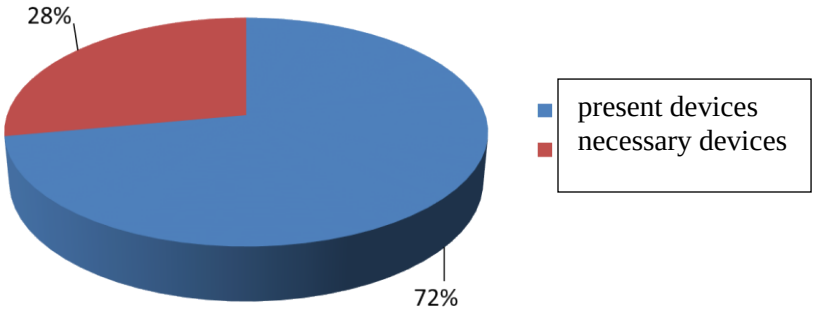

Figure 2.9. Assessment of the conformity of the endowment of the RTI (Intensive care R) section in the institutions with level III UPU according to the „Standardized Clinical Protocol of organization, functioning and practice within the RTI (Intensive care R) sections"

In conclusion, we can say with certainty that the level of quality assurance and safety of the medical act applied with the help of medical devices within the hospital institutions included in the study is far from meeting the national and international standards, as well as the expectations of the beneficiaries. The high degree of wear identified on many types of devices, the lack of the possibilities of metrological verification of many of the equipment in operation, as well as the insufficient coverage with the devices required for the medical act indicate an increased risk of violation of the patient's rights and the possibility of harm to the life and health of the beneficiary of such services.

CHAPTER III

OPINION OF THE MANAGERS ON THE MANAGEMENT OF THE MEDICAL DEVICES IN THE HOSPITAL INSTITUTIONS

Medical devices contribute directly to the quality of medical care, as long as they are functional, subject to metrological control and used by trained medical staff. Only a good management of medical devices can ensure their functionality in a system that must be prepared to respond to any case to 100% capacity, 24 hours a day.

Managers of medical institutions have a major responsibility to ensure the provision of quality services within the institutions that they manage. In order to ensure an adequate activity of the equipment of a medical institution, a manager must plan, organize, lead and control this area.

3.1 Staff training

Out of the total number of questionnaires addressed to the managers of the medical institutions, 21 opinions of the managers were completed and analyzed.

Being asked if they encounter difficulties in organizing the process of managing the medical devices in the institutions that they manage, 71% of managers appreciated this process as a difficult one, and 29% considered that they had no difficulties. In the following we will describe the causes that can make this component of the management of a medical institution in our country difficult.

Maintaining permanently trained staff in the field of proper operation of medical equipment should be a priority for a medical institution manager. Thus, the manager must have effective institutional tools that must keep the volume and quality of the knowledge of the staff working with the medical devices under control. Their renewal and improvement must be included in an annual plan of the institution.

In the questionnaires applied to the managers of the hospital institutions in the country (republican, municipal and district level), the ***question was asked regarding the need perceived by the managers on the training regarding the criticality of the medical devices.***

Most respondents confirmed that they feel the need for information / training regarding the criticality of medical devices (90%).

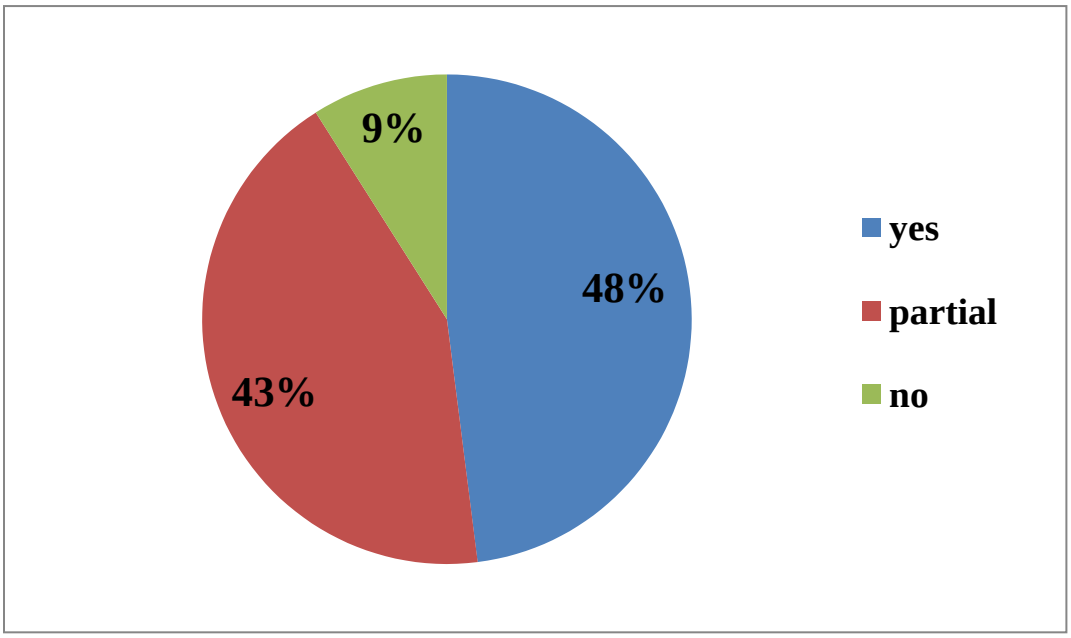

Figure 3.1. Perception of the need for information / training in the field of equipment management, %.

The managers believe that the training and improvement of the knowledge of the bioengineers will have a major impact on the health system of the Republic of Moldova and on increasing the quality of the medical act, so that the citizens can benefit from the most qualitative medical services.

The managers included in the study were asked ***whether they have qualified staff in the institution to systematically check and determine the criticality of the medical equipment***.

From the answers analyzed we observe that in the medical institutions there is still a large deficit of specialists in the field of medical devices. 57% of the respondents mentioned that they fully cover this segment with qualified staff, about 9% indicated that they are only partially insured with such staff. Accordingly, there are still many institutions (33%) that lack the qualified specialists.

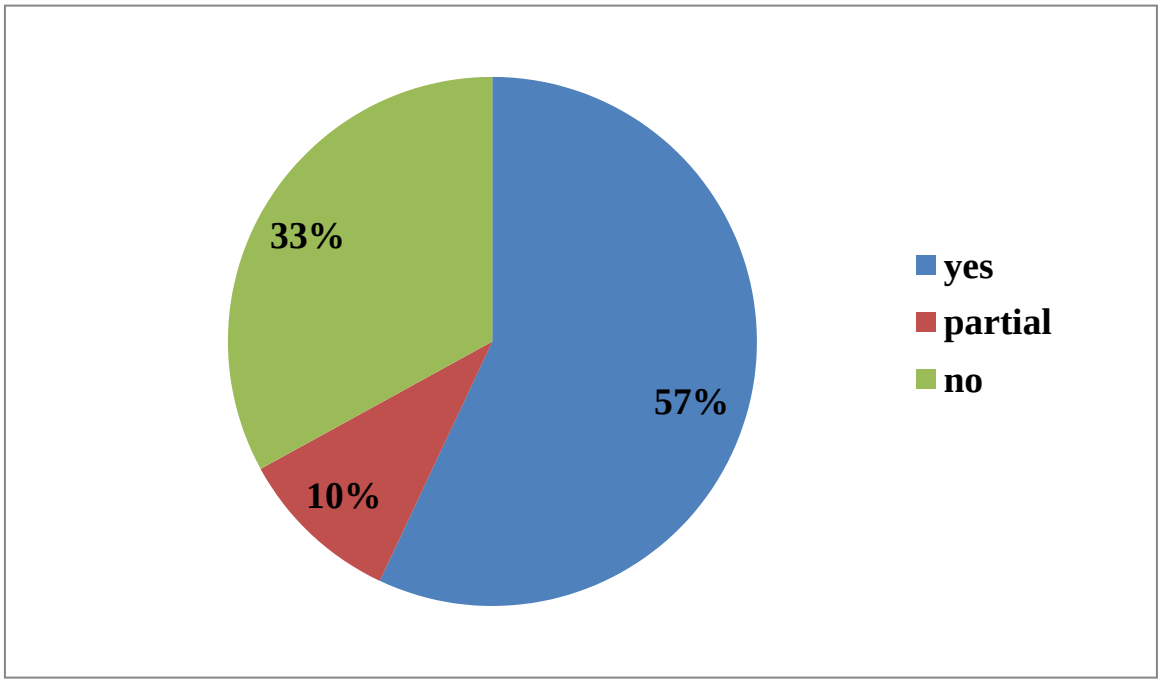

Figure 3.2. Providing institutions with employed staff to verify the criticality of medical devices, %.

The lack of such specialists calls into question the quality and professional level of the maintenance of the medical devices at the moment in the medical institutions. The function of monitoring the state of medical equipment is assumed by people who do not have specific training in this field.

In some institutions it has been reported to us that the staff currently responsible for the technical aspects of the medical equipment does not have a specific training in the field.

For this reason, we asked ***the question regarding the adequate training of the staff for the systematic monitoring, assessment and verification of the medical devices***.

Respectively, we identified that at the time of the monitoring, 43% of the responding institutions have specialists with respective vocational training, 24% have partial training (tangential, for example, engineering studies) and 33% do not have the necessary training.

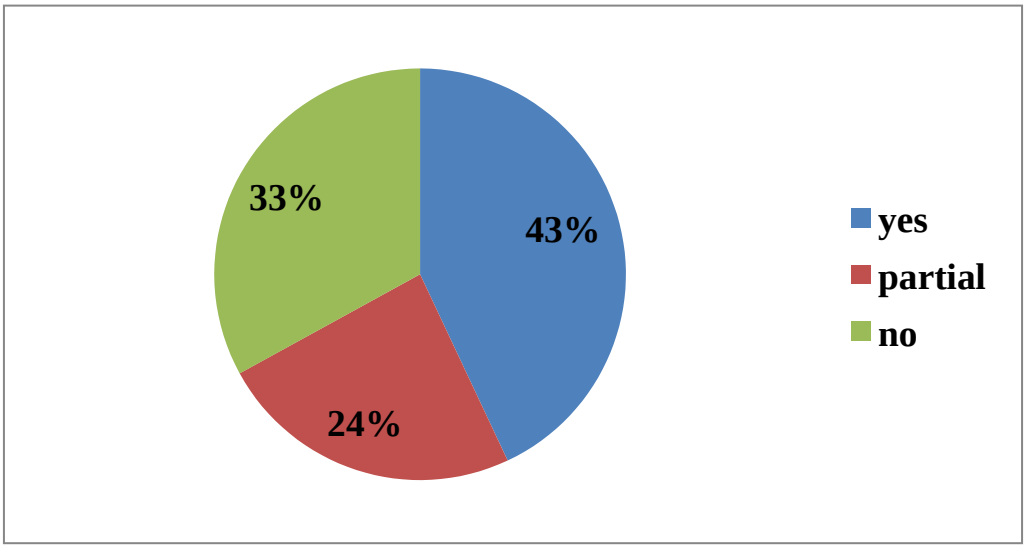

Figure 3.3. Providing institutions with adequate trained staff to be able to monitor, assess and periodically check the medical devices, %

3.2 Procedures for quality management of medical devices

According to WHO estimates, most countries look at Medical Device Management (MDM) as an integral part of public health policy. For these reasons, WHO recommends a national policy on MDM, which is essential to exist and include the provision of medical devices, ensuring the maintenance, verification and correct use of medical technologies, training of specialists in the field and creating a system of their continuous training, etc.

As we mentioned above, through the REPEMOL and PERINAT projects were analyzed all the existing procedures related to the management of the medical devices at the hospital level, was defined the necessary set of procedures and was developed the model of the procedures for managing and administering the medical devices. These two important projects were initially implemented in five pilot medical institutions. The results of the MDM assessment at the medical institution level have shown the positive impact in the efficient use of the medical devices, the reduction of the costs of maintaining the medical devices, through adequate internal services in a timely manner, the increase of the cost - efficiency and safety of the medical act. Subsequently, 5 Departments of biomedical engineering were established in public medical-sanitary institutions: Institute of Urgent Medicine, Institute of Mother and Child, Republican Clinical Hospital, the Oncological institute and the Municipal Clinical Hospital „Sf. Treime”.

However, from the results of the survey conducted, we observe that in many hospital medical institutions are identified issues related to the procedures of management of medical devices. Thus, ***being asked if they have a method of analyzing the criticality of the medical devices in the institution that they manage*** only 15% of the surveyed persons confirmed its presence, 25% replied that this method exists partially, and 60% of the managers denied its presence.

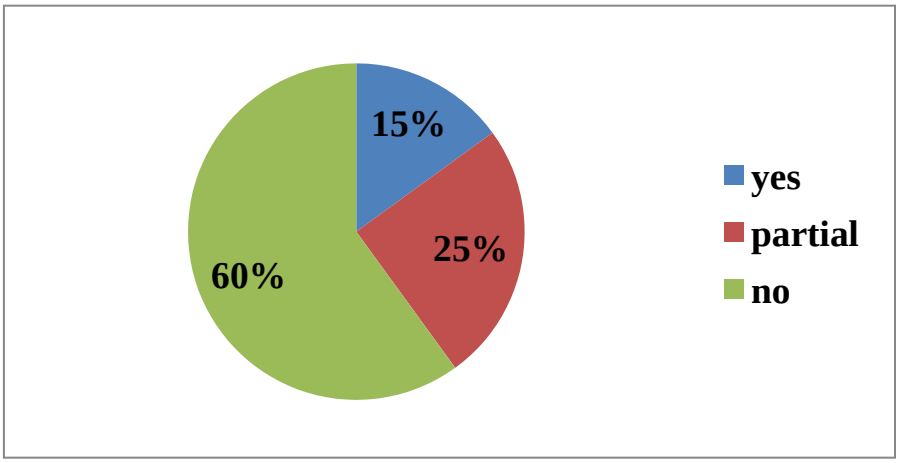

Figure 3.4. Presence of the method of analyzing the criticality of the devices, %

At the question regarding the presence in the institution of a concrete procedure related to preventive maintenance, the correction and quality control of medical devices 65% of the respondents confirmed the presence of such a procedure.

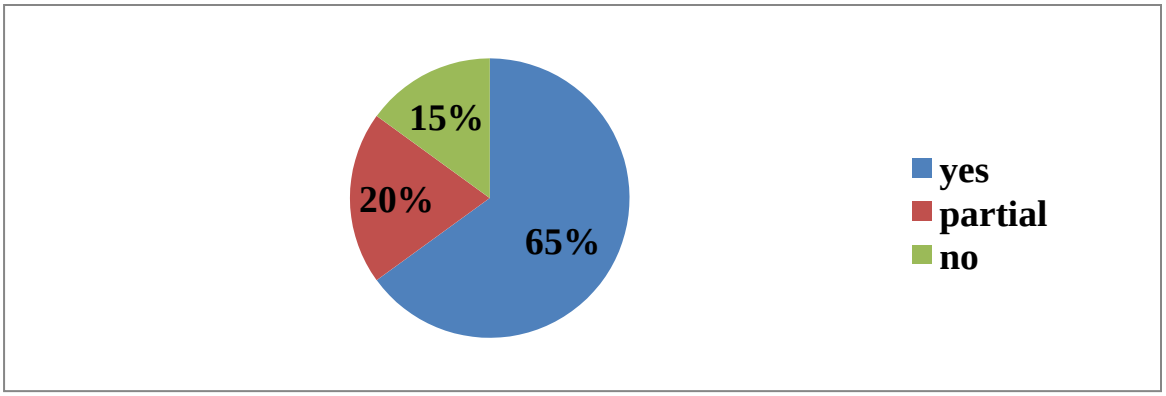

Figure 3.5. The presence in the institution of a procedure related to preventive maintenance, correction and quality control of medical devices, %

For a rational planning, the manager must know, first of all, the real situation of the institution and the identified needs.

In this context, questions were asked regarding the existence of the list of medical devices considered critical, as well as whether they feel the need to develop such a list or its impact on the quality of the healthcare provided.

62 percent of managers confirmed that they had developed a list of medical devices considered critical in the institution, at the same time 55% of those interviewed confirmed that they feel the need for such a list.

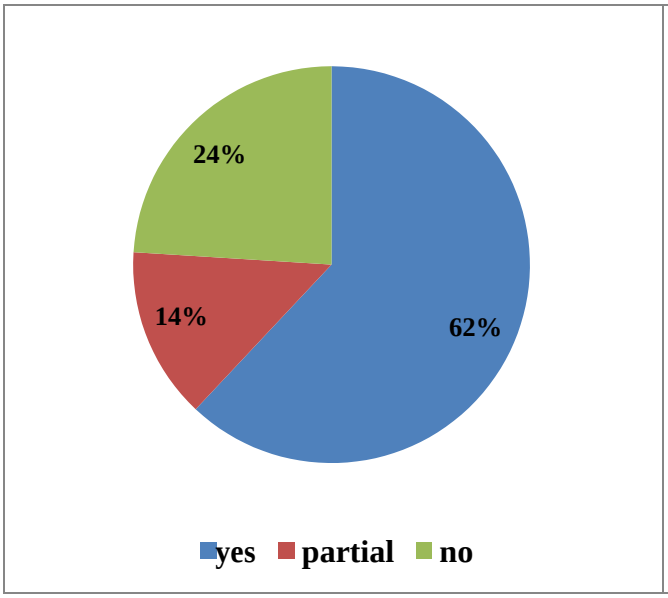

Figure 3.6
Existence of the list of medical devices considered critical

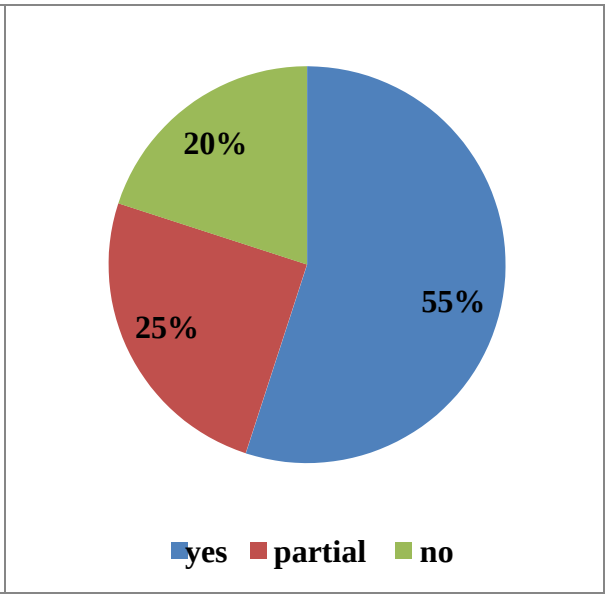

Figure 3.7
Necessity / impact of the development of the list of medical devices considered critical

The data indicate us about some problems - insufficient capacities of the managers to critically and objectively assess the real situation regarding the medical devices in the institution, but also to monitor the status of the devices involved in the medical act.

✓ Resource planning for checking and repairing the medical devices

Maintenance, operation and replacement of medical devices requires rational resource planning and adequate funding.

The next logical question asked to managers referred to ***the planning of sufficient resources for checking and repairing the medical devices.*** Thus, only 43% of the managers confirmed

the planning of the resources for this purpose, 33% partially plan, and 24% do not have a resource planning for this purpose.

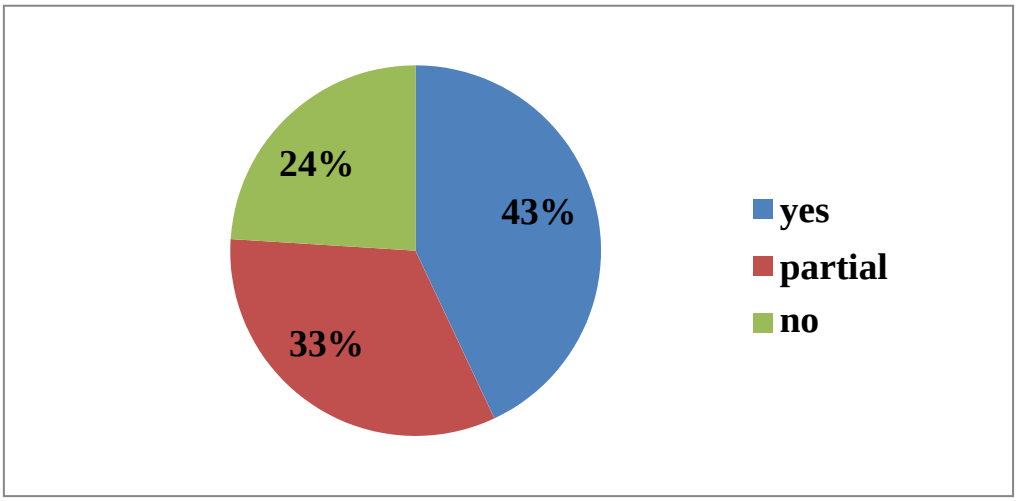

Figure 3.8. The degree of resource planning for checking and repairing the medical devices, %

✓ **Risk management for medical devices**

Risk management is a major component of the quality management of hospital institutions. The risk management standard for medical devices ISO 14971 2007 provides for the development of a process to manage and control the risks associated with the medical devices of the institution.

For this, it is recommended that responsibilities be assigned for risk management, and that staff who are involved with risk management be trained. In addition, it is necessary to define a policy that governs and controls how risk acceptance criteria are set; then to use these policies to establish acceptable risk criteria for each medical device. Finally, it is necessary to develop a risk management plan and keep a risk management file for each medical device separately.

When asked the question regarding ***the risk management procedure for the medical devices considered critical***, it is noted that 57% of the managers developed a risk management procedure for the medical devices in their institution (mapping, risk mapping), and 33% mentioned that they did not institute such a procedure.

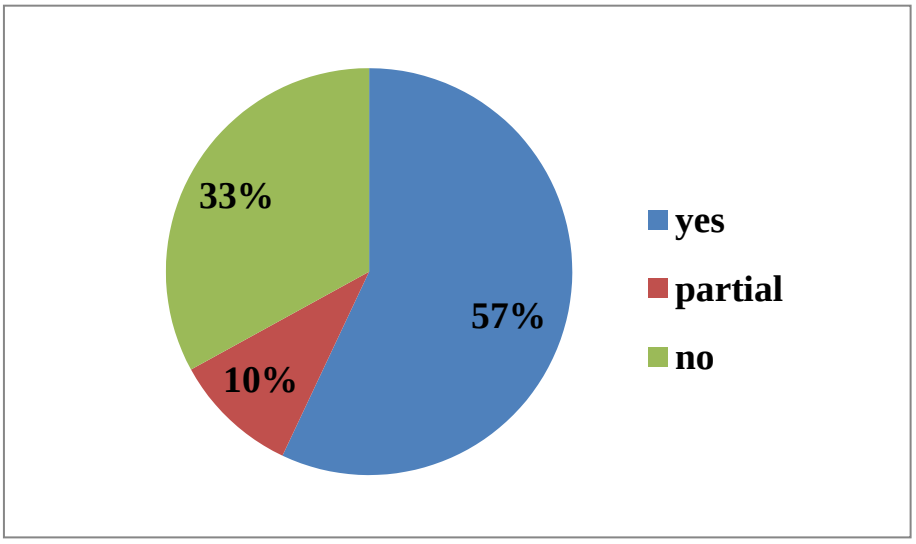

Figure 3.9. Existence of the risk management procedure, %

Regarding the ***existence of the plan for the replacement of critical medical devices***, the data indicate that out of the 21 institutions that completed the questionnaire, in 29% of the medical institutions there is no plan for replacing the critical medical devices.

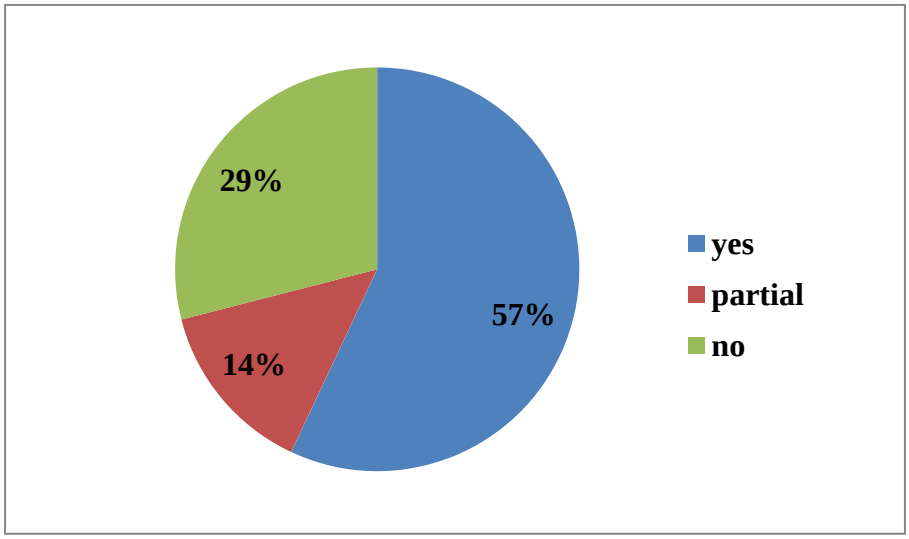

Figure 3.10. Existence of the plan for the replacement of critical medical devices, %

OTHER ISSUES IDENTIFIED

During the monitoring visits carried out by the PAO (People's Advocate Office) team in the hospital institutions, other problematic aspects were identified, which are related to the subject addressed in this report.

FINDINGS IN SOME DISTRICT LEVEL HOSPITAL INSTITUTIONS

- ***lack of medical gas insurance system (in the process of installation), the use of 10 oxygen cylinders at the time of the visit;***
- ***the only artificial respiration device was in repair at the time of the visit;***
- ***lack of artificial device in the UPU, the patient is transported to the Intensive care section***
- ***the only USG existing in the diagnostic section was used for the patients in the hospital;***
- ***lack of generator or alternative sources (for the resuscitation section and the operating room the electricity source from Moldcell is used;***
- ***lack of generator in the UPU, connection to alternative energy source (reused generator providing only 30 KW) is done manually by the electrician for 20-30 min;***
- ***lack of endoscopic device, as well as of the respective specialists;***
- ***the complete lack of infusomats or these were at an end;***
- ***Roentgen apparatus with the year of production 1954, which was to be tested (in 2018).***

FINDINGS IN SOME MUNICIPAL LEVEL HOSPITAL INSTITUTIONS

- ***endowment of the institution with only 40% of the necessary medical equipment;***
- ***lack of bioengineers;***
- ***the repair of medical devices is carried out only during the warranty period, no financial resources are available for repairs after the expiry of the warranty period;***
- ***the existence of a single specialist in imaging, which serves the patients in the Intensive care department and the consultative section (the right to respect for the patient's time);***

- ***the medical staff, the nurses also provide tasks of stretcher-bearers;***
- ***lack of bronchoscope, of USG with Doppler, the patients being served in another hospital under an inter-hospital contract;***
- ***the premises of the Intensive care section in a deplorable state, non-washable walls, used furniture to store medicines, including household-type refrigerators, ventilation is missing, flies were flying;***
- ***of the need for 60 infusomats they had only 10;***
- ***3 breathing apparatus were in repair for about 6 months;***
- ***Chinese production medical equipment of low quality.***

FINDINGS IN SOME REPUBLICAN LEVEL HOSPITAL INSTITUTIONS

Oncological Institute *- the only curative-prophylactic and scientific institution in the organization of the detection and treatment of oncological diseases in the Republic of Moldova*

- ***lack of tomography for nuclear investigations in the only institution of oncological profile in the country;***
- ***lack of an MRI;***
- ***the combination for laryngoscopy, bronchoscopy, colonoscopy, gastroscopy, the only one in the country, did not work for 3 months at the time of the visit (June 2018). For a patient with suspected larynx cancer late diagnosis may have irreversible consequences.***
- ***2 laryngoscopy devices were urgently needed, based on the daily flow of patients;***
- ***in the Intensive Care section of the required 63 infusomats they had only 10-11;***
- ***the purchase of spare parts for medical equipment takes a long time due to the difficult public procurement procedure;***
- ***about MDL 1 500 000 is spent on spare parts / repairs, because it is not possible to buy new equipment.***
- ***the Resuscitation and Intensive Care sections were in a deplorable state, the linoleum on the floor was broken, the walls were non-washable, the lack of centralized ventilation system (in summer it is difficult to deal with the situation).***

Republican Clinical Hospital

- ***RTI (Intensive care R) department in new block according to standards, centralized video monitoring;***
- ***although the RTI Department is located in a new block, the small elevators (lifts) create discomforts for the transport of patients, assisted by the device for artificial ventilation, for carrying out investigations in other sections;***
- ***a mobile cardio-vascular monitor is required;***
- ***lack of a USG in the RTI Department;***
- ***lack of extracorporeal treatment device (dialysis);***
- ***few injectomats;***

- ***lack of separators between beds, to ensure the privacy of the patient;***
- ***more oxygen devices required;***
- ***lack of a laboratory in the RTI Department;***
- ***a large centrifuge is needed in the UPU laboratory to cope with the flow of patients, a binocular and chairs for workers are needed;***
- ***the reagents are stored in the domestic refrigerator;***
- ***the 2 intensive care rooms in the UPU are not equipped with the necessary to provide first aid.***

Institute of Neurology and Neurosurgery *- specialized medical institution providing outpatient and hospital care to patients with diseases of the nervous system, including neurological rehabilitation services.*

- ***lack of an MRI (patients are transported to another hospital);***
- ***the need for an acid-basic device;***
- ***the Intensive care section does not correspond to the standards of equipment (both the infrastructure and the necessary medical equipment);***
- ***Intensive care STROKE section is overcrowded (in a room of 4 patients there are 6)***
- ***the surgery department was in a deplorable state;***
- ***unique laboratory per institution.***

SUGGESTIONS / PROBLEMS EXPOSED BY MEDICAL STAFF

- ***insufficient medical staff, stretcher-bearers;***
- ***the cumbersome procedure for purchasing medical devices;***
- ***establishing the technical requirements / needs for the purchase of medical devices is the burden of the doctors / manager, who do not have sufficient training in this field (e.g. the imaging physician has knowledge only in the clinical, not the technical field, and a disorder of the medical device may lead to the establishment of a wrong diagnosis);***
- ***high-performance devices purchased, rarely used in hospitals, either because of the lack of trained medical staff to work with them, or because of maintenance or expensive supplies;***
- ***the purchase of spare parts for medical equipment is carried out through the procedure of public tenders, which stagnates the activity of one or another section (e.g. endoscopy);***
- ***in the impossibility of purchasing the new equipment, large amounts are spent on spare parts / repairs;***
- ***the identical endowment of the UPU with medical equipment (all medical equipment must be of the same model, so that each doctor who activates in the UPU will know how it works;***
- ***the training of bioengineers in the country does not correspond to the requirements of the current performing medical devices, which imposes additional expenses for the medical institution, to ensure the training abroad of the specialist - bioengineer;***
- ***ensuring the presence of the specialist bio-engineer 24/24 hours in the institution.***
- ***the economic agents that import medical devices into the country do not have a technical service center to which the medical institutions can call;***
- ***review of transfers made by CNAM (CNAM transfers money per investigation according to prices / expenses established many years ago);***
- ***bioengineers are often required to purchase inexpensive spare parts from their own resources in order to avoid the long-term procurement procedure.;***
- ***endowment with special clothing of the medical staff (at the moment it is carried out on its own account), with the necessary furniture.***

CLOSING

The protection and realization of the right to health protection must be a primary goal of the state. Despite the economic situation, the state must identify and allocate all the financial and technical-material means necessary to ensure the health of the population. Only under these conditions will there be premises for the formation of a strong, healthy society, capable of development and progress.

An essential component in the process of ensuring the well-being of the population is the medical assistance, which must be a qualitative, accessible and high-performance one, and the assurance of an adequate level of the medical act is conditioned by the use of medical devices and modern technologies. Performing medical devices represent the indispensable part of the medical act in the process of prevention, correct diagnosis and treatment of diseases. Their efficient use involves, as a priority, increase in the number of investigations and cost-effective and qualitative treatment.

The degree of endowment of the medical-sanitary institutions with performing medical devices and ensuring an adequate level of professionalism of the medical professionals are the key tools in ensuring the good functioning of the health system and has a direct impact on the functional efficiency of the system, on the quality of the service and the degree to meet the needs of the beneficiary.

It is also argued the need for procedures of permanent compulsory registration and maintenance of the medical devices in the hospital institutions in order to ensure and maintain the safety of the medical act, to increase the satisfaction of the patients and to improve the quality of the medical services provided.

The limited financial resources on the one hand and the increased demands made by professionals in the field for the use of high-performance medical devices, as well as of the population to have access to quality services, on the other hand, make the existing needs only partially covered. The share of expenditures of the national public health budget is constantly increasing, while the cost of medical devices is increasing, while the requirements and possibilities for assessing their quality and safety are practically missing.

CONCLUSIONS

1. The health system does not have sufficient institutional and functional capacities for the full implementation of the Law on medical devices number 102 of 09.06.2017. The provisions of the national normative framework, through which the EU Directives in the field of medical devices have been transposed, are not fully implemented; it is attested the lack of an efficient system of monitoring and assessment of medical devices.

2. The health system does not have a strategic document in the field of medical device management, technical regulations, minimum standards for equipping medical-sanitary institutions of different levels. As a result, the real needs of medical devices for the medical-sanitary institutions are not determined, and the non-optimal distribution of the acquired devices determines their inefficient use. Some devices equipped with medical institutions have an operating life of up to 40 years (international norms up to 10 years), are from different manufacturers, provided by various economic agents in the Republic of Moldova. There are lacking the criteria for selecting institutions that need modernization, based on the priorities of the health sector.

3. So far, there is no clear picture of health per system with reference to the actual state of medical devices in hospital institutions. Due to registration deficiencies, not all MDs (Medical Devices) are included in the SIMDM (Management Information System of Medical Equipment), which creates great difficulties in implementing the Medical Device Management rules. Many equipment does not have technical passports, which makes it impossible to monitor their operation. The lack of a centralized system of records and monitoring of equipment in medical institutions has a negative impact on the quality of medical services.

4. It was found the lack of effective management of medical devices, which would include all the necessary actions to ensure the efficient use of medical devices, including: need assessment, procurement planning, procurement, maintenance, and replacement of medical devices, leads to a reduction in the quality of health services.

5. The assessment hound that at present the technological potential of the medical devices within some public medical-sanitary institutions is exceeded morally and physically, with major deficiencies, which presents one of the basic causes that determine the quality of the medical act. Many equipment in the diagnostic and surgical sections are worn out and without metrological verification. For example, out of the total number of Roentgen devices reported by institutions at the time of assessment (34 devices) 65% have a wear from 75 to 100%, indicating a risk of harm to patients and staff working with these devices.

6. The degree of endowment of Level III UPU and RTI of institutions with Level III UPU at national level constitutes on average 67%, which does not correspond to the approved norms. About one third of the hospital institutions report deficiency of some necessary equipment, compulsory according to the standard of equipment of the UPU. The quality of the medical services obtained as a result of such a situation, consequently, generates problems related to the evolution of the diseases and the establishment of the optimal and timely treatment.

7. There is an insufficient number of equipment required in the emergency situations for life. Most institutions (80%) report us an insufficient number of monitors for monitoring vital parameters, which do not cover the number of beds in the RTI section of the institution or if the number of monitors seems to be sufficient, they have a high degree of wear and do not meet the needs of a qualitative medical act. Some institutions report coverage of 50 or even 45%, which means that practically every second bed with a serious patient, which requires monitoring, is not equipped with such a system.

8. Medical institutions have limited capacities and limited means for the maintenance and repair of the medical devices provided (both staff capacities, as well as adequate testing and calibration devices). The underfunding of public medical institutions conditions the budget limitation for ensuring the verification of medical equipment and, respectively, endangers the patient's safety.

9. There is an acute lack of biomedical engineering specialists in the maintenance, verification and use of medical devices. The medical-sanitary institutions do not have sufficient and competent staff in the field of medical devices, which contributes to the acquisition of medical devices, whose technical parameters do not fully correspond to those contracted, but also to preventive maintenance, corrective maintenance, periodic verification, diagnosis and insufficient technical assistance of medical devices. Particularly difficult is the situation of the district level medical institutions, which are facing major deficiencies in this regard. However, in the medical institutions the continuous training of the specialists in this sector is not given priority.

The problems identified allowed us to formulate a series of recommendations that could improve the state of affairs in the field of medical device management in order to respect the patient's right to safety and the quality of the medical act.

RECOMMENDATIONS

Ministry of Health, Labor and Social Protection:
1. The management of medical devices must become a priority in the state's health policy, and a coherent policy in this area can contribute to improving the cost / efficiency ratio of the use of advanced medical technologies, to increase patient safety and not least, to increase the quality of medical care. It is necessary to elaborate a strategic document in the field of medical device management and of the instruments for monitoring their implementation. 2. Development of a centralized Plan for planning the procurement of equipment in hospitals, according to the reported needs, with the identification of financial resources. 3. Development of a motivational policy for attracting bioengineers for employment in the IMSP (Public Medical-Sanitary Institutions). 4. Obligation of the managers of the hospital medical institutions to pass certified training on the management of the medical devices and the obligatory procedures required in the institution for this.

Medicines and Medical Devices Agency
1. Finalization of the integrated database on the endowment of the public institutions with the necessary equipment, their degree of wear and the current necessity to ensure the quality of the medical act, according to the accreditation level of the medical institution. Ensuring transparency of this data by placing it on the official website of the Agency. 2. Developing a procedure for a much stricter monitoring of the process of organizing the maintenance of medical equipment in the medical institutions in the country. Identification of assistance possibilities offered to district institutions, where it is difficult to hire a bioengineering specialist at the moment. 3. Initiation and supporting a comprehensive settlement process of non-compliant devices, which do not have metrological verification from the medical institutions in the country. Reviewing

the situation of the devices received through humanitarian aid and offering the support of medical institutions for their settlement.

To the Public Health Agency:
The management of medical devices must be a priority component of the verification procedure for accreditation of medical institutions. It is necessary to introduce changes in the accreditation criteria existing at the moment in this chapter and to offer the activity permit (the activity fields of the institution) depending on the degree of endowment with medical devices conforming to the standards.

State University of Medicine and Pharmacy „Nicolae Testemitanu”:
Development of a continuous training program in partnership with the Faculty of Bioengineering, Technical University of Moldova dedicated to the IMSP (Public Medical-Sanitary Institutions) managers and partially trained technical personnel in the field, without specialized studies in bioengineering.

IMSP (Public Medical-Sanitary Institution)
Development of institutional plans for the procurement, verification and maintenance of the medical devices under management with the estimation and planning of the necessary resources.

ANNEX 1

QUESTIONNAIRE FOR THE SAFETY ASSESSMENT OF MEDICAL EQUIPMENT IN HOSPITAL INSTITUTIONS

	Year of manufacture	Year of metrological verification	Metrological agent	Wear	Mentions
Medical gas insurance system					
Oxygen delivery system with humidifier					
Oxygen bottles with pressure gauge					
Blood gas measuring device, acid-base balance, electrolytes, hemoglobin, blood glucose, lactate.					
Monitoring of vital parameters -1 / place - red area 1 / 2 places yellow area					
Equipment for measuring arterial gases / cooxymmetry					
Generator or alternative sources)					
Fan controlled ventilation and / or Fan assisted ventilation					
Defibrillator					
General anesthesia device for rapid interventions					
Infusomats - number per bed					
Portable vacuum cleaner					
Apparatus for measuring coagulation					
Bronchoscope					
Laryngoscope					
Roentgen apparatus					
USG device					
CT apparatus					

ECG device				
USG device				
Echo-Doppler				
Electroencephalograph				
Mammograph				
Laryngoscope				
Bronchoscope				
Cystoscope				
Digestive endoscopy - FGS				
Rectoromanoscop				
Roentgen apparatus				
Angiography				
CT apparatus				
MRI				
Laboratory - Biochemical blood analyzer				
Laboratory - Hemogram analyzer				
Laboratory - Urine analyzer				
Medical gas system				
Oxygen delivery system				
Oxygen bottles with pressure gauge				
Monitoring of vital parameters - 1 / place = number of RTI beds				
Artificial breathing apparatus				
General anesthesia device				
Defibrillator				
Infusomats for RTI bed				
Portable vacuum cleaner				
Gas measuring device, acid-base				

balance, electrolytes, hemoglobin, blood sugar, lactate.				
Coagulation measuring device				
Generator or alternative sources)				
ECG device				
Portable USG device				
Laryngoscope				
Bronchoscope				
Laparoscopy				
Surgical microscope				
Equipment for endovascular surgery				
Mobile device for extra-renal treatment (hemofiltration, hemodiafiltration, plasmofiltration)				
Rx portable mobile device				
Oncological Institute - Equipment for radiotherapy				

ANNEX 2

QUESTIONNAIRE FOR MANAGERS OF MEDICAL INSTITUTIONS

		YES	NO	Partial	Comments
1	Do You feel the need for information / training on the criticality of medical devices?				
2	Do You have difficulties in checking and certifying medical devices in your institution?				
3	Do You have staff to check and systematically determine the criticality of medical devices?				
4	Does this staff have the proper training to be able to periodically monitor, assess and check medical devices? To indicate in the comments the function and training of the person responsible for this field.				
5	Do You have a method for analyzing the criticality of medical devices in the institution? Please describe.				
6	Do You have sufficient resources planned for checking and repairing medical devices?				
7	Do You have a list of medical devices considered critical in your department?				
8	Do You feel the need / impact of this list on the quality of healthcare provided?				
9	Do You have a procedure in the institution of preventive maintenance, correction and quality control of medical devices?				
10	Is there a risk management procedure for medical devices considered critical (mapping, risk mapping)?				
11	Is there a plan for the replacement of critical medical devices, defined and implemented in your institution?				