CONSOLIDATION OF THE QUALITY INDICATOR SYSTEM FOR CLINICAL LABORATORY PERFORMANCE IMPROVEMENT

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Abstract

The implementation and monitoring of quality indicators should be concerned an essential component of a continuous quality improvement program. This research aims at developing a model of a quality indicator system assessment for improving the performance of medical testing laboratories. In addition, the goal is to provide insights and suggestions for the successful implementation of the quality indicator system, estimating the factors, measures, and barriers related to the knowledge, attitudes, and behaviors of laboratory professionals. This study is based on a mixed method approach comprising both quantitative (survey) and qualitative (expert interview) research methods. Based on the insights derived from the literature review, expert interviews, and survey, we developed a model for the evaluation of the quality indicator system of the medical laboratory. The model covers the entire process of conducting the research (the pre- and post-analytical, analytical phases). Moreover, it complies with the requirements of the international standard EN ISO 15189:2013 and ensures the criteria for the evaluation of health care quality measures. The authors' consolidated model for the evaluation and implementation of a quality indicator system could be a valuable tool for laboratories that implement, modify, or update quality indicator systems.

Keywords: *Medical laboratory, Healthcare service quality management, Quality indicator, Model, Paradox of quality indicators*

1. Introduction

Ensuring high-quality standards from the side of service providers is essential in today's consumer world. Clinical diagnostic laboratories are at the epicenter of the healthcare sector. Therefore it is relevant to ensure the quality of their services, since 80-90% of all diagnoses depend on laboratory tests (Agarwal et al., 2012; Chawla et al., 2010). The literature review phase has highlighted the use of quality indicators (QIs) as an effective tool for continuous improvement (Catini et al., 2015). Moreover, the development of reliable QIs is an essential step in assessing and improving the quality of care (Bucke et al., 2020; Plebani et al., 2013).

Quality indicators and their application in medical testing laboratories are one of the most important tools for the reduction of errors. However, laboratory practices vary, thus data are difficult to compare. Comparability is complicated due to differences in the quality indicators used and in the collection and evaluation of data. An analysis of the scientific literature (e.g. Aita et al., 2019; Plebani et al., 2014; Plebani, 2018a) reveals a lack of ongoing research related to the development of quality indicator systems and methodologies for laboratory medicine. In addition, the developed existing international quality indicator system is not popular and widely used in the laboratory community. This situation in laboratory practice is being identified as the “Quality Indicator Paradox”. The created national quality indicator assessment programs do not always meet the requirements of international standards and do not cover the areas of health care quality (patient safety, efficiency, patient-centeredness, timeliness, effectiveness, and equitability). The Lithuanian scientific literature does not provide information about the quality indicators used in medical

research laboratories, covering all stages of the testing process, their development, implementation, data collection, and feedback assessment. In summary, the development, implementation, and use of a quality indicator system in Lithuanian medical research laboratories are in their first steps and are not yet a part of the laboratory culture. Authors could not manage to find any scientific papers determining the barriers, measures, and factors that may influence the successful implementation of a quality indicator system in medical testing laboratories.

The purpose of the present study is to develop a consolidated quality indicator system assessment model based on the analyzed scientific literature and an empirical study. Additionally, to provide insights and suggestions for the successful implementation of a quality indicator system by estimating the factors, measures, and barriers related to the knowledge, attitudes, and behavior of laboratory professionals.

Tasks of the study:

1. After examining the scientific literature, to perform an analysis of the causes of medical laboratory errors.
2. After analyzing the scientific literature, to define the concept of laboratory quality indicators, the requirements for them, compare the practices of using quality indicators, and reveal the challenges of their selection and use to reduce the number of errors, contributing to the improvement of laboratory performance and healthcare quality.
3. After conducting the empirical study, to perform data analysis, systematize and interpret the research results.
4. Based on the interpretation of the results of the empirical study, to develop a consolidated quality indicator system assessment model; provide insights and suggestions after assessing barriers related to knowledge, attitudes and behavior; factors and measures affecting the successful implementation of a quality indicator system.

2. Literature review

2.1 The role of the medical research laboratory in healthcare

The importance of medical research laboratories in the healthcare system can hardly be denied. They are integral to many clinical decisions regarding the prevention, diagnosis, treatment, and management of patients' diseases (Ferraro et al., 2016). Laboratory data affect about 70% of medical decisions. Almost 70% of clinical diagnoses depend on laboratory results. In addition, approximately 70% of the information contained in medical records consists of the results of laboratory test (Lippi & Plebani, 2020; Trancheva, 2020). The use of diagnostic laboratory services differs according to the type of medical services provided to the patient. Nearly all, i.e. 98% of inpatients, thereabout half (56%) of emergency department patients, and nearly a third (29%) of outpatients are tested in laboratory. The aim of the tests performed is to assess the patient's condition, establish a diagnosis and prescribe treatment (Ngo et al., 2017). Clinical laboratory diagnostics is an important interdisciplinary activity in every country's health services. Hence, it contributes to its progressive development (Trancheva, 2020). This contribution of the laboratory continues to increase through research and technological advances. It manifests through improving the knowledge and skills of professionals (Dhingra−Kumar et al., 2021; Wieringa et al., 2021). Today's realities have confirmed another important role of medical research laboratories in the management of emerging and re-emerging infectious diseases. They are essential for identifying, tracking, monitoring, and managing virus threats to public health. Laboratory medicine makes an effective contribution to the fight against virus outbreaks. Laboratory tests are vital in many clinical pathways, but the main areas are: aetiological diagnosis, patient monitoring, and epidemiological surveillance, requiring in vitro diagnostics for patient diagnosis and surveillance (Lippi & Plebani, 2020). Over time, healthcare delivery and responsibilities are changing. Patient-centered healthcare is gaining international recognition. Moreover, the patient takes greater responsibility for his/her own health and is involved in decision-making with regard to the diagnosis of disease and the prescription of treatment. Laboratory medicine needs to embrace this change and therefore work in a tripartite partnership with patients and physicians using clinical laboratory services (Watson et al., 2019). Collaborative care prevails when healthcare workers from different disciplines work in partnership with patients and carers to provide comprehensive services and, accordingly, deliver high-quality personal healthcare (Watson et al., 2019). Laboratory medicine today is shifting to personalized laboratory medicine. It is based on optimizing treatment at the level of the individual patient. In addition, this type of laboratory medicine contrasts with the medicine that focuses on medical solutions adjusted to the population. Personalized laboratory medicine can be defined as the "child" of the modern age. High-throughput omics technologies are now becoming an important part of diagnostics and therapeutics. They are expected to lead to more accurate diagnoses and safer more effective treatments. They contribute, thus, to better outcomes, improved quality of life, and increased cost-effectiveness (Žitnik et al.,

2018). Kosinskienė and Ruževičius, after investigating the peculiarities of the application of quality management measures to improve the performance of health care institutions, developed a framework of good practice interfaces (Figure 1). This framework distinguishes the laboratory to be one of the important elements in the health care system. Its interaction with the good practices of all health care institutions (GMP, GPP, GDP, GCP) comprises a whole. Its purpose is "to identify and manage risk factors, guarantee safety and quality" (Kosinskienė & Ruževičius, 2011).

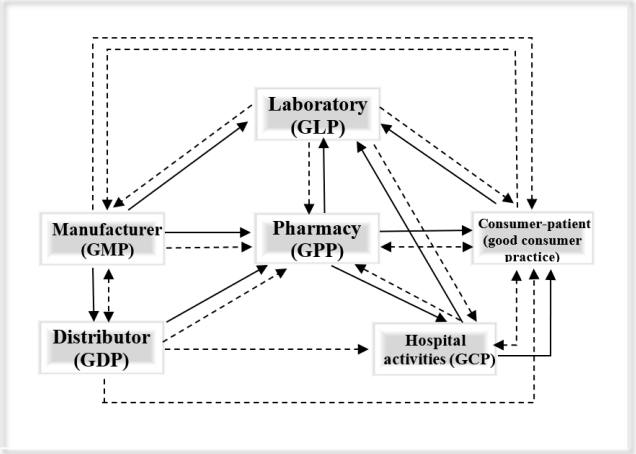


Figure 1: A framework of good practice interfaces (products →; information ⇢)
Source: Kosinskienė & Ruževičius, 2011

All subsystems of the best practice, shown in Figure 1, interact with each other to form a system of good practices (GPs). The aforementioned system has an impact on patient safety (Kosinskienė & Ruževičius, 2011). The provision of laboratory medicine services differs around the world considerably in terms of service specifications, systems, and reimbursement models (Watson et al., 2019). However, five main roles of laboratory medicine can be identified in the healthcare system. Those attributed roles are regardless of the country of the world and the scale of provided services (Figure 2).

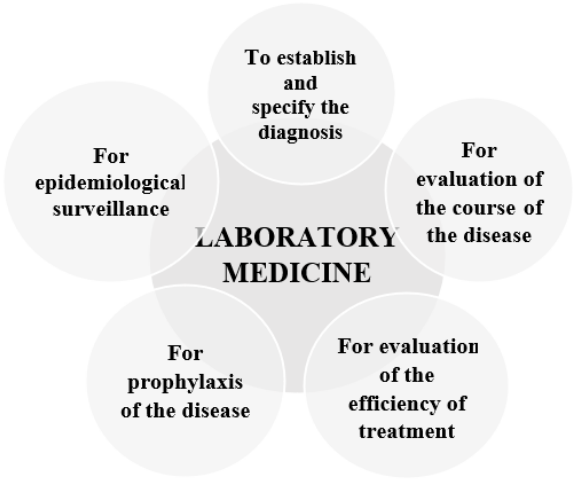


Figure 2: The role of laboratory medicine in healthcare
Source: compiled by the authors based on Ferraro et al., 2016; Lippi & Plebani, 2020; Ngo et al., 2017; Trancheva, 2020; Watson et al., 2019; Wieringa et al., 2021

To sum up, the role of laboratory medicine in the healthcare system is an important factor indicating the importance of the quality of services provided by medical testing laboratories and its management in the context of the overall quality of healthcare. The dependence of patient management on laboratory data highlights the need to ensure the quality of these services (Chawla et al., 2010). In order to achieve excellence in healthcare, it is essential to maximize the improvement of patient care through laboratory insights, to measure the performance of stakeholders using quantitative and qualitative quality indicators (Strain & Ravalico, 2021).

2.2. Links between quality in healthcare and laboratory medicine

The definition of quality often varies as per context, scientific paradigms, and levels of analysis. Various definitions of quality often refer to quite long lists of different attributes that are recognized as a part of quality. Effectiveness, patient safety, and patient-centredness have become widely recognized as key dimensions of quality in healthcare. However, many definitions include attributes such as appropriateness, timeliness, efficiency, accessibility, and equity (Busse et al., 2019). The US Institute of Medicine (IOM) defines the quality of care as "the degree to which personal and population health services increase the probability of desired health outcomes, and are consistent with current professional knowledge" (Plebani, 2017). According to the US Institute of Medicine, health care should be safe, efficient, patient-centered, timely, effective, and equitable (Table 1).

Domain	Definition
Safe	Avoiding injury to patients as a result of care that is intended to help them
Effective	Providing knowledge-based services to all who can benefit and refraining from providing services to those who are unlikely to benefit (avoiding under- and over-use respectively)
Patient- centered	Providing care that respects and responds to the individual patient's preferences, needs and values, and ensure that the patient's values guide all clinical decisions
Timely	Reducing waiting and sometimes harmful delays for both those receiving and those providing care
Efficient	Avoiding waste, including waste of equipment, supplies, energy and ideas
Equitable	Providing care that does not differ in quality on the basis of personal characteristics such as gender, ethnicity, geographical location and socio-economic status

Table 1: Six domains of medical quality
Source: Plebani, 2018a

These six principles are recognized as the six dimensions of quality (Busse et al., 2019; Plebani, 2017). The six health improvement objectives have been successfully acknowledged by the scientific community. Therefore, they remain key areas of work striving for assurance of the quality of medicine (Plebani, 2018a). In laboratory medicine, quality should include patient safety and clinical effectiveness. Services should be patient-centered, timely, effective and equitable, and ultimately designed to ensure optimal outcomes (Barth, 2012).

The contribution of laboratory medicine to the quality domains of the healthcare system is proven through the linkage to the overall goals of quality assurance in healthcare. The provision of medical research laboratory services influences patient safety. Laboratories contribute to patient safety by immediately informing physicians or other authorized healthcare professionals when test results fall within critical ranges. They could indicate a direct risk of harm or death to the patient. Laboratory physicians contribute to appropriate clinical decision-making to ensure the effective use of the laboratory. Patient-centered service in laboratories ensures the adequacy of sample quality and patients' access to their test results. The timeliness of laboratory tests is generally ensured by laboratories adhering to test turnaround times. This quality domain requires that appropriate tests, once ordered, and analyzed be reported, reviewed, and acted upon promptly. Laboratory tests must be effective, i.e. ensuring their diagnostic utility. Laboratory medicine is the area of healthcare where equitability is presumedly the easiest to ensure. Samples are processed despite gender, ethnicity, geographical or socioeconomic status (Barth, 2012).

Laboratory medicine is defined as the science of obtaining clinical information through the analysis of the concentration, composition, and/or structure of different analytes in different biological fluids. Designed laboratory medicine services should maximize productivity and thus optimize clinical efficiency. This would allow making an informed contribution to clinical decision-making. Laboratory management is generally controlled by six main paradigms, namely efficiency, effectiveness, quality, safety, sustainability, and satisfaction. Efficiency refers to achieving maximum laboratory productivity with minimum effort or cost. The focus of effectiveness is improving diagnoses and clinical outcomes. Quality includes the highest possible degree of reliability and safety of laboratory data. Safety is developed by limiting the risk of injury or harm to patients and staff. Sustainability requires avoiding the waste of human and economic resources. Satisfaction is achieved by meeting the laboratory staff and other stakeholders (patients and physicians) expectations or needs (Lippi & Mattiuzzi, 2019).

Thus, the concept of quality in laboratory medicine comprises a focus on internal processes, the real impact of laboratory information on patient care, and ensuring the health of any individual. Quality in clinical laboratories determines the assurance of properly performed every step of the entire testing process. Thus it ensures valuable medical decision−making and effective patient care. In this context, the entire testing process is defined as the set of related or interacting activities. They translate biological patient sample materials into laboratory results and information, thus contributing to the most appropriate clinical outcome (Plebani, 2012; Plebani, 2018a).

Quality in laboratory medicine contains two dimensions that can no longer be separated. The “internal dimension” is carried out in the laboratory environment to ensure efficiency. It is based on the accuracy and reliability of the test results, the timeliness of their performance and communication, and finally on cost reduction activities. The “external dimension” is

estimated by diagnostic accuracy, the value of tests and treatments, the impact on clinical and economic outcomes, and, ultimately, patient safety. The effectiveness of a testing outcome depends not only on the result submission according to defined standards which involve accuracy, timeliness, and acceptable cost. The dependence manifests through the timeliness of measures and actions taken to ensure valuable clinical outcomes and patient safety as well (Plebani, 2018b).

In summary, the quality of healthcare delivery cannot be achieved without quality assurance of laboratory medicine services. Laboratory tests provide physicians with the information they need to provide quality, safe, effective, and appropriate patient care (Ferraro et al., 2016). The quality and safety of diagnostic tests are essential for the quality and safety of healthcare. Thus laboratory medicine is linked to these areas (Lippi & Mattiuzzi, 2019). Therefore, the set of quality indicators used should provide information about the status of laboratory activities and/or processes. Additionally, the ultimate goal is to improve the provision and use of laboratory services, which contribute to the quality of healthcare and the health of the population (Shahangian & Snyder, 2009). The aim of using quality indicators in laboratory medicine is to cover the domains of health care, respectively: patient safety, efficiency, equity, patient-centeredness, timeliness, and effectiveness (Jegede et al., 2015; Warade, 2015).

3. Research Methodology, Design and Data Analysis

Several research methods were used to achieve the purpose of this research. Firstly, the analysis of scientific literature and information sources was performed. Secondly, a two-step modified "Delphi" method was used for empirical research. It was carried out in two stages, during which various quantitative and qualitative research methods were utilized for data collection. A survey questionnaire was employed for the quantitative research, while an interview questionnaire − for the qualitative research. The quantitative research was carried out by conducting surveys of laboratory specialists on the https://apklausa.lt/ website. Interviews of experts were conducted electronically. An interview questionnaire was sent to the purposefully selected experts. The data processing required such programs as Microsoft Excel and SPSS (version 26), descriptive statistics, and variance analysis to be used. The following statistical tools were used: calculation of averages, Cronbach's alpha, Shapiro-Wilk, Student's t-test, ANOVA, Mann-Whitney, Kruskal-Wallis criteria.

The design of the empirical study is summarised in Figure 3.

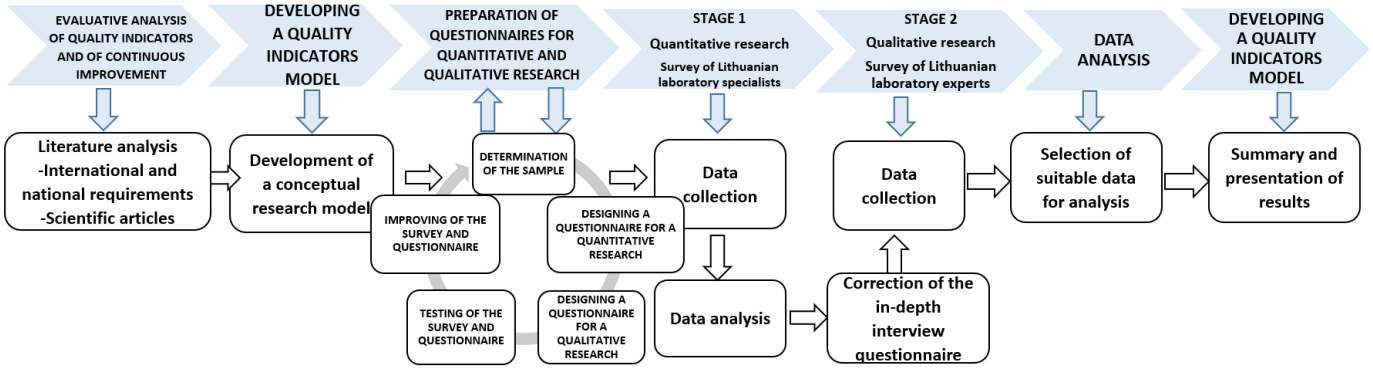


Figure 3 : Model of the empirical research process
Source: own research

A two-round modified Delphi approach was applied to achieve the objectives of the study. The Delphi technique is a structured process commonly used to develop healthcare quality indicators (Boulkedid et al., 2011; Madsen et al., 2016). The technique is based on a structured process of reaching a consensus among different expert groups. The study used expert interviews. "Experts are individuals, who due to their professional and life experience, have the greatest expertise and the most reliable and sufficiently detailed information about the problem being investigated" (Tidikis, 2003). The authors followed the principles of the Delphi method in the empirical research. The aim was to gather a larger group of experts from all over Lithuania, that allowed for a broader assessment of the opinions, knowledge, and insights from Lithuanian laboratory medicine specialists on the issues analyzed in the study.

The empirical study comprises two phases, applying different quantitative and qualitative research methods for the conduction of the interviews with professionals and experts, and data collection. The

integration of methods allowed us to address the research objectives. Thus, the results obtained allowed complementarity (Kardelis, 2002).

Study sample. Lithuanian healthcare institutions that provide laboratory diagnostics services were selected for the study to meet the objectives. Both private and public medical testing laboratories participated in the study. The population of the study consists of the employees of Lithuanian personal healthcare institutions providing laboratory services. Those employees should be allowed to provide laboratory diagnostic services according to Lithuanian legislation. It can be either laboratory medicine physicians, geneticists, medical biologists, medical geneticists, or quality managers. The sample of the study is based on a non-probability sampling method. In order to ensure the accuracy, quality, and relevance of the data on the topic of the study, the respondents had to meet the requirements for professional qualification and have at least 1 year of experience in the provision of laboratory diagnostics services. Since the number of laboratory staff in Lithuania is unknown, a minimum number of 30 subjects was set on the basis of Kardelis: "in the opinion of practitioners, the researcher seeking to process the results of his/her study statistically, should ensure the number of cases to be at least 30" (Kardelis, 2002).

Quantitative research tool. A structured questionnaire survey was used to collect empirical data and quantify the opinion of professionals. This is one of the most widely used research methods (Kardelis, 2002) and therefore it is easier to quantify obtained data (Tamaševičius, 2015). The content of the questionnaire was reconciled with the managers and experts of the laboratory medicine institutions. The questionnaire was based on studies by other authors and questions devised by the authors. The constructs for the current survey were based on a study carried out in a Netherlands intensive care unit. A previous study from the Netherlands was used as an example for assessing the barriers related to knowledge, attitudes, and behavior, as well as factors, and measures that influence the successful implementation of a quality indicator system in Lithuanian laboratories. The same elements have been studied previously in Netherlands intensive care units (de Vos et al., 2010). The constructs were translated into Lithuanian. Some statements were modified by adding some new ones to adjust them to the Lithuanian study. The knowledge assessment scale was modified as well.

The list of quality indicators was modeled on the basis of the analysis of scientific literature, the Model for Quality Indicators (MQI) of the IFCC Working Group on "Laboratory Errors and Patient Safety" and the national inventory of accessibility and quality indicators for laboratory diagnostics services, and their monitoring procedures. The list of indicators in the questionnaire was edited to remove ambiguous indicators. Duplicate indicators were merged, while certain indicators were grouped together in order to make the list of indicators shorter. This resulted in a list of 33 possible indicators.

Qualitative research methodology. Qualitative research was chosen for the second round in order to meet the objectives of the empirical study. According to Tidikis (2003), while choosing qualitative research, the researcher has to be aware of its validity and motivation. One of the prerequisites for choosing qualitative research is "to use qualitative research if a detailed (complete) picture of the subject is required" (Tidikis, 2003). A structured expert interview was chosen and carried out electronically by sending a structured interview questionnaire to a purposively selected group of experts. The selection of the experts for the second round was based on certain requirements. They had to be competent with a specific experience and knowledge of the field directly related to the subject of the study. Indicators of the experts' competence comprise their official position and length of practical experience. The qualities of the experts, namely, objectivity, integrity, and the ability to analyze the problem without succumbing to the prevailing trends, are of great importance (Tidikis, 2003). The aim of the qualitative study was to prioritize the most important quality indicators. The sequence of priority was based on the indicators from the first round of interviews. Experts were also asked to identify and determine the most appropriate evaluation methods for these quality indicators, to assess and assign each indicator to the dimensions of quality of healthcare services.

4. Results and Discussion

4.1. Analysis of the results of the quantitative study

The next stage of the study analyzed the factors and measures that influence the successful implementation of a quality indicator system (QIS). The aim was to determine whether the impact of the factors and measures on the successful implementation of the QIS is perceived differently by different groups of employees. The authors also sought to determine factors and measures that have the greatest influence on the successful implementation of the quality indicator system. For this purpose, firstly, the mean scores of the factors and measures affecting the successful implementation of the quality indicator system were analyzed (see Figure 4).

Figure 4: Assessment of the most important factors and measures affecting the successful implementation of the quality indicators system (mean score)
Source: own research

Summarising the results, the most important factor for the successful implementation of the quality indicator system is the importance of trained staff in recording the indicators (4.47 out of 5). In the second place, is clearly allocated responsibilities for monitoring, collecting, and analyzing quality indicators and their data (4.44 out of 5). In the third place − clearly established rules, policies, and procedures for setting and monitoring quality indicators (4.33 out of 5). The least important are additional material rewards for staff (2.74 out of 5) and regular reminders to staff (3.24 out of 5) (see Figure 4).

The obstacles most decisive for the implementation of quality indicators were also studied (see Figure 5).

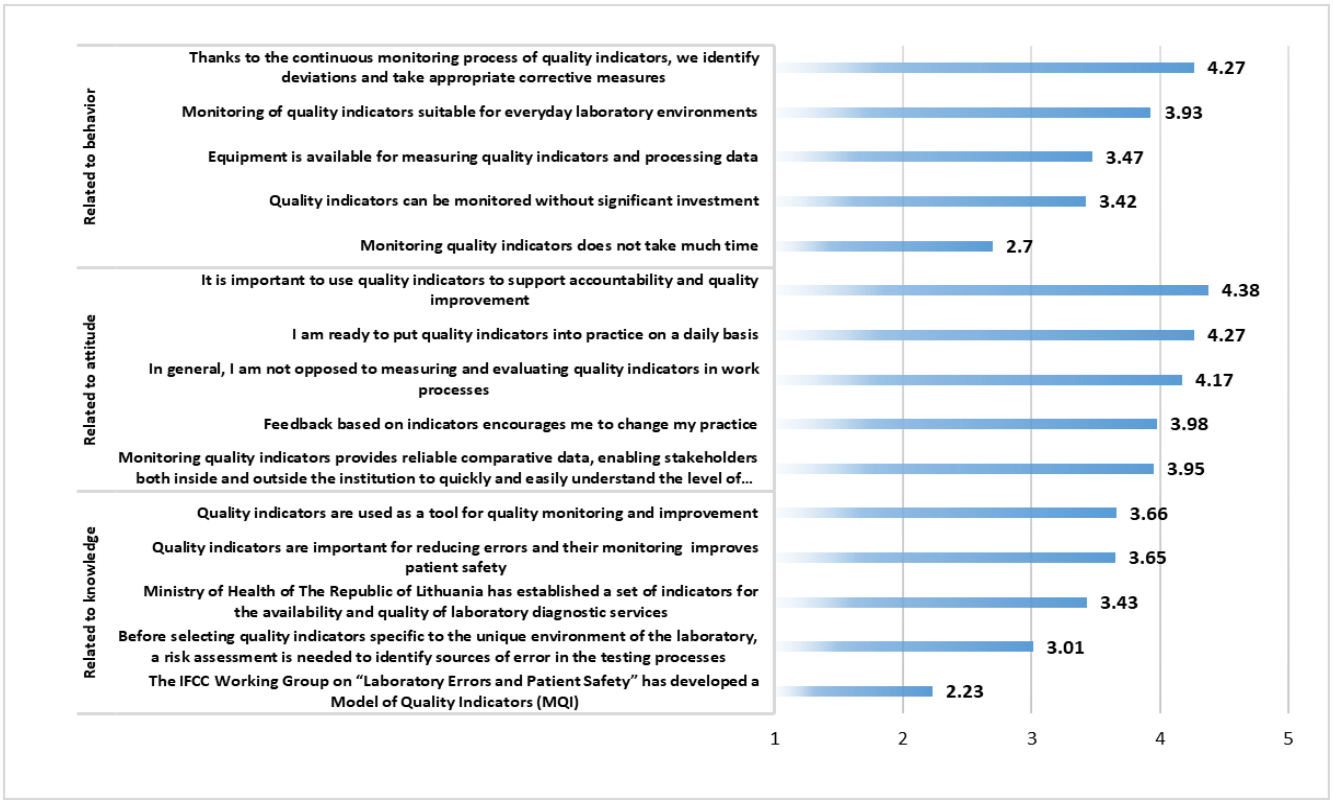


Figure 5: Assessment of the barriers that lead to the slower implementation of quality indicators (mean score)
Source: own research

Based on the data in Figure 5, the most significant barriers related to knowledge are lack of specialist knowledge of the international Model of Quality Indicators (MQI) (2.23 out of 5) and risk assessment before selecting quality indicators specific to the unique laboratory environment (3.01 out of 5). The biggest barriers related to attitude are that monitoring quality indicators provide reliable comparative data, and enables stakeholders both inside and outside the institution to quickly and easily understand the level of quality of the laboratory's services (3.95 out of 5). From the viewpoint of the laboratory's professionals, time-consuming monitoring of quality indicators is perceived as the biggest barrier related to behavior (2.7 out of 5).

The study also analyzed the assessment of the importance of quality indicators in the pre-analytical process, post-analytical process, and during the supporting processes. In a further step, it analyzed how staff in accredited (ISO 9001), nonaccredited, and certified laboratories perceive the barriers that affect the implementation of quality indicators. The results revealed that employees working in laboratories with different structures have different perceptions of the barriers related to knowledge, as the Kruskal-Wallis criterion showed a statistically significant difference in the means of the scales ($p = 0.015 < 0.05$). The mean scores show that staff working in ISO-accredited laboratories have the highest mean score (3.78 out of 5), while staff working in non-accredited laboratories have the lowest mean score (2.96 out of 5). It should be noted that staff working in non-accredited laboratories have the worst knowledge, while staff working in ISO-accredited laboratories have the best knowledge related to quality indicators.

In summary, 15 out of 33 quality indicators were selected during the quantitative study for the study as the most important, covering all stages of the testing process. The most important barriers identified in relation to knowledge are lack of knowledge about international quality indicator systems. The most important barriers related to the attitude − that the results of the QIs will be publicized and that laboratories can be compared with each other. The most important barrier related to behavior − is that the assessment of quality indicators is time-consuming. The study found that staff training, clearly allocated responsibilities, and clearly defined rules, policies, and procedures are the most important factors and measures that could be most helpful for the effective implementation and use of a QI system. The study also found that those staff working in laboratories where QI systems are already in place perceive a greater potential and positive impact of the QI system on aspects of their work than those who do not have QI systems. Significant differences were found between laboratory professionals working in different laboratories according to their legal status in terms of the behavioral barriers that could influence the successful implementation of QI in laboratories. Differences in the assessment of barriers related to knowledge between professionals working in accredited and non-accredited laboratories were found as well. The results of the study show that laboratory staff with different types of experience have different perceptions of different types of barriers. Those with more experience perceive fewer barriers, while those with less experience perceive more barriers. The analysis of the data showed that staff in different positions have different perceptions of the barriers related to knowledge that affect the implementation of quality indicators. Medical biologists and geneticists perceive the most knowledge-related barriers, while laboratory managers perceive the least. The study found significant differences in the perceived importance of quality indicators between private and public, accredited and non-accredited laboratory staff, and between professionals with different levels of experience.

4.2 Analysis of the results of the qualitative research

The qualitative study involved 8 experts in laboratory medicine, who were selected according to three predefined criteria (professional qualifications of the experts, laboratory experience, and work experience in assessing quality indicators). The interview questionnaires were sent via e-mail to each expert. Thus, giving the experts sufficient time to think about and answer the questions.

The analysis of the qualitative research data was carried out in a series of steps. It includes data preparation for analysis, disaggregation, aggregation, interpretation, and formulation of conclusions. The experts provided a description of the quality indicator, the method of calculation, the units of measurement of the QI, the frequency of data collection, and the frequency of data analysis for each of the fifteen quality indicators. The dispersion of answers was noticed while analyzing the answers given by the experts regarding the description of QI and the calculation methodologies. Based on the experts' answers, it was found that the data for the fourteen QIs should be collected daily and analyzed either monthly or annually.

The qualitative study required the experts to assign priority indices to each quality indicator. The survey asked the experts to assess and assign the laboratory's quality indicators to the quality dimensions of healthcare. The results are summarised in Figure 6.

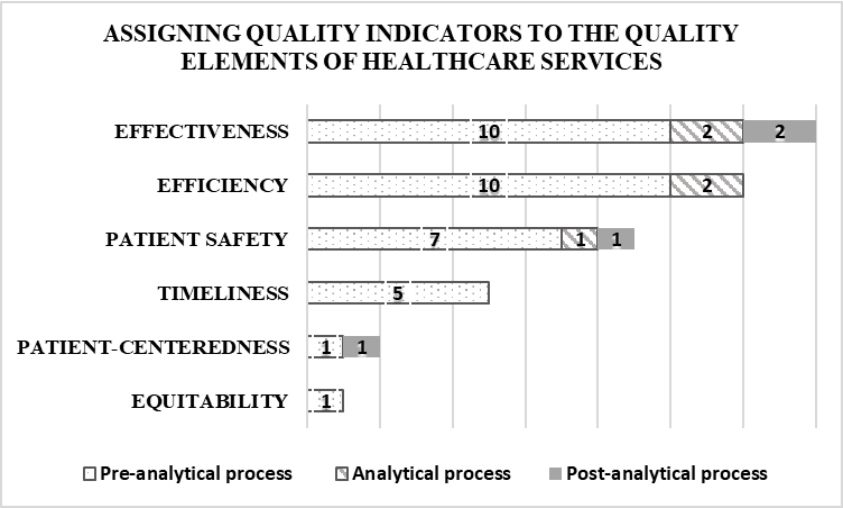


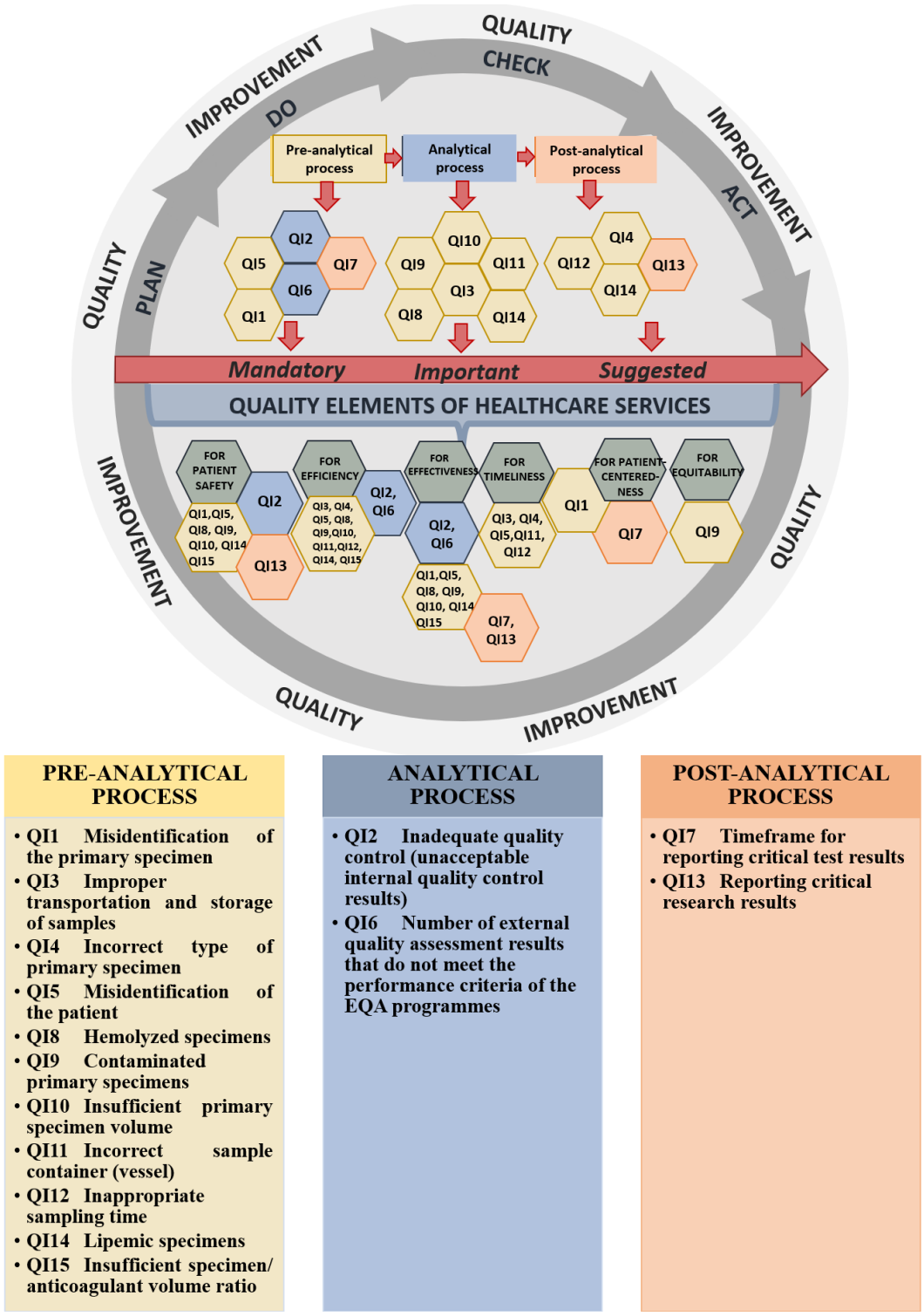
Figure 6: Results of assigning quality indicators to the quality elements of health care services
Source: own research

The quality dimensions of healthcare, that quality indicators were attributed to, are patient safety, efficiency, patient-centredness, timeliness, effectiveness, and equitability. According to the expert opinion, out of the 15 quality indicators, the highest number of quality indicators is attributed to effectiveness (14 QIs), efficiency (12 QIs), and patient safety (9 QIs). The indicators attributed to effectiveness and patient safety cover the QIs for the entire testing process (pre-analytical, analytical, and post-analytical process). Thirteen quality indicators were assigned to three elements of quality of care. One QI − to four elements of quality and one QI − to two elements.

To summarise the results of the qualitative study, it is important to note that all the objectives of the qualitative study were met. The study summarised the responses and insights of the experts and specified 15 key quality indicators during the quantitative study (Phase I). It also identified evaluation methods to develop a model for a quality indicator system that can be evaluated and compared between laboratories and stakeholders. The indicators have been given a priority index with the aim to make the developed quality indicator system dynamic. The characteristic of dynamism manifests through allowing laboratories to start with mandatory and/or essential quality indicators. The laboratory can choose to expand further by adding the proposed quality indicators. The study evaluated quality indicators according to the quality elements (dimensions) of healthcare services: patient safety, efficiency, patient-centredness, timeliness, effectiveness, and equitability. Since medical testing laboratories are an integral part of the healthcare system, the quality of the services provided by laboratories has an impact on the quality of the overall healthcare system. Therefore, it is important to ensure that the quality indicators of the laboratory also meet the requirements of the healthcare system. The qualitative study revealed that all experts considered the mandatory quality indicators to cover the stages of the whole testing process. Whereas for the 'important' ones, they assigned quality indicators to the control of the pre-analytical stage of the process. It can be concluded that the majority of quality indicators (11 out of 15) are dedicated to the control of the pre-analytical process. As a result, it confirms the conclusion drawn from the analysis of the scientific literature stating this phase is the most challenging in the overall testing process. The impact of this process is often manifested through the analytical and post-analytical process phases. The number of errors is mostly dependent on specimen management. A wide variety of information about the specimen is required to fulfill this key role in the laboratory. It should be noted that systematic daily monitoring within QI, checks, standardization, and quality control of laboratory tests ensure the accuracy and reliability of results.

4.3 Consolidated quality indicator system assessment model for improving the performance of medical testing laboratories

On the basis of the analysis of the scientific literature and the results of the empirical study, the authors developed a consolidated quality indicator system assessment model. The model covers the entire process of conducting clinical tests (analytical, pre- and post-analytical processes). It meets the requirements of the international standard EN ISO 15189:2013 and ensures the criteria for evaluating the quality of healthcare measures (patient safety, effectiveness, patient-centredness, timeliness, effectiveness and equitability)(see Figure 7).



PRE-ANALYTICAL PROCESS	ANALYTICAL PROCESS	POST-ANALYTICAL PROCESS
• QI1 Misidentification of the primary specimen • QI3 Improper transportation and storage of samples • QI4 Incorrect type of primary specimen • QI5 Misidentification of the patient • QI8 Hemolyzed specimens • QI9 Contaminated primary specimens • QI10 Insufficient primary specimen volume • QI11 Incorrect sample container (vessel) • QI12 Inappropriate sampling time • QI14 Lipemic specimens • QI15 Insufficient specimen/ anticoagulant volume ratio	• QI2 Inadequate quality control (unacceptable internal quality control results) • QI6 Number of external quality assessment results that do not meet the performance criteria of the EQA programmes	• QI7 Timeframe for reporting critical test results • QI13 Reporting critical research results

Figure 7: Consolidated quality indicator system assessment model for improving the performance of medical testing laboratories

Source: own research & design

The model is designed to monitor and evaluate processes, and reduce laboratory errors by taking effective measures for improvement of the services of medical testing laboratories. In order to be successfully implemented, the quality indicator system must comply with the PDCA quality cycle. The development of the model is based on Deming's philosophy substantiated by the continuous improvement cycle. The four steps of the cycle are emphasized: Plan − Do − Check − Act. Each indicator in the system must be responsibly planned, covering the definition of indicators and

setting of targets. This is followed by implementation. It includes the measurement of the quality indicators, the collection of data within a defined timeframe, at defined intervals and in defined ways. The data collected at the defined intervals have to be controlled and evaluated to determine the achievement of objectives. Appropriate decisions if needed have to be taken to improve the performance of the laboratory.

The presented model covers the QI, focusing on the main critical steps of the entire testing process. The model contains 5 mandatory, 6 important, and 4 suggested quality indicators, and covers the whole process of conducting medical tests (analytical, pre- and post-analytical processes). Therefore, the model can be applied gradually by introducing the mandatory and/or important QIs and progressively adding the suggested ones. The quality indicator system should be continuously reviewed and updated. Laboratories should carefully select the most appropriate indicators to be implemented from the beginning and over time. Whereas quality assurance is a never-ending journey, the implementation and monitoring of QIs should be considered an essential component of a continuous quality improvement program.

Most of the quality indicators in the model focus on the pre-analytical processes. This phase of the testing process is more vulnerable, has little control, and can determine the outcome of patient care. Each laboratory should monitor the frequency and type of errors with the help of quality indicators, and take reasonable, controlled and corrective measures at all stages of the test.

Laboratory medicine is a very dynamic part of healthcare. Quality assurance in the laboratory contributes to quality assurance in health care as a whole. Despite the unpredictable consequences of medical errors, which can range from little or no harm to a fatal outcome for the patient, healthcare systems are continuously recognizing patient safety as a key organizational objective (Plebani et al., 2021). In the model presented here, as many as 9 quality indicators are attributed to patient safety (7 QIs for pre-analytical processes and one each for analytical and post-analytical processes). Each QI involved in the model covers one to several quality elements of the quality of the healthcare system. Therefore it ensures the requirement set by the QI − to meet at least one area of quality assurance in healthcare.

In summarizing, the consistent practical use of the QIs through error monitoring and implementation of improvement, and risk management procedures, would reduce the frequency of errors, improve the quality of laboratory performance, improve patient safety and health system outcomes. Due to the role of laboratory services in the healthcare process, quality control of the medical research laboratory is a new overall strategy to ensure patient safety while maximizing efficiency and effectiveness. Quality and safety are as important in everyday medical laboratory practice as in clinical practice.

5. Conclusions & Insights

Based on the analysis of the scientific literature, it can be stated that a healthcare system must be safe, efficient, effective, timely, equitable, and patient-centered. Whereas laboratory medicine is integral to many of these goals. The concept of quality in laboratory medicine ranges from internal processes to the actual impact of laboratory information on patient care, ensuring the health of any individual and the population as a whole. Therefore, the reliability of laboratory information is a prerequisite for ensuring a quality healthcare process and reducing the risk of harm to patients through the prevention of errors and the improvement of the entire testing process. To ensure the quality of laboratory services, medical laboratories around the world are implementing quality management systems and purposely embarking on the path of accreditation. They are also carrying out planned and systematic activities to increase the confidence of all stakeholders, both patients, and physicians, in laboratory testing.

The analysis of the scientific literature has shown that an understanding of errors in terms of their type, frequency, causes, and impact on patients, is essential the identification and implementation of control measures. They accordingly allow the prevention and reduction of the risk of errors. One such key control measure is the quality indicator system.

In addition to objectivity (measurability), quality indicators require relevance, usability, reliability and validity. However, the developed international programs that provide guidance and enable laboratories to use quality indicators for process monitoring are not widely and actively used. This has conditioned the phenomenon called the “Quality Indicator Paradox”, which occurs in the practice of medical research laboratories. As a result, the best and easiest system is not useful, if it is not used. Laboratories usually estimate national or self-defined quality indicators. It is difficult to compare relevant information between laboratories with regard to decision-making for continuous improvement. This is regarding differences in quality indicator systems used by laboratories and ways of data collection and interpretation.

The study concludes that the development of a system of quality indicators as a tool for quality improvement requires not only the selection of the

quality indicators themselves but also an assessment of the obstacles and measures related to their implementation. Based on this conclusion, the design of the empirical study on the consolidation of a laboratory quality indicator system additionally included the assessment of barriers related to knowledge, attitudes, and behavior, as well as factors, and measures, affecting the successful implementation of the quality indicator system. It allowed providing suggestions and insights for the future successful implementation of the developed quality indicator model.

Summarising the results of the empirical study, the specialists of the Lithuanian medical laboratories, while assessing the importance of quality indicators for monitoring and evaluation of the laboratory's activities at critical stages of the processes, focused on the quality indicators of the pre-analytical processes. Out of 33 QI candidates submitted for the study, as many as 11 were among the 15 identified as the most important QIs. This confirmed the findings of the literature analysis. The pre-analytical phase of the testing process is the least controlled, and non-standardized. Moreover, it has the highest possibility of laboratory error occurrence. Therefore, the control of the pre-analytical processes should be given the highest priority. The error rate at this stage is mostly dependent on the management of the specimen. Hence, the majority of the selected QIs are focused on assurance of specimen quality.

Based on the interpretation of the results of the empirical study, a consolidated model for the evaluation of the laboratory quality indicator system was developed. Research results combined the insights of laboratory specialists and experts, different personal experiences, and opinions from different laboratories in Lithuania, therefore the developed model of the quality indicator system could be used in all laboratories regardless of their size, legal status, structure, maturity, or qualifications of the specialists.

The developed quality indicator system assessment model includes the entire process of conducting medical tests (analytical, pre- and post-analytical processes). It complies with the requirements of the international standard EN ISO 15189:2013 as it focuses on critical steps of the entire testing process. Moreover, the model is dynamic since the quality indicators are prioritized (i.e. mandatory, important, suggested). It ensures the criteria of the evaluation of the quality domains in healthcare. The study has identified the most appropriate measurement methods for quality indicators. It involves the description of the quality indicator, method of calculation, units of measurement, frequency of data collection, and frequency of data analysis. It allows standardization of the quality indicator system.

The consolidated laboratory quality indicator system assessment model combines three important groups of elements. It comprises the 3 stages of research execution processes (pre-analytical, analytical, and post-analytical), 15 quality indicators (prioritized by their application), and 6 elements of quality of healthcare. These three elements interact and rotate according to the Deming cycle forming a coherent framework for continuous performance improvement not only in the laboratory but in the context of the whole quality of care as well.

Successful implementation of the model proposed by the authors of this study will also depend on certain conditions. Firstly, whether laboratory professionals have a good understanding and knowledge of quality indicators. The second condition − is a positive attitude toward the use of quality indicators as a tool to improve the quality of services. Lastly, the removal of behavioral barriers such as time and organizational limitations. The biggest barriers, identified by the Lithuanian laboratory specialists, consist of lacking knowledge of the international model of QI, the publicity of the results of QIs, and the time-consuming nature of monitoring QIs. Therefore, laboratories could achieve successful implementation results of QI by eliminating these barriers before the implementation of the system.

On the other hand, the success of the implementation of the QI system also depends on the factors and measures that the laboratory manages before the introduction of quality indicators in the laboratory. In the opinion of the Lithuanian laboratory experts, the factors determining the successful implementation of the quality indicator system are the education of staff and the importance of trained staff in recording the indicators, the clearly allocated responsibilities for monitoring, collecting and analyzing quality indicators and their data, and clearly established rules, policies, and procedures for setting and monitoring quality indicators. The implementation of these measures would ensure the effective use of the quality indicator system.

Laboratory performance indicators all over the testing process allow to measure, analyze and improve the quality of services. Therefore, systematic monitoring of the entire testing process and control of the non-conformance management process is the responsibility of all clinical laboratories. Effective implementation of the QI requires the implementation of objective and standardized criteria and procedures. Moreover, it depends on staff knowledge, accountability, communication, and cooperation between all members of the healthcare team

Quality assurance is a never-ending journey, hence the implementation and monitoring of quality indicators

should be concerned an essential component of a continuous quality improvement program. The authors' consolidated model for the evaluation and implementation of a quality indicator system could be a valuable tool for laboratories that implement, modify, or update quality indicator systems.

Conflict of interest

The authors declare no conflicts of interest.

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