One way to improve the efficiency and quality of medical laboratory services is to implement a risk management system that allows identifying, assessing the consequences, and developing countermeasures aimed at limiting accidental events that cause physical and moral damage to the laboratory, its staff, and patients.

Today, there are many ways to minimize risk. The main ones are risk avoidance, risk distribution between participants, risk insurance, self-insurance, diversification, restrictions, alternative planning, creation of flexible production structure, creation of reserve funds, information monitoring, training, application of flexible technologies.

Taking into account the modern understanding of the risk management process as part of the strategic management of the organization, we conclude that the risk management system should be organically integrated into the planning and management system. The development of technologies in medicine leads to the expansion of the capabilities of the clinical-diagnostic laboratory (CDL). At the same time, the workload on CDL employees is increasing. Despite the actions aimed at labor protection, the laboratory assistant encounters biological material, runs the risk of contracting infections, primarily HIV and hepatitis. Although the appearance of disposable tableware and technical equipment has reduced the risk of infecting medical personnel, it is not possible to completely avoid it. Chemical reagents are also dangerous, among them, there are both toxic substances and flammable. The transition to modern analyzers has simplified the work of CDL, but the lack of modern equipment and disruptions in the supply of consumables for them do not allow them to completely abandon the old methods. Microscopy increases the strain on the eyes, and if the light is insufficient, the risk of vision loss increases. Insufficient equipment on the premises also adversely affects the health of CDL employees. Identification of risk factors and determination of methods of disease prevention related to the working conditions of the CDL laboratory assistant is an urgent problem of modern medical practice.

Risk management is based on the results of risk assessment, technical-technological and economic analysis of the potential and environment of the existing enterprise, as well as forecasting the regulatory framework, economic and mathematical methods, marketing, and other research. It involves the development of strategy and tactics. The CDL may refuse to apply a specific risk-related solution, and these methods can be applied to significant risks both in the pre-treatment phase and in the corrective action process. Today, the legal framework of CDL has a largely
spontaneously formed conglomerate of almost mutually inconsistent obsolete remnants of previously existing regulations and some new recommended provisions for the organization and conduct of clinical laboratory studies [1]. There are currently more than 300 international standards in the field of laboratory medicine. Ukraine still lacks a sufficient regulatory framework for the standardization of clinical laboratory tests and laboratory services.

The most favorable object - laboratory medicine - the establishment of uniform rules and conformity assessment in the implementation of practical activities. Adoption of standards that contain scientifically sound criteria for the proper implementation of a particular technological operation will improve the quality of medical laboratory research [2]. It should be noted that the term "medical error" is not provided by any legal document that would regulate the provision of medical care in Ukraine. Some medical experts believe that the term is not used legally. However, this term is traditionally widely used in clinical literature, political and popular journals. In general medical, clinical, and ethical aspects, this concept combines the shortcomings of diagnostic, therapeutic, deontological, organizational, prognostic nature, which arose due to objective and subjective reasons in the absence of illegal behavior of the doctor (medical staff) [3].


There are separate standards of risk management of a general nature:
and specialized:
- ISO / TS 22367: 2008 Medical laboratories. Reduce errors through risk management and continuous improvement

In addition, there are professional recommendations for the use of risk management in the field of laboratory medicine:

It is interesting to note that risk management is not specific to medical laboratories, but also to product manufacturers, including In-Vitro diagnostics (ISO 14971), and to medical institutions in general - so one of the requirements for JCI accreditation is risk management systems. It is also important to note that the laboratory standard ISO 22860 recommends that laboratories use ISO 14971 to manage improvements [4].

Risk is a combination of the probability of a dangerous situation and its harm. The risks associated with the provision of medical care to the patient are usually considered (this is emphasized by ISO 15189 version 2012), organizational, primarily financial risks (this is discussed in detail in ISO 9001 version 2015). As well as risks associated with staff safety [5].

The risks that arise in the process of conducting research can ultimately be assigned to one of the three groups mentioned above.
For example, in a patient with hypokalemia (K = 3 mmol / l) in need of immediate therapy, CDL obtained a distorted result (K = 4.2 mmol / l). Consider this situation from the standpoint of risk management.

The threat here is the lack of necessary medical intervention. Dangerous situation: the clinician receives an incorrect result from CDL as a result of the hemolyzed test.

To manage this situation, we need to assess the risk associated with it.

First, the probability is estimated:

Probability 1 (realization of the threat - no medical intervention, when necessary, or vice versa - unnecessary medical intervention):
- very low, if we talk about the results, which are always confirmed by the clinical picture, etc;
- average, if the doctor's qualification is insufficient;
- high, if the decision is made only on the basis of CDL data.

Probability 2 (realization of a dangerous situation - the presence of hemolysis):
- high, if the person responsible for taking the biomaterial is not qualified enough, or if it is about children's biomaterials;
- low, if qualified personnel.

If there is an automated system of input control of hemolysis, it is possible to quantify the probability of hemolysis [6].

Next, we assess the degree of damage. Consequences, in this case for the patient. Indirectly, this carries financial risks for the institution:
- high, if the wrong treatment is prescribed / not prescribed treatment can lead to serious consequences for the patient (death, disability, etc.). That is, it depends on the analysis and qualifications of doctors.

The next step is to assess what are the methods of control at all stages, which allows identifying this problem before its implementation. In risk management terminology, this is called the probability of detection or detection.

Probability of detection of hemolyzed sample:
- low if there is no input control.
- medium, if a visual inspection is carried out.
- close to 100%, if there is a continuous instrumental control. The higher the probability of detection, the lower the possibility of risk.

After conducting such a risk assessment, it is necessary to decide on methods of managing it.

Management methods are divided into two major groups: risk reduction if it is decided that the risk is not acceptable, and monitoring of acceptable risks so that they do not leave the area of acceptability.

Possible control measures for hemolyzed samples:
1) Monitoring: introduce a rule - collect statistics on hemolyzed samples on a monthly basis and monitor the dynamics.
2) Risk reduction: to introduce instrumental continuous control of samples for the presence of hemolysis; to conduct staff training (biomaterial collection, visual inspection; possibly - work with clinicians).
3) Inform the clinician about the hemolyzed test, if we can not refuse to perform the study.

After applying risk management measures, make sure that:
- the measures are taken really reduced the risk. In risk management terminology, this is called verification of actions taken.
Possible verification by hemolysis:
- We keep a constant statistical record of hemolyzed samples and conduct a comparative analysis (monitor the dynamics);
- If possible, we track information from clinicians about errors due to incorrect data results and perform an FTA analysis of each, to identify the root cause, including missed hemolysis.

The ideology of risk management assumes that any measures to reduce risks can lead to new risks.

Special tools, such as adapted FMEA analysis, will help to formalize such work. There are more or less formalized risk management tools. The simplest - various questionnaires and block diagrams. For formalization and monitoring, you can use a tool such as FMEA analysis in various modifications. To find the cause or possible cause of the problem there is a formalized method - FTA analysis, which is a more simplified form that can be implemented by the method of "five why". A special tool aimed at safety risks, similar to the food industry HACCP system [7].

It is possible to allocate the following difficulties which CDL face, at the introduction of risk management:
1) Too narrow perception of the task of risk management.
2) Lack of practice of QMS audits in terms of risk management.
3) CDL employees do not have special knowledge of risk management.
4) CDL employees do not understand the benefits of risk management.

Considering the categories of risk and risk management in this context allows us to transform the approach to assessing the probability and impact of risk from financially oriented to career-oriented. The main element of the modern management system is the person - the source and owner of intellectual potential, and most of the economic effect obtained from the organization is the result of the application of general scientific, regulatory and descriptive knowledge. Its ability to offer unobtrusive solutions is a source of renewal and progress. The main purpose of the human potential of the organization - to create and improve an effective management system that ensures its expansion, strengthening competitiveness, inhibiting the risks of production and economic activities. An important indicator of human potential is the ability to adapt to changes in the environment, to turn the sign of influence from negative to positive, to turn threats into opportunities [8].

Despite compliance with all safety measures, biological, chemical, and physical risk factors persist. Modern CDL equipment and the use of analyzers, as well as the use of closed systems for blood collection, can significantly reduce the importance of harmful factors in the work of CDL laboratory assistant. The presence of a risk management system in CDL will allow the organization to identify related risks, determine the level of risk and, using certain techniques and methods of risk management, reduce their negative impact on the financial and economic activities of CDL.

The prospect of further research is the introduction into the practice of medical laboratories of modern approaches to methods and tools of clinical laboratory research, improving the validity of decisions in risky situations, harmonization of procedures for recognizing the suitability of applied research methods, and ensuring guaranteed accurate results. This will be facilitated by the creation of an integrated management system CDL, which is to combine the methodology of risk management and quality management in the case of using the synergistic effects of both systems.

Conclusions. Further research will focus on the development of practical guidelines for the establishment of a risk management system in CDL and the
application of specific techniques and methods of risk management depending on the level of their impact. It is promising to put into practice modern approaches to methods and tools of clinical laboratory research, increase the validity of decisions 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 that combines risk management and quality management methodologies.

References: