Perspective

ISO 15189 accreditation and competence: a new opportunity for laboratory medicine

Laura Sciacovelli[1], Ada Aita[1,2], Andrea Padoan[1,2], Giorgia Antonelli[1,2], Mario Plebani[1,2]

[1]Department of Laboratory Medicine, [2]Department of Medicine-DIMED, Padua University School of Medicine, Padua, Italy

Correspondence to: Laura Sciacovelli. Department of Laboratory Medicine, Padua University School of Medicine, Via Gistiniani 2, 35128 Padova, Italy. Email: laura.sciacovelli@aopd.veneto.it.

Abstract: The International Standard Organization (ISO) 15189 accreditation has raised new enthusiasm among laboratory professionals. On the one hand, it satisfies the desire to undertake a pathway attesting the high degree of quality of laboratory performance measured according to the important role of Laboratory Medicine throughout patient care. On the other hand, it allows demonstrating how the competence of each staff member produces a great impact on the level of achieved performance. However, laboratory staff must recognize that application of ISO 15189 needs great commitment in terms of both time and efforts but, before all, in terms of ability to express competence. The application of ISO 15189 is needed for collecting experiences from different laboratories and identifying the most suitable approaches to comply with requirements and oversee challenges. A close cooperation among national Scientific Societies, as expression of medical laboratories, manufacturers of in vitro diagnostic medical devices (IVD) and national Accreditation Body is needed to guarantee success of ISO 15189 Accreditation.

Keywords: Accreditation; laboratory performance; competence; International Standard Organization (ISO) 15189; conformity

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Introduction

The achievement of accreditation complying with the International Standard Organization (ISO) 15189 in the world of laboratory medicine lights up the hopes of laboratory professionals about the possibility to demonstrate the importance of their role in providing safety care and improved outcomes (1,2).

The International Standard ISO 15189 is the gold standard for accreditation of medical laboratories, covering both management and technical requirements needed for assessing the competence of the personnel (3). Therefore, the ISO 15189 accreditation is an assurance that the laboratory has been assessed against internationally recognized standards aimed to prove the existence of a quality system, technical competence, and that the personnel is actually proficient to generate technically valid results and suitable information for the intended use of each test. Each country has its own national accreditation body, which is responsible for granting accreditation and operates according to ISO 17011, the International Standard for accreditation bodies (4).

An increasing number of medical laboratories are voluntarily undertaking a pathway towards accreditation, so ensuring practice and professional competence according to the principle of Laboratory Best Practice, and to increase confidence in laboratory testing by all stakeholders, so namely including patients and clinicians.

In order to comply with the ISO 15189 requirements, a strong involvement of laboratory professionals is needed to understand the best practice needed for satisfying the requirements according to availability of current technology and methodology, scientific documents, but also time and costs constraints. The competence of laboratory staff can be expressed through different domains, i.e., clinical, scientific, technical and also entails communication, management leadership, professional autonomy and accountability.

Nevertheless, the effectiveness of the accreditation process depends on a deep knowledge about the rationale beneath ISO 15189, the competence of the auditors performing the visit, the management of accreditation process by the accreditation body and the contribution of manufacturers of *in-vitro* diagnostic medical devices (IVD).

The core of the medical laboratory accreditation

The introduction of the International Standard ISO 15189 has moved the core of accreditation from the process itself to laboratory professional competence. This means that processes, managed within a quality system, are tools through which competence can be truly expressed.

The technical and clinical competence is based on a quality system (in terms of definition of objectives, recording documents, standard operating procedures, quality assurance tools, etc.), complying with the ISO 15189 management requirements, to emphasize the degree of compliance with the best laboratory practice for ensuring the better patient outcome.

A new prospective needs to be heralded in the accreditation process. All laboratories should be agreed on a unique objective: the laboratory information, resulting from examination procedures, needs to be ultimately appropriate and effective for driving or influencing care pathways. The ISO 15189 standard requires, in several part of the document, the conformity in relation to the intended purpose of each test. For example, it instructs laboratory staff to assess the suitability of performance characteristics of the examination procedures and whether possible limitations can be managed by the laboratory, so that a negative impact on patient outcome can be prevented.

It is hence crucial that the laboratory staff clearly acknowledges its role and provides evidence of work, not only in relation to (I) what criteria or procedures are followed, (II) how the procedures are carried out, (III) what level of adequateness the quality assurance tools have, (IV) what performance is achieved with the examination procedures, but also (V) how choices are integrated abreast of progress of medical profession (knowledge of clinical guidelines, for example) and technology or methodology commercially available. It is therefore a much broader perspective around the issue of laboratory quality.

Quality systems and competence

Before introduction of ISO 15189, other International Standards have been used by clinical laboratories for certification or accreditation. The last revision of the ISO 9001, issued in the 2015, impresses an assessment of service effectiveness, but it could yet be seen quite apart from the real world scenario of healthcare (5). In fact, when appropriate and strategic objectives do not identify the real setting of Laboratory Medicine within the entire health care industry, the effectiveness of laboratory information cannot be directly translated to measure patient outcome.

Conversely, the ISO 17025 accreditation demonstrates that the laboratory can operate with a quality management system, is technically competent and is capable to generate technically valid results (6). However, the evaluation of performance characteristics does not include considerations about the intended use of the test and there is no mention about pre- and post analytical issues. For these reasons the earlier application of ISO 9001 and ISO 17025 in medical laboratories at an international level has clearly demonstrated their unsuitability for Laboratory Medicine, a finding that has then prompted the development of the ensuing ISO 15189.

The peculiarities of the ISO 15189 are the ideal premises for its utility in medical laboratories. This Standard requires, for example, implementation of criteria and procedures to assure appropriateness of test request, or how laboratory guarantees its effective contribution to result interpretation, and how concordance of interpretation among different physicians can be granted. All these examples require specific knowledge on how the specific test result can impact its clinical use and of factors that can affect the quality of data. Beyond medical skills, competence of all the different professionals working in the laboratory (e.g., technicians, nurses, biologists, chemists) is needed. In fact, the evaluation of analytical interference and performance characteristics, the estimation of measurement uncertainty, the choice of an alternative approach for External Quality Assessment Schemes (EQAS) when specific materials are commercially unavailable, are activities that can also be managed by non-medical graduated staff. The calibration and verification of pipettes (7), the procedures for instrument maintenance or validation of Internal Quality Control (IQC) are examples of practical activities where technicians' competence can be enhanced. Similarly, decreasing unsuitable samples after establishing an accurate blood collection procedure demonstrates good nurses' skills.

Pragmatic vision

The skills of staff are very important for application of

official guidelines and recommendations. The suggestions of these documents comply with unquestionable criteria and rigorous activities, but are often difficult to be applied to the ample armamentarium of tests (for inherent features of the analytes), methods and biological fluids and, moreover, they often need additional work and extra expenditures. A pragmatic approach assuring conformity to requirements facilitates the application of procedures without affecting costs but, above all, can guarantee patient safety. To ensure that a pragmatic approach is suitable and effective, all relevant documents and skill in various activities should be acknowledged, so identifying all possible drawbacks in daily use.

Although some suggestions are already available in the current scientific literature (8-11), laboratories should undertake the accreditation pathway for sharing additional experiences, stimulating discussion and promoting the publication of consensus documents describing the best practical activities.

The scope of accreditation

Another important aspect concerns choosing the scope of ISO 15189 accreditation. Each test, independently from nature or technology, can variably impact clinical outcome and patient safety. Therefore, accreditation of clinical laboratories should involve the largest possible number of tests performed by the laboratory. In the first release of the ISO 15189, accreditation was based on so called "fixed scope" needing evaluation of competence for every single test included in the accreditation application. This approach was not well received by many medical laboratories, since the competence is often very specific of some diagnostic areas. Therefore, the diffusion of ISO 15189 accreditation has not been successful in some countries (e.g., Italy). The Accreditation with "flexible scope" seems more appropriate for the medical laboratories setting, because it is based on accrediting all tests with the same characteristics (diagnostic discipline, technology, method, type of samples, etc.) and belonging to the same group of tests previously assessed and then accredited (12,13).

The accreditation with "flexible scope" is a kind of trust from the Accreditation Body, so that laboratory professionals have an even bigger responsibility. Competence and compliance with requirements should hence be guaranteed for all tests added to the list, and which will not be verified by the auditors until the next accreditation/surveillance visit.

Training of laboratory staff

The appropriate training of laboratory staff is the first step for introducing accreditation. This clearly entails acknowledging the importance of laboratory medicine in health care and the certainty that accurate results are provided to clinicians. However, evaluation and continuous monitoring of the entire process is needed to ensure appropriateness of criteria and procedures that should guarantee the effective contribution of tests results to patient care. The extra-analytical phases need to be careful investigated for identifying all possible solutions for decreasing the risk of errors. The intra-analytical phase needs to be continuously monitored to achieve increasingly accurate performance.

The training of the staff should be scheduled in two steps. The former, in which all ISO 15189 requirements are discussed for understanding and acknowledging the rationale beneath accreditation. The latter step, managed as on-the-job training, in which all staff is involved through technical briefing according to the following items:

(I) reading and interpretation of each requirement and consensual discussion of criteria and procedures, verification of compliance with requirements and according to updated and approved guidelines and recommendations;
(II) collection of proposals for improving the degree of conformity with requirements and their evaluation according to appropriateness and feasibility;
(III) testing new criteria and/or procedures, and introduction of alternatives.

The involvement of all staff, through an on-the-job training, is crucial for the success of accreditation, thus allowing the staff to be an active actor, know the peculiarities of work according to the progress of the State-of-the-Art and stimulate the search for updated and more suitable practices. Receiving accreditation obviously raises personnel gratification since the active involvement has helped acknowledging the significance of accreditation and the actual appreciation of their competence.

The audit team

The role of the audit team is assessing whether the laboratory can judge the suitability of examination procedures and the validity of results according to a patient-centred perspective, along with awareness of need to operate in compliance with requirements of quality and competence. Therefore, the role of the auditors is not

simple, in that it needs a deep competence of the specific diagnostic area to be examined. Only practical experience allows understanding the possible challenges of a specific activity, as either concerning quality performances or organization aspects.

The Accreditation Body plays a pivotal role for accurately educating and training the auditors. The training needs to be focused on procedures and on the approach of the audit but, before all, on how the quality level of the laboratory should be emphasized, not only according to requirements conformity, but also concerning improvement initiatives and projects, which should be clearly seen as an added value. For preventing demotivation of laboratory professionals, the Accreditation Body should identify a strategy highlighting different levels of achieving compliance to requirements. These different levels should be identified according to criteria, procedures and quality specifications in use by the laboratory, so that laboratories committed to identify strategies, criteria, and more ambitious procedures will not be penalized compared to other facilities undertaking conventional and obvious choices which do not actively contribute to the progress of our profession.

IVD manufacturers

The ISO 15189 requires verifying the local validation of all the examination procedures. The information of IVD manufactures concerning the examination procedures are hence important for being used as a benchmark. When the manufacturers' data are incomplete or unsuitable, or have been obtained with unclear procedures, the laboratory staff may found it difficult to verify or even understand the information. The laboratory professionals shall hence be able to clearly evaluate manufacturers' information usually contained in the technical (package) insert. In particular they need to establish (I) the quality specifications for each test according to its inherent peculiarities, (II) the criteria of adequateness used for establishing performance characteristics of examination procedures during validation, (III) stringent quality specifications needed for purchasing analyzers and reagents, so guarantying the availability of diagnostic systems with the highest possible metrological traceability and the most accurate information about performance characteristics of examination procedures derived from official documents and guidelines.

Therefore, the role of IVD manufacturers is essential in the accreditation process, since it will support the laboratory with technical advice and high quality products.

Conclusions

At the down of the third millennium it seems now unquestionable that laboratories professionals are asked to demonstrate the high level of performance of their service, especially related to patient outcome. The competence of all laboratory staff in managing the entire testing process is an essential aspect for achieving this goal. The ISO 15189 Accreditation has been relatively well accepted by the laboratory personnel, because it allows implementing a system complying with requirements of an international approved standard, designed around the specific characteristics of Laboratory Medicine. First and foremost, accreditation also allows stimulating the implementation of a competence level that should guarantee effective patient management. However some conditions need to be fulfilled, such as (I) the laboratory should pursue accreditation for the largest possible number of tests provided, (II) the entire laboratory staff should be trained on the essential aspects underlying the rationale of accreditation, (III) the auditor team should have a high level of competence allowing the assessment of all tests under accreditation and (IV) the Accreditation Body should plan specific training of auditors on procedures used during the audit, so that a harmonized behaviour can be assured, avoiding that different approaches can have an impact on evaluation and definition of achievement conformity level, and (V) the Accreditation Body should develop and implement a system allowing that the laboratory stakeholders (i.e., patients and clinicians) have a clear understanding of the different types of laboratories according to the services offered.

The long journey toward the ISO 15189 accreditation has just now started. Laboratory professionals are asked to contribute achieving full success through its application, proposing solutions to the problems and implementing staff training about both the rationale of ISO 15189 Accreditation and the suitable approach for achieving effectiveness of Accreditation (14,15).

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Footnote

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