Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust

POINT OF CARE GOVERNANCE POLICY

POINT OF CARE TESTING POLICY AND GUIDELINES

This procedural document supersedes: CORP/RISK 8 v.5 – Policy and Guidelines for Point of Care Testing.

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Date written/revised:	1 February 2017
Approved by:	Policy Approval and Compliance Group (on behalf of the Patient Safety Review Group)
Date of approval:	15 February 2017
Date issued:	27 March 2017
Next review date:	February 2020
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 6	27 March 2017	• Contents page amended. • Committee, departmental names and Trust title amended. • Revision of Associated Trust Procedural Documents. • Update of training requirements.	Dr J Wardell Mrs F Dunn Ms D Lee
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 Mrs F Dunn 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 • Clarification of roles, section 7.5 Managers of Areas Using POCT • Slight amendment to Appendix 3 to include entry for the proposed area of application/implementation • Minor changes made throughout for clarity	Dr J Wardell Mrs F Dunn 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) • Introduction of an amendment form • More defined responsibilities • Introduction of a flowchart for implementation of POCT (appendix 2) • Introduction of a questionnaire (appendix 3) • 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 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 organization 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 same quality standards as all testing undertaken within the CPA (Clinical Pathology Accreditation) accredited laboratory.

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, used by a competent individual 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 CPA accreditation of laboratory 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) Ensure that systems are in place to enable quality standards to be maintained and to sign and date all Standard Operating Procedures. The POCT coordinator will also work with the Pathology Quality Manager to ensure that any problems identified by quality control and quality assurance procedures are rectified.

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

3.4 Managers of Areas using POCT will ensure:

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

b) That the General Manager of the Care Group 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) That all users of POCT are competent and authorised to use the devices.

d) That each Operator maintains competency and that training records are kept.

e) That quality assurance such as iQC and EQA are performed in accordance with this Policy.

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

g) Ensure a designated 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.

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) Provide technical advice and support.

b) Distribute alerts from MHRA.

c) Report technical performance problems to MHRA.

d) 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.

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 via the Trust POCT Governance Committee thus 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.

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

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.

5.2 Training

1. Training for POCT devices will be based on any outcome of the review of Medical Equipment Training Policy and on the guidelines given by ISO 22870:2016 Point-of-care Testing (POCT) – Additional Standards for POCT Facilities. 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. Succession training will occur thereafter **to** other users of the device. Evidence of training, i.e. a training record/register must be kept by the clinical area manager at a local level (Equipment Training Folder) and produced for audit purposes. 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 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.

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

e) 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.

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

g) 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.

h) 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 if 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

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 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. **- 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.	Clinical Area Manager.	Review of compliance should be carried out in keeping with the frequency of usage of the POCT equipment. This should be at the recommended interval. Reviewed quarterly.	Non-compliance with procedures will be assessed by 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.		The POCT Governance Committee will review EQA performance at each meeting and through POCT Summary reports.

What is being Monitored	Who will carry out the monitoring	How often	How Reviewed/Where reported to
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.
Instrument maintenance. Records of instrument maintenance, faults and corrective action must be kept. It is essential that the routine 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.	Clinical Area Manager, or identified link nurse, will be responsible for keeping local records. A copy should be supplied to the POCT coordinator.	As and when.	POCT co-ordinator.
AUDITS			
All POCT procedures will be subject to regular audit.	POCT co-ordinator or Instrument Manufacturer/supplier.	Annually where practicably possible.	

What is being monitored	Who will carry out the Monitoring	How often	How Reviewed/Where Reported to
INCIDENT REPORTING Any adverse incidents associated with POCT should be reported via the Trust Incident Reporting System.	All staff. CORP/RISK 13 Policy For the Reporting and Management of Incidents and Near Misses.	Please refer to CORP/RISK 13 Policy For the Reporting and Management of Incidents and Near Misses.	Please refer to CORP/RISK 13 Policy For the Reporting and Management of Incidents and Near Misses.
CLINICAL GOVERNANCE STANDARDS COMMITTEE (CGSC) REPORT An annual report is presented to the CG&Q Committee.	POCT co-ordinator.	Annual.	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.

7.2 Internal Quality Control (iQC)

iQC can be one of two processes:

a) The analysis of a sample of known concentration, ensuring that the result obtained falls within acceptable performance limits.

b) Reproduce an analysis of a sample previously tested in the lab by POCT. This is to be carried out at regular intervals, e.g. once a week, to ensure that agreement with the laboratory method is being maintained.

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).

9. ASSOCIATED TRUST PROCEDURAL DOCUMENTS

- APD Development and Management Process - CORP/COMM 1
- Medical Devices Management Policy - CORP PROC 4 v5
- Medical Equipment Training for Trust Staff - CORP/ RISK 2 v5
- Patient Identification Policy - PAT/PS 7
- Statutory and Essential Training SET Policy - CORP EMP 29 v4
- Record Keeping Standards - CORP/REC 6
- Sharps Policy – Safe Use and Disposal - PAT/IC 8
- Waste Policy and Procedures - CORP/HSFS 17
- Cleaning and disinfection of ward based equipment - PAT/IC 24

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 13 - Policy For the Reporting and Management of Incidents and Near Misses).

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. 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's Pathology CSU is responsible for the delivery of the pathology services.

Specifically it:

- **has appointed core members:**

  a) Chair - Pathology Clinical Director.

  b) Deputy Chair – Consultant Microbiologist D&P

  c) Point of Care Testing Co-ordinator.

  d) Pathology Quality Manager.

  e) Representative from Procurement

  f) Representative from Medical Devices

- **has representatives from**:

  a) All specialties within Pathology for which POCT is performed.

  b) The nursing and/or clinical support teams from each of the Care Groups which undertake POCT – e.g. matrons.

  c) An individual involved in equipment maintenance.

  d) The –Pathology Services management team.

  e) The clinical staff including Clinical Leads .

  f) PCT representative(s) - preferably an individual able to represent all PCTs and either involved in, or with an interest in, POCT.

  g) The clinical governance lead for Pathology Services.

  h) Representation from supplies, finance and information technology.

- **meets bi-annually to:**

a) Agree the use of POCT.

b) Work 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) Ensure that all equipment is properly maintained.

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

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

f) Have the authority to withdraw a POCT device if the agreed standards of operation are not met despite adequate training.

g) Submit minutes of meetings and an annual report on request.

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

i) Consider any other relevant business.

The Committee also reviews the following:

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.

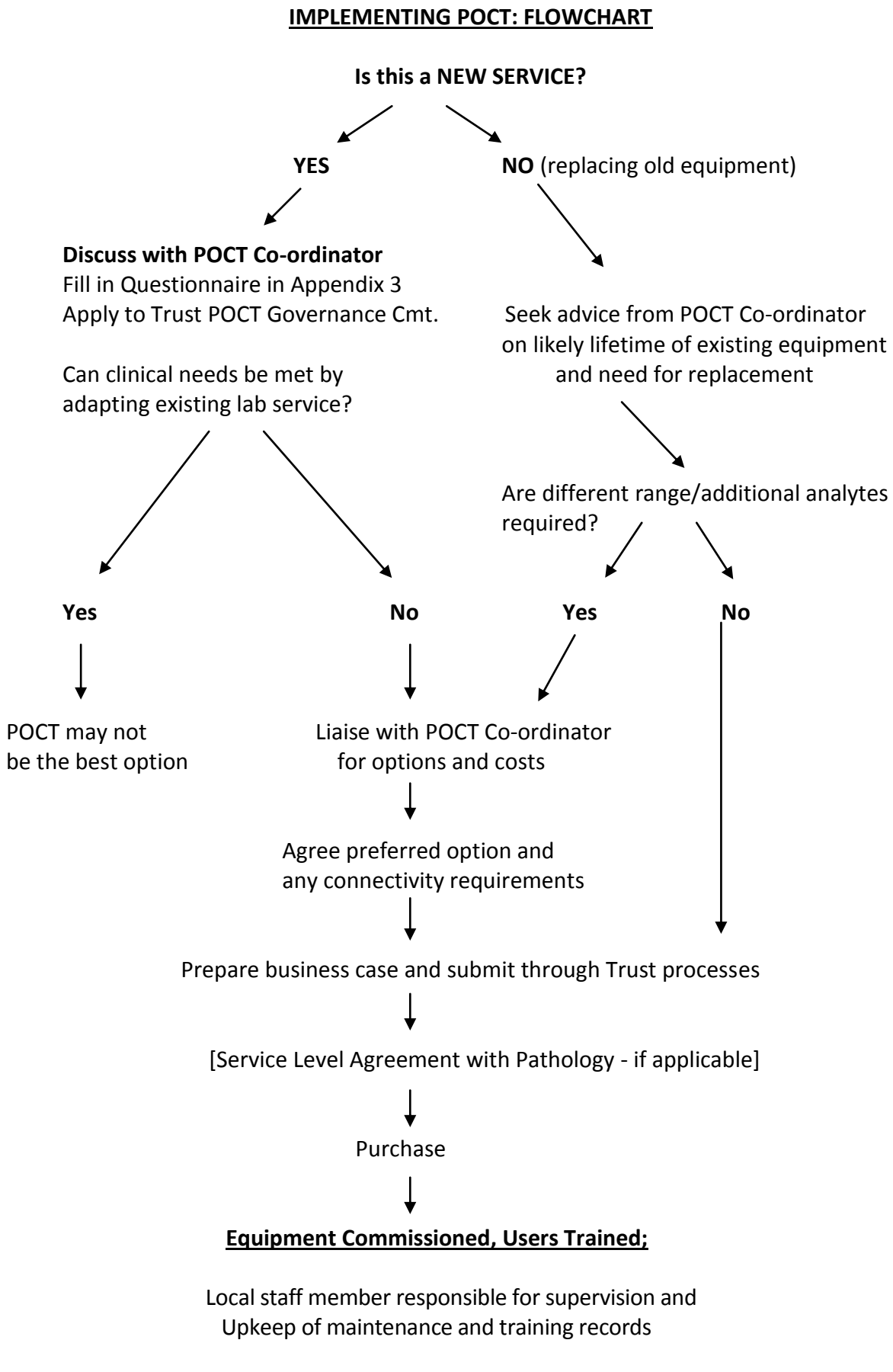
o) Suitability of trainers for each POCT procedure.

p) Review feedback from user or working groups.

Quorum at POCT Governance Committee Meetings

A minimum of 6 committee members is required comprising of at least 3 core members and 2 clinical representatives.

APPENDIX 2 – FLOWCHART FOR IMPLEMENTATION OF POCT



APPENDIX 3 – PROPOSAL OF NEW POCT EQUIPMENT

PROPOSAL FOR NEW POCT EQUIPMENT

Any proposed acquisition of new POCT equipment requires an application to the POCT Governance Committee AND the following completed form to be returned to:

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

A proposal should also be submitted for replacement of existing POCT devices, extension of existing POCT activities including equipment on loan or for use in clinical trials.

The Trust POCT Governance Committee will consider the application and notify the applicant and the Medical Devices Management Committee of their decision.

	Question	Answer
	Proposed Area of Application/Implementation	
	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? Please enclose a copy.	
10	How many samples will be analysed per annum?	
11	Are any confirmatory/additional tests required: (a) Using POCT devices? (b) Or, in the laboratory? (c) If Yes, how will this be funded?	

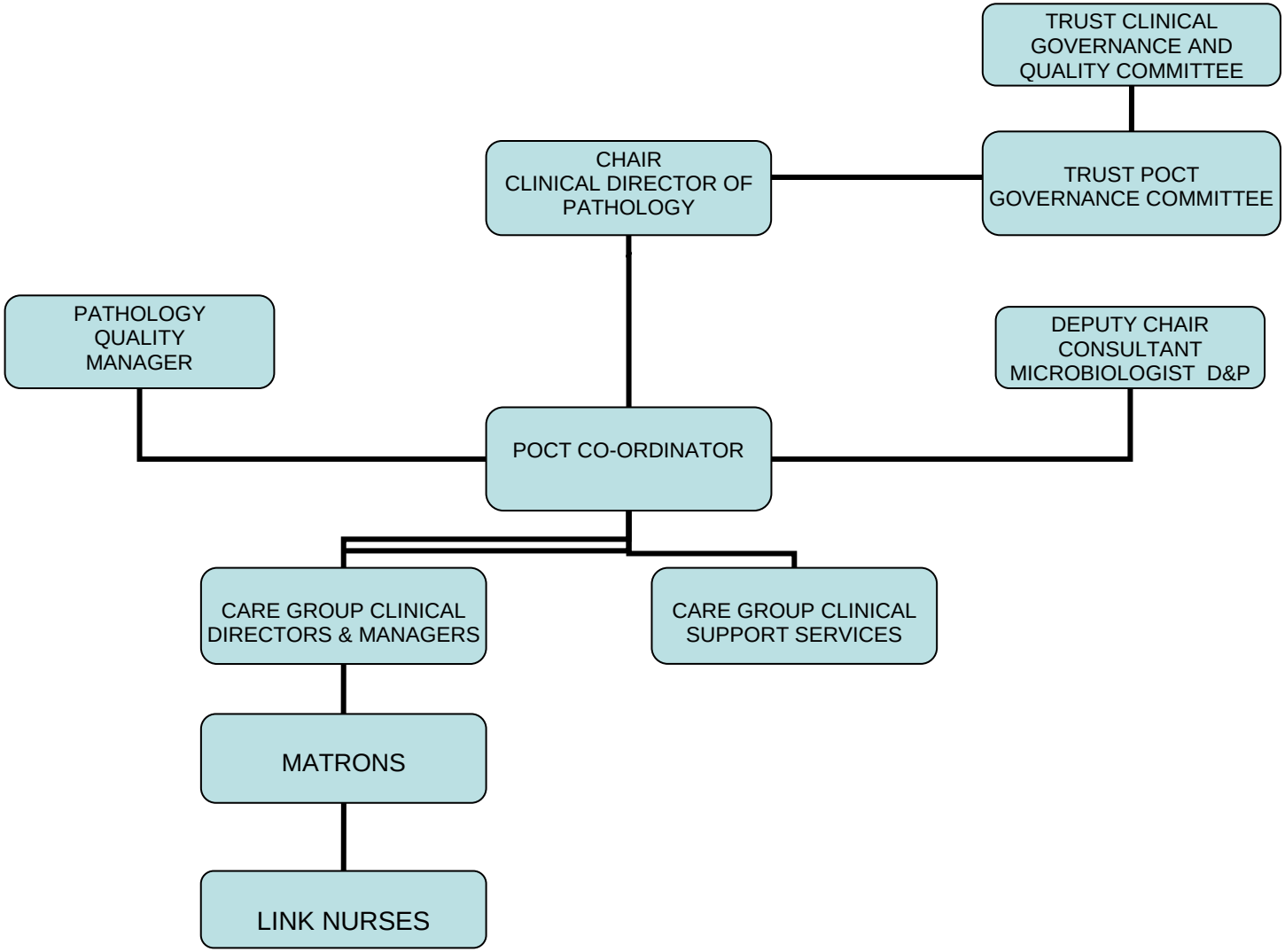
12	What are the clinical benefits of POCT?	
	Costs	
13	What is the capital cost of the instrument (including VAT)?	
14	What is the annual consumable cost per annum? (Include all consumables, collection devices, quality control, external quality assurance costs as well as devices lease if applicable.)	
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? Is the 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	
	Care Group and Ward	

APPENDIX 4 – POINT OF CARE TESTING ORGANISATIONAL CHART



APPENDIX 5 – EQUALITY IMPACT ASSESSMENT - PART 1 INITIAL SCREENING

Service/Function/Policy/Project/ Strategy	Care Group/Executive Directorate and Department	Assessor (s)	New or Existing Service or Policy?	Date of Assessment
Point of Care Testing Policy	Diagnostic and Pharmacy CG	Dawn Lee	Existing	01/02/2017

1) Who is responsible for this policy? Name of Care Group/Directorate: Diagnostic and Pharmacy CG

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? Legislation, targets national expectation, standards None

3) What factors contribute or detract from achieving intended outcomes? None

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? None

- **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? [any actions to be taken None

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: February 2020

Checked by: **D. Lee** **Date: 01/02/2017**