



Does POCT reduce the risk of error in laboratory testing?

Mario Plebani*

Department of Laboratory Medicine, University-Hospital of Padova, Via Giustiniani, 2, 35128 Padova, Italy

ARTICLE INFO

Article history:

Received 9 March 2009

Accepted 10 March 2009

Available online 17 March 2009

Keywords:

Point-of-care testing

Errors

Patient safety

Total testing process

Latent condition for error

Turn-around time

ABSTRACT

Point-of-care testing (POCT), the fastest growing segment of the current clinical laboratory testing market, is a rapid means for providing test results in different clinical settings. In theory, this tool eliminates some of the more problematic steps in the testing process, including specimen transport and result distribution. However, POCT has created new challenges, and sources of potential errors; moreover, while the upsurge in its use has generated concerns regarding the quality of test results, few data are available in the literature on errors with POCT. Nor are data available for the evaluation of errors, and the risk of errors in POCT based on all steps in the entire testing process, including test requesting and result utilization. According to a modified Kost model, which takes into account all steps of the testing process and latent conditions for error, POCT reduces errors and the risk of error in only a few steps of the testing process. There is therefore an urgent need for an evaluation of errors and risks of error in POCT that is based on the entire testing process and uses well-designed studies aiming to improve clinical outcomes and increase patient safety.

© 2009 Elsevier B.V. All rights reserved.

1. Introduction

The term “point-of-care testing” (POCT) first appeared in literature in 1994 and, 1 year later, a rapid and widespread increase was seen in the number of publications focusing on its use, and the diffusion of POCT methods described in literature [1]. Today, the implications of POCT are recognized and understood by virtually all those working in the healthcare setting. Currently, one in four tests is conducted at the site of patient care, and POCT is increasing at 12%/year. It is envisaged that, at this rate, it will account for nearly half of all *in vitro* testing conducted in the forthcoming decade [2].

POCT has been defined by numerous authors, but an effective common denominator for the myriad of definitions is: *patient specimens assayed at or near the patient with the assumption that test results will be available instantly or in a very short timeframe to assist caregivers with immediate diagnosis and/or clinical intervention* [3]. The advent of rapid POCT diagnostics has made it possible to perform testing in the nursing unit, at the patient's bedside and in the outpatients' clinic; patient self-testing can also be achieved in the home, an ambulance, helicopter or cruise ship. POCT devices are utilized by the military and have even been housed in space shuttles [4].

The rapid increase in both the use of POCT and the variety of tests currently available with POC technologies has, however, given rise to concern about the quality and risks of POCT itself. Home blood glucose testing devices account for the largest number of complaints filed with the Food and Drug Administration (FDA) for any medical device, with

>3200 incidents, including 16 deaths [5,6]. Poorly maintained urinometers and blood gas analyzers, carried from one patient room to another, can be reservoirs of infection for nosocomial and antibiotic-resistant organisms [7,8] and blood glucose testing devices have been linked to the transmission of hepatitis B infection to patients in nursing homes in the US [9]. Despite the illusion of simplicity, in practice POCT devices can compromise quality of care and patient safety [10]. There is therefore an urgent need to accurately evaluate not only the potential benefits of POCT, but also the risks that it incurs. While some benefits of POCT are evident, it has repeatedly been found that the mere transfer of testing, from a central laboratory to the point of care, cannot guarantee improved clinical outcomes [11–13].

2. Sources of POCT error

Current data on the frequency and types of laboratory errors [14,15] and the importance of the total testing process (TTP) as the right framework for patient safety in laboratory medicine [16,17] have prompted laboratory professionals to strive for consensus on the designation of laboratory error, the definition found being: “a defect occurring at any part of the laboratory cycle, from ordering tests to reporting results and appropriately interpreting and reacting to these”. Originally proposed by Bonini et al. [18], this definition was accepted and incorporated in the ISO technical report “Medical Laboratories. Reduction of error through risk management and continual improvement – Complementary elements” [19]. As for any type of laboratory testing, in POCT, the entire process, from deciding to order a test, to ordering, and collecting a sample, through the analytical process, to reporting and finally acting on the result, represents a combination of steps that must be considered a cohesive process or “system”. While error reduction in POCT was

* Tel.: +39 049 8212792; fax: +39 049 663240.

E-mail address: mario.plebani@unipd.it.

Table 1
Error classification in the entire POCT process.

Phases/steps in POCT process	Step-by-step defects
1. Preanalytical phase	
a. Test ordering	Appropriate/excessive/mistimed orders
b. Patient/specimen identification	Wrong patient/wrong specimen; erroneous patient/specimen information entry
c. Specimen collection	Inappropriate/inconsistent specimen type, volume, or application to testing surface/chamber
d. Specimen evaluation	Attributes compromising patient ID/collection quality not recognized
2. Analytical phase	
a. Method calibration	Omitted, non-protocol, or misentered calibration
b. Specimen/reagent interaction	Patient-related native interference, specimen-related non-target influences, specimen–reagent matrix effects
c. Result generation	Results outside method's validated range
d. Result validation	Lack of quality control and/or other performance monitors
3. Post-analytical phase	
a. Report formatting	Wrong units, reference intervals; machine output; mistaken human transmission/transcription absent or inappropriate
b. Critical value reporting	Critical results unrecognized, not brought to decision-maker's attention, not documented for retrieval
c. Other result reporting	Report communication failed/delayed; lost to retrieval
d. Report recording/retrieval	No correlation between initially generated/finally recorded result

once pursued through advances in technology aiming to eliminate analytical errors, today the emphasis must be shifted to the entire POCT process.

The patient-centered view of healthcare [20] is that the error continuum for POCT extends “from the wrong patient to the wrong sample to the wrong test to an incorrect analytical result to lack of the result documentation in the patient's chart, to the caregivers failure to properly receive and act on the test result to failing to take a long-term view of the patient's test results, and even to failing to capture test data for billing” [2].

According to Kost [21,22], a template for POCT error classification should take into account the pre-, intra-, and post-analytic steps. The Kost error classification framework has several attractive features: the separation of the TTP into three phases is intuitively comprehensible, and focuses the attention of laboratorian and non-laboratorian test operators on the need to investigate each and every step in the cycle. However, Kost's approach does not include an important pre-analytic variable: test order indication and frequency. According to recent data, failure to appropriately order diagnostic tests represents a major problem both in the ambulatory [23] and in the emergency department [24] setting. Therefore, a modified Kost framework, as illustrated in Table 1, should be used with the addition of the initial step and error category concerning the appropriate, not excessive and timed test order. Some authors have suggested that these initial steps might be grouped into a new phase, called “pre-, pre-analytic phase”, stressing that they are managed by, and are under the responsibility of, non-laboratory personnel [25]. However, particularly in the case of POCT, this taxonomy is not of major value, all other steps in the testing process being performed by non-laboratory operators.

3. Does POCT eliminate some problematic steps in the testing process?

While it is evident that the main advantage of POCT is reduced turn-around-time (TAT), some authors also suggest that further advantages include: “reduction of number of analytical errors, especially pre-analytical errors such as inappropriate sampling, inappropriate preparation or packaging, or inappropriate identification of patients” [26]. By reducing the steps required to produce laboratory results, POCT should reduce associated errors. In addition, “errors originating during transport are substantially reduced and post-analytical errors are practically totally eliminated, since results are presented directly to the caregiver” [26]. However, despite the illusion of simplicity, POCT devices are affected by several environmental and operator-related factors. Managing the pre-, intra-, and post-analytic processes is a main challenge in POCT, just as it is in centralized laboratories.

3.1. POCT and the pre-analytical phase

Table 2 illustrates the latent condition for errors and their potential reduction with POCT in the pre-analytical phase. Inappropriate, redundant, or repetitive testing cause the laboratory, and the health care system, considerable organizational and economic problems. POCT *per se* cannot reduce the rate of errors due to inappropriate, excessive and mistimed ordering, any reduction depending upon the knowledge and training of clinicians, and efforts must be made to prevent inappropriate laboratory tests and test panels being requested. Clinicians tend to order an excessive number of tests because they wish to “defend” themselves, the tests are readily available and they fear uncertainty [27]. Some POCT devices may perpetuate and even worsen the clinician's attitude toward inappropriate test requesting particularly where excessive and mistimed orders are concerned. This is the case, for example, of cardiac markers, frequently offered as POCT test panels that include at least three parameters (cardiac troponin, myoglobin and CK-MB) [28]. A body of evidence demonstrates that cardiac troponin is the marker of choice in view of both its specificity and sensitivity [29] and that other measurements not only fail to add any valuable information but can also lead to confusion and inefficiency. Nichols [10] recently demonstrated that, after revising the chest pain pathway for the management of patients with chest pain according to the National Academy of Clinical Biochemistry (NACB) Laboratory Medicine Guidelines [30], an improvement was achieved in consistency of care when fewer tests were conducted (eliminated reliance on multiple time-points in CK-MB and myoglobin) and less blood collected.

Since patient identification is a major patient safety issue in healthcare, and therefore in laboratory medicine [31], improving the accuracy of patient identification is the primary goal of the Joint Commission program [32]. However, a point-of-care operator in a busy emergency department is just as liable as a phlebotomist to confuse two patients with the same surname [33]. Likewise, specimen labelling may be a

Table 2
POCT and potential errors in the pre-analytical phase.

Latent condition for error	Potential reduction with POCT
•Inappropriate/excessive ordering	No
•Mistimed testing	No
•Patient identification	No/yes
•Specimen identification	Yes/no
•Specimen collection	No
•Specimen attributes	No

source of errors if automated features and connectivity between POCT devices and Laboratory (LIS) or Hospital (HIS) information systems are not assured. Computerized devices are available to record the date, time, operator and patient identification, and other valuable information, such as lot numbers/expiration dates. They can store and transmit results automatically to laboratory and hospital information systems, thus reducing the risks and errors associated with these pre-analytical variables. Therefore, the use of POCT calls for the careful selection of devices that not only allow fast laboratory testing, but also meet the patient's care needs, including the reduction of errors caused by the misidentification of patients and specimens.

Data from the larger studies on specimen collection, a frequently neglected issue, show that problems related to specimen collection are the main cause of pre-analytical errors or variability, including hemolyzed (54%), insufficient (21%), incorrect (13%) and clotted (5%) samples [18]. The differences between in- and outpatients are reflected by the different rates of errors occurring in the two categories (0.60% vs 0.039%, respectively); this discrepancy has been attributed to human factors, such as skill in drawing blood and the sheer volume of laboratory tests carried out for inpatients [34]. Therefore, patient care involving non-laboratory personnel appears to account for the majority of errors, particularly in the pre-analytical steps [35]; this highlights the fact that these steps have significant implications in POCT quality. In particular, specific issues regarding specimen collection for POCT focus on the differences between venous blood samples and finger stick “capillary” blood specimens when one or another other specimen type is introduced into a POCT device [36]. Moreover, the operators must consistently place the same specimen quantity onto the device's testing surface or intake chamber [37]. DuPlessis et al. have suggested that the extent of test operator training and the frequency with which a trained operator performs a test method influence the rate of specimen collection defects [37]. Regarding specimen attributes, the largest possible test volumes processed in hospital and reference clinical laboratories allow people who operate tests in these settings to appreciate population variations “in parallel” in test results, because numerous results are generated, and their quality is analyzed collectively. POCT operators cannot gain this type of experience as they simply experience patient-to-patient variation in results “in series” [33]. An interesting finding on evaluating the agreement between the measurement of potassium with POCT and laboratory analyzers concerns the different results obtained in hemolyzed samples. While venous samples sent to the laboratory are inspected and discarded if hemolysis is detected, arterial samples for POCT are not screened; they are put into the device and potassium measurement is obtained regardless, thus generating potentially unreliable results [38]. The operator's training is therefore of crucial importance in reducing errors and risks of error in the pre-analytic steps of POCT.

3.2. Analytical phase

Table 3 shows the latent conditions for errors and their potential reduction with POCT in the analytical phase. Analytical quality speci-

fications for the reliability performance characteristics of laboratory tests, particularly bias and imprecision, are prerequisites for quality management. Such quality specifications should be firmly based upon medical requirements, useable in all laboratories irrespective of size, type or location, including POCT [39]. While some may argue that in POCT speed of analysis surpasses other requirements, analytical quality is still a prerequisite for any laboratory testing activity. A more subtle problem is the issue of analytical quality specifications in relation to the intended use of the test. The same analyte should be measured for various clinical purposes, each requiring different and specific quality specifications as in, for example, glucose measurement. While commonly used glucose meters comply with quality specifications required for patient monitoring, they can be used neither for diagnosis, which depends on a single cut-off value, nor for tight glucose control in the intensive care unit [40]. In general, the analytical performance of POCT devices is as good as that seen for analysis in central laboratory for some analytes, such as electrolytes [41], while for other commonly performed tests including cholesterol and cardiac troponin, it is unsatisfactory and may translate into erroneous diagnoses and treatments [42].

The first analytic-phase opportunity for error is method calibration. In non-POCT tests, failure to calibrate, departure from manufacturers' specified calibration protocols, and clerical errors in processing of calibration data are well-known sources of errors [16], and POCT may magnify these problems, being performed by non-laboratory operators.

“Native interferences” are a serious source of errors in laboratory medicine; in particular, if present, heterophilic antibodies produce false negative or positive results in POC tests, whose endpoints are agglutination [33]. Specimen-related “non-target influences” include: a) 5% glucose solutions being infused immediately upstream from a stopcock through which a POCT sample is collected; b) heparin being introduced to keep the convenient stopcock open, thus inducing falsely abnormal coagulation tests; and c) cardiotropic and anti-dysrhythmic drugs interfering with calcium channels in hand-held chemistry devices [33]. While these interfering substances affect all laboratory tests, they are more difficult to detect in POCT, where results are immediately used for patient management. “Matrix effects”, inter-method differences in results of tests made using the same specimens, are due to systematic, rather than random, variation linked to the specimen-reagent combination; the most common effect is a difference between whole blood POCT and plasma INR produced by laboratory prothrombin time assays [43]. Errors related to result generation are clearly associated with the procedures of result validation/rejection, in particular internal quality control and external quality assessment programs. It has been underlined that traditional laboratory approaches to quality control (QC) cannot be easily adopted in POCT, because they are “tedious, time-consuming and costly” [44]. Some proposals for implementing valuable QC systems in POCT have been made, the program being tailored to target the particular POCT system. POCT instruments fall into three categories, which are: 1) “laboratory types”, 2) “cartridge based”, and 3) “strip based” [45]. According to the specific category, a QC program should be tailored to effectively control the POCT system. Likewise, experience has been described in the implementation and management of external quality assessment schemes (EQAS), specifically designed for POCT [46]. An interesting proposal, termed “Equivalent Quality Control” (EQC) has been issued in an attempt to replace the traditional analyst-driven “two external controls per day” concept with a reliance on manufacturers' built-in alternative controls [3]. In particular, the Intelligent Quality Management (IQM) has been introduced for some blood gas analyzers as an active quality process with real-time, automatic error detection, automatic correction of the systems, and automatic documentation of all corrective actions [47]. With this system, the manufacturer is responsible for assuring the quality of each patient test result and, in addition, ensures the automatic traceability and recording of reagents, quality control, calibration, and any other items.

Table 3

Latent conditions for errors and their potential reduction with POCT in the analytical phase.

Latent condition for error	Potential reduction with POCT
•Method calibration	No (increased risk)
•Patient-related “native interferences”	No (increased risk)
•Specimen-related “non-target interferences”	No (increased risk)
•Specimen-reagent combination-related “matrix effects”	No (increased risk)
•Result generation (results outside validated ranges)	No (increased risk)
•Result validation (QC)	Yes/No
•Quality assessment (EQA, PT)	No (increased risk)

Although this proposal is interesting, no consensus has been reached on the true “equivalence” of this system with classical IQ and EQA programs.

3.3. Post-analytical phase

Table 4 illustrates the latent condition for errors and potential reduction with POCT in the post-analytical phase. No improvement in report formatting is achieved with POCT, which may increase errors due to inappropriate or missed units of measure, reference intervals and other essential elements playing a role in results interpretation [48]. Defects due to inappropriate or missed units are occasions for misinterpretation, particularly in critical care situations. Vice versa, fundamental improvements in the appropriate routing and turn-around time of laboratory results are achieved by POCT.

A reduction in errors in critical value and other result reporting and documentation and report management cannot be achieved by POCT *per se*: this can be achieved only by means of an automated connection between POCT devices and electronic patient databases. According to some authors, clinically relevant reporting errors are seen “in the heart of battle”, where report defects are not detected by test consumers who are distracted from any critical assessment of results by their own craving for them. Failure to notice, report, or document critical values for subsequent reference is the post-analytic defect that POCT coordinators most often detect in emergency room settings [33]. Finally, misinterpretation cannot be reduced by POCT, which may compromise the appropriate interpretation of laboratory results if analytical quality specifications differ from those used for conventional, widely recognized laboratory tests.

3.4. Evidence of errors in POCT

While the literature on POCT abounds, few data are available on errors occurring when this technology is used. In a seminal paper by Meier et al. [49], three main sources and three amplifiers of POCT errors are identified: operator incompetence, non-adherence to procedures, and the use of uncontrolled reagent/equipment. Inconsistent regulation, rapid result availability and immediate therapeutic implications are the main amplifiers.

3.5. Source of errors

3.5.1. Operator incompetence

It was found by the examiners of the Centers for Medicare and Medicaid Services (CMS) that 19% of POCT testing personnel had neither been trained nor evaluated for the performance of assays that they carried out. In 32% of cases, the same test operators were unable to locate test instructions when asked by the observers to refer to them [50].

3.5.2. Non-adherence to procedure

In the above study, 25% of test operators failed to follow the manufacturers' instructions, and 7% did not make the necessary calibrations [50].

Table 4

The latent condition for errors and potential reduction with POCT in the post-analytical phase.

Latent condition for error	Potential reduction with POCT
•Report formatting (inappropriate/missed units, reference intervals)	No
•Routing	Yes
•Excessive turn-around time	Yes
•Misinterpretation	No
•Critical value reporting	No
•Critical value documentation	No
•Other result reporting	No
•Report management (verification/preservation, storage and retrieval)	No

3.5.3. Use of uncontrolled reagent/equipment

According to the CMS data, 32% of POCT operators failed to perform quality control, and 20% physically separated internal QC test fields from patient test fields in card format tests, irrespective of manufacturers' instructions; 6% used reagents beyond their expiry date, and kits no longer vouched for by the manufacturers [50]. Problems over storage and POCT reagents degraded by humidity, light and heat are also described [10]. Of course, imperfect reagents still provide results, the inaccuracy of which are a further source of error that are easily overlooked if appropriate quality control programs are not implemented.

3.6. Error amplifiers

3.6.1. Incoherent regulation

While scientific and professional organizations have developed and diffused valuable standards [51] and guidelines [52] for POCT, Meier and Jones found that regulatory incoherence is conducive to POCT errors, particularly in the “waived” test in the US legislation, the well known Clinical Laboratory Improvement Amendments (CLIA) [33]. Although the federal CLIA set minimum standards for the validation and quality control of laboratory tests, a separate category of simple testing, called “waived” tests was developed. According to the CLIA, when a test or a laboratory procedure is deemed CLIA waived, the test is considered simple enough- and innately accurate as long as the instructions for using the test are followed, the results will be correct and cause no harm [53]. Importantly, for test sites using waived methods, there are no requirements for trained analysts, internal quality control assessment, quality assurance programs, or external quality assessment. The three statutory attributes of waived tests not only seem to be restrictive enough to avoid errors, but can also be questioned. With the first statutory attribute, “cleared by FDA for home use”, the majority of currently waived analytes are not cleared for home use [54]. The second attribute is “so simple and accurate to perform that the likelihood of erroneous results could be negligible”. Yet, in a multi-institution study, 13% of warfarin patients were found to have been misclassified on the basis of POCT prothrombin times [55], and data for POCT blood glucose measurement were similarly misleading [56]. The third attribute “not posing reasonable risk to patient even if performed incorrectly” does not appear to be assured for the POCT prothrombin time measurement to guide medical management of patients who receive warfarin as an anticoagulant [57], or when POCT blood glucose determinations are used to guide the close control of blood glucose in intensive care unit patients [58].

Moreover, regulatory incoherence in the US has been extended to the application of QC and external quality assessment in waived POCT [49]. This problem, however, is not limited to the US: and, as recently underlined, the regulatory framework for diagnostic tests, including POCT, is weak, there being neither international standards nor agreement on what evidence is required by whom [59]. In Europe, regulation is covered by a European Directive, CE marking (Conformité Européenne), which simply certifies that a product meets basic European Union health, safety, and environmental standards. A more satisfactory framework is required for the evaluation and regulation of all laboratory tests, including POCT, and this should be achieved through collaboration at an international level. An international collaboration to develop a better framework for evaluating and regulating all laboratory tests, including POCT, is urgently required. The standards set should evaluate, in addition to analytic and clinical validity, clinical usefulness, and indicators should be provided for the analysis of the potential risks and benefits when technology is used in clinical practice [60].

3.6.2. Rapid result availability and immediate therapeutic implications

The other 2 main amplifiers, “rapid result availability” and “immediate therapeutic implications” are strictly connected and interrelated.

These sources of error, not “laboratorian” in origin, pertain to the human aspect of POCT and, above all, to result utilization by clinicians and caregivers as a part of the overall test and diagnostic process. Immediate result availability is the major advantage of POCT, and one of the most important achievements of laboratory medicine in the last decades, particularly for critical care [61]. However, although advanced technology yields results in minutes, clinical practice paradigms have not necessarily been changed and/or improved. In a recent study evaluating the opinion and practice of clinicians regarding the use of blood gas analyzers to measure potassium, it was found that 52% of clinicians wait for a laboratory confirmation, while only 48% base their clinical decisions on POCT results [62]. This confirms previously reported data demonstrating that only 34% of clinicians relied on POC tests to guide their clinical decisions [63]. These findings, which apparently contradict the role of POC tests “amplifiers” of *rapid result availability and immediate therapeutic implications*, should be interpreted as reflecting the clinicians’ need to use “barriers” to make the care system safer and to obviate adverse events. Reliability of results, may thus surpass any other considerations in terms of rapidity and immediate availability of results. This, in turn, underlines the importance of using the total testing process, including clinicians’ reactions to laboratory report, interpretation and utilization of laboratory information for patient management as the unique and valuable framework for evaluating quality and possible errors in all laboratory services, including POCT.

4. Risk management in POCT

The literature on errors in POCT is scarce despite the impressive number of papers dealing with decentralised, alternative site, and near-patient testing opportunities [1]. In addition, most available data are anecdotal. Table 5 shows the ten most frequently cited deficiencies in POCT. POCT eliminates some of the most problematic steps in the testing process, including specimen transport and result distribution, but creates other challenges from a risk management perspective [65]. There is therefore an urgent need for studies designed to evaluate possible errors and the risk of errors in all steps of the TTP, from test ordering to results utilization, including the benefits of POCT versus traditional laboratory testing in improving clinical outcomes. In the present scenario, on the other hand, there is a dramatic and unacceptable difference, a potential chasm, between the wild deregulation of POCT and the increasingly demanding and well-defined regulatory requirements imposed on laboratory services by national, international organizations (JCAHO, ISO, CAP) and governments.

Among the several proposals made to improve safety in POCT, those formulated by the National Institute of Health for the development of more reliable POC technologies [66] are designed to: a) produce robust technology; b) ensure quality of operation; c) provide resources for POC testing (staffing and reimbursement); and d) change practice to realize benefits.

The development in POCT devices should evolve into the production of devices that identify all potential sources of errors, and mitigate their

effects if they do occur. The introduction of automation in POCT should provide a valuable opportunity to achieve these aims as it allows a level of human intelligence to be transferred to automated machinery [67], devices and procedures designed so that the right and safe thing to do is the easiest thing to do, and that foreseeable violations of the right procedures can be countered by forcing functions and lockouts [68]. Another key element, connectivity, is of vital importance in POC testing, linking the laboratory and hospital information systems, and electronic patient records. Connectivity is therefore a tool of prime importance in improving some critical steps, such as patient identification, results recoding and retrieval.

In addition to technological advancements, however, further efforts are needed. In particular, since POCT depends upon the expertise of the operator, training and ongoing verification of competency are of crucial importance in reducing errors. In the US, current College of American Pathologists (CAP) and Joint Commission regulations require ongoing competency, ensured by observing the technique used, arranging written examinations, analysing quality control or specimens with known values, demonstrating maintenance, recording test results, and evaluating problem-solving skills.

It is important to bear in mind that automated and automated technologies can provide assistance, but cannot replace staff expertise in achieving appropriate test performance. A further, more complex aspect is the integration between POCT and patient care pathways. While POCT is considered a means for speedily obtaining test results, it is not an isolated process. Nor can the prompt provision of a test result guarantee improved patient outcomes. Management pathways also must change if they are to make better use of the faster result, and this can be done only through multidisciplinary translational research and teamwork.

Laboratory testing is only one component of a complex pathway of care that ultimately affects patient outcome. Improvement in only one step of the pathway cannot guarantee improved outcome unless all other aspects of the care process are addressed [10,66].

5. Conclusions

POCT has spread impressively, worldwide, its diffusion being driven by the illusion that it is simple to achieve, and that it provides test results fast (“you are sick, we are quick”); it is now the fastest growing segment of the modern clinical laboratory testing market. Yet, in the literature, data on errors in POCT are scarce, the main focus being on the analytical phase of testing. Available evidence, however, demonstrates that the total testing process is a valuable and unique framework for evaluating and reducing errors in all laboratory activities, including POCT. The probable connection between patient safety and POCT lies at the intersection of technical limitations, rapid availability, and the immediate therapeutic implications of this type of test. Using a modified Kost model that takes into account all steps of the testing process and latent conditions for error, it has been demonstrated that POCT reduces errors and risks of error only in few steps of the entire testing process. Moreover, from a risk management perspective, POCT presents other serious challenges. There is therefore an urgent need for a more careful evaluation of the errors and risks of error in POCT; this can only be achieved by considering the entire testing process, using well-designed studies aiming to improve clinical outcomes and enhance patient safety.

References

- [1] Kazmierczak S. Improving healthcare through advances in point-of-care technologies. Clin Chem Lab Med 2008;46:1–2.
- [2] Stephens EJ. Developing open standards for point-of-care connectivity. IVD Technology 1999;5:22–5.
- [3] Ehrmeyer SS, Laessig RH. Point-of-care testing, medical error, and patient safety: a 2007 assessment. Clin Chem Lab Med 2007;45:766–73.
- [4] Nichols JH. Quality in point-of-care testing. Expert Rev Mol Diagn 2003;3:89–98.
- [5] Greyson J. Quality control in patients self-monitoring of blood glucose. Diabetes Care 1993;16:1306–8.

Table 5

The 10 most frequently cited deficiencies in POCT [64].

Failure to

- 1) perform quality control testing
- 2) document QC activities
- 3) follow manufacturer's instructions explicitly
- 4) document personnel training and competency
- 5) document and take appropriate corrective action for control outliers
- 6) failure to perform proficiency testing or external quality assessment schemes
- 7) have a procedure manual for testing and result reporting
- 8) perform and document calibration verification at least every 6 months
- 9) verify accuracy for analytes not included in a PT program
- 10) provide for continuing education for testing personnel

- [6] Meadows S, Kubic M. Improving glucose monitoring for diabetics. *FDA Consum* 1990;32:5.
- [7] Kocka FE, Roemisch E, Causey WA. The urinometer as a reservoir of infectious organisms. *Am J Clin Pathol* 1977;67:106–7.
- [8] Acolet D, Ahmet Z, Houang E, et al. *Enterobacter cloacae* in a neonatal intensive care unit: account for an outbreak and its relationship to the use of third generation cephalosporins. *J Hosp Infect* 1994;28:273–86.
- [9] Webb R, Currier M, Weir J, et al. Transmission of hepatitis B among patients undergoing blood glucose monitoring in long-term facilities – Mississippi, North Carolina and Los Angeles County, California, 2003–2004. *MMWR Morb Mortal Wkly Rep* 2005;54:220–3.
- [10] Nichols JH. Point of care testing. *Clin Lab Med* 2007;27:893–908.
- [11] Kendall J, Reeves B, Clancy M. Point of care testing: randomized controlled trial of clinical outcomes. *Br Med J* 1998;316:1052–7.
- [12] Parvin CA, Lo SF, Deauser SM, Weaver LG, Levis LM, Scott MG. Impact of point-of-care testing on patient's length of stay in a large emergency department. *Clin Chem* 1996;42:711–7.
- [13] Nichols JH, Kikler TS, Dyer KL, Humbertson SK, Cooper PC, Maughan WL. Clinical outcomes of point-of-care testing in the interventional radiology and invasive cardiology setting. *Clin Chem* 2000;46:543–50.
- [14] Plebani M, Carraro P. Mistakes in a stat laboratory: types and frequency. *Clin Chem* 1997;43:1348–51.
- [15] Carraro P, Plebani M. Errors in a stat laboratory: types and frequencies 10 years later. *Clin Chem* 2007;53:1338–42.
- [16] Plebani M. Errors in clinical laboratories or errors in laboratory medicine? *Clin Chem Lab Med* 2006;44:750–9.
- [17] Plebani M. Errors in laboratory medicine and patient safety: the road ahead. *Clin Chem Lab Med* 2007;45:700–7.
- [18] Bonini P, Plebani M, Ceriotti F, Rubboli F. Errors in laboratory medicine. *Clin Chem* 2002;48:691–8.
- [19] ISO/TS 22367: 2008. Medical Laboratories. Reduction of error through risk management and continual improvement – Complementary elements.
- [20] Institute of Medicine. Crossing the quality chasm: a new health care system for the 21st century. Washington DC: National Academy Press; 2001.
- [21] Kost GJ. Preventing problems, medical errors, and biohazards in point-of-care testing. *Point of Care* 2003;2:78–88.
- [22] Kost GJ. Preventing medical errors in point-of-care testing: security, validation, safeguards, connectivity. *Arch Pathol Lab Med* 2001;125:1307–15.
- [23] Wahls TL, Cram PM. The frequency of missed test results and associated treatment delays in a highly computerized health system. *BMC Fam Pract* 2007;8:32–42.
- [24] Kachalia A, Gandhi TK, Pupolo AL, et al. Missed and delayed diagnoses in the emergency department: a study of closed malpractice claims from 4 liability insurers. *Ann Emerg Med* 2007;49:196–205.
- [25] Stroobants AK, Goldschmidt HM, Plebani M. Error budget calculations in laboratory medicine: linking the concepts of biological variation and allowable medical errors. *Clin Chim Acta* 2003;333:169–76.
- [26] Drenk NE. Point of care testing in critical care medicine: the clinician's view. *Clin Chim Acta* 2001;307:3–7.
- [27] Lundberg GD. How clinicians should use the diagnostic laboratory in a changing medical world. *Clin Chim Acta* 1999;280:3–11.
- [28] Kost GJ, Tran NK. Point-of-care testing and cardiac biomarkers: the standards of care and vision for chest pain centers. *Cardiol Clin* 2005;23:467–90.
- [29] Thygesen K, Alpert JS, White HD. Universal definition of myocardial infarction. *JACC* 2007;50:2173–95.
- [30] Wu AHB, Apple FS, Gibler WB, et al. National Academy of Clinical Biochemistry Standards of Laboratory Practice: recommendations for the use of cardiac markers in coronary artery diseases. *Clin Chem* 1999;45:1104–21.
- [31] Lippi G, Blanckaert N, Bonini P, et al. Review: causes, consequences, detection, and prevention of identification errors in laboratory diagnostics. *Clin Chem Lab Med* 2008.
- [32] Joint Commission. 2007 Laboratory Services National Patient Safety Goals. Available at: http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/07_lab_npsgs.htm. Accessed November 2008.
- [33] Jones BA, Meier FA. Patient safety in point-of-care testing. *Clin Lab Med* 2004;24:997–1022.
- [34] Plebani M, Ceriotti F, Messeri G, Ottomano C, Pansini N, Bonini P. Laboratory network of excellence: enhancing patient safety and services effectiveness. *Clin Chem Lab Med* 2006;44:150–60.
- [35] Lippi G, Guidi GC, Mattiuzzi C, Plebani M. Preanalytical variability: the dark side of the moon in laboratory testing. *Clin Chem Lab Med* 2006;44:358–65.
- [36] Skeie S, Thue G, Nerhus K, Sandberg S. Instruments for self-monitoring of blood glucose: comparisons of testing quality achieved by patients and technicians. *Clin Chem* 2002;49:994–1003.
- [37] DuPlessis M, Ubbink JB, Vermark WJH. Analytical quality of near-patient blood cholesterol and glucose determinations. *Clin Chem* 200; 46: 1085–90.
- [38] Johnston HLM, Murphy R. Agreement between an arterial blood gas analyser and a venous blood analyser in the measurement of potassium in patients in cardiac arrest. *Emerg Med J* 2005;22:267–71.
- [39] Fraser CG. Optimal analytical performance for point of care testing. *Clin Chim Acta* 2001;307:37–43.
- [40] Scott MG, Bruns DE, Boyd JC, Sacks DB. Tight glucose control in the intensive care unit: are glucose meters up to the task? *Clin Chem* 2009;55:18–20.
- [41] St John A. Benchtop instruments for point-of-care testing. In: Price CP, St John A, Hicks JM, editors. Point-of-care testing. Washington DC: AACC Press; 2004. p. 31–45.
- [42] Jaffe AS, Babuin L, Apple FS. Biomarkers in acute cardiac disease: the present and the future. *J Am Coll Cardiol* 2006;48:1–11.
- [43] Kemme MJ, Faaij RA, Schoemaker RC, Kluft C, Meijer P, Cohen AF. Disagreement between bedside and laboratory activated partial prothrombin time and international normalized ratio for various novel anticoagulants. *Blood Coagul Fibrinolysis* 2001;12:583–91.
- [44] Murphy MJ, Paterson JR. Point-of-care testing: no pain, no gain. *Q J Med* 2001;94:571–3.
- [45] Martin CL. Quality control issues in point of care testing. *Clin Biochem* 2008;29(Suppl 1):S79–82.
- [46] Wood WG, Hanke R, Meissner D, Reinauer H. Experience with an external quality assessment programme for point-of-care-testing (POCT) devices for the determination of blood glucose. *Clin Lab* 2003;49(3–4):151–9.
- [47] Toffaletti JG, McDonnell EH, Ramanathan LV, Tolnai J, Templin R, Pompa L. Validation of a quality assessment system for blood gas and electrolyte testing. *Clin Chim Acta* 2007;382:65–70.
- [48] Carraro P, Plebani M. Postanalytical errors with portable glucose meters in the hospital setting. *Clin Chim Acta* 2009;404:65–70.
- [49] Meier FA, Jones BA. Point-of-care testing error. *Arch Pathol Lab Med* 2005;129:1262–7.
- [50] Hassan D, Leneau R, Martin P, Kremann K. CMS CLIA waived/PPMP laboratory project; 2005. Available at: www.cms.hhs.gov/clia/cowppmp.asp. Accessed February 13.
- [51] ISO 22870:2006. Point-of-care testing (POCT) – Requirements for quality and competence.
- [52] The National Academy of Clinical Biochemistry. Laboratory Medicine Practice Guidelines. Evidence-Based Practice for Point-of-Care Testing. Published Guidelines. Available at: <http://www.aacc.org/members/nacb/LMPG/OnlineGuide/PublishedGuidelines/poct/Pages/default.aspx>.
- [53] Department of Health and Human Services, health care finance administration. Clinical laboratory improvement amendments of 1988, final rule. *Fed Regist*; 1992. p. 7001–288.
- [54] Over-the-counter in vitro diagnostic devices. Available at: www.fda.gov/cdrh/ode/otclist.html (last updated April 22, 2002). Accessed February 13, 2005.
- [55] Meier FA, Jones BA. Point of care coagulation testing: Q-Probes study 99-04. Northfield, Ill: College of American Pathologists; 1999.
- [56] Jones BA, Howanitz PJ, Bachner P. Bedside glucose monitoring: a College of American Pathologists Q-Probes study of the program characteristics and performance in 605 institutions. *Arch Pathol Lab Med* 1993;117:1080–7.
- [57] Ansell J, Hirsh J, Poller L, Bussey H, Jacobson A, Hyler E. The pharmacology and management of the vitamin K antagonists: the Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy. *Chet* 2004;126:2045–335.
- [58] Clement S, Braithwaite SS, Magee MF, et al. Management of diabetes and hyperglycemia in hospitals. *Diabetes Care* 2004;27:533–91.
- [59] Walley T. Evaluating laboratory diagnostic tests. *Br Med J* 2008;336:569–70.
- [60] Price CP, Christenson RH. Evaluating new diagnostic technologies: perspectives in the UK and US. *Clin Chem* 2008;54:1421–3.
- [61] Plebani M. The changing face of clinical laboratories. *Clin Chem Lab Med* 1999;37:711–7.
- [62] Josè RJP, Preller J. Near-patient testing of potassium levels using arterial blood gas analyzers: can we trust these results? *Emerg Med J* 2008;25:510–3.
- [63] Gray TA, Freedman DB, Burnett D, et al. Evidence-based practice: clinicians' use and attitude to near patient testing in hospitals. *J Clin Pathol* 1996;49:903–8.
- [64] Demers LM. Regulatory issues in point of care testing. In: Price CP, Hicks JM, editors. Point of care testing. Washington DC: AACC Press; 1999. p. 102–5.
- [65] Dighe AS, Makar RS, Lewandrowski KB. Medicolegal liability in laboratory medicine. *Semin Diagn Pathol* 2007;24:98–107.
- [66] National Institute of Biomedical Imaging and Bioengineering/National Heart, Lung, and Blood Institute/National Science Foundation Workshop Faculty, Price CP, Kricka LJ. Improving healthcare accessibility through point-of-care technologies. *Clin Chem* 2007;53:1665–75.
- [67] Autonomation. Strategos Ebooks. Available from <http://www.strategosinc.com/autonomation.htm>; Accessed April 20, 2008.
- [68] Ohno T. Toyota production system: beyond large scale production. Portland, Ore: Productivity Press; 1988. p. 6–7.