NHS LOTHIAN POLICY ON POINT OF CARE TESTING
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1 FUNCTION

1.1 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.

1.2 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. The Procedure 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.

2 POLICY STATEMENT

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

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

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

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

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

3 SCOPE

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

3.2 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 DEFINITIONS

4.1 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
- INR 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

4.2 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 AIMS & OBJECTIVES

5.1 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.
5.2 Ensure the principles of best practice are followed.
5.3 Promote safety, reliability and suitability of equipment and procedures.
5.4 Adhere to uniform standards across all NHS Lothian sites

6 RESPONSIBILITIES

6.1 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.

6.2 The User/Operator:

The user or operator is the person who produces results using a POCT device.
• Ensuring 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.

• Simple cleaning and decontamination procedures prior to inspection, service or repair and completion of the appropriate form which must be attached to the device.

• Ensuring that the device is left in a state fit for use.

• Ensuring that 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.

• Ensuring that they report all adverse incidents and near misses associated with a POCT device or service.

6.3 The Responsible Healthcare Professional:

The Responsible Healthcare Professional is the person responsible for managing the POCT device in the service area.

• Ensuring 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 in line with the “Policy and Procedure for visits to NHS Lothian premises by Medical Devices Company Commercial Representatives.”
  ➢ are subject to a formal equipment evaluation.
  ➢ 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, 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.

6.4 POCT Committee responsibilities

• 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.

7 POINT OF CARE TESTING COMMITTEE

7.1 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 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.

7.2 Terms of Reference

The terms of reference will comply with National guidelines on POCT; including MHRA and ISO 22870.

7.3 Membership

• The membership is to be a balanced, multi-professional group. The membership is outlined in appendix B.

7.4 Point of Care Working group

• The point of care 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.

8 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. (Appendix C) 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.
• Additional Purchase and Evaluation procedures are set out in Appendix D

9 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 as at Appendix E.

• In addition to the Operational Framework an accompanying standard operating procedure 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.
10 TRAINING & COMPETENCE

It is the policy of NHS Lothian that 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 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 and arranging for further training sessions as felt 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.
11 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.

11.1 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.

11.2 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.

11.3 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.

11.4 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.

11.5 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 Incident Reporting 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.

12.0 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;
- decontamination of equipment;
- dealing with blood spillages; and
13.0 DOCUMENTATION

13.1 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
- IQC and EQA procedures and quality control record sheets
- Health & safety
- Recording results

13.2 Record Keeping

Directorates must retain the following records (where appropriate):

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

13.2.1 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

13.2.2 Competence records

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

13.3.3 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.

13.3.4 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.

13.3.5 QC records

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

13.3.6 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.
14.0 APPENDICES

Appendix A- POCT Service Management Structure
Appendix B- Membership of POCT Committee

The membership is to be a balanced, multi-professional group which recognises the increasing use of POCT devices in Primary and Secondary Care. The membership will be representatives from the Community Health Partnerships (CHP) and the Acute Services Division. Members have a responsibility to communicate with those they represent.

- Collective representation from each of the CHPs covering both professional and geographical membership including:
  - Patient/Users
  - Pharmacists
  - Nursing

Representation from the University Hospital Services including as a minimum

- Consultant Biochemist
- Consultant Haematologist
- Area Medical Staff representative
- Clinical lead e.g. director of emergency medicine
- Nursing lead (e.g. divisional nurse – medicine / surgery, diabetes nurse specialist
- Quality manager
- Finance manager

It is expected that the committee will invite others to participate in specific pieces of work as required.
APPENDIX C – INITIAL SELF ASSESSMENT FORM

The following self assessment form is to aid the safe introduction of POCT devices/processes into NHS Lothian. It will ensure that appropriate support is available and that efforts are not duplicated eg. In the preparation of standard operating procedures, clinical governance issues including risk management and training.

**Initial Self Assessment for Proposed Introduction of POCT Device**

If any new POINT OF CARE TESTING (POCT) is being proposed please answer the following questions and send the completed form to the POCT COMMITTEE for discussion and support.

1. What new POCT process/device is proposed?

2. What is the proposed location of the new POCT process/device?

3. Name of person proposing the new POCT?

4. Reason for the POCT rather than laboratory analysis. Has discussion with the local laboratory taken place? If so, with whom?

5. What are the anticipated advantages in using POCT rather than lab analysis?

6. What are the anticipated disadvantages in using POCT rather than lab analysis?

7. Who will be the named person responsible for the new POCT device/process?

8. Who will have responsibility for necessary training and how will this be carried out?

9. What extra staff time is involved in performing the POCT device/process?
10. What maintenance requirements are necessary? Has the relevant Department (e.g. facilities) been informed?

11. What happens if the device/process breaks down?

12. What is the annual cost for the POCT device/process? (include all consumables, maintenance costs, collection devices, quality control costs, EQA schemes, interface costs – including installation & maintenance)

13. Who will manage the ordering of consumables and arrange maintenance contracts and emergency call outs?

14. Who will actually perform the POCT?

15. Will the users be restricted to staff in the location of the POCT process?

If not, please explain.

16. Has the Laboratory been consulted with regard to units, reference ranges, sample types and correlation with laboratory results?

17. What are the IT and data management requirements? (connectivity, interface with LIMS)

18. Name of person responsible for producing the Standard Operating Procedure for the POCT Process/device:

19. Have you read the NHS LOTHIAN WIDE POLICY ON POINT OF CARE TESTING policy?

Yes………………………………………………No……………………….
20. Can you assure the above requirements will be complied with if the new POCT process/device proposed is supported?

Yes...........................................................No...........................................

Signed ..........................................................  
Print name ..........................................................  
Position held ..........................................................  
Address ..........................................................  
 ..........................................................  
 ..........................................................  
 ..........................................................  
Tele ..........................................................  
Email ..........................................................  
Date ..........................................................  

APPENDIX D – PURCHASING & EVALUATION

Purchase and Evaluation must follow the procedure outlined below:

a. The appropriateness of purchasing such equipment along with the benefits and disadvantages should be considered prior to purchase. The benefits to patients both clinical and local access must be clearly stated.

b. The POCT Committee will be informed and involved in the evaluation so that they can offer advice and guidance. Results should be consistent with laboratory equipment.

c. The full life long costs of purchasing POCT equipment including cost of consumables and associated reagents, training needs and maintenance contracts etc. will be considered when evaluating the need for POCT devices or processes.

d. Purchasing of POCT devices will be in accordance with NHS LOTHIAN Standing Financial Instructions, where relevant, with the knowledge of Procurement, and the POCT Committee.

e. The service will engage (where appropriate) to order, supply consumables and standardise products used, in consultation with the Procurement Department for optimum supply strategy.
APPENDIX E– OPERATIONAL FRAMEWORK FOR A POINT-OF-CARE TESTING SERVICE

This generic document provides guidance for the provision of a point-of-care testing service. It is provided as a template that users will be able to modify to meet their own specific needs when intending to establish and provide a point-of-care testing service. The following headings are deemed appropriate to consider when setting up and providing such a service:

- Aims of Service
- Accountability and Responsibility
- Clinical Governance
- Accreditation & Reaccreditation
- Risk Assessment
- Service Arrangements
- Examples of Standard Documentation

This selection of headings is not meant to be prescriptive and it may be that a proposed service may have additional headings and/or sections included in the final document.

It is intended that this document describing a proposed service will link with one or more Standard Operating Procedures that describe how to use point-of-care testing devices that are part of the service.
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1 AIMS OF THE SERVICE
In this section outline the aims of the proposed service.

For example, it may be:

To provide a sustainable, safe, community-based service for XXXXX, that may improve patient care. Outline how this may be so.

or

Enhance the care of the patient. Outline how this may be so.

2 ACCOUNTABILITY AND RESPONSIBILITY
In this section clearly outline the accountability of all those involved in the proposed service.

Modify the examples given to suit the proposed service. For example, if the service being developed is in the community, then accountable individuals may be GPs or pharmacists. If it is to be undertaken in the Operational Division, it could be a consultant or a nurse manager. If patient self-testing is involved, then the patient-responsibilities need to be outlined.

2.1 ACCOUNTABILITY
2.1.1 INDIVIDUAL PRACTITIONERS:
If individual practitioners are accountable then complete this section.

2.1.2 OVERALL SERVICE:
Outline here who is responsible for the whole service

2.2 RESPONSIBILITIES
In this section outline the responsibilities of those groups of staff who will be involved in providing the service. Modify the examples given accordingly. These examples are not meant to be prescriptive.

2.2.1 GENERAL PRACTITIONER RESPONSIBILITIES:
If applicable, outline individual General Practitioner responsibilities here.
2.2.2 PHARMACIST RESPONSIBILITIES
If applicable, outline pharmacist responsibilities.

2.2.3 GP PRACTICES RESPONSIBILITIES
Outline any responsibilities of GP practices, if applicable.

2.2.4 HEALTHCARE PROFESSIONAL/NURSE/CLINICIAN RESPONSIBILITIES
Where a service is proposed in the Operational Division, outline any responsibilities here.

2.2.5 PATIENT’S RESPONSIBILITIES (IF SELF-TESTING)

3 CLINICAL GOVERNANCE, ACCREDITATION AND REACCREDITATION

3.1 ACHIEVING CLINICAL GOVERNANCE
In this section, outline how Clinical Governance will be achieved, e.g., lines of monitoring/reporting.

3.2 RESPONSIBILITY FOR CLINICAL GOVERNANCE
Indicate who is responsible for Clinical Governance

3.3 RESPONSIBILITY OF NHS LOTHIAN POINT OF CARE TESTING COMMITTEE
Modify as appropriate. Examples of previous Operational Frameworks have included:

To act as a multi-disciplinary review body on behalf of NHS Lothian and to consider the regular reports prepared during the course of a particular project.
  ➢ Setting Quality Standards for service delivery.
  ➢ Reviewing audit.

3.4 ACCREDITATION AND RE-ACCREDITATION
Indicate how providers of the proposed service will be accredited and reaccredited. Briefly indicating what re-accreditation will comprise. For example it may include analysis of critical events, assessment of analytical competency with a POCT device or evidence of CPD.
4. RISK ASSESSMENT

4.1 RISK MANAGEMENT STRATEGY
Briefly outline how risk will be managed within the proposed POCT service. Outline what risk assessments have been undertaken. Is there any need for inclusion within a Risk Register on Datix?

5. SERVICE ARRANGEMENTS

In this section, outline the specific arrangements, pertinent to the proposed service. These will be different for different services and there is no consistent format. Examples of subjects to consider include:

- Referral Arrangements
- Location of the proposed service
- Appointment procedure for patients attending the service
- Reporting of critical events, including definition, immediate and follow-up action
- Safe disposal of sharps, dealing with spillages and needle-stick injuries
- Record keeping
- Equipment and reference material required to provide the service. Remember to include all equipment, Sharps containers, gloves, waste bins, etc not just the POCT device
- Standard Operating Procedure for equipment used to provide the service

6 LIST OF STANDARD DOCUMENTATION

The actual and type of documentation will vary according to the proposed service. Whatever documentation is used however should be included in section 5. Without being prescriptive such documentation will include

- Referral Form – standard
- Medication Form
- First Visit Education Checklist
- Monitoring Record
- Critical Event Report Forms
- Signed Patient Consent Form
- Initial Referral and Appointment
- Treatment Continuation Query
- Discharge of patients
15.0 REFERENCES

- Management and use of IVD point of Care Test Devices, Medical Device Agency MDA DB2010(02)

16.0 REVIEW

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