Editorial

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Point of care testing: evolving scenarios and innovative perspectives

Rapid point-of-care testing (POCT) for blood gas analysis, glucose, electrolytes, prothrombin time and other parameters including cardiac biomarkers has been available for a long time and has now become a rather ordinary diagnostic tool worldwide.

By nature, POCT is a disruptive solution since it permits the rapid delivery of laboratory information at the point of need, using small amounts of sample, and most typically with no need for blood centrifugation. The steady increase in availability of POCT instrumentation of different sizes and destinations of use has contributed to increased concerns about the quality of test results. Potential problems have been described throughout the testing process, and the connection between patient safety and POCT appears at the intersection of technical limitations, rapid availability of results and the immediate therapeutic implications that are allowed by this type of testing [1]. Errors in POCT are relatively common, and their frequency is amplified by incoherent legislation, scarce focus or compliance on quality assurance issues, and insufficient training of personnel outside the clinical laboratory [2–4].

The debate around the clinical effectiveness of POCT continues to grow, and it is magnified even more by the article of Pecoraro et al. [5] that appears in this issue of the journal. The authors reviewed 85 studies for five POCT instruments (i.e., neonatal bilirubin, procalcitonin, intraoperative parathyroid hormone, troponin and blood gas analysis) and concluded that, although this type of testing has the potential to generate favorable outcomes, additional evidence is needed before we can definitely establish whether or not POCT is really useful to the clinical decision-making process across different healthcare settings. Another article, recently published in the New England Journal of Medicine [6], has depicted a different scenario, concluding that POCT is increasingly being used especially in certain areas of limited resources for disease identification, prognostication and therapeutic monitoring. Even more importantly, it is also underscored that investments in this field of diagnostics are now starting to improve patient care. As frequently occurs in science and medicine, the truth probably lies somewhere in between these two apparently conflicting perspectives.

The unarguable premise is that expansion of healthcare services is typically associated with an increased demand for diagnostic tests that may support screening, diagnosis, prognostication and therapeutic monitoring of human pathologies [7]. Under certain perspectives, classic diagnostic technologies may not be suited for meeting these expanded testing needs, since traditional laboratory testing requires complex infrastructures, controlled environment (e.g., temperature and humidity), skilled technicians and stable supplies (e.g., spare materials, electricity and water), but several of these aspects are not always available, especially in nonurban areas and in those areas plagued by natural disasters [8, 9]. Laboratory testing is typically performed in remote laboratories, and this places a substantial economical burden on the healthcare system, may be inconvenient for some patients and leaves a large number of patients undiagnosed after leaving the facility [6].

It is undeniable that the new generations of POCT, which are capable of targeting multiple biological pathways, include accurate biomarkers (e.g., nucleic acids and cell-surface markers) and take advantage of improvements in nanotechnology, microfluidics and wireless connection, which may produce a substantial and favorable impact on healthcare [10]. These devices not only enable a faster workup in the clinics but also, even more interestingly, allow reliable home-based and self-testing, even if we would all agree that additional evidence should be provided to definitely establish whether the appropriate use of POCT technology will really improve clinical outcomes for individual patients and communities, as highlighted by Jani and Peter [6].

In particular, normative bodies should provide recommendations on the most suitable approach for evaluating effective clinical needs, on the appropriate use of this technology (including guidance to ensure quality, avoidance of risk for patient safety, benefits and cost-effectiveness evaluation), on the policy for acquisition of the most suitable product according to the healthcare setting and
the intended use, on training of personnel and, last but not least, on where and how new technologies should be deployed in relation to conventional testing and laboratory facilities. The implementation of POCT should also generate tangible changes in clinical pathways and ameliorate patient management in the clinics or outside the hospitals, so that the availability of faster laboratory results can translate into more efficient diagnosis or treatment [11]. It should be further emphasized, in fact, that the availability of rapid results is only effective when this is associated with a better clinical decision-making, but up to now this target still seems unmet, as speculated by Pecoraro et al. [5]. The next generation of POCT should also be developed around the concept of total quality of diagnostic testing and thereby be characterized by improved analytical effectiveness [12], include appropriate quality control and assurance management [13], and provide systematic checks or flags in the presence of major interferences [14–16]. This instrumentation should also be specifically designed to face extreme environmental conditions, operate in the hands of inexperienced personnel and provide – whenever possible – expert systems for real-time decision support.

Evolving scenarios are disclosing innovative perspectives for POCT. Laboratory professionals should hence acknowledge that this technology represents a unique opportunity for guidance with and governance of the entire testing process, not only within but also outside the traditional laboratory. To provide clinical effectiveness, some essential criteria should be fulfilled, starting from appropriateness in test request, moving to analytical accuracy and concluding with the timeliness and effective utilization of laboratory data in patient management [17].

Ensuring benefits to patient health must be the priority for all areas of in vitro diagnostics, thus including POCT. Timeliness is one component of test evaluation, but does not capture the impact of tests on patients. The evidence that POCT “does work” is not an evidence that it is cost-effective, safe and that it really improves the clinical decision-making process and patient health. As recently highlighted by Ferrante di Ruffano et al. [18], the definition of whether or not a diagnostic test, including POCT, will change health outcomes requires a thoughtful assessment, as part of a broader management strategy. We conclude with a paraphrase of W. Edwards Deming: In God we trust; all others, including POCT, must bring data.

Conflict of interest statement

Authors’ conflict of interest disclosure: The authors stated that there are no conflicts of interest regarding the publication of this article.

Research funding: None declared.

Employment or leadership: None declared.

Honorarium: None declared.

References


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