Received: 17.05.2024 Accepted: 25.06.2024 Published online: 29.06.2024
УДК: 616-07-074/-076
DOI: 10.26212/2227-1937.2024.34.23.014

H. Bazarah[1], https://orcid.org/0009-0000-5227-5848
A.D. Nurakhova[2], https://orcid.org/0000-0003-0048-1396
A.M. Maimakova[3], https://orcid.org/0000-0002-4334-6891
T. Akhayeva[1], https://orcid.org/0000-0003-1929-4494
B.S. Utegenova[1], https://orcid.org/0009-0004-0428-5661
A.Zh. Duisenbayeva[2], https://orcid.org/0009-0002-8833-1543
[1]Al-Farabi Kazakh National University, Almaty, Kazakhstan
[2]Asfendiyarov Kazakh National Medical University, Almaty, Kazakhstan
[3] Kenzhegali Sagadiyev University of International Business (UIB), Almaty, Kazakhstan

ON THE ISSUE OF QUALITY CONTROL OF MEDICAL LABORATORY TESTS

Resume: As healthcare systems around the world increasingly rely on laboratory testing, maintaining high quality diagnostic services is imperative. In Kazakhstan, the importance of quality control in medical laboratories is being recognized, but there is a need to evaluate and improve current practices against international standards.
Purpose: The purpose of this review article is to assess the current state of quality control in medical laboratories in Kazakhstan and then compare it with quality control procedures in other countries.
Search strategy: Perform a comprehensive search in electronic databases such as PubMed, Google Scholar, Scopus and Web of Science with relevant keywords including “international standards”, “medical laboratories”, “quality control”, “quality assurance” and other. The search was limited to articles published in English between 2001 and 2023 to ensure inclusion of recent research and current practice.
Results: A total of 79 publications were selected for the study based on their significance for quality control in medical laboratories, especially in Kazakhstan. The articles covered a wide range of topics, including regulatory frameworks, accreditation requirements, training programs, equipment requirements, data management systems, and collaborative efforts. A comparative study of quality control procedures in Kazakhstan with other countries revealed its positive and negative aspects.
Key words: medical laboratory, quality control, quality management, patient care, laboratory results, Kazakhstan.

H. Bazarah[1], А.Д. Нурахова[2], А.М. Маймакова[3], Т.А. Ахаева[1],
Б.С. Утегенова[1], А.Ж. Дуйсенбаева[2]
[1] «Әл-Фараби атындағы Қазақ ұлттық университеті» КЕАҚ, Алматы қ., Қазақстан Республикасы
[2] «С. Д. Асфендияров атындағы Қазақ ұлттық медицина университеті» КЕАҚ, Алматы қ., Қазақстан Республикасы
[3] «Кенжеғали Сағадиев атындағы Халықаралық бизнес университеті» ЖШС, Алматы, Қазақстан Республикасы

МЕДИЦИНАЛЫҚ ЗЕРТХАНАЛЫҚ ЗЕРТТЕУЛЕРДІҢ САПАСЫН БАҚЫЛАУ МӘСЕЛЕСІ

Түйін: бүкіл әлемдегі денсаулық сақтау жүйелері зертханалық тестілеуге көбірек сүйенетіндіктен, диагностикалық қызметтердің жоғары сапасын сақтау міндетті шарт болып табылады. Қазақстанда медициналық зертханаларда сапаны бақылаудың маңыздылығы мойындалады, бірақ халықаралық стандарттармен салыстырғанда қолданыстағы тәжірибені бағалау және жақсарту қажеттілігі бар.
Мақсаты: осы шолу мақаласының мақсаты Қазақстанның медициналық зертханаларында сапаны бақылаудың ағымдағы жай-күйін бағалау, содан кейін оны басқа елдердегі сапаны бақылау рәсімдерімен салыстыру болып табылады
Іздеу стратегиясы: PubMed, Google Scholar, Scopus және Web of Science сияқты электрондық дерекқорларда "халықаралық стандарттар", "медициналық зертханалар", "сапаны бақылау", "сапаны қамтамасыз ету" және т.б. сияқты тиісті кілт сөздермен жан-жақты іздеуді орындау. Іздеу соңғы зерттеулер мен заманауи тәжірибелерді қамтуды қамтамасыз ету үшін 2001-2023 жылдар аралығында ағылшын тілінде жарияланған мақалалармен шектелді.
Нәтижелері: зерттеу үшін медициналық зертханаларда, әсіресе Қазақстанда сапаны бақылау үшін маңыздылығы бойынша барлығы 79 басылым таңдалды. Мақалалар нормативтік-құқықтық базаны, аккредиттеу талаптарын, оқыту бағдарламаларын, жабдыққа қойылатын талаптарды, деректерді басқару жүйелерін және бірлескен күш-жігерді қоса алғанда, көптеген тақырыптарды қамтыды. Қазақстандағы сапаны бақылау рәсімдерін басқа елдермен салыстырмалы зерттеу оның оң және теріс жақтарын анықтады.
Түйінді сөздер: медициналық зертхана, сапаны бақылау, сапаны басқару, науқастарға күтім жасау, зертханалық зерттеулер нәтижелері, Қазақстан.

H. Bazarah[1], А.Д. Нурахова[2], А.М. Маймакова[3], Т.А. Ахаева[1],
Б.С. Утегенова[1], А.Ж. Дуйсенбаева[2]
[1] НАО «Казахский национальный университет имени аль-Фараби», Алматы, Республика Казахстан

[2] НАО «Казахский национальный медицинский университет имени С.Д. Асфендиярова», Алматы, Республика Казахстан
[3] ТОО «Университет международного бизнеса имени Кенжегали Сагадиева», Алматы, Республика Казахстан

К ВОПРОСУ КОНТРОЛЯ КАЧЕСТВА МЕДИЦИНСКИХ ЛАБОРАТОРНЫХ ИССЛЕДОВАНИЙ

Резюме: Поскольку системы здравоохранения во всем мире все больше полагаются на лабораторное тестирование, поддержание высокого качества диагностических услуг является обязательным условием. В Казахстане важность контроля качества в медицинских лабораториях получает признание, но существует необходимость оценки и улучшения существующей практики по сравнению с международными стандартами.
Цель: Целью данной обзорной статьи является оценка текущего состояния контроля качества в медицинских лабораториях Казахстана, а затем сравнение его с процедурами контроля качества в других странах.
Стратегия поиска: выполнение комплексного поиска в электронных базах данных, таких как PubMed, Google Scholar, Scopus и Web of Science, с соответствующими ключевыми словами, включая «международные стандарты», «медицинские лаборатории», «контроль качества», «обеспечение качества» и другие. Поиск был ограничен статьями, опубликованными на английском языке в период с 2001 по 2023 год, чтобы обеспечить включение последних исследований и современной практики.
Результаты: Всего для исследования было выбрано 79 публикаций по их значимости для контроля качества в медицинских лабораториях, особенно в Казахстане. Статьи охватывали широкий спектр тем, включая нормативно-правовую базу, требования к аккредитации, программы обучения, требования к оборудованию, системы управления данными и совместные усилия. Сравнительное исследование процедур контроля качества в Казахстане с другими странами выявило его положительные и отрицательные стороны.
Ключевые слова: медицинская лаборатория, контроль качества, управление качеством, уход за пациентами, результаты лабораторных исследований, Казахстан.

Introduction. Quality control is a crucial component of medical laboratory operations, as it guarantees accurate, precise and dependable results [1–3]. The accepted standard of laboratory testing encounters an immediate influence on patient care, decisions regarding treatment, and overall health outcomes in the field of clinical diagnostics [4–6]. The term "quality control" refers to a broad range of procedures and actions that seek to identify, stop, and correct mistakes generated during the testing process in order to preserve the preciseness of laboratory results [7–9].

Medical laboratories perform an essential function in the diagnostic process by supporting the identification, tracking, and assessment of treatments [10–13]. For proper treatment planning, precise diagnosis, and efficient patient management, laboratory results must be accurate and dependable [14–16]. Establishing trustworthy techniques with comprehensive processes to identify, address, as well as prevent errors during testing is the primary objective [17, 18]. Medical laboratories guarantee that their tests are carried out accurately and consistently by following rigorous standards [19, 20]. Maintaining the accuracy, dependability, timeliness, and integrity of laboratory results depends primarily on quality control procedures [21, 22]. Such measures embrace a broad variety of topics, such as meticulous equipment maintenance, implementing standard operating procedures (SOPs), periodic calibration, ongoing testing condition monitoring, and proficiency testing [23–25]. It is impossible to overstate the importance of quality control given its influence on patients' health [26–28]. As Kazakhstan works to improve its healthcare infrastructure to deliver better patient care, the need of quality control in medical laboratories has come to light [29]. The medical laboratory services in Kazakhstan have advanced significantly, but in order to bring them into compliance with international standards, an assessment and improvement of the current procedures are required [30]. It is unthinkable to overemphasize the crucial role of quality control in medical laboratories [31]. Inadequate quality control procedures can result in mistaken findings, inaccurate diagnoses, ineffective treatments, and compromised patient safety [32]. On the other hand, rigorous systems for quality control guarantee that laboratory testing are carried out as precisely and consistently as possible [33]. Quality control plays a protective role, enhancing the accuracy and dependability of laboratory results by identifying and correcting mistakes or deviations at every stage of the testing procedure [34].

Objectives. This review article has two goals in consideration. First and foremost, it seeks to give a thorough picture of the condition of quality control procedures in medical laboratories today, with a particular emphasis on Kazakhstan. We aim to find opportunities for improvement and practical approaches for boosting quality control in Kazakhstan's medical laboratories by comparing our procedures with those of countries around the world. Secondly, the goal of this review article is to provide guidance to stakeholders in laboratories, healthcare providers, and policymakers regarding how to improve quality control systems by highlighting successful projects, best practices, and experiences learned from experiences across the globe.

Search strategy. The search method used an objective approach for finding relevant papers on quality control methodologies in medical laboratories, with a focus on Kazakhstan. A thorough investigation was carried out utilizing popular electronic databases, such as PubMed, Google Scholar, Scopus, and Web of Science. In order to guarantee a comprehensive search, appropriate search phrases like "international standards," "medical laboratories," "quality control," "quality assurance," "clinical laboratories," "laboratory practices," and "Kazakhstan" were employed.

Only English-language articles published between 2001 and 2023 were included in the search to guarantee the inclusion of current research and optimal methods. The time frame

was intended to include the most recent research findings and developments in the field. Exclusion criteria were used to eliminate research that did not considerably contribute to the understanding of quality control systems or were primarily focused on non-medical laboratory environments. The initial screening method consisted of assessing the relevancy of articles based on their titles and abstracts. Articles that fulfilled the inclusion parameters were chosen for additional assessment. After that, the full works of these chosen research articles were obtained in order to conduct a thorough evaluation. This review included a thorough examination of the methodology, content, applicability to medical laboratory quality control protocols, and Kazakhstan as a particular focus. During the full-text review, significant findings, information, and discoveries about quality control processes in medical laboratories in Kazakhstan were retrieved from the chosen papers. The goal of this data extraction procedure was to collect pertinent data for additional analysis and synthesis.

With a particular emphasis on Kazakhstan, a thorough compilation of papers about quality control practices in medical laboratories was found by employing this methodical search approach. These articles contributed to a thorough understanding of quality control procedures in the context of medical laboratories in Kazakhstan by offering insightful and informative information.

Results and discussion. Quality Control in the Medical Laboratories Globally. Medical laboratories worldwide rely extensively on quality standards and quality control procedures since they are essential for maintaining the reliability, accuracy and precision of test results, safeguarding well-being for patients, and facilitating efficient delivery of healthcare [35–38]. A comprehensive discussion of the main conclusions and arguments regarding the current status of quality standards and quality control procedures in medical laboratories across the globe are given in this part. Through an extensive review of numerous studies conducted in various countries, this article examines the current landscape of quality standards and quality control practices in medical laboratories on a global scale.

The study conducted by Sarah et al. (2023) examined the state of quality standards and internal quality control (IQC) practices in medical laboratories on a global scale [39]. While it was encouraging to find that a significant number of countries had established legislative statutes or accrediting prerequisites to regulate laboratory quality, the lack of universal enforcement raised concerns [39]. Inconsistent adherence to quality standards can lead to variations in test accuracy, reliability, and patient safety [6, 40, 41]. To address this issue, it is crucial for countries to prioritize the implementation and enforcement of quality standards universally [42]. The study also shed light on the variations in IQC procedures among participating countries [39]. While routine IQC performance every 24 hours and the use of two levels of IQC were commonly reported, the absence of formal IQC policies and procedures in many medical laboratories indicates a need for standardized practices [40, 43]. Developing formal programs and enhancing educational activities can help improve the implementation of IQC procedures, leading to more reliable and accurate test results [44].

In Spain, a study was conducted to evaluate the analytical performance of laboratories participating in external quality assurance (EQA) programs [45]. The findings demonstrated improvements in laboratory performance over time, indicating a commitment to quality [45]. However, the study also highlighted challenges in comparing EQA programs due to differences in design and accessibility [45]. Harmonization and collaboration among EQA program organizers are vital to ensure consistent and standardized EQA programs [43, 46]. This would enable laboratories to benchmark their performance against established criteria and improve the overall quality of laboratory testing [46].

Another important study was conducted in China that emphasized the importance of systems-based approaches in reducing variation in laboratory testing cycles and improving patient safety [47]. Laboratory accreditation initiatives were identified as crucial in enhancing the overall standard of laboratory testing [48]. Benchmarking surveys conducted in the Asia-Pacific region provided insights into Chinese laboratories' performance, which was found to be largely equivalent to that of other laboratories in the region [47]. However, variations were observed in areas such as responding to urgent samples and participating in external quality assurance initiatives [49]. This study highlighted the need for continuous improvement strategies and the standardization of laboratory testing procedures in China to ensure consistent and high-quality healthcare delivery [47].

In Canada, the examination of laboratory quality regulations and accreditation standards revealed a trend towards embracing ISO criteria among accrediting bodies [50]. This demonstrated a commitment to standardizing quality management procedures across the country [26, 51]. The formation of the Canadian Coalition for Quality in Laboratory Medicine (CCQLM) further emphasized the efforts towards standardization and collaboration among laboratory medicine stakeholders [52]. These initiatives are instrumental in promoting a culture of quality and ensuring consistent laboratory practices throughout Canada [50, 53].

The study conducted in Saudi Arabia assessed the knowledge and perceptions of medical laboratorians regarding quality management systems [54]. While the participants demonstrated a good understanding of quality control procedures, the findings indicated a need for further education and training to enhance their comprehension of quality management [54]. Active involvement of laboratory personnel in ensuring high-quality healthcare was emphasized, highlighting the importance of expanding their expertise in quality systems [54, 55]. Continuous education and training programs can empower laboratorians to contribute effectively to quality improvement initiatives and promote a culture of continuous quality improvement [54, 56, 57].

In Thailand, internal and external quality control methods have been suggested and quality control is a top priority in a variety of sectors, including hospitals and medical laboratories [58]. In order to help laboratories, comply with these quality standards, the NPTS and EQAS are required [59]. In a survey of 200 laboratories, more than 70 percent of the 57 participants had signed up for the EQAS or the NPTS, and some laboratories had even participated in both programs [58]. Furthermore, two new programs have been established for hematology and red cell serology

laboratories in recognition of the need for more external quality assessment programs [58, 60]. Nevertheless, there is a pressing need for external quality assessment programs in some laboratory categories, including coagulation, hemoglobin typing, and serology for autoimmune illnesses [61]. Thailand's attempts to set up and carry out external quality evaluation programs reflect a dedication to laboratory testing standards and quality control [62]. Labs can evaluate their level of proficiency, define areas for development, and guarantee the accuracy and dependability of their test results with the use of the EQAS and NPTS [63]. Ensuring patient safety and improving the overall quality of laboratory services in Thailand need the ongoing growth of these programs to include more laboratory specialties [64].

In Germany, the study focuses on the evolution of quality management requirements for medical laboratories since 1971, emphasizing the comprehensive character of the 2014 standards [65]. The guideline's 2014 revision, which aligns with current national and international standards and covers a comprehensive quality management effort for medical laboratories, represents a significant achievement [65]. Almost every aspect of a laboratory's analytical procedures, including the pre-analytic, analytic, and post-analytic stages, must be disclosed [65, 66]. The guideline also covers analytical techniques that were not previously subject to minimal quality criteria [67]. The first essential step in raising the standard of laboratory medicine is the adoption of the German Medical Association's 2014 Guideline on Quality Assurance in Medical Laboratory Examinations [65]. It guarantees that national and international quality standards are strictly adhered to by all laboratories in Germany that examine human specimens for medical purposes [65, 67]. Through emphasis on both structural and analytical processes, the guideline seeks to improve patient safety and laboratory medicine's overall quality [66, 68].

The study conducted in India concentrates on the subject of minimal engagement in external quality assessment schemes (EQAS) for hemostasis testing in nations with limited resources [69]. In 2000, the researchers launched an EQAS initiative in India to deal with this issue; at first, about 25 laboratories connected to the Hemophilia Federation participated in the study [69, 70]. The UK National External Quality Assessment Scheme provided assistance for the initiative, which was then partnered with the Indian Society of Haematology and Transfusion Medicine to reach a national scale in 2003 [69]. With over 100 registered laboratories receiving samples three times a year, the initiative is currently flourishing [69, 70]. Tests including prothrombin time, activated partial thromboplastin time, and factor assays are performed using the submitted samples. The initiative has been productive in pinpointing the reasons for subpar performance; going forward, the hurdles will be in growing the program's participation, enhancing the reporting of results, and offering laboratories customized assistance to improve performance [64]. The study's findings highlight the need for India to establish and grow an EQAS program for hemostasis testing [64]. It addresses the reasons behind the poor participation in EQAS programs in underdeveloped countries and emphasizes the need of regular quality assessment [71]. The program's capacity to identify performance issues draws attention to the need for increased participation, better reporting, and customized support to help laboratories become more efficient [69, 70].

In conclusion, these studies collectively highlight the global efforts and challenges associated with implementing and standardizing quality standards and quality control practices in medical laboratories. Variations in regulatory frameworks, IQC procedures, EQA programs, and laboratory quality regulations exist among different countries. The findings underscore the need for harmonization, collaboration, and continuous improvement strategies to ensure consistent and high-quality laboratory practices worldwide. By working together, countries can enhance patient safety, reliability of test results, and overall healthcare delivery.

Current state in Kazakhstan. In reviewing the current state of medical laboratory quality control in Kazakhstan, two insightful studies shed light on the country's laboratory services' strengths and areas of improvement. The first study highlights the significance of well-organized workflows and extensive quality control systems in laboratory research, as well as the need to increase participation in External Quality Assessment (EQA) programs and strengthen adherence to internal quality control practices. The second study focuses on the development of public-private partnerships, the expanding number of clinical diagnostic laboratories in Kazakhstan, and the requirement for established standards and guidelines to provide uniform quality control procedures. Together, these studies provide valuable insights into the existing state of laboratory quality control and offer recommendations for enhancing the accuracy, reliability, and overall quality of medical laboratory services in Kazakhstan.

The first study states that in Kazakhstan, internal QC practices are generally established but require strengthening adherence [72]. EQA participation has grown in clinical chemistry but remains limited for specialized testing [72]. The state of laboratory quality control in Kazakhstan at the moment, particularly with regard to clinical and laboratory services, can be evaluated [73]. An evaluation of the laboratory research quality assurance in sanitary and epidemiological examination organizations was the goal of a study carried out in Almaty City. The findings showed that a well-organized workflow involving all related phases of the research process is essential to achieving high standards in laboratory research [72]. One of the most important issues in contemporary laboratory medicine is the creation of an extensive quality control system for clinical laboratory research that considers a variety of elements and evaluation techniques [72].

In order to guarantee quality, the workers engaged in the process are crucial. This covers elements like their drive, participation in formulation and execution of decisions, and the character of connections both within the team and with management [74]. A total of 217 workers from various clinical and laboratory services, such as hospitals, research facilities, diagnostic centers, and private laboratories, were polled for the study. The information showed that employees under thirty were more common in hospitals (77%), whilst people over fifty were more common in polyclinics (about 47%). Medical centers employed 100% of their workforce as young adults under 30. The distribution of diagnostic centers was quite uniform in terms of age,

with roughly 50% of patients being under 30 and 40% being between 40 and 49 [72].

Across all responder age categories, the survey also discovered indications of close coordination between laboratory staff and clinicians. Roughly 90% of Clinical Diagnostic Laboratories (CDL) professionals gave the management of the laboratory favorable ratings. The significance of monetary incentives for providing superior services was acknowledged by professionals in the state (74%) and private (100%) healthcare sectors [72]. These results illustrate Kazakhstan's existing laboratory quality control situation and emphasize the significance of appropriate staff motivation, organizational structure, and management techniques [30, 72]. In order to guarantee the provision of top-notch healthcare services in the nation, the study highlights the significance of putting in place a thorough quality control system in clinical laboratory services, taking into account the perspectives of specialists engaged [72].

The other study, on the other hand, concur that the current state of quality control in laboratory services in Kazakhstan, particularly in Almaty city, is characterized by a growing number of public and private clinical-diagnostic laboratories [75]. This expansion reflects the increasing demand for laboratory studies, particularly driven by the private sector. The government actively supports private business development in the healthcare industry, and health services are exempt from value-added tax [75]. Consequently, private laboratories have become significant players in providing services according to the Generalized Health Care Payment Law (GVFHC) and engaging in public-private partnership (PPP) programs [75].

Public-private partnerships are particularly prominent in Almaty oblast, where the government provides laboratories with staff, equipment, and an agreed volume of Greater Vancouver Floating Home Co-op (GVFHC) services. In turn, private entities enhance service quality, equip laboratories to meet current standards, and deliver services in accordance with up-to-date guidelines. This collaboration has resulted in several quality control measures being implemented. Private laboratories offer the convenience of conducting tests at home, remote patient registration, and swift transfer of test results via courier, phone, or email. Moreover, they provide discounts to various patient categories, corporate clients, and regular customers. Private laboratories also prioritize patient comfort by providing well-equipped facilities, convenient biomaterial collection points, and electronic queuing systems [75].

In contrast, laboratories in public institutions in Almaty are known for their well-equipped facilities and high testing capacity, conducting over 1,000 laboratory studies per day. These laboratories adhere to ISO 15189 international standards, ensuring rigorous quality control practices. However, a notable concern in the current state of laboratory services in Kazakhstan is the absence of approved standards for laboratory studies. Existing regulations primarily focus on the operational aspects of laboratories, rather than the quality control of laboratory results. This has led to a reliance on reference values provided in the instructions for the reagents used, which can introduce potential errors (76). Each laboratory is expected to establish its own norms based on the region and population it serves, resulting in inconsistencies in quality control practices [75].

To address this issue and improve the state of quality control, it is essential to establish approved standards for laboratory studies in Kazakhstan [75]. These standards should encompass not only the operational aspects of laboratories but also the quality control of laboratory results [77]. Implementing consistent standards will help minimize errors, improve accuracy, and ensure the overall quality of laboratory services across the country [78]. Additionally, the development of comprehensive guidelines for laboratory testing, including standardized reference ranges for different tests, will contribute to uniformity in quality control practices [79].

To sum up, while the laboratory sector in Almaty, Kazakhstan, has experienced significant growth, the current state of quality control in laboratory services requires attention. The active presence of private laboratories, along with government support and public-private partnerships, has improved accessibility and convenience for patients. However, the absence of approved standards for laboratory studies poses a challenge to maintaining consistent quality control practices. By establishing approved standards and comprehensive guidelines, Kazakhstan can enhance quality control in laboratory services, minimize errors, and ensure accurate and reliable test results for improved patient care.

Conclusion. In conclusion, the comparison of laboratory quality control practices and studies conducted in various countries emphasizes the importance of implementing key recommendations to enhance the current state of laboratory quality control in Kazakhstan. By following these recommendations, Kazakhstan can elevate its laboratory services to meet global standards and contribute to the advancement of laboratory quality control practices worldwide.

Firstly, standardizing practices is crucial for ensuring consistent and reliable laboratory testing. Kazakhstan should prioritize the establishment and enforcement of universal quality standards across the country. This includes developing comprehensive guidelines that cover all stages of laboratory procedures, from pre-analytical to post-analytical phases. By adhering to these standards, laboratories can minimize errors, reduce variations, and improve the overall quality of their services.

Secondly, implementing comprehensive quality management procedures is essential for driving continuous improvement in laboratory services. Kazakhstan should adopt robust quality management systems that encompass all aspects of laboratory operations, including equipment calibration, quality assurance, and proficiency testing. Regular internal audits and performance evaluations should be conducted to identify areas for improvement and ensure compliance with quality standards.

Active participation in external quality assessment (EQA) programs is another critical recommendation. Kazakhstan should establish and expand EQA programs to provide laboratories with a means to assess their proficiency and compare their performance against national and international benchmarks. It is important to ensure the accessibility of these programs to laboratories across various specialties. By participating in EQA, laboratories can identify any performance gaps, address them promptly, and enhance the accuracy and reliability of their test results.

Education and training should be prioritized to promote a culture of continuous quality improvement. Kazakhstan should invest in comprehensive educational programs for laboratory personnel, focusing on quality management principles, standard operating procedures, and the latest advancements in laboratory technology. Continuous professional development opportunities and training workshops should be provided to ensure that laboratory personnel are equipped with the necessary knowledge and skills to deliver high-quality healthcare services.

Furthermore, fostering collaboration and knowledge exchange among laboratories and stakeholders is crucial. Kazakhstan should establish collaborative platforms, such as professional networks or consortiums, to facilitate the sharing of best practices, promote standardization of laboratory procedures, and drive quality improvement initiatives. Collaboration with national and international organizations, academic institutions, and regulatory bodies can provide valuable guidance, resources, and expert support to enhance laboratory quality control practices.

In addition to these recommendations, it is important for Kazakhstan to establish a robust regulatory framework for laboratory quality control. This includes the development of comprehensive regulations and licensing requirements for laboratories, as well as regular inspections and audits to ensure compliance. Clear accountability and enforcement mechanisms should be in place to address any non-compliance issues and promote a culture of quality and patient safety.

By implementing standardized practices, comprehensive quality management procedures, active participation in EQA programs, prioritizing education and training, fostering collaboration, and establishing a robust regulatory framework, Kazakhstan can significantly improve laboratory quality control. These efforts will lead to the delivery of consistent and high-quality laboratory services, ensuring patient safety and contributing to better healthcare outcomes for the population. By embracing these recommendations, Kazakhstan can play a leading role in advancing laboratory quality control practices and serve as a model for other countries striving for excellence in laboratory medicine.

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No conflict of interest has been declared.
This material has not been previously submitted for publication in other publications and it is not under consideration by other publishers. During this work, there was no funding from third-party organizations and medical
The contribution of the authors. All the authors took an equal part in writing this article.
representative offices.
Financing was not carried out.

Авторлардың үлесі. Барлық авторлар осы мақаланы жазуға тең дәрежеде қатысты.
Мүдделер қақтығысы - мәлімделмеген.
Бұл материал басқа басылымдарда жариялау үшін бұрын мәлімделмеген және басқа баспалардың қарауында жоқ. Бұл жұмысты жүргізу кезінде бөгде ұйымдар мен медициналық өкілдіктер қаржыландырған жоқ.
Қаржыландыру - жүргізілген жоқ.

Вклад авторов. Все авторы принимали равносильное участие при написании данной статьи.
Конфликт интересов – не заявлен.
Данный материал не был заявлен ранее, для публикации в других изданиях и не находится на рассмотрении другими издательствами. При проведении данной работы не было финансирования сторонними организациями и медицинскими представительствами.
Финансирование – не проводилось.

Information about authors:

№	Full name	Position, place of work	Phone	E-mail
1	Husam Ahmed Hamood Bazarah	Master's student I year of study of the Department of Fundamental Medicine, Higher School of Medicine, Faculty of Medicine and Healthcare, Al-Farabi Kazakh National University.	+7(747)6560944	hussam83072@gmail.com
2	Nurakhova Alma Dandybaevna	к.м.н., Candidate of Medical Sciences, Associate Professor of the Department of Normal Physiology with a course in Biophysics of Asfendiyarov Kazakh National Medical University.	+7(705)9904880	nurakhova.a@kaznmu.kz
3	Maimakova Akmaral Meirbekovna	Candidate of Medical Sciences, Associate Professor of the Clinical Medicine Department of International Business University named after Kenzhegali Sagadiev	+7(777)0902293	maimakovakmar@gmail.com
4	Akhayeva Tamila	PhD, Associate Professor of the Department of Fundamental Medicine, Higher School of Medicine, Faculty of Medicine and Healthcare, Al-Farabi Kazakh National University	+7(777)3060445	tamila.akhaeva@kaznu.edu.kz
5	Utegenova Bakhyt Sayatovna	5th year student of the Department of General Medicine of Medicine Faculty of Al-Farabi National University	+7(707)5050109	pretty.bahyt@gmail.com
	Duisenbayeva Altyn Zhailauovna	assistant of the Department of General Medical Practice № 2 of	+7(701)8384995	duysenbaeva.a@kaznmu.kz

		General Medical Faculty of Asfendiyarov Kazakh National Medical University		