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# Point-of-care testing (POCT): Whose responsibility?

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**Abstract**

This article addresses the clinical, technical, and administrative aspects of the point-of-care testing (POCT) in laboratory medicine. Some of us have been dealing with POCT for a while in Hong Kong and the whole arena is very controversial. Little information is available about the protocols or guidelines for the implementation, operation, or monitoring of such POCT programs. This article will not focus on the benefits of POCT, but the author would like to address the issues of (1) Why do POCT? (2) Should we do testing outside the laboratory and if so, whose responsibility? And (3) The clinical requirements and scientific promise of POCT.

*Key words: Point-of-care testing POCT.*

## Introduction

Clinical Laboratory work evolved as an integral part of the practice of medicine. Licensed physicians originally performed laboratory work in hospitals. As the complexity of laboratory technology grows and develops, laboratories are eventually operated by pathologists or scientists and technologists trained in the specialty of laboratory medicine. Recently the resurgence of interest in near patient testing and the advances in new technologies have enabled more and more tests to be performed at alternate sites by non-laboratory professionals.[1] The point-of-care testing (POCT) has evolved as an important part of laboratory medicine by virtue of its compactness, portability, and the feasibility of operation by nonlaboratory personnel, where fast and accurate testing methods are a primary concern and, as a result, improving the patient care.[2] The reasons for performing tests in this setting include convenience to the clinicians, a faster turnaround time (TAT), and advantage to the hospital administration in terms of cost savings. Concerns that have arisen with the POCT include problems with ensuring quality, potential conflicts of interest, and an uncertainty of the responsibility.[3]

## Why do POCT?

The environment of healthcare system is changing dramatically. Severe economic restraints and personnel freezes precluded the allocation of additional funding and human resource. Both the laboratory and clinicians face markedly increased pressures for reducing laboratory running costs and unnecessary utilization of the laboratory. Cost efficiency of medical care is an important policy addressed by budget holders of the healthcare system. One of the concerns about using POCT has been cost. But most point-of-care systems are generally more expensive than traditional laboratory methods, and, perhaps, it will never be as economical as central laboratory testing, therefore, why do POCT?

With regard to quality patient care, it must be recognized that, for some tests, quality can be obtained only by performing the test at bedside or near the patient, for example, arterial blood-gas analysis. Because of the near-patient or at-bedside nature, POCT will always have faster TATs than routine or stat test response. Such handheld devices have potential for a significant clinical impact on the care of patients in which immediate access to clinically relevant laboratory testing is required in support of urgent decision making. It is also an unfortunate fact that labor is the major cost in the healthcare system and hospital administrators who are pressed to reduce costs look for labor savings. POCT systems can reduce the need for porters to transport samples or for phlebotomists who draw and transport stat samples. Nowadays, for purposes of convenience and timeliness, POCT systems are replacing stat laboratories silently. It will change entirely the way of laboratory medicine in practice.

However, budgets and costs are everyone’s concern

and POCT systems are often perceived to be more expensive than bench top and batch analyzers. Cost analysis of POCT requires a detailed understanding of the nature of laboratory costs and the environment in which the testing is performed. Furthermore, savings from POCT must be judged in the context of the total costs and not just the cost of the POCT device.[4] It is crucial to establish a POCT committee to look at how a program of this nature will affect the organization. The group must be multidisciplinary and include laboratory specialists, nurses, physicians, and peoples in information technology, administration and finance. At this point one would need to evaluate the cost of implementing and supporting POCT from a system perspective. A detailed analysis of the hidden costs associated with POCT is also required.[5] If the benefits are perceived to outweigh the costs, a commitment to POCT can be made.

**Should we do testing outside the laboratory?**

In most hospitals, laboratory specialists (pathologists, scientific officers and technologists) are available for both interpretive and technical advice of laboratory tests. The dilemma is that nowadays, the clinicians will be performing a smaller spectrum of laboratory testing without the benefit of a laboratory specialist.[6] Concern was expressed over the quality of such activities. In fact, most clinicians are not familiar with how to select POCT systems appropriate to critical care situations because in the past they had no experience in setting up a laboratory. Even the laboratory itself may not be familiar with them because of the rapid growth of the POCT supply industry. Furthermore, most clinicians are unaware of the possible impact on test results that may occur from inappropriate specimen collection and handling. This raises the question of whether the clinical staff in a very hectic environment such as the Intensive Care Unit (ICU) and the Accident and Emergency (A&E) department will always maintain awareness of preanalytical variations such as proper sample mixing, and other details of quality assurance (QA), regardless of how simple the device is to operate. Many of these issues have been the concern of the laboratory alone.[7]

In fact, there are hidden problems of POCT. For example, clinical departments often don't receive reimbursement for POCT because the clinical users don't always document results in medical charts, which may also lead to problems such as lack of a permanent record and or cumulative results. We have reasons to believe that the nurses would not want to do this POCT. They perceive that introducing the POCT system will increase their workload. Nurses may repeat the test(s) if they feel uncomfortable receiving the "unexpected" result(s), and they also may send a sample down to the laboratory for confirmation.

Has the POCT impacted the way that clinicians perform patient care and if so, how? If not, why not? The full impact of POCT on the care of patient was seen only when care protocols were modified to allow faster clinical decisions by virtue of the immediacy of results in acute care settings. Decreased TAT is the most frequently cited benefit of POCT. A recent article, however, has shown that POCT will offer no timesaving if the doctors have to wait for additional results from the main laboratory before making a decision.[8]

**Whose responsibility?**

Who is responsible for the test results performed outside the laboratory - the operator, the laboratory or the manufacturer? The philosophical statement would be: all three parties must accept their responsibility toward assuring the accuracy of every single result. But ultimately it is the clinician who must decide if a result is compatible with his patient's clinical conditions and decide to act upon the result or request a repeat or further testing to confirm an "unexpected" result. This is true whether the test was performed in the main laboratory or at the bedside. In the past, the degree of confidence the clinician has in a result has depended on the confidence he has in the laboratory. With POCT, this confidence must be built on the reliability of the POCT system and, therefore, on the manufacturer. In reality, the manufacturer cannot monitor a hospital to ensure that all the recommended procedures are being followed and that documentation is adequate. To this point, the laboratory should not feel that it has been relieved of all responsibilities for the quality of these POCT results.[9] The central laboratory, when appropriate, should be responsible for evaluating each new piece of instrument and each new lot of reagent, and maintaining a performance record.

Tasks and responsibilities can be moved across traditional territories. By identifying where the process crosses territories, opportunities for

cooperating and adopting a total system perspective can lead to powerful new solutions to common problems. Typically, the cross-territory concept occurs in three areas of the hospital, i.e. the clinical user unit, the laboratory and the information technology department (ITD).[10] In order to improve the utilization of POCT and the quality of patient care, and to ensure that results are integrated into and being networked with the laboratory information system, the establishment of new relationships among the laboratory, clinicians and the ITD people is needed.[11]

**Clinical requirements and scientific promise**

Quality is a major determinant of the value of a test. An accurate and precise result is obviously important to an ambulatory setting. The need for quality results in this setting is no different from that of any other clinical laboratory.[12] If patients are to receive the benefit of POCT, reliable high-quality test results are essential. Point-of-care instruments must be shown to be comparable to standard laboratory systems before widespread use can be recommended. Despite most POCT devices have gained Food and Drug Administration (FDA) approval in the USA and extensive data validating the instruments against standard laboratory systems are already in the literature, each POCT device is likely to have its own idiosyncratic limitations, which will need to be identified and accounted for before its implementation. The next important question, of course, is whether such evaluations are sufficiently good to justify the use of POCT devices in place of standard analysers in emergency situations.[13]

As the system is intended to be used by individuals (doctors and nurses) not trained in laboratory environments, most POCT systems are designed to ensure that the quality of results is not dependent upon either user technique, skilled calibration and maintenance procedures, or the accompanying quality control (QC) regimens which ensure these procedures have been properly performed. Such POCT devices are usually designed to use disposable, single-use reaction cartridges or self-contained type of reagents, and for reasons of cost and convenience must rely on "electronic controls" or "simulators" to monitor system performance. This breaks with traditional QC procedures, i.e. it does not require QC preparations to verify performance of the equipment. The use of such electronic controls, which fail to provide quantitative data and do not check the entire analytical process has touched off great controversy in the USA among laboratory accreditation bodies, laboratories and manufacturers.

In 1996, the author's laboratory assumed responsibility for a limited bedside glucose POCT program on the diabetes Clinic. The concept of POCT was fully supported by the nursing staff members, who were to perform the tests. It is critical that the operators are extremely well instructed in the use of such kinds of devices and that their competency is checked from time to time. More recently, a new POCT system (i-STAT portable blood-gas analyzer) was also introduced into the hospital. This system was designed for use by nonlaboratory personnel in the adult ICU, paediatric ICU, and A&E department in extremely urgent situations.

In hospitals where POCT includes a variety of locations and devices, the laboratory and clinical user units must jointly develop a QC program to help monitoring the use of the POCT system. Implementation of acceptable QC or QA concepts will become issues of vital concern to both the clinicians and the laboratory. In order to set up a good POCT program, it is essential to have a POCT co-ordinator (generally a well qualified medical technologist) who reports to a designated laboratory supervisor (probably the clinical biochemist or a pathologist) to coordinate all such activities.[14, 15] Discussion and good communication with clinical users is essential. It would be the clinical user's responsibility to monitor and solve the problem, with assistance from the laboratory if requested. The most difficult part of any quality control program is the start-up phase.[16] An example of the minimal requirements for QC monitoring of a POCT system (i-STAT, a portable blood gas analyzer) is given below:

1. Within individual clinical user units, operators (Medical Officers or Nursing Officers) use the i-STAT electronic simulator on each analyzer **DAILY** to simulate actual test cycles, testing the functionality and continuity of analyzer to determine if the analyzer is performing accurately. Results from the electronic simulator are documented and transmitted to the PC computer (Central Data Station) located in the ward.

2. The laboratory will provide a **WEEKLY** performance checking on the instrument by sending control solutions to individual clinical user units to ensure a proper operation of the system, and maintain a log, documenting each quality control test for record-keeping in the laboratory.

3. In order to verify the integrity of a new shipment of cartridges. A **MONTHLY** (or on the day of delivery of cartridges to the hospital) performance verification which consists of three levels of controls covering the normal, acidosis, and alkalosis ranges will be performed on-site to document that cartridges have been received and are functioning properly.

4. Regular i-STAT user meetings involving the laboratory, clinical users and representatives from the manufacturer would be desirable.

Obviously, comparison of this regimen to traditional laboratory QC procedures one can see confusing because it does not employ QC samples to cover three shifts a day, seven days a week, and 365 days a year to enhance error detection. Following traditional QC regimens to their logical end for POCT devices would mean assaying QC samples on each analyzer, in each location, on each day of use. For four analyzers in three locations, altogether the consumable expense just in QC alone for POCT would exceed HK$130,000 (365 days x 3 shifts x 4 x HK$30) per year in our hospital, which can cost five to ten times higher than consumables in the main laboratory. The popularity of POCT is due to the efficiency and convenience that this technology offers. What the clinical users' concern is whether such a "stringent" QC requirement would make this product not suitable for their use. Indeed, they are using it just for emergency situations (5 to 10 samples per day). Any significant maintenance time and the addition of QC responsibility to the duties of an already overworked nursing staff may beat their purpose. Some of the regulation and accreditation organizations recommend the daily use of aqueous QC samples for the first month of installation, slowly stepping back the frequency as a database of performance information increases confidence levels. Healthcare regulators in the USA, however, are skeptical of the QC regimen by the use of electronic controls. By the same argument, this might be the main concern from the laboratory point of view.[17, 18]

In summary, point-of-care technology has made its greatest impact in acute care settings, where fast and reliable test results are a primary concern. The impact of POCT may differ among individual institutions. A successful point-of-care system requires extensive correlation studies, appropriate QC monitoring, meticulous data management, and cost justification. We should bear in mind that POCT is an ancillary service designed to supplement, but not replace, activities of the central laboratory. Further investigations would be necessary to elucidate the specific applicability and benefits of POCT, and to ensure that laboratory standards are satisfied and medical needs are met. Future look should centre on the development of a new cooperative relationship between the clinical user and the laboratory, share many of the same needs and concerns, and provide a common ground and powerful incentives for these two groups of professionals to work closely together.

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