

GOVERNANCE OF PREANALYTICAL VARIABILITY AND ERROR DETECTION

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In the age of evidence-based medicine, results of laboratory testing are integral to the clinical decision making, to assist diagnosis, guide or monitor therapy and predict health outcomes (1). Owing to the increasing demand placed on laboratory diagnostics and the wedging pressure from cost containment policies, the primary goal is to achieve a high degree of efficiency with as little as possible influence on the quality (2).

Although accreditation, as confirmation of competence according to the EN-45001:1989, was already practiced in medical laboratories, the end of the 1990s represented the edge of the revolution in the traditional conception of quality in laboratory medicine, coinciding with the promulgation of the US federal government's Clinical Laboratory Improvement Amendments (CLIA'88) and the International Organization for Standardization (ISO) guidelines – ISO 9000. The ISO 9000–9004 were first implemented for quality management systems in 1987 and were further modified in 1994 and rewritten in the year 2000. Accordingly, quality systems designed to improve consumer confidence and safety emerged in all sectors, developed around the new key concepts of »certification« (a third-party attestation related to products, processes, systems or persons) and »accreditation« (third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks). In spite of such revolutionary changes, nearly five years from the introduction of these international standards the new ISO 15189:2003 was promulgated, containing new issues focalized on organization and quality management system, stressing the importance of evidence, document control, and control of records and clinical material in the areas of resource management, and pre-examination, examination and post-examination processes (2). Nevertheless, despite such valuable efforts to increase and optimize the global effectiveness of clinical laboratories, there is a firm perception

that the quality of laboratory performance may still have room for significant improvements.

Although there is widespread perception that most errors in medicine occur due to mishandled therapies, both medical and surgical, they can also develop within the laboratory diagnostics, especially in the most manually-intensive preanalytical steps (3–4). Since preanalytical variability exerts a strong influence on laboratory organization, healthcare expenditures and patient outcome, governance of this crucial phase of the total testing process by the reduction of uncertainty offers the greatest potential for improving total quality and enhances stakeholders' satisfaction (3–4). Most preanalytical errors result from system flaws and insufficient audit with operators involved in specimen collection/handling responsibilities (5–7). Therefore, standardization and monitoring of most, if not all, preanalytical variables would be associated with the best organizational and clinical revenues. The most reliable strategy should hence be tailored to both predict the onset of accidental events (incidents) and decrease the vulnerability of preanalytical steps (1). The mainstay and necessary preliminary step in governance of preanalytical variability is error identification (5–7). The magnitude of laboratory errors requires, however, the introduction of comprehensive reporting systems, encompassing mistakes falling within the whole diagnostic process, once a list of performance indicators has been defined on a local basis. The most suitable approach is to develop a system including also a variety of representative preanalytic performance measures, based on criteria for specimen acceptability. These mainly refer to (i) indicators of patient identification (wrong patient identification on the sample, missing patient identification on the sample, illegible identification on the sample, request unintelligible, erroneous specification of hospital unit or request type), (ii) indicators of sample collection (collection of samples at wrong time, inappropriate or inadequate container, inappropriate volume i.e. excess or deficit in the exact volume

requested to perform the analysis, inadequate ratio volume sample/anticoagulant, visible in vitro hemolysis following centrifugation, inappropriate or undue clotting, contamination from infusion route), (iii) indicators of sample transport (storage condition i.e. temperature, light exposure, samples delivery to the laboratory outside specified time, sample lost or not received in the laboratory following a physician's request, and (iv) general indicators (physician's complain on results, sample retesting, sample recollection, correction of ordered tests, results delivery to the requesting physicians outside specified time) (8).

Computer science, robotics, preanalytic platforms and full laboratory automation have led to enormous progress over the past decade, enhancing client and employee satisfaction and increasing workload capacity while maintaining a cost-effective approach. The implementation of a systematic error tracking system in the daily practice would enable considerations on specific problems and responsibilities, grant meaningful information on the local pre-analytic processes more susceptible to errors, thus providing the ideal basis for eliminating bottlenecks and flaws, and redesigning the structure of the total testing process.

References

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