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Review Article

# Emerging challenges in point-of-care testing

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ABSTRACT

Point-of-care testing (POCT), also referred to as bedside or near-patient testing, represents the future of diagnostics and is currently dominating innovations in the medical field. This technology has brought diagnostics out of the central laboratory to the patient bedside. POCT offers several advantages over the traditional testing carried out in the central laboratories. Small compact devices and faster reports leading to rapid diagnosis and consequent appropriate treatment/interventions form a major benefit of POCT. In addition, it has reduced the sample requirements in comparison with the volumes required by the main laboratories and has played an important role in testing of labile analytes. However, numerous challenges remain in the use of POCT. POCT reagents are costly and are performed by non–laboratory-trained operators who are focused neither on the internal quality control protocols nor on the guidelines of the regulatory and accreditation bodies. Thus, training and experience of the staff remains a major issue. Because POCT contributes to better patient management by facilitating early diagnosis, internal quality protocols must be defined and incorporated in the daily routine of testing. ISO 22870:2016 "Point-of-care testing – Requirements for Quality and Competence" was introduced by the ISO and is intended for use in conjunction with ISO 15189:2012 (Medical Laboratory Testing). Newer point-of-care (POC) trends are emerging which will further strengthen the impact of POCTs in medical testing. Hence, it is essential that quality is of the optimum consideration to ensure consistency in the POC test results.



## 1. Introduction

Point-of-care testing (POCT), also referred to as bedside or near-patient testing, represents the future of diagnostics and is currently dominating innovations in the medical field. It has brought diagnostics out of the central laboratory to the patient bedside, with the aim of providing faster access to the results and quick clinical decision-making. Before the advent of POCT, samples were collected at a designated phlebotomy area, transported to the laboratory, and analyzed, followed by release of reports within a specified turnaround time (TAT). With the advent of POCT, this workflow has now changed with testing moving not only to the site of specimen collection but also to various patient care settings such as emergency departments, physician's offices, disaster areas, etc.[1]

Globally, the healthcare scenario is being guided by economic pressures as health budgets are shrinking. Primary healthcare models are being revived to reduce the load on secondary and tertiary centers, and alternative patient-centric diagnostic testing is gaining consideration. As the very basis of POCT is based on bringing healthcare delivery closer to the patient rather than the provider, this has made healthcare convenient, easy, and cost-effective, especially in remote areas.[2]

## 2. Advantages of POCT

POCT offers several advantages (Fig. 1) over the traditional testing carried out in the central laboratories. Small, compact, and portable devices with faster reporting, leading to rapid clinical decision-making and early treatment/interventions, form a major benefit of POCT. In addition, it has reduced the sample requirements in comparison with the volumes required by the central laboratories and has played an important role in minimizing errors in testing of labile analytes such as lactate and glucose.[3] This especially benefits newborn babies and patients in whom sampling is difficult. POCT has also universally been accepted to have considerably reduced the TAT, thus enhancing patient satisfaction.[1]

One of the major benefits of use of POCT has been in reducing the duration of hospital stay. Kankaanpaa et al.[4] assessed the effect

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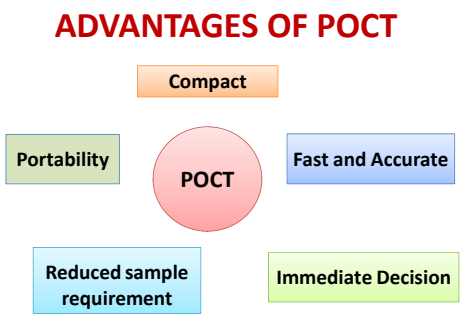


**Fig. 1.** Advantages of point-of-care testing devices.

of POCT on the length of patient stay in the emergency department and observed shortened duration of stay due to the elimination of time-consuming central laboratory testing. This observation corroborated with the results of another study by Singer et al.[5] who also reported a reduction in the length of stay of patients with chest pain in the emergency department. However, Parvin et al.,[6] also in the emergency department, studied the use of POCT devices by nonlaboratory personnel but observed no decrease in the length of stay.

## 3. Practical challenges associated with POCT

Despite the many advantages offered by point-of-care (POC) devices, numerous challenges remain in their usage. POCT reagents are manufactured as single-use ones which raises the cost. These tests are performed by clinical staff who are not oriented to the variables affecting all the three phases of examination, i.e., pre-analytical, analytical, and postanalytical phases, thus increasing error rates. The non–laboratory-trained operators are focused neither on the internal quality control protocols nor on the guidelines of the regulatory and accreditation bodies. In a study conducted in 2011 which included one nonacute and two acute hospital sites, Kane et al.[7] observed that quality error rates were higher with POC devices than in the testing carried out in the central laboratory. In the breakdown of POCT quality errors in the three phases, they observed that 65.3% of errors occurred in the analytical phase as compared with 32% and 2.7% in the pre-analytical and postanalytical phases, respectively. A huge variation was also observed in quality error rates between different test types, i.e., 0% in blood ketone meter testing to 0.65% for $HbA_{1c}$. These findings pointed to a greater need for operator training or enhanced support of POCT from the laboratory staff.[7] Training and experience of the staff is therefore a major issue in the maintenance and calibration of these devices as well as in reagent storage, temperature, humidity monitoring, etc. Appropriate documentation, an integral part of accreditation, and nonadherence to the specified test procedures too can create errors in reporting.[1] Kost[8] in his study for preventing errors in POCT classified the occurring errors as per the three phases, i.e., preanalytical, analytical, and postanalytical. Meier and Jones[9] in 2005 identified sources of POCT errors to present a classification of such errors and to formulate strategies for their prevention. They modified the error classification by Kost to include test order indication and frequency. They also concluded that testing errors are relatively common in POC testing and that incoherent regulation, rapid test availability and immediate therapeutic implications acted as amplifiers of POCT errors.

Lately another challenge facing the POCT manufacturers is the concept of “multiplexing” i.e. the ability to simultaneously measure multiple analytes on the same cartridge. Currently, very few devices like the blood gas analyzers and POC devices for cardiac enzymes, are multi-analyte POC devices. These machines have the disadvantage of measuring the entire panel of tests irrespective of whether all parameters are required to be tested or not.[2]

Since one of the major advantages of POC devices is portability, proper use and storage of reagents and quality control materials is a major challenge. Test strips are affected by light, humidity and temperature, hence they are required to be shipped and stored in sealed foil pouches or desiccant filled amber bottles to protect the stability of the testing strips.[1] Currently, another major concern with use of POC devices is the lack of harmonization of POC results with those of the Central Laboratory[10] as well as between different models of POC devices. Other challenges include proper care and sanitization of these machines including protection from moisture and regular decontamination as well as interfacing of POC devices with the Hospital Information System (HIS).

## 4. Types of POCT

POCTs can typically be divided into two broad types: small hand held POCTs which range from dipsticks to small cartridge devices (for example quantitative/qualitative strips and glucometers) and small bench top analyzers. The bench top POC devices are mini laboratory analyzers with more complex built-in fluidics[2] while hand held devices have been developed using microfabrication techniques.[11]

The ASSURED criteria (Box 1), defined by the World Health Organization, provides a good basis for evaluating POC devices. Though the ASSURED criteria can be used to evaluate the appropriate diagnostic tests, however, they are generic and have to be adapted according to the user's diagnostic needs. Also, not all test methods can be simplified to fit this criteria.[12] In an online survey conducted by Hsieh et al. regarding the order of importance of the ASSURED features, if allowed to choose, most users preferred sensitivity of 90–99%, followed by lower cost and shorter detection time.[13] However, with technological advancement, certain other features like connectivity with hospital information system, quality control charts, size of the device etc. have also become relevant.

## 5. Emerging trends in POC technology

With health care moving toward precision medicine, new technology trends in POCT are being developed. Integration of POCT data with smart phones and watches, tablets, etc. and connecting them with cloud-based servers provides interesting opportunities for telemedicine. Research is also on for providing nucleic acid sequencing on POC devices which can provide valuable information during epidemics and infectious disease outbreaks. Increased

**Box 1**
ASSURED criteria for evaluating POCT devices.[7]

1. **A**ffordable
2. **S**ensitive
3. **S**pecific
4. **U**ser-friendly
5. **R**apid and robust
6. **E**quipment-free
7. **D**eliverable to end users

**Table 1**
Comparison of internal quality control (IQC) in central laboratory and POCT devices.

| IQC in central laboratory | IQC in POCT devices |
|---|---|
| Technical staff are highly trained and aware of analytical errors | Lack training and awareness for analytical errors |
| Accepted as daily procedure before the start of testing | Viewed as additional work |
| Trained in reconstitution/pipetting/aliquoting of the IQC material | Not trained in the process of handling IQC material |
| Trained in Westgard rules and LJ charts: can identify random/systemic errors | Taught only QC pass or fail |
| IQC frequency well established as per the number of analytes/day | Frequency of testing varies, so IQC frequency varies |

POCT, point-of-care testing; QC, quality control.

multiplexing, especially in syndrome testing and where sample volume is limited as in critically ill patients, will also help to lower the cost and improve clinical utility. Minimally invasive, wearable, and continuous monitoring POC devices have been developed in the last decade, which are especially beneficial for chronic disease and wellness monitoring. This advancement has been most significant in the field of diabetes with continuous glucose monitoring. Another recent trend is near-infrared scanning which is a form of noninvasive POCT. This technology has been used to detect traumatic brain injury with intracranial bleeding.[14]

Recently, volatolomics, also known as breathomics, has been used noninvasively to analyze volatile organic compounds in human breath, thus revealing important diagnostic information.[15,16] Artificial intelligence too has been increasingly integrated with POC technology to improve interpretation and diagnosis. Mass spectrometry, nuclear magnetic resonance, paper-based microfluidics, droplet of digital microfluidics, and Sherlock assay using lateral flow are some of the other emerging technologies in POCT.[14]

## 6. Key requirements for implementation of POCT

1. Operator training and competency assessment
2. POC test order documentation records
3. Development of internal quality protocols
4. POC results documentation records
5. Calibration and maintenance of POCT devices
6. Proper use and storage of reagents
7. Interfacing of POCT devices with HIS
8. Comparison of POC results with central laboratory results
9. Accreditation of POCT devices.

## 7. Internal quality control in POCT

Internal quality controls (IQCs) are integral tools in a central laboratory, and their use in POCT is a major advancement in improving the quality of reports. As quality control–related activities are among the ten most cited deficiencies in POCT,[17] all POC devices are recommended to have a defined quality protocol.[18] The technical staff in the central laboratory are trained in the quality assurance procedures of the laboratory, as it forms a crucial part of their training. However, owing to the nonlaboratory environment that POC devices function in, certain practical challenges are commonly encountered while running daily IQC, which includes training of users, handling IQC material, documentation of the results, and review of outliers (Table 1). As there have been huge technological advancements in POC technology, and because they are conducted in varied clinical settings, the concept of a "one-size-fits-all" IQC policy is difficult to apply. Therefore, although no single strategy can be adopted for all the devices across all the different clinical settings, a flexible and balanced approach must be adopted to suit the size, scope, and technical sophistication of the devices.[19]

## 8. Accreditation for POCT – why is it essential

The rationale for the widespread use of POCT devices is that they contribute to better patient management by facilitating early diagnosis. Hence, it is essential that quality is of the optimum consideration to ensure consistency in the test results. Accreditation by an international organization was recommended for all POC devices to provide confidence in the quality of results released, as well as in technical competence of the staff performing the tests. ISO 22870:2016 (the updated version of ISO 22870:2006) "Point-of-care testing – Requirements for Quality and Competence" was introduced by the ISO and is intended for use in conjunction with ISO 15189:2012 (Medical Laboratory Testing). This standard is applicable to POCT in hospitals, clinics, and ambulatory care; however, patient self-testing in homes or community settings is excluded.

Mok et al.,[20] in 2017, quantified the conformance requirements in ISO 22870:2016 that were connected to internal auditing. This helped the laboratory to fulfill the management and technical competence requirements and develop a sound internal audit process to enhance their quality management system.[20] These findings have stressed on the importance of the internal audit process in adding additional confidence to the quality of reports. Therefore, if POC reports are to gain credibility with the clinicians and patients, focus has to be on reducing potential risks in all phases of examination.

## 9. Conclusion

The growing importance of POCT emerged from the need for test results which were accurate, at the patient bedside to enhance quick clinical decisions and be performed by non-laboratory but trained personnel. Today, these compact, user-friendly devices have become an integral part of a larger hospital setting as well as smaller clinics. Despite the obvious advantages, challenges do exist in the implementation of POCT and their inappropriate use can lead to increase in erroneous reports. POCT has to be performed in conjunction with the central laboratory; hence, it is the duty of the laboratorians to ensure that testing is as accurate and precise as is possible in the environment in which these devices are used. With the introduction of accreditation standards, the users are required to comply with the international guidelines and best practices, thus providing confidence in the reliability of POC test results.

## Declaration of competing interest

None.

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