NHS
Somerset
Clinical Commissioning Group

SOMERSET CCG POINT OF CARE TESTING POLICY (POCT)

Version:	V1
Ratified by:	Patient Safety and Quality Assurance Committee
Date Ratified:	14 October 2015
Name of Originator/Author:	Karen Taylor
Name of Responsible Committee/Individual:	Patient Safety and Quality Assurance Committee
Date issued:	1 December 2015
Review date:	1 December 2017
Target audience:	Somerset CCG / Somerset Primary Care Providers

SOMERSET CCG POINT OF CARE TESTING POLICY

CONTENTS

SOMERSET CCG POINT OF CARE TESTING POLICY

VERSION CONTROL

Document Status:	DRAFT
Version:	0.2

DOCUMENT CHANGE HISTORY		
Version	**Date**	**Comments**
0.0	16/06/2015	Draft –Karen Taylor
0.1	23/6/2015	Comments – Lucy Watson
0.2	20 August 2015	Incorporated comments from Harry Yoxall, David James, Deborah Rigby and Shaun Green. Additional text from Karen Taylor. Appendix 1 removed.

Equality Impact Assessment (EIA) Form OR EIA Screening Form completed. Date:	

Sponsoring Director:	Lucy Watson, Director Quality, Safety & Governance
Author(s):	Karen Taylor, Head of Patient Safety & Governance, Somerset CCG
Document Reference:	Somerset CCG Point of Care Testing Policy v0.2

SOMERSET CLINICAL COMMISSIONING GROUP POINT OF CARE TESTING (PoCT) POLICY

1 INTRODUCTION

Laboratory tests can now be performed more frequently at the point of care (wards, theatres, General Practice, community hospitals, Minor Injury Units) for example using blood glucose meters, urine dipsticks, INR meters, haemoglobin meters, pregnancy testing kits and blood gas analysers.

PoCT is capable of delivering results in a timely manner that allows clinical decisions to occur quickly, potentially allowing better clinical (and/or) economic) outcome.

PoCT are subject to the same levels of governance that are applied within the traditional laboratory setting, with safety and quality needing to be ensured.

Management of a PoCT service should take due account of several important areas, including clinical governance, the Consumer Protection Act (1987) and public health considerations. Poor use of PoCT leading to the production of wrong results can lead to harm to patients and may have medicolegal implications, while under the terms of the Consumer Protection Act (1987) the use of instruments for purposes for which they are not intended will lead to liability transfer from manufacturer to user. Whilst there is a need for managerial responsibility of PoCT devices and a designated individual who will take formal charge of any PoCT programme, individual users trained and approved for PoCT will have responsibility and accountability for the results that they produce.

2 SUMMARY

Before any PoCT service is considered, the clinical need to improve outcomes for patients should be clearly identified and, where appropriate, a business case made, as set out in Section 5.

The selection of PoCT equipment should take due account of independent evaluation and have been shown to have the analytical performance required for the intended clinical use.

To meet the needs of clinical governance, Somerset CCG Patient Safety and Quality Assurance Committee will review and approve any new PoCT in any service it commissions.

Somerset CCG will involve appropriate pathology expert advice to implement new services which include PoCT.

Lines of accountability for POCT must be clear and managers of the service and the end-users must take due notice of their responsibilities through clinical governance.

Providers must ensure they have suitable governance arrangements in place to support any PoCT in use within their services.

Adherence for standard operating procedures must be followed, paying particular attention to training, management, quality assurance/control and health and safety policy, and must be reviewed at frequent specified intervals.

3 DEFINITIONS

PoCT is defined by the Medical Devices Agency in 'Management and Use of IVD Point of Care Test Devices', as 'any pathology test performed for a patient by a healthcare professional outside the traditional centralised laboratory'. Other terms commonly used to describe PoCT include:

- Near patient testing (NPT)
- Bedside testing
- Extra-laboratory testing
- Disseminated laboratory testing

For the purpose of this document, PoCT is a term that is applied to tests performed by non-laboratory staff outside an accredited diagnostic laboratory. These tests may be carried out in a wide range of non-laboratory sites.

4 SCOPE

This policy applies to Somerset CCG to support commissioning of enhanced services and the commissioned GP Primary Care service providers. Contracted providers are responsible for the clinical and quality governance in the services they provide. Where the Somerset CCG commissions new services which include the requirement of PoCT, as the commissioner Somerset CCG will support primary care providers, through the provision of model standard operating procedures. The provider remains responsible for assuring SOPs are adapted and suited to their local arrangements and appropriate clinical governance oversight.

5 MAKING A CASE FOR PoCT

The management and use of PoCT as an alternative to laboratory testing should be considered under the organisational clinical governance framework and subject to examination of clinical effectiveness. Such considerations will be achieved through all proposals for use of PoCT in new or updated

commissioned services being reviewed and approved through Somerset CCG Patient Safety and Quality Assurance Committee.

Before deciding whether to implement PoCT it is essential to:

- establish a clinical need
- consider the benefit to patients of introducing PoCT
- establish PoCT performance, usability and cost

In many cases improving the patient pathway and experience could be major considerations when introducing PoCT. As regards clinical need, this should be based on establishing that the perceived need is valid. The diagnostic or care management value of doing the test with the patient present has to exceed the associated financial, organisational, training and regulatory cost. That means efficient testing is likely to be organised into clinics rather than *ad-hoc.*

In deciding whether PoCT is suitable the following issues should be considered:

- establish the clinical need for PoCT at the site
- obtain expert advice in the selection of appropriate equipment including whether the equipment is fit for purpose
- obtain expert advice on the need for IT and connectivity software
- discuss a suitable environment for placing the equipment
- perform comparisons of the point of care analytical method with the traditional laboratory method – simple correlation is insufficient
- review technical and clinical evidence
- examine the importance of a quality assurance programme required in relation to the PoCT. Best practice guidance is participation in an external quality assurance (EQA) programme, which reports issues of poor performance to an appropriate oversight panel
- the service must perform the test often enough to enable it to maintain effective internal quality control standards
- staff performing the test must do so often enough to maintain their competency

6 SELECTION

Once a service need is accurately identified, test systems should be reviewed. A suitable test system should meet the service need using equipment that is simple and reliable, but which has the necessary accuracy and precision to deliver results that alter patient management and that are similar to those produced by the routine laboratory. The system must be able to be used by individuals within that healthcare setting who are using it on a regular basis and who are performing appropriate quality checks on their work.

Somerset CCG will convene a specialist group of advisors through The Patient Safety and Quality Assurance Committee to review and approve the inclusion of PoCT in any new or revised service it commissions. This will include a representative for the intended users of the PoCT and pathology expertise.

7 TRAINING

All users of PoCT devices must be trained in the function and use of the devices as described in the standard operating procedure (SOP), and no user should be allowed to perform tests that will alter clinical management without the trainer being satisfied with the competence of the user. As PoC tests can never be 100% sensitive and specific, they work best in conjunction with assessment of clinical signs and symptoms. Staff should be aware of the potential for false positive and false negative results, and use their clinical expertise and experience to review test validity. If they have any reservations about the test result, staff should verify the result by re-testing with a different test source.

Upon completion of the training, all users must be registered and sign that they recognise the legal responsibilities of the test that they undertake. They must adhere to an SOP, including the use of internal and external quality assurance materials as detailed in a device specific SOP. A list of trained and authorised users should be maintained with each device and updated training arranged as appropriate.

Where PoCT is being used directly by patients or their carers, they must be provided with the necessary information to properly perform and interpret the test. The application of a test result to self-management by a patient must be taught by an individual who is judged competent by assessment within a teaching programme. Educational information must be specific to a patient's assessed needs, abilities and competence.

8 STANDARD OPERATING PROCEDURE

The service must ensure the use of each PoCT is controlled through the application of a Standard Operating Procedure (SOP), which is specific to use in their service.

The SOP should cover:

- clinical background
- analytical principle
- health and safety including:
    - information on COSSH (Control of Substances Hazardous to Health)
    - safe disposal of waste
    - control of infection

    - adverse incident reporting
- pre-analytical considerations
- equipment
- reagents, standards, controls and quality assurance
- test procedure
- sample analysis
- calculation of results
- assay performance
- maintenance
- record-keeping
- incident reporting

Internal quality assurance (IQA) must be used to ensure that operators of the device and/or the tests used are performing to an acceptable standard to utilise the results for patient management. External quality assurance (EQA) of devices must be mandatory but, although there are EQA schemes available, they are not at present comprehensive enough to provide universal cover for all the devices and tests available. There are processes that can be followed in such instances.

Two important and often neglected points are maintenance and record-keeping of PoCT devices. Many desktop devices now incorporate maintenance schedules into their software, preventing use until this is undertaken, and many now require valid user identification before they produce results. All analyses must be recorded in a record book or on laboratory IT and, where it is implemented directly, into an electronic patient record.

Where Somerset CCG commissions a new or revised service which requires the use of PoCT a model SOP will be drafted and approved through the CCG Patient Safety and Quality Assurance Committee.

9 CLINICAL GOVERNANCE

To ensure robust Clinical Governance of point of care testing providers must ensure there is an identified lead for point of care testing, and each test in use. The role of these individuals will be to ensure:

• Appropriate standard operating procedures are in place
• Point of care testing operators' training is undertaken and updated
• Routine audits and/or spot checks to ensure these procedures are being followed
• Routine internal quality assurance is carried out at frequent and specified intervals
• External quality assurance is carried out at specified intervals, as appropriate
• Testing results are recorded, and are monitored, and action taken where necessary.
• Patient involvement where appropriate

- Lead should be aware of their responsibilities as outlined in MHRA guidance

References:

1. The Royal College of Pathologists, Guidelines on point-of-care testing, 11 March 2004
2. MHRA, Management and use of IVD point-of-care-test devices, December 2013