EFLM Symposium - Quality in clinical laboratory: a moving target

ASSESSING THE ROBUSTNESS OF THE TOTAL TESTING PROCESS WITH QUALITY INDICATORS

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Are we good enough to monitor the quality of the total testing process and ensuring patient safety? As laboratory medicine professionals, what is the best strategy to efficiently assess quality improvement through Quality Indicators (QI)? In this presentation, international guidelines and tools available for QIs monitoring will be reviewed. Based on international and national initiatives, strategies for benchmarking as well as methodology for QIs standardization and selection will be discussed.

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EVALUATION AND MONITORING OF ANALYTICAL QUALITY

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IVD manufacturers have total responsibility in terms of the traceability of marketed in vitro diagnostic medical devices (IVD-MD). This includes the provision of a quality control (QC) material as a part of the measuring system, suitable for traceability verification and alignment surveillance by end-users in daily practice. This material [to be used for the internal QC (IQC) component I] should have unbiased target values and an acceptability range corresponding to analytical performance specifications (APS) for suitable (expanded) measurement uncertainty (MU) on clinical samples. On the other hand, medical laboratories (by the IQC component II) should improve the IQC process and its judging criteria to establish a direct link between their performance, estimated as MU of provided results, and APS defined according to models recommended by the EFLM Strategic Conference in 2014, to apply corrective actions if the performance is worsening with the risk to jeopardize the clinical validity of test results. The participation to external quality assessment (EQA) programs that meet specific metrological criteria is also central to the evaluation of performance of IVD-MDs and of medical laboratories in terms of harmonization and clinical suitability of their measurements. In addition to the use of commutable materials, in this type of EQA it is necessary to assign values to them with selected reference procedures and to define and apply maximum allowable APS to substantiate the suitability of laboratory measurements in the clinical setting.

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OUTCOME MEASUREMENT AND INTEGRATION OF QUALITY MEASURES IN LABORATORY MEDICINE

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The measurement, core to the practice of medicine, drives much of the day-to-day decision making, and laboratory information plays an increasingly dominant role in modern medicine. In view of the evidence that added value underpins the ultimate quality of laboratory testing, the changing face of quality is shifting from analytical results to a global view of the TTP, including the acknowledgment and effective utilization of laboratory information. This, in turn, calls for the revision of measurements in laboratory medicine. The internal dimension of quality in laboratory medicine is monitored using the traditional indicators of analytical and extra-analytical quality (internal quality control-IQC- and external quality assessment-EQA-, which have dramatically improved quality in the last few decades. Further efforts must be made to improve both IQC and EQA programs, particularly in the metrological traceability era, as they are formidable tools for assuring accurate and reliable laboratory results. In addition, the harmonized list of quality indicators developed by the IFCC WG LEPS is a formidable tool to monitor and improve quality in extra-analytical phases. However, the value proposition in laboratory medicine calls for additional measures, pertaining to the outcome-based approach rather than to the quality of processes and procedures. Only outcome measures may provide information on the value of laboratory testing in patient management and clinical pathways, and further efforts and researches should be promoted in this field. The adoption of more valuable measures of quality will also transform the role of laboratory professionals who, rather than being faceless executors, will become process owners and, ultimately, members of diagnostic teams.

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