RISK MANAGEMENT IN THE CLINIC – DIAGNOSTIC LABORATORIES

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Abstract. Adopting socially responsible management practices of the organization promotes greater awareness in decision-making, based on a better understanding of society's expectations, anticipation of risks, and opportunities. Responsible management of an organization can improve its relationships with stakeholders. Encouraging compliance with regulatory obligations leads to decisions that are more likely to gain the support and trust of those who implement them and who they influence. The result can be improved risk management practices and improved reputation.

The concept of "risk" today has a fairly broad meaning and is used in completely different contexts. Synonyms of risk can be such concepts as "danger", "threat", "trouble", etc. However, in many definitions of risk in the scientific literature, this term is used in a special sense, where risk is associated primarily with the concept of uncertainty. Therefore, the risk is understood as uncertainty, which can result in one or another adverse event. Clinical risks – risks that arise directly from the provision of medical care. These include clinical errors and negligence, infections in medical care, and non-consent.

The principles of risk management and the need to use them are effectively applied in many areas of economic activity and public administration, including health care, as well as institutions that provide regulatory activities in these areas, including clinical diagnostic laboratories. Today, prevention as management of patient quality of health has become a dominant part of medicine, where laboratory diagnostics, which can detect the risks of many diseases, is not the least important. The presence in the health care system of only certain fragments of activity risk necessitates the formation of an overwhelming majority of an effective integrated risk management system, which must comply with certain requirements and principles: determining the characteristics of the system; optimization of the risk management model of medical structures; substantiation of prerequisites for the introduction of a comprehensive medical risk management system and evaluation of the effectiveness of its operation.

Key words: Risk management; Laboratory medicine; Medical errors; Laboratory diagnostics; Regulatory support; Quality control; and Evaluation.

1. Introduction

Obtaining analytically reliable and reproducible laboratory results in a modern medical laboratory is possible only with the introduction of all elements of the quality assurance system of research [1]. The extremely low quality of laboratory tests can lead to adverse consequences for the development of health care in Ukraine. The current situation is a consequence of the lack of organizational, scientific, and technical principles and a systematic approach to the problems of medical laboratory services in Ukraine [2]. The issue of the quality of clinical laboratory research is one of the most relevant not only in the field of laboratory medicine but also in the health care system of Ukraine.

The variety of problems in laboratory medicine is much wider than in other fields because there is no consensus among all participants in the process of diagnosis and treatment of the patient on the importance of laboratory diagnosis, contribution to the effectiveness of treatment – diagnostic process [3, 4]. The results of laboratory tests acquire real value only in the case of their purposeful purpose and correct evaluation; use of modern equipment and quality diagnostics. The clinical laboratory is no longer its limited ecosystem, as it is increasingly integrated with patient care, helping with diagnosis, monitoring therapy, and forecasting clinical outcomes. Even though many areas of health care are still struggling with the issue of patient safety, laboratory diagnostics has always been a harbinger of this issue. A robust approach to overcoming this problem requires predicting random events (comprehensive process analysis, reassessment, and rearrangement of quality requirements, dissemination of operating guidelines and best practice recommendations, reduction of complexity and propensity to error, implementation of error tracking systems and continuous monitoring), increase and diversification of means of protection (application of several and heterogeneous systems for detection of discrepancies) and reduction of vulnerability (introduction of reliable and objective detection systems, causation, education, and training). This policy, which requires integration between requirements, full commitment, and interagency cooperation, should make laboratory activities more compatible with the integral paradigm of overall quality in the testing process [5].

An important role in the risk management system is played by the correct choice of risk prevention and minimization measures, which generally determine its effectiveness. In world practice, there are many different and quite original ways and means to reduce risk. The expediency of using different methods of risk manage-

ment is determined by the specific situation, the availability of information, the ability to predict the occurrence of a risk event. A comparison of risk management methods makes it possible to determine which of them will be most suitable for clinical diagnostic laboratories, depending on the type of risk, the place of its probable occurrence, its size, type of activity, and financial capabilities. The preference for any method of risk minimization depends on the scope of risk, the capabilities of the enterprise, including organizational, managerial, financial, and risk management capabilities.

2. Purpose of Work

To analyze the regulatory support and methodology of risks and errors in the clinical – diagnostic laboratory (CDL), which affect the correctness of the analysis of the sequence of diagnostic tests, their correction, and transformation depending on the results obtained during the examination.

3. Research Results and Discussion

Risk management is based on the results of risk assessment, technical, technological, and economic analysis of the potential and environment of the existing organization, as well as forecasting the regulatory framework, economic – mathematical methods, marketing, and other research. Besides, risk management includes the development of strategy and tactics CDL, which in its activities, may refuse to implement a decision related to risks, and these methods can be applied to significant risks at the stage of preliminary development of the decision, and in the process of activity as a corrective measure in case of unauthorized increase in risks.

To date, there are many ways to minimize risk. The main ones are risk aversion; risk distribution between participants; risk insurance; self-insurance; diversification; limitation; implementation of alternative planning; creating a flexible production structure; creation of reserve funds; information monitoring; training and coaching; application of flexible technologies.

Insurance is one of the main methods of risk management due to the negative impact of the external environment, and, as a rule, insure those risks that arise as a result of the impact of the macroenvironment and are not manageable. By reducing possible losses, insurance allows you to stabilize the income of the organization and avoid the negative impact of the external environment. Also, it can use in the event of a risk event created reserves (self-insurance).

The issues of quality of laboratory care (reduction of risk for patients, satisfaction with the quality of care) in modern medicine are now also becoming quite relevant. These questions are especially important for clinical laboratory research in health care facilities. The risk of a person deciding to use a certain strategy (technology) in uncertain conditions is the difference between the gain (result, efficiency indicator) that would be obtained if the conditions were known and the gain that is received in conditions of uncertainty. Thus, there are two formulations of the problem of choosing a solution, two possible scenarios: one is desirable to get the maximum gain, the other – the minimum risk. Optimally, of course – the maximum gain with minimal risk.

In modern medicine, there are five main sources of risk, namely:

- risks associated with serious shortcomings of the applied medical technologies;
- deciding on a medical intervention that contains a risk;
- problems with current medical procedures;
- risks associated with self-help and self-medication;
- problems related to significant consequences of scientific and technological development.

Worldwide, CDLs perform several billion laboratory tests on a prescription for patients in clinics, dispensaries, and hospitals throughout the year. Numerous objective and subjective factors create serious problems for the quality of research results. To eliminate them, a course has been taken to develop national standards in the field of laboratory medicine, using international experience in the development of standards governing the requirements for the organization of CDL and laboratory analysis tools. In the normative provision of CDL today there is a largely spontaneously formed conglomerate of almost mutually inconsistent obsolete remnants of previously valid regulations and some new recommendations and provisions for the organization and implementation of clinical laboratory studies [6].

There are more than 300 international standards in the field of laboratory medicine. In Ukraine, however, there is still a lack of a legal framework for the standardization of clinical and laboratory research and laboratory services, which prevents the introduction of world evidence-based medicine and causes non-recognition abroad of domestic laboratory results. Among various medical disciplines laboratory, medicine is the most favorable object of standardization – the establishment of uniform rules and an assessment of conformity to them at the implementation of practical activity. Adoption of standards that contain scientifically sound criteria for the proper implementation of a

particular technological operation, will improve the quality of laboratory tests in CDL [7].

It is believed that up to 80 % of the information needed to ensure the treatment and diagnostic process in the developed world is provided by medical laboratories and their importance is constantly growing. Such a role in the medical – diagnostic process can be performed by medical laboratories only under the condition of guaranteeing their quality, first of all their reliability and comparability ("unity" of medical laboratory researches).

Modern medicine places high demands on the results of clinical laboratory studies and the main ones are reliability (analytical, biological and medical), comparability (regardless of time, place and methods of analysis), efficiency (taking into account the pace of the pathological process, the timing of clinical decisions and treatment), efficiency (comparison of resource costs and medical effect) [8]. Laboratory tests provide information for the treatment – diagnostic process and should meet the needs of both physician and patient. False results of laboratory tests can lead to very serious errors in diagnosis, improper treatment of patients. According to American pathologists, up to 7.5 % of laboratory errors cause real danger to patients' lives. Therefore, clinicians have important questions: where do errors occur that lead to erroneous laboratory results and why do they occur?

The term "medical error" is not provided by any legal document that currently regulates the provision of medical care in Ukraine. Among some specialists in the field of medical law there is an opinion about the inexpediency of using this term in the legal aspect. However, this term is traditionally widely used in clinical literature and popular science publications. In general – medical, clinical, and ethical aspects, this concept combines the shortcomings of diagnostic, therapeutic, deontological, organizational, prognostic nature, which arose in connection with objective and subjective reasons in the absence of illegal behavior of the doctor (medical staff) [9].

The most obvious reasons are failures in individual activities related to attention, memory, knowledge, judgments, skills, and motivation. However, they are partly the result of the nature of medical work, such as the complexity of medical knowledge, the uncertainty of clinical prognosis, and the need for timely treatment decisions, despite limited or uncertain knowledge. And importantly, errors caused by systemic factors affect working conditions.

There is no universal criterion that would allow us to clearly distinguish the erroneous result from the objective one when obtaining the disputable values. There is still no single system for detecting errors among the results, which at first glance seem reliable. Mistakes associated with CDL can be catastrophic for the patient, as an incorrect test result can change the entire treatment plan [10]. It is proved that 70 % of all mistakes that can be made in CDL, fall on the pre-analytical stage, which is usually accompanied by organizational – methodological and material – economic problems. Pre-analytical errors are the most important in distorting the results of the analysis. The consequences of violations at this stage are disguised as problems with reagents or devices or are taken as a true pathological result of the analysis. Their appearance is often not systemic but random, they are difficult to recognize. Therefore, extremely much attention is paid to the optimization and standardization of the pre-analytical stage.

Each of the errors can distort the result by:

- distortion of the real content of a particular analysis in the studied biomaterial;
- changes in the functional activity of the test substance (eg enzymes;
- influence on steric configurations (mainly when determining the activity of enzymes, when using solid-phase methods);
- due to color change and/or optical density of the reaction (colorimetric studies).

Errors of the pre-analytical stage can be divided into errors in the process of planning the collection of biomaterial; erroneous actions in the process of biomaterial collection, during the processing of already taken biomaterial, during its transportation and storage.

Risk assessment depends on the identification of hazards and consists of an assessment of the likelihood of consequences arising from them, in terms of their control or avoidance. Risk assessment is essentially an assessment of probability. Sometimes formulated as the average value of the realization of the event, which is expected over time. The basic concept of risk assessments is to identify risks quantitatively or at least in a comparative form (qualitatively) to any other risks.

One of the ways to improve the efficiency and quality of CDL services is to implement a risk management system that allows to identify, assess the consequences and develop countermeasures aimed at limiting accidental events that cause physical and moral damage to the laboratory, its staff, and patients. According to the standard [11] Risk management should become an integral part of the quality management of the organization and be an element of all stages of activity. This standard assumes that risk management is a central management process in which risks are considered through the prism of their impact on the achievement of

the organization's goals. The standard defines the overall risk management process. The Risk Consideration phase involves developing an understanding of each risk, its consequences, and the probabilities of those consequences. He does not give preference to quantitative or qualitative methods when considering risks, because, according to experts of this organization, all methods are important. After the risk assessment, decisions are made to determine the level of risk, and, according to pre-established criteria, priority risks are determined. The Risk Elimination phase is a process of improving existing and developing and implementing new risk management methods.

Risk management is comprehensive, systematic, structured, and timely. Such a regular approach to risk management contributes to efficiency as well as sustainable and reliable results. A consistent approach to risk management in the decision-making process helps to ensure efficiency and creates an atmosphere of trust and success in CDL. This requires the use of organizational methods that allow you to take into account the risk associated with all the measures taken.

The structured approach implies a combination of accepted risk management methods with CDL management methods. The development of the structure contains the following components: development, implementation (integration), implementation, evaluation, and improvement of risk management in CDL. A timely approach shows that the processes are applied at the optimal point in the decision-making process. This partly depends on the developed structure, to which this principle is also applied. If risk considerations are made too early or too late, and if risk mitigation opportunities are missed, significant decision review costs may be required. The dependence on risk accounting time needs to be assessed and understood to determine the most effective approach to minimizing it. Risk management contributes to the continuous improvement of CDL's work and is constantly improved through training and experience. Continuous improvement in the performance of CDLs is interrelated with continuous improvement in risk management, which is based on risk assessment of decisions, can reduce uncertainty in achieving goals, minimize variability and increase the adaptability of CDL. Management is based on the best available information. Many studies have found that most health care incidents involve poor accounting and reporting. The completeness of the information is enhanced if it is comparable, verifiable, timely, and understandable. The information must be used promptly.

Prospects for further research are to implement in the practice of CDL modern approaches to methods and tools of clinical laboratory research, increase the validity of decision-making in risky situations, harmonize procedures for recognizing the suitability of applied research methods and ensure accurate results. This will be facilitated by the creation of an integrated laboratory management system, which is to combine the methodology of risk management and quality management in the case of using synergistic effects of both systems [12].

A safe environment with controlled risks that do not cause harm, damage, or side effects is important for the provision of quality medical care and medical care. This is ensured by strict compliance with the licensing conditions of medical practice and the criteria of state accreditation of institutions, standards-based on evidence-based medicine. The process of risk management following the standard [13] begins with the definition of goals that the organization wants to achieve and internal and external factors that may affect the achievement of goals. This stage is called "Set the environment", it precedes the risk review process. The "Risk Review" stage should be systematic and include the following sub-stages: "Risk identification", "Detailed risk study", "Risk assessment". Only under such conditions can we understand what can happen, how, when, and why. The risk management process includes the assessment and selection of alternatives, as well as the analysis of costs and benefits and the assessment of new risks that may be caused by the choice of a particular method of risk management. In the standard "Risk Management. Principles and guidelines "describe the relationship of components (Fig. 1).

Patient safety should be seen as one of the leading health concerns. Studies have shown that serious medical errors can occur quite often, endangering the patient's health and being very costly to the health care system. Medical error is traditionally defined as an unintentional act, failure to perform a planned action as intended, using the wrong plan to achieve a goal, when failure cannot be attributed to chance. Most errors occur due to a combination of active failures and hidden conditions. It is worth noting that diagnostic errors have often been underestimated in clinical practice. An error in the CDL is any defect that occurs in any part of the laboratory cycle, from order testing to reporting, interpretation, and response to results. Although they have traditionally been identified with analytical problems and measurement uncertainty, the scientific literature suggests that the vast majority of them arise from the post-analytical activities of the overall testing process. Data from representative studies also show that pre-analytical errors are the root cause of variability in laboratory studies [14].

Over the last few decades, the frequency of analytical errors in CDL has decreased significantly. Some facts show that the pre and post-analytical stages of the analytical process are generally more prone to errors than the analytical stage. A significant part of the errors was detected at the pre-analytical and post-analytical stages outside the laboratory. If a patient-centered approach is used in the provision of medical services, it is necessary to investigate any possible defect that could lead to a negative impact on it throughout the analytical process. Creating a classification of laboratory errors according to the degree of their severity will help to identify priorities that will improve the quality of analysis, and will contribute to the purposeful development of corrective/preventive actions. Following the publication of a report by the Institute of Medicine (IOM) entitled "To Err Is Human", patient safety has finally become the object of medical and public attention [15].

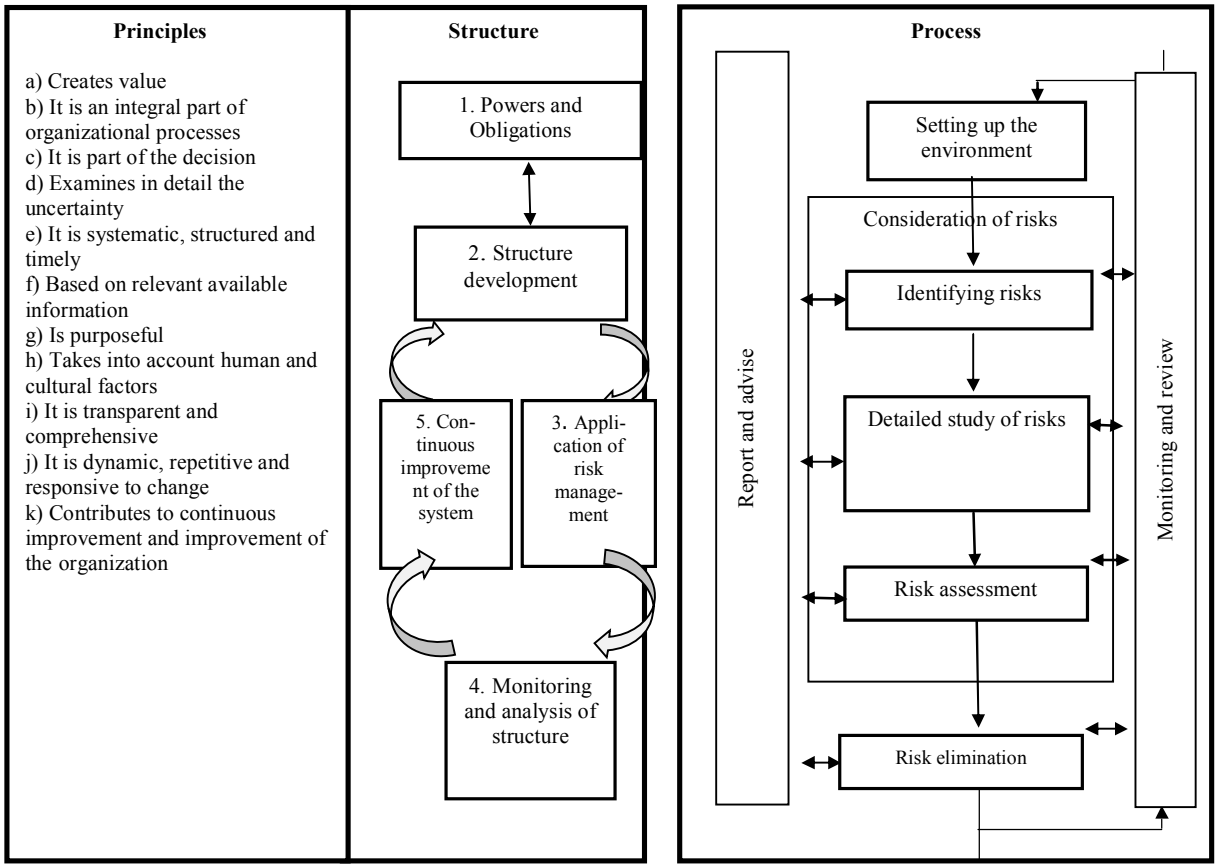

Fig. 1. The relationship between the principles, structure, and process of risk management

Table 1

Mistakes in laboratory medicine: causes of insufficient attention to the problem

1	Different and ambiguous definitions of what should be considered a laboratory mistake
2	The difficulty of detecting and identifying errors of all types, the need to develop carefully validated assessment protocols at each stage of the entire analytical process
3	The complexity of the analysis process, the need for cooperation and integration of different providers of health services
4	Insufficient awareness of the harmful effects of errors in laboratory medicine by doctors and other responsible parties
5	The reluctance of laboratory specialists to provide information about errors and frequency of their occurrence
6	Increase in the use of ancillary/alternative means of analysis (for example, at medical centers, near the patient's bed, and using self-monitoring)

Awareness and understanding of the causes of medical errors have spread rapidly, an active movement for patient safety has been launched, which advocates for improving the safety of health care through "systemic" solutions. This was made possible by the main "message" set out in the IOM report: the cause of avoidable medical errors and fatalities is not people's negligence and incompetence, but poor systems. However, in comparison with medical errors of other types, errors in laboratory medicine were given insufficient attention, and the reasons for such neglect are given in the Table 1 [16].

Errors in laboratory medicine are essentially complicated because they are difficult to identify and, even after detection, their cause is more difficult to understand than in the case of other types of medical errors. Laboratory errors have the following features:

1. There is a certain period between the performance of laboratory analysis, the actions of the doctor, and the result of these actions.

2. The analysis is a complex procedure consisting of a large number of stages and depends on many factors that ensure its implementation.

3. Physicians responsible for clinical decisions rarely consider laboratory errors as the cause of adverse effects on patients, nor do they realize that most of the shortcomings in laboratory work may be the result of errors in the preanalytical and post-analytical stages.

4. Laboratory professionals, conscious of personal responsibility and guilt, are reluctant to provide information on the frequency of errors and what errors were found in their laboratory.

Thus, there is an urgent need to assess the errors of laboratory medicine in the framework of a reliable working concept – the analytical process as a whole. From the patient's point of view, the reliability of the process as a whole, and the ability to prevent any errors at the preanalytical, analytical, and post-analytical stages are important. Recently, an interesting suggestion was made: use a neutral term, such as "insufficient quality assurance", which will alleviate the negative feeling associated with previously used terms, and there is a sense of guilt for the mistake. However, the term "error" is used in the medical literature and, therefore, should also be used to describe errors in laboratory medicine, in particular, because they are part of a wider range of diagnostic errors. In the Technical Specifications issued by the International Organization for Standardization [17], laboratory error is defined as the inability to perform a planned action as planned or the use of an incorrect plan to achieve a goal at any stage of the laboratory cycle, starting with the application for research and ending with the submission of a report on the results, the correct interpretation of the results and the use of adequate actions that correspond to the results obtained. This comprehensive definition has several advantages and, in particular, contributes to the patient-centered assessment of errors that occur during laboratory testing. It was emphasized that the development of patient-centered care should be transformed into a requirement to investigate any possible defect of the whole analytical process that could lead to a negative impact on the patient. Thus, the analytical process as a whole is a unique working concept that can be used to study and identify laboratory errors in different conditions: in the "standard" CDL, in the analysis of the treatment site, and the use of alternative methods of analysis.

For risk management, the vast majority of laboratory errors that have a little direct impact on the quality of medical services provide a thorough learning opportunity. Any error, regardless of its apparent triviality, may indicate weaknesses in general principles and specific laboratory procedures. A system for grading laboratory errors according to their severity should help identify priority areas for improving the quality of care and facilitate the choice of corrective/preventive actions. According to the technical specification of ISO/TS 22367:2015, any CDL must implement procedures designed to:

(A) identifying high-risk processes whose potential error could endanger patient safety;

(B) to identify real-world situations involving deviations from standard requirements;

(C) to assess concomitant patient safety threats;

(D) to control these threats;

(E) to monitor the effectiveness of the controls used.

This underscores the fact that laboratory errors can play a significant role in affecting the overall quality of care, including patient safety.

The potential risk to patient safety posed by laboratory errors has prompted the international laboratory community to begin studying the mechanisms of laboratory errors, the causes of misinterpretation and use of laboratory information, and to move purposefully to create a process management system that affects quality. At each stage of the laboratory research process, certain factors of influence, the degree of their significance, possible countermeasures were identified. Fig. 2 shows an action plan for the implementation of quality assurance systems for medical laboratories.

According to [18], the laboratory should evaluate the contribution of the workflow and the potential shortcomings of the study results if they may affect patient safety, and should change processes to reduce or eliminate risks, as well as document decisions and actions taken. If the results of laboratory tests are inaccurate, the risk of medical complications is 26–30 %, and the risk of incorrect actions of the doctor – 7–12 % [19].

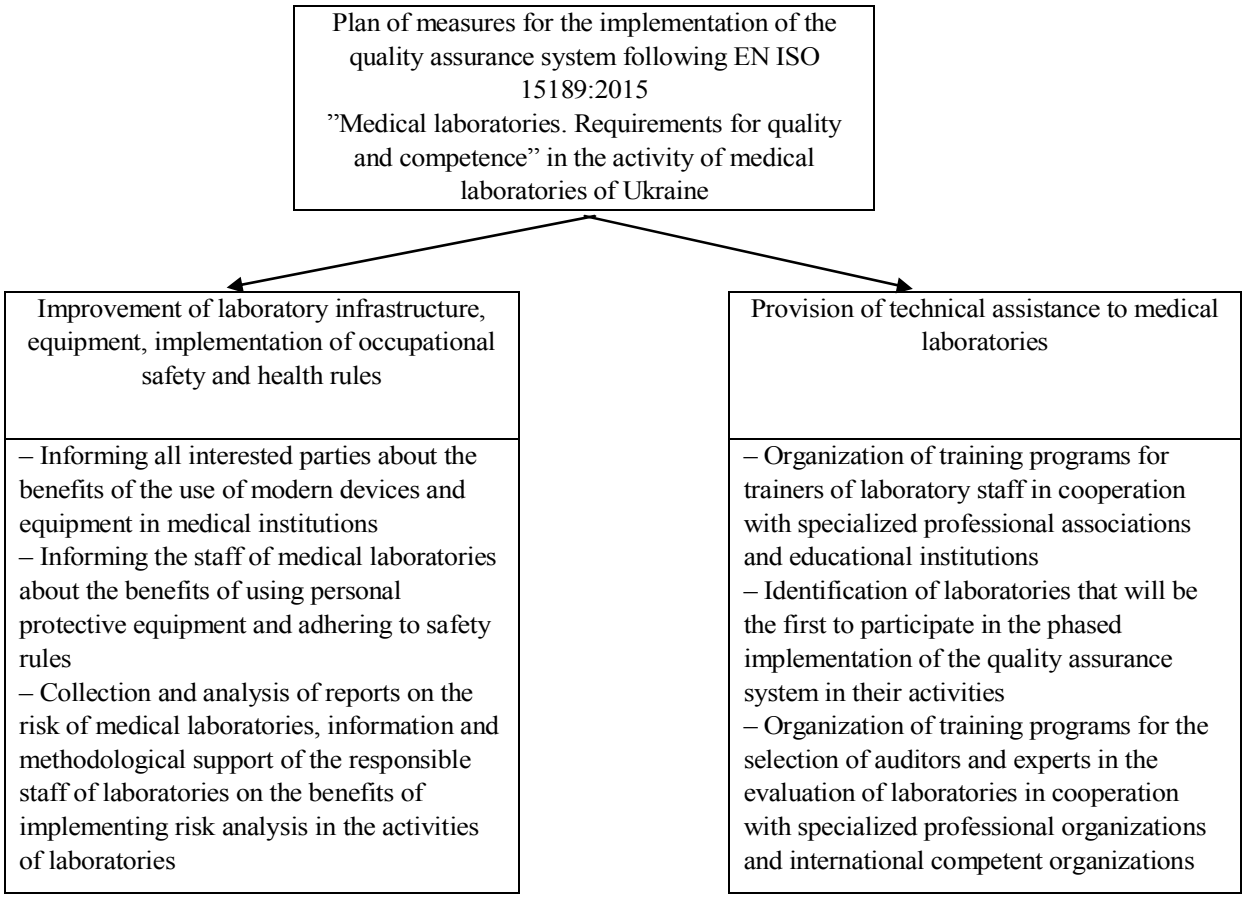

Fig. 2. Action plan for the implementation of the quality assurance system

In CDL risks can be divided into the following groups:

- risks that affect the provision of medical care to patients (incorrect results, untimely results, etc.).
- personnel risks (safety, biological, chemical, and physical risks).
- risks related to the security of personal data.
- financial risks of the institution associated with possible losses that could have been avoided.

It is necessary to assess the risks for all tests, with the probability of misidentification of reagents and to develop a procedure that excludes the very fact of simultaneous preparation and installation of such reagents. Conducting internal audits is an obligatory stage in the implementation, maintenance, and development of the CDL Quality Management System. The purpose of internal audit is to determine the compliance of the laboratory with the requirements of the quality system, first of all, the requirements of quality patient care, reduce risks for patients, as well as make appropriate corrective actions and identify ways to further improve the laboratory.

Mandatory requirement for CDL accreditation [18] is the implementation of internal laboratory and interlaboratory quality control systems using reference materials. The list of diagnostic tests with the necessary equipment, means and technology of analysis, type of biological material, and document code, which defines the relevant standard procedure, as well as the frequency of internal laboratory quality control, type of reference sample for its implementation and frequency of personnel qualification. Thus, well-established internal – laboratory quality control in CDL, highly qualified specialists, the interaction of laboratory staff with clinicians, logging, and archiving of information ensures the reliability and reliability of test results with minimal risk to patients [20].

Risk cannot be considered only as a negative phenomenon. Awareness of danger mobilizes human strength, forces to be careful, stimulates the acquisition of the necessary knowledge. Each risk must have an owner who is responsible for risk management and has decision-making powers. This can be the owner or head of the process, the head of the structural unit. This approach will help process implementers to better

understand what is at stake in their activities and what they should pay special attention to.

Risk management is the process of making management decisions that minimize the adverse effects of external and internal factors on CDL, as well as reduce losses caused by accidental events. Risk management is based on the results of risk assessment, technical – technological and economic analysis of the potential and operating environment, as well as on forecasting the regulatory framework in CDL.

To date, there are many ways to minimize risk, namely:

- risk aversion;
- risk-sharing between participants;
- risk insurance;
- self-insurance;
- diversification;
- limitation;
- implementation of alternative planning;
- creation of a flexible production structure;
- creation of reserve funds;
- information monitoring;
- education and training;
- application of flexible technologies.

Consideration of the categories "Risk" and "Risk management" from these positions allows you to transform the approach to assessing the probability and consequences of risk from financially oriented to personnel-oriented. The basic element of the modern management system is the person – the source and owner of intellectual potential, and most of the benefits of CDL are the result of the application of general scientific, regulatory and descriptive knowledge.

4. Conclusions

The analytical laboratory process as a whole is considered as a unique working concept that allows us to identify errors, reduce their number and thus minimize risks, both at the initial (patient identification and selection of tests) and at the final (transmission and interpretation of results) stages.

International projects aimed at developing quality indicators for all stages of the analytical process and setting appropriate quality specifications will allow KDL to compare, control and improve the quality of their daily work, and not only at the analytical stage.

The risk management system, as part of strategic management, should be organically integrated into the planning and management system of CDL. It is the presence of a risk management system in CDL allows you to identify existing risks, determine the level of danger, and using certain methods and techniques of risk management to reduce the negative impact on its organizational, technical, and professional activities.

One of the conditions for the effectiveness of the risk management system in CDL is the use of detailed, most reasonable, and most acceptable approaches to risk assessment. The system should provide for the presence of criteria indicators that allow assessing the effectiveness of its operation. Risk management through proper performance of functions will ensure the adoption of both strategic and tactical management decisions, which will help reduce errors in the CDL in planning and implementing the strategy.

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6. Conflict of Interests

There is no conflict of interest while writing, preparing, and publishing the article, as well as mutual claims by the co-authors.

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