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MODELS AND METHODS OF CONSTRUCTION OF "CYBERNETIC" QUALITY MANAGEMENT SYSTEMS FOR DIAGNOSIS AND TREATMENT OF CNS DISEASES OF PATIENTS IN ACCORDANCE WITH THE EUROPEAN STANDARDS ISO 9000

Abstract: The article reviews modern methods and models of quality management, in particular, in medical treatment establishments, and their conformity to the European standards ISO 9000.

Key words: methods, management, ISO 9000 standards, management model, cybernetic approach, treatment methodology, quality management, quality standards, process approach

1. Introduction

Rapid increase in the cost of health care without adequate improvement of its quality and safety is an urgent problem not only for our country but also for many economically developed countries.

International experience shows that one of the important and effective tools for enhancing the competitiveness and development of a medical and preventive treatment institution (MPTI) is the use of the potential embedded in adaptive management systems.

One of the means of achieving the greatest effect in the use of management reserves in the specified sector of the economy is the implementation and certification of a quality management system – in accordance with the requirements of ISO 9000 international standards. The mentioned management component allows to improve the quality of medical care organization management through the introduction of modern technologies of quality management of all processes and activities that, in turn, focus the MPTI leadership on adapting the process approach (according to ISO 9000) to providing medical services in order to raise the satisfaction of the needs of all stakeholders [1]. There is considerable interest to the problem of improving the medical and organizational forms of quality of medical care.

To curb the cost of medical care, it is necessary to either sacrifice its quality, which, as we understand it, is unacceptable, or to develop a system that will reduce this cost without loss of quality. These original quality assurance systems are being developed in healthcare technologies across countries.

2. Statement of the problem

To date, among medical professionals, there are three basic models of quality assurance in health care institutions: professional, bureaucratic and industrial.

The "Professional model" was for some time the basis of the quality assurance systems in medicine. The quality of medical care depended entirely on the skill of the doctor, whereas the user of a health institution was not responsible for the consequences of treatment and was intended only to create the necessary conditions for work [2, 3].

At the heart of modern "bureaucratic model" of the quality management system of healthcare technology is standardizing the volume and nature of medical services with the subsequent examination of the final result.

Today, the models of quality management of medical services in public health practice are based on the so-called "bureaucratic model" to assess the level of quality of care, that is, on the accordance of treatment methods to modern officially accepted standards and protocols of patient treatment. But experience shows that this approach often makes it impossible to identify objective reasons for typical cases of insufficient quality of treatment, significantly hampering successful implementation of the continuous quality improvement system in medicine.

Sources [2, 3] present the data on the so-called "industrial model" of treatment quality assurance. At this time, they are not sufficiently developed and quite sophisticated for practical use, since there are no criteria of readiness of health facilities to implement "industrial models" and no effective sequence of implementation of such forms of governance is developed. Therefore, these models can be used in a limited number of health facilities, with obligatory support of the highest management body of public health. However, as discussed in [2], "in today's environment this is the industrial model that is the most promising for the implementation of the quality management system" [2, 3, 4].

The authors consider it expedient to consider the concept of constructing the so-called "cybernetic approach" in the task of health care management. The attractiveness of the proposed "cybernetic approach", according to the authors of this development, should take the requirements of the international standards of the ISO 9000 series into account and be based on the traditions of modern management within the implementation of technologies of continuous quality management of products.

3. Problem solving

The model suggested in the paper (namely the “cybernetic approach”) should cover the positives of all three of these models and should contribute to the following criteria:

- be manifested in the optimization of strategic planning;
- ensure optimal financing;
- improve remuneration systems;
- provide an assessment of the effectiveness of the MPTI and its departments’ activities based on the technology for improving transitional transformations in strategic planning.

For these transformations in any health care system and every MPTI, it is necessary for doctors to be ready to understand and accept the essence of new requirements for the creation of new technology for medical services quality management and its practical implementation. For the effective organization of medical services quality management, it is necessary to clearly organize the entire relevant process based on the modern achievements of the quality management system.

4. Example of assessing the degree of compliance of a medical and preventive treatment institution (MPTI) with ISO 9001 requirements

4.1. MPTI choice to analyze the degree of compliance with the efficiency requirements of an MPTI quality management system

The aim of the paper was to trace how the disease diagnosis system was built into the activity of the MPTI and to what extent it met the requirements of the ISO 9000 (in this case ISO 9001) standards. The selected MPTI meets the following conditions:

1) the form of ownership is non-state, that is, private or a limited liability company, since in this case the management may or may not take the ISO 9001 provisions into account;

2) The MPTI’s history is long enough to have its traditions, clients, image in the Ukrainian market, as well as its "niche" in the labor market. Here it is interesting how much the PPE is ready to change its well-established quality management system;

3) the MPTI should be engaged in a type of activity that is developed in the country and has enough competitors in the field;

4) it is also known that the following has been implemented in Ukraine: in accordance with the requirements of the Ministry of Health of Ukraine Decree No. 1116 of December 20, 2013, regarding the change of criteria for state accreditation of healthcare institutions (and in particular, for obtaining a higher category in a particular medical institution) quality management system in accordance with DSTU ISO 9001: 20015 standard must be implemented and certified.

Thus, it becomes impossible to obtain a higher category for a healthcare facility without obtaining the appropriate ISO 9001 certification.

Therefore, the MPTI under research may not yet be certified in accordance with ISO 9001, but the enterprise strategy must meet the requirements for the development and improvement of the enterprise.

As an example of a medical institution that satisfies the above criteria, one can choose the Clinic of active therapy of special conditions ("ATOS") [6, 7], which specializes in the treatment of addictions and psychological dysfunctions.

The profile of the ATOS clinic includes comprehensive specialized care for persons with specific diseases (drug addiction, alcoholism, gambling, tobacco smoking, medication (food) addiction, interpersonal addiction, phobias, depressions, sleep disorders, chronic fatigue syndrome, other dysfunctions, with the influence of chemical and psychological factors, disorders of the central nervous system (CNS)).

The ATOS clinic pays great attention to the prevention and restoration of the optimal state of the body after intoxication, physiological and mental overload [7, 8]. The medical activity in this clinic is carried out in accordance with the license of the Ministry of Health of Ukraine.

Data on the composition of the clinic staff:

– number of staff - 20 people;

Head of the Clinic - Yuriy Pakin, Professor, Supervisor, Doctor of Medical Sciences;

– availability of subject matter experts: narcologist - 3 persons, psychologist - 3 persons;

number of medical staff - 7 paramedics, including 2 specialists - paramedics of the highest qualification category;

– support staff - administrator, technical staff.

At the invitation of the ATOS Clinic, Department 265 of the Cybernetics Institute conducted a study of the methods of diagnosis and treatment accepted and operating in the clinic for compliance with the European standards in the relevant

clinic profile branch in order to evaluate the possibility of certification of the quality management system of the ATOS Clinic according to the DSTU ISO 9001: 2015 standard for the highest category for a healthcare facility.

A modern medical institution, including the ATOS Clinic, can be conditionally represented as a complex system that determines the interaction of the staff, information flows, pharmaceutical products, as well as the use of modern devices, equipment and rules for conducting diagnostic and medical procedures. In order to achieve high health care outcomes, these complex elements of the system should be coordinated accordingly. Management and coordination of the interaction of these elements and processes are the most important management functions in organizing a quality management system for medical services.

4.2. Disease diagnosis and treatment methods the ATOS medical clinic

Schematically the steps of the suggested methodology are shown in Figure 1.

The first stage: obtaining the primary information (in this institution):

1) methods of diagnosing and testing of diseases in the clinic:

1.a) The first patient's visit personally or accompanied by relatives - assessment of the patient's state roughly visually with the involvement of the doctor's personal experience: listening to the patient's companions on the history of his disease in the following three sections of information:

- when the signs of the disease were discovered (alcohol, drug, medication, food, interpersonal, gambling, computer and a number of other addictions; psychological disorders - depression, phobias, sleep disorders, dysthymia (persistent depressive disorder), panic attacks, impairment of memory and attention ...);

- objective information about possible genetic disorders in family members;

- risks - the patient's propensity to suicide / aggressiveness towards others / the untruthfulness of the self-esteem / willingness or unwillingness to be treated;

1.b) immediate undergoing of medical tests and taking test samples with the support of medical personnel;

1.c) hospitalization in the form that corresponds to the identified severity and nature of the disease.

The second stage: analysis of the received primary information (in the facility) by physicians and development of treatment methods.

The third stage: treatment process with the developed and approved methodology.

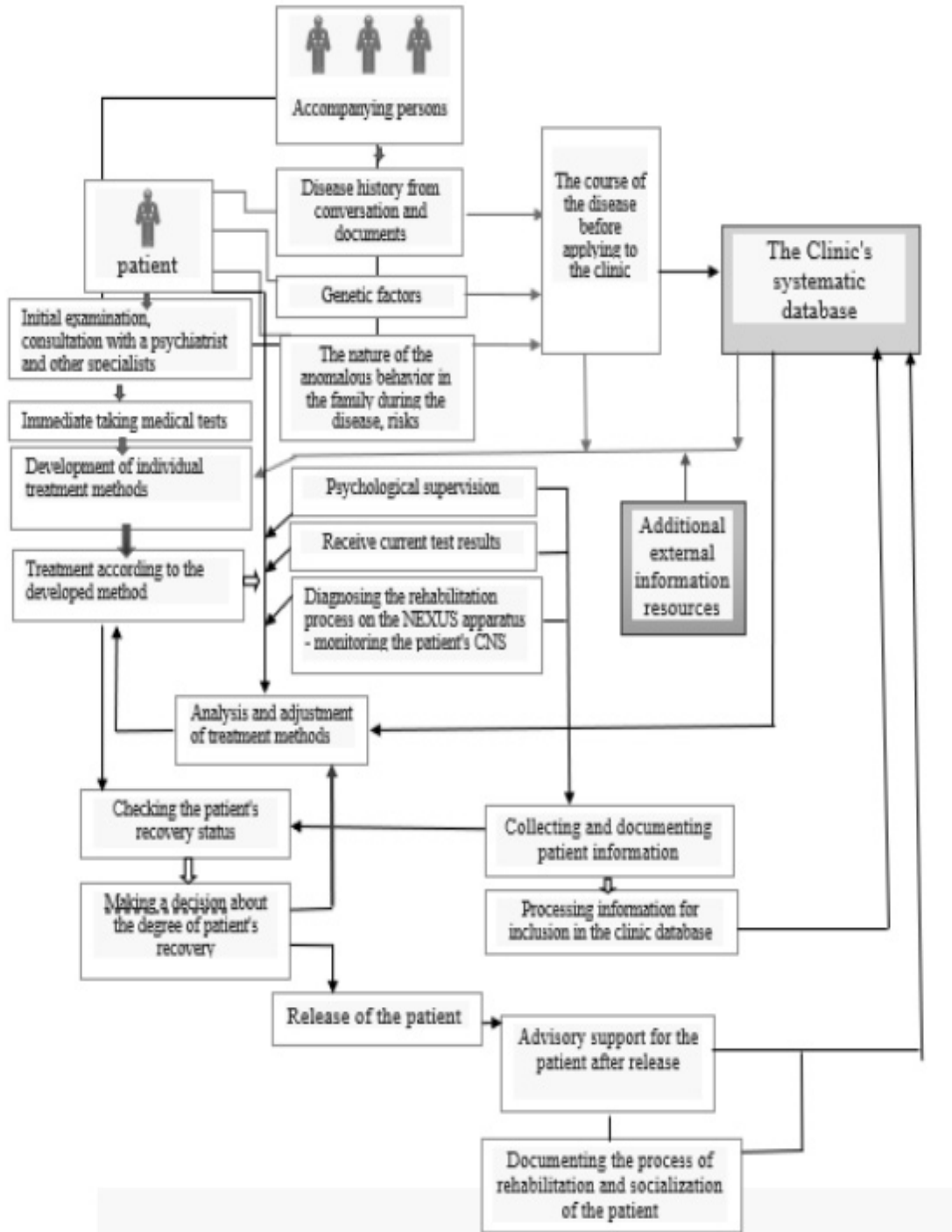


Figure. 1.

The fourth stage: the conclusion about the results of the patient's treatment and about the possibility of their release after treatment. There is a possibility of erroneous decisions by hospital staff in the interpretation of patient's the current state after completion of treatment in accordance with the third stage and assessing the patient's condition by their relatives. Evaluation of the actual situation by doctors based on the relatives' requests to discharge the patient due to "the sensation of his recovery" is a

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risk zone for further health loss by the patient and the development of disease recurrence.

The fifth stage: consultation support of the patient after discharge, with documenting of the process of rehabilitation and socialization.

Methods of diagnosis and treatment in ATOS Clinic

4.3. The way the principles of ISO 9000 are taken into account and fully used in the formation of the structure and functioning of medical institutions and systems of disease diagnosing

Principle-1. "Customer orientation". In this case, the consumer is a sick person who came on their own or at the insistence of relatives for diagnosis and treatment (that is, the patient or those persons who accompany them and look forward to their successful treatment). And the MPTI should focus on their needs. The specificity of MPTI, which will be considered here, is that requests or complaints of the patient may differ (in connection with his possible inadequacy due to the main disease) from the demands of the accompanying persons. A sick person, being under the influence of factors of the disease in a state of psychological disorientation, usually does not recognize the problem and may not want to be treated or, recognizing the problem, ceases to fight it and so is brought to the habit of dispensing the fragmented symptomatic medication that does not eliminate the disease and ultimately leads to the deepening of the crisis process. As a rule, in this case, there are behavioural (psychological, emotional) dysfunctions, in which the patient refuses to change their style of behavior and lifestyle and to get treatment, despite the obvious seriousness of the situation for health, ignoring the offered help in solving the problem.

Therefore, adhering to Principle 1, it is necessary to carefully carry out the primary stage of the survey to determine the diagnosis and assess the severity of the disease, and set goals for specific treatment of the disease.

Principle 2. Leadership. The management of this medical institution establish the unity of purpose and directions of activity of the organization. They should create and maintain an internal organizational and psychological environment in which facility employees can be fully involved in the organization's tasks, guarantee the design and implementation of internal and external processes in such a way as to maximize efficiency.

The ATOS Clinic's management defines the policy for the development of hospital treatment, showing proper professionalism and experience in diagnosing and

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treating patients (especially in the field of the clinic's specialization), as well as in the field of underlying diseases of the patient.

Principle 3. Staff Involvement. According to the policy of the clinic's management, the organizational structure of the medical team, its composition in terms of number, qualification and profile, should be optimal. Employees of such a medical facility at all levels are the basis of the clinic, their full involvement will enable the organization to profitably use their abilities. In accordance with ISO 9001 standards, a quality management system must ensure that the personnel involved in the work is qualified and capable of performing the activities for which they are intended. At this time, this may be the case, but the clinic's management may insist on expanding its operations, but not only extensively, but also in terms of expanding the scope of services provided. These new services should, in particular, be the answer to the new "diseases" of our civilized society: the spread of Internet addiction, depression of complex origin, overload at work, and more. On this basis, it is necessary to consider the prospects of additional staffing of the medical team with new specialists. It may also be crisis psychologists, psychotherapists, and hypnosis specialists.

Principle 4. Process Approach. The implementation of process approach in the practice of ATOS clinic. The clinic's activities in terms of quality management and implementation of the process approach are considered as a chain of life-cycle processes of the results of this hospital's activity, namely positive consequences of the services provided. It is a set of sequentially interconnected processes that begin with the patient's requirements and end with satisfying those requirements.

The following table illustrates the compliance of the processes used in the diagnosis and treatment of patients according to the cybernetic criterion for the development of the MTPI operation methodology and ISO 9001 principles [1].

Conformity of processes according to the method of treatment with cybernetic criteria for developing a quality management system and ISO 9001 principles

Treatment methods	Cybernetic criteria and sub-criteria for developing a quality management system	ISO 9001 principles
<p><u>The first stage:</u> obtaining primary information for the anamnesis (obtaining the most reliable information from different sources - patient and accompanying persons)</p>	<p>Compatibility of the management system and the management object. Reducing of system uncertainty as a result of information receiving</p>	<p><i>Principle 1.</i> Consumer Orientation - Consumer awareness and assessment.</p>
<p><u>The second stage:</u> the analysis of primary information obtained by physicians (in this medical institution) and development of treatment methods.</p>	<p>Using the principle of modeling, i.e., transfer of information to the system obtained by examining its model (the model is the patient, as a set of data about him is what exactly is called the anamnesis of the patient. The method of treatment, however, applies to a specific person - the patient). Using the principle of hierarchy in the development of systems (treatment system involves the creation of the patient's disease hierarchy according to their severity - basic and related). Use of acceptability and optimality principles in evaluating system performance.</p>	<p><i>Principle 6.</i> "Testimony-based decision making". - the decision about the method of treatment is derived on the basis of anamnesis</p>
<p><u>Third stage:</u> the treatment process according to the developed method. Combining different types of effects on the patient in the methodology - pharmacology, physiotherapy, psychotherapy, etc. Establishing a trusting relationship between staff and the patient and his or her relatives in order to achieve the focus on treatment effectiveness through consistent adherence to the treatment plan.</p>	<p>Increasing complexity of the managing system with increasing complexity of the managed object. Use of principles of system integrity, emergence (irreducibility of system properties to the sum of properties of its components) and synergism (interference). Use of principles of acceptability and optimality in evaluating the effectiveness of the system under consideration.</p>	<p><i>Principle 7.</i> "Relationship management". <i>Principle 3.</i> "Staff Involvement". <i>Principle 4.</i> "Process approach". <i>Principle 5.</i> "Improvement".</p>

Treatment methods	Cybernetic criteria and sub-criteria for developing a quality management system	ISO 9001 principles
<u>Fourth stage:</u> Conclusion on the results of the patient's treatment and the possibility of his discharge after treatment.	Use of principles of acceptability and optimality Development of management systems based on the principle of feedback.	<i>Principle 1</i> "Customer orientation". <i>Principle 6:</i> Decision-making based on testimony.
<u>Fifth stage:</u> patient counseling after discharge, documenting the course of his rehabilitation and socialization.	Use of principles of acceptability and optimality Development of management systems based on the principle of feedback.	<i>Principle 1</i> "Customer orientation". <i>Principle 4.</i> "Process approach". <i>Principle 6.</i> "Testimony-based decision making".

Principle 5. "Improvement". The management should consider their constant aim a continuous clinic activity improvement as a whole. For example, at this time Department 265 of Glushkov V. M. Institute of Cybernetics (the head of the Department prof V. G. Pisarenko) is carrying out scientific work in their activity field together with specialists of the ATOS clinic in Kyiv. Department 265 has professional experience in modern methods of mathematical modeling of basic functions of the human and mammal brain. It uses the results of the patient's condition interpretation based on diagnostic methods and mathematical modeling of a person's physiological state basic parameters that appear in the results of the human central nervous system testing based on the conclusions of studying the integrated model of patients' CNS and registered deviation values of basic physiological state parameters from the optimal values. The patient's physiological indicators, including basic information about the functioning of the Central nervous system, are recorded at the beginning of the treatment, during the treatment periodically, and following the results of treatment. This methodology was developed in Department 265 of V. M. Glushkov Institute of Cybernetics of the NAS of Ukraine based on theoretical developments and recommendations of this Department of the Institute of Cybernetics together with the ATOS clinic. The created methodology has also been practically tested in many joint experiments conducted in the ATOS clinic based on appropriate theoretical developments by Department 265 of the Institute of Cybernetics of NASU. Their results are reflected in scientific journals and spoken at specialized scientific conferences with participation of specialists of the clinic and V. M. Glushkov Institute of Cybernetics of NASU [5], [6]. [7], [8]. [9], [10].

Specialists of the ATOS clinic are constant participants of international and domestic conferences and medical seminars on the treatment of particular human conditions. In 2016, a monograph by Y. V. Pakin was released: "Treatment of addiction: factors of success".

Principle 6. "Decision-making based on evidence". It is clear that effective decisions are based on the analysis of the collected information. But the main difference between the activities of the organization implementing the quality management system, from the traditional organizations should be implemented by the management in the phenomenon of the continuous gathering of information about the efficiency of processes at all management levels. In the ATOS clinic, there is a practice of carefully gathering information and documenting it, both at the initial examination of the patient and during each stage of his treatment and subsequent socialization.

Principle 7. "Relationship management". According to the ISO 9001 standard, relationship management should include all stakeholders of the organization, such as customers, patients, staff, partners, investors, suppliers, society in general, etc.

In addition, the principle of "relationship management" should not be based on internal control, penalties and punitive sanctions, but on the formation of moral and material motives to the processes of diagnosis and treatment of patients among the MTPI personnel that, as a result, will contribute to the continuous improvement of medical service quality. For example, a small number of medical staff in the ATOS clinic dictates their attitude to this issue: the staff constitutes a single "team" targeted at the important and clear final result. Each member of the team understands their purpose and is interested in achieving the goal.

The structure and function of technology management systems for the rehabilitation of patients have a theoretical grounding in scientific papers [5, 6] carried out jointly by specialists of V. M. Glushkov Institute of Cybernetics of NASU (IC NASU) (Head of Department 265 IC NASU, Professor, Doctor of Physics and Mathematics V. G. Pisarenko). and the staff of the ATOS clinic (academic director Y. V. Pakin, Professor, doctor of Medical Sciences). To develop the mentioned patient rehabilitation technology management system, relevant research was conducted at the ATOS clinic with the use of modern innovative medical equipment.

5. Conclusions

The analysis of the management system in the medical institution in question allows to conclude that it is based on the so-called "professional model" of the quality

management system. The clinic is represented by several leading experts who have brilliantly proven themselves with a high level of professionalism in the prevention and treatment of patients' special conditions. However, high level of professionalism of the clinic's medical staff cannot be the means that certainly ensures the quality of the services provided in all cases. Clinical manifestations of special conditions are taking on new forms, requiring the use of innovative treatment technologies that are impossible without the use of the most up-to-date diagnostic and treatment equipment complex.

The following weaknesses were identified in the quality management system in the healthcare facility under consideration and the following recommendations were provided:

- in order to improve the quality of health care, a high level of individual professionalism must be complemented by state-of-the-art diagnostic and treatment tools that allow for high-precision measurements and the introduction of new management methods;

Department 265 of IC NASU in cooperation with the ATOS clinic provides support and improvement of technologies used in the ATOS clinic to diagnose the current CNS state of the clinic's patients at all stages of establishing a patient's diagnosis (both during the initial examination and in the course of treatment of the CNS reaction with the use of specially developed tests based on mathematical developments by VG Pisarenko [9, 10]). They implement the technologies developed jointly by the specialists of the and Department 265 of IC of NASU. This refers to the author's system of testing the current state of the patient's central nervous system based, in particular, on the system and correlation analysis of the observed dynamics of complex indicators of the current state of the patient's body obtained in the ATOS clinic. These indicators of the patient's condition include, in particular, registered electroencephalograms, the results of his cognitive testing, indicators of the state of his organism observed by a special author's hardware complex in the course of his treatment (including monitoring of the dynamics of his CNS condition, circulatory system, etc.).

Now in the IC NASU one of the authors is currently developing mathematical models for the functioning of the living brain as a system with a delayed argument. [9, 10].

In particular, mathematical models of conditioned reflexes of patients with the use of differential equations with a delayed argument have been developed.

Based on the results already obtained, further improvement of the expert-diagnostic system of support for the rehabilitation of addictive patients according to the

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results of the analysis of electroencephalograms and a set of other physiological parameters of the patient's body condition is expected. The next step is a software-based system for adapting the treatment method to changes in the patient's current state.

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