Research Article

Assessment of best practices for quality assurance in laboratories in Portuguese-speaking countries

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Laboratory best practices, Laboratory survey, Portuguese speaking countries, Quality assurance, Quality management

Abstract

Introduction: Laboratories (labs) play a fundamental role in screening, diagnosis, prognosis, and treatment of diseases. For a laboratory result to be useful, it must have guaranteed quality. In this context, there is no informative data on the best practices adopted by labs in Portuguese-speaking countries (PSC). This information is essential for formulating policies and educational strategies intended for this target audience.

Objective: To identify and assess adherence to laboratory best practices by clinical analysis labs in Portuguese-speaking countries.

Methods: A digital questionnaire consisting of 47 questions on laboratory best practices and quality management was sent to participants in the National Program for External Quality Assessment of Portugal and other labs involved in the Laboratory Quality Improvement Project for PSC-ProMeQuaLab, except from Brazil. Data were collected anonymously between July 7 and September 30, 2024 and analysed with descriptive statistics.

Results: 59 labs (ambulatory and hospital) participated in the study, but 5 institutions did not consent to the disclosure of their data, even if anonymously. Of the 54 included labs, most were from Portugal (39; 72%), followed by Cabo Verde (9; 16%), Guinea-Bissau (4; 7%), São Tomé and Príncipe (1; 2%), and 1 lab did not specify its country of origin. 57% of the labs have an implemented management system, and half of them are certified. Most labs belong to public services (63%), have a professional responsible for the management system (85%), conduct an annual training plan (85%), use quality indicators for the pre-analytical (87%) and post-analytical (83%) phases, and perform internal (70%) and external (89%) quality control. Opportunities for improvement were identified, as only 59% of labs record the causes of rejection of control sample

results, 65% develop a competency matrix, 66% construct control charts, and 72% use quality specifications to assess analytical performance.

Conclusion: Portuguese labs contributed the most to these results. Laboratory best practices are implemented, but there are opportunities for improvement. Conducting training and involving more labs from PSC will contribute to the implementation and harmonization of laboratory best practices, which can contribute to ensuring the quality of results and patient safety.

Introduction

With the aim of disseminating knowledge, building capacity, implementing best laboratory practices, and monitoring quality control measures, the Laboratory Quality Improvement Project – ProMeQuaLab – was established in 2015, focusing on Portuguese-speaking countries. The project emphasizes cooperation among countries so that they can effectively contribute to the improvement of laboratory diagnostics, directly benefiting institutions and, consequently, the general population of the participating countries. The countries involved in the project are Angola, Brazil, Cabo Verde, Guinea-Bissau, Mozambique, Portugal, São Tomé and Príncipe, and Timor [1].

The team responsible for managing a laboratory must establish an effective quality management system that enables the identification and minimization of analytical errors, aiming to ensure reliable and safe results for patients [2]. Quality management through specific indicators allows for mapping laboratory processes, identifying and quantifying errors, and subsequently implementing improvements and corrective actions. The use of indicators in healthcare services enables both internal and external comparisons with other similar services.

Laboratory quality assurance involves a set of management actions that create the necessary conditions for quality control and continuous process improvement. The primary objective of any advancement in the healthcare field is to enhance the safety of the services provided to patients [3,4].

Providing safety to patients means continuously improving all processes that affect them, ensuring the stability and predictability of those processes, and anticipating potential failures whenever possible. This requires a thorough understanding of the complexity of healthcare processes, the associated risk factors, and strict control over all critical stages within a healthcare organization [3].

High-reliability organizations are institutions that operate in high-risk environments, where even minor errors can lead to significant consequences, yet they manage to maintain low failure rates due to the implementation of robust organizational practices. Key characteristics of these organizations include:

1. A continuous concern with failures, aiming to detect and correct even the subtlest errors;
2. Avoidance of oversimplified interpretations, promoting deep and detailed analysis of the underlying causes of problems;
3. Sensitivity to operations, with constant real-time monitoring of activities;
4. A commitment to resilience, ensuring quick and effective responses to unforeseen events;
5. Deference to expertise, prioritizing decision-making based on technical knowledge [3].

At a more advanced stage, laboratory accreditation and certification promote safety, accountability, professional ethics, and efficiency, guiding the delivery of high-quality services. These processes ensure alignment with best practices and provide reliable and safe results for patients.

Clinical laboratories must strictly follow standards, regulations, and best laboratory practices to avoid errors that may affect test results. However, some countries do not have their own regulations, and laboratory accreditation is not mandatory, leaving the adoption of internationally accepted best practices at the discretion of professionals. In this context, there is a lack of informative data on the best practices adopted by laboratories in Portuguese-speaking countries. Such data are essential for the development of targeted policies and educational strategies for this audience.

Therefore, this study aimed to characterize clinical laboratories in Portuguese-speaking countries, focusing on the implementation of the best laboratory practices that are fundamental to ensuring quality in testing procedures.

Methods

A descriptive study was conducted using both qualitative and quantitative approaches to analyze data collected regarding best practices in clinical laboratories of Portuguese-speaking countries (PSC), except Brazil. Data collection took place from July 7 to September 30, 2024, through a digital questionnaire sent to participants of Portugal's National External Quality Assessment Program and other members of the Laboratory Quality Improvement Project for Portuguese-speaking countries [1]. The total number of laboratories reached by the questionnaire is unknown, since each member was asked to further disseminate the survey through the snowball method. To encourage participation, reminder emails were sent to non-respondents. Participation was voluntary and anonymous, except for the identification of the country of origin.

A research questionnaire was developed containing 47 questions, both open-ended and multiple-choice, organized as follows:

12 questions (1 to 7 and 43 to 47): Related to the laboratory's involvement with ProMeQuaLab.

12 questions (8 to 19): Regarding laboratory characteristics.

23 questions (20 to 42): Concerning laboratory best practices.

The study covered all phases of the laboratory process - pre-analytical, analytical, and post-analytical - with the aim of

ensuring greater reliability of results.

Data were collected and electronically tabulated using Microsoft Forms. The responses were counted, and results are presented as absolute numbers, ratios, or percentages.

Results and Discussion

Fifty-nine (59) laboratories participated in the study; however, five (5) did not consent to the disclosure of their data, even in anonymized form. The majority of the laboratories were from Portugal (39 out of 54, 72%), followed by Cabo Verde with 9 participants, Guinea-Bissau with 4, São Tomé and Príncipe with 1, and one laboratory that did not report its country of origin. Four countries (Angola, Brazil, Mozambique, and Timor) were not represented by any institutions in this study.

Of the survey participants, only 10 laboratories (18%) - 3 from Portugal, 6 from other PSC, and 1 that did not disclose its country of origin - have been members of the ProMeQuaLab project for more than two years. On the other hand, 14 laboratories (26%) - 11 from Portugal and 3 from other PSC - reported having visited the ProMeQuaLab website, and three (6%) - 2 from Portugal and 1 from another PSC - had previously participated in one of the project's congress editions. However, 27 laboratories (50%) - 16 from Portugal and 10 from other PSC - reported participating in the training activities promoted by ProMeQuaLab, of which 13 expressed being very satisfied and 14 satisfied with the trainings. Among all participants, seven laboratories (13%) reported having a high level of knowledge about the project's mission, while 19 (35%) stated that they either did not know or were unsure.

Regarding the laboratories' expectations for ProMeQuaLab, 38 out of 54 (70%) expressed a desire for consultancy aimed at continuous improvement; 26 out of 54 (48%) suggested the inclusion of artificial intelligence tools; 36 out of 54 (67%) supported efforts for change and innovation; and 35 out of 54 (65%) and 34 out of 54 (63%) expressed interest in the integration of virtual tools for Internal Quality Control (IQC) and External Quality Assessment (EQA), respectively.

Furthermore, laboratories expressed interest in training in the following areas: bacteriology, parasitology, biochemistry, urinalysis, hematology, microbiology, biorisk management, implementation of external quality control, training for laboratory technicians, inventory management, assay validation, implementation of quality management systems, and training and qualification of managers and human resources.

It was also suggested that ProMeQuaLab should offer more training opportunities and provide support for laboratories in implementing quality control management systems.

Table 1 presents the laboratories' responses, showing that the majority are outpatient-type laboratories (24 out of 54, 44%), with 22 located in Portugal and 2 in other PSC. Additionally, 34 laboratories (62%) offer public services, of which 21 are from Portugal and 12 from other PSC.

Table 1: Responses from all laboratories, only Portuguese laboratories and from other Portuguese-speaking countries laboratories to the questions in this study, grouped into laboratory characteristics, human resources and Quality Management system.

Questions	All Laboratories N (%)	Laboratories from Portugal N (%)	Laboratories from other PSC N (%)
Characterization of the laboratories			
Laboratory Type Public Laboratory Private Laboratory	 34/54 (63.0) 20/54 (37.0)	 21/39 (53.8) 18/39 (46.2)	 12/14 (85.7) 2/14 (14.3)
Service Type Hospital-based Outpatient Outpatient and Hospital-based N/A	 23/54 (42.7) 24/54 (44.4) 4/54 (7.4) 3/54 (5.5)	 13/39 (33.3) 22/39 (56.4) 1/39 (2.6) 3/39 (7.7)	 9/14 (64.3) 2/14 (14.3) 3/14 (21.4) 0/14 (0)
Does it have a laboratory information system? Yes No N/A	 48/54 (88.8) 5/54 (9.3) 1/54 (1.9)	 35/39 (89.7) 3/39 (7.7) 1/39 (2.6)	 12/14 (85.7) 2/14 (14.3) 0/14 (0)
Is a management system implemented? Yes No N/A	 37/54 (68.5) 15/54 (27.7) 2/54 (3.7)	 32/39 (82.0) 5/39 (12.8) 2/39 (5.2)	 5/14 (35.7) 9/14 (64.3) 0/14 (0)

If not, is there a plan to implement a management system? Yes No N/A	10/54 (18.5) 4/54 (7.4) 1/54 (1.9)	2/39 (5.2) 2/39 (5.2) 1/39 (2.6)	7/14 (50.0) 2/14 (14.3) 0/14 (0)
If yes, which management system is implemented? Accredited Certified N/A	8/54 (14.8) 26/54 (48.2) 3/54 (5.5)	9/39 (23.1) 23/39 (58.9) 2/39 (5.2)	0/14 (0) 4/14 (28.6) 1/14 (7.1)
Human Resources			
Number of laboratory assistants? 0 1-5 6-10 >10 S/R	8/54 (14.8) 28/54 (51.9) 8/54 (14.8) 2/54 (3.7) 8/54 (14.8)	6/39 (15.4) 20/39 (51.2) 6/39 (15.4) 2/39 (5.2) 5/39 (12.8)	2/14 (14.3) 8/14 (57.1) 1/14 (7.1) 0/14 (0) 3/14 (21.4)
Number of clinical laboratory technicians? 0 1-5 6-10 >10 S/R	2/54 (3.7) 19/54 (35.2) 11/54 (20.4) 18/54 (33.3) 4/54 (7.4)	1/39 (2.6) 15/39 (38.5) 4/39 (10.2) 16/39 (41.0) 3/39 (7.7)	1/14 (7.1) 4/14 (28.7) 7/14 (50.0) 1/14 (7.1) 1/14 (7.1)
Number of specialists in Clinical Laboratory Science/Clinical Pathology? 0 1-5 6-10 >10 S/R	6/54 (11.1) 19/54 (35.2) 7/54 (13.0) 8/54 (14.8) 14/54 (25.9)	1/39 (2.6) 18/39 (46.1) 7/39 (18.0) 8/39 (20.5) 5/39 (12.8)	4/14 (28.6) 1/14 (7.1) 0/14 (0) 0/14 (0) 9/14 (64.3)
Number of graduates in other fields? 0 1-5 6-10 >10 S/R	5/54(9.3) 6/54 (48.2) 4/54 (7.4) 3/54 (5.5) 16/54 (29.6)	4/39 (10.2) 21/39 (53.9) 3/39 (7.7) 3/39 (7.7) 8/39 (20.5)	1/14 (7.1) 5/14 (35.8) 1/14 (7.1) 0/14 (0) 7/14 (50)
Quality Management System			
Does the laboratory implement an annual training plan? Yes No N/A	46/54 (85.2) 6/54 (11.1) 2/54 (3.7)	34/39 (87.1) 3/39 (7.7) 2/39 (5.2)	11/14 (78.6) 3/14 (21.4) 0/14 (0)
Is a competency matrix implemented? Yes No N/A	35/54 (64.9) 16/54 (29.6) 3/54 (5.5)	30/39 (76.8) 7/39 (18.0) 2/39 (5.2)	5/14 (35.8) 8/14 (57.1) 1/14 (7.1)
Is there a professional responsible for the management system? Yes No N/A	46/54 (85.2) 6/54 (11.1) 2/54 (3.7)	37/39 (94.8) 0/39 (0) 2/39 (5.2)	9/14 (64.3) 5/14 (35.8) 0/14 (0)

Quality Indicators and Specifications			
Does it use quality indicators for the pre-analytical phase? Yes No N/A	47/54 (87.0) 5/54 (9.3) 2/54 (3.7)	33/39 (84.6) 4/39 (10.2) 2/39 (5.2)	13/14 (92.9) 1/14 (7.1) 0/14 (0)
Does it use quality indicators for the post-analytical phase? Yes No N/A	45/54 (83.3) 7/54 (13.0) 2/54 (3.7)	31/39 (79.4) 6/39 (15.4) 2/39 (5.2)	13/14 (92.9) 1/14 (7.1) 0/14 (0)
Are there written procedures for conducting the tests? Yes No N/A	50/54 (92.6) 1/54 (1.9) 3/54 (5.5)	36/39 (92.3) 0/39 (0) 3/39 (7.7)	13/14 (92.9) 1/14 (7.1) 0/14 (0)
Does it use quality specifications to assess analytical performance? Yes No N/A	39/54 (72.2) 11/54 (20.4) 4/54 (7.4)	32/39 (82.1) 4/39 (10.2) 3/39 (7.7)	6/14 (42.9) 7/14 (50.0) 1/14 (7.1)
Which? From the manufacturer Based on EQA (External Quality Assessment) Based on Biological Variation N/A	5/54 (9.3) 19/54 (35.2) 13/54 (24) 17/54 (31.5)	4/39 (10.2) 14/39 (35.9) 12/39 (30.8) 9/39 (23.1)	0/14 (0) 5/14 (35.8) 1/14 (7.1) 8/14 (57.1)

N/A (Not Applicable); PSC (Portuguese-speaking counties)

In our study, as previously mentioned, the results are predominantly from laboratories in Portugal, and the very limited participation from laboratories in other Portuguese-speaking countries significantly restricts any meaningful comparative analysis. Most of the laboratories have an information system and a management system implemented (Table 1). Although the majority of laboratories from other PSC have an information system, most do not have a management system implemented, although they plan to do so. However, due to the very small number of responding laboratories from these countries, these observations must be interpreted cautiously and cannot be generalized. A Quality Management System aims to provide a solid framework for quality in laboratories, contributing to preventive actions [5].

In our research, of the 39 participating Portuguese laboratories, 32 (82%) have some type of management system implemented, with 72% (23/32) certified and 28% (9/32) accredited (Table 1). In comparison, in Brazil, only 922 (3.43%) have at least one accreditation/certification, according to a survey conducted by Pires et al. (2023) [6]. Of these, 183 (19.84%) are accredited by the national standard PALC, 449 (48.70%) by the national standard DICQ, 155 (16.81%) by the national standard ONA, 10 (1.08%) are accredited by the international standard CAP, 121 (13.12%) are certified by the international standard ISO 9001, and only 4 (0.43%) are accredited by the international standard ISO 15189. A study conducted by Kopčinović et al. (2022) [7] in Croatia showed similar results, indicating that only a small portion of laboratories (9%) had accreditation. According to Souza (2016) [8], the pursuit of accreditation is essential for improving laboratory services, as well as the need for international consensus. Standards outline the requirements for a management system to achieve customer satisfaction and continuous improvement in the system's effectiveness. Lescowicz et al. (2018) [9] found no relationship between the size of the laboratory and the organizational quality structure. However, the authors noticed a trend of implementing a quality system in larger laboratories. On the other hand, they inferred that smaller laboratories found it easier to achieve accreditation [9]. However, due to the small number of laboratories that participated in this study, and the predominance of responses from Portugal, comparisons with other countries data are presented only for contextual reference and not for direct comparison.

The research by Lescowicz et al. (2018) [9] found that 40% of laboratories reported a lack of professionals in the market with training in quality assurance. The researchers also reported that one-third of establishments face difficulties in promoting ongoing education for employees due to cost and lack of

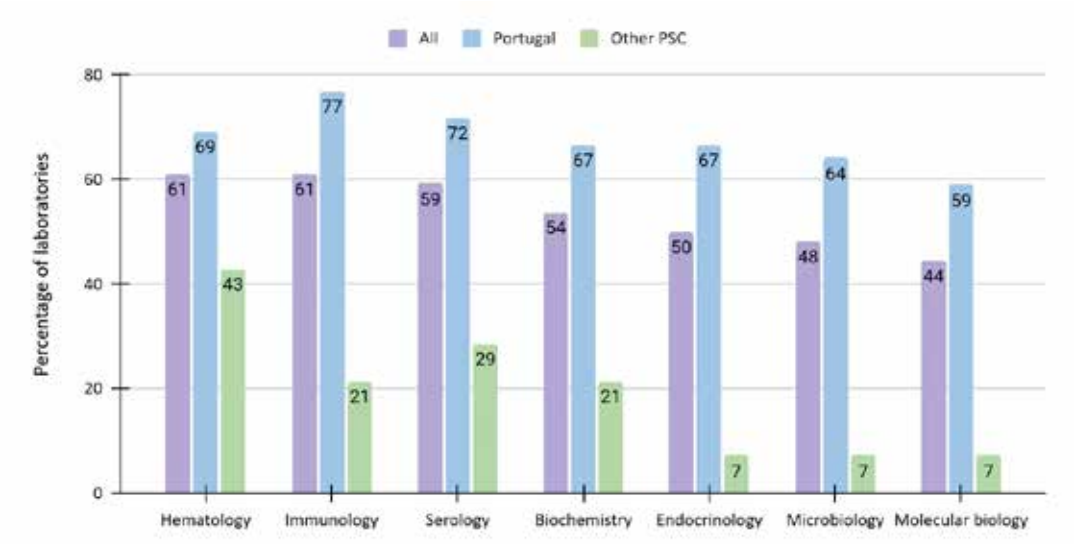
available time. In this context, the mission of ProMeQuaLab seeks to meet the laboratories' demand for training, which is available on the project's website at no cost and can be completed in real-time or at a time convenient for the professionals.

The majority (92%) of laboratories reported having written operational procedures (Table 1), which is a higher proportion than observed among laboratories surveyed in Brazil (70%) [9]. Similar to Brazil (90%) [9] and European countries [10], most of the laboratories in our study use quality indicators for the pre-analytical (87%) and post-analytical (83%) phases.

The proportion of laboratories conducting internal quality control (IQC) in our study (46/54, 85%) was slightly lower than in Brazil, where the rate was 95% [9].

Most laboratories, 38 from Portugal and 8 from other PSC countries, have implemented internal quality control (IQC). Two (4%) laboratories, one from Portugal and one from another PSC country, did not respond, and 6, consisting of 5 from other PSC countries and 1 from an unknown origin, do not perform IQC. As a limitation of our study, it is not possible to state that laboratories that did not respond about performing IQC do not perform the specialties. Among the laboratories conducting IQC, the areas covered are presented in Figure 1.

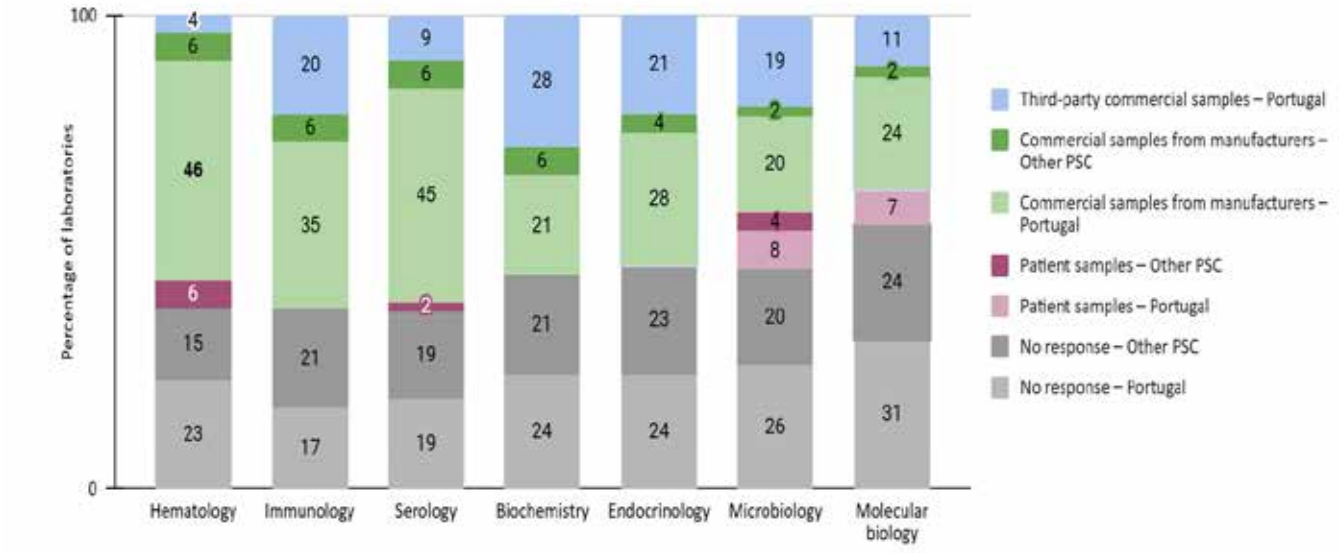
Figure 1: Percentage (%) of laboratories conducting internal quality control in various laboratory areas.



The purple columns represent the percentage among all laboratories in the study, the blue columns represent the percentage among Portuguese laboratories, and the green columns represent the percentage among laboratories from other Portuguese-speaking countries (PSC).

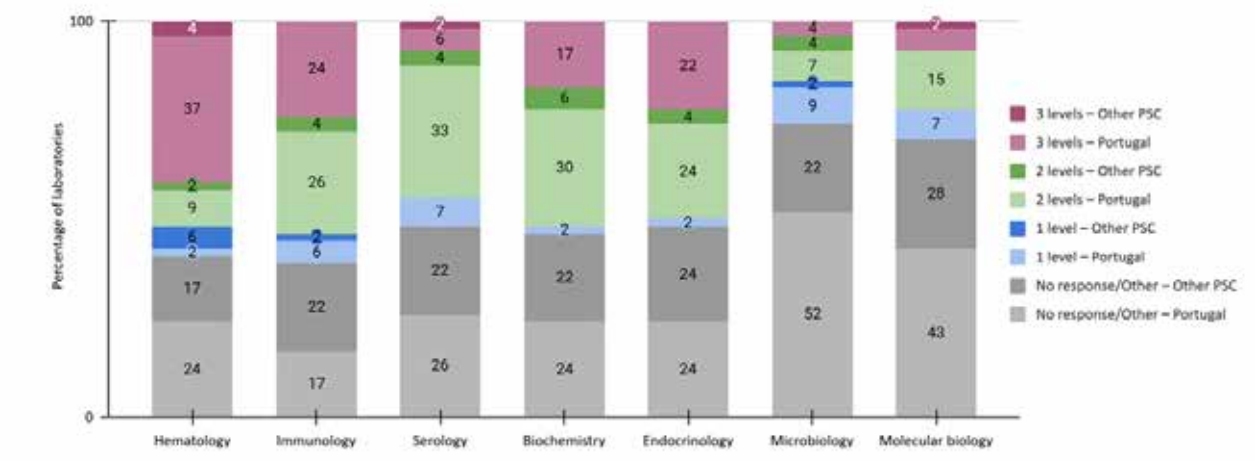
The types of control samples used for IQC by different laboratory areas are shown in Figure 2.

Figure 2: Control materials used in different laboratory areas conducting IQC.



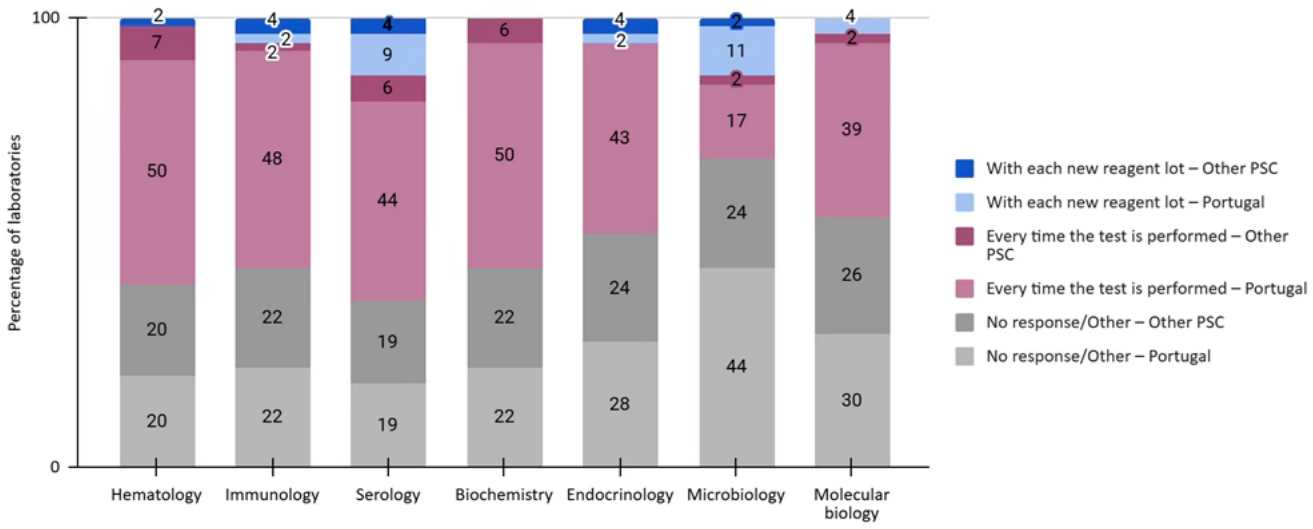
Overall, despite the high number of non-responding laboratories, the areas of hematology, serology, and immunology primarily use control samples from manufacturers, followed by third-party samples in laboratories in Portugal and patient samples in laboratories from other PSC countries.
IQC can be performed with patient samples, commercial samples from the reagent manufacturer, or commercial samples from third parties. It is desirable that IQC be performed whenever the test is executed, with each batch of analyses, and at least once a day using third-party samples. The use of control samples with different concentration levels is also recommended (ISO 15189:2022; 11).
The concentration levels of control samples used in IQC by different laboratory areas are shown in Figure 3.

Figure 3: Concentration levels of control samples used in internal quality control in different laboratory areas.



Despite the high number of non-responding laboratories, in general, the use of 3 concentration levels of control samples is more common in the hematology area, while in other areas, the use of 2 concentration levels is more frequent.
The frequency of IQC implementation by different laboratory areas is shown in Figure 4.

Figure 4: Frequency of internal quality control implementation in different laboratory areas.



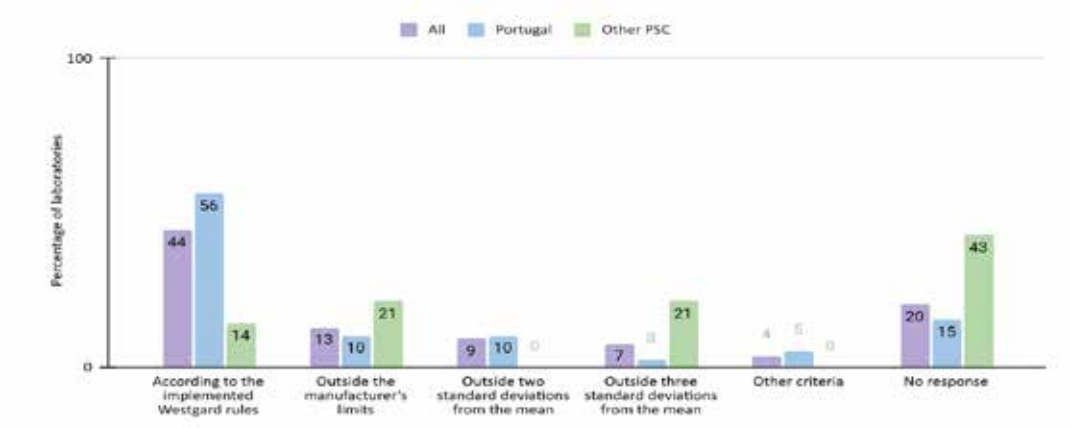
Similarly, to the findings reported by laboratories in a study conducted in Nepal in 2024 by Pant et al. [11], most laboratories in our study perform IQC daily/whenever they conduct the test. In this study, it was observed that most laboratories perform internal quality control on analyses using commercial samples provided by the manufacturer. In contrast, the 2024 study conducted in Nepal showed different results, revealing that the majority of participants (88%) use third-party commercial samples. The use of control samples from the manufacturer is produced under the same conditions as the reagent, which may not allow the detection of changes in analytical performance [11].
More specifically, comparing with the 63% (33/52) of hematology laboratories that reported performing IQC in our study, a survey indicated that 100% of Croatian laboratories perform IQC [12]. Among those who perform IQC in hematology in our study (33), 28 (84%) use commercial samples from manufacturers, compared to 98% of Croatian

laboratories [12].

The majority (36/54, 67%) of laboratories, 32 from Portugal and 4 from other PSC countries, use control charts to monitor control results, 10 laboratories (18%), 6 from Portugal and 4 from other PSC countries, do not use them, and 8 (15%), 1 from Portugal and 6 from other PSC countries, did not respond. The percentage of laboratories that reported monitoring analytical quality through control charts in our study (67%) was similar to the Brazilian rate (75%) [9]. However, although a large part of the laboratories (24/52, 46%) use Westgard rules as criteria for rejecting control samples, 21% (11/52) did not answer the question, suggesting the need to improve knowledge on interpreting control charts.

The majority of laboratories (32/54, 59%), 25 from Portugal and 7 from other PSC countries, also record the causes of control sample rejection results, but 11 (20%), 10 from Portugal and 1 from other PSC countries, do not record them, and 11 (20%), 4 from Portugal and 6 from other PSC countries, did not respond. The criteria used by laboratories to reject control sample results are shown in Figure 5.

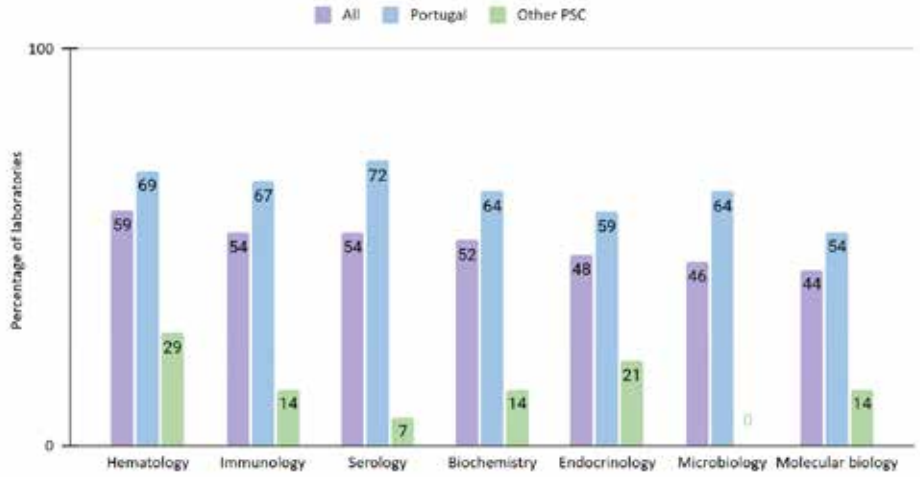
Figure 5: Percentage of laboratories using criteria for rejecting control sample results.



Other criteria: MQC program, Multiple control charts; EWMA, exponentially weighted moving average statistic (EWMA). The purple columns represent the percentage across all laboratories in the study, blue columns represent the percentage of laboratories in Portugal, and green columns represent the percentage of laboratories from other Portuguese-speaking countries (PSC).

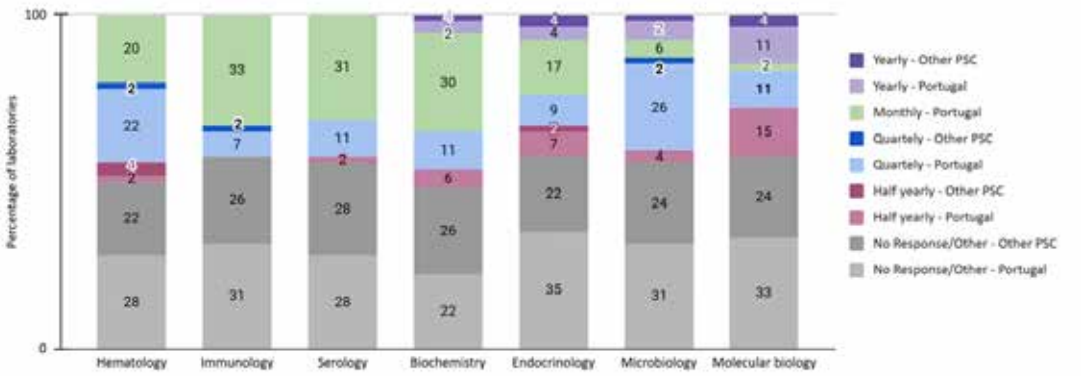
The majority of laboratories (48/54, 89%), 39 from Portugal, 8 from other PSC, and one that did not report its country of origin, participate in EQA programs, while 5 (9%) from other PSC do not participate, and one did not respond. As a limitation of our study, it is not possible to state that laboratories that did not respond about performing EQC do not perform the specialties. The laboratory areas and the frequencies they perform EQA are shown in Figures 6 and 7, respectively.

Figure 6: Percentage (%) of laboratories conducting external quality control in different laboratory areas.



The purple columns represent the percentage across all laboratories in the study, blue columns represent the percentage of laboratories in Portugal, and green columns represent the percentage of laboratories from other Portuguese-speaking countries (PSC).

Figure 7: Frequency of participation in EQA by different laboratory areas.



The purple columns represent the percentage across all laboratories in the study, blue columns represent the percentage of laboratories in Portugal, and green columns represent the percentage of laboratories from other Portuguese-speaking countries (PSC).

Overall, despite the high number of non-responding laboratories, the most common frequency of participation in EQA is monthly, followed by quarterly.

The majority of laboratories indicated that participation in EQA leads to improved analytical performance (39/54, 72%) and detection of systematic errors (34/54, 63%). However, 8 (15%) laboratories, 2 from Portugal and 6 from other PSC countries, did not share this perception and did not answer the question. However, in our study, a higher rate of laboratories (90%) reported conducting EQA compared to Brazilian laboratories (55%). In Brazil, among the challenges to implementing IQC and EQA, cost and the difficulty in finding a single supplier for control samples for all tests were reported [9].

Overall, opportunities for improvement were identified, as only 59% of laboratories register the causes for rejecting control sample results; 65% use a competency matrix, 66% use control charts, and 72% use quality specifications to assess analytical performance.

The main difficulties reported by laboratories for quality control implementation were lack of control materials, human resources, software for analyzing internal quality control results, technicians trained in quality management, team stability, training and capacity building, use of analytical performance specifications, appropriate infrastructure, and the measurement of uncertainty calculations.

Despite efforts to provide free online educational training, such as the webinars of the International Federation of Clinical Chemistry (IFCC), foreign languages can be a barrier to accessing knowledge. A recent survey performed on behalf of the Task Force for Global Education and Learning and Task Force for Laboratory Medicine Practice Guidelines of the IFCC [13] clearly points to topics requested by professionals to complement their training and also guide PROMEQUALAB's actions.

Our study has some limitations, such as the laboratory response rate, the large number of questions to cover all phases of laboratory activities, and since an individualized questionnaire was used, we cannot rule out the possibility that participants provided "desirable" answers instead of reporting their actual practices. The low participation rate significantly affects the generalizability of the results, and this low response rate may be partially explained by the length and complexity of the questionnaire, which contained 47 questions. This extensive format may have discouraged completion, particularly among laboratories with limited human resources or high workload. Shorter or more focused questionnaires may improve response rates in future studies.

Excluding data from Portugal, the results from other PSC laboratories indicate a low level of GLP implementation, which may be associated with several factors, such as financial limitations, access to training and control material, laboratory computerization systems and the guarantee of calibration/ maintenance of laboratory equipment. However, due to the extremely small number of respondents from these countries, these findings cannot be extrapolated or interpreted as representative.

Given the limited number of participating laboratories and the imbalance in representation across countries, the findings and interpretations of this study should be understood as applicable mainly to the Portuguese laboratories included in the dataset.

Conclusions

Despite the existence of international guides for the standardization of procedures, based on our research, it was possible to observe that the degree of implementation of good practices is still partial, and we can infer that there are challenges in the implementation and efficient use of a quality management system in laboratories. These challenges include the need for well-qualified professionals committed to quality management, as well as the increasing requirement for continuous professional development in response to the rapid evolution of laboratory processes.

The small number of laboratories that responded to the survey represents a major limitation and restricts the interpretation of the findings primarily to the Portuguese context. The low response rate may be associated with the length of the

questionnaire - comprising 47 questions - which may have discouraged participation, particularly from laboratories in other Portuguese speaking countries.

Despite the limitation, it was possible to identify opportunities for improvement across all phases of the analytical process in the participating Portuguese laboratories. None of the evaluated requirements - including the implementation and interpretation of internal and external quality control, and the use of quality specifications to assess analytical performance - were met by all laboratories.

These findings highlight the need to enhance dissemination of ProMeQuaLab in PSC, as this project offers free training that may support the harmonization and continuous improvement of laboratory practices. In addition, the results provide valuable insights to guide future training initiatives and encourage develop strategies to increase laboratory participation, potentially contributing to the quality of results and patient safety in PSC countries.

Conflict of Interests

None to declare.

Ethics approval

Not applicable as this study only involved anonymised survey responses.

Research Funding

None received.

Author contributions

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Consent for Publication

Consent to submit has been received explicitly from all coauthors, as well as from the responsible authorities. Authors whose names appear on the submission have contributed sufficiently to the scientific work and therefore share collective responsibility and accountability for the results.

Data availability

The data included in this study is available upon request to the corresponding author.

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