

DETERMINING THE NEED FOR THE APPLICATION OF THE INTERNATIONAL STANDARD ISO 15189:2012 FOR THE QUALITY AND EFFICIENCY OF MEDICAL LABORATORIES AND ITS IMPACT ON THE SATISFACTION OF USERS OF Test RESULTS IN A SAUDI HOSPITAL IN THE EASTERN PROVINCE.

Bandar Ali Al hader¹, Bader Saed Mohamed Alsalaten², Ahmad Abdulrazaq Aldulaijan³, Rayan Mohammed Almesned⁴, Ali Hassan Alhussain⁵, Fatimah Ali alzahir⁶, Dalal Ahmed albandri⁶, Zainab Qassim Alhasan³, Amani Abdullah almagaslah⁸, Asrar Saleh Alqurashi³

¹ Lab specialist, Dammam, Saudi Arabia.

² Laboratory Medicine, Dammam, Saudi Arabia.

³ Staff Nurse 1, National Guard hospital Dammam, Saudi Arabia.

⁴ Radiology Technologist 1 National Guard Hospital, Dammam, Saudi Arabia.

⁵ Medical technologist I, Al-Ahsa, Saudi Arabia.

⁶ Pharmacist 2, Dammam, Saudi Arabia.

⁷ Pharmacy Technician, Dammam, Saudi Arabia.

⁸ Medical technologist 2, Dammam, Saudi Arabia.

Abstract:

This study aimed to evaluate the quality of the services provided by medical laboratories and the level of satisfaction of test users with the results in a Saudi hospital in the eastern province. It also aimed to highlight the role and importance of applying the International Standard ISO 15189:2012 for the Quality and Efficiency of Medical Laboratories in improving the quality of services provided by medical laboratories. The study also aimed to determine the extent to which the technical and administrative requirements of the standard are met from the perspective of the study sample and to compare them with the overall level of satisfaction with the quality and efficiency of the services provided by the laboratories.

The results of the study showed a strong positive correlation between the satisfaction of test users with the results and the degree of application of the administrative and technical requirements of the standard. This indicates that the satisfaction of users of test results is affected by the degree of application of all the clauses of the international standard for the quality and efficiency of medical laboratories. The results also showed that the level of satisfaction of users of test results (doctors) with the quality of services provided by medical laboratories was weak and that the level of application of the ISO standard clauses in the laboratories in the study sample was weak in general.

The study concluded with a set of recommendations, the most important of which is the need to improve the quality of services provided by medical laboratories through the adoption and

application of the International Standard ISO 15189:2012 for the Quality and Efficiency of Medical Laboratories.

Keywords: ISO 15189:2012, Medical laboratories, Quality and efficiency, User satisfaction, Quality management, Saudi hospital, Eastern Province.

Introduction:

Quality is what the consumer seeks in the product and what the producer seeks to achieve in the product. However, we find several definitions of quality. J.M.Juran and his colleagues defined quality as the fitness for use of the product. Quality has also been defined as conformance to requirements. The International Standard ISO 9000:2000 defines quality as the degree to which a set of inherent characteristics fulfills the requirements of the customer.[1, 2]

Quality is also defined as the production of a good or the provision of a service at a high level of outstanding quality that can meet the needs and desires of its customers in a way that is consistent with their expectations and achieves satisfaction and happiness for them. This is done through pre-established measures for the production of goods or the provision of services and finding the trait of excellence in them.[3, 4]

Medical laboratories are organizational entities that need to implement a quality system to ensure the quality of the services they provide to their customers. Medical laboratory services are essential for patient care and must be available to meet the needs of all patients, clinical staff, and those responsible for caring for these patients. These services include arrangements for test requests, patient preparation, patient identification, sample collection, transportation, storage, preparation, and examination of clinical samples, along with interpretation of results, report writing, and consultation, in addition to safety and ethical considerations in medical laboratory work.[5, 6]

The Eastern Province of Saudi Arabia, known for its diverse population and growing healthcare demands, serves as a pertinent backdrop for this study. Understanding the implementation of ISO 15189:2012 in the local healthcare landscape is crucial not only for aligning with international benchmarks but also for optimizing laboratory services to meet the unique needs of the region. Furthermore, assessing the impact of ISO 15189:2012 on user satisfaction with test results adds a crucial dimension to this study, emphasizing the patient-centric approach in healthcare quality management.[7-9]

The quality of medical laboratory services is essential for patient care. The results of medical laboratory tests are used to make important medical decisions, such as the diagnosis of disease, the selection of treatment, and the monitoring of treatment outcomes. Therefore, the quality of medical laboratory services can have a significant impact on patient health and well-being.[10-12]

The International Organization for Standardization (ISO) has developed a standard for quality and competence in medical laboratories, ISO 15189:2012. This standard provides requirements for medical laboratories to ensure that they meet the needs of their patients and other users.[13-15]

The concept of customer satisfaction is increasingly being used by service and manufacturing organizations as a measure or standard of quality. The importance of customer satisfaction is attributed to global competition. This is reflected in the Malcolm Baldrige National Quality Award, where customer satisfaction accounts for 30% of the total points.[16-18]

Doctors are the primary customers of medical laboratories. Obtaining their feedback provides laboratory managers with opportunities to identify areas for improvement.[19-21]

Previous studies:

A study by Al-Zahrani and Zani (2015) entitled "Satisfaction of doctors with laboratory services at the Maternity and Children's Hospital in Mecca": The study aimed to investigate the level of satisfaction of doctors with laboratory services at the Maternity and Children's Hospital in Mecca. The study found that overall satisfaction with the services provided was limited to an average of 6.4 out of 10. The respondents were not satisfied with the basic elements, with an average ranging from (3.4), (not sure), to (2.3, not agree). Most of the doctors were satisfied with the kindness and gentleness of the laboratory staff, with an average of 3.4, the accuracy (validity) of the laboratory results, with an average of (3.2), and the support of the staff for research projects, with an average of (3.1). The lowest satisfaction rates were during the examination time for urgent and routine tests in the cases of inpatients and outpatients.[22]

A study by Elhoseeny and Mohammad (2013) entitled "Quality in the Clinical Laboratory Department in a Specialized Hospital in Alexandria, Egypt": The study aimed to measure the current completion time for measuring bilirubin samples in the outpatient department and evaluate doctors' satisfaction with the laboratory services. The study found that the average completion time for 110 bilirubin tests (58.1 minutes + 31.8) was within acceptable limits and that the average satisfaction of doctors was (4.6). The highest scores were given to the courtesy of the workers, and the lowest to the responsiveness of the laboratory administration, the time to complete the work for outpatient cases, and the reporting of critical values. Doctors also saw that the quality and reliability of the results were the most important factors.[23]

A study by Kader (2009) entitled "Satisfaction of doctors with clinical laboratory services in hospitals in Aden Governorate, Yemen": This study aimed to assess the level of satisfaction of doctors with clinical laboratory services in hospitals and the factors related to it in Aden Governorate, Yemen. The study found that the overall satisfaction of doctors was 3.30 on average. A link was also observed between the satisfaction of doctors and the institution type in 11 categories, as well as less satisfaction among doctors in public institutions compared to the private sector in all services. The study also found a decrease in satisfaction in the category that exceeds the period of experience over twenty years. These results may help improve the quality of services in clinical laboratories.[24]

Aim of the study

The general objective of the study is to evaluate the quality of services provided by medical laboratories and the level of satisfaction of users with test results. The following objectives are derived from this objective:

- To highlight the role and importance of applying ISO 15189:2012 for the quality and

competence of medical laboratories in improving the quality of services provided by medical laboratories.

- To identify the gap between what users of test results perceive from the quality of services provided by medical laboratories and the reality of what these laboratory administrations provide.
- To increase and spread the culture of quality among laboratory workers.

In addition to the general objective of the study, which is to evaluate the quality of services provided by medical laboratories and the level of satisfaction of users with test results, the study also aims to achieve the following specific objectives:

- To determine the level of satisfaction of users with test results and the quality of the results.
- To identify the impact of the experience and academic degree of users of the results on their level of satisfaction with the quality of the results.
- To evaluate the extent to which the technical and administrative requirements of the International Standard ISO 15189:2012 for the quality and efficiency of medical laboratories are met and to compare them with the overall level of satisfaction with the quality and efficiency of the services provided by the laboratories.

Hypotheses of the Study

The reality of work in medical laboratories and the extent to which they are committed to and adopt the principles of quality do not reflect the level of customer satisfaction with the quality and efficiency of work. Based on the objectives and problems of the study, it is based on the following main hypothesis:

Main Hypothesis:

There is no statistically significant relationship between the application of the requirements of the International Standard ISO 15189:2012 and increasing satisfaction among users of test results.

This hypothesis is derived from the following subsidiary hypotheses:

- There is no statistically significant relationship between the achievement of the administrative requirements of ISO 15189 and the satisfaction of users of medical test results.
- There is no statistically significant relationship between the achievement of the technical requirements of ISO 15189 and the satisfaction of users of medical test results.
- There are no statistically significant differences between the types of users of medical test results (doctors, pharmacists, and nurses) and their satisfaction with the test results.
- There are no statistically significant differences between the age of users of medical test results and their satisfaction with the test results.
- There are no statistically significant differences between the academic degree of users of medical test results and their satisfaction with the test results.
- There are no statistically significant differences between the years of service of users of medical test results and their satisfaction with the test results.

Methodology

Problems and Research Questions

There is a lack of awareness of the impact of the quality and efficiency of medical laboratory services on the health and economic aspects of society, both at the individual, community and national levels. This is evident in the practice of traveling abroad for treatment, dispensing medications and healthcare to people who do not need them, or denying medications and healthcare to people who need them.

Therefore, the problem of this study is that there is no trend towards the application of quality systems in medical laboratories.

The problem of the study can be further highlighted by answering the following questions:

- What is the need for the application of the requirements of ISO 15189:2012 in medical laboratories in a Saudi hospital in the eastern province.?
- What is the level of satisfaction of users of test results with the quality and efficiency of medical laboratory performance in a Saudi hospital in the eastern province.?
- What is the level of application of the administrative requirements of ISO 15189:2012 by medical laboratories?
- What is the level of application of the technical requirements of ISO 15189:2012 by medical laboratories?
- Is there a statistically significant relationship at the significance level (0.05) between the satisfaction of users of test results and the extent to which medical laboratories apply the administrative and technical requirements of the standard?

Importance of the Study

The importance of the study stems from its field of application, as the services provided by medical laboratories represent an important pillar in the process of medical care provided to patients, which primarily affects their lives and other economic and psychological aspects.

To more accurately and clearly define the importance of the study, it can be highlighted in the following:

Scientific Importance: The scientific importance of the study can be highlighted through the following points:

- Studying the possibility of applying the International Standard ISO 15189 to medical laboratories in Saudi represents a scientific addition that contributes to testing the possibility of applying the requirements of the standard.
- The study seeks to know the impact of applying the requirements of the standard on the satisfaction of users with the results. How can this standard enhance the satisfaction of customers of medical laboratories?
- This study attempts to highlight the importance of including technical requirements to improve the efficiency and effectiveness of the quality management system in medical laboratories.

Practical Importance: According to the knowledge of the researchers, there is not a single laboratory in the Saudi hospital in the eastern province that has been accredited to the

International Standard ISO 15189 for the quality and efficiency of medical laboratories. Therefore, the practical importance of this study is highlighted in the following:

- The study sheds light on the feasibility of adopting and applying the International Standard ISO 15189 for the quality and efficiency of medical laboratories.
- The study seeks to encourage those working in the field of providing medical laboratory services to adopt quality management systems that are appropriate for the nature of work as provided by this standard.
- Supporting legislative bodies in taking advantage of these requirements in the legislative aspect, as the legislation issued by them is mandatory to protect citizens.
- This study helps to raise awareness among those working in the field of medical laboratories and users of test results of the importance of applying the requirements of the International Standard ISO 15189.
- The study contributes to activating the role of accreditation for medical laboratories in the International Standard ISO 15189:2012 to ensure the quality and efficiency of the services provided by laboratories, as this standard is optional and not mandatory, from the side of increasing the level of satisfaction among customers and enhancing the competitive position of these laboratories.

Study-limitations:

The present investigation encountered several challenges and limitations while attempting to fulfill the requisites of the study. Foremost among these challenges is the absence of medical laboratories in a Saudi hospital in the eastern province accredited to the international standard ISO 15189, as per the discernment of the researchers. This limitation significantly constrains the ability to directly observe and analyze the application of ISO 15189 within the context of Saudi hospitals in the eastern province medical laboratories, thereby potentially affecting the comprehensiveness of the study findings.

Another notable limitation pertains to the researchers' experience of weak cooperation and response from the private sector. The lack of active collaboration from private entities may impede the collection of essential data and insights crucial for a thorough examination of the study objectives. The extent of private sector involvement in adhering to international standards such as ISO 15189 remains a critical aspect, and the limitations in cooperation pose a challenge to obtaining a holistic understanding of the subject matter.

Additionally, a noteworthy limitation arises from the dearth of existing studies within the spatial boundaries defined for this investigation. The scarcity of prior research in the specified geographical area restricts the availability of comparative data and benchmarks, hindering the establishment of a robust contextual framework. The absence of a comprehensive body of literature in this field within the study's spatial boundaries underscores the need for cautious interpretation and generalization of findings.

Data collection and analysis methods:

The data collection methods for this study were based on two main sources:

Secondary sources: These included Arabic and foreign books, as well as specifications, documents, and publications of the International Organization for Standardization (ISO), as well as many research papers and university theses that were obtained through the Internet or the digital library of the National Information Center of the Saudi hospital in the eastern province.

Primary sources: These included the design of a questionnaire with three axes: the first axis measures the level of satisfaction with the results of the tests from medical laboratories, the second axis measures the possibility of achieving satisfaction through the application of the administrative requirements of the ISO 15189:2012 standard, and the third axis measures the possibility of achieving satisfaction through the application of the technical requirements of the ISO 15189:2012 standard.

Methods and Procedures

This section describes the study's methodology, the study population and sample, data sources and collection tools, the study tool used, and its preparation methods. It also includes a description of the procedures and treatments used in the analysis and application of the study.

Study Methodology

To achieve the objectives of the study and test the hypotheses, a descriptive-analytical approach was adopted. This approach is defined as a method of study that deals with events, phenomena, and practices that exist and are available for study and measurement as they are without interfering with their course. This approach enabled the study to test the hypotheses related to determining the need to apply the ISO 15189:2012 international standard for the quality and efficiency of medical laboratories and its impact on users of test results.

Study Unit

The study unit may be an individual, institution, government, state, or a specific trend or behavioral pattern. In this study, the study unit is represented by doctors and laboratory specialists working in the hospitals of the Saudi hospitals in the eastern province medical laboratories, which are defined as the sample of the study.

Study Variables

Based on the study's questions and hypotheses, the study variables include the following:

Independent Variables:

The administrative and technical requirements of the ISO 15189:2012 international standard. The extent of its reflection on the reality of implementation is measured by a questionnaire distributed to the examiners working in Saudi hospitals in the eastern province medical laboratories.

Demographic variables: These are the personal characteristics and attributes of an individual that distinguish him from others. The demographic variables in the current study were defined as gender, age, educational level, years of service, and place of work.

Dependent Variable:

The dependent variable is represented by the satisfaction of users of test results (doctors).

Study Population

The study population is represented by all users of test results (doctors) and laboratory specialists working in the Saudi hospitals in the eastern province medical laboratories. This is because it is compatible with the nature of the data required for the study.

Study Sample

The study sample was selected from the major hospitals in the eastern province based on the availability of resources and academic capabilities so that the problem could be estimated at its lowest level. Six hospitals were selected, as follows:

Data for this study are collected from Six hospitals and medical laboratories located in the Eastern Province of Saudi Arabia.

The study tool used was a questionnaire designed specifically for the study. The questionnaire was divided into two main axes: Axis 1: Measures the level of satisfaction with the results of the tests from medical laboratories. Axis 2: Measures the possibility of achieving satisfaction through the application of the administrative requirements of the ISO 15189:2012 standard. The questionnaire was piloted on a sample of 20 doctors and laboratory specialists to ensure its validity and reliability. The questionnaire was then distributed to the study sample.

Table 1: Construct validity of the satisfaction axis statements, n = 172, for the final sample

Code and phrase number	Correlation coefficient
V1	0.726
V2	0.609
V3	0.61
V4	0.632
V5	0.732
V6	0.598
V7	0.619
V8	0.581
V9	0.59
V10	0.639
V11	0.614
V12	0.711
V13	0.642

As can be seen from the Pearson correlation coefficients in Table 1, the level of construct validity for the satisfaction axis items was high, that is, higher than 0.7. This means that there is a positive and strong correlation between the items on the axis, which means keeping the items as they are.

Reliability of the Study Tool

The stability of the scale refers to the ability to obtain the same results or the same answers when the scale is repeated or when the same questions are repeated to the same group under almost the

same conditions, meaning the consistency of the results and the absence of errors. The study used the Cronbach's alpha equation to calculate the stability of the current study tool, which is as follows: $\text{Alpha} = 1 - (\Sigma(\text{Square of the deviation between the item mean and the total mean}) / (N * (\text{Sum of squared deviation from the mean of all items})))$

Table 2: shows the stability coefficient for the study variables (satisfaction axis and quality and efficiency axes of administrative and technical laboratories using "Cronbach's alpha coefficient")

Variables	Phrase Code	Number of phrases	Alpha coefficient
Component of the Satisfaction Axis	X	13	0.929%
Component of the Administrative Requirements Axis for Quality and Efficiency	Y1	45	0.989%
Component of the Technical Requirements Axis for Quality and Efficiency	Y2	30	0.989%
Total Component of the Administrative and Technical Requirements Axis for Quality	Y	75	0.988%
Total		88	

The previous table shows that the stability coefficients for the data collection tool are within the acceptable range, which indicates that the questionnaire has a high degree of stability.

Statistical analysis

The results obtained by the researchers will be displayed and analyzed, Data were fed to the PC and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp). We will display the arithmetic means of the questionnaire responses obtained from the sample and present the standard deviations to identify the degree of variation in those responses by displaying the frequencies and their percentages to identify the level of responses about the variables.

Results and Discussion

The researchers distributed the questionnaire to the study sample to collect the necessary data for this study. A total of 200 questionnaires were distributed to both doctors and examiners in the participating hospitals. 148 questionnaires were returned from the number of questionnaires distributed to the examiners, and 8 were excluded for being unfit for analysis. This leaves 140 questionnaires that are valid for analysis, representing a response rate of 70%, which is considered an acceptable rate. 172 questionnaires were returned from the number of questionnaires distributed to the doctors, all of which were valid for analysis. This represents a response rate of 86%, which is considered a high rate. The average response rate for both categories is 78%, which is considered a high rate. This is shown in Table 3:

Table 3: The number of distributed, lost, recovered, excluded, and analyzable questionnaires and the percentage of each.

Targeted entity/audience		Distributed forms	Retrieved forms	Missing forms	Eliminated Forms	Forms suitable for analysis
Doctors	N	200	172	28	0	172
	%	100%	86%	14%	0%	86%
Inspectors	N	200	148	52	8	140
	%	100%	74%	26%	4%	70%

This section includes answering the questions and testing the study hypotheses by presenting and discussing the results based on the results of the statistical analysis that was performed on the questionnaire, according to the descriptive and inferential statistical indicators as follows:

Presentation of the results of the level of quality of services provided by medical laboratories from the users' point of view. The arithmetic means percentages and standard deviations of the items of the quality of services provided by medical laboratories from the users' point of view were extracted. It is clear from Table (4) that the relative importance of the items of the quality of services provided by medical laboratories for the study sample from the point of view of users of test results reached an average of (2.86) with a percentage of (48) and a standard deviation of (0.88).

Table 4: shows the level of quality of services provided by medical laboratories in the study sample from the point of view of users of examination results, according to the final sample (n= 140)

Assessment Sections	Mean	Percentage %	SD	Rank
The information in the examination reports is characterized by clarity.	3.1	52%	0.847	1
The reports contain sufficient information.	3.1	52%	0.857	1
The examination results align with the patient's clinical condition.	3	50%	0.748	2
The laboratory responds appropriately with the aim of expediting result delivery.	3	50%	0.896	2
The reports include the necessary interpretations.	3	50%	0.896	2
Measurement credibility is available for laboratory examination results with high accuracy.	2.99	50%	0.866	3
Examination reports include acceptance criteria for results with reliable references whenever necessary.	2.96	49%	0.753	4
The laboratory staff handles examinations with high professionalism.	2.9	48%	0.79	5
The laboratory positively responds to improvement suggestions.	2.78	46%	0.957	6
Repeated measurement of the same sample in multiple laboratories yield almost the same results.	2.72	45%	0.794	7
There is stability in the quality of work in medical laboratories 24 hours a day.	2.65	44%	0.959	8

Reports include recommendations for the physician to assist in diagnosis.	2.6	43%	1.077	9
All required examinations are available at the laboratory.	2.41	40%	1.013	10
The overall average for the quality of service provided by laboratories from the perspective of users of examination results, namely physicians.	2.86	48%	0.88	-

Presentation of the results of the level of application of administrative requirements in laboratories in the study sample from the point of view of examiners:

The arithmetic means percentages and standard deviations of the items of the application of administrative requirements in laboratories in the study sample from the point of view of examiners were extracted. It is clear from Table (5) that the relative importance of the items of the application of administrative requirements in laboratories in the study sample from the point of view of examiners reached an average of (3.02) with a percentage of (50%) and a standard deviation of (1.189). This is shown in Table (5) below:

Table 5: shows the level of application of administrative requirements in laboratories in the study sample from the examiners' point of view, according to the final sample (n = 140)

Administrative requirements	Mean	Percentage %	SD
Average of administrative requirements	3.02	50%	1.189

Presentation of the results of the level of application of the items of the administrative requirements in the laboratories in the study sample from the point of view of the examiners according to the specified fields

The arithmetic means percentages and standard deviations of the items of the administrative requirements in the laboratories in the study sample from the point of view of the examiners were extracted. It is clear from Table (6) that the relative importance of the items of the administrative requirements in the laboratories in the study sample from the point of view of the examiners reached an average of (2.91) with a percentage of (49%) and a standard deviation of (1.04). This is shown in Table (6) below:

Table 6: shows the level of application of administrative requirements in laboratories in the study sample according to the specific fields in the final sample (n = 140).

Administrative requirements	Mean	Percentage %	SD	Rank
Management and organizational responsibility	3.19	53%	0.807	1
Definition and control of non-conformities	3.18	53%	0.995	2
Supply and external services	3.17	53%	0.984	3
Consultancy services	3.13	52%	1.284	4
Examination by state laboratories	3.12	52%	1.034	5
Corrective action	3.06	51%	0.982	6
Records control	2.93	49%	0.993	7
Quality management system	2.9	48%	1.15	8

Preventive action	2.87	48%	1.061	9
Service agreements	2.86	48%	1.083	10
Document control	2.74	46%	1.074	11
Continuous improvement	2.72	45%	1.138	12
Management review	2.61	44%	0.933	13
Inspection and assessment	2.59	43%	0.978	14
Complaint resolution	2.58	43%	1.122	15
Average of administrative requirements	2.91	49%	1.04	-

Presentation of the results of the level of application of the technical requirements in the laboratories in the study sample from the point of view of the examiners:

The arithmetic means percentages and standard deviations of the items of the application of the technical requirements in the laboratories in the study sample from the point of view of the examiners were extracted. It is clear from Table (7) that the relative importance of the items of the application of the technical requirements in the laboratories in the study sample from the point of view of the examiners reached an average of (3.22) with a percentage of (54%) and a standard deviation of (1.139).

Table 7: shows the level of implementation of technical requirements in laboratories in the study sample according to the final sample (n = 140)

Technical Requirements	Mean	Percentage %	SD
Average of Technical Requirements	3.22	54%	1.139

The order of application of the technical requirements can also be determined through Table (8), where the first place was the field of equipment, reagents, and consumables with an average of 3.47, and the least applied field was the field of individuals with an average of 2.97. The rest of the fields are shown in the following table:

Table 8: The level of application of technical requirements in laboratories in the study sample by field Specified by the final sample (n = 140)

Administrative requirements	Mean	Percentage %	SD	Rank
Management and organizational responsibility	3.47	58%	0.851	1
Definition and control of non-conformities	3.33	56%	0.956	2
Supply and external services	3.17	53%	1.089	3
Consultancy services	3.07	51%	0.364	4
Examination by state laboratories	3.06	51%	0.98	5
Corrective action	3.06	51%	1.175	5
Records control	3.05	51%	0.93	6
Quality management system	3.03	51%	1.054	7
Preventive action	3.03	51%	1.054	7
Service agreements	2.97	50%	0.887	8
Average of administrative requirements	3.12	0.52	0.93	-

Hypothesis Testing

Basic Hypothesis

There is no statistically significant relationship between the application of the requirements of the International Standard 15189:2012 and the increase in satisfaction among users of test results.

To test this hypothesis, the Pearson correlation coefficient was calculated between the satisfaction of users of test results and the degree of application of the standard, and the results were as follows:

Table 9: Pearson correlation coefficient between user satisfaction with test results and the overall application of the requirements of ISO 15189:2012

Hospital code	Average implementation of international standard requirements ISO 15189:2012	Average satisfaction of examination results in users
1	2.31	2.78
2	2.55	2.67
3	2.73	2.49
4	3.08	2.9
5	3.92	3.24
6	4.04	3.11
Correlation coefficient		0.8336*
P-Value		0.0328

Correlation coefficient with statistical significance at a 95% confidence level

From the previous table, it can be seen that there is a very strong positive correlation between the axis of the satisfaction of users of test results and the axis of the degree of application of the requirements of the International Standard 15189:2012 ISO, where the correlation coefficient value reached (0.8336), which is a statistically significant value at the level of statistical significance (0.0328).

Through the presentation of the study results, it was found that the null hypothesis (H₀) was rejected and the alternative hypothesis (1:H) was accepted, which states that "there is a statistically significant relationship between the application of the requirements of the International Standard 15189:2012 ISO and the increase in satisfaction among users of test results, that is, the more the requirements of the International Standard 15189:2012 ISO are applied in medical laboratories, the stronger the satisfaction of users of test results (doctors), and vice versa, the less the application of the requirements of the International Standard 15189:2012 ISO in medical laboratories, the weaker the satisfaction of users of test results (doctors).

Testing the Sub-Hypotheses

Sub-Hypothesis One

There is no statistically significant relationship between meeting administrative requirements and user satisfaction. To test this hypothesis, the Pearson correlation coefficient was calculated

between the satisfaction of users of test results and the degree of application of the administrative requirements of the standard, and the results were as follows:

Table 10: Pearson correlation coefficient between user satisfaction of inspection results and overall implementation of the administrative requirements of ISO 15189:2012

Hospital code	Average implementation of Administrative standard requirements ISO 15189:2012	Average satisfaction of examination results in users
1	2.05	2.78
2	2.44	2.67
3	2.64	2.49
4	2.92	2.9
5	3.86	3.24
6	3.71	3.11
Correlation coefficient		0.8110*
P-Value		0.0432

Correlation coefficient with statistical significance at a 95% confidence level

From the table above, it can be seen that there is a very strong positive correlation between the axis of the satisfaction of users of test results and the axis of the degree of application of the administrative requirements of the International Standard 15189:2012 ISO, where the correlation coefficient value reached (0.811), which is a statistically significant value at the level of statistical significance (0.0432).

Through the presentation of the study results, it was found that the null hypothesis (0:H) was rejected and the alternative hypothesis (1:H) was accepted, which states that "there is a statistically significant relationship between meeting administrative requirements and user satisfaction," that is, the more the administrative requirements of the International Standard 15189:2012 are applied in medical laboratories, the stronger the satisfaction of users of test results (doctors), and vice versa, the less the application of the administrative requirements of the International Standard 15189:2012 in medical laboratories, the weaker the satisfaction of users of test results (doctors).

Sub-Hypothesis Two

There is no statistically significant relationship between meeting technical requirements and user satisfaction. To test this hypothesis, the Pearson correlation coefficient was calculated between the satisfaction of users of test results and the degree of application of these requirements. The results are as follows in Table (11) below:

Table 11: Pearson correlation coefficient between the satisfaction of users of the examination results and the total application of the technical requirements of the international standard ISO 15189:2012

Hospital code	Average implementation of administrative standard requirements ISO 15189:2012	Average satisfaction of examination results in users
1	2.57	2.78
2	2.67	2.67
3	2.81	2.49
4	3.24	2.9
5	3.97	2.24
6	4.36	2.11
Correlation coefficient		0.8382*
P-Value		0.0318

From the table above, it can be seen that there is a very strong positive correlation between the axis of the satisfaction of users of test results and the axis of the degree of application of the technical requirements of the International Standard 15189:2012 ISO, where the correlation coefficient value reached (0.8382), which is a statistically significant value at the level of statistical significance (0.0318).

Through the presentation of the study results, it was found that the null hypothesis (0:H) was rejected and the alternative hypothesis (1:H) was accepted, which states that "there is a statistically significant relationship between meeting technical requirements and user satisfaction," that is, the more the technical requirements of the International Standard 15189:2012 are applied in medical laboratories, the stronger the satisfaction of users of test results (doctors), and vice versa, the less the application of the technical requirements of the International Standard 15189:2012 in medical laboratories, the weaker the satisfaction of users of test results (doctors).

Sub-Hypothesis Three

There are no statistically significant differences between the social status of users of the results and their satisfaction with the results.

To test this hypothesis, the mean scores and standard deviations of all the items in the axis of the satisfaction of users of test results about the services provided by medical laboratories were calculated, and Table (12) shows this. The Independent Samples T-test was also applied to find the differences in the answers of the sample members according to their social status.

From the table, it can be seen that there are no statistically significant differences in the satisfaction of users of test results due to social status. The results of the analysis of the t-test for the significance of the differences for the variable of the satisfaction of users of results according to the type showed a high average value for the statistical significance value of (0.497), which is higher than the value of the statistical significance at (0.05) and an average value of t of (0.523).

Through the presentation of the results of the study, it was found that the null hypothesis (H₀) was accepted, which states that "there are no statistically significant differences between the social status of users of results and their satisfaction with the results," and the alternative hypothesis (1) was rejected, which states that "there are statistically significant differences between the social status of users of results and their satisfaction with the results.

Table 12: The effect based on the gender of users of examination results on their level of satisfaction with examination results: number of males = 79 and number of females = 47 (N = 172)

Administrative requirements	Gender	Mean	SD	T-Value	P-Value
Measurement credibility is available for laboratory examination results with high accuracy	Male	3.04	0.863	0.834	0.389
	Female	2.9	0.899		
Repeated measurement of the same sample in multiple laboratories yields almost the same results	Male	2.71	0.838	-0.124	0.863
	Female	2.73	0.751		
The laboratory responds appropriately to expedite result delivery	Male	2.95	0.922	-0.705	0.455
	Female	3.07	0.882		
Reports contain sufficient information	Male	3.06	0.844	-0.54	0.543
	Female	3.16	0.91		
The information in examination reports is characterized by clarity	Male	3.17	0.892	1.156	0.416
	Female	2.99	0.793		
Reports include the necessary interpretations	Male	3.03	0.872	0.474	0.61
	Female	2.94	0.967		
Examination reports include acceptance criteria for results with reliable references whenever necessary.	Male	2.94	0.749	-0.315	0.726
	Female	2.99	0.789		
Reports include recommendations for the physician, assisting in diagnosis	Male	2.61	1.101	0.139	0.88
	Female	2.58	1.076		
Examination results align with the patient's clinical condition.	Male	3.1	0.713	1.744	0.072
	Female	2.84	0.808		
All required examinations are available at the laboratory 24 hours a day	Male	2.57	1.073	2.354	0.012
	Female	2.13	0.88		
There is stability in the quality of work in medical laboratories	Male	2.63	0.96	-0.164	0.862
	Female	2.67	0.995		
Laboratory staff handles examinations with high professionalism	Male	2.98	0.771	1.34	0.184
	Female	2.77	0.84		
The laboratory positively responds to improvement suggestions.	Male	2.8	1.01	0.262	0.782
	Female	2.82	0.62		
Avrage	Male	2.89	0.892	0.497	0.523

Administrative requirements	Gender	Mean	SD	T-Value	P-Value
	Female	2.81	0.862		

Sub-Hypothesis Four

There are no statistically significant differences between the age of the users of the results and their satisfaction with the results.

To test this hypothesis, the mean scores and standard deviations of all the items in the axis of the satisfaction of users of test results about the services provided by medical laboratories were calculated, and Table (13) shows this. The one-way ANOVA test was also applied to find the differences in the answers of the sample members according to age.

From Table (13), it can be seen that there are no statistically significant differences in the satisfaction of users of test results due to age. The results of the analysis of the one-way ANOVA test for the variable of the satisfaction of users of results according to age showed a high average value for the statistical significance value of (0.362), which is higher than the value of the statistical significance at (0.05) and an average value of F of (1.113). It also appears that there are no statistically significant differences between all the answers to the satisfaction items for the sample members according to age.

Through the presentation of the results of the study, it was found that the null hypothesis (H0) was accepted, which states that "there are no statistically significant differences between the age of users of results and their satisfaction with the results," and the alternative hypothesis (1) was rejected, which states that "there are statistically significant differences between the age of users of results and their satisfaction with the results.

Alternative hypothesis (H1). That is, there is agreement among all age groups regarding the answers to the items on the axis of user satisfaction with examination results.

Table 13: The effect of age of users of examination results on their level of satisfaction with examination results

Age Group (Years)	Mean	SD	F-Value	P-Value
20-30	2.02	0.68	1.113	0.362
31-40	2.85	0.56		
41-50	3.01	0.66		

Sub-Hypothesis Five

There are no statistically significant differences between the educational level of users of results and their satisfaction with the results.

To test this hypothesis, the mean scores and standard deviations of all the items in the axis of the satisfaction of users of test results about the services provided by medical laboratories were calculated, and Table (14) shows this. The One-Way ANOVA test was also applied to find the differences in the answers of the sample members according to educational level.

From Table (14), it can be seen that there are no statistically significant differences in the satisfaction of users of test results due to educational level. The results of the analysis of the one-way ANOVA test for the variable of the satisfaction of users of results according to educational

level showed a high average value for the statistical significance value of (0.689), which is higher than the value of the statistical significance at (0.05) and an average value of F of (0.346). Through the presentation of the results of the study, it was found that the null hypothesis (H0) was accepted, which states that "there are no statistically significant differences between the educational level of users of results and their satisfaction with the results" and the alternative hypothesis (1) was rejected, which states that "there are statistically significant differences between the educational level of users of results and their satisfaction with the results."

Table 14: The effect of the academic degree of users of examination results on their level of satisfaction with examination results.

Academic Degree	Mean	SD	F-Value	P-Value
Doctor	2.81	0.6	0.346	0.689
Specialist	2.88	0.66		
Consultant	3.04	0.57		

There are no statistically significant differences between the years of service of users of the results and their satisfaction with the results.

To test this hypothesis, the mean scores and standard deviations of all the items in the axis of the satisfaction of users of test results about the services provided by medical laboratories were calculated, and Table (15) shows this. The one-way ANOVA test was also applied to find the differences in the answers of the sample members according to years of service.

From Table (15), it can be seen that there are no statistically significant differences in the satisfaction of users of test results due to years of service. The results of the analysis of the one-way ANOVA test for the variable of the satisfaction of users of results according to years of service showed a high average value for the statistical significance value of (0.026), which is higher than the value of the statistical significance at (0.05) and an average value of F of (3.188).

Table 15: The effect of years of service for users of examination results on their level of satisfaction with examination results

Years of Service	Mean	SD	F-Value	P-Value
0-2	2.78	0.553	3.188	0.026
3-5	3.06	0.640		
6-8	2.89	0.487		
≥9	2.61	0.691		

After reviewing, analyzing, discussing, and testing the study hypotheses, the researchers reached the following conclusions:

There is a strong positive correlation between the satisfaction of test users with test results and the degree of application of the administrative and technical requirements of the International Standard 15189:2012 ISO. This indicates that the satisfaction of users of test results is affected by the degree of application of all the clauses of the international standard for the quality and efficiency of medical laboratories. This relationship was positive, meaning that increasing the

application of the clauses of the international standard leads to increased satisfaction of users with the test results.

The level of satisfaction of users of test results (doctors) with the quality of services provided by medical laboratories was weak, with a percentage of agreement of (49%) and a verbal meaning of "somewhat agree." This percentage is weak and does not meet the required level of diagnostic medicine in the medical field, which affects human life. This weakness in satisfaction was the result of the weak quality of services provided by medical laboratories due to the administrative systems applied in these laboratories, which did not enhance the quality of their services.

The level of application of the administrative requirements of the International Standard 15189:2012 ISO for the quality and efficiency of medical laboratories was weak in medical laboratories, with a percentage of application of (50%) and a verbal meaning of "applied to some extent." This percentage is weak and does not enhance the efficiency and quality of the services provided by these laboratories.

The level of application of the technical requirements of the International Standard 15189:2012 ISO for the quality and efficiency of medical laboratories was weak in medical laboratories, with a percentage of application of (58%) and a verbal meaning of "applied to some extent." This percentage is weak and does not enhance the efficiency and quality of the services provided by these laboratories.

There is no trend to improve the current status of the administrative systems applied in the laboratories to improve the quality of the services provided. The researchers reached this conclusion as a result of a set of sub-results, which the study provides as follows:

The clause of corrective actions received a percentage of application of (54%), higher than the clause of preventive actions, which received a percentage of application of (49%). This indicates that the administrative systems applied in medical laboratories adopt a reactive approach rather than proactive actions in the case of non-compliance.

The study found that the clause of continuous improvement is one of the weakest administrative clauses in terms of application, with a percentage of application of (46%).

Recommendations:

Based on the results of the study, the researchers recommend the following for medical laboratories:

- Adopt and implement the International Standard 15189:2012 ISO for the quality and efficiency of medical laboratories. This will help to ensure that medical laboratories meet the highest standards of quality and efficiency.
- Promote a culture of quality among all employees in medical laboratories, at all levels of management. This will help to ensure that everyone is committed to providing high-quality services.
- Adopt a customer-oriented approach. This means focusing on the needs and expectations of users of medical laboratory services.
- Increase attention to human capital, represented by the individuals working in the

laboratory. This includes developing their skills and knowledge through continuous training and providing a supportive work environment.

- Activate the role of continuous improvement in the administrative system applied in the laboratory and diversify its inputs. This will help to ensure that the laboratory is constantly striving to improve its services.
- Participate in interlaboratory evaluations to assess the reliability of test results, strengthen the trust of laboratory workers, and support the trust of laboratory customers.
- Pay attention to feedback from customers, consider their complaints, and solve them. This will help to ensure that the laboratory is meeting the needs of its customers.
- Meet the needs of its customers by providing all the required tests, either by conducting the tests in-house or by contracting with external laboratories to conduct the tests.
- Work to improve the operational efficiency of medical laboratories by strengthening the role of employees in this through training and providing a suitable work environment.

Reference

- [1] M. Juran Joseph and A. Blanton Godfrey, "Juran's Quality Handbook," *New York: Mc Gray-Hill Book*, 1999.
- [2] H. D. Isack, M. Mutingi, H. Kandjeke, A. Vashishth, and A. Chakraborty, "Exploring the adoption of Lean principles in medical laboratory industry: Empirical evidences from Namibia," *International journal of lean six sigma*, vol. 9, no. 1, pp. 133-155, 2018.
- [3] D. Abhijith, K. Kusuma, and M. Suma, "Laboratory accreditation and customer satisfaction," *APIK Journal of Internal Medicine*, vol. 9, no. 1, pp. 25-28, 2021.
- [4] N. Lamovsek and M. Klun, "Efficiency of medical laboratories after quality standard introduction: Trend analysis of selected EU countries and case study from Slovenia," *Cent. Eur. Pub. Admin. Rev.*, vol. 18, p. 143, 2020.
- [5] N. BALCI, M. AKSARAYLI, P. TUNCEL, and G. T. BAKIRCI, "Accreditation impact on service quality in medical laboratories: University hospital staff viewpoints," *Hacettepe Sağlık İdaresi Dergisi*, vol. 24, no. 4, pp. 729-746, 2021.
- [6] B. Msemwa, V. Silago, C. I. Mtemisika, N. S. Golola, and M. F. Mushi, "Preparedness of district clinical laboratories towards ISO 15189: 2012 accreditation scheme in Lake Zone, Tanzania: a descriptive cross-sectional study," *Pan African Medical Journal*, vol. 41, no. 1, 2022.
- [7] R. B. Carey *et al.*, "Practical guidance for clinical microbiology laboratories: implementing a quality management system in the medical microbiology laboratory," *Clinical microbiology reviews*, vol. 31, no. 3, pp. 10.1128/cmr. 00062-17, 2018.
- [8] W. Mtotela, "Strategies for Implementing the International Organization for Standardization 15189 for Medical Laboratories," Walden University, 2020.

- [9] K. Ngeno and F. Kinoti, "ISO 15189 accreditation projects and performance of Medical Laboratories in Nairobi city county, Kenya," *International Academic Journal of Information Sciences and Project Management*, vol. 3, no. 3, pp. 235-58, 2019.
- [10] A. S. Chaudhry, Y. Inata, and E. Nakagami-Yamaguchi, "Quality analysis of the clinical laboratory literature and its effectiveness on clinical quality improvement: a systematic review," *Journal of Clinical Biochemistry and Nutrition*, vol. 73, no. 2, p. 108, 2023.
- [11] F. Nwaokorie and E. Ojo, "Overview of the implementation of quality management system in Nigerian medical laboratories," *University of Lagos Journal of Basic Medical Sciences*, vol. 6, no. 1 & 2, 2021.
- [12] J. A. Ombewa, "Total Quality Management in Iso 15189 Accredited Medical Laboratories in Kenya," university of nairobi, 2018.
- [13] N. S. Etukudoh and U. M. Obeta, "Patients'(clients) satisfaction with medical laboratory services contributes to health and quality improvement," in *Healthcare Access: IntechOpen*, 2021.
- [14] I. Sydorko and R. Baytsar, "Providing quality of clinical diagnostic laboratory activity," *Measuring equipment and metrology*, vol. 79, no. 2, pp. 66-73, 2018.
- [15] K. Tasheska Trajkovska *et al.*, "External quality assesment of medical laboratories: requirement of MKS EN ISO 15189: 2013," *Clinica Chimica Acta*, 2022.
- [16] N. Hirjee, "Evaluation of the performance of analytical quality indicators on the quality management system in a medical establishment," 2022.
- [17] K. Tasheska-Trajkovska, "LABORATORY QUALITY MANAGEMENT," *KNOWLEDGE-International Journal*, vol. 38, no. 4, pp. 871-875, 2020.
- [18] K. T. Trajkovska, S. Cekovska, I. Kostovska, J. Bogdanska, J. Brezovska, and S. Topuzovska, "Quality management: illuminating the path to ISO 15189 accreditation-A view from the Republic of North Macedonia," *Turkish Journal of Biochemistry*, 2019.
- [19] F. Hrvat, S. Cifric, A. Aleta, A. Dzuho, L. G. Pokvic, and A. Badnjevic, "ISO/IEC 15189 Implementation in Microbiology Laboratory-General Concepts," in *2020 IEEE International Workshop on Metrology for Industry 4.0 & IoT*, 2020: IEEE, pp. 611-616.
- [20] V. Valdivieso-Gómez and R. Aguilar-Quesada, "Quality management systems for laboratories and external quality assurance programs," *InTech*, vol. 22, p. 21, 2018.
- [21] Ž. Žemčugovienė, V. Buckė, and J. Ruževičius, "Consolidation Of the Quality Indicator System for Clinical Laboratory Performance Improvement," *Quality-Access to Success*, vol. 24, no. 193, 2023.
- [22] R. Zaini and R. G. Zaini, "Physician's satisfaction from laboratory services in maternity and children hospital in Makkah," *Int J Lab Med Res*, vol. 1, no. 1, pp. 2-5, 2015.
- [23] T. Elhoseeny and E. Mohammad, "Quality of the clinical laboratory department in a specialized hospital in Alexandria, Egypt," *EMHJ-Eastern Mediterranean Health Journal*, 19 (1), 81-87, 2013, 2013.

[24] N. M. Adulkader and B. Triana, "Physician satisfaction with hospital clinical laboratory services in Aden Governorate, Yemen, 2009," *East Mediterr Health J*, vol. 19, pp. 555-560, 2013.