Point-of-Care Testing (POCT): key factors to ensure efficiency and high quality

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This article discusses the results of a recent study in the OLVG hospital, Amsterdam, which show that it is possible to implement a point-of-care testing (POCT) system without any negative data quality or cost consequences. For this to happen, certain key points have to be observed. Principal among these is the use of a flexible, high performance IT connectivity system.

The theoretical clinical advantages of point-of-care testing (POCT) are clear. Obtaining vital and potentially life-saving critical-care diagnostic data from the patient in a rapid and accurate fashion means that health-care professionals can initiate or adapt treatment of their patients much faster, not to mention having more time with their patients. It is no surprise that ever-increasing numbers of clinicians are insisting on POCT and asking for more and more tests to be made available in POC format in their medical areas.

Along with the theoretical advantages of POCT, there are, however, practical issues which have to be faced. One such issue from which POCT is not spared is the general pressure in the healthcare sector, and in particular in hospital diagnostics, to continuously improve the quality of patient care at the same time as reducing costs within ever-tightening budget restrictions. Many clinicians assume, erroneously, that such budgetary constraints are incompatible with setting up and operation of POC testing systems, or that in some way both the efficiency of the system and the quality of the diagnostic data will suffer as a consequence.

In fact it has been shown that if POC testing is carried out within the framework of a dedicated system, that includes not just up-to-date instrumentation and reagents, but also, crucially, a powerful and flexible data management software system, then it is possible to achieve high quality and efficiency within even the tightest budgetary constraints. Such systems not only improve the process, but also ensure that the Laboratory Manager, the Point-Of-Care-Coordinator, or any other person designated as being responsible, are firmly in control.

Quality assurance and control are key aspects in decentralised point-of-care testing and require appropriate tools to manage POCT efficiently and effectively. Controlled quality assurance is vital.

Challenges to be met for successful POC testing

There are several questions which need to be answered when implementing a POC system. These include:

1. Are POCT results comparable to those from the central lab? Are the tests reliable? Can any discrepancy of POC results nevertheless be acceptable while still assuring safe and efficient clinical practice?

The validity and reliability of POC tests in the critical care area (for example, blood gas analysis, electrolyte and metabolic analysis, coagulation monitoring, etc.) is of vital clinical importance. It has been shown that POCT tests and instruments in such areas can indeed provide data that are equivalent or acceptably similar to those generated by central lab systems from the point of view of quality and reliability. Many different scientifically-controlled studies carried out over the last several years have demonstrated this [1, 2]. It is of course mandatory that in such situations regular quality control procedures be carried out to guarantee that high quality/reliability levels are maintained.

2. Who is responsible for the overall POCT system?

Within the hospital, just one body should have final responsibility for POCT. In most cases this is the central laboratory since testing is its core competence. Nevertheless the question arises as to exactly how the central lab should control decentralised POC-instruments? IT connectivity is the optimal solution to this key question. If hospitals connect their instruments to a suitable POC Data Management system and configure the system so that the quality controls are the most relevant for covering their particular processes and needs, there will be no problem with control. Such a system will control not only the quality of the test and the decentralised instruments that carry out the test, but also the operators/users.

This structure is one which gives the central lab the control over the decentralised POCT, without necessitating additional effort, but still ensuring better patient care.

3. Do POCT systems needlessly increase the complexity of hospital diagnostics?

It is commonly supposed that the co-existence of POCT systems with central lab testing inevitably means the addition of an extra level of complexity to the overall hospital diagnostics process. In fact, if the hospital ensures that all instruments are inter-connected through appropriate IT systems, this need not be the case. All modern diagnostic instrumentation devices are designed for use with a POCT data management system and in particular have bi-directional communication capabilities. This means not only that results and additional important information can be sent from the instrument to the data manager, but also that information and commands can be sent in the opposite direction. The implementation of such a POCT structure means that in fact the overall complexity of the hospital's diagnostic system can be simplified. For this to be achieved, it is however necessary that certain key processes and workflow systems be implemented. These include:

Management of operators

Operator IDs are important to make sure that only those operators who are authorised on the basis of their ability, qualifications and/or experience to carry out a test are actually doing so. The system should be able to manage from one central point all approved operators, whether there are 20 or 2000 of them, and to allocate them on a hospital-wide basis to individual instruments and/or tests. The system should have the possibility, again from one central point, to remove the authority of an individual operator to carry out a particular test (e.g. if the operator’s certificates are no longer valid) or re-authorise them (e.g. after having certificates renewed). Appropriate IT systems are again the key to such operator management.

Management of instruments

The system should be able to monitor the status of all decentralised POC instruments, and

<table>
<thead>
<tr>
<th>Central laboratory glucose measurement</th>
<th>Point of Care glucose measurement</th>
<th>Labour (Time)</th>
<th>Labour (Time)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hands-on time clinical department</td>
<td>Write an order for the lab and label the sample</td>
<td>2 min</td>
<td>Control POCT system and log in the system as user with a personal identification number in barcode.</td>
</tr>
<tr>
<td>Identify patient and take a capillary blood sample</td>
<td>3 min</td>
<td>Identify patient, scan barcode of the patient and take a capillary blood sample</td>
<td>3 min</td>
</tr>
<tr>
<td>Distribute sample and order form to the lab</td>
<td>3 min</td>
<td>Analyse sample using POCT system</td>
<td>0.5 min</td>
</tr>
<tr>
<td>Transport</td>
<td>2-20 min</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 1. Cost breakdown comparison between POCT and central lab testing in OLVG hospital, Amsterdam.
to be able to lock and unlock them from one single point. Knowing exactly which instru-
ment needs troubleshooting (and where it is physically located) is possible through modern
IT connectivity systems.

Quality control
This is one of the most important tasks to be carried out by the system. A correctly-config-
ured IT system means that the following key requirements for the maintenance of quality
assurance can easily be achieved:
- Ensuring that quality control is performed on a regular basis in accordance with labora-
tory guidelines,
- matching QC operations with shift patterns or testing routines,
- ensuring that individual instrument set-ups maintain the highest level of quality assur-
ance without needing to interrupt hospital workflows.

Material management
This can be achieved via the IT system by coordination and analysis of reports and results
from all the decentralised instruments.

From all the above it can be seen that with the appropriate IT system, POC testing can actu-
ally be carried out with fewer steps and a reduced workload. The data management system
takes care of the transmission and handling of all results which are either forwarded already
validated to the Laboratory Information System (LIS) or forwarded for later validation in
the LIS. In both cases, full traceability is available.

4. Why is POCT so expensive? Why are tests more expensive than the central lab tests?
And why should hospitals pay for the IT solutions necessary for the correct operation of
POC systems?
It is a fact that a single POC test strip is usually more expensive than the individual equiva-
 lent assay carried out in the central lab. However, a meaningful comparison of the cost of
POCT with central labs involves considering more than just the cost of the individual test.
The (relatively) high cost of a single POC strip is due to the sophisticated technology used
in its design and construction. As a result the test is easier and quicker to use. In fact, when
comparing all costs including personnel time, transport, etc., the overall cost of POC sys-
tems is significantly less than centralised lab-based systems.

This conclusion is borne out by detailed analysis carried out in the Onze Lieve Vrouwe
Gasthuis (OLVG), a teaching hospital located in central Amsterdam, The Netherlands [3].
This study showed that savings in time reached 50% and that total cost savings were as high
as 43% (Table 1). The OLVG study showed that the investment in the IT systems necessary
to run the POC testing system was rapidly paid off. Break-even was reached in less than 6
months whereafter significant cost-savings were generated compared to central lab testing
which would have been the alternative for blood glucose measurements.

Such positive financial benefits are only achievable through the implementation of a very
powerful and flexible data management software that can reengineer and/or optimise the
POCT workflows and processes. Such dedicated data management software (development,
im-provement, maintenance) systems are expensive, but still relatively cheap compared to
other software systems. The OLVG study confirmed that the investments in a POC soft-
ware solution made both financial and operational sense. In addition, the implementation
of the system reduces workload, administrative tasks and time-consuming workflows, thus
freeing up the personnel to provide more time dealing directly with and caring for the
patients.

Conclusion
POCT provides a significant medical advantage and can result in considerable economical
benefit if correctly implemented and used. There is no question that POCT should com-
pletely replace testing in the central lab, or vice versa. Both diagnostic areas are important
and needed for the optimal functioning of the hospital. Ideally they complement each other.
Since POCT is part of the diagnostic service of the lab, quality assurance and control should
be integrated into the overall quality assurance system of the central lab. This is no problem
if appropriate IT connectivity and POC Data Management Systems are used. POC testing
improves the quality of patient care, improves the treatment capabilities of clinicians,
reduces the requirements of care-givers and creates cost-savings. As a result, the hospital
staff, from clinicians, nurses and lab staff through to the administrators, become more moti-
vated and, at the same time, the level of patient care is improved.

Table 2. Control processes needed by a POC optimised Data Management IT Solution.
From tests to managed information, it is necessary to have adequate control to achieve use-
able and reliable healthcare information.

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