Health Technology Management

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Abstract – Maintenance, Verification and Health Technologies Management became priorities in health policies of many countries, many studies show that coherent policies in this domain may improve the proportion price – efficiency of utilization of advanced medical technologies, improve the safety of patients and last not least raise the quality of the medical service. In the framework of reforms in the health system, and of major investments in medical devices, which took place in the last years in the Republic of Moldova, the promotion and introduction of a comprehensive health technology management at all levels of the health system is vital. The importance given to medical devices must be similar to the importance given to drugs and infrastructure.

Keywords – maintenance, verification, management, medical technologies, medical devices

I. INTRODUCTION

The worldwide industry of healthcare, with an annual financial value of roundabout $250 billion and an annual growth of 7%, is one of the few areas that are expected to grow for a long time. Healthcare includes 15 000 registered manufacturers, about 10 000 generic devices and over a million of products and brands[1]. About 50% of all diagnosis and treatment methods used today didn't exist 10 years ago. Annual allocations in Medical Technologies Management are 50-200 Euro per capita in EU.

Maintenance, control and management of medical technologies have become a priority in the healthcare policy of many countries; many studies prove that usage of coherent policies in this area, will improve the cost/efficiency ratio of usage of advanced medical technologies as well as patients' security and the overall quality of the medical act [2-3].

World Health Organization uses the term of "Medical Technologies", which is defined as "devices, medications, medical or surgical procedures – and knowledge associated with those – used in prevention, diagnosis, or treatment of infections, rehabilitation procedures and organizational systems used for providing attendance". Anyway, the term of "Medical Technologies" used within the boundaries of this article refers only to the physical hardware (from WHO's definition), which has to be maintained. Medication is usually covered by separate policy initiatives or is controlled from different departments.

II. THE SITUATION ON NATIONAL AND INTERNATIONAL LEVELS

Therefore, as shown in a report published on the site of WHO, despite the billions of dollars annually spent on medical devices and equipment, the vast majority of countries still regard management of medical devices as an acquisition question rather than an integrated part of the public healthcare policy [4]. More than 95% of medical technologies in developing countries are imported; a large part of these do not match the actual needs of their national healthcare system. It has been estimated that in developing countries about 50% of medical equipment is non-functional, used incorrectly and is poorly maintained – a situation with grave consequences for patients care. This is why the existence of a national policy regarding management of medical technologies is essential; the policy would include e.g. appropriate acquisition procedures, rules and regulations for effective maintenance, control and correct usage of medical technologies, training of specialized personnel and creation of a continuing education.

Another report, from the American Medical Resources Foundations (AMRF), shows that in most cases hospitals in low- and middle income countries do not have the means for maintenance and repair of the provided medical devices, in terms of qualified personnel, appropriate devices for testing and calibration, management structures and financial resources. In these circumstances, services offered by representatives of device manufacturers have an extremely high price in these countries. An inadequate maintenance of medical devices leads to a decrease in the patient's security. AMRF has proven through pilot studies in hospitals from several developing countries (where it trained personnel and provided equipment for testing, calibration and control) that expenses for the above-mentioned services were greatly reduced. These pilot centers became, at the same time, training centers for local personnel. According to the European Alliance for Medical and Biological Engineering & Science, training of specialists in Biomedical Engineering in 2005 was performed in 195 universities in 28 countries from Europe. While the number of students in engineering departments was quite constant in the last 10 years, the number of students in Biomedical Engineering has increased 8 times. Internationally, concepts for training of specialists and international accreditation and evaluation criteria are being developed.

The situation in the Republic of Moldova is similar to those of other in low- and middle income countries; although important sums are invested in medical technologies, maintenance and control of medical devices are not provided. At present, there are 250 active medical institutions, more than 180 enterprises and firms, whose occupation revolves around import and installation of medical technologies, and over 35 enterprises and firms licensed for maintenance in medical technologies. Also, as a new direction, the scientific-applied domain of elaboration and manufacturing of new biomedical technologies is being developed (the Academy of Sciences of Moldova, research

and branch production institutes, other private firms and enterprises). At present, there is a severe lack of specialists in the field of biomedical systems and devices, since specialists in the corresponding field have not been prepared.

Among the major problems and difficulties regarding the management of medical technologies in Moldova can be mentioned:

- A severe lack of specialists in the field of maintenance, control and diagnostic of biomedical devices, including those recently imported;
- Non-existence of a coherent policy regarding development of activities in this field, including conformation, evaluation and preventive/corrective maintenance;
- Non-existing or weak managerial and technical competence for control and maintenance of medical devices on the level of all hospitals, or insufficiently used competences where actually present;
- Non-existence of regulations for continuous improvement, which is mandatory for specialists who are active in technical service of medical devices, inclusively for specialists who are active in the field of marketing and operation of medical devices;
- Services offered by the providers of medical devices are costly and often late.
- No monitoring of timeliness and quality of services provided

III. ORGANIZATION OF HEALTH TECHNOLOGY MANAGEMENT

Health Technology Management involves organizing and coordinating the following activities, which ensures the successful management of medical devices:

- Gathers basic information about equipment;
- Plans technological needs and adequate resources for them;
- Purchases suitable models and installs them effectively;
- Provides sufficient resources in order to use them;
- Operates with them safely;
- Maintains and repairs equipment;
- Resigns, liquidates and replaces unsafe and obsolete parts;
- Ensures that staff has the skills to use the equipment correctly.

Management of Medical Technologies includes several components: (Fig.1).

Based on actual information from various soures, causes of defects and accidents with medical equipment can be classified as follows:

10% - Technical failures;

30% - Inappropriate maintenance strategy;

60% - User's fault.

A correct implementation of management of medical technologies allows 80% of problems to be solved by 20% of the resources.

The reference system in the policy for maintenance of medical devices is shown in fig. 2.

The strategy for maintenance of medical devices implies the following levels:

Maintenance on user level, which implies competent users (with good knowledge of medical and technical rules of use of the device) – information and preceding training of all users (authorization, accreditation), permanent access to information of use of the device (folders which include a summary of functionality, user manual, Internet etc.). Respecting the norms of control and use, specific norms of maintenance, cleaning and sterilization are mandatory.

Preventive maintenance imply competent technical personnel, accredited according to national norms, and maintenance of devices including cleaning and component lubrefiation; *of calibration and control of functionality in terms of safety, of replacing spare partss, accumulators etc.*

Corrective maintenance implies specialists authorized by medical device manufacturers, repairs in the warranty and post warranty periods, overhauls, upgrades.

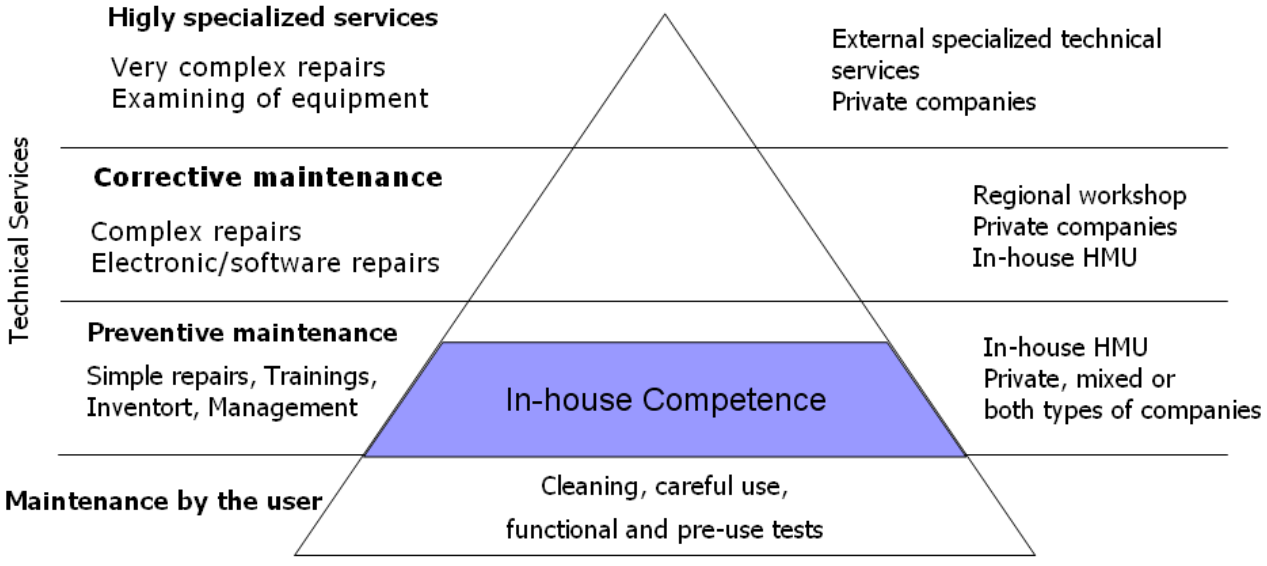

Fig.1.The structure of Management of Medical Technologies (with courtesy of SwissTPH)

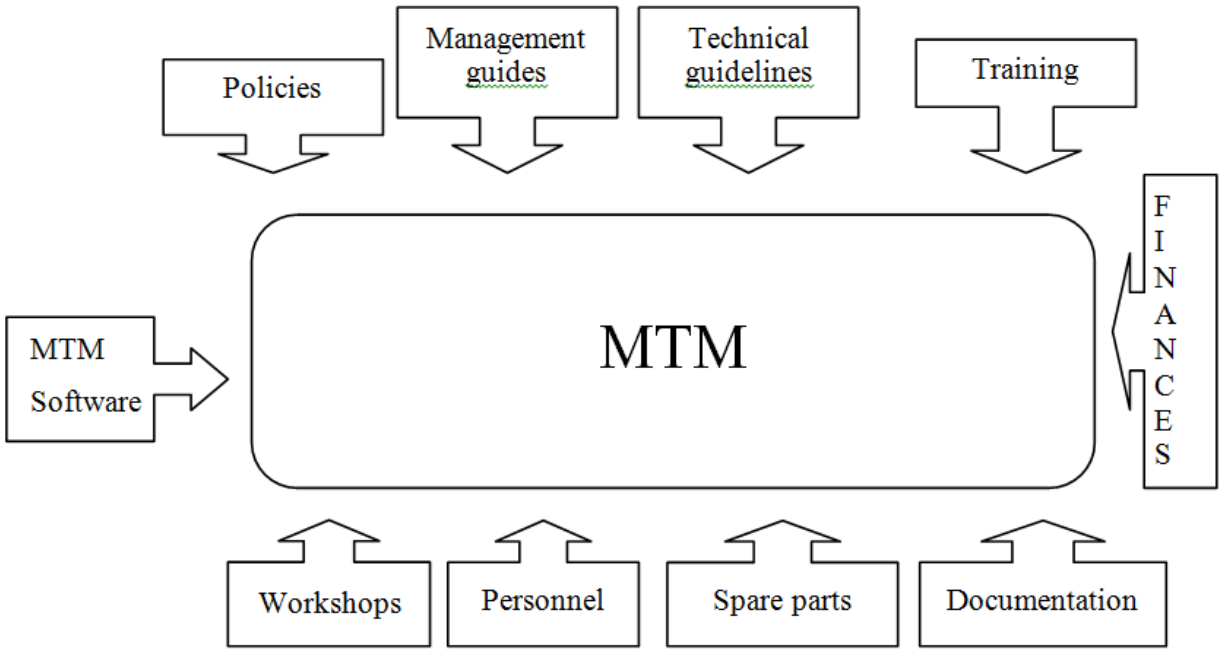

Fig.2. Reference system in the policy of maintenance of medical devices (with courtesy of SwissTPH)

The implementation of Health Medical Technologies has the following objectives:

1. Framing of activities within national (European) and local norms regarding management of medical devices.
2. Framing of usage activities and service within norms recommended by medical devices manufacturers, within a framework of a maintenance adequate to the device;
3. Reduction of inadequate use of modern technologies and ensuring a continuous and effective availability of medical equipment for services corresponding to the field of healthcare;
4. Monitoring of the activities of maintenance, correction of errors, development of specific protocols, and prediction of costs.

For a complete objective fulfilment an implementation of the strategy of mixed medical device maintenance is proposed – basic maintenance by own personnel with creation and development of a Department (workshop, section) of Management of Medical Technologies and specific maintenance through authorized firm specialists.

At the first stage, it is necessary to implement an organizational structure of Management of Medical Technologies as a component of Quality Management with defined activities and responsibilities and bonds on each level (fig. 3)

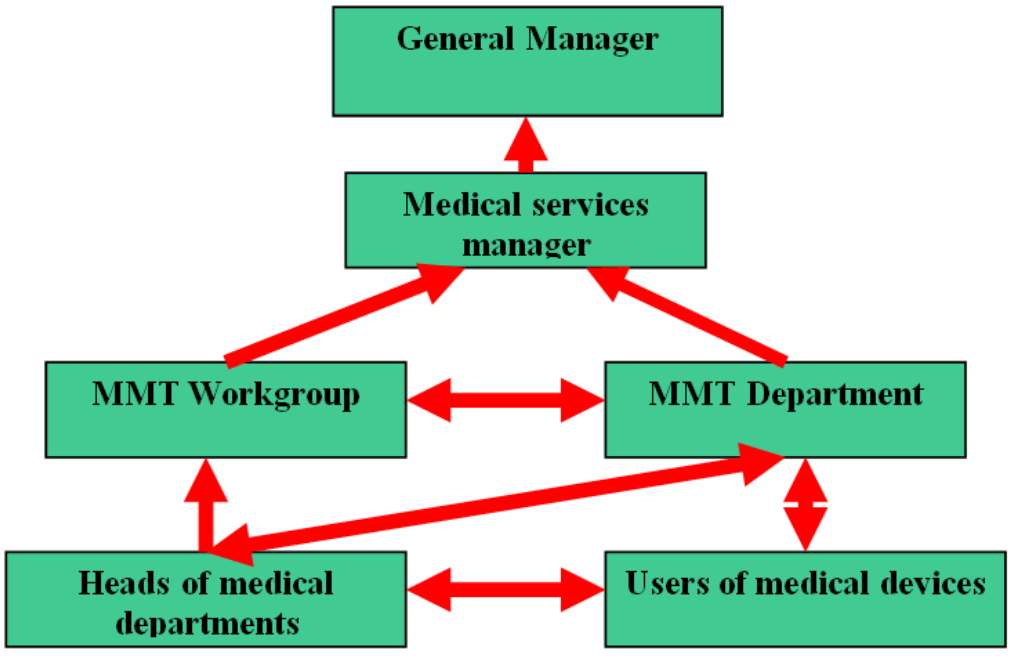

Fig.3 Organizational structure of MMT on a hospital level

At the second stage, an implementation of norms in MMT is necessary:

1. Local norms (at the level of medical unit, department):

- Regulation on organization and functioning of Organizational Structure
- Rules of Procedure regarding Organizational Structure
- post descriptions of all personnel from Organizational Structure
- Call log
- Maintenance file of the Medical Device
- User guides
- Medical device usage log
- Maintenance report
- Medical device service file
- Annual plan of medical device maintenance
- Annual plan for necessity of consumables
- Electronic evidence log of the medical device
- Electronic registry of medical devices
- Electronic registry of consumables and spare parts
- Maintenance protocols specific to the medical unit

2. National norms:

- Decree of the Government of the Republic of Moldova nr. 96, from January 26, 2007 "Regarding establishing of terms for market placement and usage of medical devices"
- Regulation regarding establishing of terms of market placement and usage of medical devices in the Republic of Moldova.

3. European(international) norms:

- Active Implantable Medical Devices (AIMDD**) .** Directive 90/385/EEC - OJ L189/ 20.7.90
- Medical Devices Directive (MDD). Directive 93/42/EEC - OJ 169/ 12.7.93.
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IV. IN VITRO DIAGNOSTIC DIRECTIVE (IVDD). DIRECTIVE 98/79/EC - OJ331/ 7.12.98

Expected results

- Medical institutions can offer all required medical services, and are not limited by non-functional technologies;
- Equipment is correctly used, correctly maintained and verified;
- The personnel use equipment to its maximum capacity, following written procedures and good practice;
- Health service institutions are provided with adequate information regarding:
    1. functional state of the equipment;
    2. Performance of the maintenance services;
    3. requried abilities and experiences of the personnel using the equipment;
- A reduction of medical devices maintenance expenses, redirection of works connected to preventive maintenance, which are 70% of all maintenance expenses (service, repair of medical devices) towards solving by specialists from the medical institution.
- The personnel controls the immense financial investments in equipment, which leads to a more qualitative and efficient service, as well as a lowering of financial allocations regarding to maintenance of medical devices.

V. PROPOSALS REGARDING DEVELOPMENT IN MMT

1. Promotion of the profession of *biomedical engineer* within the national healthcare system in relation to the requirements and quality standards of the medical act, equalizing the status of a bioengineer with the one of a doctor in the field of healthcare.
2. Development of a policy adequate to the norms of EU, regarding the progress of activities in the domain of MMT and standards in the field.
3. Establishing of a "Department of Medical Technologies" charged with all tasks and problems connected to management and administration of Medical Technologies; at the first stage on the level of national, municipal and district (group of districts) health institutions,
4. To reduce expenses of maintenance of medical devices, it is necessary to introduce stringent preventive maintenance (service and repair of medical devices have to be performed by specialists from the medical institution), which represent 70% of maintenance expenses.
5. Creation of an information system "Management and administration of Medical Technologies"
6. Development of a regulation of continuous training, mandatory for specialists who woirk in the field, including specialists active in the field of marketing and operation of medical devices.

ACKNOWLEDGMENTS

This work was supported by the Swiss Development Cooperation (SDC) who financially supported HTM in the frame of the two projects in R. of Moldova.

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