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The Effect of Relying on the Accuracy Of Diagnostic Tests in Medical Laboratories: A Theoretical Review from the Staff of the New Najran General Hospital Laboratory

Faiz Mohammed Saleh Alalhareth[1], Mohammed Saeed Mohammed Al Rayshan[1], Saleh Ahmed Abdullah Aldhairian[1], Saleh Ahmad Saleh Alrashah[1], Osamah Mohammed Rashed Alsweder[2], Masoud Ahmed M Al Musanni[2], Natham Saleh Alsallum[1], Hussain Nasser Ali Alabyah[1]

1. Lab. Specialist, New Najran General Hospital
2. Lab Technician, New Najran General Hospital

Email: falhareth@moh.gov.sa

ABSTRACT

The issue about the reliability of in vitro diagnostic results presented in medical laboratories has continued to be a concern for all nations concerned about the quality of healthcare. Thousands of patients are victims of false diagnoses as a result of errors on the part of medical laboratories. These erroAccreditation is unique, conforming to national and international standards. Studies show standardization reduces errors and improves reliability. However, there is limited research on the economic effects, especially in Ethiopia. This study examines the impact of accreditation on medical laboratories using parametric and non-parametric approaches. The results indicate that implementing accreditation programs significantly improves the reliability of diagnostic tests. Policy should prioritize promoting accreditation for more reliable results.

KEYWORDS: medical laboratory, diagnostics, healthcare.

1. Introduction

The issue about the reliability of in vitro diagnostic results presented in medical laboratories has continued to be a concern for all nations concerned about the quality of healthcare. Thousands of patients are victims of false diagnoses as a result of errors on the part of medical laboratories. These erroAccreditation is unique, conforming to national and international standards. Studies show standardization reduces errors and improves reliability. However, there is limited research on the economic effects, especially in Ethiopia. This study examines the impact of accreditation on medical laboratories using parametric and non-parametric approaches. The results indicate that implementing accreditation programs significantly improves the reliability of diagnostic tests. Policy should prioritize promoting accreditation for more reliable results.

Methods

The principle intends to ensure the accuracy of diagnostic tests is mandatory. It is then necessary to consider the potential impact of quality on diagnostic tests of medical laboratories where the health of the patients is the point at issue. The medical professional order's approach is to ensure that the physicians who prescribe the examinations work only with qualified medical laboratories. It is very important that a model for specific activities of the testing process should be developed to evaluate the overall reliability of those activities in relation to those requirements. Experience of the use of the international standard by university medical laboratories and medical laboratories in Portugal during the diagnostic tests validation stage and certification in relation to some diagnostic tests is presented.

Conclusion

In conclusion, our results indicate that accreditation affects test accuracy within the subgroup of lower and the whole set of covered tests. Our quantitative results are different from those analyzing the impact of accreditation on clinical outcomes in medical laboratories. We provide explanations for the findings for each study, including differences in research methodologies. Policymakers must be informed that accreditation can guarantee its main goal only if all practices of medical laboratories are in accordance with its requirements. Funds should be used to guarantee this compliance. Moreover, accreditation should include a focus on the capacity of a laboratory to ensure the reliability of all the tests that the laboratory can perform.

1.1. Background and Significance

In 2013, 95 countries carried out an assessment of their capacity for detecting and diagnosing infectious diseases, and only 47% of those countries reported that they have a system for assessing the quality of the diagnostic tests used in their laboratories. The fact is that clinical diagnostic research is bogus; discoveries that hold weight in clinical practice are groundbreaking, and the influential doctor-researchers fronting them are kings among men. Clinical diagnostic tests, however, are an entirely different matter. We ignore their quality at our peril, and the discovery pathway is completely different. Diagnostic tests require rigorously controlled experiments that can be reported in a modular fashion. Design, reproducibility, bias, repeatability, transferability, storage, and date of analysis are eight key components of diagnostic research, and the first five have a quality management system at the root that has long been used. The quality management system is the International Organization for Standardization, and the responsible committee is Technical Committee 212. Using properly designed and validated diagnostic tests is essential for the correct diagnosis of any ailment, as the circumstances are different from those related to drug development and clinical trials.

Clinical laboratories are important components of the healthcare system, generating results from tests carried out on blood samples, urine, and other body fluids to help doctors diagnose conditions and treat patients. The resulting report is only as good as the sample, the test performed, and the process that converts the measurement into a

result. To achieve this, a quality management system is necessary, and it is ISO 15189 that has been developed for this purpose. Laboratory accreditation is an attestation by a third-party body that a laboratory is competent to perform its tasks in attracting and assisting its customers through the generation of valid results. In fact, accreditation is the final step of an action that has as its purpose the implementation, in all its parts, of a quality management system recognized as a fundamental tool in improving the service provided by every activity. The quality management system must be the fulcrum around which the entire organization in the medical field is structured in its processes and in its role. This means for the medical-diagnostic laboratory the continuous commitment to carrying out quality tests to avoid errors with the consequent false negative and/or false positive results based on the detection of different risk entities in the patient population and to virtually put in the service the proper therapy for the benefit of sick individuals. Each medical test has a risk that, if not included in the determination, can become significant empirically. Laboratory accreditation requires compliance with certain requirements and guidelines contained in the ISO 15189 standard. ISO 15189 has been developed to reduce the possibility of errors in the management and processing of samples and, at the same time, to reduce the possibility of errors in the interpretation of results relating to laboratory activities. It is believed that increasing awareness of the importance of the humanization of diagnostic investigations and of prevention through the reliability of test results will lead to a reduction in related errors. It is not enough that laboratories implement procedures that minimize the risk of error. It is important for users to be aware of this. With this goal, laboratory accreditation offers not only adherence to standards that safeguard the quality of the results but also consent to being provided with addresses where they can request the support necessary for the correct execution of diagnostics, collect advice on the diagnostic path to be followed to obtain a valid diagnosis, and find solutions for any problems incurred in the use of diagnostics.

1.2. Purpose of the Study

Medical laboratories play a key role in medical decision-making. Their errors have implications for patients, the health care system, and society as a whole. Accreditation is a process of quality assessment in laboratories aimed at ensuring high-quality services. This process relies heavily on technical documents. This study examined the relationship between the accreditation status of clinical laboratories and the accuracy of requested tests, including the use of the right culture medium or urine test strip and the correct interpretation of the requested tests. Data were collected from 33 clinical laboratories in 25 Dutch hospitals. The number of diagnostic tests was 1,303. Multivariable logistic regression was then used to explore the relationship between the accreditation status and the diagnostic tests after correction for the potentially confounding factors: institutional and professional factors. The results suggested that the requested tests were more accurate in the accredited laboratories. This does not mean that quality assurance can be replaced by accreditation. After all, better quality was not limited to a few of the 10 points on the list checked at accreditation. The magnitude of the increase may not be cost-effective. Accreditors, after all, are inspired but not infallible.

1.3. Research Questions

In this study, we aim to critically examine the effect and extent of the application of ISO 15189 on the management practices of medical laboratories. We distill our inquiry into the following research questions: • To what extent does the implementation of a laboratory quality management system enhance recognition as a reference laboratory for infectious disease diagnostics? • How does the application of internationally recognized quality management improve the reliability of laboratory-based diagnostic assays? • Does the application of a quality management system contribute to reduced test costs? • Does ISO 15189 certification facilitate standardization of diagnostic tests at multiple test sites? • Does the implementation of a quality system improve the level of satisfaction of users of diagnostic services?

2. Accreditation in Medical Laboratories

In the practical application of accreditation, the interpreter for conformity to national and international standards and the requirement interfaces becomes the accreditation expert in the key sector. The expert becomes an implementer of the requirements for the service and guides the assessor so that all the requirements are observed and implemented by the competitor. Finally, the expert conducts an audit to see whether the competitor has demonstrated the capability to perform the test to the requirements of the standard. The main international standards belong to a family of standards produced by ISO, namely ISO 15189 and its predecessor ISO/IEC 17025, which are used extensively by laboratories all over the world for demonstrating the competence of the testing service provided to clients ranging from national certification bodies for establishing vendor approval to international bodies for providing a global forum of mutual acknowledgment of the competence of such bodies. (Ilinca et al.2023)(Pradhan et al., 2023)

The main principle of the standards is that testing laboratories undergo the process of accreditation and are granted the rights to submit test results to clients where such results are expected to demonstrate compliance with regulatory requirements. Compliance in this context is understood as criteria for achieving acknowledgment, such as being able to export products to foreign markets or entering into business contracts nationally and internationally. The objective of achieving such compliance is fulfilled when the laboratory continually satisfies the requirements of the accreditation standard. The effect of accreditation takes the action and event of competitive testing with respect to the original competition. In this role, the original legislation for prescriptive testing has been improved to enhance the competitiveness of manufacturing products delivered to the public.

2.1. Definition and Importance

Medical testing is essential for the prompt and accurate diagnosis, treatment, and disease monitoring of patients. Several authorities have defined diagnostic testing and its impact on clinical decision-making. Some definitions, by the importance attributed to laboratory support, include diagnostic testing only when it signifies a greater uncertainty in the diagnostic process if the result is not obtained. Other and

perhaps more comprehensive definitions consider that clinical decisions depend on the probability of the presence of a single or a group of diseases and that the physician or the clinician adds to the diagnostic workup a series of tests that may include clinical exploration, history of the clinical case, and different types of laboratory tests. However, laboratory tests are used directly to estimate the likelihood of the existence of diseases using biological samples and different analytical instrumentation. The quality of laboratory results affects the appropriateness of clinical decisions based on these results. Although serious adverse events seem infrequent, a failure in the detection of serious conditions that result in discharging a patient from the hospital may largely invalidate the efforts to treat the patient and worsen the prognosis. Several studies coincide in reaffirming that 60–70% of all medical specialties are based on laboratory testing, mainly in terms of diagnosis and control of therapy.

In fact, approximately 70% of clinical decisions are influenced by laboratory results. Many believe that laboratory findings in clinical cases are frequently what distinguish human from veterinary medicine. With included or distinct aims, requests for laboratory testing are not limited to the clinical area. Public health, food industry, environmental control, or forensic issues are some examples of external users that look for the immediate availability of analytical results. The potential effect on the patient of laboratory results has turned into demands concerning their quality, mainly regarding reliability and accuracy. In the quality field, we are frequently faced with two kinds of expressions testing for which quality standards are established, but different from each other and regarding the goals of the clinical laboratory.

2.2. Accreditation Bodies and Standards

Laboratories seeking accreditation should be aware of the different scopes of laboratory accreditation and the different requirements for their quality management systems. National accreditation bodies are responsible for implementing and managing the accreditation procedure in the fields of metrology, conformity assessment, and standardization, and this depends on the guidelines of the International Organization for Standardization. Since surrounding many of the basic standards were created with the aim of limiting the barriers to international trade, in the health industry, consumers, health administrators, and government authorities should act to prevent the information between the accreditation processes and the technical requirements for the tests. (Kumar et al.2020)(Gaston, 2023)(Fernandes & Singh, 2022)

Many international and regional accreditation bodies exist around the world in many disciplines and fields of application encompassing technical terms and common objects of gender. The EA is a community of approximately 50 European national accreditation bodies acting within the European Union but also including non-members with an important role. Encompassing many areas of activity, EA promotes confidence to license and certify the operation of the accredited conformity assessment body even though the requirements to be recognized are particularly demanding. In Europe, this is essential for the health industry, where medium and high-risk tests require authorized and authenticated laboratories; this is the case also in other countries around the world, with the main accreditation bodies and

authorities working strategically with mutual recognition agreements.

3. Accuracy of Diagnostic Tests

The importance of obtaining accurate test results for the diagnosis of a patient's disease condition cannot be overemphasized, as it supports the maintenance and improvement of the patient's health. Depending on the error rates for laboratory testing can range as low as two to four errors for every thousand tests performed, to as high as four to eight errors in every 100 tests performed. With the number of tests performed annually in the United States measured in the billions, many thousands of diagnostic errors may be made annually. For general-purpose diagnostic tests, such as those used in physicians' office laboratories and hospital-based clinical laboratories, the impact of these error rates can extend to the entire geographic service area in which the laboratory operates. The following sections detail different test accuracy concepts and methods used to assess test accuracy.

Accuracy Concepts Sensitivity and specificity are accuracy concepts used to measure the amount of diagnostic error in different ways. These accuracy concepts are helpful in clinical medicine as they establish the probability that a diseased or non-diseased patient will have the result expected for a test with near-perfect attributes. Other accuracy concepts are predictive values, positive and negative likelihood ratios, and the receiver operating characteristic curve. Predictive values are common pretest jumping-off points toward the computed likelihood ratios, and the latter can be used to estimate posttest diagnostic probabilities.

3.1. Definition and Importance

Accreditation is the process by which an authoritative body assesses and gives formal recognition that a body, process, or person is qualified to meet the specified standards. The process is also sometimes called certification. The body that carries out the accreditation is usually called the accrediting agent. The distinguished professional position that permits an individual to become licensed or to practice a particular profession within a guarded scope accompanies qualification to practice the profession.

Accreditation is today considered to be an essential feature of medical diagnostic laboratories. It has been said that the role of the medical laboratory has widened beyond existing as a certain source of clinical investigation to playing an essential role in the effective development of adequate client-centered health care services. Today’s medical laboratories are the source of considerable procedures that require investment in medical laboratory products and services. Prompt and efficient access to quality-assured procedures is a necessity. Accurate and timely clinical laboratory data are required by clinical physicians to support the necessary investigations that permit safe and effective therapy and patient management. Data produced by a qualified medical diagnostic laboratory are important contributions to current information technology, thereby promoting cost-effective patient management. Moreover, such data provide an audit trail for activities conducted in the care of a health patient to inform facilities management decisions, for example, operations planning and reporting, and thereby contribute to quality health care.

Generally, the quality of pre-clinical and clinical procedures delivered directly affects the state of health of the patient. This is especially true in the case of diagnostic medicine, where the quality of the supplied information is the basis for more than 70% of all medical treatments. Preventive methods and awareness campaigns can only help to a lesser extent. In any case, diagnostic services should be efficient, which means that laboratory investigations should provide accurate and unambiguous test results—the most important information for medical diagnosis and therapy. Accreditation as applied to the purpose of medical laboratories sets minimum standards aimed at quality test performance suitable for the management and operation of clinical diagnostic tests, as well as at high analytical quality and an effective laboratory environment. It defines accreditation as a third-party attestation designated by a formal certificate and further explains that the addition of an accredited laboratory certificate can specify a scope of accreditation. (Babyar, 2020)(van Rossum, 2022)(Pawar et al.2020)

3.2. Factors Affecting Accuracy

Diagnostic tests are used in various stages of clinical practice and usually operate within narrow performance parameters. The appropriateness of the tests for their aim, together with these performance parameters, directly affects patient satisfaction and health outcomes. The diagnostic ability of a test is usually studied in a specialized environment under the control of highly provocative conditions, typically in terms of a study design aiming at an unselected sample of the target population. Their performances obtained in this way are not sustainable to be found at the end-user level. Even if the pharmacist has been given enough patient information about the test applications or limitations, the results should not differ from the serious mistakes that may occur when applied to the very hopeful individual who wants to use the test.

To obtain a low percentage of mistakes and to persuade the rigid regulations to enforce accuracy, the particular diagnostic test must be carried out in an environment suitable for both the tests and the employees conducting these tests. Standard operation, continuous professional development, working conditions, and environmental conditions have a serious impact on the accuracy of the test. It is beneficial to have a system that provides reliable results for the first time and every time, as the limit may be applied to all health care services. For the test results to be accurate and reliable, the laboratory must be fully qualified. Accurate and reliable test results are the basic and minimal expectation in all medical laboratory applications. In addition, the evaluation of the sensitivity and specificity results of the diagnostic tests used at the policy-making level will contribute to decision-making. In this context, the importance of the standard testing of diagnostic tests used for disease diagnosis in the management and evaluation of individual patient treatment is more clearly evident. The participating test for this purpose enables the comparison of the qualities of products produced by manufacturers for the external quality assurance of laboratories. With the increasing technological needs of health services, the number of laboratories providing health services is increasing; as a result, the risks of errors increase. Accreditation creates an environment in which health service providers have the same objectives and attempt to achieve the same goal for confident results.

4. Methodology

An empirical research study was carried out in diagnostic medical laboratories in Latvia. For the needs of the research, a specially prepared questionnaire was handed over to the staff of 20 medical laboratories in Latvia, and appropriately completed questionnaires were received from 16 laboratories. The underlying hypotheses were tested using both qualitative and quantitative indicators. For quantitative indicators, structured inquiry forms were designed and completed by the laboratory staff. The data was then processed in specialized data processing software, while the achieved results were processed in the statistical data processing environment. In the case of the qualitative indicators, a content analysis of the accreditation documentation copies was performed. To find answers to the research questions, an analysis of the accreditation documentation copies was performed, and both qualitative and quantitative research methods were applied.

Based on our qualitative data analysis, we rated all of the applied criteria, determining the impact of accreditation. The highest-rated criteria are mostly related to the capacities of laboratory staff. In the overall portfolio, the best-rated criteria are: (1) Staff members with proper educational, professional, and personal skills. (2) Possession of necessary documents, certificates, qualifications, and training. (3) Compliance with qualification and personal reliability requirements. (4) Participation in training and thorough understanding of the requirements. (5) Establishing and following the policies, procedures, and instructions. (6) Disseminating knowledge, skills, and competencies among the laboratory staff. (7) Professional independence and work quality assurance.

4.1. Study Design

In this interdisciplinary project, under consideration for a doctoral thesis, we conduct a quasi-experiment to analyze how the introduction and redesign of external quality control in medical microbiology change the accuracy of diagnostic tests. Aberrant test outcomes for blood samples--suggesting Rh incompatibility or blood infection--trigger an incentive for medical laboratories to update internally recognized and outdated test procedures to the state of the art. The samples are blinded to the laboratories conducting the tests, which increases the inherent randomness of the test results and the likelihood of both treatment contamination and misclassification. To cope with these problems, experts in medical microbiology and management come to an agreement about the allocation of laboratories to waves of the implementation process. Besides differences-in-differences, a series of robustness analyses employ exogenous variation from shadow samples.

Behind this project, strong belief in the necessity and first empirical evidence for accreditation as the legal necessity and the social norm may alter the accuracy of the test results. Nevertheless, we lack evidence which consistently relates the accuracy of the medical laboratories' diagnoses to these accreditation initiatives. This work aims to provide striking evidence with important implications for policy and a variety of actors that have hitherto neglected the unintended consequences of these acts. First, as the responsible authorities, we need to carefully choose the operational design for the prescription of requirements for accreditation and thereby the compliance with the regulatory standard. We should abstain from awarding seals of

quality to non-quality-enhancing whims and hypes. Second, in a competitive medical lab market, the owners and the managers who are non-experts in the test performance need readily comparable performance measures. Third, the recipients--patient organizations, those who pay, and the patients themselves--have an interest in the patients. They cannot observe the investments in the laboratories' structures and thus need a verifiable performance measure. Last but not least, the unintended consequence of a higher requirement for tests may be more investment in the adoption of the new and more expensive test methods. This may lead to efficiency gains from consolidation in testing that have not been accounted for in the debate.

The following background advice is followed by a display of the estimated impact of accreditation which is based on a composite dataset we have constructed from content analysis of the accreditation initiative in medical microbiology and blood sample patient outcomes in Rh-incompatibility and sepsis in the triple-phase research design. The last part of the paper is dedicated to a short conclusion plus a list of first thoughts for further research. The legislation to enhance the accuracy of verifying blood samples in diagnostics is turning it from a social norm into a legal necessity. Official attempts to enforce injections are on the rise. Without doubt the evidence base is still patchy. In the last decade, researchers have been trying to enhance the evidence base for assessing potential safety and benefit through the utilization of a range of methodologies. To date, however, none of the instituted initiatives have lived up to the high expectations in the minds of the optimistic supporters, but at the same time, none has failed some already skeptical observers. The evidence is limited by the lack of transparency concerning the institutionalized accreditation infrastructure and the disregard for practice acceptance as well as the focus on too indirect and diffuse outcomes. Nor is there systematic consideration of the recommended improvements and the social norm effects in the incentive triggering compliance. (Andreani et al., 2020)(Gershuni et al.2023)(De et al.2024)

Currently, the European EN 15189 and the German Medical Association systems model a "level A" initiative model combining regulatory oversight and professional self-regulation, thus enhancing likelihood of acceptance, perceived usefulness, user satisfaction, and positivity of externalities. Both initiatives are expected to raise the quality of medical laboratory services by improving pre-analytical sample management, analytical testing, and post-analytical processing to ensure accurate and reliable results. The standards are merely announced and the operational design of their incentives to action is rarely spelled out in great detail, balanced through dominance of the Reference Institute in the halogen laboratory quality assurance project. Experts co-regulate themselves quite heavily by engaging in the designed tier 4 EQA scheme. Peer pressure increases according to the adopted classification of tests. Labs report test items and achieve a score of just two out of a maximum of ten points. Typical for this tier 4, as Tier 2, the extra-analytical steps are given much more weight to assess the competence to effectively manage sample degradation. Nevertheless, QM, medical laboratories, and some professional organizations who have specialized training requirements celebrate the directive.

4.2. Data Collection Methods

This study utilized a structured questionnaire to obtain information related to the

variables under investigation. The questionnaire was divided into two main sections designed to collect data from the technical and quality managers of hospital-based medical laboratories. The first section was designed to collect data on laboratory capacity and diagnostic test output, the details of the different diagnostic tests offered, the total number of tests performed (as a monthly average), and the number of tests produced (as a monthly average) for each type of test undertaken. The second section was designed to collect data on laboratory accreditation, specifically whether or not a laboratory has an accreditation certificate, and to obtain information from laboratories' technical and quality managers regarding the existence of internal as well as external quality control procedures for different diagnostic tests undertaken in medical laboratories. Information regarding the accuracy of diagnostic tests could have been obtained from comparative experiments between internal controls and diagnostic tests, with differences between the majority of diagnostic test results and those of comparison tests used to measure test inaccuracy.

4.3. Data Analysis Techniques

Data analysis is the discovery of the unknown from the known. Hence, statistics is a set of methods that enable a person to "know" the unknown by the use of the "known." The goal of statistical tests is to make valid inferences about a population from the study of a sample. Thus, a statistical test provides a mechanism for making an estimate of how likely it is that the results from a sample can be generalized to a larger population. Parametric tests are used when specific conditions or assumptions can be made about the population distribution. Such characteristics of the parametric tests can be used by the samples characterized by a particular set of parameters. On the other hand, non-parametric tests are used when the data cannot be characterized by a particular set of parameters.

The data for this study were charted against the variables that were expected to be a determinant of the use of clinical laboratory services. Collecting the data involved the identification and recording of letters in the dataset that related to test or service outcomes, test systems located in computer modules, fact grid indications, headings, outcomes, and the medical specialties with which the tests were associated. To estimate utilization of laboratory tests in the various determinative variables for fiscal year 1984, descriptive statistics were calculated for each variable. Lists and cross-tabulations showed the frequency and proportion that a variable chose a particular outcome. Also estimated for each variable were mathematical proportions and percentages. The data were, furthermore, adjusted to the total number of completed questionnaires. This adjustment was done to show a more accurate relationship between the number of responses to the reference file and the number of responses by workspace.

5. Literature Review

In this literature review, we are not aware of any empirical study to determine the link between the accreditation of medical laboratories and the accuracy of diagnostic tests and provide evidence that could be attributable to this relationship. The study presents a unique opportunity to investigate the question of whether there is an

association between the two within-client sample results. The question of the public benefits resulting from improved accuracy in laboratory testing has been addressed in a series of policy studies. Most such studies contain highly favorable conclusions about the outcomes to be expected from laboratory regulation. The evidence used to support such a conclusion is, however, weak.

The selected studies providing empirical data on whether regulatory intervention has any substantial effect on results. No significant increases in the number of outliers were established to result from the lack of accreditation. The authors themselves highlighted the uncertainties and limitations surrounding their conclusions. These reported results can only be extended and verified by an international study such as the present research. Accurate diagnosis is a crucial part of the accurate location of the disease within a patient, through which the patient can reach the correct treatment to regain health. Accurate laboratory tests contribute to the accuracy of disease diagnosis. However, in the last two years, some notorious errors have been recognized, including cases in both our laboratories. Always, the circle of those responsible is very wide and profound, and alterations to the normative frameworks guiding laboratories are constantly under discussion.

5.1. Previous Studies on Accreditation and Accuracy

Previous studies on accreditation and accuracy focused on clinical laboratories and were predominantly qualitative in nature. Non-accredited laboratories are reported to have lower scores in terms of performance measures: reliability, test accuracy, and precision, to be defective in shortcuts and quality, and to show lower indexes in conducting quality control in comparison with those laboratories accredited by using formal methodologies. However, these criteria, instead of being considered deficiencies, should be seen as signs that lead to a distinction in the quality management level of laboratories. A one-time measurement of a laboratory's performance does not provide sufficient evidence to define its continuous quality. No relationship between quality systems and diagnostic accuracy has been proven in most of the previous studies. There were only unsystematic and anecdotal experiences, and no rigorous study determined the impact of quality systems in primary care. Accurate conclusions can only be drawn with the vast amounts of documentary evidence available about the system, and confident judgments can only be made with appropriate and adequate statistical analysis. All accreditation standards and processes should thus ideally be based on a validation study. Such a study should ideally examine each and every standard used in an accreditation system – something that has not been done before.

There have been validation studies that demonstrated the influence of both individual and external validation and the implementation of standards regarding patient outcome measures in general medical care. Accreditation of clinical laboratories reduces customer complaints. Clinical laboratories accredited by private organizations had lower post-analytic errors and pre-analytic errors, but similar analytic errors in comparison to an isolated hospital laboratory and to clinical laboratories accredited by a comparative organization. Recently, it was reported that primary care patients from accredited general practices had better technical quality results for the majority of the outcome indicators than patients in practices that were

not accredited. These better outcomes referred to the items cervical cytology, monitoring of diabetes patients, and chronic obstructive pulmonary disease. The last two items used measurements while the previously existing studies used histological and blood specimens in their analysis. Accurate conclusions can only be drawn with the vast amounts of documentary evidence available about the system, and confident judgments can only be made with appropriate and adequate statistical analysis.

6. Results

Statistical analyses were applied to discriminate between accredited and non-accredited medical laboratories in terms of the agreement with test results. The problem of verification of diagnostic test analyses could be treated as a binary classification task where positive is the laboratory that delivers test results in agreement with the results. Whichever method at hand, the results of 17 tests were statistically analyzed in the combined collective. These tests comprise the variables cholesterol, HDL cholesterol, LDL cholesterol, triglycerides, glucose, total bilirubin, direct bilirubin, AST, ALT, GGT, total protein, albumins, urea, uric acid, creatinine, and CK. The analysis attempted to determine whether the laboratory is accredited or not on the basis of values acquired by diagnostic test operations.

The results of influence consolidation for non-accredited and accredited medical laboratories were obtained using logistic regression. The probabilities were calculated by logistic transformations of the statistics developed by variance considerations in the classification tree terminal nodes, genetic algorithms, and misclassification error rate criteria. The fit was excellent, indicating no difference in the overall tendency to consolidate positive audit influences but differences in the specific supervised influence distributions of some categories. Unsaturated fats comprised the most numerous lipid insignia. These indications could be characterized as regional, tribal, or anthropogeographical. The influence consolidations could depend on many enzymes, or on the creatinine test result for renal insignia, respectively. These were the only indications with the dimensions of the influence distributions, calculated by logistic regression.

6.1. Overview of Findings

This section presents a synthesis of the impact of accreditation and ISO 15189 on financial and non-financial indicators from the six studies that we reviewed. We hypothesized that accreditation, and in particular the ISO 15189 standard, are likely to have direct and mediating effects on the financial and also non-financial performance of medical laboratories and, subsequently, of the healthcare organizations that use those laboratory results to inform their work. The medical laboratories studied represented various sectors of the market and were located in Asia, Europe, and the United States. Only five demographic and organizational influences were acknowledged and considered in the six studies reviewed. These were medical laboratory classification and size, years of experience with accreditation, test volume, and result turnaround time.

There are large differences in the reported magnitude of the influences presented

below, not only because of the type of influences but also because of other factors such as the financial performance data sources and methods of estimation employed, as well as variations in the measurement of non-financial performance. The majority of the data were collected for the pre-period and on at least a two-year basis. Consequently, the findings presented are not necessarily definitive and certainly warrant updated and replicated analysis and also new research. However, this current body of work represents a considerable basis for comparative meta-analysis. From a theoretical standpoint, accredited medical laboratories were hypothesized to deliver superior non-financial and also financial or efficiency performance.

7. Discussion

The majority of participating laboratories reported improvement in satisfaction and morale during or after the accreditation process. The most common improvements were related to organizational issues such as increased understanding, trust, and improved communication, better organized personnel, procedures, records, and systems; and increased awareness of customers and a decrease in external problems. In addition, several laboratories reported improvements in medical aspects. Laboratories in community hospitals and clinics reported more sustained effects in work quality than did laboratories in other types of services. According to staff in the laboratories, the accreditation process increased motivation, inspiration, and pride. After several years of experience with the program, staff attitudes were for the most part still positive, with increasing involvement in the field of quality management, increased team spirit, and decreased internal politics being mentioned. When it came to the main effects of the accreditation on personnel, the staff themselves considered the improved awareness, image, and appeal resulting from the permanent quality programs to be the most important.

The National Agency for Accreditation in Serbia and Montenegro increased awareness of the significance of accreditation for customers, laboratories, their staff, and managing authorities, and started significant promotional activities for recognition. It helped to establish reliable accrediting infrastructure, to create surrounding conditions supporting project aims, to prepare potential customers for accreditation, and to familiarize the market with accreditation. It has accredited by-laws, as well as available human and material resources. While evaluating the influence of upgrading and disseminating human tissues, it observed customer processes. A price list approved by the Council of the National Agency for Accreditation of Serbia was also used for budget preparation. Accreditation leads to customer satisfaction with laboratory services. A guide on the importance of accredited laboratories and sanitary-hygienically correct working methods of sanitary services, and a guide for producers, importers, subject officials, and managing authorities, supports the Council's laboratory activities. Once national accreditation benchmark standards were met, laboratories proved independent.

The managers who were apprehensive at the beginning of the program perceived improved staff motivation and prospects. After the first periodic audits, the manager of laboratory four was very concerned primarily about applicants' results. The visible people-related benefits of the program were staff self-confidence, motivation, and

satisfaction; the other benefits were professional remuneration, a clear structure of duty and professional responsibility, and recognition in the community and among customers. Laboratory work focused on continuous quality control and involvement in administrative tasks, work organization, and objective public institutions. A few managers of participating laboratories left employment; most completed the program and remained satisfied. The vacancies were offered to highly qualified employees. Due to a high level of competition, the selection process has represented a problem. The international participants are encouraging all the laboratories to maintain their quality-oriented attitude. They believe that the exchange of experience related to accreditation and international relations will have positive effects on local normative acts, which have lagged behind modern practices. The cooperation organized by the employer and funded by the employer has focused on humanitarian activities and building a team. They discern a genuine interest in the program, though it has taken place in a setting of positive countrywide development trends for the encouraged market position.

7.1. Interpretation of Results

In Table 7, the results of tests carried out in laboratories with and without a certificate are compared with the results of a reference method. The ideal index of laboratory test accuracy is sensitivity. This shows the probability of receiving a positive test result when the condition actually exists. This should be as high as possible (ideally, equal to 1) in tests for establishing a diagnosis. Therefore, the higher the sensitivity, the more reliable the results of the study being carried out. The data in this study show that in facilities that are not certified, only 36.7% of the necessary positive results are obtained. In laboratories with a certificate, the sensitivity is much higher – 83.6%. The diagnostic accuracy of the test can be determined by sensitivity and by specificity. Sensitivity is the ratio of the number of true positive test results to the number of false negative and true positive results. The higher the value of this index, the more reliable the results of the study being carried out. Special indications of the results of laboratories are used in making decisions regarding appropriate patient management. The diagnostic accuracy of the test can be determined by sensitivity and by specificity. Sensitivity is the ratio of the number of true positive test results to the number of false negative and true positive results. The higher the value of this index, the more reliable the results of the study being carried out. Data from the study show that in facilities that are not certified, only 36.7% of the necessary positive results are obtained. In laboratories with a certificate, the sensitivity is much higher – 83.6%.

7.2. Implications for Practice

It was suggested that schemes should give some thought to integrating quality control testing within the accreditation process of participating laboratories. Schemes in general should also think about ways of improving the administrative, technical, and communication skills of microbiology laboratory staff. The laboratories that participated in this study appeared to come from diverse agricultural and industrial communities, so the operational performance of the received negative samples could still quite possibly be challenged and therefore warrants continued investigation. The high percentage of false negative results recorded during the course of this study

points to the necessity for increasing awareness and maintaining vigilance and a high index of suspicion when working in cross-border microbiology control schemes. Results from this study further suggest that training and continuing education programs are needed to increase the quality of the predictably very important work performed in the laboratories that receive these samples. There may be value in an exchange visit of participating laboratory management on an annual basis. Cost sharing may be another way for schemes to improve the accuracy of their diagnostic testing component. In order to achieve a significant reduction in the false negative rate for diagnostic tests performed in the participating laboratories, it is essential that laboratories use effective quality measures to monitor and improve the sensitivity of technical assays conducted. The examination of the overall approach to the design, conduct, and evaluation of microbiology diagnostic tests in the sending laboratories may benefit all. It emerges that the study raises crucial issues of public health risk and underscores various inadequacies in the practice of screening and testing for important pathogenic microbial entities. Mandatory proficiency testing of national laboratories in recipient countries by scheme sending laboratories might assist in preempting these challenges. The study also provides clues as to how laboratory work on imported samples could be improved. Over a significant period of time, research study findings may suggest a complete reorganization of this phase of international trade control procedures. System-wide transitions are typically brought about by a phased approach. Continued development and refinement of internal quality control measures are essential for the satisfactory performance of all microbiology laboratories.

8. Conclusion and Future Directions

Patient care undergoes a significant trust especially in the area of pathology due to the inability of the patient to appreciate the quality of the tests. The increase in demand for health care services from pathology laboratories increased the need for regulation, and thus accreditation came into existence. This is achieved through conformation to standards or collaboration among participating laboratories to establish a quality process that is acceptable. The underlying objectives of accreditation are far reaching. One of the many benefits of establishing a quality process in the clinical chemistry laboratory is accuracy. This is usually expressed as the percentage bias at a predefined time post analytical and concept of accuracy including many other entities in the medical laboratory has attracted the attention of regulatory agencies. Zero bias is very difficult to achieve and this has posed a challenge to participating laboratories to narrow the existing gap by enhancing the accuracy of their test results. The financial implications of reference bias being zero are far reaching and puts more burden on the patient. Also, recently clinicians have questioned the cost-effectiveness of multiplex testing. Accurate diagnostic tests are essential for effective medical problem-solving. Zero bias in medical laboratory has a cost and strategic plan, the must be put in place for the responders to maintain a role in addressing the increasing demand for their services.

8.1. Summary of Key Findings

Accurate medical diagnostic tests are fundamental to standard medical care. Indeed,

tests are an integral part of clinical decision-making. However, empirical reports suggest that a proportion of tests provided by many hospitals and free-standing medical laboratories are incorrect and that a major type of error is the production of positive results when in reality the correct diagnosis for a diseased patient is negative. The purpose of this chapter is to explore the hypothesis that full compliance by a medical laboratory with both the letter and spirit of its precision-based accreditation standards can reduce the proportion of incorrect test results. This hypothesis applies even where both the precision-based standards and the accreditation itself are by design silent about, and independent of, the accuracy of the test's calibration and reference intervals.

The data set consists of repeated verifications of test results for a single analyte by diagnostic tests with two different reference standards. The results suggest that both false positive results and analytical nonconformities can be minimized by full compliance with precision-based new and more stringent standards, on-site assessments, and adherence to basic principles of fundamental measurement.

8.2. Recommendations for Future Research

It is likely that the fallacy logic model could be applied to the accuracy of diagnostic tests related to the accreditation of medical laboratories in non-OECD countries, with a focus on the overall health system in which the medical laboratory operates, and local variables such as the awareness of stakeholders about the necessity and goals of laboratory accreditation. In addition to the cost associated with obtaining and maintaining laboratory accreditation, the accreditation model, and the variables applied in the retrofitting theoretical model, a sequential methodology that contemplates the calibration of models of nested binary regression should be used, considering the time that the organization has operated with the accreditation, as well as the standard parameters for the assessment of the laboratory in the health system, compliance with this standard, and agreement between the accuracy of the tests and their fulfillment by the accredited laboratory.

Additional variables should also be studied to enable replication of the arguments identified, pointed out as extremely important by the revised model, as well as the use of mixed methodologies that allow the specification of the mechanisms analyzed and statistical findings. Since there are logistical, cultural, and political differences between health systems, the operationalization of the methodology proposed in this research should be widely discussed, recalling the limitations about the ecological point of view, to recognize causal relationships between medical laboratories and the health system, especially due to the general lack of regulatory mechanisms for laboratory tests.

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