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Development and validation of a work quality questionnaire in medical biochemistry labs

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ABSTRACT

Introduction: Medical biochemical laboratory professionals play a critical role in diagnostics, research, and patient care, performing complex tasks that require extensive knowledge, professional attitudes, and adherence to best practices. Understanding their knowledge, attitudes, and practices (KAP) is essential for improving laboratory performance, ensuring quality, and enhancing patient outcomes. Despite the importance of quality control systems and international standards, the existing literature reveals a lack of validated instruments to assess KAP among laboratory professionals. This study aimed to develop and validate a comprehensive questionnaire targeting key domains of laboratory practice, with the goal of identifying operational gaps and guiding future interventions.

Methods: The questionnaire was developed through a four-phase process: Literature review, item construction, questionnaire distribution, and validation. Psychometric evaluation included internal consistency testing and factor analysis to ensure reliability and validity.

Results: The final instrument, titled KAP of Laboratory Professionals on Standards and Work Quality Systems, comprised 73 items across six domains. The overall Cronbach's alpha was 0.673, indicating moderate but acceptable internal consistency. The questionnaire effectively identifies gaps in KAP related to quality control in medical-biochemical laboratories. Its results can support laboratory managers in recognizing areas for improvement, ultimately enhancing service quality and patient outcomes.

Conclusion: This descriptive and analytical study presents a validated and reliable tool for assessing KAP regarding standards and quality control systems in medical-biochemical laboratories. Its application can guide targeted interventions to address deficiencies and strengthen practices in laboratory medicine.

Keywords: Laboratory staff; quality control; questionnaire

INTRODUCTION

Medical biochemical laboratory professionals play a pivotal role in diagnostic procedures, research, and patient care. Their responsibilities encompass complex tasks that demand a robust foundation of knowledge, appropriate professional attitudes, and strict adherence to best practices (1). Understanding the knowledge, attitudes, and practices (KAP) of healthcare professionals in biomedical laboratories is essential for optimizing patient outcomes, ensuring service quality, and identifying areas for improvement within this critical domain (2,3).

Achieving these goals requires rigorous quality assurance across all phases of the laboratory process. This involves implementing techniques and procedures that monitor error sources, quantify their impact, and alert staff to deficiencies in key operational segments. Active participation of all laboratory personnel in quality monitoring is crucial to ensure the analytical reliability of test results (1).

Quality standards form the backbone of laboratory quality systems. Their implementation facilitates consistent monitoring of laboratory functions and promotes safety and reliability. The International Organization for Standardization (ISO) has developed several standards applicable to biochemical laboratories, aimed at enhancing quality, safety, efficiency, and reproducibility, thereby providing a technical foundation for health assessments (2).

According to ISO guidelines, errors can occur at any stage of the laboratory cycle. Comprehensive control across all phases is achievable through the implementation of a total quality management system, which emphasizes adherence to good laboratory practice. Quality indicators (QIs) serve as essential tools for evaluating each step of the laboratory

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testing process, which includes pre-analytical, analytical, and post-analytical phases. Recognizing the importance of these phases, the International Federation of Clinical Chemistry and Laboratory Medicine, has developed a QIs framework to support error-free analytical procedures (4,5).

Maintaining high standards in medical biochemical laboratories requires an sufficient number of qualified professionals. The design and equipment of laboratory facilities are governed by legal regulations to ensure the safety and satisfaction of both staff and patients. Compliance with laboratory safety standards has implications not only for individuals and teams but also for the broader community (6-9). National legislation, including the Regulation on Norms and Standards for the Practice of Health Care and the Law on Health Care, prescribes specific spatial and equipment requirements for medical-biochemical laboratories to uphold these standards (10,11).

A comprehensive review of the literature reveals persistent challenges faced by medical-biochemical laboratories in daily operations (5,12-14). To investigate these issues, the use of questionnaires as research instruments enables the simultaneous collection of quantitative and qualitative data, offering a holistic view of healthcare professionals' perspectives. Questionnaires are widely used for surveying large populations and are valued for their cost-effectiveness. However, their effectiveness depends on the relevance and clarity of the questions posed. Researchers must carefully design questionnaires to elicit credible and comparable responses. Before deployment, it is essential to validate the reliability and accuracy of the instrument through statistical analysis. Reliability refers to the consistency of measurement results, while validity assesses the extent to which the instrument measures what it is intended to measure (15-17).

Exploring KAP and working conditions provides valuable insights into strengths and areas for improvement in laboratory practice. This approach has been employed in numerous studies and serves as a practical tool for identifying errors and informing corrective program design (18,19). Among the phases of laboratory testing, the pre-analytical phase is particularly vulnerable to errors, often stemming from human factors. These errors significantly contribute to uncertainty in laboratory results. Investigating laboratory professionals' KAP regarding service quality and standardization is vital for minimizing error rates (20-25).

Numerous KAP studies have focused on laboratory professionals, examining topics such as biosafety, work quality, medical waste management, and occupational accidents. Our literature review confirms the existence of various operational challenges in medical-biochemical laboratories (5,22-25). Notably, the literature revealed a lack of validated instruments specifically addressing KAP and quality systems among professionals in medical-biochemical laboratory diagnostics. The objective of our study was to develop a questionnaire targeting critical domains of laboratory practice to facilitate problem identification and guide future improvements.

METHODS

The development of the questionnaire designed to assess the KAP of laboratory professionals in medical-biochemical laboratories, as well as the quality of their work, was conducted in four distinct phases.

Phase I: Literature and regulatory review

The initial phase involved a comprehensive analysis of the existing scientific literature, relevant legal frameworks in Bosnia and Herzegovina, the neighboring countries, and the European Union. This review served to establish the theoretical foundation for the study, define research objectives, and identify key variables.

Phase II: Item generation and expert review

In the second phase, two experts in laboratory medicine and quality control formulated potential questionnaire items. These items were designed to explore KAP related to laboratory operations, equipment, and the implementation of quality systems and healthcare standards. Sources included peer-reviewed scientific publications, international standards, and national and local guidelines (5,12-14,26-47). The draft questionnaire was then reviewed by professionals in medical and clinical biochemistry. While experts recommended rephrasing certain items for clarity, no new items were added or removed. Based on this feedback, the items were organized into thematic domains: Knowledge, attitudes, practices, and laboratory equipment.

Phase III: Distribution and sampling

The third phase involved the dissemination of the questionnaire through Google Forms, with response submission limited to one per participant. An introductory section explained the study's purpose and provided instructions for completion. Given the limited size of the target population, a snowball sampling method was employed to maximize participation. Laboratory professionals were encouraged to share the questionnaire with colleagues working in medical-biochemical laboratories.

Phase IV: Statistical analysis and validation

Responses were coded and analyzed using IBM Statistical Package for the Social Sciences Statistics 25.0 (IBM Corporation, Armonk, NY, USA). Internal consistency was assessed using Cronbach's alpha for each domain and the overall instrument. Factor structure was evaluated using Bartlett's test of sphericity and the Kaiser-Meyer-Olkin (KMO) measure, which confirmed adequate sampling and significant inter-item correlations ($p < 0.0001$).

Descriptive statistics were reported as mean values and standard deviations. KAP domain scores were expressed as percentages, with thresholds defined as follows: 0–54.9% indicating areas of weakness, 55–75% suggesting potential for improvement, and >75% representing areas of strength. Scale scores were interpreted in relation to the overall mean.

Correlations among factors and with socio-demographic variables were analyzed using Pearson's or Spearman's correlation coefficients, depending on data distribution. Pearson's coefficients were interpreted as follows: 0.0–±0.10 (insignificant), ±0.11–±0.30 (very weak), ±0.31–±0.50 (weak), ±0.51–±0.70 (moderate), ±0.71–±0.90 (strong), and ±0.91–1.0 (very strong). Spearman's coefficients followed similar grading: 0.0–±0.10 (negligible), ±0.11–±0.25

(weak), ±0.26–±0.60 (moderate), ±0.61–±0.80 (strong), and ±0.81–±1.0 (very strong).

The Chi-square test (χ^2) was used to assess differences between expected and observed frequencies in contingency tables. When >20% of cells had expected counts <5 or contained zeros, Fisher's exact test was applied. Group differences in total scores were tested using analysis of variance (for three or more groups) and t-tests (for two groups), with *post hoc* analysis identifying specific group differences. Multiple linear regression was employed to examine the influence of independent variables on dependent outcomes.

Final instrument structure

The validated questionnaire, titled KAP of Laboratory Professionals on Standards and Quality Systems, comprised 73 items across six domains:

- Socio-demographic characteristics (9 items)
- Equipment of biochemical laboratories (11 items)
- Organization of work in biochemical laboratories (17 items)
- Knowledge of laboratory professionals on quality control (14 items)
- Attitudes toward quality control (5 items)
- Practices related to quality control (17 items).

The study received ethical approval from the University of Sarajevo – Faculty of Health Studies (Ref. 04-7-4/21) and was conducted in accordance with the principles outlined in the Declaration of Helsinki.

TABLE 1. Socio-demographic characteristics of respondents

Socio-demographic characteristics	
Sex	
Male	28
Female	102
Age	37±9.45
Country	
Bosnia and Herzegovina	61
Croatia	25
Serbia	16
Montenegro	14
North Macedonia	14
Level of education	
Medical high school	47
Bachelor	57
Master	24
PhD	2
Degree obtained on	
Faculty of health sciences	74
Faculty of pharmacy	8
Faculty of natural sciences	2
Faculty of medicine	1
Length of work experience	12±9.93
Health sector	
Public	90
Private	40

RESULTS

To validate the questionnaire, a total of 130 laboratory professionals were included in the study. As presented in Table 1, the majority of respondents were female (78.46%), from Bosnia and Herzegovina (46.92%), held a university degree (63.85%), and were employed in the public health sector (69.23%).

The overall internal consistency of the instrument, measured by Cronbach's alpha, was 0.673, as shown in Table 2. The socio-demographic domain was excluded from factor analysis (categorical variables); therefore, Cronbach's alpha and KMO tests were not conducted for this section. The domain assessing equipment capacities and workspace – comprising 11 items related to spatial and ergonomic conditions – demonstrated high internal consistency (Cronbach's alpha = 0.795). The domain on laboratory organization, which evaluated the adoption and implementation of international standards in laboratory medicine through 17 items, yielded a Cronbach's alpha of 0.667.

The domain assessing knowledge of laboratory professionals regarding the entire laboratory process, based on 14 items, showed the lowest internal consistency (Cronbach's alpha = 0.605). The attitudes of laboratory staff toward quality control, assessed through 5 items, showed an alpha value of 0.643. The practice domain, consisting of 17 items, had a Cronbach's alpha of 0.617. Analysis of the sample by region, education level, and employment sector confirmed its adequacy and representativeness (KMO = 0.694), indicating moderate confidence in the results. Bartlett's test of sphericity confirmed significant correlations among the factors ($p < 0.0001$), as shown in Table 3.

DISCUSSION

The questionnaire has proven to be a valid and practical instrument for collecting essential and key data, and its development and validation represent a critical step in the research process (8,26). Sharing this instrument with other researchers may facilitate problem identification and resolution, particularly in fields such as medical and clinical biochemistry. Recognizing the absence of such a tool in our region, we developed and validated the questionnaire titled

TABLE 2. Analysis of questionnaire reliability

Domain	Number of questions	Cronbach's alpha	Kaiser-Meyer-Olkin	Bartlett's test of sphericity	
				p	x^2
Socio-demographic domain	9	-	-	-	-
Medical biochemical laboratory equipment	11	0.795	0.830	<0.001	423.32
Organization of work in medical biochemical laboratories	17	0.667	0.710	0.001	138.15
Knowledge of laboratory professionals about quality control	14	0.605	0.685	0.001	247.41
Attitudes of laboratory professionals toward quality control	5	0.643	0.751	<0.001	347.13
Practices of laboratory professionals toward quality control	17	0.617	0.701	<0.001	289.68
Total	73	0.673	0.736	<0.001	140.05

TABLE 3. KMO factor analyses and Bartlett's sphericity test

Test		
Kaiser-Meyer-Olkin adequacy of sample		0.694
Bartlett's test of sphericity	Approx. x^2 test	27.079
	Df	3
	p	<0.0001

KMO: Kaiser-Meyer-Olkin

KAP of Laboratory Professionals on standards and quality control systems.

The final questionnaire consisted of 73 items across six domains:

- Socio-demographic characteristics (9 items),
- Equipment of biochemical laboratories (11 items),
- Organization of work in biochemical laboratories (17 items),
- Knowledge of laboratory professionals on quality control (14 items),
- Attitudes toward quality control (5 items),
- Practices related to quality control (17 items).

Psychometric testing confirmed the questionnaire's reliability and validity, making it suitable for future scientific research. Although some domains exhibited alpha values in the range of 0.6–0.8, these are considered acceptable for exploratory research and do not compromise the usability of the questionnaire (48). The results may serve as a foundation for designing continuing education programs for laboratory professionals. The instrument enables the identification of critical issues across all three phases of laboratory work: Pre-analytical, analytical, and post-analytical.

The socio-demographic profile of respondents provides important context for interpreting the KAP findings. The predominance of women aligns with the broader feminization of the health workforce, which may shape perceptions of teamwork and quality culture (49). The high proportion of respondents with a university degree likely contributed to the moderate knowledge and practice scores, as higher educational attainment has been associated with better understanding of quality control and assurance in laboratory settings (2), which, in our study, likely influenced the distribution of KAP scores. Country of origin also plays a role: Nearly half of respondents came from Bosnia and Herzegovina, where training curricula, regulatory expectations, and exposure to accreditation systems vary from neighboring countries, potentially influencing both attitudes and practices related to quality systems.

Employment sector further contextualizes our results. Most participants worked in public laboratories, which generally operate under more formalized regulatory structures and are more frequently linked to ISO 15189 accreditation (50). Such environments tend to reinforce structured workflows, documentation, and internal quality control, explaining the relatively stable, but not high scores observed. Studies show that accreditation and standardized quality systems can improve awareness of quality requirements and reduce laboratory errors (51), implying our sample may represent settings with comparatively stronger quality.

Generalizability is influenced by several contextual factors. Regulatory systems differ substantially between countries, particularly regarding accreditation requirements and oversight mechanisms (50,51), which affects laboratory professionals' exposure to quality management concepts. Infrastructure, availability of internal quality control materials, and opportunities for continuous training also vary across regions and have been identified as determinants of quality-related practices in KAP studies. Cultural attitudes toward error reporting and hierarchical communication represent additional sources of variation that must be considered when applying the instrument internationally (52).

By highlighting gaps in knowledge, attitudes, practices, and organizational or equipment-related factors, the questionnaire supports targeted improvements in laboratory performance. Addressing these gaps can enhance operational efficiency, reinforce quality control, and reduce testing errors, ultimately contributing to more accurate diagnoses and improved patient safety.

This study and its accompanying questionnaire offer several advantages, detailed in the supplementary material. Notably, this is the first published instrument in our field focused on quality control in medical-biochemical laboratories. Its application can assist laboratory managers in evaluating and improving the quality of laboratory processes by identifying deficiencies among staff. The questionnaire is applicable not only in Bosnia and Herzegovina and neighboring countries but also internationally, wherever laboratory quality control is a priority. Positive outcomes are expected in settings that adhere to the international and local standards used to develop the instrument.

Future work should include cross-country validation to examine whether the six-domain structure and reliability indices remain stable in diverse regulatory and educational environments (53). Cultural and linguistic adaptation – following internationally accepted guidelines for cross-cultural instrument translation and validation will be essential before wider use (54). Pilot testing in different healthcare settings (e.g., primary care laboratories, tertiary referral centers, and private diagnostic centers) should also be conducted to assess the instrument's sensitivity to structural and resource-related differences. Longitudinal studies evaluating whether targeted educational interventions improve KAP scores and laboratory performance would further support the questionnaire's utility as a quality-improvement tool.

Study limitations

However, the study has limitations. Data collection occurred during the COVID-19 pandemic, which limited participation, resulting in a smaller sample size. In addition, the questionnaire was specifically developed and validated for use in the aforementioned countries. Adaptation for use in other regions is possible with the author's permission to modify and adapt the given questionnaire.

CONCLUSION

This qualitative, descriptive, and analytical study presents a rigorously developed and validated instrument for assessing the KAP related to the implementation of standards and quality control systems in medical-biochemical laboratories. The questionnaire enables the identification of gaps and deficiencies within laboratory medicine,

thereby informing targeted interventions for improvement. Psychometric evaluation confirmed the tool's reliability and validity, supporting its use in future scientific investigations. Moreover, the findings derived from its application can serve as a foundation for designing continuing medical education programs aimed at enhancing the competencies of laboratory professionals.

SUPLEMENTAL MATERIAL

Authors will provide questionary on request.

DECLARATION OF INTEREST

Authors declare no conflicts of interest.

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