IFBLS' Guidelines regarding Point of Care Testing (POCT)

Point of care testing (POCT) involves collecting specimens and performing biomedical analyses near the patient. Patient safety and quality assurance are best addressed by virtue of a multi-disciplinary governance system.

Point of care testing is performed in the following "near-patient" areas:

- **Within hospitals:** in emergency units, in acute departments, e.g. anaesthesia and intensive care units, other hospital departments and outpatients' departments.
- **Outside hospitals:** in institutions, in nursing and care units, in community treatment centres, at clinics in primary health care, in physician's offices and in patients' homes.
- As part of the ambulance services or other mobile facilities.
- Patients' self-testing.

Terms and Abbreviations
Several terms and abbreviations are used to describe Point of care testing:
Point of care testing – POCT
Near-patient testing – NPT
Bedside testing – BT
Patient self testing – PST

Introduction
Modern healthcare and laboratory medicine constitute elements of a society in continual development. New medical advances and new technology provide us with new opportunities to meet human needs for accessible and safe health care. Health care previously requiring prolonged and highly specialised institutional care can today be performed close to where people live and work in their day-to-day lives (1).

Point of care testing has an important role to play in the delivery of an efficient healthcare service because of its ability to provide a rapid test result, in a timely manner, close to the patient. This may lead to increased clinical effectiveness and improved outcome for patients. However, this is only true if the result delivered is accurate and reliable.

It is important that where POCT is delivered there is a clearly defined and well structured approach and robust clinical governance framework, in order to ensure that it is performed in a safe and effective manner and conforms to acceptable analytical and clinical standards (2).

It is highly recommended that the guidelines drawn up in this document is adopted by those responsible for POCT.

The development of point of care testing will impact on professional roles and functions within health care. Professional groups, or individual patients, – who, today, lack formal training or practical knowledge of laboratory methods now become responsible for performing analyses. In order to meet this need, laboratory medicine has to develop functions which take on responsibility for quality assurance of POCT, but which also support planning, purchasing and validation of analysing equipments and tests. Other important functions are training, supervision and working consultatively, not only with personnel performing POCT, but also with patients performing their own analyses.

Biomedical Scientists have the necessary expertise and competence to take a lead role in ensuring safe and effective governance of POCT. This includes the responsibility for areas such as selection and validation of equipment, education and training of users, internal and external quality assurance, maintenance, record keeping of quality and patient data, incident reporting, risk management and clinical audit, advice and interpretation.

Self testing

Self testing is a laboratory analysis performed in the homes of patients with chronic conditions (e.g. diabetes), or by individuals in order to screen their own state of health. Such equipment can be purchased at a chemist or through the Internet. The quality of self testing depends on the precision of the test, adequate user guidance, an understanding of the analytical procedure involved and knowledge of how to interpret the result of the analysis (1).

Patient safety

Today, it is a relatively simple and quick process to produce test results using point of care testing. An essential element of POCT is equipment and methods should be relatively straightforward in order to achieve a high degree of user friendliness.

It is important to bear in mind that patients depend on accurate and reliable results from POCT devices to allow for effective diagnosis and monitoring of treatment. Operator competence is essential for optimal POCT performance.

A central role for laboratory medicine is to provide expertise and resources in order to have overall governance of quality assurance work within POCT (3).

Certification and accreditation of point of care testing

Use of POCT must be accredited or certified if this is required by national laws and regulations.

All POCT should comply with the requirements of the International Organization for Standardization (ISO)

ISO 22870 Point-of-care testing (POCT) – Requirements for quality and competence (4).

ISO 15189 Medical laboratories – Particular requirements for quality and competence (5).

ISO 15190 Medical laboratories – Requirements for safety (6).

Policy statement and primary principles for point of care testing in Health Care

Policy statement
Biomedical laboratory scientists are responsible for the quality assurance and quality improvement of all analysis carried out in near-patient areas, and for the evaluation of benefit and resource allocation in near-patient analysis.
This means biomedical laboratory scientists are responsible for:

- The evaluation and selection of methods and equipment to be used in point of care testing.
- The content of user guidelines (standard operating procedures) and practical training for users.
- Training and guidance to ensure that methods are carried out and equipment is used in accordance with approved protocols and to secure patients safety.
- Designing and conforming to internal and external quality control protocols.
- Organising quality systems for all measures surrounding the POCT analysis.
- Protocol for reporting analytical results from POCT analysis.

Primary principles for point of care testing in Health Care
In order to safeguard care and treatment of patients, comply with these guiding principles for point of care testing:

- Point of care testing should be integral to a quality system and be embraced by the same quality requirements which are required of analysis within the clinical laboratories.
- POCT activities should take place in cooperation with an acknowledged/accredited clinical laboratory.
- POCT activities should be integral to a quality control program.
- Local protocols for cooperation between partners in respect of POCT should be established.
- The clinical laboratories shall be responsible for ensuring equipment and procedural guidelines are adapted for POCT and they are accessible to those performing POCT.
- The clinical laboratories shall be responsible for continuous education and follow up to ensure that those performing POCT are competent to perform the analyses in question.
- The clinical laboratories shall be responsible for evaluation of a quality system in respect to POCT.
- Protocols shall exist for obtaining results from and documenting POCT analysis.
- Instrument data should be recorded and retention times should be linked with quality assurance and patient data, if possible.
- An instrument log, which should be retained for the life of the instrument, is essential.
- Cooperation between clinical laboratories and equipment manufacturers should be developed with regard to evaluation, purchasing and service.
- All those performing POCT should be fully familiar with factors present prior to, during and following testing, which may influence the test result.
- Patients who analyse their own specimens and evaluate the results, with regard to their disease, should regularly be offered appropriate training, follow-up and access to quality assurance, in respect of the method of testing and equipment used.

Questions to consider before introducing point of care testing in Health Care

Potential advantages of POCT include:

- Improved turn-around time.
- Enhanced clinical management.
- Better patient compliance with results of analytical tests.
- Savings in cost and time for patients.

Potential disadvantages of POCT include:

- Inappropriate testing leading to increased costs with no benefits to the patient.
- Inaccurate results, leading to less than optimal health outcomes for the patient with additional testing and treatment.
- Possible health damages to the patient.
- Possible increased consultation and waiting times.
- Analytical results from POCT possibly not being reported as part of the patient chart or electronic health record (EHR)

Questions to consider before introducing POCT in Health Care

- Is the use of POCT providing a faster result to effect clinical treatment?
- Is it good patient safety to perform POCT?
- Is the effectiveness of POCT at least as good as for the same clinical laboratory analysis?
- Is it the same or more cost-effective to perform POCT compared with clinical laboratory analysis?
- How will POCT be financed?
- Are there differences between POCT environments, such as rural or urban settings, and target populations?
- How will laws and regulations apply to implementation of POCT?
- Possible microbiological, chemical and environmental hazards.

Criteria for selecting tests suited for POCT

- Clinical needs in public health.
- Minimal risk to patients.
- Following clinical evaluations documenting test performance.
- Easy to perform and interpret for the intended users.
- Approved risk assessment (7).

Consider these elements before introducing point of care testing (8, 9):

Decision criteria for or against POCT

- Medical aspects
- Clinical benefits
- Turnaround Time (TAT)
- Sample volume
- Analytical quality

Organizational aspects

- Personnel
- Storage and safety
- Training
- Management and leadership

Economical aspects

- Fixed costs
- Variable costs
- Personnel costs
- Cost-effectiveness

Quality assurance

- Adequate sensitivity / specificity
- Internal quality control
- External quality control
- Documentation

Quality assurance of point of care testing

The chronological link between test results, quality control results and instrument status must be retained. Any users of POCT must comply with any relevant standards that may be required under national and international regulations (10).

Internal quality control (IQC)
IQC is a system for validating the results before they are issued. This means that the operator must know the acceptable range of results for the QC material. It is important to devise a protocol that will distinguish between instrument malfunction and a procedural error.

External quality assessment (EQA)
EQA involves the analysis of samples received into a clinical area from an external source – this could be from the local laboratory itself, from the manufacturer or from an external body, such as a NEQAS, CAP or similar national or international bodies. It is a means of validating the results after they are issued, which means that the acceptable range of results is unknown to the operator.

Organisation of Point of care testing

Primary responsibility for quality coordination
A multi-disciplinary team consisting of staff from the clinical laboratories and the wards/clinics performing point of care testing shall be established. They will coordinate activities, to ensure organisation and continual re-evaluation of point of care testing.
Before performing point of care testing, the multi-disciplinary team shall evaluate whether the analyses in question are suitable for POCT, i.e. with regard to operator competence, patient safety, health economics, and that the point of care methods have been evaluated against corresponding analyses at the clinical laboratory (1).

Local point of care testing coordinators
Coordinate:

- Point of care testing activities on the ward/clinic or equivalent
- Together with biomedical scientists from clinical laboratories, train and certify personnel who are to perform point of care testing
- Maintenance and simple troubleshooting
- Internal quality audits
- Competency maintenance and development

Descriptions of procedures and equipment
For each measuring instrument, there shall be written instructions/procedures for equipment maintenance/use and a technical description.
For each point of care method, there shall be a procedural description, in respect of how the testing shall be performed, possible sources of errors and reporting protocols for the measurement result.
The method description should include:

- Clinical indication
- Patient preparation, sampling technique and sample material
- Handling of samples
- Measuring principle
- Apparatus and additional equipment
- Reagents, storage and shelf-life
- Internal and external controls
- How to carry out analysis
- Reference range/therapeutic range
- Maintenance log
- Sources of error and deviation management
- Recording, reporting and interpreting results
- Contact persons at the laboratory

Documentation of measurement result
Analysis results from POCT shall be properly documented in the patient's medical chart. It shall be clearly stated in the medical chart that the measurement result is derived from near-patient testing.

Documentation of quality assurance work
The results of control tests performed, deviations and management of these shall be documented and evaluated by internal audit. The documentation shall include the name of the person performing the measurement, the time, deviations and procedures followed when the controls are out of range.

Method development
The clinical laboratories are responsible for monitoring national and international developments in the area of POCT and for disseminating information in respect of these. Change of method must be done in cooperation between the POCT coordinators on the ward/clinic and the POCT responsible biomedical scientists at the clinical laboratories.

Annual evaluation and quality audit
Local POCT coordinators on the wards/clinics lead and support quality assurance work to ensure compliance with protocols and undertake internal audits. Once annually the cooperating clinical laboratory performs a quality audit and a joint evaluation of POCT activities takes place.

References:

1. Point of Care Testing. NITO The Norwegian Institute of Biomedical Science. 2. edition, revised 2008.
2. Guidelines for Safe and Effective Management and Use of Point of Care Testing. Approved by the Academy of Medical Laboratory Science, Association of Clinical Biochemists in Ireland, Irish Medicines Board and RCPI Faculty of Pathology. November 28, 2007. Ireland
3. Near patient testing activities - a development of the health care process. Vårdförbundet (The Swedish Association of Health Professionals) and IBL (The Swedish Institute of Biomedical Laboratory Science), April 2005.
4. ISO 22870:2006 Point-of-care testing (POCT) - Requirements for quality and competence.
5. ISO 15189:2007 Medical laboratories - Particular requirements for quality and competence.
6. ISO 15190:2003 Medical laboratories - Requirements for safety.
7. Australia: Point of Care Testing trial. PoCT in general practice. May 7th, 2009. http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pathology-poctt-index.htm.
8. Rizzottia P, Villanib A. Il caso del Point of Care Testing. Riv Med Lab - JLM, 2004, 5: Suppl. al n. 3.
9. Briedigkeit L, Müller-Plathe O, Schlebusch H, Ziems J. Recommendations of the German Working Group on Medical Laboratory Testing (AML) on the introduction and quality assurance of procedures for Point-Of-Care Testing (POCT) in hospitals. Clin Chem Lab Med, 1999, 37: 919-925.
10. Point-of-Care Testing (Near-Patient Testing). Guidance on the Involvement of the Clinical Laboratory. Institute of Biomedical Science, United Kingdom

Suggestions for further reading:

- Clinical and Laboratory Standards Institute, CLSI: www.clsi.org
- International Organization for Standardization, ISO: www.iso.org
- College of American Pathologists, CAP: www.cap.org
- United Kingdom National External Quality Assessment Service, UK NEQAS: http://www.ukneqas.org.uk
- Scandinavian evaluation of laboratory equipment for primary health care, SKUP: http://www.skup.nu/
- Umgang mit Point-of-Care-Testing – labmed-Empfehlungen: http://www.labmed.ch/doc/doc_download.cfm?uuid=11F2BEBDD9D9424C46B2DA91FAB1EB25&&IRACER_AUTOLINK&&. Labmed Schweiz Suisse Svizzera.
- Management and Use of IVD Point of Care Test Devices: http://www.mhra.gov.uk/Publications/Safetyguidance/DeviceBulletins/CON007333 The Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom.
- Point of care testing - top 10 tips: www.mhra.gov.uk/Publications/Postersandleaflets/CON008382. The Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom.
- SIMeL-POCT Position Paper 2009. Available at http://www.simel.it/it/notizia.php/101573.
- Point of Care: The Journal of Near-Patient Testing & Technology: http://journals.lww.com/poctjournal
- NHS Guides and evaluations on Point of care and self testing, United Kingdom: http://www.pasa.nhs.uk/PASA/Templates/Content.aspx?NRMODE=Published&NRNODEGUID=%7BD41FABCF-73FC-4D96-974E-EB457B152037%7D&NRORIGINALURL=/PASAWeb/NHSprocurement/CEP+old/outputs/Labmed.htm&NRCACHEHINT=NoModifyGuest#POC .