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Implementation of Moroccan GBEA requirements in private laboratories: Current status and future perspectives

Anass Kharrazi[1*#], Sobha El Ftouh[1,2#], Hicham El Annaz[3,4], Amine Idriss Lahlou[4,5], Khalid Ennibi[3,4], Mohammed El Feniche[1], Rida Tagajdid[3,4], Rachid Aabi[4,5], Bouaiti El Arbi[1,4]

1. Laboratory of Biostatistics, Clinical Research and Epidemiology, Faculty of Medicine and Pharmacy, Mohammed V University, Rabat, Morocco
2. Research laboratory, Ibn Sina University Hospital, Rabat, Morocco
3. Virology Laboratory, Center of Virology, Infectious and Tropical Diseases (CVMIT), Mohamed V Military Instruction Hospital, Rabat, Morocco
4. Biomedical and Epidemiology Research Unit (URBE), Center of Virology, Infectious and Tropical Diseases (CVMIT) Mohamed V Military Instruction Hospital, Rabat, Morocco
5. Faculty of Medicine and Pharmacy, Mohammed V University, Rabat, Morocco

ABSTRACT

Background: The Moroccan Good Practice Guide for Laboratory Analyses (GBEA) provides the normative framework ensuring good practices and quality assurance within clinical laboratories. While some laboratories rely solely on the GBEA as their quality assurance framework, others opt for certification or accreditation to strengthen their quality management system. This study aims to explore the status of adherence to the GBEA requirements by private clinical laboratories in the Fez-Meknes region during the second half of 2025.

Methods: An exploratory cross-sectional quantitative study assessing compliance, consisting of measuring the degree of compliance of the structures investigated with a predefined regulatory framework (GBEA). The data collection period lasted six months, from July to December 2025, and statistical analyses were performed using SPSS version 20 software.

Results: The participating laboratories (n=30) answered all questions. Laboratories with years of experience seem to have the highest rates, unlike laboratories with less than five years, which have the lowest rates, with $p<0.001$. Six laboratories had the highest rates, ranging from 92% to 100%, while the lowest compliance rates were between 50% and 54.5%. Challenging aspects for laboratories are quality control, documentation, procedures for recording equipment reagents and consumables, as well as procedures for accessing and using the premises.

Conclusions: Although the GBEA is a legislative and regulatory framework covering good practice and quality assurance in Moroccan laboratories, it is intended to be reinforced by an explanatory guide on standardized procedures and processes, staff training and monitoring through scheduled audits, to help laboratories establish a culture of quality and continuous improvement.

Keywords: Fez-Meknes region, GBEA requirement compliance, Moroccan GBEA, private laboratories, quality assurance

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INTRODUCTION

Quality in clinical laboratories is essential to ensuring the reliability of results, which enables accurate diagnosis. For many years, quality has been seen as a culture requiring continuous improvement, moving from the concept of quality control to quality assurance and finally to quality management [1]. This has prompted many countries to implement regulations and standards governing the clinical laboratory profession, particularly regarding the analysis process. Some have adopted their own national standards and laws, such as the Clinical Laboratory Improvement Amendments (CLIA) [2] in the United States and International Organization for Standardization (ISO 15189) [3] on a voluntary basis, while others have chosen to harmonize their standards with international standards, such as France, which has adopted the requirements of ISO 15189 as mandatory. In Morocco, the Guide to Good Analytical Practice (Guide de bonnes executions des analyses - GBEA) was the first guide to bring together various requirements in order to facilitate the effective operation of medical laboratories [4].

* Corresponding author: Anass Kharrazi, Laboratory of Biostatistics, Clinical Research and Epidemiology, Faculty of Medicine and Pharmacy, Mohammed V University, Rabat, Morocco. E-mail: anass_kharrazi@um5.ac.ma
# These authors contributed equally to this work and share first authorship

It was established in order to create a common framework of good professional practices applicable in public and private laboratories. This guide aims to ensure compliance with the technical, organizational, ethical, and regulatory standards of the sector. It covers the entire analytical process, including the pre-analytical, analytical, and post-analytical phases, as well as cross-cutting areas such as documentation, equipment management, quality assurance, and health and safety. ISO 9001:2015 certification [5], in its version adapted to medical laboratories, and ISO 15189:2022 accreditation remain optional. ISO 15189 accreditation is issued by the Moroccan Accreditation Service (SEMAC) (under the supervision of the Ministry of Industry and Trade) via the Moroccan Institute for Standardization (IMANOR), which is the body responsible for accrediting clinical laboratories [6, 7]. Although the law has been in effect since 2010, few studies have evaluated its practical application in Moroccan laboratories. This study aims to evaluate the adherence to the GBEA requirements through a questionnaire survey of clinical laboratories in the Fez-Meknes region, identifying both the requirements that have been met and those that need improvement.

The enforcement of the GBEA does not involve regular inspections by government institutions, which poses a significant challenge to its effective implementation. [8]. Accordingly, our study was conducted to highlight the challenges faced by most Moroccan laboratories and recommend appropriate solutions that could serve as a foundation for adopting a quality management approach.

METHODS

An exploratory cross-sectional quantitative study assessing compliance, consisting of measuring the degree of compliance of clinical laboratories investigated with a predefined regulatory framework (GBEA). The data collection period lasted six months, from July 2025 to December 2025. The questionnaire focused on private clinical laboratories in the Fez-Meknes region. Initial contact consisted of delivering the questionnaire to laboratory directors for preliminary review and scheduling appointments. During a second contact, interviews were conducted by a researcher with professional experience in medical biology quality management. Before each interview, participants were informed about the impartiality of the process and assured of the anonymity of their responses.

Sample characteristics

Inclusion criteria: Private clinical laboratories in the Fez-Meknes region and Laboratories that agreed to respond to the questionnaire. Exclusion criteria: Laboratories that had been operating for less than one year, public laboratories and university hospital laboratories, and laboratories outside the Fez-Meknes region.

Public laboratories were not included due to differences in their organizational structure and access constraints. In addition, certain provisions applied only to private clinical laboratories.

Questionnaires

The interview consists of a guided qualitative questionnaire including 33 items conducted in an individual interview lasting between 20 and 30 minutes, with the aid of the researcher. Responses are classified as: “No” (the requirement is not fulfilled), “Partial” (the requirement is partially satisfied), and “Yes” (the laboratory fully complies with the requirement). The interviews were not recorded, and the forms were returned to the participants for verification and final approval.

This assessment was inspired by the “Stepwise Laboratory Quality Improvement Process Towards Accreditation” (SLIPTA) checklist model [9], with responses scored as: “YES” = 3 points, “Partial” = 1 point, and “NO” = 0 points. The results were expressed as an overall compliance score, calculated by summing the points assigned to each question.

Statistical analysis

Thematic analysis was conducted by two researchers. The results were collected in an Excel file, coded, and analyzed using SPSS v20. Qualitative variables were expressed as counts and percentages and then compared using the Chi-square test. A 3×3 contingency table was constructed in which the rows represented years of experience, and the columns represented compliance level. The rows were defined as follows: 0–5 years (score=1), 5–10 years (score=2), and >10 years (score=3). The columns represented compliance categories: no compliance (score=1), partial compliance (score=2), and full compliance (score=3). The assumptions required for the Chi-square test were satisfied for all instances of the table, with expected cell values greater than 5 (n>5).

The themes were predetermined based on the following dimensions: Premises and structure, consumables, equipment and reagents, personnel, analytical process, quality assurance, and health and safety. Each item received from 0 to 3 points, for a maximum possible total of 99 points (33 questions × 3 points). To facilitate interpretation and comparison of results, the raw score was converted into a percentage using the following formula: Compliance rate (%) = [Score obtained / 99] × 100.

The calculation can be illustrated using the “premises and structure” dimension example, which consists of three items, each item being scored 0, 1 or 3. Therefore, the maximum score for one laboratory within this dimension is: 3 (items) × 3 (maximum score) = 9. This calculation was generalized across 30 laboratories included in the study, resulting in a total maximum score = 9 (maximum score per lab) × 30 (laboratories). These total scores were sub-

sequently used to compute compliance percentage using the formula compliance (%) = (score obtained /score max) × 100. Based on these percentages, laboratories were classified in six levels of compliance: low compliance < 55%, limited compliance (55–64%), medium level of compliance (65–74%), good compliance (75–84%), very good compliance (85–94%), and excellent compliance > 95%. This categorization will enable a detailed analysis of each laboratory's weaknesses and strengths.

RESULTS

Overall, of the 30 laboratories that answered all questions, more than half (17) had less than 5 years of experience, 6 had 5 to 10 years, and 7 had more than 10 years. Certain limitations were encountered during data collection, which explains the relatively small number of participants. Twenty-three laboratories were categorized as having "low to medium compliance," while seven had "good to excellent compliance." Six laboratories had the highest rates, ranging from 92% to 100% (100% for one laboratory), whereas the lowest rates were between 50% and 54.5%. Most laboratories met requirements related to health and safety (87%), personnel (86%), and the management of equipment, reagents, and consumables (76%). The dimensions with the lowest compliance rates are the information system, quality control, and the pre-analytical phase. Among the requirements that pose major challenges for laboratories are: Standard Operating Procedure (47%), staff training (43%), pre-analytical phase procedures (47%), procedures for reporting results (42%), procedures for managing the information system (30%), participation in EQA (43%), and establishing their procedures (11%).

Table 1. Compliance with GBEA requirements across all laboratories participating in the study

REQUIREMENTS	Compliance			
	Partial (n)	Total (n)	Lack of (n)	Overall score* (%)
Premises requirements	17	11	2	56
Access and use of premises procedures	14	11	5	52
Blood collection facilities	-	30	-	100
Manufacturer procedures for the use of equipment, reagents, and consumables	-	30	-	100
Standard Operating Procedures	24	6	-	49
Registration of DIMDIV	19	11	-	76
Reagent and consumable registration file	15	9	6	47
Automated machines are periodically inspected and maintained	2	28	-	95
Director's responsibility	-	30	-	100
Staff competence	-	30	-	100
Staff files	-	30	-	100
Training program				43
Establishment of sampling and identification procedures	22	8	-	51
Procedure for receiving and accepting samples	19	9	2	51
Procedures for preparing and handling samples	21	9	-	53
Procedures for transporting and storing samples	21	9	-	60
Alternative procedures for sampling techniques and transmission	15	11	4	60
Biological reference intervals	-	30	-	100
Information related to the analysis and interpretation of results	2	26	1	90
Management of critical results	24	4	2	40
Procedures for reporting results	20	6	4	42
Outsourcing of results	18	9	3	40
Periodic inspection of automated systems	-	30	-	42
Maintenance program	20	10	-	57
Documentation and archiving	17	11	2	56
Information system management procedures	18	9	3	30
Frequency of IQCs	-	30	-	100
Internal quality control (IQC) procedures	20	8	2	49
Participation in EEQs	16	14	-	43
EEQ control management procedures	24	4	2	11
Safety equipment	-	30	-	100
Storage of toxic and hazardous products	-	30	-	100
Waste management	3	27	-	93
Safety and hazardous product handling procedures	7	23	-	56

A total of 30 laboratories were included in the analysis. The questionnaire comprised 33 items, with responses scored as follows: 3 points for full compliance, 1 point for partial compliance, and 0 points for no compliance.
* For each item, the overall compliance score was expressed as a percentage of the maximum possible score (i.e., 90 points, corresponding to 30 laboratories × 3 points, assuming full compliance across all laboratories).

Table 2. Compliance rates based on laboratories' years of experience

Years of experience	Labs (n)	Total compliance	Partial compliance	Non-compliance	*p* value
0-5 years	17	(264) 47.1%	(233) 41.5%	(64) 11.4%	
5-10 years	6	(131) 66.2%	(57) 28.8%	(10) 5.1%	< 0.001
>10 years	7	(172) 74.5%	(43) 18.6%	(16) 6.9%	
Category (level of compliance)					
Weak / limited	13	(175) 40.8%	(186) 43.4%	(68) 15.8%	
Medium	10	(177) 53.6%	(131) 39.7%	(22) 6.7%	-
Good / Very good / Excellent	7	(209) 90.5%	(19) 8.2%	(3) 1.3%	

For compliance rates by years of experience, each category was assigned a maximum of n × 33 observations, where n represents the number of laboratories in that category and 33 corresponds to the number of assessed laboratory dimensions. For example, in the 0–5 years of experience category, there were 17 laboratories (maximum 561 observations). Of these, 264 instances showed full compliance (47.1%), 233 showed partial compliance (41.5%), and 64 showed no compliance (11.4%). The same approach was applied for classification according to levels of compliance. Laboratories were categorized into one of six compliance levels (ranging from weak to excellent); the criteria for this classification are described in the Methods section.

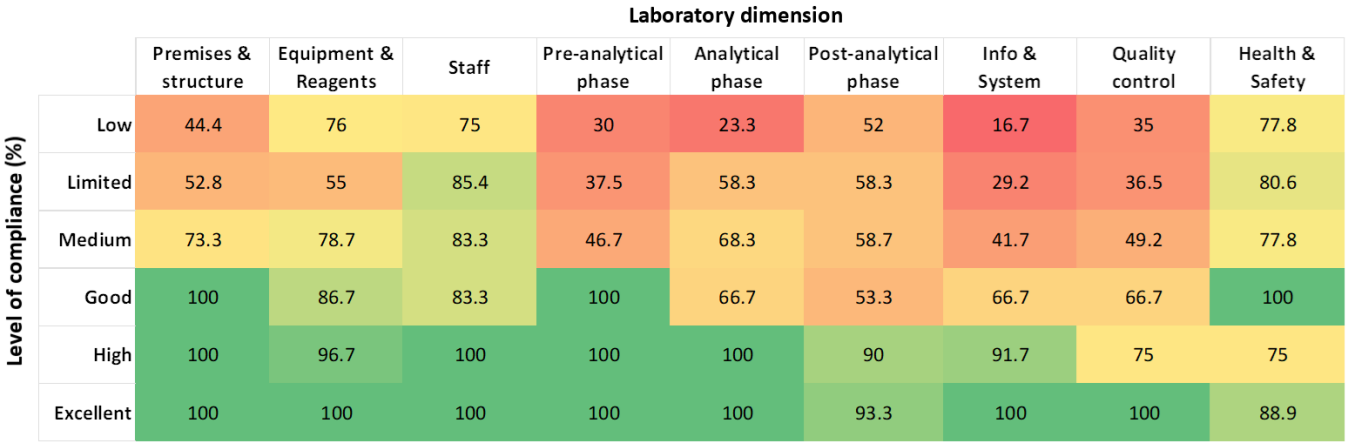

Figure 1. Heatmap of compliance scores by dimension

DISCUSSION

Laboratories tend to show higher compliance rates as their years of experience increase. Compliance rises from 47.1% among laboratories with 0–5 years to 74.5% for those over 10 years (see Table 2). The results indicate a significant increase in overall compliance in laboratories with more than 5 years of experience, with a *p*-value <0.001. This may reflect mature organizational structures and quality systems as well as the development of various resources (training, materials, etc.) over time. One-third of the responses are labeled "partial," particularly concerning the analytical process and quality assurance, revealing that the main weaknesses lie in documentation, process-based management, and the implementation of operating procedures. Thus, 23 laboratories need substantial improvements to meet GBEA requirements, which serve as the legislative foundation and are necessary for potential ISO 15189 accreditation.

Structure and premises

The results highlight that structures and premises management are a notable weakness, particularly for laboratories categorized as having a "low and limited level of compliance," unlike laboratories rated as "good to excellent compliance " which appear to have good to complete control. The findings indicate that all laboratories comply with the requirements of the GBEA and Minister of Health Decree No. 2008-05 concerning premises [10]. However, most laboratories do not document the changes made after obtaining authorization to operate. These results are contrasted by a study conducted in India, to which 96% of laboratories (n=50) meet the standards for premises, facilities, and environment [11].

Staff

This dimension is a common strength across all laboratory categories, with compliance rates from 67% to 100%. Despite these positive results, certain dimensions need improvement in the "low and limited level of compliance" categories, and optimization efforts are necessary for the "good level of compliance" category. The training and continuing education program has a compliance rate of 43%, mostly with responses marked as "partial." This is relatively low compared to the 40% and 49% compliance rates found in studies from Nigeria and Ethiopia, respectively [12,13]. Therefore, laboratories should implement structured staff training and skills assessment programs [14].

Analytical process

Our study shows a 54% compliance rate across the pre-analytical phases, with procedures at this stage being the weakest link, particularly in laboratories with "low to medium compliance." This rate is below the 60% and 84% levels reported in the private sector in Cameroon

and in various laboratories in Gaza [15,16]. Since this phase is most affected by non-compliance in the analytical process [17] management of non-compliance related to identification, sampling, and pre-treatment of samples (both primary and secondary) could be affected, potentially impacting the quality of the results [18, 19].

All laboratories adhere to GBEA requirements for reporting results. However, this seems insufficient, as the document does not include standardized templates, which leads to confusion when interpreting results [20]. Twenty-four laboratories lack complete procedures for reporting results. Although GBEA sets requirements for managing and transmitting results, particularly critical ones, it does not provide sufficiently detailed guidelines, a gap also noted in ISO 15189 [21]. This highlights the need for developing secure and effective communication procedures. However, no literature has been found addressing specific reporting models and procedures for result communication.

Equipment, reagents, and consumables

All laboratories use reagent and consumable instructions, as well as instrument operating instructions, as standard operating procedures, in compliance with GBEA requirements. However, only seven laboratories (23% with a compliance rate of 49%) report adherence to all internal laboratory procedures, which is relatively similar to findings in laboratories in India [22], where 45% of laboratories have established their operating procedures.

Laboratories (n=13) with "low to limited level of compliance" demonstrated poor traceability of equipment and reagents; in contrast, this remains a point of strength for those with "medium to excellent level of compliance" (n=17). Half of the laboratories maintain complete records of consumables and reagents, nine record them partially, and six have no records at all, with an average compliance rate of 60%. A study in Uganda reveals that all laboratories lack standard operating procedures (SOPs) for equipment, including details on purchase dates, validation, repair, disposal of obsolete equipment, and emergency plans in case of breakdown [23].

All laboratories conduct inspections and periodic maintenance of equipment and materials, these results are relatively higher than those reported in Nigerien laboratories (90%, n = 42), which report performing regular equipment maintenance[12]. Although Moroccan laboratories show positive results, these remain insufficient for effective maintenance management, as 40% do not have their own preventive maintenance programs and schedules, depending mainly on plans provided by suppliers.

Quality assurance

This dimension has one of the lowest scores, particularly in information system, documentation, and quality control, especially for laboratories with "low to medium compliance." Conversely, those with "good to excellent level of compliance" generally need only moderate improvements. Managing documentation and information system poses a challenge for laboratories at 56% and 30% respectively. Compared to some laboratories in Ghana, the average score was 2.4 (48%) for documentation and 2.1 (42%) for the information system on a scale of 5 [24], while Gaza's public clinical laboratories scored of 96%, presenting a good performance in a conflict zone [16]. The information system is managed externally by all the laboratories surveyed, which is a strong point as it allows for continuous supervision of the analytical process, significantly reduces errors, and optimizes the analytical flow [25].

All laboratories meet GBEA requirements by conducting daily IQCs, with 49% implementation rate for establishing their procedures. Compared to the results obtained in 45 countries by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), laboratories reported performing IQCs at a rate ranging from 50% to 100%, with 57.1% of controls performed every 24 hours [26]; however, internal quality control procedures were not evident for all tests performed. This comparison highlights a weakness in establishing operating procedures, particularly those for IQC, which leads to challenges in managing non-compliances [27].

Participation in EQAs and the establishment of their policies and procedures pose a significant challenge for the laboratories surveyed. Thirteen laboratories (43%) engage in this control, which is higher than reported results in Nigeria, where only 21% of laboratories participate in EQA [12]. Only 7 out of 30 laboratories have implemented EQA procedures. In comparison to a global survey conducted by the IFCC, which revealed that the majority of countries (38 out of 41) reported that their laboratories had implemented EQA policies and procedures [28]. In our context, this is probably due to the GBEA's limited detailed management procedures (frequencies, analyses to be evaluated, procedures for correcting non-compliances, etc.), as well as the limited monitoring of results by state institutions. [7]. Participation in EQAs could be useful to laboratories in several areas, such as assessing test quality, enhancing patient safety, verifying the metrological traceability of tests, and identifying measurement deviations. [29]

Health and safety

All laboratories comply with GBEA requirements for safety equipment and hazardous material storage areas. A study from Saudi Arabia confirms that most laboratories comply with safety standards relating to buildings and equipment [30]. Moroccan laboratories manage Infectious Healthcare Waste (IHW) in accordance with Law 28.00 on waste management [31]. Similar results have

been observed in Greece [32]. Despite these positive outcomes, the absence of management procedures for these areas and safety equipment (23/30 partially established and 7/30 complete) appears to be a major challenge for laboratories in Morocco and Greece, with 50% and 58.3% compliance rate, which could pose a major risk to laboratory staff due to a lack of expertise in the use of this equipment and the risks associated with hazardous reagents. [32]

Findings from the literature and interviews indicate that laboratories should establish a culture of quality management, fostered by strong management commitment, staff involvement from the outset of planning, and the implementation of structured change management practices with clear communication and ongoing support. The development of structured training programs is essential to cover QMS principles and technical skills. These training programs must be supplemented by regular skills assessments to address skill gaps. [33].

Although GBEA covers several aspects of quality assurance practice, laboratories encounter requirements that are not explicitly stated. In this regard, specific guidelines are essential to help laboratories implement the guide effectively. This includes a structured program with standardized checklists, supported by staff commitment and proper training [34], a procedures manual detailing processes and procedures, and a technical manual offering recommendations for managing analytical phases. This process approach promotes the application and standardization of the Guide's main requirements [22]. The expansion of legislative and regulatory frameworks must be reinforced by continuous evaluation and monitoring through scheduled audits, which are essential for laboratories to support continuous quality improvement [35].

CONCLUSIONS

The results of this study emphasize common challenges faced by most clinical laboratories, especially those with less than 5 years of experience, including quality control (specifically EQA), documentation of procedures, traceability of equipment, reagents and consumables, and laboratory access procedures. Identifying these weaknesses in new laboratories is crucial for early intervention and should be managed proactively. Therefore, the GBEA should be strengthened by providing clear guidelines detailing procedures and processes to ensure full compliance and promote standardization and harmonization of good medical analysis practices. Adopting a process-oriented approach fosters a culture of quality. Additionally, ongoing supervision through scheduled audits is one of the most effective methods to ensure continuous quality improvement.

ABBREVIATIONS

CLIA – Clinical Laboratory Improvement Amendments

IQC – Internal Quality Control

IHW – Infectious Healthcare Waste

EQA – External Quality Assessment

GBEA – Guide de Bonnes Execution des Analyses (Guide to good laboratory practice)

IFCC – International Federation of Clinical Chemistry and Laboratory Medicine

IMANOR – Institut Marocain de la Normalisation (Moroccan Institute for Standardization)

ISO – International Organization for Standardization

NM – Normes Marocaines (Moroccan Standards)

SEMAC – Service Marocain de l'Accréditation (Moroccan Accreditation Service)

SLIPTA – Stepwise Laboratory Quality Improvement Process Towards Accreditation

SOP – Standard Operating Procedure

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AUTHORS' CONTRIBUTION

A.K: conceptualization, methodology, investigation, formal analysis, data visualization, writing (original draft).

S.EF: conceptualization, methodology, formal analysis, data visualization, writin (original draft).

H.EA: data visualization, writing (review and editing).

A.I.L: data visualization, writing (review and editing).

K.E: data visualization, writing (review and editing).

M.EF: data visualization, writing (review and editing).

R.T: data visualization, writing (review and editing).

R.A: data visualization, writing (review and editing).

B.EA: conceptualization, methodology, visualization, validation, supervision.

All authors have read and approved the final version of the manuscript.

CONFLICT OF INTEREST

None to declare.

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