

БІОМЕДИЧНІ ВИМІРЮВАННЯ ТА ПРИЛАДИ

MANAGEMENT DECISIONS IN CLINICAL LABORATORY DIAGNOSTICS

УПРАВЛІНСЬКІ РІШЕННЯ У КЛІНІЧНІЙ ЛАБОРАТОРНІЙ ДІАГНОСТИЦІ

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Анотація. Сучасна медицина, на жаль, не позбавлена помилок. Тому існує ймовірність непередбачуваних ускладнень, встановлення неправильного діагнозу, а як наслідок – некоректне лікування. Розв'язуючи різні медичні завдання (збирання інформації щодо хворого, діагностика, вибір тактики рішення), лікар стикається із проблемою прийняття рішень, до того ж постійно зростають вимоги до точності діагнозу і його достовірності, інакше кажучи, до його істинності. Науковий підхід є основним інструментом у процесі пошуку істини, і, отже, під час прийняття рішень. Відповідно до сучасної моделі прийняття клінічного рішення компетентність лікаря визначається знанням механізмів захворювань і клінічним досвідом, умінням оцінювати і використовувати у практиці наукову інформацію. Клінічна лабораторна діагностика – це особлива індустрія надання медичних послуг. На результатах лабораторного обстеження пацієнта ґрунтується близько 80 % інформації, необхідної клініцисту для підтвердження чи встановлення діагнозу.

Стратегія розвитку клінічної лабораторної діагностики повинна підпорядковуватися загальній концепції розвитку охорони здоров'я та її діагностичній доктрині. Йдеться про послідовну структурування високотехнологічного виробництва, що охоплює клінічно й економічно обґрунтовані дії з відповідними організаційними рішеннями, штатним і матеріальним оснащенням, уніфікованою документацією. Управлінські рішення в медицині можуть істотно впливати і на загальний фінансовий стан медичного закладу, результати показників лікувально-профілактичного процесу, і на життя багатьох пацієнтів та працівників. Управлінська робота обов'язково пов'язана з прийняттям рішень, адже це вибір певної дії із безлічі можливих варіантів. Необхідність прийняття рішень є обов'язком у діяльності менеджера з управління організацією, починаючи від формулювання цілей і завершуючи їх досягненням.

Ключові слова: охорона здоров'я, ризик, діагностика, підтримка і реалізація рішень.

Abstract. Unfortunately, modern medicine, unfortunately, is not without errors. Therefore there exists a probability of unpredictable complications, establishment of an incorrect diagnosis, and in consequence and improper treatment. When dealing with various medical problems (collecting information about the patient, diagnosis, choice of solution tactics), the doctor faces the problem of decision - making. At the same time, the requirements for the accuracy of the diagnosis and its reliability are constantly increasing. The scientific approach is the main tool in the process of finding the truth, and, consequently, in the decision making process.

According to the modern model of clinical decision making, the competence of the physician is determined by knowledge of the mechanisms of diseases and clinical experience, the ability to evaluate and use scientific information in practice. Clinical laboratory diagnostics is a special industry of providing medical services. The results of the laboratory examination of the patient are based on about 80 % of the information of the necessary clinician to confirm or establish a diagnosis. The strategy for the development of clinical laboratory diagnosis should be subordinated to the general concept of health care development and its diagnostic doctrine. It is about the consistent structuring of high - tech production, which includes clinically and economically sound actions with appropriate organizational solutions, staffing and material equipment, and unified documentation. Management decisions in medicine can have a significant impact on both the overall financial health of a medical institution, the results of the indicators of the treatment prophylaxis, and the lives of many people who work there and receive assistance. Management work is necessarily linked to decision-making, because it is the choice of a particular action from the set of possible options. The need for decision-making is the responsibility of the management of the organization management, from the formulation of goals and to their achievement.

Key words: Healthcare, Risk, Diagnostics, Support and implementation of solutions.

Introduction

Under the decision-making understand the special process of human activity, aimed at choosing the most appropriate solution to the problem. An example is

the decision-making process on the type of the disease, based on known source information (results of analyzes, external manifestations of the disease), or solving the problem of so-called, group choice decisions, where the

main task is to indicate “fair” principles of individual accounting elections leading to a reasonable group decision. Medicine is a weakly structured knowledge industry, which creates serious difficulties for the decision-making process. In some cases, characterized by classical manifestations of the disease, the hypothesis or even the final decision arises already in the process of examination, in others - only after a special examination. It is important to note that the sequence of diagnostic studies can be subject to correction, and sometimes radical transformation, depending on the results obtained in the process of examination. The speed of decision-making depends on the qualifications and diagnostic “senses” of the doctor, and on the peculiarities of the manifestation of the disease in a particular patient. Today, the development of intelligent decision support systems based on medical information systems [1] is relevant today. The main approaches, tools and principles of developing an intellectual decision support system. The human body is a biological system with numerous and inexperienced interconnections between elements and habitats. Clinical and laboratory parameters of the patient are in a complex relationship with each other. In most cases, the state of the patient can not be judged not by the importance of individual indicators, but by combinations of a large set of the most informative of them.

To identify such indicators and after combining their values to “recognize the image” of the disease or to identify the severity of the patient's condition can only be using methods of system analysis, in particular statistical analysis of data.

Clinical and laboratory parameters of the patient are in a complex relationship with each other. The Clinical and Diagnostic Laboratory (further – CDL) is a technological complex - specialized production of a larger enterprise - polyclinic or inpatient institutions, and more recently as independent institutions within the city, regional health services of Ukraine. The functions of the laboratory as an integral part of the treatment and prevention institutions medical treatment facilities anticipate the provision of the laboratory information (analysis results) [2]. The head of the CDL should ensure that the laboratory conforms to the nomenclature, quality and productivity according to the needs of the medical institution. However, for the time being, this is not enough. Acceptable efficiency of the selection process for analysis depends on the choice of equipment, a combination of automated and manual methods of research, division of labor, quality management, accounting and rational use of material resources, etc. From the technological complex as part of the company, the laboratory gradually becomes an enterprise within the medical treatment facilities area. In this regard, the

economic efficiency of CDL activity, which is determined by economic expediency, appears on the foreground. Nomenclature and scope of research are subject to the adoption of management decisions, and the source of renewal of fixed assets – the laboratory itself. Such conditions of CDL activity are a guarantee of development in the market of laboratory services. Responsible task of the head of this body is to strengthen the position of the laboratory in the market through the effective use of available resources. An important role in solving managerial problems is played by different decision support systems.

The purpose of the work

The aim is the analyze of the methodology of manager decision-making in the clinical laboratory diagnostics, affecting the correctness of the analysis with the sequence of diagnostic studies, their transformation, depending on the obtained results, and consideration of the expediency of decision-support systems based on available medical information.

Results of research and their discussion

Health informatics creates the preconditions for exploring and developing decision support systems. Today, under the conditions of rapid development of informatization of health care, by means of automation of the work process, the implementation of the informational system of support for the adoption of management decisions for improving the quality of medical care provision and document circulation is directly relevant to the implementation of the latest medical standards [3]. The process of laboratory research, its comprehensive informatization and increase of the economic efficiency of the CDL activity are closely interconnected. The role of the CDL leader in these processes is extremely high. The main way to improve the quality of the results of laboratory analyzes and to reduce the cost of their production is the optimal management of production processes, which should be standardized and available for control. The consequence of this organizational transformation should be the separation of traditional and new management functions between several CDL managers working in the commercial laboratories.

The costs of laboratory studies and the definition of criteria for assessing the efficiency of the CDLs define the existence of laboratories in modern conditions. It seems impossible to exclude the pursuit of the correct way in the clinical laboratory diagnostic service reforming. It has to determine the direction of development and find the assuring means. This will be the first correct step of the CDL to a real autonomy, where, in future, financial results, clinical and economic justification and effectiveness will become the main

criteria when making managerial decisions. Simultaneously, solutions are searching for the complex issues. Comprehensive informatization of the CDL activity is the only real way of solving them.

An important factor in the work of the information system is the ability to transfer data to other institutions and management bodies through the network structure. Since the format of data storage in systems may differ, the necessary condition for completeness, security of transmission of medical data is the application of standard forms. Currently, there are several popular standards for managing, storing and sharing medical data. The well-known ones include HL-7 CDA and open EHR. The HL-7 standard is a worldwide standard for sharing, managing and integrating medical information [4]. One of the factors inhibiting the active use of medical information systems is the complexity of assessing their effectiveness, which is far from always can be expressed in figures, as it is practiced in the workplace.

Efficiency or achievement of any concrete results with the minimum possible expenses is the next factor. In assessing the result of automation of health facilities, three main components of effectiveness are distinguished - clinical, organizational and economic [5]. The methods and principles that guide a health-care system manager in their practice are also altering. Instead of policy guidance and control over activities that are characteristic of the hierarchical structure, modern managers take the position of discussing and developing common management decisions in professional groups that include not only practitioners but also health organizers.

In order for an administrative decision to be effective and to ensure the achievement of goals, it must satisfy a set of specific requirements [6], namely:

- Clear target orientation - targeting the achievement of a specific goal or goal system;
- Ability to solve a complex of problems of political, economic, demographic and environmental nature.

The development of new medical technologies and raising the level of education in health matters contributes to increasing the cost of medical care and raising the expectations of citizens regarding their quality [6, 7]. The human body is a biological system with numerous and inexperienced interconnections between elements and habitats. CDL parameters of the patient are in a complex relationship with each other. In most cases, the state of the patient can be judged not by the values of individual indicators, but by combinations of a large set of the most informative ones. Identify such indicators and after combining their values to "recognize the image" of the disease or to identify the severity of the patient's condition can only be using methods of system analysis, in particular statistical analysis of data [8]. Comprehensive reason for a management decision

requires the use of sufficiently complete and reliable information on the state and methods of development of the medical system or institution and the environment, the degree of compliance with the decision taken for development. In real conditions, the manager always faces the need for a decision in the limited information, since no information can fully reflect the real status of the elements of the institution, the totality of all external conditions. In this case, the experience and intuition of the manager, his professionalism plays an important role. It should be guided by such concepts as:

- Addressing – A clear focus on a specific managed object and specific performers, on their capabilities, qualifications and competencies. Consistency with previously adopted decisions – contradiction in a consistent set of decisions, the need for their constant adjustment or adaptation testify to the incompetence of management, the weakness in the processing of available information;

- Eligibility – compliance with the rights and powers granted to the body or person, which implies a balance of rights and responsibilities of all levels and authorities. Violation of this requirement for management decisions substantially affects the effectiveness of their implementation, both in case of overestimation of powers, and in the case of substitution of duties by subordinates;

- Efficiency – the minimum need for resource support in developing a management solution and its implementation in order to achieve the desired result. The managerial decision in the healthcare system, which is not targeted to the needs of patients, is not differentiated depending on the intensity of medical care, but aimed at maintaining health facilities with a high level of development of highly specialized and specialized medical care, leads to inefficient use of resources and poor quality of medical care;

- Timeliness – the management decision should be made not earlier, but not later than the necessary terms. A premature decision falls on an unprepared ground (organizational, psychological, material, and etc.). In this case, the effect may be insignificant or even the opposite of the expected. A delayed decision is also practically ineffective, moreover, may have a negative effect that discredits a manager or management body;

- Completeness, conciseness, clarity – a set of components that cover all aspects of the solution's impact (the purpose, means and resources used to achieve the goals, the main ways and means of achieving them, the timing, place of work and management at all stages and stages of implementation decisions). Management decisions must not contain unnecessary, minor details that are not relevant to the merits of the case. The clarity of managerial decisions eliminates the ambiguity of interpretation, uncertainty of the powers of the performers, their rights and responsibilities;

• **Compromise** – an agreement based on mutual concessions. In practice, it is rarely possible that a managerial solution, especially complex, would have no negative consequences. At the same time, achieving good results in achieving all possible goals almost never fails. Thus, almost all managerial decisions are

based on a compromise between positive and negative results.

Responsibilities that rely on a manager in modern conditions require him to possess managerial skills in solving problems. This process consists of a series of stages shown in Fig. 1 [5].

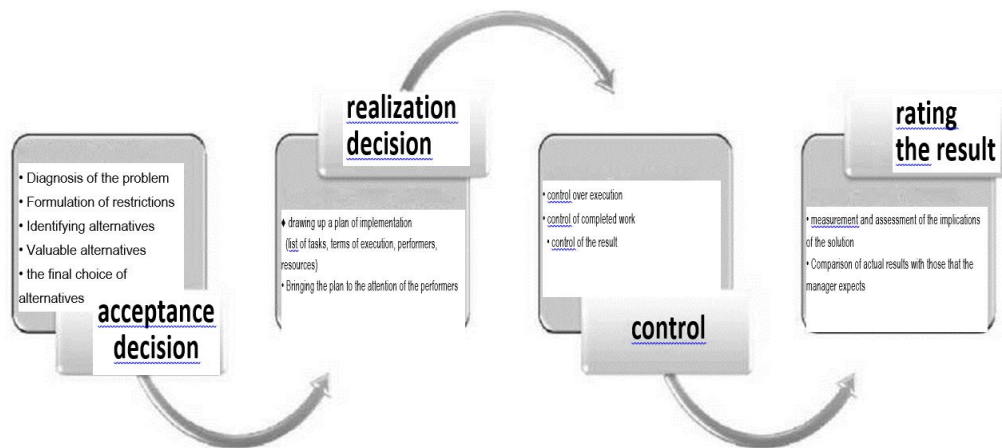


Figure 1. Decision-making process by Healthcare Manager

While decision-making, it becomes necessary to choose a strategy of medical technology that is optimal comparing with others. The absence of natural counteraction makes the situation qualitatively different. The simplest case for choosing a solution in dealing with nature is a case when some of the strategies clearly outperform others. This dominant can be evaluated in terms of clinical efficacy, better safety or economic feasibility. Obviously, in this situation, it is necessary to introduce such indicators that would not only give a win in this strategy, but would reflect the “success” or “failure” of choosing this strategy in this situation for mathematical reasons. To this end, the concept of “risk” is introduced in the decision theory. The risk of a person deciding to use a particular strategy under uncertain conditions is the difference between the winnings (the result, the indicator of efficiency) that would have been obtained, if known conditions, and the winnings, under conditions of uncertainty.

Consequently, there are two sets of solving issues, or two possible scenarios: the first, we would prefer to get the maximum profitability; the second one consists in a minimal risk. Of course, optimal would be the maximum profitability with minimal risk. Thus, when making a decision, choosing technology would bring in the question of what you need to get: the maximum profitability at a rather high risk, reduce the risk as much as possible with a relatively low result or choose a “golden mean”. An intuitive solution is an option based solely on the feeling that it is correct. At the same time, the decision maker does not deliberately weigh all “pros” and “against” for each alternative, that is, he does not understand the situation. The chances

for the right choice without the application of logic are low. Judgment-based solutions are a choice based on the knowledge and experience gained by the decision-maker. An expert always relies on his own experience, his colleagues' experience, which can be largely correct and include elements of a scientific approach. However, the excessive focus on experience changes the solution, which may lead to the loss of a new alternative that would be more effective than familiar choices. In his professional activity, the doctor is constantly faced with situations in which information is not complete and only indirectly related to the fact that he really needs to know about the patient. In such cases, the physician is compelled to make a decision about the diagnosis and treatment in the conditions of uncertainty, inaccuracy, fuzziness, immaturity, vagueness, obtuse, ambiguity, non-specificity, or falsehood. Obtaining the additional information, doctor tries to reduce uncertainty. The diagnosis and choice of action are the terms applied in the decision-making process of human activity (Fig. 2).

In medicine, they are equivalent to the terms of diagnosis and treatment. The decision-making processes regarding the diagnosis, the choice of treatment are most closely related and should be considered together. As noted above, additional information is not always a sufficient condition for removing the uncertainty faced by a doctor when dealing with a particular patient. Therefore, it is very important to choose a method that would help the physician to make the most effective decision on the diagnosis and choose the best treatment. The term “optimal treatment” lies within the concept of the maximum expected value, as well as the associated

concept of the minimum expected loss and is important in choosing treatment. Referring to the category of problems associated with decision-making technology, the medical diagnosis is inherent in a probabilistic nature and involves testing hypotheses. Attempts to achieve better performance and effectiveness are combined with ethical factors.

Factors determining the quality of managerial decisions are divided into internal and external. Internal factors associated with management. So, the management systems include qualifications of personnel, technology and methods, management culture, sustainability of the management system, susceptibility

to managerial decisions, etc. Among the external factors characterizing the impact of the environment are changes in legislation, the socio-economic situation, the limitation of the resource provision of the process, the coherence of both systems (psychological climate, managerial authority, professional qualification personnel, the state of executive discipline, etc.), a system of assessments of the quality level and effectiveness. In transitional conditions characterized by the instability of the political and socio-economic environment, external factors are dominant in determining the quality and effectiveness of management decisions in health care.

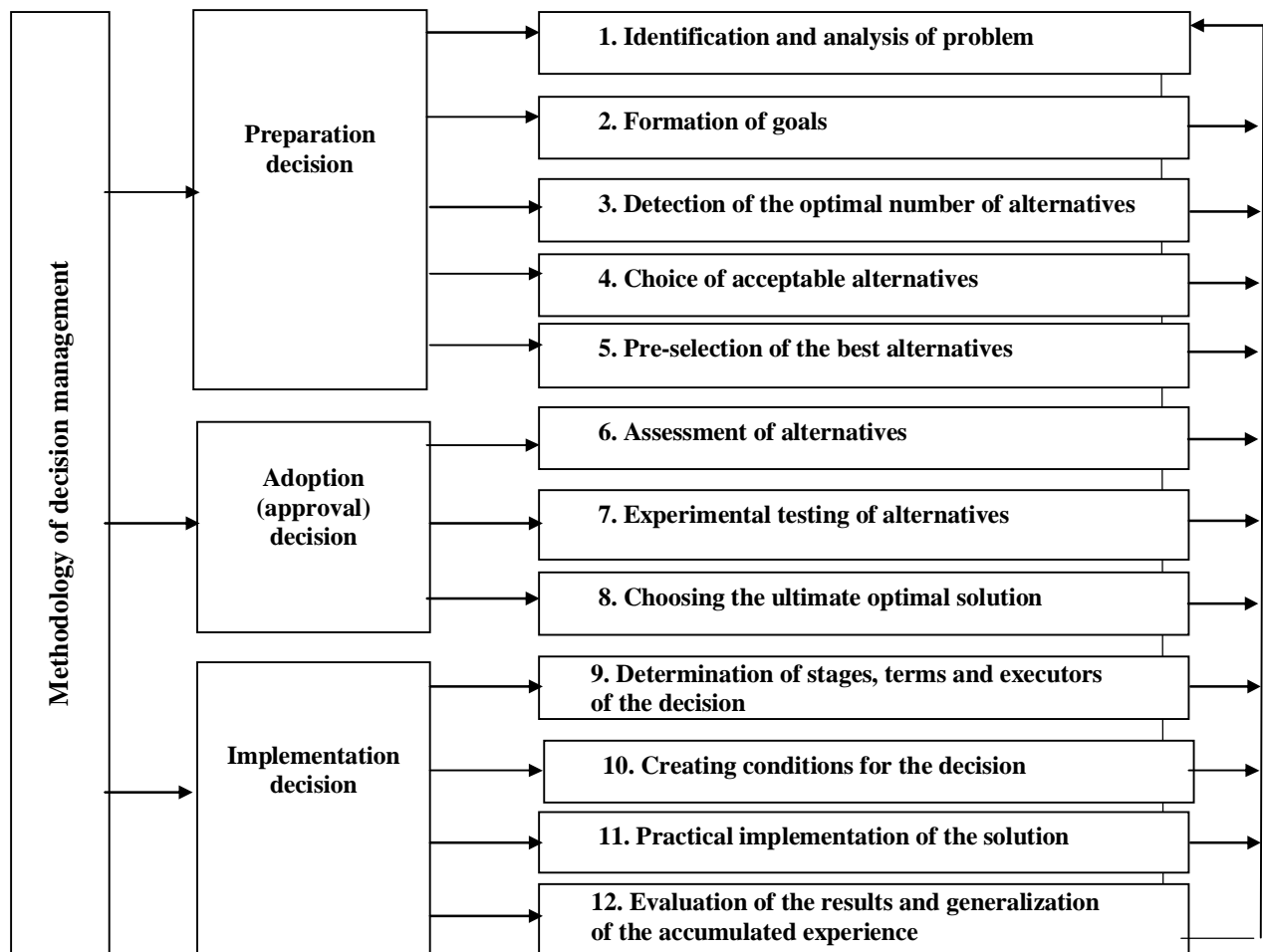


Figure 2. Stages of preparation and approval of managerial decisions

It should be born in mind that almost all managerial decisions are made in a timely manner. That is, in practice, for preparation of decision-making allocated less time than is necessary for the full use of all knowledge or more complete information about the problem situation. It can reduce the quality of the decisions taken as a result of the inability to process all alternatives and inefficient use of resources. Therefore, the main role is complied with temporary detection of problem situations. The decision-making process

consists of five steps: diagnosing the problem, formulating constraints and criteria for decision-making, identifying alternatives, evaluating alternatives, final selection of alternatives. At the first stage, the identification and description of the problem situation to be solved is carried out. The diagnosis of the problem should be complete and correct. Identifying the root cause and source of the problem may require a large amount of information and a thorough analysis. As a result, the diagnosis of the problem is often turned into a

multi-stage procedure with the adoption of intermediate solutions related to:

- establishing the symptoms of the difficulties that help determine the problem in general terms;
- defining the novelty of the problem and the situation in which it arose;
- identifying the causes and sources of the problem;
- considering the possible relationships of the existing problem together with other solved before problems, which allows discover the problem dependence; it permit to classify interrelated problems (main secondary, urgent and non-terminating), contributes to the development of an integrated solution;
- installing of the degree of completeness and reliability of the information necessary for decision making, and the establishment of the possibility of solving the problem.

Concerning the formation of limitations and criteria for decision-making, it is necessary to analyze the resources available in the system that may be needed for decision-making and adoption (temporary, material, labor, etc.) before identifying possible solutions to the problem. At this stage, alternative solutions to the problem are identified and formulated. Ideally, it is desirable to identify all possible actions to eliminate the causes of the problem and thus organize the actions to achieve established goals. However, in practice, the manager does not always have sufficient knowledge or time to formulate and evaluate each alternative. As a rule, he is limited to minimal available choices that are best suited for his aims. At the same time is raising the role of the experience and intuition. Effective can be the development and adoption of collective solutions.

Decision Support System (further DSS) is a system designed to support various human activities when deciding on structured or non-structured problems. DSS provides an objective domain analysis in difficult conditions [9]. The use of DSS in medical practice makes it possible not only to reduce the likelihood of error in the course of prognosis and treatment, but also to simplify the work of physicians. In addition, the application of such systems for correction of treatment tactics is urgent. The mentioned system eliminates the severity of the problem by minimizing the number of errors and their weight. While constructing medical DSS, it needs to take into account the following specific features:

- the human body is an extremely complex functional system, about which we still know not so more. Due to lack of information, medical knowledge has a rather complex structure, which complicates their formalization;
- diseases are prone to natural variability and, as a rule, medical tasks are poorly structured;
- flexible and easy-to-use computer-based methods of medical knowledge are not developed

sufficiently, and formalization of the decision-making procedure is mainly absent;

- diagnostic coding systems are now more versatile, but a detailed range of signs and symptoms, formats for data registration, and the organization of records are determined individually;
- there is no standardization in the terminology, format, and scale of medical data measurement;
- there is much common between patients with the same disease, but each case is deeply individual;
- decision-making in medicine is directly related to human health, therefore, the decisions would be as reliable as possible.

At present, the most promising methods of DSS constructing are expert methods, mathematical modeling, statistical and heuristic methods. It can be conditionally distinguished three stages of creation of expert systems [10]:

- the 1st stage involves the collection and initial processing of information about patients for the medical staff that is directly involved in the treatment. Accumulation and processing of methods for forecasting the course of diseases and possible complications;
- the 2nd stage involves the automation of the collection and processing of information for its analysis by the administration of the institution, health authorities and health insurance funds;
- the 3rd stage is directly related to the creation of a knowledge base and the development of an expert systems which help the doctor in choosing the optimal treatment strategy and tactics by analyzing the completeness of the performed diagnostic and therapeutic measures.

The status of alternatives assessment is considered by the analysis and evaluation of the identified alternative options aiming the solution of existing problem by the established criteria and taking into account the previously defined restrictions. Based on the analysis of the problem and the evaluation of alternatives, the final solution is chosen – an alternative with the most favorable and effective consequences. Decision-making is the choice of the best option from many possible ones. Such a choice is made using established criteria and taking into account resource constraints. This may require additional information. When choosing the final decision, experts can be involved. Implementation of the decision, monitoring and evaluation of the results allow achieve an appropriate level of quality. The task of the manager at this stage of implementation of the decision is to compile a plan for the implementation of the decision, proof of this plan and the decision itself to the attention of the executives, control over its implementation. The plan of implementation of the decision should contain a list of tasks, terms of their implementation, the composition of the executives, the necessary resources. In the process of

implementation of the decision it is necessary to monitor the implementation of the work and the results obtained. Another prerequisite for a successful management solution is to establish feedback, measure and evaluate the implications of a solution, and compare actual results with those that the manager hoped to receive. The results of the management activity are reflected in the documentary design of the management decision. Different types of managerial decisions are made in the form of regulatory documents through which operational management is carried out. The main function of regulatory documents is regulation of activity, which allows the body to manage, to ensure the implementation of the tasks set before it and to obtain maximum efficiency. The decisions fixed in the regulatory documents are aimed at improving the organizational structure, nature, content, means and means of implementing the main activities of the institution, providing it with financial, labor, material, informational and other resources. Such documents include: orders, orders, resolutions, decisions, instructions and decisions.

Conclusions

The development of Ukraine in line with the world standards requires the professionalism and theoretical knowledge in the field of management for the adoption of appropriate, viable and proper managerial decisions. Healthcare requires leaders of an entirely new structure, prudent in responding to a rapid change in the situation, with the knowledge of the legal framework. At the known communication the task to get an expression about the link between the solved problem and the needed means, is almost always solved. If such a connection is not known then another way of displaying problem situations has to be chosen. It can be determined the patterns based on statistical data or functional dependencies. If it cannot be performed, choose or develop the theory that contains a number of statements and rules that allow formulate the concept and construct a decision-making process based on it.

In the absence of a theory, the hypothesis is put forward and basing on it the imitative models are created. Trying to solve the issue in a short time, it is needed to analyze the goals, to identify possible means, to select the necessary information, and then by using the techniques and methods of system analysis to get an expression that links the purpose with the means. Prospects for further research include the development and implementation of measures for enhancing the knowledge on management issues with an assessment of managers' effectiveness. It helps introducing the optimal management decisions, and developing the effective disease prevention programs.

To solve the mentioned tasks, an intellectual decision support system should be set up with the goal of providing personalized health-care system. The latter should be based on the ontologies of clinical recommendations and computer-based knowledge representation. Applying an ontological approach for creating a system is most desirable since it allows describe the obtained from the clinical guidelines knowledge, replenish it, and apply in the decision-making process.

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Conflict of interest

The conflict of interest during the writing, preparation and publication of the article is absent, as well as the mutual claims of co-authors.

References

- [1] Y. Antonova, V. Moskovsky, "Research into the feasibility of using decision support systems in medicine. Analysis of shortcomings and approaches to their elimination", *Sc. Journ. "ScienceRise"*, vol. 11, no. 6, pp. 49–52, 2015.
- [2] T. Shevchenko, P. Polushkin, *Organization of laboratory work with the quality management system of laboratory research*, Dnipropetrovsk National University, Ukraine: 2016.
- [3] V. Kiselev, O. Kovalenko, O. Yakovenko, "Information system for decision making support", *Internat. Sc. Journ. "Internet science"*, vol. 28, no. 6, pp. 45–59, 2017.
- [4] HL7 XML Implementable Technology Specification for Vers.3 Composite Mess. [Online]. Available: <ftp://ftp.ihe.net/International,Europe,HL7%20V2.5,Version%203%20Ballot%20Cycle%204%20>
- [5] I. Laprun, "The effectiveness of the implementation of medical information systems", *PC Week Doctor*, no. 1, March 2008.
- [6] V. Pyshchikov, Y. Mazepa, Y. Yashchenko, "Features of decision-making by managers in health care", *Bull. problems of biology and med.*, no. 2, pp. 301–305, 2015.
- [7] I. Sydorko, R. Baitsar, "Providing quality of clinical-diagnostic laboratory activity", *Meas. equipment and metrology*, vol. 79, no. 2, pp. 53–59, 2018.
- [8] ISO EN ISO 15189: 2015 Medical Laboratories. Requirements for quality and competence (ENISO 15189:2012, IDT).
- [9] P. Bidyuk, O. Gozhii, L. Korshevniuk, *Computer Decision Support Systems*, Kyiv, Ukraine, 2010.
- [10] V. Simankov, "Systemic Approach to the Development of Medical Decision Support Systems", *News of Higher Educational Establishments, North Caucasian reg. Techn. Sc.*, no. 1, pp. 29–36, 2010.