Brighton and Sussex University Hospitals NHS Trust

Procurement, Management and Use of Clinical Point Of Care Testing Equipment Policy

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Linked Documents:	See Section 9

Contents

1. Introduction

1.1 General

1.1.1 Point-of-care testing (POCT), sometimes referred to as Near Patient Testing, is both practicable and in some situations desirable. Like all new technologies its apparent simplicity often belies its complexity and masks an enhanced need for attention to detail.

1.1.2 Clinical POCT users should be encouraged to adopt a policy of integration of clinical POCT with clinical laboratory services in order to reduce all unplanned use and abuse of this equipment which is not only wasteful and divisive but potentially dangerous. A medical devices equipment management group or clinical point of care testing committee is a preferred forum to co-ordinate this activity within the healthcare environment.

1.1.3 All Trust employees, including those responsible for introducing clinical POCT devices and those who are responsible for their support, will need to cooperate closely in the financial implications of procurement and use of this equipment. Clinical POCT should be adopted only if it benefits clinical practice within the hospital and community as a whole. (Adapted from ref.[1]).

1.1.4 Guidance is available to ensure that clinical POCT is introduced in a coordinated fashion, meeting appropriate clinical and financial criteria, from the Medicines and Healthcare Products Regulatory Agency (MHRA)[2].

1.1.5 The potential advantages of clinical POCT may be:

- Improved turnaround time.
- Potentially improved monitoring of certain conditions where frequent testing is desirable.
- Smaller sample and reagent volumes.
- Less invasive.
- Suitable for areas remote from laboratory where access is limited.
- Economic (may be a cost-benefit in avoiding patient coming to the hospital for treatment).
- Greater patient involvement in their own care.

1.1.6 The potential disadvantages may be:

- Duplication of equipment.
- Tests may be performed by employees with non-analytical background.
- Ensuring users are trained and accredited is complicated.
- Lack of ownership for actions required on abnormal or erroneous results.
- Reduced control over possible inappropriate or unnecessary use of equipment.
- Less robust data recording and inadequate transfer of results to the patient record.

- Incompatibility of results with those from the laboratory (e.g. if reference ranges differ)
- Greater expense, including 'hidden costs' in training and QA.

1.2 Tests for Which POCT Techniques are Available

1.2.1 Examples of clinical POCT devices, which is by no means exhaustive, is seen below;

- Urinary stick tests and meters, Pregnancy test, Tests for infectious diseases, Blood gases, Blood glucose and other sugars, Therapeutic drugs and drugs of abuse, Haemoglobin A1C, Hormones, Creatine Kinase, Haemoglobin, Full Blood Count, Coagulation, Bilirubin, Carbon monoxide, Alcohol, Cholesterol.

1.2.2 Clinical POCT techniques known to be in use in the Brighton and Sussex University Hospitals Trust

- Urinary stick tests, Blood gases, Blood glucose, Pregnancy tests/HCG high sensitivity, Bilirubinometer, Carboxyhaemoglobin, Haemoglobin, Coagulation

1.2.3 Clinical POCT devices are also in use in the community;

- e.g. Blood glucose, Pregnancy Tests, Urinalysis strips, Cholesterol

1.2.4 Other non-laboratory medical devices that perform analytical functions, such as pulse oximeters, ECG machines, thermometers, etc., may fall within a broader definition of POCT devices, but are the remit of the Medical Devices Committee, and are not covered by this policy).

2. Purpose

To set standards for the procurement and management of clinical point of care testing equipment within BSUH NHS Trust according to the following key principles for the safety of patients:

- To guarantee the safe and proper treatment of patients.
- To ensure proper and appropriate procurement of clinical POCT equipment in liaison with the Trust.
- To ensure that employees are appropriately trained in equipment use.
- To ensure that all clinical POCT equipment is properly maintained, calibrated and serviced to ensure negligible impact on the patient healthcare pathway.
- To ensure that procedures are in place for the use of all clinical POCT equipment used by employees.
- To ensure that quality control and quality assurance procedures are in place and operated for the safe and proper treatment of patients.

- To ensure that a method of recording and monitoring errors and incidents is established.
- To ensure that appropriate root cause analysis and corrective action is instigated to bring all non-conforming equipment and practices into compliance as soon as is feasible.
- To ensure that sufficient security is in place for all clinical POCT equipment to eliminate inappropriate and untrained use.
- To ensure that advances and updates in equipment and practices are appropriately evaluated and introduced safely.

3. Definitions

Point of Care means at or near the bedside of the patient.

4. Responsibilities, Accountabilities and Duties

4.1 Responsibility of Chief Executive and Trust Board

4.1.1 Whilst ultimate responsibility is vested in the Trust Board, executive responsibility is delegated to the Chief Executive for managing clinical POCT equipment. A Medical Equipment Management Group has been set up to be responsible for ensuring the most effective clinical POCT equipment management for the needs of the Trust are made available and that the principle of standardization is progressed wherever possible.

4.2 Responsibility of Managers

4.2.1 All Line Managers of users of clinical POCT devices are responsible for ensuring that individual users have completed training for any clinical POCT equipment used in their clinical area. They must maintain a list of all employees who have received training. They must ensure that employees who have not received training are identified and that they do not use the clinical POCT equipment until training has been completed

4.2.2 Clinical managers will be responsible for selecting employees within their area of responsibility as Key Trainers. These employees may be clinicians, nurses, radiographers or any other suitably qualified individuals as determined by the Manager. The appointed individuals will have the authority to give training on all aspects of the use of equipment, or specified equipment, within their particular area of responsibility.

4.2.3 All clinical POCT equipment users must be acquainted with the requirement to comply with agreed quality assurance procedures. All quality control results must be recorded and retained for a minimum of 8 years in accordance with pertinent Royal college of Pathologists (RCPATH) guidelines on record control. The responsibility for the holding and storage of these records must be agreed between the POCT team and the clinical POCT user.

4.3 Responsibility of the POCT Coordinator and the POCT Team

The POCT Coordinator and POCT Team is responsible for:

4.3.1 Helping to devising and deliver clinical POCT devices education and training programmes.

4.3.2 Education and support of Key Trainers for clinical POCT equipment in liaison with the medical devices trainer and equipment manufacturers and maintaining a list of Key Trainers in BSUH. This list to be updated at least every three years.

4.3.3 Leadership and management of clinical POCT equipment training throughout the trust.

4.3.4 Maintaining regular contact with Key Trainers by email. Notification of upcoming training events, both general and Key Trainer training will be communicated in this way and through BSUH trust wide employee communications. Training meetings will be held when significant alterations to clinical POCT equipment in use or procedural requirements occur; for example, the introduction of new clinical POCT equipment.

4.3.5 The POCT Coordinator is a member of several BSUH committees involved in the selection, purchasing and management of clinical POCT equipment to provide a training perspective. These are the Medical Equipment Management Group - MEMG, the Decontamination Committee and the Product Selection Group – PSG.

4.3.6 An introductory session for incoming medical employee at Foundation Level 1 will be provided covering the processes by which BSUH manage clinical POCT equipment and the responsibilities of all users. Training on a selection of commonly used clinical POCT equipment will also be provided. A summary of medical employee responsibilities will be made available for each attending doctor.

4.3.7 The Point of Care Testing Coordinator will inform the MEMG of any serious incidents for the chairperson to cascade to Medicines and Healthcare Products Regulatory Authority (MHRA) in conjunction with the Trust's Medical Devices Liaison Officer where necessary.

4.4 Responsibility of Key Trainers or Responsible Officer

Key Trainers/Responsible Officers are responsible for:

4.4.1 Being the first point of contact regarding any training issues for clinical POCT equipment within their area.

4.4.2 Disseminating clinical POCT equipment training information in their local area. Trainers receive both generic and medical device manufacturer training for equipment relevant to their area.

4.4.3 Ensuring they maintain attendance at all their own required updates, mandatory and statutory training and any Link activities.

4.4.4 Advising local employee of training opportunities.

4.4.5 Providing training where able.

4.4.6 Being a local champion for the safe and effective use of clinical POCT equipment.

4.4.7 Informing the POCT Coordinator or Medical Devices Trainer of any significant training incidents or shortfall in their area.

4.5 Responsibility of Lead Consultant

It is the responsibility of the Medical Director to ensure that Lead Consultants of clinical services have organised training for medical employees in that service for clinical POCT equipment particular to that service.
The Direct Observation of Procedural Skills (DOPS) assessment has been introduced for new employees either joining or rotating through various medical specialities. A number of procedures are selected by employee for individual assessment and completion & noted on individual portfolios. The Medical Director for the trust is responsible for ensuring all medical departments carry out this process.

4.6 Employee Responsibilities

4.6.1 All employees using clinical POCT equipment will adhere to the provisions set out in this policy and its related processes without exception.

4.6.2 All employees utilising clinical POCT equipment will do so only in accordance with accepted protocols and will not knowingly use such equipment if it is obviously identified as faulty or is knowingly producing errant results.

4.6.3 All employees will report all equipment malfunctions as soon as possible to their direct supervisor or the POCT Coordinator or both, to enact a speedy resolution.

4.6.4 All employees will be responsible for logging the details of any errors or incidents on forms available to them.

4.6.5 Untrained employees **will not use** or cascade train any employee in the use of any clinical POCT equipment. Training in the use of POCT equipment can be sourced from the manufacturer themselves, the key trainer or from the POCT team via the POCT Co-ordinator.

4.6.6 Employees assigned a unique personal security identifier to use clinical POCT equipment will not divulge or make this identifier openly known such that untrained operators could access and the equipment. ***To do so is a breach of***

Trust IT security protocols and may leave the employee member in question open to disciplinary action. If an employee discovers a breach of their own personal security identifier or that of another employee they will inform the POCT Coordinator as soon as possible who will resolve the issue.

4.6.7 Employees will only work within the limits of the risk assessments and COSHH for the processes that they are trained to use and observe all requirements for personal protective equipment.

4.6.8 All accidents or incidents, including user error, with clinical POCT devices that could impinge on patient care must be reported to senior employee, the Point of Care Testing Co-ordinator and/or the Point of Care Testing Team and be evidenced on the Trust DATIX incident management system.

4.6.9 Clinical POCT has several features that can increase the pressure on the person responsible for interpretation. The analysis is often performed under emergency conditions and the results acted upon quickly. Even if all the precautions and guidelines outlined above are taken the results may still not be subjected to the same processes of scrutiny and validation undertaken by clinical laboratories. It is important therefore that the person responsible for interpretation and clinical action be aware of these limitations and if in any doubt repeat the analysis or seek confirmation from the clinical laboratory.

4.7 Responsibilities of the Organisation

4.7.1 The Trust and the MEMG will work closely with all employees both procuring and using clinical POCT equipment to remove the possibility of inappropriate patient treatment.

4.7.2 The chair of the MEMG will ensure that all proposals for clinical POCT equipment are appropriately reviewed by the MEMG group

4.7.3 On discovering that untrained employees are knowingly operating clinical POCT equipment the Trust and the MEMG will sanction the POCT Team to take such action as is necessary to halt these practices. This may include the removal of identified equipment with immediate effect to ensure the safety of patients.

4.7.4 The Trust will also authorise the POCT Team to investigate and make known to the organisation any areas of poor equipment operation through the line management structures of the employees involved for the safety of patients.

5. Policy

5.1 Procurement

5.1.1. A proposal for procurement (or change of practice) could arise from many sources, such as medical or nursing managers. All proposals for clinical POCT equipment must be submitted to the MEMG for consideration in the first

instance.. The clinical and financial case for procurement of any new clinical POCT system must be established prior to any procurement and must comply with Trust policies and procedures for the purchase and management of medical equipment and devices and the stipulations of the MHRA[2] .

5.1.2 The principles of clinical governance are essential to this process. A consensus must be achieved with supporting departments, e.g. the appropriate discipline within Pathology (e.g. Biochemistry, Haematology, Microbiology, Histopathology) at an early stage before proceeding to purchase.

5.1.3 Proposals for procurement should take account of the following:

- demonstrable clinical need
- fitness for purpose of equipment
- capital and revenue costs including maintenance
- anticipated workload
- impact on costs and workload within the laboratory
- availability and costs incurred in training, accreditation and revalidation of employees
- clinical action to be taken in response to results
- any potential cost benefits or cost savings (e.g. reduction in bed-stay, or in laboratory costs).
- ongoing costs, including quality assurance and IT connectivity and management systems

5.1.4 Equipment and reagents used for clinical POCT should be compatible with equipment and reagents used elsewhere within the Trust and yield similar analytical results to those produced in the main laboratory. This objective can only be achieved by involvement of clinical laboratory employees in the choice of equipment and associated reagents at an early stage. Uniformity of equipment, and where appropriate of techniques, is advantageous in terms of simplification of training, comparability of results, ease of maintenance and supply and storage of reagents. It also increases purchasing power resulting in potential savings on maintenance and reagents. The procurement flowchart is presented in Appendix 1.

5.1.5 Furthermore it should ensure that equipment is purchased only from companies with a known good track record for supply of quality systems backed by comprehensive training, maintenance and support services. Manufacturers must demonstrate that their products conform to the In Vitro Diagnostic Medical Devices Directive (98/79/EC). Compliance will be indicated by a display of a CE mark, which is a pre-requisite for selecting equipment. However award of the CE mark does not demand clinical utility for a given application, so fitness for purpose will still need to be assessed by users and laboratory employees.

5.1.6 Consideration must be given to the compliance of all new equipment with ‘Connectivity Standards’(POCT 01-2A[3]) which will allow automatic storage and

ultimate transmission of operator identity and QA results to the laboratory QA systems and patient results to the electronic patient record.

5.1.7 Standard operating procedures must be available to the responsible officer, or another individual that officer designates (e.g. the trainer*),* and all employees involved with the use of the equipment as part of the training/accreditation procedure.

5.2 Medico-legal Considerations

5.2.1 The Professions Supplementary to Medicine Act 1960 requires Biomedical Scientists to be properly educated, qualified and trained in order to protect patients. This underlying principle should apply to all employees performing clinical point of care testing.

5.2.2 The certified operator and the clinical unit are responsible for using any clinical POCT equipment properly.

5.2.3 For medico-legal reasons, adequate and appropriate data must be recorded to ensure that the chronological relationship between test results, quality control results, device status and training is retained. The data must be recorded either in a logbook or electronically on the instrument/remote computer.

5.2.4 The providers of a Pathology service from a peer review body accredited laboratory have a duty to ensure that the service is carried out within the recommended national and local quality assurance schemes. Accreditation although not mandatory is a recommended route for clinical POCT for offering enhanced patient safety.

5.3 Health and Safety

5.3.1 The following legislation applies to point of care testing sites irrespective of location or size: Health and Safety at Work Act 1974, Consumer Protection Act 1987, The Management of Health and Safety at Work Regulations 1999, Control of Substances Hazardous to Health Regulations 2002 as amended.

5.3.2 Employees performing clinical point of care testing must be aware of the microbiological hazards of the patient samples, the chemical hazards of reagents and the physical/electrical hazards of devices.

5.3.3 A process health and safety risk assessment should be carried out before devices are commissioned. The infection control team/and or medical microbiologist need to be involved in decisions on the placement and safe maintenance of devices.

5.3.4 Trust policies on spillages and leaks of samples as well as safe disposal of biological materials must be followed. Standard operating procedures must outline routine decontamination and handover practice for devices before the servicing and/or repair of equipment.

5.3.5 Equipment should be sited to prevent unauthorized use and ensure that safety regulations are not contravened as well as to allow access to suitable employees for maintenance.

5.3.6 Any item of clinical point of care equipment that fails to perform to specification and cannot be easily remedied ***must*** be withdrawn immediately from service until full remedial action has been completed.

5.4 Quality Control (QC)

5.4.1 Quality control serves to verify the correctness of any patient sample tested on clinical POCT equipment. It is performed regularly, e.g. daily for some POCT devices, with material supplied by the manufacturer.

5.4.2 Quality control procedures will be device dependent, but can include either or both of the following,

- The use of material which mimics a patient's sample to check that results fall within agreed limits.
- Use of an optical or electrical test system to check performance of measurement device.

5.5 External Quality Assessment (EQA)

5.5 1 EQA involves the analysis of controlled samples received from an external source that independently check the correctness of the testing process. These can be received from the Laboratory, the manufacturer or another external body. Participation in relevant external quality assurance systems, whether run on a local or national level, should be undertaken whenever feasible and available. Organisations, such as the National External Quality Assessment Service (NEQAS), will be contacted to establish which schemes are available and relevant.

5.5.2 EQA will be distributed to the POCT site periodically by the POCT Team to whom results should be returned.

- EQA samples ***must*** be handled in a manner as similar as possible to that of a patient test sample.
- EQA results must be recorded with the date and time of analysis, device used and operator identification. The results must be reviewed by the POCT team and where necessary appropriate action taken.

5.6 Calibration

5.6.1 All calibration requirements will be outlined in relevant operating procedures for the particular item of clinical POCT equipment. Calibrations must be completed as specified, whether this is daily, monthly or every time the equipment is used by the responsible person or the individual whose responsibility it is to calibrate the equipment. The importance of calibration and meeting the required time frames must be clearly highlighted during the training of employees in the use of the equipment. The POCT Team in liaison

with manufacturers and responsible officers, will ensure that any training material makes appropriate stipulations on calibration requirements where needed. Many items of CPOCT carry out internal calibration however.

5.7 Test Results and Device

5.7.1 Results from patients and controls should be recorded with specified device performance data to enable a full audit trail.

5.7.2 If a device **log/QC book** is used, the records must include: -

- Device name and identification number
- Analytical range (if appropriate)
- Patient ID: name, hospital number (NHS number if available)
- Type of sample
- Date and time of sample test
- The result obtained
- The name of the operator
- Calibration details (if appropriate)
- Quality control results
- Batch number of reagents/cartridges (date of batch number changes), if appropriate

5.7.3 Bar codes are the preferred route for data entry.

5.8 Interpretation of Results

5.8.1 The following regulatory requirements will be met by locally generated procedures.

a) actions to be taken following the diagnostic test results including timescales.

When a clinical test result from a clinical POCT analyser has been produced the user will ensure that the POCT test has been processed and resulted appropriately and that the result is within expected values (normal results). All normal clinical results will be dealt with as specified in local procedures with a hard copy of results saved in the patient notes as well as updating the clinical team where clinical teams use such results for routine patient monitoring, such as a drug dosing.
When an abnormal result (one that is outside of expected values) is obtained from a correctly working device then this will be communicated to the patient's clinician/clinical team as soon as possible. The only exception to this is where protocols clearly state a duplicate test is done before clinical team update.
In some situations a separate sample must be sent to the main laboratory for confirmation before treatment is initiated, e.g., insulin for an unexpected high glucose, where an incorrect result potentially carries a significant risk of mistreatment to the patient. This will be clearly defined in local procedures.

b) process for recording who is informed of the diagnostic test.

The process of reporting will be agreed by clinical employees and declared in operating procedures. In all events clinical test results will be accessible to the clinical teams supervising/treating the patient. The accuracy and acceptability of all conveyed information will be the subject of regular quarterly compliance auditing by device users.

c) process for recording actions.

The process for recording actions will be declared in operating procedures, which will importantly direct the clinical POCT user to those forms/analyser outputs to be filled in or saved and their location. Hard copies of results will also be held in patient notes. Compliance with recording actions will be the duty of the responsible person for the designated area in liaison with the POCT Team. Only official methods of recording results will be permitted.

The process for monitoring compliance with the above will be covered in the activities outlined in section 7 'Monitoring Arrangements'.

5.8.2 It is therefore important the following are met;

- Performance limits and clinical limitations must be established and documented in operating procedures.
- Advice should be available regarding abnormal results and referral guidelines.
- Criteria for referring results or enquiries and the procedure for seeking expert or analytical advice should be agreed in advance of the use of the device.

5.8.3 If quality control results fall outside of the documented allowable limits advice must be sought and corrective action taken in accordance with accepted processes **prior** to undertaking any patient analyses.

5.9 Documentation

5.9.1 Prior to use of the POCT device for clinical analysis a detailed standard operating procedure must be produced in agreement with the relevant laboratory or other support department covering the items below. A copy must be kept near the device for ease of access. Patient data from clinical POCT equipment may be kept as a manual record and/or on an electronic database that may or may not be linked to other Trust databases. In some cases recording results in a patient's notes or record chart may be appropriate. Compliance with the requirements of the Data Protection Act 1998 is mandatory.

- the operating procedure
- training and competency records
- health and safety
- responsibilities for use and IT security
- maintenance
- error logging and cascade of issues

- advice on quality control or action to take if quality assurance checks fail and advice on clinical actions to be taken with particular levels of results.
- contra-indications and limitations of the device and technique.
- procedure required to perform routine maintenance, decontamination and how to deal safely with spillages and accidents.
- the safe disposal of biological materials.
- a list or reference to a part of a document where error messages and basic troubleshooting are identified in case of instrument malfunction.
- procedure for obtaining consumables including reagents, controls, calibrators, batteries etc.
- the procedure for advice and guidance if a problem is unresolved (contact telephone numbers must be included)
- a statement of who is responsible for removing a device from service if it is not being used properly or it is not performing satisfactorily
- alternative arrangements for analysis in the case of device failure.

5.10 Maintenance Procedures

5.10.1 No analytical system is error free and in order to operate at maximal levels of accuracy, precision and reliability equipment must be maintained to the minimum standards specified by the manufacturer. This will include regular maintenance together with periodic full maintenance by the manufacturer. The maintenance regime must be documented in the standard operating procedure and must be adhered to at all times. A logbook should be kept containing full documentation of maintenance, breakdowns, breakdown repair (of the equipment) or other difficulties experienced during its use.

5.11 Audit

5.11.1 Periodic checks or audits must be carried out to examine:

- Quality control performance including calibration requirements
- Patient result record quality and retention
- Training record
- Device maintenance record
- Review of continual suitability of assay at the Point of Care

Additionally, a useful item of audit activity will be;

- A review of POCT inventory management, devices removed and added during the year.

5.11.2 For simplicity a schedule for auditing is advisable (produced in liaison with the POCT Team) for the user to follow. Once produced all attempts should be made to stick to the schedule.

5.12 Accreditation

5.12.1 Where appropriate clinical POCT equipment will be considered for accreditation to an appropriate peer review accrediting body such as the United Kingdom Accreditation Service (UKAS). Clinical POCT equipment must also be operated in line with the ISO standard, BS EN ISO 22870: 2006, Point-of-care testing (POCT) – Requirements for quality and competence.

5.13 Adverse Incidents

5.13.1 Adverse incidents with the use of equipment may only occur in specific circumstances that are not generally known to the user or even the manufacturer. Such previously unreported incidents must be reported to the Trust via the DATIX System. For clinical POCT devices a member of the POCT Team must be informed.

5.14 Governance Arrangements

5.14.1 Governance is best fulfilled with a multidisciplinary group including senior managers, members of the laboratory, clinicians, nursing staff, pharmacists, diabetes specialist nurses, medical electronic engineers and others who will co-ordinate POCT activities locally nominally named the Medical Equipment Management Group (MEMG).

5.14.2 The MEMG may raise appropriate issues on planned procurement with other committees or ask the proposer to contact these in order to clarify aspects of the proposal. These may include the Medical Devices Group and Safety and Quality and Committees. The MEMG includes a range of individuals and departments who may assist in assessing proposals, including for example, Supplies, Medical Devices Training Officer, Infection Control, the appropriate Pathology discipline, Pharmacy. Should a procurement proposal be acceptable to the Medical Equipment Management Group (which includes a supplies department representative) will ensure compliance with Trust procurement procedures.

5.14.3 The role of the MEMG is described below. The full terms of reference of the committee are given in appendix 3. Appendix 1 includes a flow chart of the procedure for raising a POCT proposal or other concerns.

5.14.4 The POCT roles of the MEMG are,

- To determine if clinical POCT is justified at a particular location. This will include a clear demonstration of clinical effectiveness.
- To ensure that no clinical POCT device is used in the hospital unless it has gained the approval of the MEMG.
- To ensure the presence of a responsible person (or a link nurse) at ward level.
- To include representatives from primary care and the community where necessary.

- To ensure that users are trained and certified in the use of clinical POCT devices and that they are fully aware of all contraindications and limitations.
- To sanction the removal or removal from service of any clinical POCT equipment that has been found to be operating unsafely to ensure the continued protection of patients.

6. Training Implications

6.1 Requirements

6.1.1 The success of clinical point of care testing regimes depends on the effectiveness of the training of employees. All employees involved in clinical POCT ***must*** be formally trained to the correct level for the application of a particular technique they will use. This will include (as appropriate);

- blood sampling and its associated hazards
- the importance of clinical contraindications
- sample handling data recording
- stability of sample and reagents
- calibration of equipment
- quality control
- limitations of the technique
- interferants, such as drugs and contaminants
- decontamination and troubleshooting procedures, including guidance from the laboratory
- patient preparation (is an important factor to be considered).
- incident and error reporting
- security of information and IT awareness

All training given will comply with the general provisions of section 2.2(c) of the Health and Safety at Work Act 1974 and the specific requirements of Regulations 8 and 11 of the Management of Health and Safety at Work Regulations 1999.

6.1.2 Training must be applied consistently across the Trust. Providing the content and procedures for the training is agreed, suitable mechanisms may include training by the clinical laboratory, training by others with expertise, cascade training or training support by clinical POCT suppliers.

6.1.3 In some cases training prior to appointment within the Trust may be taken into account. However, in that case there also must be an agreed, possibly shorter, training session to orientate employees to practices within the Trust (e.g. local procedures for supplies, quality control, maintenance, etc.)

6.1.4 A system of re-accreditation of employees at agreed intervals by demonstration of continued competence must be instigated.

7. Monitoring Arrangements

This policy will be monitored for effectiveness by the MEMG. The following reports and assessments will be produced for the MEMG by the POCT Coordinators/Team.

Measureable Policy Objective	Progress Report	Frequency	Responsibility for Performing	Where is monitoring reported and which groups/committees will be responsible for progressing and reviewing action plans
Report on Functioning of Clinical POCT In BSUH	Report	Yearly	POCT Coordinator	MEMG Chair
Correct Procurement of Clinical POCT Equipment	Review at POCT Meeting	Quarterly	POCT Coordinator	Recorded in POCT Team Minutes
Training of Employees	Review at POCT Meeting	Quarterly	Suppliers/ Responsible Officer/POCT Team	Recorded in POCT Team Minutes
Full Compliance with SOPs	Review at POCT Meeting	Quarterly	POCT Users	Recorded in POCT Team Minutes
Full Compliance With IT Security Requirements for POCT Equipment	Review at POCT Meeting	Quarterly	POCT Users	Recorded in POCT Team Minutes
Review of Calibration Maintenance and Quality Control Practices	Review at POCT Meeting	Quarterly	POCT Coordinator	Recorded in POCT Team Minutes
Error logging, proper root cause analysis and corrective action	Review at POCT Meeting	Quarterly	POCT Team and POCT Users	Recorded in POCT Team Minutes
Review of POCT Inventory Management	Review at POCT Meeting	Quarterly	POCT Coordinator	Recorded in POCT Team Minutes

8. Due Regard Assessment Screening

As an NHS organisation, BSUH is under a statutory duty to set out arrangements to assess and consult on whether their complaint policy and function impact on equality with regard to race, ethnic origin, nationality, gender, culture, religion or belief, sexual orientation, age, disability. A review of the assessed impact of this policy against these criteria can be seen in Appendix 4.

9. Links to Other Trust Policies

The following policies are linked to this policy.

Policy and Procedure for the Correct Identification of all Patients:
Policy for the Quality Assessment of Blood Gas Analysers:
Privacy and Dignity Policy:
Management of Screening and Diagnostic Testing Procedures Policy
Safeguarding Children and Young People Supervision Policy
Policy for Caring for Adult Patients with a Learning Disability in the Acute Hospital:
Venepuncture in Adults:
HIV Testing Policy for Adult Patients:
Chaperone Policy for Children and Young People:
Sepsis: recognition, diagnosis and early management Policy:
Sepsis: recognition, diagnosis and early management Policy:
Health and Safety Policy and Statement of Intent:
Fire Safety Policy:
Control of Substances Hazardous to Health:
First Aid Policy:
Personal Protective Equipment Policy:
Safety Alerts and the Reporting of Medical and Non-Medical Equipment Related Incidents Policy:
Waste Management Policy:
Portable Appliance Testing (PAT) Policy and code of practices:
Managing Medical Devices Policy and Procedures:
Policy for Sharps Injuries and Body Fluid Contamination:
Policy for undertaking and learning from Clinical Audit:
Policy for the dissemination and implementation of NICE guidance:
Policy and Procedure for the Reporting and Investigating of Incidents (including Duty of Candour:
Policy for the Development and Management of Trust Policies:

10. Associated Documentation

Terms of reference for the Medical Equipment Management Group

11. References

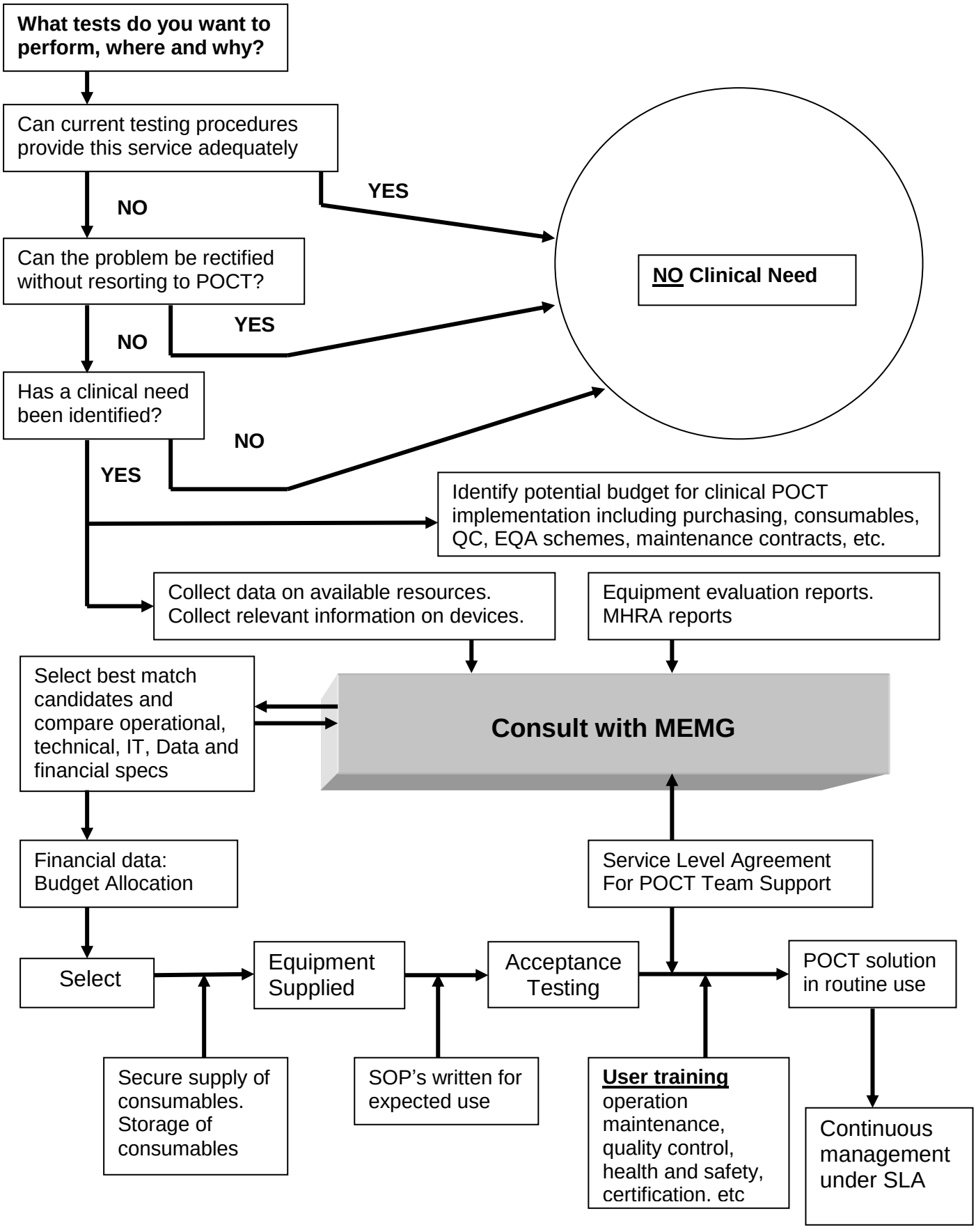
1 '*Essential considerations in the provision of near-patient testing facilities'*.

Marks V. Ann. Clin. Biochem. 1988; 25 : 220-225

2 '*Management and use of IVD point of care test devices'*, December 2013, www.MHRA.org.uk.

3 '*Point of Care Connectivity, Approved Standard'* Wayne, PA: -2nd Edition, CLSI Document POCT 01-A2, Clinical and Laboratory Standards Institute, July 2006

Appendix 1 - Clinical POCT Equipment Purchase – Procurement and Justification



Appendix 2 - Application for Acquisition and Implementation of Clinical POCT Equipment

To be submitted to the Medical Equipment Management Groupfor consideration at next review meeting.

Item To Define	RESPONSE
Request from (Clinical unit /Hospital)?	
Type of Clinical POCT device required?	
Manufacturer(s)/Supplier(s) for consideration	
What is to be measured?	
Proposed location of device?	
Who will use the device?	
European Tender? (Y/N)	
A full business case, cost benefit analysis and laboratory evaluation in support of this proposal is attached? Y/N	(The proposal is submitted under the terms and conditions of the Trust clinical POCT policy).
Clinical Unit Manager:	Name: Signature:
General Manager:	Name: Signature:

Please ensure full discussion with relevant departments before submission.

Appendix 3 - Terms of References (ToR) for the Medical Equipment Management Group (MEMG)

The ToR for the POCT team are those of the Medical Equipment Management Group (MEMG) and the POCT team representative (POCT Coordinator) or deputy shall report issue and problems into this group.

MEMG ToR as follows:

Purpose The purpose of the group is to ensure that there are clear lines of accountability for the management of medical devices throughout the Trust. The Medical Equipment Management Group will supervise device management and standardisation across the Trust. It is the responsibility of the group to prioritise the Capital Replacement Programme within designated funding. To advise on the appropriateness of medical device trials in the Trust (please see Medical Device, Medical Equipment and Product Trials Policy) and work with Clinicians and Procurement to develop specifications for purchase.

Membership

Medical Consultant- (Chair)
EBME Manager (Deputy Chair)
Head of Risk Management
Sterile Sevices Manager
POCT Coordinator
Finance Services
Procurement Business Commercial Manager
Clinical Procurement Manager
Materials Management Manager
TBMU Technical Consultant
Medical Director
(11 members)

Quorum
Membership of 5

Deputies
Deputies required for all members.

Key Outputs

- Assurance
- Managed
- Achievement
- See Appendix A for details

Time, Frequency & Duration
Quarterly – 2 hours e.g. 10:00 – 12:00

Support Arrangements

Venue:	AEB
Secretary:	Materials Management Manager
Agenda	Set by MHRA and Medical Devices Regulation 2002
Papers:	Circulated 7 days prior to meeting

Linkages to other meetings & groups

Governance, rules and behaviours (STANDARD)

- Decision maker – meeting Chairman
- All members are expected to attend – absenteeism is an exception other than during authorised leave
- Meetings will start and end on time
- Papers to conform to Trust guidance on Board and Committee papers.
- All mobiles must be switched off unless expressly agreed by the Chair
- Authority to cancel meeting: Chair

Standing agenda

1. Introduction and Apologies for Absence
2. Declarations of Interest
3. Minutes of Previous Meeting
4. Matters Arising from previous meeting
5. Meeting Quorate
6. Capital Investment Programme
7. Point of Care Testing update
8. Clinical Incident report and MHRA review
9. Medical Device training update
10. Any other Business
11. Date of Next Meeting

Appendix A – Key Outputs:

- To review and prioritise the Capital Replacement Programme and monitor progress.
- To prepare and monitor the Medical Equipment Management policy
- To facilitate standardization of Medical Devices in the Trust.
- To make recommendations on a formal training policy and receive reports of training that has taken place
- To regularly review all entries on the Trust risk register that relate to issues with medical devices
- To monitor serious adverse incidents, implement action to prevent recurrence and promote continual improvements.

Sub-groups

The committee may appoint sub-committees and working groups consisting wholly or partly of members of the committee as appropriate. They shall have clear terms of reference and report their proceedings to the committee.

Appendix 4 – Due Regard Assessment Tool

To be completed and attached to any policy when submitted to the appropriate committee for consideration and approval.

		Y/N	Comments
1.	**Does the document/guidance effect one group less or more favourably than another on the basis of:**		
	Age	N	
	Disability	N	
	Gender	N	
	Gender identity	N	
	Marriage and civil partnership	N	
	Pregnancy and maternity	N	
	Race	N	
	Religion or belief	N	
	Sexual orientation, including lesbian, gay and bisexual people	N	
2.	**Is there any evidence that some groups are effected differently and what is/are the evidence source(s)?**	No	
3.	**If you have identified potential discrimination, are her any exceptions valid, legal and/or justifiable?**	N/A	
4.	**Is the impact of the document/guidance likely to be negative?**	N	
5.	**If so, can the impact be avoided?**	N/A	
6.	**What alternative is there to achieving the document/guidance without impact?**	N/A	
7.	**Can we reduce the impact by taking different action and, if not, what, if any, are the reasons why the policy should continue in its current form?**	N/A	
8.	**Has the policy/guidance been assessed in terms of Human Rights to ensure service users, carers and employees are treated in line with the FREDA principles (fairness, respect, equality, dignity and autonomy)?**	N/A	

If you have identified a potential discriminatory impact of this policy, please refer it to the Pathology Quality Manager, X3678, together with any suggestions as to the action required to avoid/reduce this impact.
For advice in respect of answering the above questions, please contact the POCT Coordinator, Pathology, X4109.

Appendix 5 – Helpful Checklists for Device Acquisition.

Check Lists					
Device?	**Y/N**	**Installation of New Device?**	**Y/N**	**Training?**	**Y/N**
Evaluation of proposed device:		**Device:**		**Device:**	
Instrument description:		**Clinical Unit:**		**Designated trainer:**	
dimensions:		**Unit manager:**		**Training manual:**	
accessories:		**Link nurse (Responsible Person):**		**SOP:**	
reagents:		**Trainer:**		Pre-analytical considerations/sample collection	
Calibration:		**Location of device:**		Contraindications	
Operation:		**Health & Safety risk assessment completed/ Infection Control inspection?**		Reagent/sample stability	
QC:		**Log book:**		Operational procedures	
Patient samples:		**QC record book:**		Limitations of assay	
Data handling:		**Register of users:**		Performance characteristics	
Method comparison:		**Operating procedures:**		Maintenance	
Reagent batch comparison:		**Service Level Agreement:**		Reference ranges	
Imprecision:		**Device:**		Health & Safety/Hazard notices	
Interferences:				Decontamination/cleaning procedures	
Sample volume:				QC/EQA	
Operator dependency:				Recording data/data protection	
Health & Safety implications:				Clinical significance of results/responsibilities/confirmatory testing	
Costs:				**Requisition/supplies:**	
Conclusions:				**Contact names/numbers:**	
Purchase:				**Certified user list:**	
				Arrangements for cascade/update training:	
				Equality and Diversity Impact Training:	