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Quality Assurance for the POCT Systems

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1. Introduction

Point-of-care testing (POCT) is in the fact laboratory testing provided near the site of patient care or directly in this place. POCT includes in the present time bedside testing, near-patient testing, physicians' office testing, extra-laboratory testing, decentralized testing, off-site, ancillary, and alternative testing, and, of course, point-of-care testing. Laboratorian and clinical staff often use these terms synonymously, but POCT can be delivered in many different ways. Different tests and technique can be also hidden in different terms.

The history of the POCT is relatively old. We can see now very sophisticated techniques and methods. However, in the beginning of laboratory tests was everything in the hands of the practitioners. The number of tests was arising during the time and laboratory tests were moved to the laboratories. Laboratories were higher and higher and time for the results was longer and longer. From these reasons some tests move back near to the patient. The typical and one of the oldest POCT test is chemical examination of the urine on the strip. But more and more tests are common outside of the hospitals and laboratory. Above all we can mention glucose, APTT, CRP, HbA1c, hCG, lactate, drugs or lipid's profile. And the development of POCT brings new methods – bilirubin, microbiology tests, PTH etc.

The development of the POCT tests depends on many different factors (1). Here are the availability of the tests, the price, patient's requirements for the tests and the technology development. However it's clear, the main factor is the last factor (technology development). This development enables enlargement test's spectrum for the POCT. New technologies make possible to provide a lot of tests not only in practitioner's office or in the terrain, but also at home with the connection via internet to the doctor. The wide of the new tests in the hospital POCT is limited, as the majority of laboratory tests is in the right time with the better price and quality provided in the central lab.

And, what is important, new technologies improve the quality and the validity of the results. The rapid development of POCT is in the agreement with current trends in the healthcare and POCT could be the main diagnostics tool in 21st. century.

We have to know where are the main sources of errors for the assurance of quality patient care, including. The errors can arise in different parts of the whole process – inappropriate tests, inappropriate evaluation of results, errors in the analytical and the preanalytical process etc. We can evaluate errors when we judge the whole process on the principle:

The right result, for the right investigation on the right specimen from the right patient, available at the right time, interpreted using the right reference data, and produced at the right cost.

POCT reduces the risk of errors in the pre-examination and the post-examination processes. Additional, current POCT technologies are guarantees valid results.

Of course, quality assurance system depends on the location and on the type of POCT. If is POCT in hospital, quality assurance is in the hands of laboratory staff. The quality assurance for the other types and systems (GP offices, home, off-site...) depends on the keeping of the rules and the regulations.

The most effective management for ensuring quality in any situation is a quality system (3, 4). Various quality systems are in use, though there is an increasing of the ISO standards. The quality system has a number of components. All components of a quality system should be in place and operating in order to fully achieve the end product of good quality laboratory service. Excessive attention to any one individual component, to the neglect of others, will not achieve lasting improvements in quality. A balance approach is essential.

2. POCT – Current situation

The 2004 tsunami in Southeast Asia and Hurricane Kathrina in the USA revealed significant weakness in public health planning, immediate rescue and follow-up care (1, 2). These disasters also convinced political and health care leaders of the need for rapid response and readiness. Rapid development of POCT technologies parallels current trends towards distributed health care. Point-of care testing is well positioned to become a dominant diagnostic approach in the 21st century.

The professional point-of care market, as distinct from the very large home testing area, is composed of 2 general segments: hospital testing and decentralized testing. Hospital POCT is usually an extension of central laboratory testing. For example, immediate turnaround of blood gases and electrolytes are very helpful in the operating room or the emergency department. Pregnancy tests or cardiac monitoring tests in the emergency department can be very helpful to manage patients with critical illnesses. However, here POCT can be used in distinctly different way to provide decentralized testing of selected parameters on whole blood in key locations throughout the hospital.

A main component of decentralized testing segment consists of physician office laboratories, nursing homes, pharmacies, and other noninstitutional settings in which health care providers perform fast, simple near patient diagnostic tests for the purpose of screening, therapy, and disease monitoring. Key physician groups here include general practitioners, cardiologists and internal medicine specialists.

Is very important to know what tests are provided by POCT, what tests are important to be a part of the POCT and what techniques are used in POCT (15). We can find very different requirements for the POCT tests. It usually depends on the author, on his specialization. Different view exists from laboratory specialists, from hospital clinicians and from practitioners. In table 1 you can find variety tests available in the POCT format for some group of tests. However, here are only the main tests here.

Group	Tests	material
Diabetes	HbA1c, glucose	blood
	Microalbumin	urine
Drug of Abuse screening	The whole spectrum of drugs	urine, saliva, sweat
Alcohol	Alcohol (Ethanol)	saliva, blood
Metabolites	Lactate	blood
Lipids	Cholesterol, TAG, HDL	blood
Pregnancy, hormones	hCG, LH, FSH, PTH	blood, urine
Urine strips	Chemistry	urine
Coagulation	PT, APTT	blood
Renal tests	Creatinine, Urea	blood
Liver tests	ALT, GGT	blood
Cardiac markers	TnI, TnT, Myoglobin, BNP...	blood
Serology	HIV, helicobacter pylori etc	blood, saliva
Hematology	Hemoglobin, hematocrit	blood

Table 1. Group of tests in POCT

Devices for POCT must be simple to use, robust both in terms of storage and usage, capable of producing results consistent with the clinical requirement, and safe both in storage, use and disposable(12, 15 ,16). Analytes that require only a qualitative response can be detected with stand-alone disposable devices that do not need instrumentation, although there have been methods where a quantitative result can be achieved without instrumentation. However, in the majority of cases when a quantitative result is required, the disposable analytical device requires a reader. The reader may also facilitate or control parts of analytical reaction, e.g., temperature control, timing of absorbance reading, fluorescence, etc. The design template for any POCT device is based on the creation of the cell in which the reaction takes place. This cell can be either a porous material, a chamber, or a surface.

We can divide POCT devices to the three main categories – single-use devices, hand-hold sensor systems and bench top small instruments. Of course, many systems could be the combination of above mentioned or untypical. Single use devices are the oldest. The typical example is urine strip. However, various detection systems can be used for single-use disposable devices. The simple classification is in the Table 2

Technology	Detection
Single or multi-pad stick	visual read, reflectance read
Enzyme chromatography	analog signal
Immunoassay flow through or lateral flow	visual read, reflectance read
Immunoassay chromatography	analog signal
Cassette devices	optical read
Microfabricated devices	optical read
Biosensors	electrochemical, optical diffraction, ellipsometry, etc.

Table 2. The main technology in POCT

The development of microsensors opened in the late 90's way for so called hand hold sensor systems. These systems are easy portable with better analytical quality than previous technology. A few analytical principles are using for hands-hold devices: enzyme based systems (optical or amperometric detection), optical motion detection (for coagulation with magnet detector), ion-selective electrodes (amperometric or potentiometric detection), immunochemistry (visual, optical detection) and solid phased chemistry (reflectance detection).

The last systems (bench top) are near to the classical laboratory devices. There are very similar detection systems, but usually it working with the whole blood.

3. The development of POCT

The scope of POCT now includes testing in home, pharmacy, supermarket, physician's office, and at hospital bedside. Future expansion in the scope and volume of testing may depends on a series of factors. These include government healthcare policy and laws about POCT; the availability of POCT; the view of general public on POCT; cost of testing; new technologies that make POCT easier, more reliable, and more likely to be accepted; and broader developments in Web-based electronic health record.

3.1 Health care policy, regulations, and availability of POCT

Sale of tests for use by members of the general public or direct access of the general public to a testing service is regulated in many countries (17). In the US, for example, clinical testing is regulated by the Clinical Laboratory Improvement Amendments (CLIA) which was passed in 1998. A test must achieve a waived test status for it to be available to the general public for use as a self-test. An alternative source of POCT is to purchase testing at one of a number of retail health clinics that have sprung up in supermarkets and pharmacies. Although above mentioned tests offer a new source of POCT for the general public, they have met with opposition from medical professional organization. Variety of recommendations and guidelines exist for POCT. Finally, it is possible for the general public to purchase a sampling kit and send in a specimen to a laboratory and have a variety of clinical tests performed - so-called direct access testing.

3.2 New technologies for POCT

An important factor in the future of POCT is the technological innovation that makes it easier, more reliable, and more likely to be accepted (1, 12, 16). Such developments provide a possible and significant stimulus to POCT that has already seen an amazing progression from the early tablet-based tests do dipsticks, to quantitative measurement using meters, then to all-in-one 1-step-devices, and finally, to real time assays using implantable sensors.

The next source of innovation is being drawn from a number of areas. These include the consumer electronic industry, and examples include the development of disposable POCT devices that include electronic components, such as some pregnancy or HbA1c tests. In addition, developments in Wi-Fi and graphical interfaces promise connectivity and the ease of use now associated with cell phones. Another source of technology adaptable to POCT includes the extensive developments in devices for field-testing for bio-warfare agents.

These range from chemical agent monitors to integrated polymerase chain reaction-based devices for infectious agents. The design specifications for a device for field-testing for bio-warfare agents and a POCT device for clinical testing share many similarities – inexpensive, quick, accurate, robust, easy to use, and connected – and the sizable research and development investment in this area should eventually provide spin-off into POCT.

Two technology areas that hold promise for POCT are microtechnology and nanotechnology, principally because they offer routes to miniaturization and simplification of POCT devices. Microtechnology has already provided a wide range of miniaturized analyzers (so-called lab-on-chip type devices) that in principle have a potential for POCT. In particular, microtechnology enables integration and miniaturization of complex multistep and dynamic tests, thus, extending the range of tests that could migrate to POCT, such as polymerase chain reaction – based assays and flow cytometry. Nanotechnology offers an exciting array of new analytical strategies and nano-sized structures that have analytical potential. Typical examples are a DNA sequencer based on a nanopore fabricated in a small chip and contact lens-based glucose analyzer that use nanoarrays of beads or gratings to detect glucose in fluid bathing the eye.

3.3 Web-based electronic health records

There has been an increased interest in providing Web-based locations for collecting and storing medical information. New electronic health care aids are intended to be safe and secure and to help patients gather medical records from physicians, hospitals and pharmacies. Electronic systems are also designed to connect with personal health and fitness devices to consolidate all medical information in one place. A possible consequence of this new direction for health care is that patients will become more interested in gathering clinical data and thus, become more motivated to perform self-testing to obtain the data they seek. The net result would be an expansion in POCT.

4. Advantages and disadvantages of POCT

4.1 Advantages

For POCT, the analytical time is short, on the order of minutes, allowing for a result often while the patient is still being examined. This decreases the therapeutic time and offers the “potential” to improve patient outcome by reducing delays in wait time for laboratory results. When patient management is dependent on the test result, laboratory testing can be a significant bottleneck, resulting in longer wait times and poorer outcomes in particularly unstable patients. POCT, providing a rapid result, can prevent such bottleneck.

Clinician time can also be reduced, since physicians can obtain results while the patient and diagnostic issues are still fresh in his minds. If a sample needs to be collected and sent to a laboratory, the clinician is going to move on to other patients. Once test results are available, clinicians will need time to refamiliarize with the patient, their diagnosis, and where they left off in the treatment pathway. Thus, POCT has the potential to improve physician efficiency by enhancing result turnaround time and better fitting within clinical workflow.

POCT also reduces the risk of errors in the pre-examination and the post-examination processes. Above all are reduced pre-examination errors, there are no confusion of patients (the same exist for post-examination errors), no errors in sample transport.

The small volume of specimen required for POCT is also benefit for patients with bleeding disorders, neonates, and other for whom collection of standard sample volume could be a problem. POCT utilizes unprocessed specimens, which further reduces the amount of specimen required for tests such as electrolytes, glucose, and enzymes that are traditionally conducted on serum or plasma in centralized laboratories, requiring larger volume for centrifugation and the removal of erythrocytes. Elimination of sample processing is an additional feature of POCT that contributes to a faster result.

4.2 Disadvantages

Managing the quality of POCT is a challenge due to the number of different devices and scenarios for delivery of testing. With the rapid rise in POCT popularity, quality has become a growing concern. There are many different problems – result's misleading, bad storing of reagents, poorly cleaned POCT devices (reservoir of nosocomial). Misleading results have been noted on proficiency surveys, comparative that are sent blinded to all laboratories performing testing in order to determine the accuracy of the testing process. Higher failure rates have been noted in POCT when compared with hospitals, with the same testing devices. Historically, the better performance has been linked to staff competency and having staff trained in laboratory science supervising the testing process.

Staff training and clinical focus may be one source of quality problems. Clinical staff does not have formal laboratory education and tend to be patient centered. The performance of laboratory testing requires dedicated attention to detailed, stepwise analysis. When a patient is in trouble, clinicians and nurses are going to react in the aid of the patient. The laboratory test becomes a secondary concern. Staff may forget to precisely time the testing device, or may not take note of specific sample collection details. Nurses and clinical staff may also not fully appreciate the preanalytical variables that can interfere with the test result. They often assume that if the test gives a result, it must be the correct result. This leads staff to believe that POCT is equivalent and freely interchangeable with a central laboratory test. The glucose is a glucose test, a pregnancy is a pregnancy test, etc. Historical management pathways developed from the use of central laboratory tests now utilize POCT without necessarily accounting for differences in methodology or test limitations. However, POCT differs still in precision and accuracy from its central laboratory counterpart. It utilizes different chemistries in order to provide a faster result. Thus, POCT has technical unique from the central laboratory methods.

Patient population characteristics can also contribute to POCT and central laboratory differences. Hospital use of POCT stresses the technical performance of devices that are approved and marketed for home use applications. Home patients are ambulant, generally well, and utilize easily collected samples, such as urine, saliva or capillary blood. Yet, hospitalized patients have a variety of acute and chronic illnesses, are confined to bed, and are on number of medications. Use of device in this patient population may be challenged by unusual samples, such as arterial and venous blood and blood drawn from intravenous line. Hematocrits are higher (neonates) or lower (oncology, surgical and trauma patients) than in the outpatient population. POCT on inpatients is thus a very different scenario. Application of devices to patient populations that have not been validated through clinical trials may lead to result discrepancies that were not predicted from studies on home use patients.

5. POCT Quality management

Quality management is the total process of supporting the quality of the testing service and is comprised of measure taken to ensure investigation reliability. These measures start with the selection of appropriate tests and continue with the obtaining of a satisfactory sample from the right patient, followed by accurate and precise analysis, prompt and correct recording of the result with an appropriate interpretation, and subsequent action on the result. Adequate documentation forms the basis of a quality assurance system in achieving standardization of methods and traceability of results on individual specimen. Regular equipment monitoring, preventive maintenance and repair when needed are other important components of quality management.

5.1 Standards and accreditation

Accreditation of laboratories or of users of POCT is a process of inspection by a third party to ensure conformance to certain pre-defined criteria. The main sources for accreditation are the ISO standards – for laboratory ISO EN 15189:2007 - Medical laboratories – Particular requirements for quality and competence. The special standard exists for POCT – ISO EN 22870:2006: Point-of- care testing (POCT) – Requirements for quality and competence. This special standard includes only additional requirements to the 15189 (10, 13).

In the US, under the CLIA all clinical laboratory testing including POCT examining “materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease...” is regulated. These CLIA mandates are based on test complexity – waived and nonwaived – and focus on 3 phases of testing: preanalytical, analytical and postanalytical. Does it mean all testing procedures performed POCT must be conducted under an appropriate CLIA certificate. Point-of-care testing sites within a hospital typically fall under 1 or 2 broad scenarios: (1) central laboratory holds a single CLIA certificate that covers all institutional testing, including POCT, or (2) POCT sites within the institution have their own, separate CLIA certificates. Freestanding POCT sites, such as physician office laboratories (POLs) and clinics, must have their own CLIA certificates. CLIA includes requirements for procedure manuals, quality systems, method verification, quality control, personnel, proficiency testing and inspection. Voluntary accreditations also exist in US – the Joint Commission(special standards for POCT), the laboratory accreditation program of the College of American Pathologist and the Commission of Office Laboratory Accreditation (COLA).

5.2 Standardization and harmonization

Standardization is a practical process aimed at achieving consistency among measurement procedures through application of high scientific standards (4, 12). Standardization has become an important concept in clinical diagnostics, both nationally and globally. Key components of standardization include higher-order materials and measurement procedures, such as the Standard Reference Materials (SRMs) for diagnostic tests developed by the National Institute of Standards and Technologies (NIST).

Results of routine daily measurement are standardized through calibration to the reference method and/or material (traceability) but, when the reference system is lacking, are only referred to a manufacturer’s selected procedure and corresponding calibrator. Ideally, for

example, manufacturers of metabolite assays (eg. glucose) could use SRM 1950, once fully developed, to assess the validity of their calibrators. This practice will result in standardized measurement with closer agreement of results in clinical practice. In support of the standardization practice, societies such as the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) have set forth to promote extensive global standardization in laboratory medicine.

The POCT notion of bringing the test immediately to the patient is accomplished via convenient handheld, portable, or transportable devices, many of which used whole-blood sample for result. The rapid technological advances in POCT permit measurement of multiple analytes in whole-blood samples. However, the lack of whole-blood SRMs reveals the standardization deficiency in POCT field that can adversely impact diagnoses, treatment decision, and patient outcomes. Therefore, the first is for global standardization in POCT, which will ultimately result in an improvement of clinical interpretation of laboratory results to benefit patient.

Harmonization in medicine means bringing diagnostic standards and treatments into consonance or accord. However, at this point in time, no single reference or calibration method correlating plasma and/or whole-blood glucose and other analytes has been adopted universally among manufactures. Additionally, if we adopt a bedside perspective, then most reference instruments should not show statistically significant bias relative to the point of care. Currently, however, there is a proven lack of harmonization of reference instrument used in hospital across the US or Europe when viewed from bedside perspective. This deficiency in harmonization potentially introduces complications in clinical management, which can adversely affect treatment and care of patient.

Now, adding “global” into the equation would mean unifying international standards to create worldwide harmony in diagnostic testing. In the absence of global harmonization, the likelihood that a result may be misinterpreted and the patient may be misdiagnosed is increased because of different assays exhibiting nonequivalent analytical responses. A spectrum of different values may result from testing of the same specimen by different methods. Data reporting comparisons of global SRMs show an international bias resulting in noncomparable patient outcomes due to different field methods. Bias in measurement has also shown to impact medical decision making.

Additionally, too long, the perspective has been clouded. Preanalytical delays and other confounding factors deteriorate samples before they are assayed in clinical laboratories. In many cases, bedside results may reflect actual in vivo condition more accurately.

5.3 Quality Assurance

Quality Assurance (QA) is a management approach that attempts to ensure the attainment of quality, enabling appropriate and timely clinical action (11, 12, 13). QA thus encompasses much more than analytical quality. POCT presents particular quality concerns. Surveys have shown that POCT, carried out by non-laboratory staff outside conventional laboratories, is widespread in both the hospital sector and the community sector, with an increasing range of tests and number of testing sites. Systems used for POCT are increasingly sophisticated, with more aspects of quality built in or controlled through manufacturing quality control. The equipment and procedures seem easy to use, but quality is not provided automatically

and QA is essential. The first aspect of quality in POCT is whether the test should be done at all. Before such testing is introduced or extended, clinicians must discuss and agree on the pattern for service provision, based on clinical needs. Even where investigations are deemed appropriate for POCT, audit of testing quality and effectiveness should be ongoing.

The most effective management tool for ensuring quality in any situation is a quality system. Various quality systems are in use, though there is increasing utilization of the International Organization for Standardization's (ISO) 9000 series of international standards. Accreditation and quality systems are in principle as applicable to POCT as to conventional laboratories, though practice and legislation may differ from country to country.

All components of a quality system should be in place and operating in order to fully achieve the end product of good quality laboratory services. Excessive attention to any one individual component, to the neglect of others, will not achieve lasting improvements in quality. A balanced approach is essential.

Components of Quality system:

Quality Assurance. QA is the total process of supporting the quality of the testing service and is comprised of measures taken to ensure investigation reliability. These measures start with the selection of appropriate tests and continue with the obtaining of a satisfactory sample from the right patient, followed by accurate and precise analysis, prompt and correct recording of the result with an appropriate interpretation, and subsequent action on the result. Adequate documentation forms the basis of a quality assurance system in achieving standardization of methods and traceability of results on individual specimens. Regular equipment monitoring, preventive maintenance, and repair when needed are other important components of QA. Quality assurance must not be limited to technical procedures. Those who obtain specimens for analysis make a significant contribution to the reliability of the results through correct specimen collection and handling. Inappropriate specimen collection is a major source of variation, which must be minimized through careful training and adequate supervision.

Internal Quality Control (IQC). IQC assesses, in real time, whether the performance of an individual testing site is sufficiently similar to its previous performance for results to be issued. Thus IQC controls reproducibility or precision, ensuring that sequential results are comparable and credible, and maintaining continuity of patient care. Most IQC procedures analyze a defined control material and ascertain if the results obtained were within previously established limits of acceptability.

External Quality Assessment (EQA). EQA, in contrast to IQC, compares the performance of different testing sites. This is made possible by the analysis of an identical specimen at many sites, followed by the comparison of individual results with those of other sites and the "correct" answer. The process is necessarily retrospective, and it provides an assessment of performance rather than a true control for each test performed on patients' specimen.

Audit. Audit is a process of critical review. Internal audit examines local processes conducted by senior staff. Such reviews measure various parameters of performance, such as timeliness, accuracy and cost of reports, and identification of weak points in the system where errors can occur. External audit widens the input by involving others in the evaluation of analytical services. The users of services are asked how they perceive the quality and relevance of the service provided.

Accreditation. Accreditation of laboratories is a process of inspection by a third party to ensure conformance to certain pre-defined criteria. Accreditation can be linked to a formal system of licensing, whereby only accredited testing sites are legally entitled to practice, or it may be a voluntary system. In many cases, accreditation of POCT sites is subsidiary to the accreditation of the laboratory responsible for them, through independent accreditation of POCT site may be permitted in some circumstances.

Validation of Results. Validation is an attempt to measure quality by re-examining previously analyzed specimen.

Training and Education. This is probably single most important component in any QA program. Issues to be addressed include national policies and curricula for staff training, both during primary training and in follow-up. Professional status and career development are related factors. Training should be continually monitored, and where new needs arise (such as introduction of new methods), or where QA reveals the need for improvements, courses and workshops may be introduced.

Evaluation. Determining whether reagents and equipment are suitable for use may make significant contribution to overall quality. Choice of equipment and reagents requires considerable thought and co-ordination and may be cost effective in reducing duplication of effort and preventing repetition of expensive mistakes. It cannot be assumed that equipment and assays designed for use in one situation will perform well in another.

Documentation. Documentation of all procedures is a universal accreditation requirement, and incorporation of controlled documents within the framework of a formal quality manual in accordance with ISO 9000 standards is highly desirable.

5.4 Internal Quality Control

IQC in laboratory medicine was developed by adapting systems used in the manufacturing industry. In laboratory practice, however, specimens are not expected to be identical, so quality control material must be included with each batch of patients' specimen to probe the performance of analytical system (5, 12, 14). Validated procedures have been developed for the statistical interpretation of control data generated from quantitative analysis, though these may not be directly transferable to establishments carrying out POCT. Some systems used in decentralized testing either do not require any calibration (standardization) by the user as they are factory-calibrated or require infrequent recalibration. Much of the variability of results from these methods originates from variations in operator technique. The analysis of an appropriate control material before starting and during analysis of clinical specimens can provide reassurance, that the system and operator are performing correctly.

Results obtained with control materials must be recorded and interpreted. Representation in graphical form is strongly recommended. For a quantitative analysis, control results must be compared with the acceptance limits determined as from previous experience as on the basis of analytical goal settings. There is an internationally accepted, 5-tiered hierarchical model for this setting of analytical goals for the imprecision, bias, and total allowable error of laboratory tests. Where data are available from more than 1 approach, models higher in hierarchy are considered to hold greater weighting than those from lower levels. The highest quality standard is required when analytical quality has a direct effect on medical decision making in a specific clinical situation (e.g. HbA1c). Analytical goals for broader clinical need can be

derived from biological variability or from clinical survey how clinicians use test results. Three classes of analytical goals (minimum, desirable and optimal), based on fraction of within-individual biological variation, have also been developed for the imprecision of commonly tests. The desirable analytical goal for most biochemical analytes is that the analytical imprecision (Coefficient of variation, CVa) should be less than one half of the average within-person biological variation (0,5 CVw). However, for those analytes for which the desirable goals derived using this formula are readily achievable with current methodology, it is recommended that an optimal analytical goal be used, based on the formula $CVa \leq 0,25 CVw$. For those analytes for which desirable goals are not readily attainable by current methodology, a minimum analytical goal is recommended, based on formula $CVa \leq 0,75 CVw$. Many national and international groups have also set profession-defined analytical goals; government or external quality assurance program organizers also set analytical quality specification.

As an overarching principle, analytical goals for POCT should be equivalent to those used for laboratories to ensure that the use of POCT does not compromise standard of patient care and clinical decision making. However, it is important to acknowledge that the POCT environment is often very different to the laboratory settings. First, long-term retention of staff as POCT operators is an ever-present problem for rural and remote health services, creating difficulties in sustaining not only POCT but other health programs in general. Second, there needs to be a balanced approach to goal setting. There is limited value in setting analytical goals there are too stringent and which current POCT instruments cannot achieve. On the other hand, there is a clinical imperative to ensure that excessive analytical noise from POCT methods does not mask clinically significant changes in patient results. Minimum analytical goals for the imprecision of non-laboratory based POCT should be set where sufficient data are available with the proviso that performance outside the minimum goal should be investigated and acted upon by the clinician responsible for clinical governance of POCT. Third, when assessing analytical performance in POCT environments again published literature, should be noted that the majority of published evaluation of POCT instruments have been conducted in the laboratory settings by trained laboratory staff. Analytical goals may also vary depending upon the intended purpose of the test. For example, different goals may be needed for diagnosis versus monitoring of test result.

The main problem for IQC in POCT is in personal working with it. These workers have no education in the laboratory field, poor knowledge about QC in laboratories. So, the IQC system must be easy and simple. IQC must be run with appropriate frequency. Ideally, IQC should be run with every batch of clinical specimens, but this may not be practicable or necessary. In POCT, specimens are often analyzed individually rather than in batches, and running IQC once per operator per shift (before analyzing the first clinical specimen) appears satisfactory in most situations.

The main requirements for IQC in POCT:

- Controls for blood gases and electrolytes measure on three levels each day. If are used instruments with equivalent QC, the QC system must be validated before using the instrument for patient. Following the producer rule is the basic requirement.
- Glucometres must be daily control on two levels of control material
- Personal glucometres must be regularly controlled by some lab.
- The other instrument and test must be controlled daily
- Evaluation of results IQC is on the same rules and processes as in the labs.

The best approach to IQC for POCT is keeping of standard procedures by laboratory staff. But it isn't usually assured, many instruments and techniques are outside of some hospital or laboratory. Some instruments are so called single use devices. From these reasons exists equivalent system IQC:

- Instruments with fixed controls inside and with regular measuring (7),
- Equivalent controls (8),
- Electronic control (EQC),
- Automatic controls (onboard control, OBC),
- iQM (intelligent quality management) (6)

Equivalent controls (Eqc) is the procedure allows further reduction from daily QC to weekly or monthly QC for certain analytical systems that contain internal procedural controls. To implement eqC, the test site needs to determine the extent to which the manufacturer's internal/procedural controls adequately evaluate and monitor the analytical process and test components. The test site then selects the appropriate eqC option for evaluation. There are 3 options – option 1 is for test systems with internal/procedural control(s) that monitor the entire analytical process; option 2 is for systems that monitor a portion of the analytical process; option 3 is for instruments that monitor none of the analytical process.

For single-use devices without an instrument for reading the results, internal procedural controls may have been built-in by manufacturer. These are designed to ensure that results can only be obtained if the specimen has been applied properly and the reagents have worked correctly, and are particularly useful for non-quantitative. i.e., positive or negative, investigation. Nevertheless, acceptance testing of each lot or container of devices with positive and negative controls may provide an invaluable quality control measure before issue to testing site.

Some systems are equipped with electronic control. Here a "dummy" device module mimics electronically the output from a real device, so that the reading instrument gives a valid "result"; the same module may mimics several different concentrations. These modules are stable, and provide excellent validation that the reading instrument is working correctly for maintenance or troubleshooting purposes. The EQC unit can be use repeatedly to check the reader portion without having to reconstitute control solution or use the disposable portion of the test system. EQC is not new. Photometer checks, cuvette checks, blank (zero) checks, and a variety of electronic voltage checks have long been used as a part of the monitoring system for laboratory instrument.

As unit-use test systems evolved, many manufacturers began to introduce products with a control that was included as an integral part of the disposable component of the device. This is often called automatic control or onboard control (OBC). With this method, some type of control is built into the disposable component and provides a QC result that is run simultaneously with the patient sample. Current versions include calibration checks and multiple channels for low and high controls; in one system, three levels of controls are run.

Intelligent quality management (iQM) is proposed on IL's GEM Premier 3000 as an alternative to traditional IQC. The theoretical aspects of this concept have been evaluated by Westgard, who has demonstrated the potential value of an increase in the frequency of control testing.

5.5 External Quality Assessment

EQA, in opposite to IQC, compares the performance of different testing sites (9). This is made possible by the analysis of an identical specimen at many sites, followed by the comparison of individual results with those of other sites and the „correct“ answer. EQA is retrospective, and it provides an assessment performance rather than a true control for each test. An EQA, or proficiency testing program, when applied to POCT, is designed to provide regular, objective and independent assessment of an in vitro medical devices and its operator's ability to provide an acceptable standard of service by comparison with peers. POCT EQA is equivalent to the well established processes of interlaboratory comparison in the central laboratory setting. It is an integral part of the total quality management system. The process is organized by the impartial agency.

5.6 Training and education

This is probably the most important component in any quality assurance program. Issues to be addressed include national policies and curricula for staff training, both during primary training and its follow up. Professional status and career development are related factors. Training needs should be continually monitored, and where needs arise, or where QA reveals the need for improvements, courses and workshop may be introduced.

Errors are more often associated with lack of understanding, inadequate training, and miscommunication rather than the analytical systems. Appropriate training of both the trainer and the user is therefore essential for a first class POCT service. The management of the training and competency assessment is usually managed by POCT coordinator, more often recruited from within the laboratory rather than from a nursing background. Often the training requirements vary greatly between institutions. Both theoretical and practical training program for all POCT personnel should be implemented where only personnel who have completed training and demonstrated competence shall carry out POCT. The knowledge/skill requirements include the ability to demonstrate an understanding of the appropriate use of the device, the theory of the measurement system, and appreciation of the preanalytical aspects of the analysis, including the following:

- sample collection,
- its clinical use and limitations,
- expertise in analytical procedure,
- reagent storage,
- QC and quality assurance,
- Technical limitation of device,
- Infection control practice,
- Response to result that fall outside of predefined limits,
- Basic maintenance of the device,
- Correct documentation.

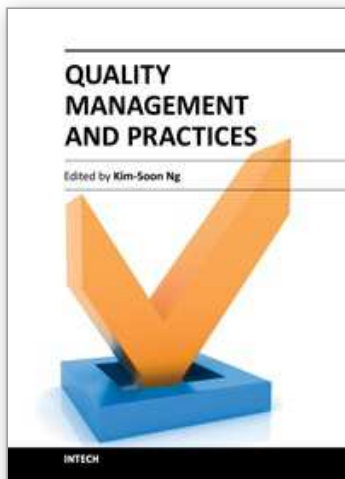
Operators' competence should be objectively and independently assessed through practical demonstration. Records of training/attestation and of retraining should be retained as evidence.

6. Conclusion

The quality in the POCT is on the way for improvement, but in the comparison with laboratories is still not so good. Sigma value is usually below 3.5, standardization and traceability are poor, and systems of IQC are in the beginning. Fortunately national recommendations are arising, some strict rules also exist (ADA, Rilibak, CLIA). However POCT systems will certainly develop and quality assurance will be better and better.

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