Executive summary of the public audit report

HOW IS EXAMINATION WITH EXPENSIVE MEDICAL DEVICES ORGANISED?

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ABBREVIATIONS AND DEFINITIONS

EMD – expensive medical devices listed in an exhaustive List of expensive medical devices[1]:

ANGE – angiography equipment;

GC – gamma camera;

LA – linear accelerator;

MRTE – magnetic resonance tomography equipment;

KTE – computer tomography equipment;

MMG – mammography equipment;

USDD – ultrasonic diagnostic equipment;

XDD – X-ray diagnostic equipment.

WHO – World Health Organisation –specialized institution of the United Nations, the largest international health organization.

MoH – Ministry of Health.

SHCAA – State Health Care Accreditation Agency under the Ministry of Health.

RPC – Radiation Protection Centre.

THIF – Territorial Health Insurance Fund.

NHIF – National Health Insurance Fund.

CHIF – Compulsory health Insurance Fund.

PIP – Public Investment Programme.

MI – medical facilities (public and private medical facilities).

Large hospitals – university and national hospitals.

Diagnostic and treatment methodology – a document prepared by universities, research institutions, professional associations of doctors and based on evidence of medical science and practice, which sets out common health problems and disease diagnostic and treatment guidelines[2].

Diagnostic and treatment procedure – a document approved by an order of the Minister of Health, which lays down the procedure for diagnostics and treatment compensated from the Compulsory Health Insurance Fund[3].

Patient – a person who uses services provided by health care facilities, regardless of whether he is healthy or sick.

Teleradiology – the transmission of images of radiological examination carried out in one medical facility over computer networks (the Internet) or in a digital storage device (DICOM standard) to another medical institution, evaluation and description of radiological images and

[1] Annex 3 to the Procedure for the installation, use and maintenance of medical devices approved by Order No. V-383 of the Minister of Health of the Republic of Lithuania of 3 May 2010 (as amended on 1 February 2011, No. V-94).

[2] Law on the Rights of Patients and Compensation of Damage to their Health, 3 October 1996, No. I-1562 (as amended on 19 November 2009, No. XI-499), Art. 2(4).

[3] Ibid, Art. 2(6).

transmission of the radiological examination data and results (description of the images) to the medical facility which conducted the radiological examination[4].

Medical device – an apparatus, instrument used alone or in combination with other appliances, including software, to diagnose human disease, injury or disability, to monitor and treat the disease[5].

Maintenance of the medical device – a whole of the technical maintenance of the medical device (including daily maintenance) and inspection of its technical condition[6].

Inspection of the technical condition – mandatory inspection of the medical device carried out in the procedure and within the periods laid down in the legislation on the use of medical devices and by the manufacturer of the medical device, as well as inspection of all parameters of the medical device and safety testing of the medical device[7].

[4] Procedure for the provision of teleradiology services and payment of their expenses from the budget of the Compulsory Health Insurance Fund approved by Order No. V-944 of the Minister of Health of the Republic of Lithuania of 19 October 2012 (as amended on 1 February 2011, No. V-94), par 2.

[5] Lithuanian Medical Standard MN:2009 'Safety technical regulation for medical devices' approved by Order No. V-18 of the Minister of Health of the Republic of Lithuania of 19 January 2009.

[6] Procedure for the installation, use and maintenance of medical devices approved by Order No. V-383 of the Minister of Health of the Republic of Lithuania of 3 May 2010 (as amended on 1 February 2011, No. V-94), par. 5.

[7] Ibid.

EXECUTIVE SUMMARY

There are eight devices specified in the List of Expensive Medical Devices[8]: angiography equipment, gamma camera, linear accelerator, magnetic resonance tomography equipment, computer tomography equipment, mammography equipment, ultrasonic diagnostic equipment, and X-ray diagnostic equipment. According to the State Health Care Accreditation Agency, there were 1580 expensive medical devices in medical facilities in 2013, with ultrasonic X-ray diagnostic equipment accounting for the largest share of these devices.

Expensive medical devices are used to diagnose diseases of heart and blood vessels, bones, joints, muscles, internal organs, cancer, and to monitor and treat the diseases.

The amount of funds used for the acquisition of expensive medical devices in 2010-2012 under the Public Investment Programme totalled LTL 178.7 million: LTL 163.9 million of EU and co-financing funds and LTL 14.8 million of state budget funds. The funds used for the acquisition of expensive medical devices accounted for 25 per cent of the PIP funds allocated for the implementation of health investment projects in 2010-2012[9].

The audit was conducted in view of the fact that the use of expensive medical devices, problems related to their upgrading are issues relevant to the public, since they concern the safety, quality and availability of health care services.

The objective of the audit was to assess how examination with expensive medical devices is organised:

- is availability of examination with expensive medical devises ensured;
- are there preconditions in place in medical facilities for quality examinations.

The audit was conducted at the Ministry of Health and the State Health Care Accreditation Agency under the Ministry of Health. Data and information were gathered from the Radiation Protection Centre, Health information Centre of the Institute of Hygiene, National Health Insurance Fund, territorial health insurance funds. We surveyed 47 of 100 personal health care providers which have and use expensive medical devices[10]. Additional audit procedures were conducted in 13 clinics and 3 hospitals. We also surveyed 190 patients who have been examined using expensive medical devices over the past three years.

The audit conclusions were formulated after analysing the data on expensive medical devices and their use collected by various institutions (Ministry of Health, Radiation Protection Centre, National Health Insurance Fund under the Ministry of Health, territorial health insurance funds, State Health Care Accreditation Agency under the Ministry of Health, Health Information Centre of the Institute of Hygiene, public and private medical facilities providing personal health care services paid from the Compulsory Health Insurance Fund), evaluating the information provided by representatives of the Lithuanian Radiologists Association and Ultrasound Association of

[8] Annex 3 to the Procedure for the installation, use and maintenance of medical devices approved by Order No. V-383 of the Minister of Health of the Republic of Lithuania of 3 May 2010 (as amended on 1 February 2011, No. V-94).

[9] According to the data in the use of public funds of the Ministry of Finance allocated for capital investment by managers of the appropriations over the period 2010-2012.

[10] Of these, 80 are public medical facilities (hospitals or clinics), others – private ones. The assessment did not include institutions providing primary health care and dental services.

Radiologists and expert opinions, and analysing documents related to radiologists (licensing, organization of work, performance of radiological examination).

The audit covered the period 2011-2012, the data analysis also used the data of earlier periods and of the year 2013.

The following public audit conclusions and recommendations were drawn upon the assessment of the audit findings.

CONCLUSIONS

1. The number of expensive medical devices is in line with the indicators of the neighbouring EU countries, the devices are evenly distributed by regions, emergency examination with expensive medical devices is carried out immediately; however, the availability of scheduled examination in public medical facilities is insufficient because of the following:

1.1. There is a lack of control of the flows of patients waiting for diagnostics because there is no common patient flow management system in medical facilities. None of the surveyed medical facilities was registering patients for examination in other institutions, meanwhile patients do not have enough information and so choose medical facilities at their own discretion. This causes the longest queues for examination in large (university and national) medical facilities of the country.

1.2. 45 per cent of the surveyed medical facilities indicated a shortage of radiologists, however, they do not engage radiologists of other medical facilities for describing radiological images remotely by electronic means, i.e. there are untapped opportunities for teleradiology. 92 per cent of the surveyed institutions have systems for storing examination results, most of them (97 per cent) do not exchange the images obtained during the examination with other institutions.

1.3. The list of indications for examinations and procedures to be carried out using expensive medical devices established by the Minister of Health is incomplete and needs to be adjusted. Therefore, it is not always that examinations are carried out when they are needed.

1.4. As a result of the procedure for the payment for expensive examination (when payment for the service to the medical institution depends on a variable point value), medical facilities carry out targeted regulation of the amount of services (form queues for examination).

1.5. Differences (up to 2-3 times) in the number of staff working with expensive medical devices, in the working hours of the unit where examinations are carried out and of the specialists working with the device determine that the performance indicators of similar expensive medical devices in medical facilities of the same level (units performing similar functions) differ several times. Therefore the capacity of the devices has not been fully used.

2. There are no appropriate preconditions in place for ensuring high quality of examination:

2.1. diagnostic and treatment methodologies have been developed only for a small number of diseases, not all descriptions of the examinations completed are informative because there are no uniform requirements for the description of results;

2.2. medical facilities pay insufficient attention to maintenance and safety of expensive medical devices, violations of the operation of expensive medical devices were identified in half of the inspected medical facilities. Not all medical facilities properly document maintenance of expensive medical devices, so it is not possible to check whether maintenance is actually carried out. According to the SHCAA, 37 violations related to inadequate documentation of maintenance were identified in 2010, 6 violations were registered in 2011, and 12 ones – in 2012;

2.3. there is improper management of the equipment failure risk: 8 per cent of the institutions pointed out equipment downtime due to its failure, one third of some expensive medical devices (ultrasonic equipment, X-ray equipment, gamma camera) have been operated for more than ten years, however, only 50 per cent of the surveyed medical facilities are planning to upgrade the existing equipment or buy new devices.

RECOMMENDATIONS

To the Ministry of Health of the Republic of Lithuania (including doctors' societies/associations):

1. In order to ensure targeted and reasonable performance of examination with expensive medical devices:
1.1. to revise the list of indications of when expensive medical devices can and should be used;
1.2. to develop diagnostic and treatment methodologies or protocols specifying the diagnostic and treatment activity to be carried out for a patient with a certain disease, including certain tests;
1.3. to establish requirements for the description of the results of examination with expensive medical devices.

To the State Health Care Accreditation Agency under the Ministry of Health:

2. In order to ensure safer operation of expensive medical devices:
2.1. to improve their maintenance procedure – to obligate medical facilities to provide documents on the maintenance of the devices to the Agency in a regular manner;
2.2. to increase the scope of inspections of medical facilities using expensive medical devices.

PROPOSALS

To the medical facilities using expensive medical devices:

3. In order to ensure the availability of diagnostic health care services and efficient use of expensive medical devices:
3.1. to analyse the loads of the existing equipment and possibility of the distribution of patient flows between medical facilities and to take appropriate measures – to sign agreements between medical facilities and to install the necessary equipment for managing patient flows;
3.2. to provide for conditions for using teleradiology in medical facilities – to install the necessary equipment, to sign agreements with other medical facilities on the exchange of diagnostic images, to engage radiologists of other medical facilities for remote description of examination results by electronic means in case of a shortage of radiologists, etc.;
3.3. to carry out regular maintenance of expensive medical devices used in medical facilities;
3.4. to develop plans for upgrading expensive medical devices.