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# Point of Care Testing Policy	Copy No. 1
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Area of Standard (s)

ISO 22870:2016 4.1.2.1, 4.1.2.2, 4.1.2.3, 4.1.2.4, 4.1.2.5

ISO 15189:2022 Appendix A – A.2 Governance
ISO 15189:2022 Appendix A – A.2 Governance
IS0 15189:2022 6.7.2 Agreements with POCT operators
ISO 15189:2022 Appendix A – A.2 Governance
ISO 15189:2022 6.4.3 Equipment acceptance procedure
ISO 15189:2022 7.3.3 – Validation of examination methods
ISO 15189:2022 Appendix A – A.2 Governance

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1. Introduction

"Point of Care Testing (PoCT)" is the term used to describe testing near or at the site of a patient with the result leading to a possible change in the care of the patient. These tests may be performed by any grade of health care professional and in a variety of locations, such as GP surgeries, clinics or hospital wards.

Several professional bodies have produced guidelines for the implementation and management of PoCT systems.

Development of this policy is based upon the guidance, recommendation and standards associated with the Joint Working Group on Quality Assurance, the Institute of Biomedical Sciences (IBMS), the Association for Laboratory Medicine, the Royal College of Pathologists, Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom Accreditation Service (UKAS) and the British Standards Institution (BSi). In general, their guidelines are corroborative and have identified a requirement for an organisational policy for the management of PoCT.

Background

The South of Tyne and Wear Clinical Pathology Services (SoTW CPS) including PoCT is part of Gateshead Health NHS Foundation Trust (GHNT).

The SoTW CPS encompasses the multi-disciplinary pathology services including PoCT of three local foundation trust hospitals: City Hospitals Sunderland (CHS), South Tyneside Hospital (STH), and Queen Elizabeth Hospital Gateshead (GHNT).

The legal responsibility and ownership of pathology services including PoCT transferred to GHNT on April 1st 2013. The consolidation of services from the three local foundation trusts has resulted in the consolidation of the laboratory management structure, personnel, processes and the development of a new quality management system to ensure the services continue to deliver high quality results to all stakeholders.

Policy Scope

This policy outlines responsibilities for the management of Point of Care Testing on the three hospital sites South of Tyne and Wear and associated community areas.

The aim of the policy is to ensure that whenever PoCT is used:

- There is an established clinical need for PoCT
- It is suitable for its intended use.
- It has been properly assessed, procured and the benefits of standardisation considered.
- It is properly understood by the Professional User, who has undertaken training and is aware of its limitations.
- Training records are maintained.
- There is a written protocol or standard operating procedure (SOP)
- It is subject to quality testing and quality improvement e.g. Internal Quality Control (IQC) and External Quality Assurance (EQA) and that audit and continuous improvement measures are carried out.
- Patient results are treated confidentially, and are recorded in an auditable format.
- Electronic data capture is used where possible.
- PoCT devices are maintained in a safe and reliable condition

This policy should be used in conjunction with the following policies:

Gateshead Users are referred to the Trust Policies available on the Trust Intranet:

- RM30 Procurement, management and use of Medical Devices policy
- RM45 Training Policy for Medical Devices
- OP43 Best Practice Policy

South Tyneside and Sunderland Users are referred to the Trust Medical Devices policy which is available on Q-Pulse (PC-MAN-EXT-002.ST.SR)

2. Point of Care Personnel

Point of Care Team

The Point of Care team comprises of the Clinical Lead for PoCT, the PoCT Departmental Manager (BMS4), the PoCT Technical Manager (BMS3), PoCT Coordinators (BMS2), BMS staff, Associate Practitioners (AP) and PSW staff.

See Pathology Organisational Charts for details – BO-MAN-ORG-001.UN, BO-MAN-ORG-002.UN

Clinical Lead for Point of Care

Clinical lead for Point of Care is responsible and accountable for the provision of PoC services provided by the laboratory. The clinical lead is responsible for:

- Planning the provision of the PoC service
- Setting the strategic goals and aims for PoC
- Considering all proposals to introduce any product, device or system for PoCT
- Establishing measurable quality objectives

Pathology Point of Care Departmental Manager and Point of Care Technical Manager

The Point of Care Departmental manager (BMS4) is responsible for the organisation and management of PoCT to ensure effective PoCT service provision. The Point of Care Departmental manager (BMS4) is responsible for planning and maintaining the integrity of the quality management system to meet the requirements of the service and the quality objectives. This is supported by the Point of Care Technical Manager (BMS3).

Pathology Point of Care Co-ordinators

Provide a point of contact for advice and liaison on matters relating to PoCT across the organisations, support agreed training and development needs across the organisations and ensure the successful implementation of the PoCT Policy.

Point of Care BMS/AP/PSW staff

Ensure the daily support of point of care services including training and maintenance of devices and consumables.

3. Clinical Governance Framework

Point of Care Senior Staff meeting

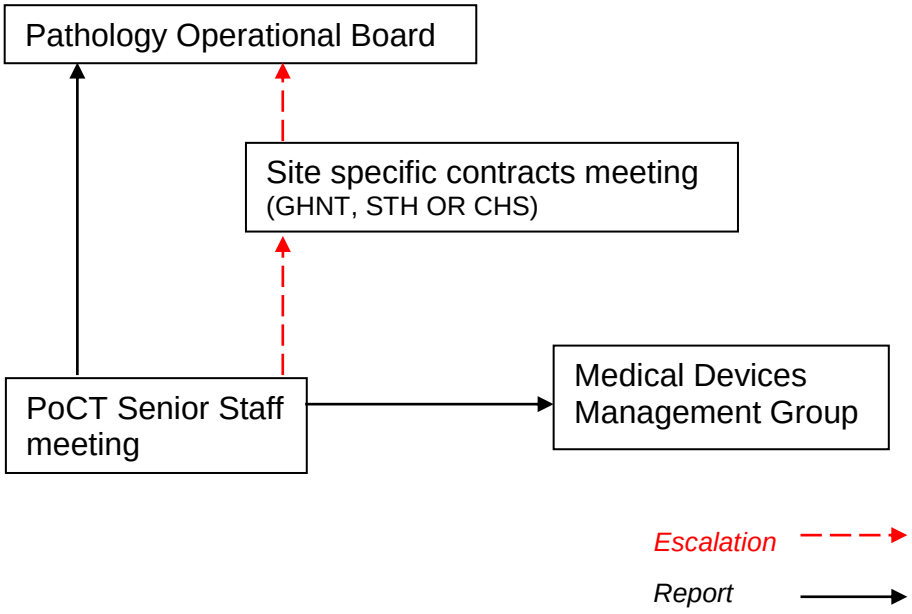
The Point of Care senior staff meeting serves as a forum to discuss strategic, quality and performance issues relating to PoC. This meeting reports to the Pathology Operational board. The Point of Care senior staff meeting escalates any serious PoCT governance issues to the site specific contracts meeting (see flowchart below). Meetings are held with users to discuss their PoC service directly and includes any PoC issues, requirements and ongoing suitability.

Clinical Risk

Clinical risk issues relating to the use of PoCT arising out of the clinical incident reporting mechanism within the organisations are brought to the attention of the clinical area for appropriate investigation and/or dissemination.

Clinical risk issues are also brought to the Point of Care senior staff meeting.
In addition, national MHRA (Medical and Healthcare products Regulatory Agency) Hazard notification and reports will also be considered by the Point of Care senior staff meeting.

Relationship of PoCT within the organisations



4. Summary of Responsibilities

Management Responsibilities

The Chief Executive of each Trust and the equivalent manager of each primary care organisation shall be responsible for ensuring

- That the staff follow the relevant procedures and quality framework established by the Point of Care Service

- All Health and Safety regulations and approved guidance is complied with
- That the Point of Care team are aware of all Point of Care devices.

In practice, tasks and responsibilities for ensuring that regulations, guidelines and policies relating to PoCT are complied with will be delegated to Senior Managers, but overall responsibility will remain with the Chief Executive of each Trust and the equivalent manager of each primary care organisation.

The Clinical Lead for PoCT has the delegated responsibility (from the Chief Executive for Gateshead Health NHS Foundation Trust) for the management of the PoCT service. In practice this responsibility is managed by the PoCT Departmental Manager (BMS4), the PoCT technical manager (BMS3) and the PoCT team within Pathology.

Point of Care Procedures

The Point of Care technical manager (BMS3) has responsibility for ensuring Point of Care investigation procedures outside the laboratory, have clearly defined procedural guidance which includes when it is necessary to compare a result with a laboratory processed sample.

Point of Care Results

For fully managed PoCT services, the PoCT team work in compliance with ISO 15189:2012 and ISO 22870:2016 and are transitioning to ISO 15189:2022
The South of Tyne and Wear Clinical Pathology Services including PoCT hosted by Gateshead Health NHS Foundation Trust take responsibility for the results.

For partially managed PoCT services, then PoCT will apply best practice and endeavor to work to the requirements of ISO 15189:2012, ISO 22870:2016 and ISO 15189:2022 where possible. In these instances, the service user shall be legally responsible for the results.

For definitions of a fully managed or partially managed PoCT service, see Scope of Point of Care Testing.

Clinical Decisions

Any clinical decision based on a PoCT result is the responsibility of the appropriate Clinical Lead for the ward or department within each Trust or the

equivalent manager in each primary care organisation (local clinical leads). The local clinical lead must decide for which patient groups the PoCT process is appropriate in consultation with the appropriate SOP and guidance and provide guidelines for interpretation of results and further patient management. These guidelines should include the procedure for communication of results and timeframes.

Following Procedures

Local clinical leads shall also be responsible for the selection of staff deemed suitable to use Point of Care instrumentation and the minimum criteria or level of qualification/grade required.

Ward or Departmental Managers and the equivalent manager in each primary care organisation must ensure that all users within the department 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 and organisation policies. They must ensure that staff who have not received training are identified and that they do not use the device until training and competency have been completed. Only trained and accredited operators may use PoCT equipment. Managers have a responsibility to ensure correct procedures are followed at all times. Managers are responsible for ensuring that the equipment is maintained in good working order, cleaned in line with infection control policy and that devices are used and consumables stored within the environmental condition limits recommended by the manufacturer.

All users are responsible for their own safety and for ensuring their PoC training is updated and their competence maintained. The responsibility to correctly and safely perform any PoCT lies with the person performing the test. Once deemed competent users are responsible for the results they obtain including any actions taken on the results. Staff must always adhere to local policy & clinical protocol for any actions taken on results, including who should be notified and any relevant timescales.

The Scope of Point of Care Testing

Registration of devices and where they are located is held in the Asset module of Q-pulse. For any system not individually listed on Q-pulse, these can be found in the files below:

POCT Asset List.xlsx

Changes to the current scope of Point of Care testing will be made after consideration at the Point of Care senior staff meeting.

If financial support is required for the project a business case will be submitted and considered according to Trust procedures.

The scope of Point of Care testing for STH and CHS is detailed within the service specification documents for Sunderland Trust and South Tyneside Trust Changes to these provisions will also have to undergo formal change control procedures (LM-GEN-SLA-006.SR.QE and LM-GEN-SLA-008.ST.QE)

The Provision of Point of Care Testing

The Point of Care clinical lead has responsibility for:

- Considering all proposals to introduce any product, device or system for PoCT taking into account:
  - the clinical need for PoCT
  - it's financial implications
  - technical feasibility
  - the ability of the organisation to fill the need
  - standardisation

This information will form part of any business case for Point of Care Testing.

The Point of Care Team has responsibility for:

- Carrying out the evaluation of PoCT devices and systems including consideration of:
  - Practicability
  - trueness,
  - precision

  - detection limits
  - use limits
  - interferences
- Carrying out verification and reverification of PoCT devices.
- Maintain records of primary and secondary equipment installations
- Carrying out a risk assessment of the system and the area in which the PoCT device is to be deployed, this risk assessment will include assessment of the environmental conditions in the area
- Providing access to training
- Maintaining records of training
- Providing Standard Operating Procedures (SOP's)
- Reviewing Internal and External Quality Control (IQC and EQA)
- Ensuring PoCT devices are maintained in a safe and reliable condition
- Achieve and store PoCT data for connected analysers
- Audit of PoCT systems to ensure compliance with procedures

A fully managed Point of Care service refers to devices for which the PoCT team have responsibility as listed above.

A partially managed Point of Care service refers to devices in which the PoCT team support parts of the service where requested, for example the provision and administration of EQA schemes.

Point of Care Users have responsibility for:

- Undertake theoretical and practical training of PoCT equipment used within their organisation
- Undertake competency assessment in the use of PoCT equipment
- Is aware of the correct use of patient identification entered on all Point of Care devices
- Maintaining competency and to undergo revalidation or training as required
- Ensure the equipment selected is suitable for purpose required
- Ensure that correct supplies are selected for use with particular device
- Ensure that equipment is cleaned after use according to manufacturer's instructions and organisational policies
- Ensure that equipment and consumables are appropriately stored in accordance with the manufacturer's instructions

- Ensure that malfunctioning devices are returned to the Point of Care for repair/replacement, following certificated decontamination
- Ensure that PoCT devices are maintained, calibrated and quality control checked regularly, in line with advice from the PoCT team and SOP guidelines
- To be aware of any local policies and procedures appertaining to PoCT

Management of Non-Conforming Point of Care Equipment

Point of Care Testing equipment and devices that are not identified within the scope of Point of Care located within the Trusts will be considered at the Point of Care senior staff meeting using the Point of Care Application Process and documented within the CAPA module of Q Pulse.

Following consideration the non-conformity will be resolved by:

- Taking action to eliminate the detected non-conformity
- Authorising its use, release and acceptance
- Taking action to preclude its original intended use of application

Malfunctioning Point of Care Equipment

Point of Care testing should be discontinued and central laboratory testing should be employed in any case of equipment malfunction or suspected malfunction if there is not a backup piece of equipment available.

The error or defect should be reported to the Point of Care team at the earliest possible opportunity using the Trust incident reporting system. For community users the issue is reported using the Trust incident reporting system by a member of the Point of Care team and the PoCT manager (BMS4) or technical manager (BMS3) will nominate an investigator.

The Point of Care team will arrange service/replacement of equipment where appropriate.

The Point of Care clinical lead, PoC Manager (BMS4) or PoC technical manager (BMS3) have responsibility for reporting any device defect / failure that causes an incident to the MHRA

The Quality of Point of Care Testing

The Pathology Quality Manager has overall responsibility for the Quality of PoCT including review of the requirements related to PoCT. The Point of Care Team have delegated responsibilities for PoCT including:

- Establishing annual quality objectives that are measurable.
- Periodically reviewing the relative benefits of PoCT and monitor test ordering patterns. This is carried out as part of the revalidation process.
- Carrying out audits of conformity to PoCT requirements including record keeping
- Reviewing critical value reports and ensuring that critical values are followed up with laboratory testing where appropriate.
- Reviewing the reports of the quality assurance programme.
- Providing information for submission to the annual management review.

Training

The Point of Care technical manager (BMS3) will manage the theoretical and practical training programme and competency assessment for PoCT Personnel.

Training records will be maintained by the PoCT team and the PoCT team will ensure that only trained and competent staff shall carry out PoCT.

Operator competence will be monitored by the PoCT team using audit and monitoring of the quality assurance program.

Change Control of Point of Care Equipment

Any changes to Point of Care devices, systems or processes should be considered by the Point of Care senior staff meeting. All changes should be documented in Q-Pulse under the change control process together with the results of any validation/verification testing.

Procurement of Point of Care Devices or Systems

The Clinical Lead for Point of Care has responsibility for the selection, development, modification, validation and verification of methods. The PoC

clinical lead has responsibility for procuring evaluating and selecting all PoCT devices, reagents and systems including quality control material.

Advice on procurement will be sought from the relevant Procurement Department to ensure impartiality and to comply with Trust(s) Standing Orders, Legal obligations and European Legislation in respect of tendering & contract procedures for the procurement & supply of equipment

Point of Care Supplies

Primary storage areas for consumables on the three sites are:
Gateshead – Pathology stores and Hub laboratory
Sunderland - Pharmacy and main laboratory
South Tyneside – Pharmacy and main laboratory
Consumables supplied via the Managed Laboratory Service (MLS) are ordered via Sunderland and South Tyneside Pharmacy and the PoCT team.
Consumables outside of the MLS are ordered via the PoCT team, orders can be called off via the supplies manager.

Control of Infection

The control of infection department provides advice on:

- cleaning, disinfection, decontamination and where appropriate the method of sterilisation of the device
- the provision and use of Personal Protective Equipment

This is done through PoC attendance at the Serology and Molecular Oversight Group (MC-MAN-AGE-003.UN)
The Point of Care team provide guidance on cleaning and disinfection during training.
The user has responsibility for ensuring that devices are cleaned and disinfected.

5. User Training

Any person using PoCT devices should be adequately trained in the safe and correct operation of the equipment.
Training on the use of PoCT Devices will be undertaken using a variety of methods both centrally delivered and also delivered at Ward / Directorate level.

Centrally delivered training will avoid potential duplication of effort and ensure a consistent standard across the Trusts. Local training will reflect the particular needs at Ward/Directorate level.

All training will include appropriate use of device, the theory of the measuring system and the preanalytical aspects of the analysis including:

- Sample collection
- Clinical utility and limitations
- Expertise in the clinical procedure
- Reagent storage
- Quality control and quality assurance
- Technical limitations of the device
- Response to results that fall outside of predefined limits
- Infection control practices
- Correct documentation and maintenance of results

Training will also cover the clinical governance aspects of Point of Care including:

- Positive operator identification and sole use of log in passwords
- Positive patient identification procedure.

Online programs for re-training may be accessed where appropriate.
The Pathology PoCT team will provide direction and advice on appropriate training programmes for a range of PoCT Devices in common use.

6. Selection and Procurement of Equipment

Selection of Equipment
The selection of new equipment is very important to ensure that the maximum benefit is obtained from the purchase.
A number of factors need to be taken into account before the final decision is made:

1. Clinical Requirements – Is there a clinical need for PoCT? Is the device suitable for the application?

2. Standardisation - Does the organisation have a policy of standardisation for that device?

3. Analytical Quality - Results of the technical validation/verification, which should include details of accuracy, precision, detection limits, use limits, ease of use, contraindications and interferences, quality control/External Quality Assurance provision

4. Clinical Governance - Does the device benefit from operator lockout? Does the device benefit from QC lockout?

5. Service Requirements - Are spare parts and service information available? What are the maintenance costs? Does the device comply with all the necessary safety standards?

6. Cleaning and Disinfecting - Is the equipment capable of adequate cleaning and disinfecting and are the manufacturer's guidelines available?

7. User Training - Are users trained to use the device or have arrangements been made to ensure users are trained?

8. On-Going Revenue Costs **-** Have all revenue costs been built into the cost of ownership financial model?

Advice on procurement will be sought from the relevant Procurement Department to ensure impartiality and to comply with Trust(s) Standing Orders, Legal obligations and European Legislation in respect of tendering & contract procedures for the procurement & supply of equipment.

Purchase of Equipment

All purchases of PoCT equipment should satisfy the necessary standards as laid down by the Medical and Healthcare products Regulatory Agency and other statutory bodies. Information should be sought relating to the equipment's Country of origin, manufacturer, CE Marking, Quality Assurance, Safety Standards, Service/Spares/Installation, Decontamination and Warranty prior to purchase. Where the organisation has a policy upon standardisation of the particular item this must be adhered to unless a robust case can be made for

variation from this, this must be presented to the PoCT senior staff meeting as appropriate for consideration before the order will be progressed.

New Clinical Procedures/Techniques

An Application for Point of Care Testing Devices form (PC-MAN-FOR-008.UN) must be completed for all new devices. All applications will be reviewed by the Clinial Lead at the Point of Care senior staff meeting. The completed application should provide details prior to purchase which will ensure the device, aftercare, training needs etc. are met by the device & manufacturer. Completed forms should be stored within Q-Pulse for reference purposes.

A service level agreement (SLA) will be put in place in for all newly approved procedures/techniques outlining the roles and responsibilities of the user department and PoCT. The SLA will also incorporate an annual review or activity, the ongoing clinical requirement and issues.

Purchasing via charitable funds

Equipment purchased via charitable funds should satisfy the same product selection criteria as those purchases made through exchequer monies. Requisitions must be vetted by the Financial Services department to ensure adequate funds are available prior to purchase. Expenditure from Charitable Funds must be approved as per relevant procedure.

Disposal of equipment

When equipment owned by the Trust is either to be permanently removed from service or disposed of the point of contact is the Electronics/Medical Engineering Department. Users in the community are required to liaise with the PoCT team to organise the disposal of the device.

Decommissioning aims to make devices safe and unusable, by removing critical components or disabling such parts while minimising damage to the environment. Any device deemed unfit for use should be decommissioned.

Instruments that are on loan as part of reagent rental agreements should be returned to the manufacturer via the Point of Care team.

In both instances the instrument should be decontaminated prior to decontamination or return.

Equipment on Loan for Assessment

Organisations occasionally have PoCT equipment on loan for assessment purposes or for replacement to cover a period of instrument repair. In both instances it is important that the safety of the equipment can be demonstrated prior to it being used.

The procedure to ensure that any potential risk offered by the use of loan equipment is controlled is two-fold and detailed below.

1. Product Liability Indemnity.
   To ensure that the supplier of the loan equipment is aware of their responsibilities and clearly understands that although the equipment is being used by our staff, on our premises they still retain the responsibility for the safe function of the equipment. This stage is covered by ensuring that a suitably authorised representative of the company reads and signs the trusts Equipment on Loan for Trial or testing indemnity form.

   Should the equipment supplier already be registered within the NHS Supplies Master Indemnity Scheme, then the requirement is only for the completion of a Delivery Note for equipment on loan and free issue, which identifies the equipment by serial number etc.

2. Electrical Safety Testing.
   This shall be carried out by a technician from the Electronics & Medical Engineering Department who will as part of the testing regime complete an equipment acceptance sheet for the equipment.
   Upon completion of the testing a coloured label shall be attached in a prominent position on the equipment, advising that the test has been carried out.

It shall be the responsibility of the user to ensure that they are confident in the correct and safe operation of the equipment. It shall be the responsibility of the person carrying out the assessment of the equipment to ensure that the correct

procedure is followed insofar as ensuring that the necessary paperwork and safety tests have been carried out.

Equipment that is on loan to replace an instrument that is being repaired should be validated for use using local control and verification procedures. Following validation the equipment can be used for the purposes of PoCT testing.
Trial equipment on loan for the purposes of evaluation as a potential PoCT instrument should only be used alongside existing testing methodologies for the purposes of result comparison; these results should not be used to affect patient care.

Standardisation of Equipment

In line with the recommendations of the National Audit Office Report and the Management of Medical Equipment in NHS Acute Trusts in England, the PoCT Senior staff meeting will actively pursue a standardisation of PoCT Devices in conjunction with the users.

7. Summary

This policy is continuously developing and the organisations, through the Pathology PoCT team, will add to the policy on a continuous basis.

8. References/Related Documents

1. RM30 Procurement, management and use of Medical Devices policy
2. RM45 Training Policy for Medical Devices
3. OP43 Best Practice Policy
4. South Tyneside and Sunderland Medical Devices Policy (PC-MAN-EXT-002.ST)
5. Organisational Charts BO-MAN-ORG-001.UN, BO-MAN-ORG-002.UN
6. Service Specification Document for Sunderland Trust (LM-GEN-SLA-006.SR.QE)
7. Service Specification Document for South Tyneside Trust (LM-GEN-SLA-008.ST.QE)
8. Generic Validation/Verification Pro-forma (LM-GEN-TEM-015.UN)
9. Application for Point of Care Testing Devices (PC-MAN-FOR-008.UN)
10. Replacement PoCT Device Installation Template (PC-GEN-TEM-001.UN)

11. Serology and Molecular Oversight Group Meeting Minutes (MC-MAN-AGE-003.UN)