

Research Article

The College of American Pathologists (CAP) Laboratory Accreditation Program (LAP): Accreditation Process and its Impact on Laboratory Practice and Patient Safety

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Keywords

Accreditation impact, CAP LAP, Laboratory Accreditation Program (LAP), laboratory quality, patient safety, and quality management

Abstract

This study aimed to assess the laboratory professional perceptions on how the College of American Pathologists (CAP) Laboratory Accreditation Program (LAP) is associated with the laboratory processes and patient safety across multiple countries in the Middle East and South Asia. The objective was to determine how CAP LAP influences laboratory quality and safety culture, and participants reported that error-related events appeared to decrease following the CAP LAP. A quantitative, cross-sectional design was used, employing a structured electronic questionnaire distributed to CAP-accredited laboratories in Saudi Arabia, other Gulf countries, Egypt, and Pakistan. A total of 300 valid responses were analyzed using descriptive statistics and marginal homogeneity testing to compare the respondents' perceived condition pre- and post-accreditation performance in areas such as staff competency, quality management, turnaround time, and safety practices. Respondents assessed conditions before and after accreditation in pre-analytical, analytical, and post-analytical areas, including quality management systems, staff competence, turnaround time, equipment upkeep, communication, and safety culture. We examined paired ordinal responses using marginal homogeneity tests. The CAP LAP was therefore viewed as highly valuable for improving both laboratory performance and patient safety. This study provides empirical evidence from multi-country CAP LAP accredited laboratories, filling a regional gap in accreditation research. It demonstrates that the CAP LAP functions as a strong governance mechanism enhancing quality and safety within diverse healthcare systems. It is advisable to conduct future longitudinal and comparative studies among CAP, ISO 15189:2022, and national accreditation systems to evaluate the durability of enhancements and their impact on laboratory personnel behavior. These results indicate that laboratory professionals view CAP LAP as linked to significant enhancements in laboratory operations and safety protocols. However, the results are based on people's own reports of their perceptions and don't show cause-and-effect relationships or measure objective safety outcomes. Future research incorporating objective performance metrics and longitudinal methodologies is essential to assess the causal influence of accreditation on patientsafety.

Introduction

Clinical laboratories are the cornerstone of modern healthcare, supporting approximately 70% of medical decisions related to diagnosis, patient monitoring, and prognosis [1]. The laboratory testing process includes three key phases: pre-analytical, analytical, and postanalytical. Each phase involves specific procedures, with unique challenges and risks for potential errors [2]. Accreditation programs appear to improve the structure and process of care, with a substantial body of evidence showing that they improve clinical outcomes. Accreditation programs in medical laboratories such as ISO 15189 and other international and national laboratory accreditation programs emphasizes risk-based approaches and patient safety [3-6]. In 1961, CAP started the Laboratory Accreditation Program (LAP) as one of the most internationally recognized laboratory accreditation programs to provide labs a strict, peer-based inspection accreditation program addresses all the laboratory areas, including directorship, quality control, test methodologies, reagents, control media, equipment, specimen handling, procedure manuals, test reporting, proficiency testing and monitoring, as well as personnel safety and overall management practices that distinguish a quality laboratory [7-10]. Although the benefits of CAP LAP are well-documented in terms of overall laboratory performance, limited research has explored the specific perceived impact of accreditation on laboratory processes (preanalytical, analytical, and postanalytical). There is a regional knowledge gap in understanding the perceived influence of CAP LAP standards in the Middle east region [9]. Therefore, the primary objective of this study is to assess the perceived impact of the CAP LAP on laboratory procedures, professional competencies, and patient safety outcomes across CAP LAP accredited laboratories in Saudi Arabia, Gulf countries, Egypt, and Pakistan.

Materials and Methods

Study design

The study used a quantitative cross-sectional survey design. A self-administered questionnaire was distributed electronically to laboratory staff working in CAP LAP accredited laboratories. Respondents were asked to compare the laboratory practices prior to accreditation and after achieving CAP LAP accreditation [19].

Conceptual Framework

The study hypothesized that CAP LAP as independent factor positively influences laboratory process and improve laboratory process and patient safety as dependent factor [19]. The proposed conceptual framework follows the following pathway: CAP LAP → Quality management and governance mechanisms (mediator) → Lab Processes → Patient Safety outcome.

Setting and Participant

The participants include laboratory directors, quality managers, section heads, supervisors, laboratory technologists and technicians, and other senior lab staff across Saudi Arabia (the main focus), other Gulf countries, Egypt, and Pakistan. The inclusion criteria were laboratory professionals (directors, quality managers, supervisors, and technologists) working in CAP-accredited laboratories; individuals with at least one year

of laboratory experience. The exclusion criteria encompass staff from laboratories lacking CAP LAP, administrative personnel not directly engaged in laboratory operations or patient safety, and incomplete or duplicate survey responses. A Sample of 300 respondents completed the survey.

Survey Instrument

A structured electronic survey with 29 questions was developed based on the following themes

- Demographics and laboratory profile (role, lab type, years accredited, staff size, hospital-based or standalone laboratory).
- Perceptions prior to CAP (inspection, QMS, staff competency, error reporting, safety, LIS, communication).
- Perceptions subsequent to CAP (identical indicators for direct comparison).
- Impact on patient safety (effectiveness of error reporting, reduction of near-misses, culture, corrective actions, communication).
- Evaluation of the accreditation process (preparedness, training, clarity of CAP standards, inspector support, challenges).
- Overall outcomes value of CAP LAP, enhancements in quality and safety.

Questions include Multiple-choice questions (role, lab type, years accredited), Likert scale (1–5, strongly disagree → strongly agree), linear rating scales (1 = very poor → 5 = excellent), before vs. after comparisons, and checkboxes for multiple areas of improvement/challenges.

Survey Instrument Development and Validity

The survey was created by looking at the literature on laboratory accreditation, quality management systems, and patient safety in medical labs, with a focus on the requirements of the CAP Laboratory Accreditation Program. A preliminary pool of items was created to address important areas, such as quality management, laboratory process performance during the pre-analytical, analytical, and post-analytical phases, safety culture, and patient safety outcomes. A pilot test with (15–20) laboratory professionals from (CAP LAP) labs was conducted to see how clear, understandable and relevance it was to fill out. Based on feedback minor revisions were made to question wording and response scales to improve clarity, consistency, and ease of completion.

Internal consistency Reliability was assessed using (Cronbach's alpha) and the values were: Pre-(CAP LAP): $\alpha = 0.93$ (Excellent) Post-CAP LAP: $\alpha = 0.92$ (Excellent), Improvement Scale: $\alpha = 0.88$ (Good) and Safety Culture Scale: $\alpha = 0.87$ (Good), the results of reliability tests show strong psychometric reliability of the instrument. All domains exhibited satisfactory to exceptional internal reliability ($\alpha = 0.78$ – 0.91), Internal consistency was assessed using Cronbach's alpha ($\alpha \geq 0.70$).

Data Collection Procedures

The survey was distributed electronically between August and October 2025. Participation was voluntary and anonymous; the

fully completed responses were included in the database.

Ethical Considerations

The study involved anonymous survey responses from laboratory professionals and didn't include patient data or clinical intervention. The study involved minimal-risk survey data from professionals. Implied informed consent was obtained, and confidentiality was maintained.

Statistical Analysis

The data was analyzed using the Statistical Package for Social Science (SPSS 27) and Python software. Descriptive statistics: Frequency and percentage were used for categorization of the variables. Marginal homogeneity test assesses the statistical significance of the difference of a variable with multiple categories measured. The P-value represented the level of significance $P > 0.05$: Non-significant (NS). $P < 0.05$: Significant (S). N/A responses were treated as missing and excluded pairwise from the analysis.

Results

A total of 300 professionals working in CAP-accredited medical laboratories in Saudi Arabia, other Gulf countries, Egypt, and Pakistan participated in the survey. The results are presented in the following sections

Characteristics of Participating Laboratories

The general data assessment shows that among participants, 37% were laboratory directors, followed by 22% technologists/technicians, 20% section heads/supervisors, 17% quality managers, and only 4% in other roles. Most laboratories were independent/private (72%), while 28% were hospital-based. Regarding CAP LAP, more than half (54%) had been accredited for over 6 years, while 24% reported 1–3 years, 16% reported 4–6 years, and only 6% had less than 1 year. In terms of staff size, 52% of laboratories had between 20 and 50 employees, 38% had more than 50, while only 10% operated with fewer than 20 staff members. The demographic characteristics of the participating laboratories are summarized in Table 1.

Table 1: Demographic Characteristics of Participating Laboratories.

Variables	Category	N (%)
Participants role in the laboratory	Laboratory Director	111 (37%)
Participants role in the laboratory	Laboratory Technologist/Technician	66 (22%)
Participants role in the laboratory	Quality Manager	51 (17%)
Participants role in the laboratory	Section Head/Supervisor	60 (20%)
Participants role in the laboratory	Other	12 (4%)
Type of laboratory	Hospital-based	84 (28%)
Type of laboratory	Independent/private	216 (72%)
Number of years the lab has been CAP-accredited	Less than 1 year	18 (6%)
Number of years the lab has been CAP-accredited	1–3 years	72 (24%)
Number of years the lab has been CAP-accredited	4–6 years	48 (16%)
Number of years the lab has been CAP-accredited	More than 6 years	162 (54%)
Approximate number of staff in the lab	Less than 20	30 (10%)
Approximate number of staff in the lab	20–50	156 (52%)
Approximate number of staff in the lab	More than 50	114 (38%)

Main Challenges During CAP LAP Accreditation Preparation

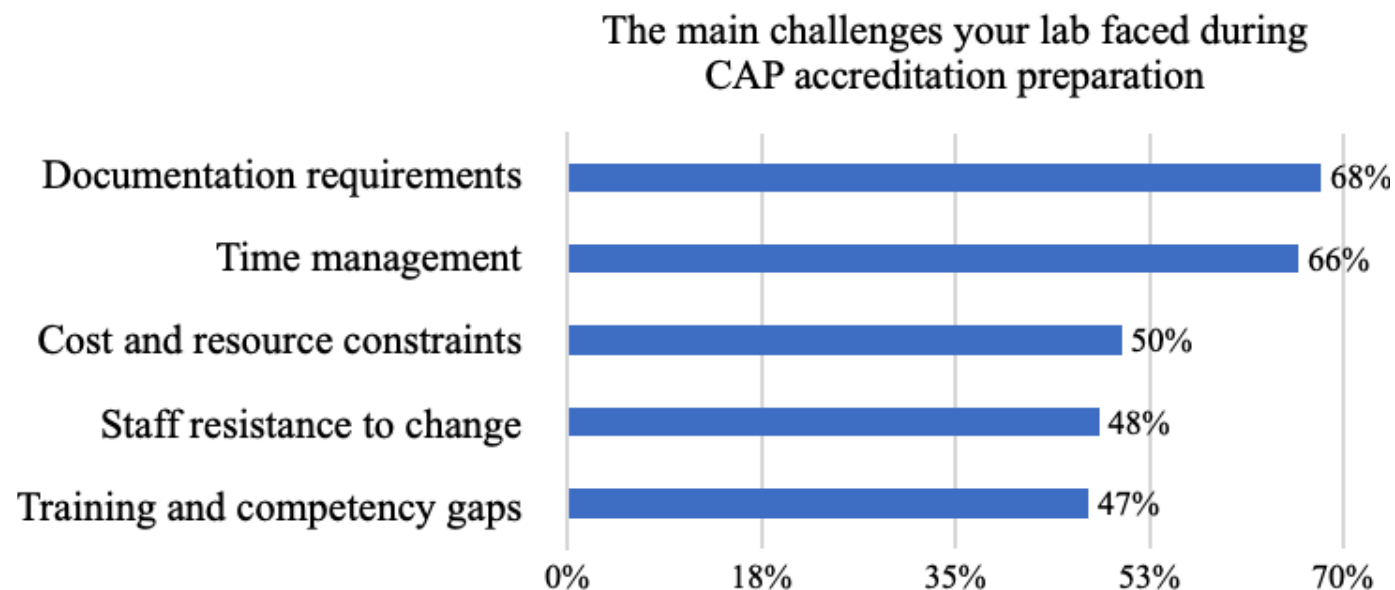
The main challenges during CAP LAP preparation were dominated by documentation requirements (68%) and time management (66%), followed closely by cost/resource constraints (50%) and staff resistance to change (48%). Training and competency gaps were also a significant barrier (47%). These

findings indicate that the administrative workload and time pressure associated with CAP LAP accreditation implementation. The main challenges during CAP LAP accreditation preparation are summarized in Table 2 and Figure 1.

Table 2: The main challenges the lab faced during CAP LAP preparation.

Variable	N (%)
Staff resistance to change	144 (48%)
Documentation requirements	204 (68%)
Time management	198 (66%)
Cost and resource constraints	150 (50%)
Training and competency gaps	141 (47%)

Figure 1: The main challenges faced by the laboratory during CAP LAP preparation.



Impact of CAP LAP accreditation on Laboratory Practice

A comparative analysis of laboratory practice before and after CAP LAP accreditation demonstrated statistically significant improvements across all domains (p-values <0.001) the improvement observed in self-inspection process, inspection, quality management system, staff training and competency, turnaround times, error reporting and corrective action processes, equipment maintenance and calibration, patient safety practice, staff engagement and morale, communication with clinicians, Laboratory safety program and data integrity and LIS policies. process shows a consistent pattern of increase in agreement and increases in strong agreement. For example, disagreement on checklist self-inspection fell from 18% to 0%, while

strong agreement rose from 32% to 84%. In staff competency assessment, strong agreement increased from 36% to 86%. Turnaround time strong agreement grew from 43% to 78%, and error reporting strong agreement rose from 36% to 83%. Similarly, strong agreement on equipment maintenance rose from 38% to 84%, and patient safety prioritization from 42% to 88%. Staff morale and communication with clinicians also improved, with strong agreement reaching 77% and 76%, respectively Overall, these results confirm a consistent and significant improved in laboratory performance following the CAP LAP accreditation. The comparative analysis of laboratory practice before and after CAP LAP accreditation are summarized in Table 3.

Table 3: Comparative analysis of laboratory practice before and after CAP LAP accreditation.

Variable	Category	Before	After	Marginal homogeneity	
		N (%)	N (%)	p-value	Sig.
self-inspection process	Strongly Disagree	18 (6%)	0 (0%)	<0.001	S
Inspection process	Disagree	54 (18%)	0 (0%)		
	Neutral	72 (24%)	18 (6%)		
	Agree	60 (20%)	30 (10%)		
	Strongly Agree	96 (32%)	252 (84%)		
	Strongly Disagree	6 (2%)	0 (0%)	<0.001	S
	Disagree	60 (20%)	0 (0%)		
	Neutral	66 (22%)	12 (4%)		
	Agree	78 (26%)	48 (16%)		
	Strongly Agree	90 (30%)	240 (80%)		
Quality management system was well-established	Strongly Disagree	0 (0%)	0 (0%)	<0.001	S
	Disagree	36 (12%)	0 (0%)		
	Neutral	75 (25%)	6 (2%)		
	Agree	81 (27%)	51 (17%)		
	Strongly Agree	108 (36%)	243 (81%)		
Staff competency and training were regularly assessed	Strongly Disagree	6 (2%)	0 (0%)	<0.001	S
	Disagree	75 (25%)	0 (0%)		
	Neutral	36 (12%)	6 (2%)		
	Agree	75 (25%)	36 (12%)		
	Strongly Agree	108 (36%)	258 (86%)		
Turnaround times met clinical needs	Strongly Disagree	0 (0%)	0 (0%)	<0.001	S
	Disagree	27 (9%)	0 (0%)		
	Neutral	60 (20%)	18 (6%)		
	Agree	84 (28%)	48 (16%)		
	Strongly Agree	129 (43%)	234 (78%)		
Error reporting and corrective action processes were effective	Strongly Disagree	0 (0%)	0 (0%)	<0.001	S
	Disagree	39 (13%)	0 (0%)		
	Neutral	93 (31%)	6 (2%)		
	Agree	60 (20%)	45 (15%)		
	Strongly Agree	108 (36%)	249 (83%)		
Equipment maintenance and calibration were consistently performed	Strongly Disagree	6 (2%)	0 (0%)	<0.001	S
	Disagree	27 (9%)	0 (0%)		
	Neutral	78 (26%)	6 (2%)		
	Agree	75 (25%)	42 (14%)		
	Strongly Agree	114 (38%)	252 (84%)		
Patient safety was prioritized in daily operations	Strongly Disagree	0 (0%)	0 (0%)	<0.001	S
	Disagree	48 (16%)	0 (0%)		
	Neutral	66 (22%)	6 (2%)		
	Agree	60 (20%)	30 (10%)		
	Strongly Agree	126 (42%)	264 (88%)		
Staff engagement and morale were high	Strongly Disagree	18 (6%)	0 (0%)	<0.001	S
	Disagree	51 (17%)	0 (0%)		
	Neutral	63 (21%)	12 (4%)		
	Agree	72 (24%)	57 (19%)		
	Strongly Agree	96 (32%)	231 (77%)		

Variable	Category	Before	After	Marginal homogeneity	
		N (%)	N (%)	p-value	Sig.
Communication between lab and clinicians was effective	Strongly Disagree	0 (0%)	0 (0%)	<0.001	S
	Disagree	45 (15%)	0 (0%)		
	Neutral	69 (23%)	18 (6%)		
	Agree	90 (30%)	54 (18%)		
	Strongly Agree	96 (32%)	228 (76%)		
Laboratory safety program	Strongly Disagree	0 (0%)	0 (0%)	<0.001	S
	Disagree	60 (20%)	0 (0%)		
	Neutral	48 (16%)	6 (2%)		
	Agree	90 (30%)	42 (14%)		
	Strongly Agree	102 (34%)	252 (84%)		
Data integrity and LIS policies	Strongly Disagree	21 (7.14%)	0 (0%)	<0.001	S
	Disagree	57 (19.39%)	0 (0%)		
	Neutral	48 (16.33%)	6 (2%)		
	Agree	54 (18.37%)	42 (14%)		
	Strongly Agree	114 (38.78%)	252 (84%)		

Marginal homogeneity test showed statistically significant differences between pre- and post-accreditation responses ($p < 0.001$).

Patient Safety Culture

Patient safety culture ratings showed significant improvement after CAP LAP accreditation ($p < 0.001$). Before accreditation, the highest proportions were at level 4 (34.78%) and level 3 (30.43%), while only 21.74% rated it at the highest level (5) and 13.04% rated it as low (2). After accreditation, there was

amarked shift, with 69.57% rating safety culture at level 5, 28.26% at level 4, and only 2.17% at level 2. This demonstrates a strong positive impact of CAP LAP accreditation on patient safety culture perceptions. The results illustrating the improvement in safety culture following CAP LAP accreditation are summarized in Table 4.

Table 4: Improvement in Patient Safety Culture Following CAP LAP Accreditation.

Variable	Rating	N (%)	Marginal homogeneity	
			p-value	Sig.
How would you rate the laboratory’s patient safety culture before (CAP LAP)? (Linear scale 1–5)	2	36 (13.04%)	<0.001	S
	3	84 (30.43%)		
	4	96 (34.78%)		
	5	60 (21.74%)		
How would you rate the laboratory’s patient safety culture after (CAP LAP)? (Linear scale 1–5)	2	6 (2.17%)		
	4	78 (28.26%)		
	5	192 (69.57%)		

Perceived improvements in laboratory performance and patient safety

Respondents reported strong improvements in several parameters of laboratory performance following CAP LAP accreditation. 72% reported significant increase in staff awareness of patient safety protocols, 50% reported significant reduction in patient laboratory error and 28% reported transformational reduction. 48% of respondents thought that communication between

laboratory staff and clinicians was very effective, and 38% thought it was effective. 66% of respondents thought that corrective actions were very timely, and 22% thought they were timely. Regarding prevention of adverse outcomes, 50% reported significant improvement, 32% transformational, overall, 80% of respondents consider CAP LAP accreditation is extremely valuable for improving laboratory performance, the results are summarized in Table 5.

Table 5: Perceived improvements in laboratory performance and patient safety following (CAP LAP).

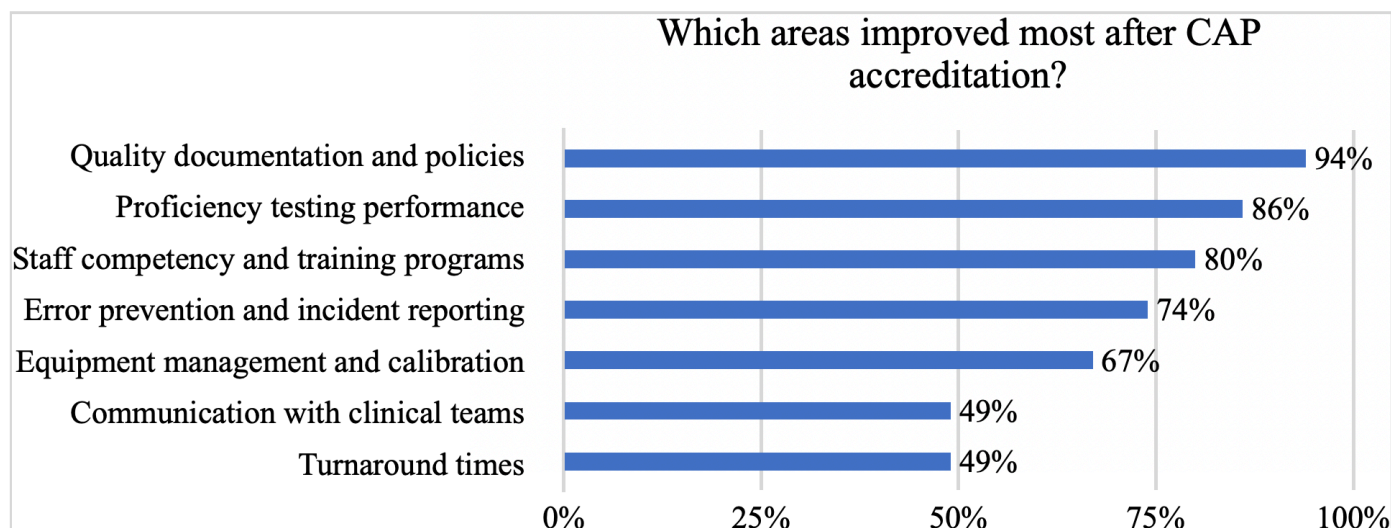
Variable	Category	(%)
Staff awareness of patient safety protocols has:	Decreased	6 (2%)
	Significantly increased	216 (72%)
	Slightly increased	54 (18%)
	N/A	24 (8%)
To what extent has (CAP LAP) reduced patient-related laboratory errors?	Moderate reduction	24 (8%)
	No reduction	6 (2%)
	Significant reduction	150 (50%)
	Slight reduction	12 (4%)
	Transformational reduction	84 (28%)
	N/A	24 (8%)
How effective is communication between laboratory staff and clinicians regarding patient safety after (CAP LAP)?	Effective	114 (38%)
	Neutral	18 (6%)
	Very effective	144 (48%)
	N/A	24 (8%)
How timely are corrective actions implemented after identifying safety issues?	Neutral	12 (4%)
	Timely	66 (22%)
	Very timely	198 (66%)
	N/A	24 (8%)
Has (CAP LAP) improved your lab’s ability to prevent adverse patient outcomes?	Moderately	18 (6%)
	Significantly	150 (50%)
	Slightly	12 (4%)
	transformational	96 (32%)
	N/A	24 (8%)
How valuable do you consider (CAP LAP) for improving laboratory performance?	Extremely valuable	240 (80%)
	Moderately valuable	6 (2%)
	Valuable	54 (18%)

Respondents were asked to identify which operational areas within their laboratories showed the greatest improvement following CAP LAP accreditation.

The areas most improved after accreditation were quality documentation and policies (94%) and proficiency testing performance (86%). Staff competency and training programs also showed strong gains (80%), followed by error prevention and

incident reporting (74%). Equipment management and calibration improved in 67% of laboratories. Meanwhile, turnaround times and communication with clinical teams were reported improved in 49% each. The results illustrate the domains where the impact of accreditation was most strongly perceived are summarized in Figure 2.

Figure 2: Areas improved after CAP LAP accreditation.



Discussion

The present study evaluates the perceived impact of college of American pathologist laboratory accreditation program CAP LAP on laboratory process and patient safety our come. Our findings indicate that accreditation was associated with improvements in numerous operational and quality-related areas of laboratory services, Participants reported greater adherence to standard operating procedures, improved documentation practices, and stronger implementation of quality management systems following accreditation.

Comparison with other studies

The demographic profile of our respondents is consistent with regional patterns observed in the Middle-East. Our findings that 54% Laboratories are accredited for more than 6 year and the distribution of the hospital-based lab 28% and Independent/private 72% are aligned with Westgard, 2021 [22] found that 50.79% of the laboratories in the region are CAP accredited labs and there’s an interesting mix between public and private hospitals in the Middle East. Our finding that the approximate number of staff in 52% of the laboratories from 20-50 and 10% is less than 20 employees is aligned with Westgard, 2021) [22] reported that there is a peak number of what we might call “mid-sized” modest laboratories in the region. The staff composition of 37% Laboratory Directors, 22% Technologists/Technicians, 17% Quality Managers, 20% Section Heads/Supervisors supported by Parikh, & Rupani, (2025). [23] documenting those participants including Quality Managers, Head of laboratory, Technicians, and technical staff.

Our study findings that the main challenges during CAP LAP preparation were dominated by documentation requirements (68%) and (47%) training and competency gap supported by Alsayyah and Almulhim [1] reported that the documentation and training are primary concern during the preparation of thee accreditation, additionally our study findings where (66%) of the respondent reported Time management and 50% reported Cost and resource constraints are the main challenges during preparation of accreditation supported by AbdelWareth et al.

[12] reported that time management and resources allocation are critical part. Our study finding where (48%) of the respondents reported that Staff resistance to change is one of the main challenges supported by Abdurabuh et al. (2024) [16] reported that accreditation process needs active change management.

The finding from the comparative study demonstrated that the CAP LAP accreditation has statistically signification impact on different area of laboratory practice. 12 variables assessed with (p<0.001 for each) provide evidence that there is improvement in medical laboratories performance following the CAP LAP accreditation. This aligns with Alsayyah and Almulhim [1] who found, showing that laboratories with more than accreditation more likely to have standards operating procedures (P=0.039) and review their policies more often (P=0.002) in Saudi Arabia. The huge increase in laboratories reporting well-established quality management systems (from 36% to 81% Strongly Agree) illustrates the foundational significance of certification in developing lasting quality culture this align with AbdelWareth et al. [12] who concluded that accreditation ‘establishes a firm platform on which any new organization can construct a lasting quality improvement culture, this is further supported by Andiric et al. [21], who described how laboratory strengthening initiatives toward accreditation generate a ‘culture of quality’ and enable discovery of inadequacies. The observed improvement in patient safety prioritization (from 42% to 88% Strongly Agree) and error reporting effectiveness (36% to 83% Strongly Agree) following accreditation is aligns with Peter et al. [11], who documented that accreditation reduces testing errors and attendant decreases in inappropriate treatment. Abdurabuh et al. [16] also established a ‘strong connection between accreditation and better patient safety’ in Saudi healthcare facilities. The significant improvement in staff competency assessment (36% to 86% Strongly Agree) and staff engagement (32% to 77% Strongly Agree) after accreditation report one of the major pre-accreditation challenges identified in our study (staff resistance, 48%). This aligns with Hawkins’ [17,18] observation that accreditation requirements drive laboratories to take greater responsibility for activities beyond analytical phases, including training and competency

development. The remarkable improvements in turnaround times (43% to 78% Strongly Agree), equipment maintenance (38% to 84% Strongly Agree), and communication with clinicians (32% to 76% Strongly Agree) reflect the CAP LAP accreditation benefits. These operational gains align with Alkhenizan and Shaw's [14], systematic review which found reliable evidence that accreditation programs improve both processes of care and clinical outcomes across healthcare system. The remarkable improvements in laboratory safety programs (from 34% to 84% strongly agreeing) and data integrity/LIS policies (from 38.78% to 84% strongly agreeing) demonstrate the comprehensive impact of CAP LAP accreditation. These areas, which are often unnoticed in routine laboratory operations, become systematized through the accreditation process, reducing risks to both patients and laboratory personnel.

The findings provide persuasive evidence that laboratory professionals perceive major improvements in patient safety and laboratory performance with CAP LAP accreditation. The consistently high positive responses across all studied domains support the significance of accreditation as essential factor for quality advancement in medical laboratories. The finding that 72% of respondents indicated greatly enhanced awareness and 18% reported slightly increased awareness of patient safety practices following CAP LAP accreditation supports the program's success in fostering a safety-conscious culture. This aligns with Alsayyah and Almulhim's [1] survey of Saudi laboratory practitioners, which indicated that accreditation has had a positive impact on laboratory practices and patient laboratory testing in Saudi Arabia. This heightened awareness is important to the CAP accreditation philosophy, which demands laboratories to build comprehensive quality management systems that infuse safety awareness into daily operations. The perceived reduction in laboratory errors following accreditation is prominent: 50% of respondents reported significant reduction, 28% reported transformational reduction, and only 2% reported no reduction. These perceptions are strongly validated by the literature and aligns with Peter et al. [11] who reported that laboratory accreditation "has the potential to improve the quality of health care for patients through the reduction of testing errors and attendant decreases in inappropriate treatment". Similarly, Serteser et al. [15] demonstrated how ISO 15189 accreditation assures patient safety through robust quality management systems, noting that "applying the performance improvement strategies focusing on different phases in total testing process will significantly reduce the errors and therefore will improve the patient safety", also The systematic study by Alkhenizan and Shaw [14] gives the largest framework, stating that "accreditation programs improve the process of care provided by healthcare services" and "improve clinical outcomes of a wide spectrum of clinical conditions". Zima [13] further indicates that "accreditation of labs improves facilitation of accurate and rapid diagnostics, efficiency of treatment and reduction of errors in the laboratory process". The improvement in interdisciplinary communication following CAP LAP accreditation is supported, with 48% reporting very effective and 38% effective communication. This finding addresses a major determinant of patient safety that extends beyond the laboratory's

walls. This aligns with Hawkins [17&18] who explored whether laboratory quality improvement through accreditation satisfies expectations and concluded that accreditation bodies require clear and effective procedures for patient/sample identification and communication of critical results. Hawkins [17&18] also stated that laboratories can play a greater role in minimizing errors and enhancing patient safety through better clinical interaction, The finding that 66% of respondents reported extremely timely and 22% reported timely implementation of corrective actions steps after recognizing safety issues illustrates the extensive quality management systems that CAP LAP accreditation establishes. This aligns with AbdelWareth et al. [12], who underlined that accredited laboratories build "a sustainable quality improvement culture" that permits methodical methods to quality management in their implementation evaluation of CAP and ISO 15189 accreditation. Andiric et al. [21] described how laboratory strengthening programs toward accreditation establish "a culture of quality in laboratories and allow the identification of gaps", allowing the institutionalization of timely remedial actions, The perception that CAP LAP accreditation significantly (50%) or transformationally (32%) improved laboratories' ability to prevent adverse patient outcomes. This aligns with Howanitz [20] who gave practical lessons for increasing patient safety through error reduction in laboratory medicine, similarly Milner and Holladay [2] claimed that laboratories serve as the "core for health systems building," stating that increasing laboratory quality through certification has rippling effects throughout healthcare systems. The finding that 80% of respondents consider CAP LAP extremely valuable and 18% consider it valuable for improving laboratory performance (98% total positive responses) provides strong confirmation from the laboratory professionals who experience accreditation personally. This aligns with Alsayyah and Almulhim's [1] observation that Saudi laboratory practitioners recognize the impact of accreditation in their daily practice. Similarly, AbdelWareth et al. [12] concluded their implementation evaluation by noting that "accreditation is a perfect means toward building quality medical laboratories in a diverse workforce environment and improving patient safety, also the analysis by Alkhenizan and Shaw [14] provides strong evidence that across many healthcare settings, healthcare professionals consistently value accreditation for its role in enhancing processes and outcomes

Limitation

First, the study utilized a cross-sectional design, which captures participants' impressions at a specific point in time and so cannot establish causal linkages between accreditation and observed improvements. In addition, the data were collected through self-administered questionnaires, depending on respondents' perceptions of laboratory practices before and after accreditation rather than on explicitly measurable performance indicators. Second, the study did not use objective laboratory information system (LIS) data, such as verified turnaround time records, laboratory error reports, near-miss registers, or quality indicator dashboards. As a result, the findings represent perceived improvements rather than statistically documented changes in laboratory performance or patient safety outcomes. Third, the sample distribution exhibited a regional imbalance, with the

majority of replies emanating from laboratories in Saudi Arabia. Furthermore, the study did not obtain data from laboratories that were not participating in the CAP Laboratory Accreditation Program CAP LAP, which limits comparisons between accredited and non-accredited laboratories. Finally, response bias may have influenced the results, as those with more pleasant experiences with accreditation may have been more willing to engage in the survey. In addition, retrospective recall of procedures before accreditation may have led some respondents to overstate observed improvements.

Conclusion

In conclusion, this study highlights the significant role of the college of College of American Pathologists Laboratory Accreditation Program CAP LAP in improving laboratory processes and patient safety. This improvement was observed from the results of the study across all laboratory measured areas. CAP LAP not only standardizes procedures but also develops organizational culture, increases staff participation, and promotes continual quality improvement. The study indicates considerable improvements across laboratory practice areas, with strong evidence supporting the impact of CAP LAP accreditation and a clear relationship between enhanced safety culture and fewer laboratory errors. It is recommended in future studies to include the non-CAP or ISO 15189-accredited laboratories in future research; this could enable comparative impact analysis and further validate the unique contribution of CAP LAP to laboratory excellence and patient safety.

Patents

The authors declare that no patents are associated with this work.

Supplementary Materials

No supplementary materials are available for this manuscript

Author Contributions

Abdelaziz Sanad contributed to the study design, data collection, and initial data analysis. He also assisted in drafting and revising the manuscript, contributed to algorithm development, computational analysis, and technical validation of the study.

Mai S. Mabrouk led the study concept and design, oversaw the computational framework implementation, ensured technical rigor and reproducibility, contributed to data interpretation and manuscript revision. provided guidance on methodology, assisted with validation of the computational framework, and critically reviewed the manuscript for scientific accuracy

Samir Y. Marzouk participated in methodology development, supervised the data analysis, and contributed to interpreting the results.

Funding

This research received no external funding.

AI Statement

No artificial intelligence tools were used in the design, analysis, or writing of this manuscript.

Institutional Review Board Statement

The survey conducted in this instance was voluntary, anonymous, and non-interventional and exempt from IRB review

Informed Consent Statement

Informed consent was obtained electronically from all participants prior to survey submission.

Data Availability

The anonymized survey dataset supporting the findings of this study is available from the corresponding author upon reasonable request. Researchers interested in accessing the dataset should contact A. Sanad at asanad83@yahoo.com

Acknowledgments

The artificial intelligence tool (ChatGPT) was used solely for language editing and Grammer check.

Conflicts of Interest

The authors declare no conflicts of interest.

Abbreviations

CAP	College of American Pathologists
CLIA	Clinical Laboratory Improvement Amendments
CLSI	Clinical and Laboratory Standards Institute
CMS	Centers for Medicare & Medicaid Services
FDA	Food and Drug Administration
ISO	International Organization for Standardization
ISQua	The International Society for Quality in Health Care
LAP	Laboratory Accreditation Program
TAT	Turnaround Time
LIS	Laboratory information system
NS	Non-significant
OSHA	Occupational Safety and Health Administration.
QC	Quality Control
QMS	Quality management system
S	Significant
SOPs	Standard operating procedures
SPSS 27	Statistical Package for Social Science

References

1. Alsayyah, A.; Almulhim, A. What Has Been the Impact of Laboratory Accreditation in Saudi Arabia? A Cross-Sectional Survey of Laboratory Practitioners. *J. Datta Meghe Inst. Med. Sci. Univ.* 2023;18,398–404. https://doi.org/10.4103/jdmimsu.jdmimsu_80_23.
2. Milner, D.A., Jr.; Holladay, E.B. Laboratories as the Core for Health Systems Building. *Clin. Lab. Med.* 2018;38,1–9.
3. International Organization for Standardization (ISO). ISO 15189:2012- Medical Laboratories- Requirements for Quality and Competence; ISO: Geneva, Switzerland, 2012.
4. Joint Commission International (JCI). Laboratory Accreditation Program. Available online: <https://www.jointcommissioninternational.org/what-we-offer/accreditation/accreditation-programs/laboratory/> (accessed on 15 October 2025).
5. CBAHI. Saudi Central Board for Accreditation of Healthcare Institutions - Portal. Available online: <https://portal.cbahi.gov.sa/> (accessed on 15 October 2025).
6. GAHAR. General Authority for Healthcare Accreditation and Regulation (CARE Standards). Available online: <https://gahar.gov.eg/> (accessed on 15 October 2025).
7. Merrick, T. (Ed.). College of American Pathologists Commission on Laboratory Accreditation: Laboratory Accreditation Manual; College of American Pathologists: Northfield, IL, USA, 1996.
8. Hamlin, W.B. Requirements for Accreditation by the College of American Pathologists Laboratory Accreditation Program. *Arch. Pathol. Lab. Med.* 1999;123,465–467.
9. Shahbaz, A.; Younas, M.; Khanzada, F.A.; Meer, K.R.; Ahmad, L.; Ameer, R.; Zahid, M.A. Analyzing the Impact of College of American Pathologists Laboratory (CAP) Accreditation Program on Post-Analytical Error. *Res. Med. Sci. Rev.* 2024;2,586. Available online: <https://thermsr.com> (accessed on 29 November 2025).
10. Mark, H.F.L.; Watson, M.S. Evolving Standards of Practice for Clinical Cytogenetics. *R. I. Med. J.* 1994;77,375–377.
11. Peter, T.F.; Rotz, P.D.; Blair, D.H.; Khine, A.A.; Freeman, R.R.; Murtagh, M.M. Impact of Laboratory Accreditation on Patient Care and the Health System. *Am. J. Clin. Pathol.* 2010;134, 550–555. <https://doi.org/10.1309/AJCPH1SKQ1HNWGHF>.
12. AbdelWareth, L.O.; Pallinalakam, F.; Ibrahim, F.; Anderson, P.; Liaqat, M.; Palmer, B.; Mirza, I. Fast Track to Accreditation: An Implementation Review of College of American Pathologists and ISO 15189 Accreditation. *Arch. Pathol. Lab. Med.* 2018, 142, 1047–1053.
13. Zima, T. Accreditation of Medical Laboratories- System, Process, Benefits for Labs. *J. Med. Biochem.* 2017;36, 231–237. <https://doi.org/10.1515/jomb-2017-0023>.
14. Alkhenizan, A.; Shaw, C. Impact of Accreditation on the Quality of Healthcare Services: A Systematic Review of the Literature. *Ann. Saudi Med.* 2011;31,407–416. <https://doi.org/10.4103/0256-4947.83204>.
15. Serteser, M.; Coskun, A.; Inal, T.C.; Unsal, I. How ISO 15189 Laboratory Accreditation Assures Patient Safety. *J. Med. Biochem.* 2012;31,345–352.
16. Abdurabuh, A.; Hamid, M.D.; Che Hassan, C.R.; Fatani, M.I. Evaluating the Impact of Hospital Accreditation on Patient Safety Culture in Saudi Arabia Healthcare Facilities. *J. Multidiscip. Healthc.* 2024, [ahead of print], 5021–5033.
17. Hawkins, R. Laboratory Quality Improvement through Accreditation: Are We Meeting Expectations? *Clin. Chem. Lab. Med.* 2012;50,1115–1122. <https://doi.org/10.1515/cclm-2011-0944>.
18. Hawkins, R. Managing the Pre- and Post-Analytical Phases of the Total Testing Process. *Ann. Lab. Med.* 2012;32,5–16. <https://doi.org/10.3343/alm.2012.32.1.5>
19. College of American Pathologists (CAP). Laboratory Accreditation Program. Available online: <https://www.cap.org/laboratory-improvement/accreditation/accreditation-program/laboratory-accreditation-program> (accessed on 29 November 2025).
20. Howanitz, P.J. Errors in Laboratory Medicine: Practical Lessons to Improve Patient Safety. *Arch. Pathol. Lab. Med.* 2005;129,1252–1261.
21. Andiric, L.R.; Chavez, L.A.; Johnson, M.; Landgraf, K.; Milner, D.A. Strengthening Laboratory Management toward Accreditation: A Model Program for Pathology Laboratory Improvement. *Clin. Lab. Med.* 2018;38,131–140.
22. Westgard, S. (2021, November). The 2021 Middle-East QC survey results. Westgard QC. <https://westgard.com/qc-applications/basic-qc-practices/2021-middle-east-qc-survey-results.html>
23. Parikh KD, Rupani MP. Exploring the impact of national laboratory accreditation on quality and practices: a qualitative study from a government medical college in western India. *BMC Health Services Research.* 2025;25(1):1005. doi:10.1186/s12913-025-13195-6.

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