Editorial

Uncertainty, quality, safety and accreditation in laboratory medicine

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Laboratory diagnostics is conventionally defined as a science devoted to generate clinically useful information by analysing the concentration, composition and/or structure of aminoacids, proteins, lipids, carbohydrates, nucleic acids, cells, microorganisms and other exogenous compounds (i.e., drugs or toxics) in body fluids (1). The quality of test results generation, developing through a kaleidoscope of preanalytical, analytical and postanalytical activities, is a hallmark characterizing *in vitro* diagnostic testing, both from an analytical and safety standpoint (2). The former aspect mainly concerns the assurance that test results actually reflect the clinical condition *in vivo*, whilst the latter aspect especially regards patient safety, since diagnostic errors not only derange the clinical decision making and managed care, but will also jeopardize patient safety (3).

The process of improving quality in laboratory diagnostics can be figured out as a very long and windy journey, which has now been lasting for more than 100 years and has not yet even approached the chequered flag (4,5), as reflected by the still unacceptably high vulnerability of the total testing process (6). It is unquestionable that many progresses have been made over the past decades, some of which were directly promoted by laboratory professionals whilst others were powerfully stimulated by healthcare organizations such as the World Health Organization (WHO) or the US Institute of Medicine (IOM) (3). Yet, there is still room for improvement and some viable options are already available.

Accreditation, one of the 10,000 most commonly used words in the Collins dictionary, is typically defined as a process of defining whether or not an educational qualification or institution is compliant with a given standard. This concept is somehow distinguished from that of certification, which is meant to provide confirmation of certain characteristics of objects, persons or organizations. These definitions are not so different from those endorsed by the International Organisation for Standardisation (ISO), which characterizes certification as "*a procedure by which a third party gives written assurance that a product, process or service conforms to specific requirements*" (7), while defining accreditation as "*a procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks*" (8). This apparently marginal difference is not meaningless, since the accreditation process is not limited to evaluating documentation and functioning of quality management system, but should also prove that competence and technical resources are appropriate for performing a specific activity. In a broader sense, therefore, accreditation can be granted not only when an entire process is well conducted, under control and monitored (as for certification), but also whether facility and staff have appropriate resources, competence and skill. In terms of quality improvement, accreditation should hence be seen as an important step forward towards providing quality care and safeguarding patient safety. It is a paradigm shift, entailing a journey from a concept of "meeting requirements" towards that of "performing in accordance with requirements".

Although accreditation of medical laboratories has rapidly become the paradigm of quality management in many countries around the world (9), a recent survey carried out on behalf of the European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) revealed that the percentage of the total number of accredited laboratories is dramatically heterogeneous across Europe, ranging between <1% (Albania Bosnia-Herzegovina, Bulgaria, Hungary, Italy, Slovenia and Turkey) to over 80% (Finland, Ireland, Sweden. Switzerland, and United

Table 1 Drawbacks for widespread diffusion of accreditation

Conceptual challenge of shifting from certification to accreditation
Long time needed for preparing documentation
Reorganization of activities as for the ISO 15189:2012 standard
Doubts surrounding the procedures for accreditation of special tests (i.e., molecular biology)
Understanding the underlying significance of "flexible" accreditation
Personal convincement that accreditation is an obligation and not an opportunity for quality improvement
Perception of weird, worthless or extremely complicated items in the checklist
Lack of a supranational organization providing supervising standard translation
Costs to be paid to national accreditation bodies
No prizes are awarded to accredited laboratories

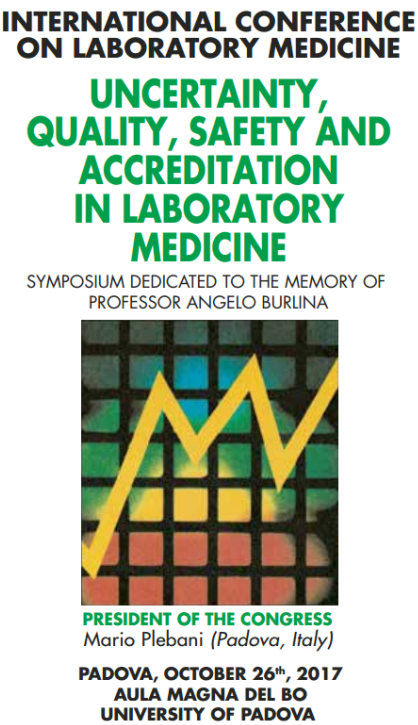

Figure 1 The International Conference of Laboratory Medicine will be held in Padova (Italy), 26 October 2017.

Kingdom) (10). In Italy, for example, the only two medical laboratories accredited with the most recent ISO 15189:2012 reference standard are those directed by the two authors of this editorial (i.e., Padova and Verona).

The reasons for which accreditation is not so popular in many countries are many and multifaceted (*Table 1*). The entire staff, thus including the director of the laboratory, must be really persuaded that accreditation is not a compelling need imposed by Governments or Hospital administration, but is instead a great opportunity for improving the quality of service. Then, personal experience shows that the entire process of laboratory accreditation is not an easy task, but needs long time and large personal commitment for document preparation and reorganization of the entire testing process, thus including extra-analytical activities, as for the ISO 15189:2,12 standard. Some doubts still surround the procedures for accreditation of special tests, such as molecular biology, whose popularity is supposed to be broadened in a predictable future dominated by personalized laboratory medicine (11). Many requirements may even appear weird, worthless or extremely complicated (e.g., the assessment of traceability and measure uncertainty) (12,13), but need to be fulfilled since the team of inspectors will go trough all the different items of the check-list during the inspection. The lack of a supranational organization supervising standard translation in the different languages is another important hurdle, since there is an inherent risk that the sense of many requirements may be lost or misinterpreted after local translation (14). In a world with limited resources, just now recovering from an unprecedented economic crisis, the cost to be paid to the national accreditation bodies by laboratories or hospital administrations is another sizeable issue. Finally, no particular prize is supposed to be awarded to the accredited laboratories, either in countries where ISO 15189 accreditation is not mandatory. Therefore, accreditation should be seen as a mostly voluntary enterprise toward increasing the quality of the service, providing better care to the patients and, last but not least, as a personal gratification for achieving enhanced professionalization.

The many important advantages, brought together with the already emphasized drawbacks, have led the way to devote the 2017 International Conference of Laboratory Medicine, which is annually held in October in Padova (Italy) since the 1994 to the actual issue of uncertainty, quality, safety and accreditation in laboratory medicine (*Figure 1*). The program of the conference will include many issues such as the global concept of quality in laboratory medicine (portrayed by laboratory

Figure 2 Prof. Mario Plebani, Department of Laboratory Medicine, University-Hospital of Padua, Padua, Italy.

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professionals, stakeholders and representatives of *in vitro* diagnostic industry), the analysis of uncertainty, total error, performance specifications, the description of pragmatic approaches for management strategies and assay verification or validation, as well as debate around specific topics of the ISO 15189 accreditation (i.e., definition, development of competence-based management, role of laboratory professionals and accreditation bodies).

We are hence delighted to give the opportunity to the readers of *Journal of Laboratory and Precision Medicine* to access the text of some of the presentations that will be delivered throughout the conference (*Figures 2,3*). We also wish to thank all the authors of these manuscripts for their valuable contribution, hoping that these articles may be of interest for the readership of the journal.

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