Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust

***Please Note: This policy is currently under review and is still fit for purpose.***

# POINT OF CARE GOVERNANCE POLICY

# POINT OF CARE TESTING POLICY AND GUIDELINES

**This procedural document supersedes: CORP/RISK 8 v.6 – Policy and Guidelines for Point of Care Testing.**

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| Executive Sponsor : | Dr Tim Noble |
| Author/reviewer: (this version) | Katherine Wright - Trust POCT Lead |
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| Target audience: | All staff, Trust-wide |

## Amendment Form

Please record brief details of the changes made alongside the next version number. If the procedural document has been reviewed **without change**, this information will still need to be recorded although the version number will remain the same.

| Version | Date Issued | Brief Summary of Changes | Author |
|---|---|---|---|
| Version 7 | 21 January 2021 | • Accreditation standards now United Kingdom Accreditation Service (UKAS)/ISO rather than Clinical Pathology Accreditation (CPA).<br>• Reference to reporting and monitoring non-conformances via DATIX.<br>• Changed references to Care Groups to Divisions.<br>• Responsibilities of Medical Technical Services regarding PAT testing and maintenance of asset register.<br>• Requirement to review SOPs.<br>• Removed reference to Medical Equipment Training Policy.<br>• Requirement for recertification of competency.<br>• Additional monitoring in section 6 e.g. non-sense patient ID, blood gas analyser error reports and DATIX trend analysis.<br>• Changes to Appendix 1 (Terms of Reference of POCT Clinical Governance Committee) and Appendix 4 (POCT Organisational Structure) to reflect changes in Clinical Governance reporting to Divisional CG meetings (agreed at Trust CG Meeting 20/4/18).<br>• Minor changes to Appendix 2 and 3. | Miss K Wright |
| Version 6 | 27 March 2017 | • Contents page amended.<br>• Committee, departmental names and Trust title amended.<br>• Revision of Associated Trust Procedural Documents.<br>• Update of training requirements. | Dr J Wardell<br>Mrs F Dunn<br>Ms D Lee |

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| Version 5 | 25 March 2014 | • Reviewed and formatted POCT Policy in line with CORP/COMM 1 v.6 – APD Development and Management. Inclusion of revised Section 6 – Monitoring Compliance with Procedural Document. | Dr J Wardell<br>Mrs F Dunn<br>Ms D Lee |
| Version 4 | March 2012 | • Reviewed and formatted POCT Policy in line with CORP/COMM 1 v.5 – Development and Management of Procedural Documents Within the Trust<br>• Clarification of roles, section 7.5 Managers of Areas Using POCT<br>• Slight amendment to Appendix 3 to include entry for the proposed area of application/implementation<br>• Minor changes made throughout for clarity | Dr J Wardell<br>Mrs F Dunn<br>Ms D Lee |
| Version 3 | February 2009 | • Reviewed and formatted in line with 'An organization -wide policy for the development and management of procedural documents' (NHSLA)<br>• Introduction of an amendment form<br>• More defined responsibilities<br>• Introduction of a flowchart for implementation of POCT (appendix 2)<br>• Introduction of a questionnaire (appendix 3)<br>• Addition of a POCT organizational chart (appendix 4) | Mrs H Chapman |
| Version 2 | March 2007 | • Inserted 3.7 – Role of POCT Co-ordinator | Dr J Wardell<br>Dr R Stott |

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# 1. INTRODUCTION

For the purposes of this document point of care testing (POCT) refers to any form of diagnostic testing undertaken by a healthcare professional outside of an accredited laboratory environment. The requirements of this document apply when POCT is carried out in a hospital, clinic and by a healthcare organisation providing ambulatory care.

This policy is designed to ensure that all point of care testing (POCT) systems within the Trust are appropriately managed and quality assured in accordance with national guidelines and accreditation standards and that all risk and governance issues are addressed.

It is also designed to ensure that the introduction of new point of care testing technology within the Trust is appropriate and consistent.

## 1.1 Accreditation of POCT Governance

All POCT within Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust (DBTH) is subject to strict governance and must be performed to the quality standards as outlined in ISO 22870:2016 (United Kingdom Accreditation Service - UKAS) and the Medicines and Healthcare products Regulatory Agency (MHRA) recommendations. The service is not currently accredited under ISO 22870:2016 standards and is not covered by the Pathology ISO 15189:2012 accreditation.

# 2. PURPOSE

The aim of this document is to provide guidance for safe and effective management and use of POCT systems that are fit for their intended purpose and used by competent individuals on the correct patient, giving quality results which become part of the patient's record.

## 2.1 Rationale for the Use of Point of Care Testing Devices

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 a laboratory for analysis with the results being returned by telephone, electronically 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, in the clinic or GP surgery is preferred. This type of testing is termed 'point of care' testing (POCT).

Improvements in technology have permitted a number of analyses, which previously could only be performed in the laboratory, to be carried out at the bedside or in the clinic. Like all new technologies, however, the apparent simplicity of POCT often belies its complexity and masks the need for attention to detail in order to achieve optimum and accurate results.

Situations in which point of care testing may be appropriate include:

a) Where clinical management in an acute or life threatening situation may be aided by the result of a diagnostic test.

b) Where availability of the result in the clinic may enable more effective counselling of the patient and/or change in therapeutic management.

c) Where the total attendance time for the patient can be reduced.

d) Where the clinician can assess the patient and initiate or change subsequent management in a single visit.

## 3. DUTIES AND RESPONSIBILITIES

The role and responsibilities of departments and individuals in the management of POCT devices are described below.

### 3.1 The POCT Governance Committee will:

Be accountable to the Trust Clinical Governance and Quality Committee for ensuring the delivery of a high quality POCT service.

### 3.2 The POCT Co-ordinator will:

a) Be responsible for day-to-day operational matters of all the point of care testing sited within DBTH.

b) Ensure the overall co-ordination and supervision of all POCT training and development of staff from various professions throughout the Trust in the use of POCT equipment. This ensures adherence to national standards in compliance with UKAS accreditation of POCT services.

c) Be responsible for the co-ordination, documentation and planning of the future POCT requirements of the Trust, on behalf of the Trust POCT Governance Committee.

d) Maintain effective communication between the POCT Governance Committee and Trust staff/ Trust Medical Technical Services Manager/ Trust Procurement.

e) Produce and review Standard Operating Procedures to ensure that systems are in place to enable quality standards to be maintained.

f) Ensure that internal quality control (iQC) and external quality assurance (EQA) procedures are in place and followed by all those involved in POCT.

g) Report and investigate DATIX incidents related to POCT.

### 3.3 End Users of POCT Devices will:

a) Be individually accountable for their practice and ensure that they acquire, and maintain skills in the use of POCT devices.

b) Ensure all POCT results are correctly documented in the patient records.

c) Ensure that POCT ID barcodes are NOT shared or used by other operators.

d) Report any adverse incidents/non-conformances through DATIX.

### 3.4 Managers of Areas using POCT will:

a) Ensure all requests for new POCT systems are made in accordance with the selection and procurement criteria as described in this policy.

b) Ensure that the General Manager of the Division in which the device is to be used is responsible for the authorisation of any business cases for the use of the POCT devices before submission to the Trust POCT Governance Committee.

c) Ensure that all users of POCT are competent and authorised to use the devices.

d) Ensure that each operator maintains competency and that training records are kept.

e) Ensure that quality assurance such as internal quality control (iQC) and external quality assurance (EQA) are performed in accordance with this policy.

f) Designate appropriate grade staff who will be responsible for ordering consumables and the upkeep and maintenance of analysers (as appropriate to that instrument). Assistance from the POCT coordinator (or the manufacturer of the device) should be sought if the need arises.

g) Designate a Ward Manager, Link person or Clinical Educator will be responsible for training of new users of the device, update training and upkeep of associated training records.

h) Report and investigate DATIX incidents related to POCT.

i) Ensure that instrument logs (iQC data, maintenance and calibration) are stored for the required period as instructed by the POCT committee in line with RCPath guidance.

### 3.5 Pathology Services will:

a) Support the POCT Co-ordinator.

b) Provide advice concerning the limitations of POCT devices and interpretation of POCT derived results.

### 3.6 The Medical Equipment Department will:

a) Maintain an up to date asset register of all POCT equipment/analysers.

b) Electrical safety testing of POCT equipment/analysers.

c) Distribute alerts from MHRA.

d) Report technical performance problems to MHRA.

e) Be involved in the purchase of new equipment.

### 3.7 The Trust Procurement Department will:

a) Liaise with the Trust POCT Governance Committee before any POCT equipment is acquired.

b) Lead in the tender and procurement process of any new POCT equipment.

c) Inform the POCT Governance Committee of any requests or purchasing intensions.

### 3.8 The IT Department will:

a) Advise on POCT data management and connectivity to appropriate host systems.

b) Liaise with suppliers and Pathology to set up network connections to the hospital and laboratory computer systems.

### 3.9 Patients Lacking Capacity

Sometimes it will be necessary to provide care and treatment to patients who lack the capacity to make decisions related to the content of this policy. In these instances staff must treat the patient in accordance with the Mental Capacity Act 2005 (MCA 2005).

- A person lacking capacity should not be treated in a manner which can be seen as discriminatory.
- Any act done for, or any decision made on behalf of a patient who lacks capacity must be done, or made, in the persons Best Interest.

- Further information can be found in the MCA policy, and the Code of Practice, both available on the intranet.

**There is no single definition of Best Interest**. Best Interest is *determined on an individual basis. All factors relevant to the decision must be taken into account, family and friends should be consulted, and the decision should be in the Best interest of the individual. Please see S5 of the MCA code of practice for further information.*

# 4. PROCEDURE

## 4.1 Choosing the POCT equipment

Advice regarding POCT should be sought before any equipment is considered. Approval by Trust POCT Governance Committee must be obtained before any equipment is purchased thus ensuring:

a) Results are comparable to results produced by the laboratory.

b) Reliability of equipment and spares.

c) Good cover by service engineers/maintenance procedures.

d) Reliability and regular supply of reagents.

e) Avoidance of multiple suppliers of similar equipment.

f) All clinical, cost effectiveness and practical aspects are covered adequately in the business case.

g) Connectivity requirements are met wherever possible.

h) Adherence to protocols established by the Trust's Procurement Department.

i) Enrolment into EQA schemes where available.

j) Ensure business continuity measures are in place e.g. UPS for electrical equipment.

k) All health, safety and infection control aspects are considered.

## 4.2 Equipment and Consumables Procurement

Initially, the need for POCT should be discussed with the POCT Co-ordinator. All decisions relating to POCT must then be made through the relevant Clinical Governance Committee ensuring post acquisition maintenance and operation will comply with Trust POCT policy.

The flow chart in Appendix 2 should be used to help the requestor before the process of implementing a new POCT device is considered.

The questionnaire in Appendix 3 must be completed and returned to the POCT Co-ordinator prior to the initiation of the procurement process.

## 4.3 Process of Procurement

A business case, where required, for the introduction of all POCT should identify the criteria required for the proposed service. The process of procurement should be in accordance with established protocol. Tenders for the business should be reviewed by the POCT Governance Committee to ensure that the necessary criteria are met. The cost effectiveness should be reviewed in consultation with the Trust's Procurement Department.

## 4.4 Standard Operating Procedures (SOP)

All techniques employed in the delivery of DBTH POCT service are subject to adherence to a Standard Operating Procedure (SOP). Each SOP should include or refer to the following:

a) Clinical relevance/purpose of examination.

b) Underlying principles of the test.

c) Correct preparation of the patient, specimen requirements and means of identification.

d) Equipment and special supplies.

e) Storage of reagents, standard or calibrators and internal control materials.

f) Calibration.

g) Instructions for the performance of the procedure.

h) Limitations of the procedure including interferences, cross reactions and reportable intervals.

i) Recording and documentation of results and appropriate action to be taken.

j) iQC procedures need to be documented ensuring that the results lie within the manufacturers reference range/criteria.

k) Patient reporting reference ranges.

l) Alert limits and critical values must be incorporated where appropriate.

m) Included in the responsibilities of personnel authorising, reporting and monitoring results, is the duty to identify abnormal results that must be brought to the immediate attention of a clinician.

n) Hazards and safety precautions to be highlighted, including disposal of consumables and cleaning of equipment.

o) Performance criteria.

A copy of the SOP is available for all staff using POCT. The SOP(s) should be kept close to the equipment used.

SOPs must be reviewed on a regular basis, minimum 2 yearly.

# 5. TRAINING/ SUPPORT

## 5.1 Personnel

Only appropriate members of staff who have achieved satisfactory levels of competence are able to use the POCT devices.

Each certificated operator must be recorded as having training and by implication understand the procedure that they use.

## 5.2 Training

1. Training for POCT devices will be based on guidelines given by ISO 22870:2016 Point-of-care Testing (POCT) – Additional Standards for POCT Facilities.

2. The manufacturer of the device will instruct and certify, in the first instance, the POCT coordinator and primary trainers in the correct use of the equipment. Cascade training will occur thereafter to other users of the device.

3. Evidence of training, i.e. a training record/register must be kept by the clinical area manager at a local level and produced for audit purposes.

4. The training programme will be tailored to the technology and its complexity, but should include understanding of:

   a) Basic principles of the analytical method, its limitations and the clinical relevance of the results produced. The latter should include knowledge of any results that must be made known to the clinician immediately, results which are indicative of an error, failure in the procedure or of a possible interfering substance.

   b) The correct procedure for the preparation of the patient.

   c) The correct procedure for checking and documenting the patient ID.

   d) The correct procedure for preparation of the reagents, devices and/or equipment e.g. warming of reagents stored in the refrigerator to room temperature before use, to ensure correct performance of the test.

   e) The correct procedure for performing a test and pitfalls associated with incorrect protocol.

   f) Agreed protocol for documentation/reporting of a result including the correct way to identify personal Operator ID as part of the patient's record. Identification of results which may have an adverse effect on the patient's treatment must be brought to the immediate attention of a clinician.

g) The correct quality control procedures which must be completed, validated and recorded before release of the patient result.

h) The correct procedure for the disposal of consumables, reagents and used analytical devices should be included in the programme. Awareness of any decontamination procedure required.

i) The processing of iQC and EQA samples.

## 5.3 Certification

When a member of staff has completed a training course, the trainer must assess the individuals competence to perform the POCT procedure.

A central record should be kept by the Clinical Area Manager in the Equipment Training Folder. This must be maintained of all those who have been shown to be competent. The record must be kept up to date and any individual whose competence fails must be removed from the register until their competence has been re-established.

The identification of each certified operator must be incorporated into POCT logs and/or entered into the patient's records.

No operator should:

a) Give their ID to another person in order for a test to be undertaken.

b) Use another person's ID.

c) Perform a point of care test without proper certification/ID.

## 5.4 Re-certification

Re-certification and assessment of competence is required at regular intervals as defined for each test and agreed by the Trust Clinical Governance Committee and/or Patient Safety Review Group.

If any operator is shown to be performing below the required standard, a supportive course of action should be implemented. In the first instance of poor performance the operator in question needs to be assessed by their identified trainer. Closer monitoring of performance should be implemented and re-assessment carried out. Should this fail then, certification must be withdrawn until competence can be demonstrated. If unresolved, escalation to the POCT coordinator may be necessary and corrective action will be implemented as appropriate.

## 6. MONITORING COMPLIANCE WITH THE PROCEDURAL DOCUMENT

| What is being Monitored | Who will carry out the Monitoring | How often | How Reviewed/ Where Reported to |
|---|---|---|---|
| **MONITORING PERFORMANCE**<br><br>Participation in internal quality control (IQC) and external quality assessment (EQA) is mandatory for all POCT and resources for this must be met by the user. Quality assurance is the duty of operators of POCT equipment. The exact nature of the procedures will depend very much on the technology and details will be documented in the Standard Operating Procedure for each method/device.<br><br>**- Quality Assurance** | | | |
| *IQC* will be performed by the users of POCT equipment on a regular basis as specified in the Standard Operating Procedure for each particular POCT instrument. The recorded data should also identify the tolerance limits of acceptable performance. If IQC is within tolerance, and therefore acceptable, patient results may be released. | POCT co-ordinator. | Annual audit or in response to non-conformances. | Non-compliance will be reported to the Clinical Area Manager, in the first instance. Root cause should be resolved through for e.g. training needs analysis or changes to the duty rota. Any areas of persistent non-compliance will be escalated to the POCT Governance Committee via the POCT co-ordinator. |
| *EQA* must be performed by the users of POCT equipment. The results submitted to the POCT co-ordinator will be reviewed by the POCT Governance Committee. If poor performance, persistent non-participation or gross performance problems are not rectified, then it may result in withdrawal of the POCT equipment. | POCT co-ordinator. | Dependant on test - monthly, bi-monthly or quarterly. | Any non-returns or out of conformance results will result in a DATIX report which should be investigated by the Clinical Area Manager with support from the POCT co-ordinator. A summary of EQA results will be presented at the 6 monthly Clinical Governance meetings. |

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| **MONITORING COMPLIANCE** | | | |
| **- Documentation and Record Keeping** | | | |
| *Patient results* along with the time and date of analysis, operator ID and the POCT equipment used, must be recorded within the patient's healthcare record. It is mandatory that procedures are in place to ensure the correct patient has been identified and correspond to patient notes or wrist band details. The requesting clinician must be made aware of the POCT result. Where possible, systems that allow the connectivity of POCT devices to the laboratory data system, including the electronic patient record must be used. | Clinical Area Manager | Periodic and local vertical audits by the Clinical Area Manager. | Documentation on request by POCT coordinator. |
| **- Patient ID** | | | |
| Incidence of blood glucose tests being undertaking using non-sense patient ID. | POCT co-ordinator | Monthly | % of non-sense patient ID reported to the 6 monthly Clinical Governance meetings. Persistent offenders will be escalated to Clinical Area Managers. |
| **- Blood Gas Barcode Use** | | | |
| GemWeb workload report looking for multiple uses of the same barcode over prolonged periods/number of tests carried out by users. | POCT co-ordinator | Monthly | Concerns will be raised with the relevant Clinical Area Manager. |
| **- Blood Gas Error Reports** | | | |
| GemWeb advanced reports detailing e.g. aborted samples, clotted samples. | POCT co-ordinator | Monthly | Concerns will be raised with the relevant Clinical Area Manager and re-training for the operator arranged where required. |
| - **Instrument maintenance** | | | |
| Records of instrument maintenance, faults and corrective action must be kept. It is essential that the routine | Clinical Area Manager, or identified link nurse, will be responsible for keeping local records. A | As and when. | POCT co-ordinator. Concerns will be raised with the relevant Clinical Area Manager and re-training for the |

| | | | |
|---|---|---|---|
| maintenance and/or calibration of equipment is carried out according to the manufacturer's instructions. Failure to properly maintain equipment may give misleading or dangerous results. Maintenance records must be kept for audit purposes. | copy should be supplied to the POCT coordinator. | . | operator arranged where required. |
| **AUDITS**<br><br>All POCT procedures will be subject to regular audit. | POCT co-ordinator or Instrument Manufacturer/supplier. | Annually where practicably possible. | Non-conformances raised as DATIX reports for investigation by the Clinical Area Manager and POCT co-ordinator. |
| **INCIDENT REPORTING**<br><br>Any adverse incidents associated with POCT should be reported via the Trust Incident Reporting System.<br><br>**- Trend Analysis**<br><br>Total number of incidents per Division.<br><br>Number of incidents of each type e.g. EQA out of consensus, EQA non returns, incorrect patient ID, training issue, IT issue, analyser failure. | All staff.<br>CORP/RISK 33 Incident Management Policy.<br><br>POCT co-ordinator<br><br>POCT co-ordinator | Please refer to CORP/RISK 33 Incident Management Policy.<br><br>Monthly<br><br>Monthly | Please refer to CORP/RISK 13 Policy For the Reporting and Management of Incidents and Near Misses.<br><br>Reported monthly to Pathology Audit and Governance Meeting, and 6 monthly to Trust Clinical Governance and Divisional Clinical Governance Meetings. |
| **CLINICAL GOVERNANCE STANDARDS COMMITTEE (CGSC) REPORT**<br><br>A 6 monthly report is presented to the CG&Q Committee. | POCT co-ordinator / POCT Lead | 6 monthly | CG&Q Meeting. |

# 7. DEFINITIONS

## 7.1 External Quality Assessment (EQA)

EQA is the process whereby samples with unknown values are tested. Results are then subject to peer group assessment and statistical analysis to compare results across different sites. EQA is a retrospective analysis of performance.

## 7.2 Internal Quality Control (IQC)

The analysis of a sample of known concentration, ensuring that the result obtained falls within acceptable performance limits. Analysis is carried out at regular intervals as detailed in the SOP.

## 7.3 POCT Equipment / Process

This refers to all equipment and processes used outside the laboratory to perform analytical testing. For the purpose of this policy the word 'device' is used to include the whole range of items from simple urine dipstick tests to sophisticated desktop analysers.

## 7.4 The User

The user is any person who handles a device whether it is used directly to produce results or for maintenance or quality control procedures. This includes clinicians, nursing staff, healthcare assistants and healthcare scientists.

# 8. EQUALITY IMPACT ASSESSMENT

An Equality Impact Assessment (EIA) has been conducted on this procedural document in line with the principles of the Equality Analysis Policy (CORP/EMP 27) and the Fair Treatment For All Policy (CORP/EMP 4).

The purpose of the EIA is to minimise and if possible remove any disproportionate impact on employees on the grounds of race, sex, disability, age, sexual orientation or religious belief. No detriment was identified. (See appendix 5).

The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are disadvantaged over others. Our objectives and responsibilities relating to equality and diversity are outlined within our equality schemes. When considering the needs and assessing the impact of a procedural document any discriminatory factors must be identified.

# 9. ASSOCIATED TRUST PROCEDURAL DOCUMENTS

- Approved Procedural Documents (ADPs) - Development and Management Policy - CORP/COMM 1
- Medical Devices Management Policy - CORP/PROC 4
- Medical Equipment Training for Trust Staff - CORP/ RISK 2
- Patient Identification Policy - PAT/PS 7
- Statutory and Essential Training (SET) Policy - CORP EMP 29
- Record Keeping Standards - CORP/REC 6
- Sharps Policy – Safe Use and Disposal - PAT/IC 8
- Waste Management Policy and Manual - CORP/HSFS 17
- Cleaning and disinfection of ward based equipment - PAT/IC 24
- Incident Management Policy - CORP/RISK 33
- Equality Analysis Policy - CORP/EMP 27
- Fair Treatment For All Policy - CORP/EMP 4
- Risk Identification, Assessment and Management Policy CORP/RISK 30

## 9.1 Risk Management

**a) Health and Safety**

All POCT should be undertaken in a way that does not place the patient or any member of the Trust's staff at additional risk. All Trust health and safety policies must be strictly adhered to.

The Standard Operating Procedure for each device should identify all specific health and safety precautions that must be taken to protect both patients and staff.

Any health and safety incidents must be reported to the Trust POCT Governance Committee via the Pathology POCT Coordinator.

A risk assessment by the Infection Prevention Control Team must be carried out before the installation of a new piece of POCT equipment and similarly before an existing piece of POCT equipment is moved to another location. A copy of all associated documentation must be forwarded to the POCT Co-ordinator.

**b) Infection Control**

Before purchasing any point of care equipment please ensure you have consulted with a member of the Infection Prevention & Control Team. The potential issues of storage and decontamination need to be considered before purchasing equipment.

Once you have obtained the approval of the Infection Prevention & Control Team and purchased the equipment, please include decontamination in your daily maintenance programme referring to the Decontamination Policy PAT/IC 24.

Please contact the POCT Co-ordinator or a member of the Infection Prevention & Control Team for further advice.

**c) Adverse Incident Reporting**

Any adverse incidents involving POCT devices e.g. instrument failure, health and safety issue or clinical incident must be reported in accordance with the Trust's Incident Reporting System (CORP/RISK 30 Risk Identification, Assessment and Management Policy).

An adverse incident is an event that causes, or has potential to cause, unwanted effects. In a POCT environment this may involve the health and safety of patients, users or other persons. Examples are an incorrect result which could lead to a delay in treatment, exacerbation of a life-threatening illness, cause serious deterioration in health or even death.

The Medical Devices Agency (MDA) is responsible for investigating adverse incidents associated with all medical devices. Safety Notices and Product Alerts are issued by the MHRA, circulated and disseminated by the Trust's Medical Devices Manager.

## 10. DATA PROTECTION

Any personal data processing associated with this policy will be carried out under 'Current data protection legislation' as in the Data Protection Act 2018 and the General Data Protection Regulation (GDPR) 2016.

For further information on data processing carried out by the trust, please refer to our Privacy Notices and other information which you can find on the trust website: https://www.dbth.nhs.uk/about-us/our-publications/information-governance/

## 11. REFERENCES

1. International Standard, ISO 22870 – Point-of-care Testing (POCT) – Additional Standards for Point of Care Testing (POCT) Facilities.

2. International Standard, ISO 15189 (2007) – Medical Laboratories – Particular Requirements for Quality and Competence.

# APPENDIX 1

## POCT GOVERNANCE COMMITTEE

## TERMS OF REFERENCE

The POCT Governance Committee is responsible for overseeing all aspects of the delivery of point of care testing within the Trust. It may also be asked to take a similar responsibility for point of care testing in other environments where the Trust is responsible for the delivery of the pathology services.

Specifically:

- **Has appointed core members:**

  a) Trust POCT Lead - Consultant Biochemist

  b) Trust POCT Co-ordinator

These members report on a 6 monthly basis to the Trust Quality and Governance Committee and to each Divisional or Speciality Clinical Governance meeting as appropriate

- **Other members will be consulted as required:**

  c) Pathology Clinical Director

  d) Head of Pathology Services

  e) Pathology Quality Manager

  f) Pathology Clinical Governance Lead

  g) Representative from Procurement

  h) Representative from Medical Technical Services

  i) Specialists from specific Pathology disciplines related to the POCT test

  j) Clinical staff including Clinical Leads from the relevant area

  k) Nursing and/or clinical support teams from the relevant area

  l) General and/or Business Manager from the relevant area

  m) Representative from Finance

  n) Representative from IT

o) Representative from Estates

p) Other members of the Pathology Services Management Team

q) Representative from Training and Education

r) CCG representatives

***For any new equipment tenders or introduction of new test, the following members of the committee should be consulted (as a minimum):***

Trust POCT Lead - Consultant Biochemist
Trust POCT Co-ordinator
Representative from Procurement
Representative from Medical Technical Services (if equipment required)
Representative from finance
Clinical Representative from the relevant areas
General and/or business managers (budget holders) from the relevant areas
Representative from IT (if applicable)

**The Committee is responsible for:**

a) Agreeing the use of POCT

b) Working with the Trust's Procurement Department to ensure Procurement rules are adhered to and safeguard value for money whilst ensuring the needs of clinicians are always met.

c) Ensuring that all equipment is properly maintained.

d) Overseeing the maintenance of appropriate health and safety procedures in environments where POCT is performed.

e) Undertaking audits of POCT as appropriate to the needs of the Trust.

f) Withdrawing a POCT device if the agreed standards of operation are not met despite adequate training.

g) Submitting 6 monthly Divisional reports and a summary report to the Trust Quality and Governance Committee.

h) Disseminate information regarding contraindications/interferences in POCT systems in use within the Trust and Community.

i) Consider any other relevant business.

j) New business cases for POCT.

k) Quality control and quality assurance performance data.

l) Incident reports and action taken.

m) Status of staff training, certification and recertification requirements.

n) Standard operating procedures and modify as appropriate.

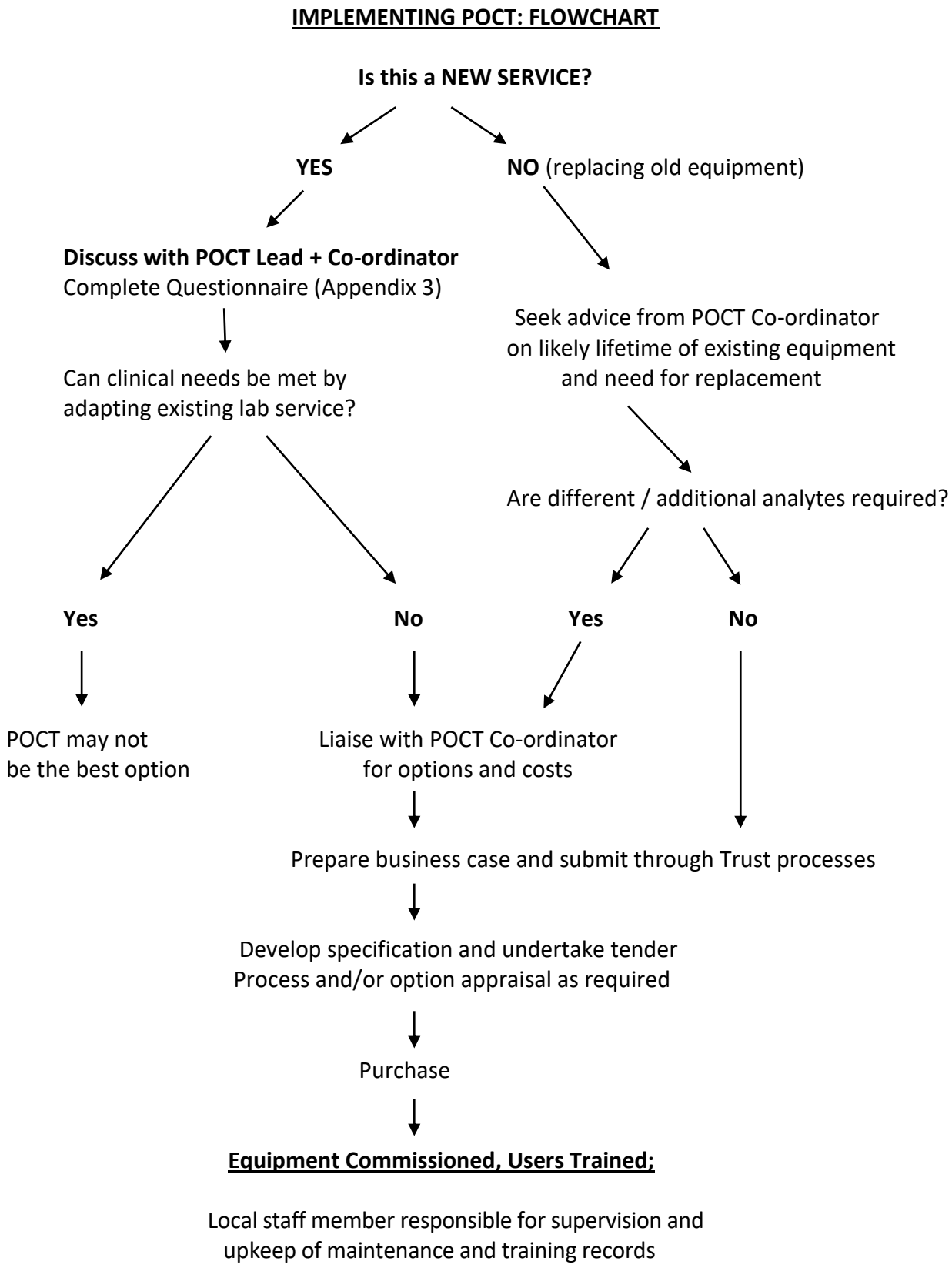
o) Suitability of trainers for each POCT procedure.

p) Review feedback from user or working groups.

**Standard items in the 6 monthly reports to Clinical Governance Meetings include:**

Review of equipment
Internal quality control
External quality control
DATIX summary
Compliance reports e.g glucose meter patient ID, blood gas barcode usage, error reports
Project reports
Training

# APPENDIX 2 – FLOWCHART FOR IMPLEMENTATION OF POCT



# APPENDIX 3 – PROPOSAL OF NEW POCT EQUIPMENT

## PROPOSAL FOR NEW POCT EQUIPMENT

This proposal should be completed (as far as possible) for any proposed acquisition of new POCT equipment, this includes:

1. Tests not currently employed within the Trust
2. Replacement of existing POCT devices
3. Change of supplier/technology
4. Extension of existing POCT activities
5. Loan equipment for trial or evaluation purposes
6. Equipment or tests to support clinical trials

Completed forms should be sent to:

Point of Care Co-ordinator, Pathology Services, Doncaster Royal Infirmary.

for consideration by the POCT Governance Committee.

| | Question | Answer |
|---|---|---|
| | **Proposed Area of Application/Implementation :**<br><br>*Please include contact details of all relevant parties.* | |
| | **Background Information** | |
| 1 | What new POCT process/device is proposed? | |
| 2 | Does the proposal for equipment to be acquired, fully comply with the requirements of the Trust Point of Care Testing Policy? | |
| 3 | Is the test available in the laboratory? | |
| 4 | Why should the testing be done on the ward/unit rather than sending samples to the laboratory? | |
| 5 | Has discussion with the POCT Coordinator and/or relevant Department taken place? | |
| 6 | If so, with whom? | |
| 7 | What resources have been identified to support this POCT? | |
| 8 | Which group of patients need the test? | |

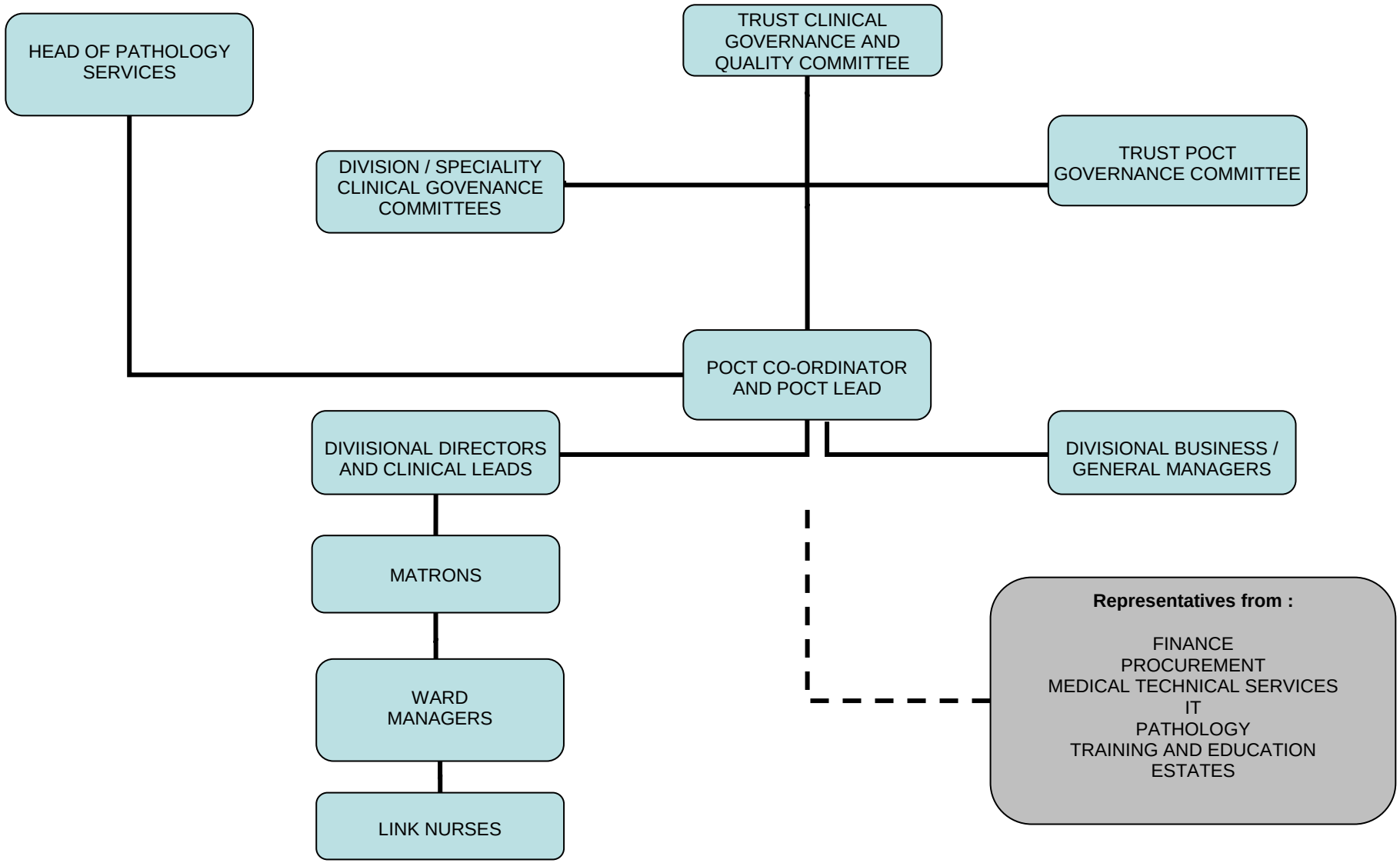
| | | |
|---|---|---|
| 9 | Is there a protocol or set of guidelines for selecting patients to test?<br>*Please enclose a copy.* | |
| 10 | How many samples will be analysed per annum? | |
| 11 | Are any confirmatory/additional tests required:<br>(a) Using POCT devices?<br>(b) Or, in the laboratory?<br>(c) If Yes, how will this be funded? | |
| 12 | What are the clinical benefits of POCT? | |
| | **Costs** | |
| 13 | What is the capital cost of the instrument (including VAT)? | |
| 14 | What is the annual consumable cost per annum?<br>(Include all consumables, collection devices, quality control, external quality assurance costs as well as devices lease if applicable.) | |
| 15 | What are the maintenance/servicing costs after expiry of guarantee? | |
| 16 | Is the cost of interfacing the device to the laboratory or hospital computer system included in the cost? | |
| 17 | If not what is the cost to interface? | |
| 18 | Does an IT port need to be installed? | |
| 19 | Is the cost of software/hardware to monitor and control the device from the laboratory included? | |
| 20 | Have you considered what support you may require from Pathology? | |
| | **Devices** | |
| 21 | What device is most suitable for your purpose? | |
| 22 | Is the device CE marked? | |
| 23 | Has the equipment been evaluated by an external professional organization e.g. PASA or MDA? | |
| 24 | Will there be any health and safety problems? (A risk assessment by Infection Prevention & Control is mandatory prior to the approval of POCT equipment.) | |
| 25 | Are there adequate facilities for disposal of samples and consumables? | |
| 26 | What is the distance to the nearest hand-wash sink? | |

| | | |
|---|---|---|
| 27 | Is room air-conditioning required? | |
| 28 | Are the appropriate amenities available e.g. power, water, electricity, network point? | |
| 29 | Does the device have a UPS (Uninterrupted Power Supply) unit? | |
| 30 | Where will the devices be located? | |
| 31 | Are there adequate facilities to perform POCT? | |
| 32 | What space is available for the storage of stock items/consumables? | |
| 33 | Can an engineer have easy access to the equipment? | |
| 34 | Will POCT device provide the required accuracy and precision? | |
| 35 | Is the instrument able to be password protected? | |
| 36 | What happens if devices/process breaks down? | |
| 37 | Who will manage the ordering of consumables including quality assurance materials? | |
| 38 | Who will take overall responsibility for the devices? | |
| 39 | Who will arrange maintenance contracts and emergency call-outs? | |
| | **Staff/Personnel Requirements** | |
| 40 | Who will be performing the tests? | |
| 41 | What extra staff time will be required? Are enough staff currently available? | |
| 42 | Is extra staffing resourced? | |
| 43 | Will the users be restricted to staff working in the location of the POCT process? | |
| 44 | Who will have responsibility for the necessary training? | |
| 45 | Will Pathology need to be involved? | |
| | **Reports/Results** | |
| 46 | Has Pathology been consulted with regard to units, reference ranges, sample types and correlation with laboratory results? | |
| 47 | Who will be responsible for interpretation of results and any clinical action based on the POCT result? | |
| 48 | How will the results be recorded and stored? | |

| | | |
|---|---|---|
| 49 | Can the device be interfaced to the laboratory computer or the hospital information system? | |
| 50 | Do you need IT support? | |
| 51 | Has the IT department agreed to your requirements? | |
| 52 | Have you insured that the proposal for the equipment meets the requirements of the Trust POCT Policy fully? | |
| | **Post POCT Committee Approval** | |
| 53 | Have you applied to the Medical Equipment Group for approval? | |

| | | |
|---|---|---|
| | **Applicant signature** | |
| | **Print name** | |
| | **Position held** | |
| | **Division and Ward** | |

# APPENDIX 4 – POINT OF CARE TESTING ORGANISATIONAL CHART



# APPENDIX 5 – EQUALITY IMPACT ASSESSMENT - PART 1 INITIAL SCREENING

| Service/Function/Policy/Project/ Strategy | Division/Executive Directorate and Department | Assessor (s) | New or Existing Service or Policy? | Date of Assessment |
|---|---|---|---|---|
| Point of Care Testing Policy CORP/RISK 8 v7 | Clinical Specialties | Katherine Wright | Existing | 10/08/2020 |

**1) Who is responsible for this policy?** Name of Division/Directorate: Clinical Specialities

**Describe the purpose of the service / function / policy / project/ strategy?** Who is it intended to benefit? What are the intended outcomes? The aim of this document is to provide guidance for safe and effective management and use of POCT systems that are fit for their intended purpose, used by a competent individual on the correct patient, giving quality results which become part of the patient's record.

**2) Are there any associated objectives?** ISO 22870:2016 (UKAS) - Currently not accredited

**3) What factors contribute or detract from achieving intended outcomes?** Trust and staff engagement, Compliance, Funding

**4) Does the policy have an impact in terms of age, race, disability, gender, gender reassignment, sexual orientation, marriage/civil partnership, maternity/pregnancy and religion/belief?** No

- **If yes, please describe current or planned activities to address the impact** [e.g. Monitoring, consultation]

**5) Is there any scope for new measures which would promote equality?** Not Required

**6) Are any of the following groups adversely affected by the policy?**

| Protected Characteristics | Affected? | Impact |
|---|---|---|
| a) Age | No | |
| b) Disability | No | |
| c) Gender | No | |
| d) Gender Reassignment | No | |
| e) Marriage/Civil Partnership | No | |
| f) Maternity/Pregnancy | No | |
| g) Race | No | |
| h) Religion/Belief | No | |
| i) Sexual Orientation | No | |

**7) Provide the Equality Rating of the service / function /policy / project / strategy – tick (✓) outcome box**

| Outcome 1 √ | Outcome 2 | Outcome 3 | Outcome 4 |
|---|---|---|---|

**If you have rated the policy as having an outcome of 2, 3 or 4, it is necessary to carry out a detailed assessment and complete a* **Detailed Equality Analysis form in Appendix 4**

**Date for next review:** August 2023

**Checked by:** **K. Wright** **Date: 10/08/2020**