Point Of Care Testing Policy

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Changes from last version of this document

Updated to new template

Change of reference of CPA to UKAS

Change reference of Directorate Manager to Care group Manager

General update

Contents:

1 Purpose and Scope

Analysis of constituents in blood and other body fluids is a vital part of the decision making process associated with the diagnosis and management of disease. Typically specimens are sent to the laboratory for analysis with the results being returned by telephone or electronically and/or with a hard copy report. In some cases, delays caused by sending the specimen to the laboratory are unacceptable to the clinical and/or operational situation; in these circumstances testing at the bedside or in the clinic or GP surgery is preferred. This type of testing is termed 'point-of-care testing (POCT) or sometimes near patient testing (NPT). In this context POCT refers to "any analytical test performed for a patient by a healthcare professional outside the conventional laboratory setting".

There are a wide range of different diagnostic tests performed outside the laboratory from simple urine dipstick tests to those carried out on sophisticated analysers with varying degrees of adherence to good practice in relation to training, certification of staff, quality control and record keeping.

POCT has developed in a somewhat ad hoc way in the early years with evidence of poor training of staff, poor quality control and poor maintenance of equipment - all of which provide opportunities to put the patient at risk. This is reflected in the fact that there have been several hazard notices published following incidents of poor practice leading to the production of erroneous results. In one such notice, it was stated that all testing outside of the laboratory environment should only be undertaken in collaboration with, and support from, laboratory professionals.

Guidelines on the organisation of POCT have been produced by a number of organisations notably the Medicines & Healthcare products Regulatory Agency (MHRA), formerly the Medical Devices Authority (MDA) and the Welsh Office and endorsed by accreditation bodies.

It is now implicit in the ISO 15189 standards for laboratory services that there are appropriate accreditation guidelines of POCT equipment with the appropriate involvement of laboratory professionals. It is also expected in the accreditation of hospital-wide services that POCT will be subject to guidelines that ensure the maintenance of the highest quality of service.

Failure by staff undertaking point-of-care testing to adhere to the required protocols, standards of training, record keeping and quality control are not only putting patients at risk but also exposing themselves and the Trust to loss of income, damaged reputation and potential litigation. This policy is aimed at all Trust healthcare professionals who perform analytical tests for any patient outside the conventional laboratory setting.

These analytical tests include, but are not limited to, tests carried out to measure blood glucose, blood gases, HbA1c levels, bilirubin in neonates, INR levels, pregnancy tests and urinalysis.

2 References

The requirement for this policy is evidenced in the following documents:-

- Management & use of in vitro diagnostic medical devices MDA DB2002 (02).
- Management & use of IVD point of care devices MDA DB2002 (03).
- United Kingdom Accreditation Service, Standards for accreditation of medical laboratories.

- ISO 15189/22870 Laboratory/POCT standards.
- Point of Care Testing: The use of diagnostic equipment and procedures outside the diagnostic laboratory. The Welsh Office.

3 Definitions

POCT, Point-of-Care Testing

NPT, Near Patient Testing (an alternative name for POCT)

UKAS, United Kingdom Accreditation Service

NHSLA, National Health Service Litigation Authority,

QSG, Quality & Safety Group

MHRA, Medicines & Healthcare products Regulatory Agency

4 Responsibilities

All staff involved in the management, use and delivery of point-of-care testing are required to ensure that such testing is conducted to the required standards for clinical governance, NHSLA and UKAS accreditation purposes in order to minimise risk to patients, themselves and the Trust.

All staff undertaking point-of-care testing must comply with the requirements set out in this policy. Failure to do so may result in disciplinary action.

Operational implementation, delivery and monitoring of the policy reside with:-

A POCT Committee which is established within the Trust to oversee the management of POCT and to ensure a high quality POCT service is maintained. It will be made up of representatives from Laboratory Medicine, POCT Coordinator, Nursing staff, Medical staff, the POCT service users, the Medical Equipment Manager, representatives from primary care (where appropriate), and a representative from the Purchasing Department (where necessary).

The Committee will:-

- Draw up the terms of reference on which it meets
- Meet on a regular basis
- Be accountable through the Patient Safety Group (PSG) to the Medical Director.
- Review of all business cases associated with POCT.
- Standardise all POCT equipment within the Trust.
- Oversee adherence to this policy.
- Review and update this policy
- Review such aspects of POCT equipment & training as necessary
- Review audit of POCT.
- Review AIRS reports relating POCT

The success of this policy is dependent on a range of individuals being involved in the implementation of this document. The responsibilities on individuals in ensuring compliance with this document are detailed below:-

The Point-of-Care Testing Co-ordinator nominated from within Laboratory Medicine will:-

- Ensure day-to-day operational aspects required in this policy are adhered to.
- Validate and introduce new items of POCT equipment and methodologies.
- Draw up standard operating procedures for POCT equipment, which will include the following:- correct preparation of the patient & sample type; correct storage of the device, reagents, calibrators & quality controls (QC); basic housekeeping & troubleshooting procedures, correct performance of the analysis; QC procedures that must be adhered to; correct documentation of patient results and QCs; COSHH risk assessments and other health and safety information; the correct disposal of any consumables & cleaning of any contaminated surfaces; the significance of results produced and appropriate action to be taken; the limitations of the procedure and any known causes of interference which may give rise to erroneous results.
- Maintain a virtual POCT file on Staffroom containing the POCT policy and appropriate up to date SOPs.
- Carry out necessary training in POCT instrumentation and techniques, including appropriate sample preparation, quality control, safe practice, basic housekeeping and maintenance, record keeping and significance of results produced and relevant action to take.
- Maintain a log of current certified operators of POCT devices.
- Have the authority to remove an individual's permission to use a POCT device where there are clear breaches of this policy. This will only be done as a last resort and following consultation with the Chairperson of the POCT Committee and/or the Medical Director. Initially, the individual's breaches will be reported to that person's clinical, medical or technical line manager and opportunity given for improvement and/or further training.
- Have the authority to remove a POCT device from a ward or unit because of breaches of the policy or because of persistent poor performance or poor return rate in external quality assessment. This will only be done as a last resort and following consultation with the Chairperson of the POCT Committee and/or the Medical Director. Initially, poor performance will be reported to the matron and lead clinician responsible for the ward or unit and an opportunity given for improvement.
- Carry out an annual audit to review POCT equipment in use in the Trust to include aspects such as training, performance in external quality assessment, and adverse incidents.
- Investigate adverse incidents related to POCT & coordinate any response.
- Coordinate any corrective actions required as a result of issues raised from assessment by external bodies
- Give performance reviews as necessary to the POCT Committee and/or Clinical Risk Group.

Care Group Managers will:-

- Ensure compliance with the POCT policy throughout their area of responsibility.
- Ensure staff are aware of the policy.

Matrons will:-

- Ensure compliance with the POCT policy throughout their area of responsibility.
- Ensure staff are aware of the policy.
- Be aware of maintenance and breakdown procedures.

Individual operators will:-

- Ensure that they are certified competent before attempting to use a POCT device or technique
- Ensure that all aspects of the Standard Operating Procedure (SOP) are adhered to, including: - carrying out any routine maintenance & cleaning; using the correct sample; the correct procedure; any QC is within acceptable limits; results are documented.
- Ensure that there is documentary evidence for who and why the POC test has been requested.
- Ensure that there is documentary evidence to show both the patient and the clinician treating the patient has been informed of the results.
- Ensure that any treatment to the patient required as a result of the test is carried out in a suitable time frame.
- Report faulty or malfunctioning equipment immediately to their line manager or ward manager or the POCT Co-ordinator and ensure the equipment is removed from use.

5 Training

Training is not part of the Corporate Statutory and Mandatory Training.

Training can be accessed by one of the following and must be completed every two years:-

- E learning, via the Learning Hub
- Locally arranged training via;
    - Point-of-Care Testing team
    - Recognised POCT link trainer

Initial training must always be carried out face to face by a suitably qualified person, as per the training policy (PC-POL-TRAIN)

6 Publication and Distribution

This policy is to be published and distributed to all staff within the Point of Care Testing department through the Q-pulse document module. It will also be published in the POCT virtual folder on Staffroom, available to all end users of POCT equipment.

7 Process for Monitoring Compliance and Effectiveness

In order to fully monitor compliance with this policy and ensure effective review, the policy will be monitored as follows:-

Minimum requirement to be monitored	Process for monitoring	Responsible Individual/ committee/ group	Frequency of monitoring	Responsible individual/ committee/ group for review of results	Responsible individual/ committee/ group for developing an action plan	Responsible individual/ committee/ group for monitoring of action plan
Production of a documentary controlled policy drawn up according to the Development and Management of Policies template	By audit	Policy manager	Every 2 years	Healthcare Governance Directorate	POCT Committee	Healthcare Governance Directorate
Inventory held within Q-Pulse of all reusable medical devices	By audit	POCT Team	As per audit schedule on Q-pulse	POCT Coordinator	Quality Management & POCT Coordinator	Quality Management & POCT Coordinator
Records of maintenance and repair of all POCT equipment	By audit & automatic renewal reminders by Q-pulse.	POCT Team	As required depending on equipment needs.	POCT Coordinator	POCT Committee	POCT Committee
A list of trained and competent staff for the various POCT instruments and/or procedures	Records held on POCT middleware	POCT Team	Reviewed monthly for access expiry	POCT Coordinator	POCT Committee	POCT Committee
Written training	2 yearly review of	POCT Team	Every 2 years	POCT Coordinator	POCT Committee	POCT Committee

requirements for type of instrument and frequency of recertification	documents held on Q-pulse and Staffroom					
A list of diagnostic tests exists as a series of SOPs	Q-pulse	POCT Coordinator	As new equipment is procured.	POCT Coordinator	POCT Committee	POCT Committee
Any known risks associated with POCT will be documented	Via Datix, FSN, H&S quarterly audit, risk assessment	Quality Manager & POCT Coordinator	As they occur	POCT Committee	POCT Committee	Q&S Group

8 Appendices

Appendix 1: Policy Management

1- Consultation Process

The Trust will involve stakeholders and any member of staff who uses POCT equipment in the development of its policies.

2- Quality Assurance Process

The author has consulted with the following to ensure that the document is robust and accurate:-

Following consultation with stakeholders and relevant consultative committees, this policy has been through quality assurance checks prior to being reviewed by the authorising committee The policy has also been proof read and the review checklist completed by the Policy Manager prior to being submitted for approval.

3- Approval Process

The approval process for this policy complies with that detailed in the Policy Guidance. The approving body is the POCT Committee.

4- Review and Revision Arrangements

The POCT Coordinator will be responsible for review of this policy in line with the timeline detailed on the cover sheet. Subsequent reviews of this policy will continue to require the approval of the POCT Committee.

5- Dissemination and Implementation

Within Laboratory Medicine this policy will be kept in documentary control on the directorate's Q-Pulse document module. This policy will also be stored on Staffroom under Lab Med & POCT Services, Virtual Folder. The Laboratory Medicine area of the Website will be maintained by the Quality Manager, Laboratory Medicine.

6- Register/Library of Policies/Archiving Arrangements/ Retrieval of Archived Policies

On review of this policy, archived copies of previous versions will be automatically held on the version history section of each policy document on Q-Pulse. The Healthcare Governance Directorate will retain archived copies of previous versions made available to them. Policy Authors are requested to ensure that the Policy Manager has copies of all previous versions of the document.

To retrieve a former version of this policy from Q-Pulse, the Policy Manager should be contacted.

7- Standards/Key Performance Indicators

- The number of DATIX should not increase beyond the standard background rate.
- The maintenance of up to date policies, procedures and records relating to POCT
- The number of staff successfully trained
- Improved performance in both internal & external quality assurance testing.