Point of Care Testing Policy

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Executive Summary

The aim of this policy is to ensure that all Point of Care Testing (POCT) processes within the NHS Lothian are practised in a manner which is harmonised and consistent, and that all processes and governance are based on current regulation with regard to national and local policies (e.g. infection control, COSSH). The policy is produced using recommendations from the Joint Working Group on Quality Assurance. The policy outlines the requirements for staff, including education and competency assessment, to ensure that all those involved with Point of Care Testing are able to do so safely and competently.

Point of Care Testing Policy

NHS Lothian

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1.0 Purpose

To ensure that all Point of Care Testing (POCT) devices used within the NHS Lothian system are well managed and produce good quality, accurate results, which are used to aid patient care.

The benefits to the organisation will include the medico-legal advantage of working within a system-wide Procedure as well as access to Standard Operating Procedures (SOP), Operational Framework, Training Packs, potential savings on purchase price and maintenance of POCT devices. This policy is produced using recommendations from the documents Medical Device Agency (MDA) February 2010 and Guidelines on point-of-care testing, The Royal College of Pathologists, 2004.

Ensure that POCT is a value added activity and that no harm is rendered to any patient as a result of mismanagement or inappropriate use of a POCT device.

Ensure the principles of best practice are followed.

Promote safety, reliability and suitability of equipment and procedures.

Adhere to uniform standards across all NHS Lothian sites

2.0 Policy statement

POCT devices must only be purchased after a case for clinical need has been approved by the POCT committee

A designated, POCT manager will take responsibility for providing advice on the purchase of devices, training, maintaining and monitoring the quality of these services.

There must be close liaison between users, POCT manager and the POCT committee on all issues relating to POCT.

All staff who use POCT must be authorised, trained and have a valid certificate of competence for that specific device.

POCT which fails to meet the requirements of this policy will be suspended by NHS Lothian until compliance can be demonstrated.

3.0 Scope

This policy applies to all healthcare staff employed by NHS Lothian, including those on honorary contracts, and students working within NHS Lothian.

Whilst NHS Lothian acknowledges that Primary Care Contractors have different accountability arrangements from direct employees of NHS Lothian, it does support a framework for good practice guidance and may be used in conjunction with their own professional bodies' requirements.

4.0 Definitions

Point of Care Testing, for the purposes of this document is defined as any analytical test, performed on a specimen collected from a patient that traditionally has been undertaken by the laboratory. Examples include:

- Blood glucose meters
- NR meters
- Cholesterol meters
- Drugs of abuse kits
- HbA1C
- Haemoglobin
- Chlamydia testing
- Activated Clotting Time (ACT) Testers
- Blood Gas analysers
- Platelet, WBC & Neutrophil counts for Clozapine patients
- Urine dipstick testing

Quality Assurance in the context of POCT is the process of assuring that the diagnostic services involved in the delivery of patient care have been accomplished in a manner appropriate to maintain excellence in medical care.

5.0 Implementation roles and responsibilities

5.1 POCT manager

The POCT manager (or coordinator) is a senior healthcare scientist responsible for the day-to-day management of POCT in NHS Lothian

- Liaise with healthcare professionals and manufacturers as appropriate to ensure the development and provision of training programmes.
- Provide advice on all aspects of POCT, including the selection and purchase of POCT devices
- Assist in the production of business cases for POCT
- Monitor, evaluate and audit quality assurance and quality control of POCT
- Report to the NHS Lothian POCT committee

5.2 The user/operator

The user or operator is the person who produces results using a POCT device and they must ensure that:

- They access the relevant training, maintain their competencies and follow the Standard Operating Procedures, ensuring that the correct sample is being used and for the correct operation of the equipment or process. If there are problems operating the equipment or it is non-functional the user must remove it from use and inform the named person

responsible for the machine as soon as possible. (Refer to the Standard Operating Procedure for breakdown procedure)
- The recording of results obtained and for notifying the responsible healthcare professional when results or quality control results are outside of expected limits.
- They carry out simple cleaning and decontamination procedures prior to inspection, service or repair and completion of the appropriate form which must be attached to the device.
- The device is left in a state fit for use.
- All consumables used, i.e. reagents, dip sticks, quality control materials are appropriate for the equipment, and that they are within expiry dates and have been stored correctly as per manufacturer advice and recommendations. Used items such as strips, lancets etc should be disposed of safely in accordance with the relevant SOP.
- they report all adverse incidents and near misses associated with a POCT device or service

5.3 The responsible Healthcare Professional

The Responsible Healthcare Professional is the person responsible for managing the POCT device in the service area. They must ensure that all users within the service understand the concept of POCT and have been trained and assessed as competent to use the POCT device or process correctly, safely and in accordance with the manufacturer's recommendations. This will include:

- sampling, processing, quality control techniques, interpretation of results and error codes or messages.
- Ensuring that any offers of free equipment are subject to a formal equipment evaluation and have appropriate indemnities from the supplier.
- Where POCT does not involve equipment purchase then the same financial considerations must be considered. If the POCT process is to be extensively used the Service must consider staffing implications
- Identifying a named person responsible for the co-ordination of POCT acquisition and usage in their service area.
- Ensuring that all POCT devices have a Standard Operating Procedure (SOP) available and users are familiar with this.
- Ensuring that the legal requirement of decontamination is understood by the users, and that they are able to action decontamination prior to service, and inspection or repair of any equipment. Standard pro-forma documentation is normally supplied with the device.
- Ensuring that POCT devices and processes produce reliable results. This will be achieved by establishing that robust local Quality Control systems are in place and carried out by the operator and that results are accurately recorded. To ensure this, equipment must be correctly used and maintained in accordance with Manufacturer's advice and guidelines.
- Ensuring that POCT processes take part in External Quality Assurance Schemes, where available.
- Ensuring Service level agreements, as appropriate, are negotiated between the laboratory and the appropriate manager.

- Ensuring that the POCT Committee is involved at all stages of the evaluation of any new products and consumables.
- Ensuring that all POCT equipment has been procured in line with the NHS Lothian procurement policies (and Scottish National Procurement guidelines where applicable) including maintenance contracts.
- Engaging with Pharmacy or other supplier to order and supply consumables and standardise products used where appropriate, in consultation with the Procurement Department for optimum supply strategy.
- Ensuring the reporting and investigation of all adverse incidents and near misses associated with a POCT device or service.
- On issuing a POCT device, will ensure that the patient is assessed as competent to:
- Perform such tests with periodic review.
- Correctly calibrate and quality control their device where indicated; all results must be recorded.
- Take appropriate action in respect of their results.

5.4 Point of Care Testing Committee

The purpose of the Point of Care Testing Committee is to ensure that all Point of Care Testing (POCT) devices used within the NHS Lothian system are well managed and produce good quality, accurate results, which are used to aid high quality patient care.

The Committee authorises the implementation of any new POCT service and manages the POCT policy. The Committee has the authority to seek discussion with any existing POCT service which does not operate in accordance with this policy.

The committee's membership is to be a balanced, multi-professional group. The membership will comply with National guidelines on POCT; including MHRA and ISO 22870.

The POCT committee are:

- To be informed about and involved in the introduction of POCT services within NHS Lothian.
- To encourage the standardisation of POCT devices in use throughout NHS Lothian.
- To be assured that appropriate internal and external Quality Assurance processes are in place and employed effectively.
- To promote audit of the management and use of POCT devices within NHS Lothian.
- To ensure that POCT service provision is consistent with the POCT policy.
- To provide support and advice as required in areas such as risk management and quality assurance.
- To ensure that appropriate training has been provided.
- To be informed and involved in the accreditation and revalidation of POCT devices/process operators.
- To review and update the POCT policy
- To prepare reports, as required, on the use of POCT devices within NHS Lothian for the Healthcare Governance committee.

5.5 Point of Care Testing Working Group

The POCT committee will establish a working group, which will consist of representatives from each laboratory specialty involved with the provision of POCT. The working group will report to the POCT committee and liaise closely with the POCT manager.

5.6 Making a case for POCT

If considering the purchase of a POCT device, the Service Manager will complete the Initial Self Assessment for Proposed Introduction of POCT Device form [hyperlink to be added] which will be forwarded to the POCT Committee for discussion, guidance and support.

Independent Contractors who may purchase POCT devices are encouraged to also follow this process.

Please consult the Purchase and Evaluation Procedures [hyperlink to be added] for further details.

5.7 Introduction of new POCT devices

All POCT devices/processes will have a locally agreed and established Standard Operating Procedure (SOP). All new POCT developments will have an Operational Framework completed to describe:

a) Aims of Service
b) Accountability and Responsibility
c) Clinical Governance
d) Accreditation
e) Service Arrangements
f) Examples of Standard Documentation

This will be described using the Generic Operational Framework [hyperlink to be added]

In addition to the Operational Framework the Standard Operating Procedure (SOP) [hyperlink to be added] will contain the following:

a) Instructions that exactly reproduce the manufacturer's instructions for use and a procedure for ensuring that all existing copies are updated as appropriate and old copies destroyed.
b) An established method for recording all patient sample results, internal quality control and external quality assessment.
c) Maintenance arrangements and breakdown procedures. Those POCT devices which have negotiated service contracts will have this stated in the SOP.
d) Reference of the Control of Substances Hazardous to Health, (COSHH, regulations 2002) Assessment process having been carried out. The master copy of the Operational framework and SOP will be forwarded to the POCT committee.

All NHS Lothian contracts including renewals and terminations will have the full consent and knowledge of NHS Lothian Procurement Team.

5.8 Training & Competence

In accordance with this policy, only operators who have received approved training may use POCT equipment. Manufacturers may be involved in staff training following the commissioning of new equipment and may also provide subsequent refresher courses.

It is the responsibility of the healthcare professional for ensuring that appropriate arrangements for initial and continuing staff training are in place. This may involve other designated staff (e.g. diabetes link nurses) working in collaboration with the the POCT manager and laboratory staff. In general, training will include the following:

- patient preparation and sample collection techniques
- contra-indications and limitations of the method
- familiarisation with policy and procedures to ensure good practice
- interpretation of results
- maintenance of equipment and corresponding log
- recording of patient results
- internal quality control and log
- external quality assessment
- waste disposal and health and safety aspects
- responsibility for ensuring continuing competence in performing analyses
- arranging for further training sessions as deemed appropriate.

A register of trained staff must be kept. Training will be incorporated into the induction of all new staff, including both nursing and junior medical staff, who may be required to carry out POCT. Training should be formally documented in individual staff training records. Refresher training will be offered on a regular basis and all staff will be encouraged to attend.

If the technology and resources allow, unique operator ID numbers should be set up to ensure only trained users access the equipment.

5.9 Quality Assurance

Quality Assurance is an essential component of POCT. It ensures optimal accuracy of results through continuous monitoring of operator performance, reagents and equipment. Quality assurance procedures in POCT should be applied to exactly the same standard as in the routine laboratory setting. There are two components to quality assurance: internal quality control, and external quality assessment (EQA). Both must be undertaken (where an appropriate EQA scheme is available) to ensure reliability of results.

5.9.1 Internal Quality Control

This involves the analysis of material of known analyte concentration to test the performance and reliability of the equipment and some aspects of staff technique, thereby increasing confidence in the results obtained. It does not assess sample collection which is a major source of poor quality of results in POCT.

Regular internal quality control must be undertaken, using at least two controls at different analyte concentrations, with stated acceptability limits. The frequency of internal quality

control testing will be determined by the POCT manager and POCT working group. Patient results may only be accepted when quality control results are within the preset acceptability limits. Quality control records must be available for periodic inspection.

5.9.2 External quality assessment (EQA)

EQA involves the analysis of samples of unknown analyte concentration from an external source, usually an accredited national EQA scheme. Results are compared with other users; individual results are confidential to each site. Providing that an appropriate scheme is available, all locations at which POCT is carried out are required to participate in the regular EQA of their analytical performance through the measurement of samples of unknown analyte concentration distributed via the laboratory. This is intended to provide evidence of continuing satisfactory analytical performance and the opportunity for remedial action if an instrument or location is shown to have poor results. The laboratory will collate results and a confidential report of performance returned to each location.

5.9.3 Poor performance

If a particular item of equipment demonstrates persistent poor performance, the cause must be investigated and addressed. If indicated, advice and further training may be offered by the POCT manager, or POCT working group. A user who demonstrates persistent poor performance will not be allowed to use POCT equipment until he/she has undergone refresher training and satisfied those carrying out the training that he/she is competent to perform these assays to a satisfactory standard.

If a particular location demonstrates persistent poor performance (a definition which includes non-participation in internal quality control and/or external quality assessment and non-compliance with policies and procedures) this will be drawn to the attention of senior clinical or nursing staff and the POCT committee and the equipment may be withdrawn from that location.

5.9.4 Accreditation

All NHS Lothian laboratories are registered with UKAS and subject to their accreditation system. The UKAS ISO15189 standards include standards for POCT activities which must be complied with.

5.10 Incident Reporting

All adverse incidents and near misses associated with a POCT device or service will be reported and investigated in Datix. NHS Lothian employees should follow the procedures outlined in the NHS Lothian Adverse Event Management Procedure. Independent contractors should agree procedures for reporting and investigation with the POCT committee prior to the use of a POCT device or establishment of a POCT service. The POCT committee must also be contacted to initiate an investigation.

5.11 Health and Safety

The Infection Control Team must be involved in decisions on the selection, placement maintenance and operation of equipment. A risk assessment must be performed and documented in collaboration with Infection Control staff and appropriate advice included in the Standard Operating Procedure which will include guidance on:

- personal hygiene
- personal protective equipment
- the disposal of waste and sharps
- dealing with blood, and
- procedures to be followed in the event of any accident (e.g. needlestick injuries)

5.12 Documentation

5.12.1 Operating Procedure

A copy of the standard operating procedure (SOP) for the equipment must be readily available at the work station. This document must contain:

- Principle of examination
- Sample Requirements
- Reagent storage
- Calibration procedure
- Testing procedure
- Maintenance procedure
- Reading results
- Competency & interpretation
- Dealing with abnormal or unexpected results
- Limitations of procedure
- QC and EQA procedures and quality control record sheets
- Health & safety
- Recording results

5.12.2 Record Keeping

Directorates must retain the following records (where appropriate):

- Certificate of competence
- Reagent logs
- Service/maintenance records
- Instrument printout/electronic report
- QC records, EQA reports & audit reports
- Incident reports & action taken

5.12.3 Training records

Records of formal POCT training must be maintained and should include:

- Name and location

- Trainers name
- Date of last training
- POCT device
- Date of assessment
- Expiry date of training

5.12.4 Competence records

Competency records must be held with the end user. They can be incorporated into continuing professional development portfolios.

5.12.5 Service/Maintenance records

An inventory of all POCT equipment in NHS Lothian will be maintained by the POCT manager. Periodic and episodic maintenance will be documented and monitored.

5.12.6 Reagent Log

Records of materials and reagents purchased for POCT will be recorded which allows an audit trail to any test performed.

Records of batch numbers of test kits used, opening dates and expiry dates must be kept for all reagents.

5.12.7 QC records

Results of all IQC and EQA samples, time, date & operator must be recorded and available for inspection.

5.12.8 Patient Results

It is a legal requirement that all patient results are recorded. Paper records will have restricted and named person access.

Electronic records will require authorised access and these will be recorded in such a manner as to ensure a complete audit trail.

All records will note the operator, date of analysis and the batch number of reagents.

6.0 Associated materials

- POCT Service Management Structure and Committee membership
- Initial Self Assessment for Proposed Introduction of POCT Device
- Purchasing and Evaluation Procedure
- Operational Framework for a Point of Care Testing Service

7.0 Evidence base

- Management and use of IVD point of Care Test Devices, Medical Device Agency MDA DB2010(02)
- Guidelines on Point-of-Care Testing, The Royal College of Pathologists, 2004
- Guidelines on near to patient or point of care testing. Joint Working Group on Quality Assurance 1999

8.0 Stakeholder consultation

POCT Stakeholders may be asked to attend POCT meetings relevant to their area of expertise these include:

- Laboratory – POCT Management
- Wards / OPD/ GP's
- IT Department
- Product company
- Procurement
- EQA organisations
- Pharmacy
- Infection control

9.0 Monitoring and review

This policy will be reviewed every 2 years, or sooner as appropriate