

Increasing efficiency for the medical rehabilitation projects in Russia as a part of a large-scale healthcare system

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ABSTRACT: *The relevance of projects for the development of medical rehabilitation, its technical and economic support is due, primarily, to an increasing number of people suffering from physical disabilities caused by non-communicable diseases (cancer, neurological, cardiovascular, etc.). According to the World Health Organization, the main causes of death are currently the consequences of these diseases. The paper deals with the issues of medical rehabilitation as a part of the world large-scale healthcare system, its technical, metrological and economic feasibility and support as well as implementation of best world and European experience in Russia.*

KEY WORD: *healthcare projects, process approach, medical rehabilitation, large-scale healthcare systems, competitiveness, metrological support*

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I. INTRODUCTION AND LITERATURE REVIEW

The prevalence of non-communicable diseases, which determine the limitations of a person's motor activity, is rapidly increasing, bringing the global economy almost trillion losses [1-3]. An important place in the fight against noncommunicable diseases and their consequences is medical rehabilitation.

European Academy of Rehabilitation Medicine (EARM), Section of Physical and Rehabilitation Medicine of the European Union of Medical Specialists (UEMS) define rehabilitation as one of the most important interventions, "allowing people with disabilities to achieve and maintain maximum independence, full physical, mental, social and professional ability and full inclusion, and participation in all aspects of life». Therefore, the outlined concept calls on sovereign states to "organize, strengthen and expand services in the area of comprehensive development of skills and rehabilitation, especially in the areas of health, employment, education and social services".

The system of comprehensive rehabilitation in Europe is formulated and described in detail in the Guidelines and regulations on physical and rehabilitation medicine (PRM) in Europe, which are compiled by four European organizations: European Academy of Rehabilitation Medicine - EARM, European Society of PRM - ESPRM, European Union of Medical Specialists - Section PRM, European Board PRM - ECPRM, served by the European Union of Medical Specialists - Council PRM and provide a guide for physicians PRM (physical therapists and rehabilitologists) in Europe in the form of the so-called WB - "White Book".

The book has many goals: the creation of a unified governance structure in the field of PRM for European countries, informing decision-makers at European and national levels. The book provides training materials for interns and physicians of the PRM and information about the PRM to the medical community, other rehabilitation specialists and the public. The WB emphasizes the importance of the PRM as a primary medical specialty, which is represented throughout Europe by a special corpus discipline, general premises and history. PRM is recognized as an independent structure at the international level and is a partner of major international organizations, including the World Health Organization (WHO).

The work of the PRM is largely based on the United Nations (UN) and WHO documents, such as the Convention on the Rights of Persons with Disabilities (2006), the World Report on Disability (2011), the WHO Global Plan of Action on Disability 2014-2021 . (2014) and the WHO Rehabilitation 2030: Call to Action Initiative (2017). The spectrum of diseases with which PRM specialists deal, is extremely wide, since many of the patient's conditions are associated with a particular form of disability. Among them are diseases of the musculoskeletal system, nervous, circulatory, respiratory, urogenital systems, as well as skin and gastrointestinal

tract. The clinical activity of PRM is also associated with some of the most common problems associated with diseases such as immobilization, spasticity, pain, communication disorders, and others. Diagnostics in PRM is a combination of medical diagnostics (diagnosis of the disease) and specific functional assessment of PRM (evaluation of functioning).

The last mentioned type of diagnosis is based on the conceptual structure of the ICF (WHO standard for measuring the state of health and disability) and is the result of functional assessments and tests. Professionals of the PRM can apply a wide range of interventions, ranging from medicines, exercises, manual therapy, physical influences, technical means, educational programs and the patient's adaptation to the environment.

Modern main problems of the Russian healthcare system in the field of medical rehabilitation organization can be characterized as follows: the lack of a unified system of institutions that provide assistance for medical rehabilitation; late start of rehabilitation activities; ineffective models of organizing medical rehabilitation measures and mixing tasks and models of preventive and rehabilitative medicine. In order to form an adequate system of rehabilitation assistance in the Russian Federation, the main provisions and minimally sufficient requirements for medical rehabilitation assistance were developed according to the medical care profile, reflected in Federal Law No. 323 "On the Principles of Citizens' Health Protection in the Russian Federation" and the procedure for organizing medical rehabilitation (approved by order of the Russian Ministry of Healthcare dated December 29, 2012 No. 1705n).

Let's consider main stages of medical rehabilitation in accordance with regulatory documents mentioned above:

Stage I provides provision of medical rehabilitation assistance in the acute period of the course of the disease or injury in the intensive care unit, specialized clinical departments of hospitals in the profile of care provided.

Stage II provides provision of medical rehabilitation assistance in the early recovery period of the course of a disease or injury in specialized rehabilitation departments of multi-disciplinary hospitals or rehabilitation centers.

The third stage of medical rehabilitation provides provision of medical rehabilitation assistance in the early, late rehabilitation periods, the period of residual disease, during the chronic course of the disease without exacerbation to patients who are independent in everyday life in the implementation of self-care, movement and communication, in outpatient health care facilities, paramedics - obstetric points, inpatient stays of one day, in sanatorium-resort institutions, as well as mobile teams at home [1]. Understanding and introducing phased assistance in medical rehabilitation is extremely important for building a large-scale national system in this area and evaluating its effectiveness in terms of personnel training and the provision of high-tech medical products and technologies [4-6].

II. METHODOLOGY

In this paper, using the methodology of the process approach, the issues of clinical practice for the rehabilitation of patients with motor impairment are considered. At the same time, in some cases, medical personnel in the rehabilitation process use motion imitation technologies without the usage of technical means. This imitation allows the body to restore, at least partially, the skills of motor functions, reduce depressive factors of no movement and morphological changes in biological tissues. However, there are significant shortcomings of such procedures directly by a medical professional: 1 - it takes considerable time and physical effort of both the medical staff and the patient, 2 - the procedure is difficult to reproduce the "geometry" of movements, the assessment and reproducibility of which are quite subjective. These reasons necessitate the usage of mechanical devices during the procedures. In this case, it is customary to talk about mechanotherapy. Its principles were formulated by I.V. Zabludovsky and other Russian doctors at the beginning of the 20th century, which allowed the development and introduction of simple mechanotherapeutic devices into the clinic. At present, technical implementations of devices represent complex design and hardware-software solutions and require appropriate methods of their application to ensure the elimination of the above negative factors of imitation of movements in a patient by medical staff [4].

III. RESULTS

Modern devices for mechanotherapy should provide not only the possibility of introducing the initial parameters that regulate the load, but also the possibility of current monitoring of impact level and the main physiological parameters characterizing the admissibility for those engaged in continuing exercise. In particular, heart rate indicators, oxygen saturation, blood pressure, ECG changes, which are universal criteria for the safety and effectiveness of performing any type of work on a mechanical therapy simulator, should be taken into account. In addition, an increase in the effectiveness and standards of the target usage of the apparatus for

mechanotherapy is possible only when evaluating specific criteria that characterize the movement itself. These criteria include: the volume and degree of movement, the amount of effort applied by the patient, the nature of muscular work (isotonic, isometric, isokinetic, eccentric), speed, reproduction accuracy of a task, issued using non-verbal commands (tactile, vibrational, temperature, visual and commands audio therapist). Apparatus for mechanotherapy should be safe not only in terms of probability to cause injury or functional overstrain, they should not cause cognitive discomfort and psycho-emotional overexcitement. At the same time, well-studied mechanisms of the influence of motor activity, varying in intensity and type, on different systems of the human body, make it possible to predict therapeutic effects and control the effects of load elements that reproduce any type of motor activity and, thanks to the ability to reproduce in detail the geometry of the selected movement, accurately dose the load, evaluate its parameters. Therefore, physical activity with the use of equipment for mechanotherapy allows the use of mechanotherapy and for diagnostic purposes as well. Partially these questions are reflected in [5-7].

The concepts of modern medical rehabilitation with the expansion of indications, the earlier start of the rehabilitation process, the priority of the kinesiotherapeutic (movement therapy) approach in restoring motor function were the prerequisites for the further development of technical means of rehabilitation using complex hardware and software solutions. Over the past decades, devices for mechanotherapy have undergone significant changes, and the indications for mechanotherapy have expanded significantly. Reviews devoted to modern aspects of hardware rehabilitation [1-6] consider two large groups of devices that provide: 1 - active, 2 - passive, and 3 - active-passive mechanotherapy. Active mechanotherapy is the usage of the motor skills and abilities available to the patient, enabling him to drive the mechanotherapy apparatus with various actuators (mechanical, electromechanical, electromagnetic, hydraulic, pneumatic, etc.). In the apparatus of passive mechanotherapy to ensure the forced movement of human limbs, in case of violations of voluntary motor activity, the energy of moving elements (actuators of devices for mechanotherapy) is used. The most widely used are the combined apparatus for active-passive mechanotherapy / rehabilitation (APR). The increasing usage of devices and techniques of robotic mechanotherapy should be pointed out [6-8].

For the first time, the concept of “robot” was introduced by the writer Karel Chapek with the goal of describing the activity of mechanisms that partially possess the functions inherent in man. Based on the generally accepted definition, “... a robot [Czech., Robot] is a term denoting machines (devices) with the so-called anthropomorphic (human-like) action, which partially or completely replace a person when working in conditions dangerous for life, as well as when the object is relatively unavailable”. Based on this definition, those devices that provide complete or partial replacement of the impaired motor function of a patient or replacing the functions of a medical specialist during rehabilitation can be classified as robotic devices for mechanotherapy. At the same time, automated (using biofeedback - BFB) monitoring and adjustment of movement parameters are usually carried out, replacing visual and tactile controls by the patient and the doctor. BFB can determine the range of allowable amount of movement or effort when performing robotic mechanotherapy, in order to increase the mobility of peripheral joints and limbs, or implement a special option, such as the “antispasm” option for mobilizing soft tissues and joints in diseases of the nervous system. The technical characteristics of the APR advertised by manufacturers include the following options:

- registration and processing of information obtained when working with a patient, recording data on electronic and paper carriers, high image contrast, selection of color gamut's and sufficient alphanumeric values on the screen, maximum patient involvement in the rehabilitation process, turning the rehabilitation process into a game or competition. With a large flow of patients - less visual fatigue and faster decision making in emergency situations (this function, in part, is implemented in the equipment of medica medizintechnik GmbH);

- ensuring the possibility of simultaneous training of the upper and lower extremities, the introduction of additional restrictions on ensuring the safety of training (this property is implemented in the equipment of the company RECK MOTOMed GmbH);

- introduction of biofeedback and the possibility to choose training modes (“neuro”, “ortho”, “cardio”, “kinetics” - an option that is available only for the equipment of medica medizintechnik GmbH), saving the results of a patient's examination in a database, transferring records from the control panel to a personal computer, an extended spastic detection program with the ability to adjust the sensitivity of the simulator to spastic (option available only for equipment of medica medizintechnik GmbH);

- functioning of the emergency stop system, including when a patient gives a beep or touches the alarm button on the handle or the simulator display.

A promising direction in the development of these simulators is the possibility of electromyostimulation, providing a flexible system for monitoring the presence of a spasmodic condition on each of the limbs. It should be noted that domestic developments, in particular, the firms of Nevrokor LLC practically provide many of the listed options and have additional, such as providing conditions for the use of virtual reality gaming in the process of medical rehabilitation. Based on the tasks formulated in the rehabilitation

program, in the clinical research process, it is advisable to implement the BFB scenarios in the virtual reality environment with the game component while synchronizing the BFB game scenarios with the functions of the locomotor simulators. It is possible to use both the 2D monitor and the virtual reality helmet combined with the movement tracker for visualizing the BFB. At the same time, the virtual reality game character is controlled by means of bio control with neurointerfaces. Through a non-invasive neurointerface of the new generation, it is possible to provide remote activation and adjustment of the actuators of the training modules. As information signals, the activity of coherent connections, rhythms, EEG amplitudes can be used, including the ability to connect third-party libraries with mathematical algorithms for processing native EEG, using both “dry” electrodes for recording electrical activity of the brain and the standard EEG system “10-20” in the neural interface with gel conductive layer. At the same time, the technological solution of the complex should ensure the possibility of monitoring the patient’s condition according to the EEG parameters and the motor activity (range of motion) of the patient during the entire procedure, muscle activity and tremors during the entire procedure, creating a data bank for storing and analyzing therapeutic results, procedures, personalization of patients and the procedures they perform, the inclusion of a system for remote monitoring of patients via a local network or via the global network [5].

Such complex high-tech products, as a rule, are innovative and require harmonization of efforts in the development and implementation of them in clinical practice, both from technical specialists and from medical personnel, which is not always realized in practice. Compiled terms of reference, approved by the management of the manufacturer, often reflect only the requirements for the technical parameters of medical devices, the effectiveness and potential risks of which are identified at the stage of clinical operation. At the same time, financial and resource costs for development and production can no longer be recovered, and, in some cases, these costs are incurred using budgetary funds received, in particular, as a result of successful completion of competitive selection for R & D. But to our opinion, the innovative development cycle of high-tech medical products should be formed in this way, when at the stage of generating ideas, doctors join the work, assessing possible prospects and areas of application, and potential risks of using the product at the clinic for patients and medical workers. The most effective such interaction of medical and technical specialists is manifested on the basis of integrated structures [10].

Samples and demonstration of the technology of active-passive mechanotherapy are shown in Figure 1 during the training sessions to improve the skills of specialists in the development, maintenance and operation of medical devices.

Figure 1: Demonstration of commercially available devices for active-passive mechanotherapy

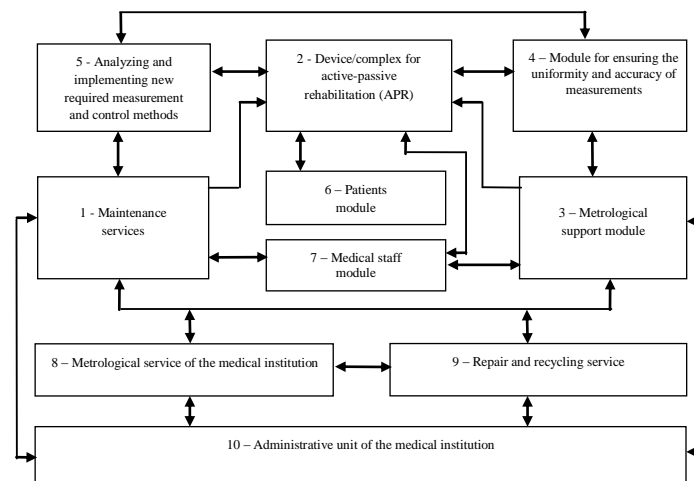


Source: Authors

One of the areas of mechanotherapy for patients with significant impairment of motor function is the usage of exoskeleton, the development and production of which is carried out both in Russia and abroad [7-9]. Initially, the ideology and model of the exoskeleton were also developed in Russia already in 1890 by N. Young. In the sample were used gas actuators, ensuring the movement of the created structure. The prototype of the modern exoskeleton was developed by General Electric, tentatively in 1960. The robot was named Hardiman, it lifted 110 kg, with a load felt by a man - 4.5 kg. Improvements allowed to increase the raised weight. Later, these technologies began to develop, including the USSR, while targeting them for use in medicine. The first exoskeleton for the rehabilitation of patients with paraplegia and similar diseases with pneumatic actuators and the corresponding software was tested by Belgrade Orthopaedic Clinic in 1972. The area of medical exoskeletons usage in orthopaedics is divided into: a) restoration of the musculoskeletal system, b) usage during disease period providing the possibility of abandoning a wheelchair or permanently in bed (augmentative exoskeleton). These exoskeletons allow them to be worn for several hours a day, the main

problems that they have today and do not allow the widespread use of the following: high cost, maintenance complexity, including hygienic and energy supply problems. At present, Japan has developed exoskeletons for the patients care, in particular, when lifting or transporting patients. Currently, the development of exoskeletons for medical purposes is also occupied by high-tech enterprises of the Russian Federation. Some of them have already been introduced into clinical practice [1, 6, 7].

Figure 2: The structure of the interaction of technical services in the implementation of metrological support for active passive rehabilitation equipment (APR)



Source: Authors

Analysis of the proposed scheme (Fig. 2) shows that the traditional maintenance system (module 1), which provides the operation of module 2, is added with: the metrological support module (module 3), module 4 - ensuring the uniformity and accuracy of measurements, module 5, analyzing and implementing new required measurement and control methods. The usage of these modules increases the efficiency of module 3 and, accordingly, the competitiveness of the product as a whole. Taking into account the introduction of these modules, physiological information signals from the patient 6 arrive at the input measuring system of module 2 and, if necessary, to the medical staff 7, ensuring the implementation of the rehabilitation process with application 2. The metrological service 8 of the medical institution, interacting with the maintenance services (module 1) and metrological support (module 3), if there is a need, informs employees of the repair and recycling service (module 9) about the expediency of performing certain actions. Responsibility for the effective implementation of the introduction of metrological support in the operation of the APR complex, as well as for the entire rehabilitation process, rests with the administrative unit (module 10).

Assessing the social and economic place of medical rehabilitation in a large-scale health care system, we note that the economic and social weight of disability in society is significant and tends to increase, although it is difficult to quantify it. Direct costs are variable and include the extra daily expenses of people with disabilities and state disability benefits. Medical rehabilitation plays a key role in reducing these costs by promoting personal recovery and increasing efficiency by changing the environmental factors that affect the disabled, such as attitudes from friends, acquaintances and strangers. The results of cost savings by rehabilitating people with severe disabilities are very significant. In modern society, there is also an expectation of quality, on the basis of large-scale health care systems, which imposes additional requirements on all medical services, including the work of PRM doctors. Dealing with the consequences of illness and injury, such as spasticity after haemorrhage in the brain or spinal cord, means not only improving the lives of patients, but also benefiting the health economy by reducing the cost of treating these complications. This will have a direct impact on care, work and pensions. In particular, to reduce such problems as immobility, impaired motor activity, pain, nutrition, incontinence, speech disorders, mood disorders and behaviour.

These problems are becoming extremely important in addition to systemic diseases and complications leading to disability. Rehabilitation is effective in reducing the burden of disability and in expanding opportunities for people with disabilities. Rehabilitation can be cheaper than none. In addition, the development and production of high-tech products for medical rehabilitation refers to innovative processes in industry, ensuring the further development of the country's production and technology complex, ensuring its national

security and economic independence. A further stage in the implementation of innovation processes is the choice of a financing scheme. In this case, it is possible to use project financing methods that take into account the increased risks of both the production of MD, the provision of medical services, and the risks of the financing organization. The recouping of its own or allocated budget funds, at the same time, is supposed to be carried out at the expense of cash flows generated during the operation of the investment activity object, which increases the responsibility of both developers and medical personnel for the effective introduction of products into clinical practice [10]. Taking into account the introduction of metrological support for APR procedures for people with limited motor activity, the importance of medical rehabilitation in a large-scale health care system increases many times due to the involvement of a new cohort of patients of this system who were previously unavailable due to contraindications and insufficient harmonization of procedures with their physiological capabilities.

At the same time, it is important to emphasize the importance in social rehabilitation of issues of social adaptation, including for people with disabilities movement facilitation, self-service, communication and security. In this case, it is customary to talk about technical means of rehabilitation, which, in particular, include special means for orientation, including guide dogs with a set of necessary equipment, training kits, for example, literature for the blind, orthopaedic shoes, eye prostheses, means for moving - wheelchairs, sports equipment.

IV. FINDINGS AND CONCLUSIONS

Medical rehabilitation projects occupy a significant place in large-scale healthcare system in Russia and they are intensively developing from year to year [1-4]. Therefore it make sense to increase the economical and social efficiency of such projects.

When analyzing the feasibility and possibility of acquiring an MD for rehabilitation, a comparative assessment of the competitiveness of a given MD should be made, as well as the possibility of attracting trained personnel to ensure effective operation and maintenance of acquired MD, the basics of biophysics of exposure to it [5, 10].

In addition to price and functional characteristics of MD, it is necessary to analyze the possibility of using this type of APR in a large-scale healthcare system for rehabilitation based on patients, their number, it is possible to use methods widely used in economics, expert assessment methods and the process approach.

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