Point/Counterpoint

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Total testing process: roots and state-of-the-art

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The paper by Rubinstein on the roots of the term "total testing process (TTP)" [1] provides the opportunity to reappraise the value of laboratory testing, and the role of clinical laboratories in medicine. The first formal definition of TTP, cited by Rubinstein, rightly takes into consideration "all processes and procedures…from the time the patient enters the testing system to the time action is taken by health professional to exert an effect on patient health management and outcomes" [2, 3]. This definition is closely related to the seminal concept of the "brain-to-brain loop" described by Lundberg in 1981 [4], as it considers all steps of the testing cycle from the initial clinical question to the diagnostic/therapeutic action for the individual patient (or community) on the basis of laboratory information (or rather on the basis of all available clinical information, including laboratory data). This patient-centered definition represents a unique and valuable framework for assessing the quality of laboratory testing, and addressing initiatives designed to reduce diagnostic errors, including the adoption and monitoring of quality indicators in intra- and extra-analytical phases of the testing cycle [5, 6]. However, in the last few decades, the focus has been on turning the laboratory into a mega-factory business through consolidation of analytical processes in high-volume "core laboratories" aiming to optimize productivity, decrease cost per test and improve internal efficiency [7]. The delivery of laboratory services has thus been designed and executed in individual silos managed according to internal performance metrics "that match the laboratory discipline itself rather than the products of services to improve clinical pathways, clinical and economic outcomes, and patient safety" [8]. In a recently published paper, George D. Lundberg, the father of the "brain-to-brain loop" concept, emphasized the trends that have led to the commoditization of laboratory medicine, stating that "in the late 1960s into the 1970s, as a forerunner of the 'medical industrial complex', for-profit corporations entered the clinical laboratory field. They have used modern industrial management techniques and aggressive sales strategies to wrest away huge numbers and varieties of clinical lab tests from pathologist-directed hospital laboratories, and pathologist-owned private, and physician office laboratories" [9]. However, there are now several reasons for counteracting the vision of the clinical laboratory as a commodity and focusing on cost reduction through economy of scale; the drivers of this new, necessary paradigmatic change have been described and reported on [10]. Accordingly, we emphasized the need to conceive the brain-to-brain loop as a continuum from the initial test request, through all other steps to the final phase, involving the provision of information that enables appropriate action to be undertaken on the patient's behalf (diagnosis/therapy) [11]. From this viewpoint, it is of utmost importance to recognize the fundamental interrelationship between the different phases of the cycle, in particular the interdependence between the pre-analytical phase and analytical quality, and the role of the post-analytical steps in affecting the quality of the ultimate laboratory information provided. This view has led to the redefinition of the TTP as "a set of interrelated or interacting activities that transform biologic patient sample materials into laboratory results and information to ultimately assure the most appropriate clinical outcome". To restore the true value of the TTP (brain-to-brain loop), a model should be developed based on "five rights" in all phases of the cycle, thus highlighting the need for appropriate requests as well as appropriate interpretation/utilization of laboratory information in order to assure the right patient outcome [12, 13].

Using the aforementioned framework, numerous studies and publications have elucidated the nature of errors in laboratory testing by exploring the initial and final steps of the testing process, which have been classified as "pre-pre-analytical" and "post-post-analytical" phases [14–16]. In particular, "exploration of the initial steps of the procedures, usually performed neither in the clinical laboratory, nor, at least in part, under the control

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of the laboratory personnel" [17], has led to an improved understanding of the causes of, and mechanisms underlying, most pre-analytical errors [18]. Again, in the final steps of the loop, a delayed acknowledgment of laboratory reports, as well erroneous interpretation, follow-up and documentation of laboratory data were found to be responsible for a high percentage of errors in various clinical settings [19]. The framework described is thus consistent with the recommendation released by the International Organization for Standardization in a Technical Specification (ISO/TS 22367), which defines laboratory error as "*failure of planned action to be completed as intended, or use a wrong plan to achieve an aim, occurring at any part of the laboratory cycle, from ordering examinations to reporting results and appropriately interpreting and reacting to them*" [20]. Therefore, the reappraisal of the roots of the definition of the TTP represents a unique opportunity to re-evaluate the origins and true scopes of laboratory testing, and to restore the role of medical laboratories, which must provide essential clinical services, be well integrated in diagnostic-therapeutic pathways, and offer invaluable information in predicting susceptibility to disease, thus enabling prevention and early diagnosis of diseases. This information, furthermore, is the key to establishing the patients' prognosis and providing personalized treatment. In addition, this strategy should be seen as crucial to paving the way for renewed efforts to suitably educate new laboratory professionals in playing their role as key members of diagnostic management teams.

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