MANAGEMENT OF POINT OF CARE TESTING (POCT) DEVICES POLICY

Version 2.0
February 2010
<table>
<thead>
<tr>
<th><strong>Policy Checklist</strong></th>
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<tbody>
<tr>
<td><strong>Name of Policy:</strong> Management of Point of Care Testing Devices</td>
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<tr>
<td><strong>Purpose of Policy:</strong> To manage POCT effectively and limit risk associated with its use.</td>
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<tr>
<td><strong>Directorate responsible for Policy:</strong> Acute Services Directorate</td>
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<tr>
<td><strong>Name &amp; Title of Author:</strong> Dr Peter Sharpe Consultant Chemical Pathologist, Chairperson POCT Committee Dr Derek McKillop, Principal Clinical Scientist, POCT Co-ordinator.</td>
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<tr>
<td><strong>Does this meet criteria of a Policy?</strong> Yes</td>
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<td><strong>Staff side consultation?</strong> Yes</td>
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<tr>
<td><strong>Equality Screened by:</strong> POCT committee members</td>
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<tr>
<td><strong>Date Policy submitted to Policy Scrutiny Committee</strong> 1st March 2010</td>
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<tr>
<td><strong>Members of Policy Scrutiny Committee in attendance:</strong> Kieran Donaghy, Stephen McNally, Siobhan Hanna, John Graham, Dawn Connolly, Danny McKevitt, Vivienne Toal.</td>
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<tr>
<td><strong>Policy Approved/Rejected/Amended</strong> Implementation Plan requested; Sent and full policy approved by Scrutiny Committee on 14/6/10</td>
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<tr>
<td><strong>Communication Plan required?</strong> The POCT Policy will be communicated to all Trust Staff through</td>
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<tr>
<td>(a) The Staff Newsletters – Up2date and Staff Ebriefing</td>
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<td>(b) POCT device specific training</td>
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<td>(c) POCT web site</td>
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<td>(d) POCT application process</td>
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<td><strong>Training Plan required?</strong> As stated on the POCT training SOP, All Staff involved in POCT will be provided device training that will include an overview of the Trust POCT policy and how to locate the policy and other relevant documentation. Training provision will be advertised by Global email, POCT web site and through Staff Newsletters – Up2date and Ebriefing.</td>
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<tr>
<td><strong>Implementation Plan required?</strong> Coordinated by the POCT committee</td>
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<td><strong>Any other comments:</strong></td>
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<td><strong>Date presented to SMT</strong> 23/06/10</td>
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<td><strong>Director Responsible</strong> Dr Gillian Rankin</td>
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<tr>
<td><strong>SMT Approved/Rejected/Amended</strong> Approved</td>
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<tr>
<td><strong>SMT Comments</strong> Additional comment added to 6.1.1</td>
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<tr>
<td><strong>Date returned to Directorate Lead for implementation (Board Secretary)</strong></td>
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<tr>
<td><strong>Date received by Office Manager (HQ) for database/Intranet</strong></td>
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<tr>
<td><strong>Date for further review</strong> 2 year default</td>
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| **Title** | Management of Point of Care Testing devices  
Version: 2.0  
Reference number/document name: |
|---|---|
| **Supersedes** | Supersedes:  
Description of Amendments(s)/Previous Policy or Version:  
Legacy Trust policies related to the management of Point of Care Testing devices |
| **Originator** | Dr Peter Sharpe Consultant Chemical Pathologist, Chairperson POCT Committee  
Dr Derek McKillop, Principal Clinical Scientist, POCT Co-ordinator. |
| **Policy Scrutiny Committee & SMT approval** | Referred for approval by:  
Date of Referral:  
Policy Scrutiny Committee Approval (Date)  
SMT approval (Date) |
| **Circulation** | Issue Date:  
Circulated By:  
Issued To: As per circulation List (details below) |
| **Review** | Review Date:  
Responsibility of (Name): Dr Peter Sharpe  
Title: Consultant Chemical Pathologist, Chairperson POCT Committee |

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1.0 Introduction

1.1 The appropriate use of POCT as an alternative to central laboratory testing should be considered as a clinical governance\(^1,2\) issue and therefore be subject to examination of clinical effectiveness. Where possible, analytical investigations should be performed in clinical laboratories or other suitable environments by suitably trained and registered laboratory staff\(^3\). Before deciding whether to implement POCT it is essential for potential users to establish a clinical need, including an examination as to whether reconfiguration of a central laboratory service would be a viable option. The clinical need should be evidence based clearly identifying the risks and benefits of introducing a POCT service.

1.2 This document specifically applies to the use of POCT in secondary care and community services. General practitioners, pharmacists and other primary sector users are recommended to adopt the practices outlined in this policy and referenced guidelines, including close liaison with the relevant Pathology Department. This approach facilitates the production of ‘quality’ results and appropriate management of the many associated risks.

2.0 Definitions

2.1 Point of Care Testing\(^4\) (POCT) refers to analytical tests undertaken by non-laboratory staff outside a recognised diagnostic laboratory. These range from disposable hand-held strip readers to desktop analysers.

3.0 Purpose and Aims

3.1 To manage POCT effectively and limit the risks associated with its use.

4.0 Policy Statement

4.1 The Trust promotes an open and positive approach to Point of Care Testing devices and management.

4.2 An effective quality management system must be set up to ensure that POCT is carried out according to applicable National and International guidelines\(^4-11\) Clinical Pathology Accreditation (UK) Ltd (CPA) standards\(^12-13\) and Health & Safety policies\(^14-16\).

4.3 The Trust management of POCT should be assessed as part of the Pathology accreditation process as carried out by Clinical Pathology Accreditation (UK) Ltd (CPA).

4.4 A multidisciplinary POCT Committee must be formed within the Southern Health and Social Care Trust with representatives from the laboratory disciplines holding key positions. This committee should have the authority to regulate and oversee the POCT quality management system.
The Trust Committee should consist of representatives from the main POCT users and stakeholders, and should meet no fewer than 3 times a year. This committee should be positioned within the Trust’s management structure and report as such. A representative of the Trust’s committee should attend and report to any Regional POCT and Northern Ireland Pathology Network POCT meetings.

4.5 The core of any Trust’s quality management system should be based upon key personnel (with suitable protected time allocation) tasked with implementing and monitoring same (see responsibilities).

4.6 The Trust should appoint a senior laboratory professional to provide Clinical and Professional leadership of the POCT service. This individual must hold FRCPath or equivalent.

4.7 All requests for future POCT equipment must be submitted to the POCT committee for approval with details of clinical need and assessment of outcomes including costs. The POCT committee should decide on the appropriateness of any request, the reliability and robustness of the equipment available, the interfacing requirements, the risk-benefit and cost-benefit analyses, quality assessment and compliance with Trust policies including infection control\textsuperscript{15,16} and COSHH\textsuperscript{17}. Where necessary advice should be sought from the Trust’s Infection Control Team and POCT departmental leads. The Trust’s Supplies Department should not allow purchase of POCT devices without prior approval by the POCT committee. POCT devices must be procured according to the Trust’s Standing Financial Instructions.

4.8 POCT must not be considered where a laboratory can provide a result in a timely manner appropriate to clinical need.

4.9 All POCT devices adopted should:
- Be evaluated and procured in collaboration with Trust POCT committee and the POCT departmental leads of the appropriate laboratory department to ensure satisfactory standards of performance and safety and also conform to the requirements of the In Vitro Diagnostics Directive\textsuperscript{18}.
- Align with laboratory-based methods, where possible and practical, in current practice in the Trust.
- Where possible IT Connectivity should be made available and resourced to appropriate specification to allow central management of POCT devices and documentation of results in accordance with robust quality management.
- Be used in accordance with manufacturer’s or suppliers instructions.
- Be subject to regular maintenance as specified by the supplying manufacturer or supplier.
- Details of maintenance performed, faults and corrective action taken, should be documented as per CPA.
- Only be used for the purpose it has been evaluated for.
4.10 Device specific Standard Operating Procedures must be developed, implemented and made available to all POCT users.

4.11 Regular Audit of POCT must form an integral part of any quality management system.

4.12 Appropriate External Quality Assurance and Internal Quality Control programmes must be established for all POCT.

4.13 Where possible and practical, electronic devices rather than devices requiring a subjective visual read by the user should be used. (It is recommended that where such visual read devices are in use, the results are checked by at least two trained members of staff)

4.14 Only trained, certified and competent staff should use POCT equipment. Where possible such equipment should be password-protected and only accessible to trained / certified users.

4.15 All patient and quality control testing results must be recorded. Patient results must be recorded in such detail as to allow unequivocal identification of the patient, the actual result, date and time of analysis, reagent lot/expiry date and the name of the analyst. This record must be in addition to records made in the patient notes, and where available should be electronic. Such records should be kept according to guidelines issued by the RCPath

4.16 All adverse events relating to POCT must be reported back to the POCT committee which must have the authority to withdraw or suspend service in the event of a safety-related or performance issue or lack of clinical or cost effectiveness.

4.17 All staff who recommend the use of POCT systems or devices for use by patients must ensure that the devices have been approved by the Trust’s or NI Regional POCT committee.

4.18 Management arrangements between the Trust Pathology Laboratory and POCT users, outside of those stated in this document must be agreed and documented in a service level agreement

5.0 Scope of the Policy

5.1 The policy is applicable to all of Southern HSC Trust sites and staff performing POCT.

6.0 Responsibilities

6.1 All Staff involved in the provision of POCT should be aware of their individual role and responsibilities under clinical governance as outlined below.
6.1.1 Trust’s Chief Executive
The Trust’s Chief Executive as “Accountable Officer” has overall responsibility for ensuring the aims of this policy are met. The POCT Chairperson reports to the Chief Executive through the Director of Acute Services.

6.1.2 Multidisciplinary POCT Committee
The aims and objectives of the committee are
- To ensure that the Trust is compliant with national and local POCT policies
- To evaluate new applications for POCT devices.
- To regulate and oversee the POCT quality management system.

6.1.3 Point of Care Testing Chairperson:
The POCT Chairperson is responsible for coordinating the activities of the POCT committee. The POCT Chairperson is engaged to provide reports on POCT activity to the Director of Acute Services and ensure that the POCT Committee remit is performed effectively. The Chair would normally be expected to be an experienced laboratory professional.

6.1.4 Point of Care Testing Departmental Leads:
POCT Departmental Leads should be identified to provide specialist knowledge and advice to the POCT Committee, POCT staff and users of POCT devices.

6.1.5 Point of Care Testing Coordinator
The POCT Coordinator is immediately responsible for the daily coordination of POCT provision within the Trust. The Coordinator is engaged to provide the POCT chair with assurance of the proper running of the POCT quality management system.

6.1.6 Managers
All Trust Directors, Assistant Directors, Heads of Service and Managers have responsibility for the management of POCT devices and equipment within the areas of their remit and control, and for ensuring that processes are fully implemented as part of the Trust’s integrated governance requirements.

6.1.7 Clinicians
Clinicians are responsible for identifying areas of clinical need where the introduction of POCT could be appropriate and submit an application to the chairperson of the POCT committee for approval prior to procurement. They can only undertake POCT testing themselves after adequate training and certification. They need to be familiar with the information provided by the manufacturer and in local SOPs, particularly in relation to the shortcomings of the POCT results that they use for their patient management.
6.1.8 Link Nurse/ Person
Link nurses will be drawn from ward and departmental staff and will have sufficient clinical experience and standing to have authority with colleagues and managers. The POCT Link Nurse/Person is directly accountable to the Ward or Area Manager for over seeing the daily operation of defined POCT devices in a specified area. The Link Nurse/Person will liaise with the POCT co-ordinator and ensure that staff performing POCT in their area are informed and aware of the Trust policies and procedures.

6.1.9 Users
The Health and Safety at Work Act legislates that all staff are responsible for ensuring that their acts and omissions do not put themselves or others at risk. Healthcare Professionals are also bound by their Code of Ethics and Scope of Professional Practice which emphasise the individual’s responsibility when using equipment or undertaking actions that they are not trained or competent to perform. Users should therefore undertake POCT only after adequate training and certification and should familiarise themselves with and adhere to all POCT Trust policies and related procedures.

7.0 Legislative Compliance, Relevant Policies, Procedures and Guidance

7.1 All Trusts must develop, implement and enforce a policy for the control of POCT that is consistent with the Health and Safety at Work Act (1987), the Consumer Protection Act (1987), COSHH - COSHH regulations (1989) and Safe Working and the Prevention of Infections in Clinical Laboratories (1991) and ISO 22870:2006 Point of Care Testing (POCT) - Requirements for quality and competence.

8. Equality and Human Rights Considerations

8.1 This policy has been screened for equality implications as required by Section 75, Schedule 9, of the Northern Ireland Act, 1998. Equality Commission for Northern Ireland Guidance states that the purpose of screening is to identify those policies which are likely to have a significant impact on equality of opportunity so that greatest resources can be targeted at them.

8.2 Using the Equality Commission’s screening criteria, no significant equality implications have been identified. This policy will therefore not be subject to an equality impact assessment.

8.3 This policy has been considered under the terms of the Human Rights Act, 1998, and was deemed to be compatible with the European Convention Rights contained in that Act.
8.4 This policy will be included in the Trust’s register of screening documentation and maintained for inspection whilst it remains in force.

8.5 This document can be made available on request in alternative formats, e.g. Braille, disc, audio cassette and in other languages to meet the needs of those who are not fluent in English.

9.0 Sources of Advice and Further Information

9.1 Further advice and information regarding this document can be obtained from the Chair of Point of Care Testing committee.

10.0 References

11. BS EN ISO 15189:2003 Medical laboratories – Particular requirements for quality and competence.
12. Clinical Pathology Accreditation (UK) Ltd (Version 2.01 March 2009) Standards for the Medical Laboratory. CPA Ltd, Sheffield, UK. http://www.cpa-uk.co.uk/

