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# Assessment of the application of the ISO 9001 standard in the biology laboratory of the Cardiology Institute of Abidjan

**N'guessan Déto Ursul Jean-Paul[(1)]*, Coulibaly Songuigama[(1)], Konan Amoin Marie Desirée Lydia**

*Department of Therapeutic Chemistry and Organic Chemistry, UFR Pharmaceutical and Biological Sciences, FHB University, 01 BP V34 Abidjan, Côte d'Ivoire*

Corresponding email: nguessanursul@gmail.com

**ABSTRACT**

*This study assesses the knowledge, perception, and satisfaction of laboratory staff regarding the implementation of the ISO 9001 standard at the Cardiology Institute of Abidjan (ICA). As an internationally recognized quality management standard, ISO 9001 has played a crucial role in enhancing service delivery and operational efficiency within the institute. A descriptive and analytical cross-sectional survey was conducted among 27 laboratory staff members across various roles and units. Data were collected through a structured questionnaire integrating both quantitative (dichotomous and multiple-choice questions) and qualitative (open-ended responses) approaches. Variables analyzed included knowledge of ISO 9001, perception of its implementation, and job satisfaction. Descriptive statistics and comparative analyses were applied, with a dissatisfaction rate above 10% considered critical. The findings indicate universal awareness of ISO 9001 among staff, with most respondents acknowledging its role in enhancing client satisfaction and service quality. However, knowledge gaps were identified regarding broader aspects such as governance and risk management, highlighting a need for expanded training. Perceptions of ISO 9001 as a shared responsibility reinforce the importance of a collaborative approach to quality management. Satisfaction levels varied. While teamwork (96.3%) and task distribution (77.8%) were strengths, dissatisfaction emerged in areas such as working conditions (70.4%), material availability (77.8%), and remuneration (87.5%). Technological advancements were acknowledged by 68% of respondents, and 96.3% confirmed the implementation of corrective actions for client complaints, reflecting progress in continuous improvement. While the findings highlight ICA's commitment to quality, they also identify critical areas for improvement. Recommendations include targeted training to strengthen staff understanding of ISO 9001, investment in infrastructure and resources, and enhancements in remuneration and recognition. Addressing these gaps will enable the institute to fully optimize the benefits of ISO 9001, fostering sustained client satisfaction and operational excellence.*

**Keywords:** ISO 9001, Quality Management, Laboratory, Certification.

## INTRODUCTION

A quality management system (QMS) is a set of coordinated activities to ensure and improve quality in an organization, including medical laboratories (Dhara Patel *et al*., 2024). It covers all stages of the analytical phase to provide accurate, reliable, and timely results to support clinical and public health care (Dhara Patel *et al*., 2024), (Pillai, S. *et al.*, 2022) (CLSI, 2021). International standards, such as ISO 9001 and those of the Clinical and Laboratory Standards Institute (CLSI), as well as internal policies, guide the implementation of the QMS to enhance test quality and safety (Dhara Patel *et al*., 2024), (Pillai, S. *et al.*, 2022) (CLSI, 2021). Quality management encompasses areas such as quality control, assurance, and evaluation. These elements are essential to achieve and maintain an effective quality system, although their complete integration can be complex. A QMS relies on key components including organizational structure, resources, processes, and strong and committed leadership (Humphries, R. *et al.*, 2021), (Westgard, *et al*., 2014). Laboratory staff play a central role in implementing a QMS. Adequate training and awareness of regulatory requirements are essential for their commitment (Westgard, *et al*., 2014), (Tanasiichuk, *et al.,* 2023). The correlation between positive attitude towards quality and staff commitment is well documented. Thus, laboratory technicians must recognize quality management as an integral part of their responsibilities, understand its impacts on operations and master the quality systems used within their laboratory to ensure optimal performance (QACL, 2022).

The implementation of the ISO 9001 standard in healthcare laboratories is a crucial step toward ensuring quality management systems that enhance service delivery and client satisfaction (Paula, K. *et al*., 2010) ; (Koh, Y. *et al*., 2014) ; (Guo, S. *et al.,* 2017). For instance, at the Cardiology Institute of Abidjan, the certification has led to more streamlined processes, better resource allocation, and improved client feedback mechanisms, significantly boosting patient trust and global satisfaction to 84,43% in 2019 (ICA, 2021). At the Cardiology Institute of Abidjan, this certification represents a commitment to continuous improvement, client satisfaction, and operational efficiency (ICA, 2021). Despite its critical importance, there is limited research on the knowledge, perception, and satisfaction of laboratory personnel regarding the application of ISO 9001 in healthcare institutions in Côte d'Ivoire. This gap is significant as it hinders the ability to evaluate the broader impacts of quality management standards on healthcare delivery (Obeta, M. U. *et al.,* 2019), (Almatrafi, D. *et al.,* 2018), (Bamidele, A. *et al,* 2011) *(*Lochoro, P. 2004). Without such insights, institutions may struggle to identify barriers to effective implementation or leverage the full potential of ISO 9001 to enhance service quality, operational efficiency, and staff engagement [(Paula, K. *et al*., 2010) ; (Koh, Y. *et al*., 2014) ; (Guo, S. *et al.,* 2017)., *(*Lochoro, P. 2004)].

This study aims to evaluate the knowledge and perception of the ISO 9001 standard among ICA laboratory staff, alongside their satisfaction with its implementation. By examining these dimensions, the study seeks to identify areas for improvement and provide recommendations, such as enhancing staff training, improving material availability, and optimizing task distribution, to maximize the benefits of ISO 9001 within the laboratory (Paula, K. *et al*., 2010).

## MATERIAL AND METHODS

The methodology, based on a mixed approach (quantitative and qualitative), allows a complete assessment of staff knowledge, perception and satisfaction regarding the implementation of the ISO 9001 standard within the ICA laboratory.

**Type of study**

The study is a descriptive and analytical cross-sectional survey conducted among the laboratory staff of the Abidjan Institute of Cardiology (ICA). It includes technicians, biologists, secretaries, pharmacists, engineers, members of the quality department and trainees.

**Target population and sampling**

• Population studied: 27 employees of the ICA laboratory, distributed in different units (biochemistry, bacteriology, samples) and seniority levels.

• Sampling method: Exhaustive sampling was carried out among available and voluntary employees, ensuring a faithful representation of the different categories of staff.

• Inclusion criteria: All ICA staff members, including trainees, who responded to the questionnaire.

**Data collection**

• Tool: A structured questionnaire administered online, including:

o Closed questions:

- Dichotomous questions (yes/no) for specific assessments (e.g. level of satisfaction).
- Multiple-choice questions to assess knowledge of the ISO 9001 standard and opinion on the conditions of implementation.

Examples of questions:

- "Concerning the implications of the ICA management's commitment to the quality of the services offered, this guarantees..."
- "The objectives of the quality policy are..."
- "What can promote continuous improvement?"

o Open questions: To collect suggestions and comments.

• Variables studied:

o Socio-demographic data: Gender, age, function, seniority, affiliation unit.

o Job satisfaction: Working conditions, distribution of tasks, remuneration, available equipment, teamwork, implementation of corrective actions.

o Perception of quality and improvements: ICA commitment, consideration of customer complaints, technological advances.

**Evaluation criteria**

The questionnaire assessed three key areas:

1. Knowledge of the ISO 9001 standard:

o Awareness of the standard, details of the certification and perceived implications.

2. Perception of the ISO 9001 standard:

o Understanding of its objectives and the role of staff in its application.

3. Satisfaction with implementation:

o Working conditions, availability of materials, and institutional support.

**Data analysis**

• Descriptive analysis:

o Calculation of frequencies and percentages for categorical variables (e.g.: percentage of women among respondents).

o Intervals for continuous variables (e.g.: age, seniority).

• Comparative analysis:

o Comparison of satisfaction levels between groups (e.g.: by seniority or work unit).

o Identification of areas for improvement by considering a dissatisfaction rate > 10% as a critical threshold.

**Qualitative analysis**

Responses to open-ended questions were categorized into themes to provide contextual depth, complementing the quantitative data.

**RESULT AND DISCUSSION**

**Study Population**

The study included 27 laboratory staff members.

**Staff Profile**

The survey included 27 individuals from ICA's laboratory staff, distributed across various roles:

The workforce was predominantly technicians (33%) and trainees (18%), with a smaller proportion of quality assurance staff (7%).

Most respondents were experienced, with 40.7% having over 10 years of service at ICA.

Gender distribution: The majority of respondents were female (70.4%), as illustrated in figure 1.

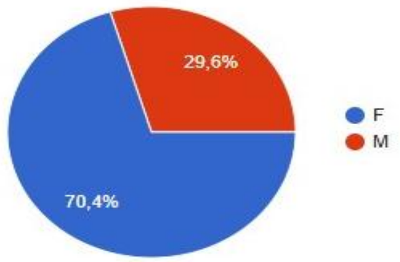


**Figure 1 :** Gender distribution

- **Age distribution**: The most represented age group was 35–50 years (44.4%), followed by 18–35 years (33.3%), with the remaining 22.2% being over 50 years old (figure2).

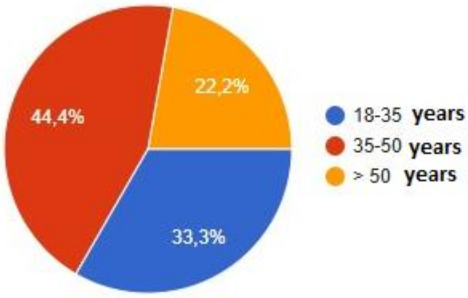


**Figure 2 :** Age distribution

**Knowledge of ISO 9001**

- **Awareness:** All respondents (100%) had heard of the ISO 9001 standard, indicating widespread awareness within the laboratory (figure 3).

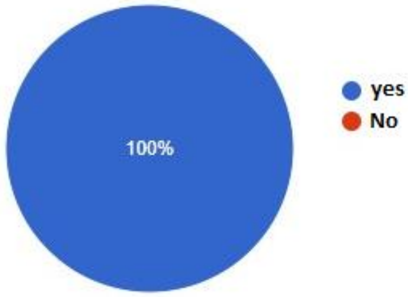


**Figure 3** : Awareness of ISO 9001 certification

- **Certification Year**: The majority believed that the Cardiology Institute of Abidjan had been certified in 2015, the year the ISO 9001 standard was released. Only 11% were aware that the institute had been certified since 2018, reflecting poor communication of this important milestone for the organization (Figure 4).

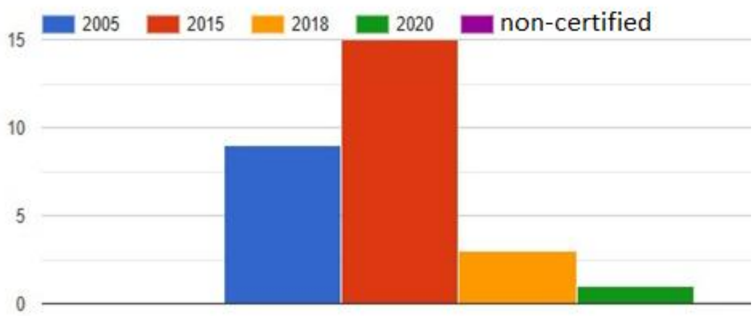

**Figure 4 :** Awareness of ICA's certification year

- **Perceived Implications**: Respondents highlighted client satisfaction (60%) and service quality (30%) as the primary outcomes of ISO 9001 implementation. Scientific contributions were less frequently mentioned (10%).

**Perception of ISO 9001**

- **Application Responsibility**: Most respondents (75%) viewed ISO 9001 implementation as a collective responsibility involving all staff (Figure 5).

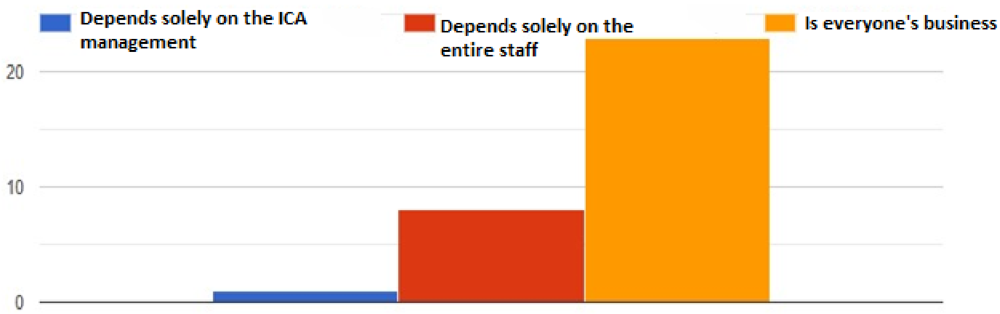


**Figure 5 :** Application of ISO 9001 Responsibility

- **ISO 9001 Recognition:** A significant majority understood institute's ISO 9001 certification, associating it primarily with ensuring quality services and fostering a capable workforce (Figure 6).

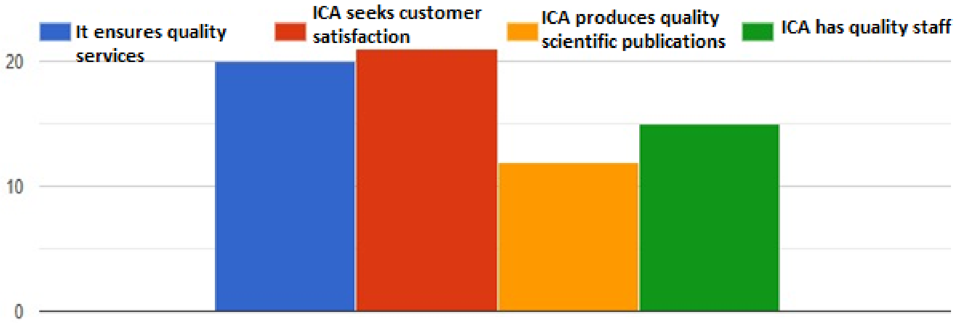


**Figure 6 :** Conception of the implications of ICA management's commitment

- **Policy Objectives**: For the five quality policy objectives of the management of ICA (table 1), Key objectives identified included improving stakeholder satisfaction (70.4%) and ensuring continuous improvement of the quality management system (63%) (table). This indicates a fairly good recognition of the commitments of the Cardiology Institute of Abidjan management by the laboratory staff. 5 people were unaware that the objectives of "improving staff attendance" and "improving staff income" are not part of the management commitment related to ISO9001 certification.

**Table 1** : Policy Objectives and proportion of their knowledge by the laboratory staff

| Policy Objective | Percentage |
|---|---|
| Improve stakeholder satisfaction | 70.4% |
| Ensure continuous improvement | 63% |
| Improve ethical governance | 55.5% |
| Strengthen staff competence | 51.8% |
| Manage risks and opportunities | 48.1% |

**Satisfaction with Implementation**

Working Conditions: Only 29.6% of staff expressed satisfaction with their working conditions (figure 7). In addition, the staff expressed dissatisfaction with their remuneration (87.5% dissatisfaction) and material availability.

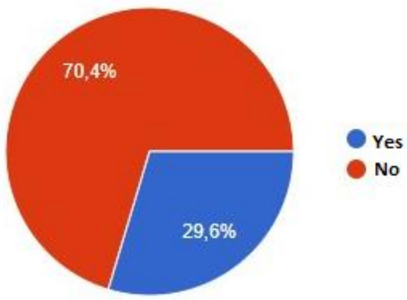


**Figure 7 :** Working Conditions

- **Material Availability:** A majority (77.8%) were dissatisfied with the availability of materials and reagents (Figure 8).

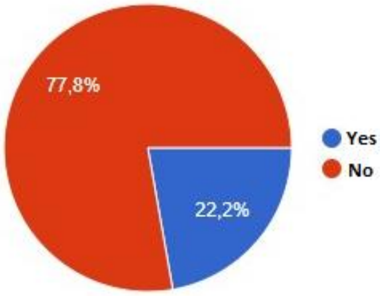


**Figure 8** : Material Availability

Task Distribution and Teamwork: Despite the challenges, 77.8% found their tasks well-distributed, and 96.3% reported strong teamwork (table 2).

**Table 2 :** Task Distribution and Teamwork

| Indicator | Percentage |
| --- | --- |
| Tasks Well-Distributed | 77.8% |
| Strong Teamwork | 96.3% |

Recognition: While 74.1% reported receiving encouragement, 25.9% felt underappreciated (figure 9).

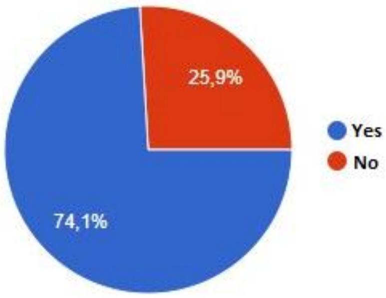


**Figure 9 :** Recognition of encouragement

**Continuous Improvement**

Collaboration: Almost all staff (96.3%) acknowledged strong interprofessional collaboration.

Training: Over 85% reported participating in regular training, and 81.5% had access to laboratory procedures (Figure 10).

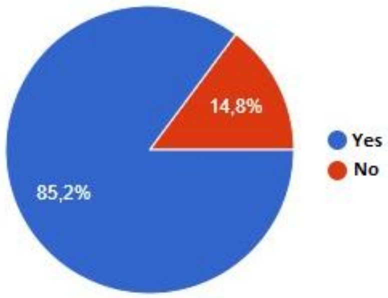


**Figure 10 :** Training of ICA laboratory staff

Technological Advancements: Most respondents (68%) acknowledged progress in adapting to technological advancements (Figure 11). Respondents noted improvements in equipment, though challenges remain regarding device reliability and adequacy.

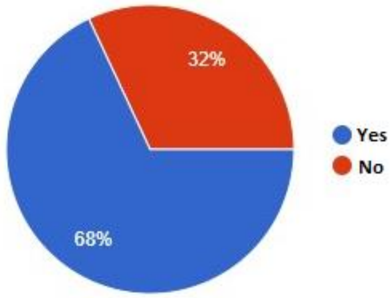


**Figure 11 :** Improvement in the level of the equipment

Corrective Actions: An overwhelming 96.3% confirmed the implementation of corrective actions for client complaints (Figure 12).

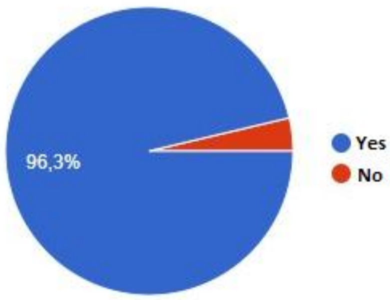


**Figure 12 :** Corrective Actions

Challenges Identified: Staff highlighted insufficient personnel and recurrent shortages of reagents as critical barriers to performance.

**DISCUSSION**

**Knowledge and Awareness**

The universal awareness of ISO 9001 among staff demonstrates the success of communication efforts within the Cardiology Institute of Abidjan laboratory. However, misconceptions regarding the certification year and a narrow understanding of the standard's implications highlight areas where further education is necessary. Training initiatives could focus on broadening staff's comprehension of ISO 9001 beyond client satisfaction to include research contributions and risk management.

Comparatively, a study conducted by Abebe *et al.* (2023) in Ethiopia also reported high awareness levels among laboratory professionals, attributing this to frequent workshops and institutional policies promoting ISO standards. However, like the Cardiology Institute of Abidjan study, their findings highlighted knowledge gaps in specific technical and managerial aspects of ISO 9001, suggesting a common need for targeted educational interventions across different regions (Abebe, D. *et al,* 2023).

**Perception of the Standard**

The perception of ISO 9001 as a shared responsibility aligns with the collaborative ethos required for quality management. Nevertheless, the limited acknowledgment of governance and risk management as policy objectives suggests a gap in strategic alignment. Addressing this could involve integrating these elements into training and operational practices.

In contrast, findings from Teresa and Bekele in Ethiopia showed a more comprehensive understanding of ISO objectives among staff, likely due to their focus on continuous risk management training. This underscores the potential benefits of incorporating governance and risk strategies into regular ISO 9001 training programs at Cardiology Institute of Abidjan) (Teresa, M. *et al,* 2016*)*.

**Satisfaction Levels**

The findings on satisfaction reveal a mixed picture. While teamwork and task distribution are strengths, dissatisfaction with working conditions, material availability, and remuneration highlights systemic issues that could undermine staff morale and engagement. In fact, participants highlighted recurring problems related to the material and technical resources needed for the laboratory to function optimally. This situation is reflected in the participants' comments when asked what difficulties they encountered: "problem with materials", "lack of reagents"," breakdown of devices sometimes", " Problem with reagents". Investments in infrastructure, consistent supply of reagents, and competitive salaries are essential to address these concerns. These solutions are in line with the participants' answers to the question "What do you propose to improve the service?". Indeed, the answers were: "recruit additional staff to reduce workloads", "increase the budget for purchasing reagents and consumables", "replace obsolete or defective equipment", "improve employee well-being by meeting transport and training needs".

Similar challenges were noted in a study by Ferreira *et al.* (2023), which identified inadequate infrastructure and resource shortages as major barriers to staff satisfaction in healthcare laboratories globally. Their recommendations for improving laboratory efficiency align closely with the needs highlighted at Cardiology Institute of Abidjan, emphasizing universal challenges in maintaining laboratory standards (Ferreira, D. *et al,* 2023).

**Continuous Improvement**

The positive reception of technological advancements and corrective measures for client complaints reflects progress in fostering a culture of improvement. However, the minority who perceive no significant technological progress indicate the need for greater visibility of upgrades and their impact on operations.

Aligned with these findings, Al-Abri and Al-Balushi (2014) emphasized the importance of clear communication about technological upgrades and their benefits to staff, as a means to foster better engagement and satisfaction. Their work underscores the need for Cardiology Institute of Abidjan to make advancements more transparent and involve staff in discussions about ongoing improvements ) (Al-Abri, R., and Al-Balushi, A. 2014).

## CONCLUSION

The study reveals a high level of awareness and a generally positive perception of ISO 9001 among ICA laboratory staff. Strengths such as teamwork and commitment to continuous improvement underscore the laboratory's potential to excel as a quality-driven institution. However, challenges related to working conditions, material availability, and remuneration necessitate immediate attention.

By addressing these gaps and enhancing staff education on ISO 9001, the Cardiology Institute of Abidjan laboratory can maximize the benefits of its certification, ensuring both client satisfaction and operational excellence. Continuous engagement with staff and stakeholders will be critical to sustaining progress and achieving long-term quality goals.

This study contributes to the limited research on ISO 9001 application in Côte d'Ivoire, offering insights for healthcare institutions aiming to enhance their quality management practices.

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