

ЗАБЕЗПЕЧЕННЯ ЯКОСТІ ДІЯЛЬНОСТІ КЛІНІКО-ДІАГНОСТИЧНИХ ЛАБОРАТОРІЙ

PROVIDING QUALITY OF CLINICAL-DIAGNOSTIC LABORATORY ACTIVITY

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Анотація. Розглянуто актуальні питання управління якістю медичних послуг і втілення їх в практичну діяльність. Серйозні проблеми, пов'язані із якістю результатів досліджень, створює багато об'єктивних і суб'єктивних чинників. Для усунення проблемних чинників розпочато розроблення національних стандартів у галузі лабораторної медицини з використанням міжнародного досвіду розроблення стандартів, що регламентують вимоги до організації діяльності клініко-діагностичних лабораторій та засобів лабораторного аналізу. Гострою проблемою лабораторних досліджень є забезпечення точності результатів. У Європейському співтоваристві давно існують вимоги щодо забезпечення метрологічної простежуваності калібраторів і контрольних матеріалів та метрологічного забезпечення лабораторного устаткування, а також методик досліджень.

Забезпечення якості лабораторних досліджень є однією з центральних проблем сучасної лабораторної медицини. Основною вимогою для таких досліджень є надання клієнтам надійної інформації. Це, передусім, визначає вимогу щодо якості клінічних лабораторних досліджень клінічних і діагностичних лабораторій, що забезпечує правильне та своєчасне призначення аналізу пацієнту, виконане на належному аналітичному рівні з необхідною інформацією для його інтерпретації. Тільки за умови чіткої організації та якісного проведення лабораторних досліджень можна очікувати, що кожен результат, відображений у авторизованому звіті, лікар зможе використати для прийняття діагностичних рішень або рішень, які змінюють схему лікування. Одним зі способів визначення компетентності клініко-діагностичних лабораторій та якості їх досліджень є проведення незалежної оцінки якості. Лабораторна медицина надає 70–80 % інформації, необхідної для прийняття рішень щодо діагностики, лікування та профілактики захворювань. Надання достовірної інформації клініцистам – важлива вимога до якості клінічних лабораторних досліджень клініко-діагностичних лабораторій, яка забезпечує правильне і своєчасне призначення аналізу пацієнтові. Тільки за умови якісного виконання лабораторного дослідження можна розраховувати на правильне прийняття діагностичних рішень і належне лікування.

Ключові слова: якість життя, клініко-діагностична лабораторія, точність результатів, якісне оцінювання, лабораторні дослідження, контроль якості, порівняння лабораторій.

Annotation. Article deals with topical issues of quality management of medical services and their implementation in practical activity. For quality of research results, serious problems are created by a lot of objective and subjective factors. To eliminate the problem factors, the course was aimed at developing national standards in the field of laboratory medicine, using international experience that regulate the requirements for the organization of clinical diagnostic laboratories and laboratory analysis facilities. The acute problem of laboratory research is to ensure the accuracy of the results. EC has long been required to provide metrological traceability of calibrators, control materials and metrological provision of laboratory equipment, as well as research methods. Basic requirement for such research is to provide reliable information to the customers. First of all, it defines the requirement for the quality of clinical and diagnostic laboratories studies, which ensures the correct and timely assignment of a patient's analysis, performed at the appropriate analytical level with the necessary information for interpretation. One way to determine the competence of clinic and diagnostic laboratories and the quality of their research is to conduct an independent quality assessment.

Key words: quality of life, clinical diagnostic laboratory, accuracy of results, quality assurance, laboratory research, quality control, between laboratory comparisons.

Introduction

In many countries of the world, in order to improve the safety of medical care, reduce spending on its provision and increase the population's satisfaction with medical services, the issue of quality management of medical care is actively being developed and implemented into practical work. «Solving quality problems is a book that is constantly adding new sections, but the latter will never be written...» Armand Feigenbaum (author of the concept of integrated quality management). In 2001, the Institute of Medicine at the National Academy of Sciences of the United States proposed six dimensions of quality care for the 21st Century:

- Patient orientation – to provide review assistance and according to the individual needs and preferences of patients in order to meet the patient's expectations become fundamental to making all clinical decisions.
- Security – to protect patients from injuries in the process of providing medical care.
- Effectiveness (Clinical Effectiveness) – assist in evidence-based medicine only to those who are in a position to improve the condition and not to provide it in cases where help can be damaged (avoid insufficient and excessive interference).
- Timeliness – reduce waiting times and avoid delays that can sometimes be detrimental not only to

those who receive the service but also to those who provide them.

- Rationality (economic efficiency) – avoid inappropriate use of equipment, resources, ideas and energy.

- Justice – respect for the rights of the patient, to provide medical care of one level of quality regardless of personality characteristics such as gender, nationality, place of residence and socio-economic status.

In 1948, WHO identified health not only as a lack of disease but also as a physical, psychological and social well-being. Since that time, medical practice has increasingly begun to focus on the quality of life that affects primarily the state of health, so in this case, the correct use of the concept of «quality of life related to health» (in the English-language literature «health-related quality of life»).

In the modern world, clinic-diagnostic laboratories (KDLs) in medical health organizations throughout the year perform several billion laboratory tests for the appointment of doctors for patients in polyclinics, clinics, hospitals. For the quality of research results, serious problems arise from numerous objective and subjective factors. 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 that regulate the requirements for the organization of KDL activities and laboratory analysis tools. The international standard ISO 15189, which establishes the requirements for the quality and competence of the KDL, was introduced in Ukraine from 01.01.2016, as DSTU EN ISO 15189: 2015 «Medical laboratories. Requirements for quality and competence». Compliance with the requirements of this standard by the medical laboratory means that the CDL meets both the requirements of technical competence and the requirements of the quality management system. [1] In addition, it will apply to all currently recognized types of medical laboratory services and is based on the specified standards ISO 17025 and ISO 9001.

Taking into account the basic requirements for the QMS and the technical requirements, considerable attention is paid to the very specific aspects of the implementation of the processes in the three main stages of the laboratory research: transnational, analytical and post-analytic.

In order to ensure the accuracy of the results of laboratory tests in the EU for a long time there are requirements of metrological traceability of calibrators and control materials and metrological provision of laboratory equipment, as well as research methods. The task of providing metrological traceability is to the manufacturers of equipment and control materials [2].

If the KDL is included in the structure of a medical institution, it is certified in accordance with the

standard DSTU ISO 9001 [3], this does not mean that the laboratory complies with the standard DSTU EN ISO 15189: 2015. If the medical laboratory is accredited according to EN ISO 15189: 2015, then certification according to DSTU ISO 9001 can not be carried out. In DSTU EN ISO 15189, unlike DSTU ISO 9001, more specialized requirements are set for the personnel, in particular to his competence, premises, environment, working environment, sampling and research procedures. It provides for a risk management process and ensures the reliability of the research results. In some cases, it is advisable to apply standards to staff [4, 6].

DSTU EN ISO 15189 was developed and intended for use only by medical laboratories. This standard establishes certain requirements for the quality and competence of medical laboratories. It is a guideline for quality management in KDL and for technical processes to ensure the quality of medical laboratory research.

The tests in KDL can not be considered reliable without quality control. The accreditation procedure for KDL still does not meet the requirements recommended by EU experts. These requirements stipulate the need for their implementation in the practice of KDL. To date, none of the existing domestic KDLs has been accredited for compliance with the given standards. The level of the requirements for the competence of such laboratories is much higher than established in the international standard [4]. A comparative analysis has shown that standard requirements [4] for laboratory competence are more stringent than in [1], especially with regard to elements of the management system, personnel training, analysis by the quality control test team, continuous improvement, validation of the methodology. If a health facility is really interested in providing a quality patient service, it will never lose the opportunity to once again verify the accuracy of its diagnostic and medical equipment. Also important are the methodological aspects of organizing a quality management system and improving the effectiveness of medical care.

Research results

The quality of medical care for the population allows us to assess the degree of compliance with the state (health care institution) guarantees stated in accordance with established criteria and quality indicators, taking into account the satisfaction of the population in obtaining appropriate medical care.

Quality control of medical care in Ukraine is carried out at different levels: medical institutions, health care institutions, insurance medical organizations. But given the fact that health insurance has not become widespread, the healthcare quality control system is obsolete.

The quality of life of a sick person in modern medicine is considered as an integral characteristic of her condition consisting of physical, psychological, and social components. Each of them in turn contains a number of components, for example, physical – the symptoms of the disease, the ability to perform physical work, the ability to self-service; psychological – anxiety, depression, hostile behavior; social – social support, work, public relations, etc. Their comprehensive study allows you to determine the level of quality of life and find out their influence on it. It is a fact that the patient is involved in the assessment of his condition and his active involvement in collaboration is important, since only the patient can provide adequate information about the degree of satisfaction with aspects of his life that are directly related to the symptoms of the disease and its psychological, social and other consequences.

The study of quality of life is used:

- for a comprehensive examination of the patient, taking into account his own, subjective definition of his condition;
- evaluating the effectiveness of drugs and treatments in clinical practice and research, determining the level of trust and commitment of the patient to the prescribed treatment;
- establishment of psychological problems and social status in patients with general practice;
- determination of the prognosis of the disease and preventive correction of risk factors, selection of rehabilitation measures and conducting medical and social examination;
- analysis of the ratio of costs and effectiveness of medical care, in the medical audit.

For a real assessment of the quality of life, questionnaires (Table) containing a range of questions are used, answering which people are as exhaustively as possible to provide information on the various aspects of their lives or health. There are special centers in the USA and Europe working out and testing such questionnaires. For example, in France, the main coordinator of research in the field of life is MAPI Research Institute. In general, all existing surveys can be divided on certain grounds.

Thus, quality of life is recognized as an integral part of a comprehensive analysis of new methods of diagnosis, treatment, prevention, quality of treatment and provision of medical care. In economically developed countries, quality indicators of quality of care or «clinical indicators» have become widely used as an

instrument for identifying possible problems and / or opportunities for improving the quality of patient care or the immediate treatment process. With proper use, indicators can be used to compare options for providing similar health services in different institutions and to assess the level of these services in relation to national standards [7].

They serve as indicators for identifying possible problems and/or opportunities for improving quality. Indicators do not provide answers to questions, but rather draw attention to those areas where it is expedient to conduct special studies or take measures to improve quality. They also ensure the homogeneity of the methods for evaluating the results in the form of benchmarking.

International experience shows that there is not and there can not be a «Universal Indicator», which could comprehensively measure and characterize such a complex and multi-faceted concept as the quality of medical care. The ultimate goal of the health care system is not to improve the value of individual indicators but to improve the quality of health care provision. At the same time, each of the indicators can provide useful information on certain aspects of the medical service. The description of each indicator should include guidance on its proper calculation, analysis, interpretation and application. The assessment of the quality and reliability of the methodologies and output data used in the calculation of indicators should be preceded by any comparison and analysis, and especially conclusions.

Consumer confidence indices are potentially valuable tools for comparing the quality of the activities of various organizations, regions and even countries, provided that the data provided is reliable. Perspective directions of development of the indicator system in Ukraine are considered below. The main current trend in the process of improving the quality of medical care is the transition to comprehensive quality assurance at all stages of the provision of medical care - prevention, diagnosis, treatment, follow-up of patients – from a fractional analysis of individual stages and medical interventions. Accordingly, the information provision of such a concept should include the integration and further analysis of all possible information about the patient, which becomes technically feasible with the development of modern means of communication and information technology.

Distribution of questionnaires on quality of life according to the main characteristics

| By specificity | By volume | By technical construction and method of calculation of results | By way of information received | According to the respondent |
|------------------|-----------------------------------|--|--|---|
| General specific | Complete form. Shortened form. | Scales Indices. Profiles. | Self-response. Interview. Phone. E-mail. | Patient. Doktor. Family patient. Guardian. |

Modern means of automated information processing allow us to translate processes of operational quality control of primary information into a qualitatively new level, to apply automated procedures for the search and removal of false and duplicate records in databases. The introduction of such technologies and procedures aimed at improving the quality, completeness and consistency of the original documentation should precede the introduction and widespread use of healthcare quality indicator systems, as it is not possible to obtain qualitative information based on inadequate output data. Thus, the main prospects for the development of a system of quality indicators for health care in Ukraine are related to the creation and development of national databases and information technologies, with the improvement of automated electronic information processing and the systematic improvement of the quality and completeness of medical information.

Clinical laboratory diagnostics is one of the most important components of the health care system, which provides diagnostic assistance to patients in assessing the health status, diagnosis of diseases, monitoring of the results of treatment, further prediction of the course of the disease and quality of life, which has national significance for the preservation and improving the health of the population, as well as reducing morbidity and mortality. Every year more than 2,500 medical laboratories in Ukraine perform more than 650 million laboratory tests. Certain tactical steps to develop the state system of quality control of clinical laboratory research have already been made: the Concept of the quality management system in the medical laboratories of Ukraine has been approved in accordance with the requirements of international standards and the Plan of measures for its implementation. The state standard DSTU EN ISO 15189: 2015 [1], which has established special requirements for the quality and competence of medical laboratories, has been approved at the state level. The state system of external evaluation of quality of clinical laboratory research has been established and functioning through the implementation of the programs of interlaboratory comparisons of the results of the measurements, the network of reference centers has been established, and Laboratory, which is being improved now, the Ukrainian School of Quality Management of Laboratory Medicine was established. Adjacent standards on the technical competence of laboratories and reference centers have been introduced and in place. But a number of problems have remained. This is evidenced by the results of the programs of external quality assessment of laboratory research conducted in Ukraine for the tenth year in a row among almost 600 medical laboratories of different forms of ownership and

subordination from all regions. Despite significant achievements, around 9 % of the results are unsatisfactory. The Ministry of Health considers it necessary to continue implementing the international standard DSTU EN ISO 15189: 2015 as the single and basic standard for medical laboratories.

A change in the outlook and culture of technical competence is the introduction of quality management systems, the preparation of methodological support, and the creation of a document circulation system in laboratories. Formation of the relevant regulatory framework is a priority activity of the Ministry of Health of Ukraine. One of the mechanisms for improving the quality of medical care is the material incentive for the staff, which provides: the link between remuneration and its volume and, most importantly, its quality. The primary development of paid services in Ukraine's health care was considered as a factor in the expansion of consumer rights to choose the provider of medical services. Under these conditions, it is extremely important that the quality of the services provided meets the existing standards.

The problem of quality assurance of laboratory research is one of the central problems of modern laboratory medicine [5]. The main requirement for such studies is to provide reliable information to clinicians. This, first of all, defines the requirement for the quality of clinical laboratory research, which ensures the correct and timely assignment of the analysis to the patient, performed at a sufficient analytical level with the necessary information for its interpretation. Only with a clear organization and qualitative conducting of a laboratory study one can expect that each result, reflected in an authorized report, can be used by a physician to make diagnostic decisions or decisions that change the treatment scheme. One way to determine the competence of laboratories and the quality of their research is to conduct an independent quality assessment. Research in a clinical diagnostic laboratory can not be considered reliable without quality control. The European Laboratory Accreditation Cooperation (EA) has traditionally paid attention and attention to issues of competence assessment and the specifics of the requirements for the competence of laboratories dealing with specific types of tests (eg, microbiological, organoleptic or KDL). The KDL should develop and implement a selection procedure for reference laboratories (similarly, as well as independent assessment consultants.) Monitoring of their quality should be monitored to ensure that this laboratory or «referral consultant» sufficiently competent to perform the assessment. Use of the same external laboratory control of each methodology is a prerequisite for the competence of the laboratories. Quality indicators should be established for

systematic monitoring and assessment of the contribution of the laboratory to the satisfaction of patients.

The quality control of clinical laboratory studies at the level of the Ukrainian healthcare system (Interlaboratory quality control) should be carried out by the state system of external quality assessment (EQA). The purpose of the EQA is to assess the degree of compliance with the results of studies performed in the laboratories of various health institutions, established norms of accuracy. It should be conducted in accordance with the regulatory documents of the Ministry of Health of Ukraine and the Department of Technical Regulation of the Ministry of Economic Development and Trade of Ukraine. Participation in the activities of the state system of external quality assessment is obligatory for laboratories of public health institutions of all forms of ownership and is taken into account in their accreditation. Along with this, the participation of laboratories in other programs (international, commercial, regional) is allowed, including for indicators missing in the state system EQA.

Checking the quality of the measurements is the use of interlaboratory comparisons of the results to determine the ability of the laboratory to conduct measurements. The aim of the program is to: help clinical laboratories in an objective assessment of the quality of the research carried out and develop recommendations for its improvement, inform laboratories, key specialists in clinical laboratory diagnosis and health authorities on the comparative quality of the sets of reagents, calibrators and equipment used in domestic practice, as well as new means and methods of research. The program is aimed at identifying the real inconsistencies that occur in the work of laboratories in the analysis of samples. To this end, measures are taken to ensure that the participating laboratories do not require the creation of «special conditions» in the testing of control samples, and measures are taken to prevent any direct administrative sanctions based on the results of the quality assessment of the analyzes. This is ensured by the confidentiality of the participation of a specific laboratory in the study: all laboratories are encoded, and information about the quality of research in the laboratory is reported only to the head of the KDL. The order of the study of control samples suggests that these studies should be performed in a routine series of trials of conventional samples entering the laboratory for analysis, under the same conditions, with the same reagents, on the same equipment. The data obtained from the laboratories are viewed, while their compliance with the established pattern of analysis of control samples, the correct use of units of measurement, etc., is concluded that they can be further processed. The results provided by the KDL are analyzed using statistical data processing methods and evaluated for their correctness and reproducibility.

Interlaboratory comparisons (MPRs) is a voluntary procedure for an independent assessment of the quality of laboratory tests carried out by comparing the results of this laboratory with the results of other laboratories to assess the correctness and to identify systematic errors in the work. The system of external quality assessment provides a comparison of the results of research between different laboratories, and promotes the harmonization of the results of laboratory research in general and helps to improve laboratory quality control. Laboratories that did not receive 100 % conformity of the results should evaluate the results of the MPR to focus their activities on corrective actions to ensure the reliability of laboratory studies at each stage of laboratory diagnosis (pre-analytical, analytical, post-analytic). Thus, the main strategic direction of the development of modern laboratory diagnostics is the continuous improvement of the system itself and the continuous improvement of the quality of clinical laboratory research. This will break the vicious circle (Fig. 1) in the national laboratory diagnostics.

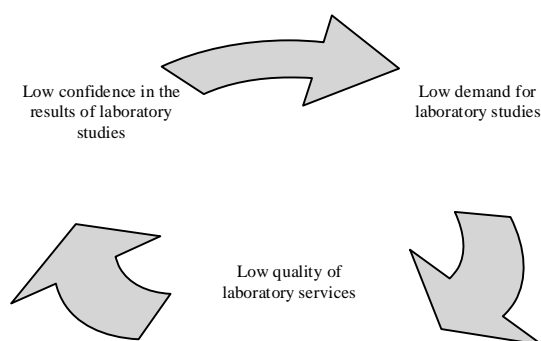


Fig. 1. Damage circle in national laboratory diagnostics

The question 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 as a whole. Laboratory medicine is a complex diagnostic system for the study of human biological material in order to detect changes in the characteristics of its components, evidently related to the presence of pathology. The Medical Laboratory, in accordance with the definition of ISO 15189: 2012, is a laboratory for biological, microbiological, immunological, chemical, immunity-hematological, hematological, biophysical, cytological, pathological, genetic or other studies of materials derived from the human body for the purpose of obtaining information for diagnosis, prevention and treatment of disease or for assessment of person's health that can provide advice on all aspects of laboratory testing, including the interpretation of results and recommendations the necessary further research. Laboratory information obtained during laboratory studies is a product of a medical laboratory used by

clinicians in most cases to substantiate diagnostic and clinical decisions. Therefore, the biological and analytical reliability of the results is a component of the safety of medical care. It is possible to obtain reliable laboratory information and to objectively evaluate the patient's health only if all the stages of the laboratory process and the operation of the risk management system are in place at the appropriate quality for laboratory errors. The risk to the patient's safety, caused by laboratory errors, prompted the international laboratory community to begin to study the mechanisms of laboratory errors, the reasons for misinterpretation and the use of laboratory information, and to begin a deliberate move towards creating a quality control system for processes that affect the quality of the patient. At each stage of the laboratory research process, certain factors of influence, degree of their significance, possible measures of counteraction were determined. In fig. 2 provides a plan of measures for implementation of the quality assurance system for medical laboratories.

Medical laboratories that have implemented the quality management system work practice, confirm their competence by accrediting the laboratory for compliance [1]. The development of the state system for quality management of clinical laboratory research in Ukraine began in 2010. Under the quality in laboratory medicine is understood the level at which a combination of inherent characteristics meets the requirements (ISO 15189: 2012). According to the definitions of the Institute for Clinical and Laboratory Standards (CLSI), the International Organization for Standardization (ISO) and the World Health Organization (WHO), laboratory quality can be defined as the accuracy, reliability and timeliness of the results issued for effective use in the treatment-diagnostic purposes. A quality management system can be defined as coordinated actions that direct and control the organization's activities in relation to quality. In the quality management system, all aspects of the laboratory activity, including organizational structure, processes and procedures, are considered in terms of providing and improving quality.

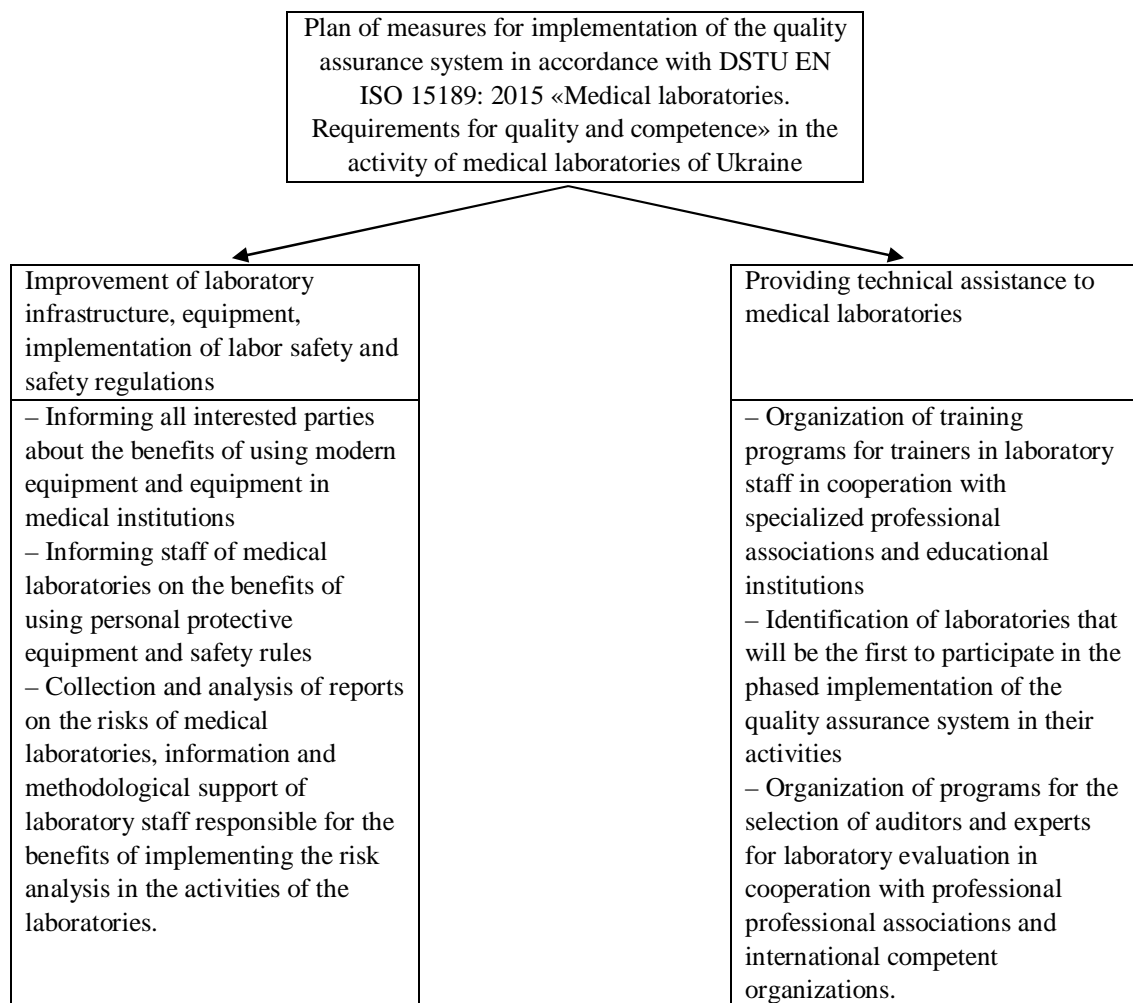


Fig. 2. The plan of measures for implementation of the quality assurance system according to DSTU EN ISO 15189: 2015

Conclusion

According to the results of research, priority directions of improvement of medicine at the present stage are determined. In particular, the need for further close cooperation between state institutions of the medical sector and numerous private institutions is established. That not only raises the level of competitiveness of all subjects, but also solves the task of improving the quality of medical services.

Substantiation of foreign experience introduction, in particular the application of quality standards in the provision of medical services, the focus on the consumer, which eventually increase the level of medical institutions to the European. Analysis indicates the need for further attention to the issue of quality in the medical sector and in the activities of the CDL. Problem of ensuring the quality of laboratory research should be solved at the national level in Ministry of Health of Ukraine, in health care institutions and at the level of each individual CDL. This can help to implement the requirements of the international standard «Medical Laboratories. Quality and Competency Requirements», which aiming the creation of quality management system for KDLs and their subsequent accreditation. Participation in the Ministry of Health is part of this general system of quality assurance of laboratory research and increases their effectiveness in the diagnostic, preventive and curative process. For the vast majority of laboratory studies, the precise execution of techniques does not yet ensure the reliability of the results. This is due to the fact that the study of biological material – a complex multi-stage process, which involves difficult-controlled operations that affect the accuracy of the results. Knowledge of errors that may occur at different stages of the patient's examination, sufficient theoretical and practical competence of doctors

in the field of laboratory diagnosis, proper assessment of the factors influencing the interpretation of the results will help eliminate defects in diagnosis and conduct timely treatment. The main task of the Medical Laboratory (KDL) is to provide clinically relevant information, rather than simply presenting the results of the research. Methods of research can be different, the goal is the only – a comprehensive examination of the patient. Therefore, if the diagnosis is based on laboratory data, the doctor should be sure of the qualitative performance of the research. Establishment of continuous cooperation and mutual understanding between laboratory specialists and clinicians is a prerequisite for the contribution of the KDL to the activities of the medical institution to be really weighty and properly appreciated.

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