Point of Care Testing in Clinical Trials

Point of Care Testing

Point of care (POC) testing is diagnostic testing performed promptly and conveniently in the vicinity of the patient, avoiding the often lengthy procedure of sending samples to be processed in a central laboratory. This gives rise to the alternative names of near-patient and bedside testing. The requirement for POC testing is increasing, with the global POC testing market predicted to rise from $12.8 billion in 2008 to $17.8 billion in 2014 (Life Science Intelligence, 2009)

Looking back through history, POC testing has been around from the very start. In Ancient Egypt, patients' urine was analysed at the bedside for abnormalities, and in India around the same time, the practice of tasting urine to detect glucose first arose. Later in the 1600s, this technique reoccurred when Thomas Willis associated sweet-tasting urine with diabetes. During the 1960s, as technology advanced, it became necessary for samples to be sent to centralised laboratories for analysis by qualified scientists using large analytical equipment and a variety of complicated scientific procedures. Now however, with further advancement of analytical technologies, such as solid phase chemistry and integration of microprocessors, analysers are becoming smaller and more compact, meaning we can take diagnosis back to the patient's bedside; to the point of care.

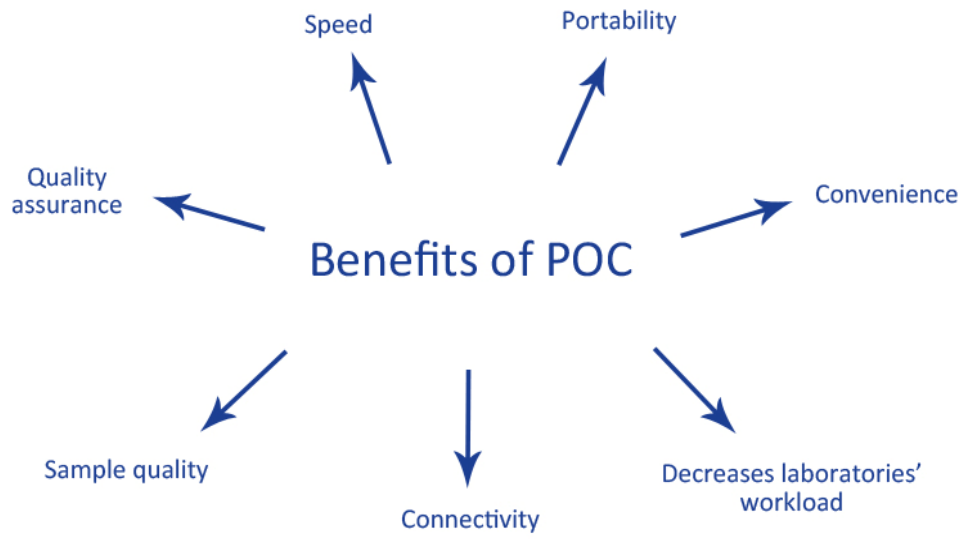
POC testing can be implemented using disposable testing kits, such as dipsticks and cassettes; handheld analysers and monitors; or small benchtop analysers, all of which require little or no maintenance. This equipment can be applied to a range of different tests such as blood gases, electrolytes, coagulation, pregnancy assessment and drugs of abuse testing, covering a variety of fields including biochemistry, haematology and virology.

Why POC?

In certain settings POC offers many benefits and opportunities over the conventional laboratory approach, making it an exciting ever-developing alternative (Figure 1).

- SPEED - The most significant advantage of POC testing is the marked decrease in turnaround time. The testing procedures themselves can produce results in minutes and sometimes seconds. It eliminates the need for samples to be sent to centralised laboratories whereby clinicians have to wait for the specimens to be processed and results returned. A faster patient diagnosis means faster implementation of treatment and all-round better management of the patient and their condition. This is particularly important for a rapid response to critical values.
- PORTABILITY - POC devices are often small and portable and sometimes battery-powered, giving particular advantage when used out in the community or on large hospital sites. Even the larger POC analysers are small enough to be installed in areas such as GP surgeries, thus providing greater accessibility for the people who use them.

Figure 1. Benefits of POC over the conventional laboratory approach



- CONVENIENCE – Clinicians, through the use of POC, spend less time organising the necessary logistics involved when sending samples to a laboratory. Time isn't wasted filling in forms and organising the shipping of specimens or looking for results once completed.
- DECREASES LABORATORIES' WORKLOAD - Pressure is taken from overworked laboratories as appropriately trained clinicians and other non-laboratory staff can carry out testing otherwise performed in the laboratory.
- CONNECTIVITY - Connectivity of POC devices provides even greater convenience, meaning patient and quality control results can be input into a central database where they can be collated, accessed and shared by those who need them. Several methods are implemented by different POC devices, including USB and wireless connections, this eliminates the need for manual transcription, thus reducing errors. Inputting these results into a central database also means they can be used for data mining and research purposes. Usernames and passwords can help eliminate the risk of non-authorised personnel gaining access to patient records.
- SAMPLE QUALITY - With samples being tested immediately, their quality is no longer compromised by time and environmental conditions that are exerted when a sample is transported to a central laboratory.
- QUALITY ASSURANCE - Special POC testing schemes have been set up by the Clinical Pathology Accreditation (CPA) accreditation scheme and the National External Quality Assurance Scheme (NEQAS) to ensure the quality of the results generated by the POC devices and their users.

With all the above points considered, POC testing, when used in conjunction with the traditional centralised laboratory approach, becomes a very powerful, effective tool in diagnostics.

Appropriate Governance and Quality Assurance

In taking laboratory testing outside the confines of the CPA accredited laboratory and out of the hands of the qualified laboratory staff, POC testing becomes an area that requires strict governance and application of quality assurance. This is an issue that is highlighted in the *Review of NHS Pathology Services in England* (The Carter Report), chaired by Lord Carter of Coles. The report represents a thorough and informed appraisal of pathology and the direction in which this key diagnostic service should develop to meet the requirement for high-quality patient care. The Carter Report calls for POC testing to be covered by CPA regulations. In response to this the CPA organisation have set out several external quality schemes for POC testing that relate to each area of testing. The Institute of Biomedical Science (IBMS) has suggested future integration of CPA and NEQAS to create an independent strengthened accreditation service, which also extends to POC testing.

Abbott i-STAT Portable Clinical Analyser

The IBMS, in conjunction with The Royal College of Pathologists, have published a set of guidelines on POC testing to direct POC users in the appropriate implementation of POC technologies. The guidelines advise that POC testing should be overseen by a CPA accredited laboratory who would have the relevant knowledge and experience to ensure quality assurance is implemented correctly. To meet the needs of clinical governance it is recommended that all the laboratory disciplines are under the guidance of a POC testing committee. NHS POC testing committees typically include managers with an understanding and authority for implementing a POC program, members of the hospital laboratory such as the POC testing manager (quality manager), pathology services manager and a co-ordinator of the laboratory's quality assurance schemes, as well as various other individuals who are using the POC testing devices in the hospital or general practice. In general practice the committee will be under the guidance of the local Primary Care Trust (PCT). The POC guidelines recommend that POC committees based in hospitals and those in local primary care involve members from both sectors to ensure an overview of POC devices across the divisions.

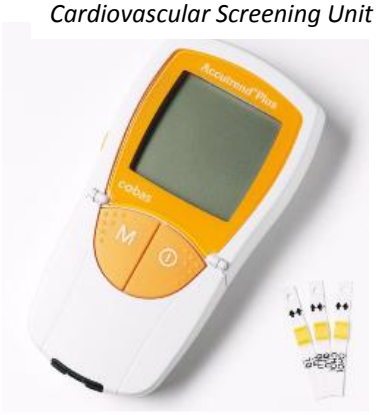
These POC committees are designed to ensure that the cost and clinical need for a POC test are first considered before purchase and implementation; that internal quality schemes are in place to ensure the device and the user are performing to an acceptable standard, and participate regularly in the relevant external NEQAS schemes and that performance in these schemes is reviewed. It is essential to monitor POC testing to ensure devices are well maintained by qualified Biomedical Scientists; users are kept up-to-date with training and that Standard Operating Procedures (SOPs) are written and adhered to, to appropriate standards. It is also important that any results obtained by patients using devices at home, that are indicative of an infectious disease, are reported to the Health Protection Agency (HPA).

As mentioned, the POC testing device operators are required to be adequately trained to maintain a high-quality service. The user should be trained using SOPs and not be allowed to perform tests that will alter clinical management until the trainer is satisfied with the user's competence

and this is documented. When training is complete the user should be registered, and sign to accept legal responsibility for the results they generate. It is also important to keep the user's skills up to date with Continuing Professional Development (CPD). In the situation where a device isused by a patient to self-manage a condition, it is important the individual is not only trained appropriately in the use of the device, but also in how to correctly interpret the result and the application of this to self-management. The SOPs should be written to the standard of CPA and NEQAS and according to the IBMS guidelines, must include the following points;

- Clinical background
- Analytical principle
- Health and safety including:
    - Information on COSHH (Control Of Substances Hazardous to Health)
    - Safe disposal of waste
    - Control of infection
    - Adverse incident reporting
- Pre-analytical considerations
- Equipment
- Reagents, standards, controls and quality assurance
- Test procedure
- Sample analysis
- Calculation of results
- Assay performance
- Maintenance
- Record-keeping

Roche Accutrend Plus Cardiovascular Screening Unit



POC testing in Clinical Trials

Results generated by POC devices can be utilised in clinical trials as decision-makers prior to administering treatment, or results can be used as actual trial data. Companies exist that can supply POC equipment and reagents to sponsors and CROs on a global scale. It is essential that these companies are suitably equipped to provide an efficient and reliable service as this is a highly specialised area of expertise. Biomedical scientists with a high level of knowledge and experience are required to provide global training and technical support. It is important to have a well-equipped service department with qualified engineers to ensure equipment is fully calibrated and maintained. Experience in logistics is also essential to maintain the supply of sensitive reagents worldwide. Reagents need to be kept at correct stable temperatures throughout the shipping process, so it is vital to work with the correct logistics companies who can move equipment and reagents across borders and through difficult countries whilst ensuring the cold chain is maintained and documented.

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Authors

Mike Wickham is the Managing Director of Woodley Equipment Company. Mike is a Chartered Scientist and Fellow of the Institute of Biomedical Sciences with 36 years experience specialising in Haematology, Blood Transfusion and Point of Care devices for all disciplines. Email: mikew@woodleyequipment.com

Dave McComas is the Biomedical Technical Manager at Woodley Equipment Company. Dave is a Biomedical Scientist and Fellow of the Institute of Biomedical Sciences with a BSc in Biology and an MSc in Biomedical Sciences specialising in Haematology, Blood Transfusion and Point of Care devices for all disciplines. Email: davem@woodleyequipment.com

Charlotte Wickham is a Biomedical Specialist in the Technical Service Department at Woodley Equipment. Charlotte is a trainee Biomedical Scientist with an MSc and BSc in Biomedical Sciences with Forensic studies, specialising in Haematology, Biochemistry and Point of Care devices for all disciplines. Email: charlottlew@woodleyequipment.com

For further information on the Point Of Care range Woodley Equipment can offer, including their supporting services; Biomedical Scientists, logistics management, medical electronics and technical support, please visit www.woodleyequipment.com or contact us on +44 (0)8456 777001.