**Title:** Northern Ireland Regional Point-of-Care Testing Policy

**Author:** Northern Ireland Pathology Network Point of Care Testing Specialty Forum

**Approved by:** **Northern Ireland Pathology Network Board**

**Date of Ratification:** 20 April 2021

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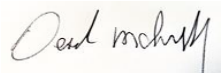
| **Date:** 21 April 2021 | **Signed:**  |

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## Document Reader Information

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|---|---|
| Title | Northern Ireland Regional Point-of-Care Testing Policy. |
| Document purpose | Harmonization across all HSC Trusts of POCT standards required to ensure good governance and safety of patients. |
| Author | Northern Ireland Pathology Network Point of Care Testing Specialty Forum. |
| Publication date | 21 April 2021 |
| Target audience | • Consultants<br>• Ward managers<br>• Governance leads |
| Circulation list | As above. |
| Description | Policy. |
| Superseded documents | Regional Policy, authored by Dr P Archbold. |
| Action required | • Disseminate this policy to the target audience.<br>• Review and, as necessary, amend your Trust procedures. |
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## Contents

## Background

Point-of-Care Testing[1] (POCT) refers to testing that is performed near or at the site of a patient (as opposed to central laboratory testing) with the result leading to possible change in the clinical management of the patient. POCT most commonly involves testing in body fluids such as blood or urine but may include other modalities such as transcutaneous measurements or the analysis of exhaled air. The types of analytical equipment employed may range from single use visual inspection testing strips, hand held strip readers to desktop analysers. POCT is generally (but not always) performed by clinical rather than laboratory staff. POCT is widely used to support the clinical management of patients.

Although POCT may bring benefits in patient care, POCT may also introduce risks that derive from the inherent characteristics of the device, operator error and in result interpretation. The use of POCT as an alternative to central laboratory testing should be considered as a clinical governance issue and therefore be subject to examination of clinical effectiveness. Before deciding whether to implement a particular point-of-care test it is essential to establish a clinical need, including an assessment as to whether reconfiguration of a central laboratory service would be a more effective option. Consideration of clinical need should be evidence based where possible and clearly identify benefits and risks of introducing a point-of-care test.

The purpose of the Policy is to ensure that POCT is effectively managed in the HSC Trust so as to maximize the clinical benefit of POCT in patient care and to limit the risks to patients and staff associated with its use. It will ensure that POCT systems in the HSC Trust is managed in accordance with national/international best practice guidelines and accreditation standards, in particular ISO 15189:2012 (Medical Laboratories - Requirements for quality and competence)[2] and ISO 22870:2016 (Point-of-Care Testing [POCT] – Requirements for quality and competence).[3]

Risk to the patient can be managed by a well-designed, fully implemented quality management system that facilitates:

- Evaluation of new or alternative POCT instruments and systems;
- Evaluation and approval of end-user proposals and protocols;
- Purchase, installation and maintenance of equipment;
- Maintenance of consumable supplies and reagents;
- Training, certification and recertification of POCT system operators; and
- Quality control and quality assurance.

This policy applies to all HSC Trust staff undertaking or having responsibility for POCT and to all Departments and Services in which POCT is undertaken.

This policy refers exclusively to POCT undertaken in a hospital or community using equipment procured by the HSC Trust and undertaken by HSC Trust staff. Patient self-testing falls out-with the scope of this policy.

## Policy

1 The POCT service should be Clinically and Professionally led by a senior member of laboratory staff (Consultant Pathologist or Consultant Clinical Scientist). The POCT Professional Lead shall plan and develop the processes needed for POCT in line with the requirements of ISO 15189; 2012 and ISO 22870:2016. These will include quality objectives and requirements for POCT; establishment of processes and documents and provide resources specific to POCT; verification, validation and monitoring of activities specific to POCT; maintain records to provide evidence that POCT processes and procedures meet requirements.

2 The POCT Professional Lead may delegate selected duties and/or responsibilities to qualified personnel. The POCT Professional Lead shall maintain the ultimate responsibility for the overall operation and administration of the POCT service, within the scope defined by the POCT Multidisciplinary committee.

3 The HSC Trust will aspire to have compliance with relevant ISO Standards [ISO 15189; 2012 and ISO 22870:2016] assessed by an external body such as United Kingdom Accreditation Service (UKAS) or other competent body.

4 The POCT Professional Lead shall have a documented reporting line to the governing body of the HSC Trust which will have responsibility for ensuring that appropriate measures are in place to monitor the accuracy and quality of POCT conducted within the organization.

5 The POCT Professional Lead shall establish, document, implement and maintain a quality management system for POCT and continually improve its effectiveness.

6 The POCT quality management system shall include a quality policy, quality manual and quality objectives,

7 The POCT Quality Manual shall outline the procedures for the audit of all aspects of POCT activity including the identification and control of non-conformities and determine corrective and preventive actions to eliminate the cause of potential non-conformities.

8 The HSC Trust will establish a multidisciplinary professional grouping which will be responsible to the governing body for defining the scope of POCT to be made available, taking into consideration the clinical need for POCT, its financial implications, technical feasibility and the ability of the organization to fulfil the need. To obtain approval from the POCT group, a **New or Replacement Point of Care Testing Proposal Form** (*Appendix 1 of this policy*) should be submitted to the multidisciplinary professional group.

9 The POCT Professional Lead will establish a multidisciplinary POCT management group to advise on the provision of POCT. The POCT management group will ensure responsibilities and authorities for POCT are defined and communicated within the HSC Trust. The management group will consider all proposals to introduce a new POC test. The management group will assist in the selection and evaluation of POCT devices.

10 The POCT Professional Lead shall implement a periodic [ideally annual] management review of the functioning of the POCT service.

11 No POC tests should be procured or introduced into clinical care without the approval of the POCT Professional Lead.

12 All requests for the introduction of POCT equipment / tests must be submitted to the POCT Professional Lead for consideration [in conjunction with the multi-disciplinary POCT management group] with details outlining the clinical need and assessment of outcomes including costs. The POCT Professional Lead in conjunction with the POCT management group will consider 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 other HSC Trust's policies including infection control[4,5] and COSHH.[6] Where necessary advice should be sought from Finance, Infection Prevention and Control and other teams as necessary. POCT devices which have been approved must be procured in line with the HSC Trust standard procurement procedures.

13 The use of POCT should not be considered where a laboratory can provide the relevant test result in a timely manner that meets the requirements of clinical efficiency and effectiveness.

14 POCT equipment and tests which have not been approved by the POCT Professional Lead must not be used.

15 Technical Requirements of the POCT service: the POCT Professional Lead shall define the technical requirements for POCT in line with ISO 15189: 2012 and ISO 22870:16 and will include:

- Personnel including staff to deliver and manage the POCT service, evaluate POCT devices / tests, training and competency assessment;
- Accommodation and environmental conditions;
- Equipment including selection criteria for the procurement of equipment, material and reagents;
- Pre-examination procedures including sample identification and traceability;
- Examination procedures including standard operating procedures for each test;

- Assuring the quality of pre-examination procedures including quality control, external quality assurance procedures;
- Post-examination procedures including sample handling and disposal; and

- The reporting of results and incorporation of the result into the patient's medical record (in a manner which distinguishes the result from those of the central laboratory), the identity of the person performing the test.

16 All POCT tests/devices procured by the HSC Trust shall:

- Be evaluated and procured in collaboration with the POCT Professional Lead;
- Align, where possible and practical, with the laboratory-based methods in current use in the HSC Trust;
- Where possible have IT connectivity of appropriate specification to allow central management of POCT devices and documentation of results and transmission of results to the patient Electronic Care Record;
- Be used in accordance with manufacturer's or supplier's instructions;
- Be subject to regular maintenance as specified by the supplying manufacturer; and
- Only be used for the purpose for which it has been evaluated and approved.

17 All POCT must be enrolled in an External Quality Assurance scheme (if available), or, if this is impractical arrangements for parallel testing with the local laboratory should be considered. Internal Quality Control must be performed according to the test / instrument specific Standard Operating Procedure (SOP).

18 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).

19 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.

20 Device specific Standard Operating Procedures (SOP) must be developed, implemented and made available to all POCT users. SOPs will include pre-examination procedures, examination procedures and post examination procedures. The SOP will outline relevant internal and external quality control procedures.

21 Only staff that have been trained and assessed as competent can use POCT equipment. Training in the use of POCT devices will only be

delivered by staff who have been approved to do so by the POCT Professional Lead. Where possible POCT equipment will be passcode-protected and only accessible to certified users. Sharing of passcode in breach of this policy may result in disciplinary action.

22 Retraining and recertification intervals will be established by the POCT Professional Lead.

23 All patient and quality control testing results must be recorded. The procedure for this shall be outlined in the relevant SOP. Patient results must be recorded in such detail as to allow unequivocal patient identification, the result, date and time of analysis and the name of the person performing the test. This record must be in addition to records made in the patient notes, and where available should be electronic. Such records should be retained in accordance with guidelines issued by the RCPath.[7]

24 All reagent/cartridge/consumable lot numbers must be recorded to facilitate patient tracking in the event of product recall. Storage conditions must be adhered to. These procedures shall be outlined in the relevant SOP.

25 All adverse events relating to POCT must be reported according to the HSC Trust's Incident Reporting Procedures policy and drawn to the attention of the POCT Professional Lead [by the relevant ward manager] as soon as possible. There should be a low threshold for reporting suspected incidents – IF IN DOUBT – REPORT. The POCT Professional Lead has the authority to withdraw or suspend a POCT service in the event of a safety-related or performance issue or lack of clinical or cost effectiveness. The POCT Professional Lead shall be responsible for ensuring that any relevant learning opportunities are shared in a timely manner with the NI POCT Specialty Forum members and where necessary reported to NIAC (MHRA).

27 The POCT Professional Lead has the authority to suspend the certification of a POCT operator in event of failure of the operator to adhere to required operating procedures.

## Staff who should have knowledge of this Policy

The following staff should observe this policy and follow its procedures:

- Any member of staff who performs POCT;
- Any member of staff with managerial responsibility for POCT within his/her clinical service; and
- Any member of staff wishing to introduce POCT into a clinical service.

## References

1 Price CP, St John A Hicks JM. Point of care testing Washington DC: AACC Press, 2ndedition 2004

2 British Standard EN ISO 15189:2012 (Medical Laboratories - Requirements for quality and competence)
The British Standards Institution 2012; BSI Standards Ltd 2012

3 British Standard ISO 22870:2016 (Point-of-Care Testing [POCT] – Requirements for quality and competence).
The British Standards Institution 2012; BSI Standards Ltd 2012
.

4 Department of Health Advisory Committee on Dangerous Pathogens (2003) Infection at work controlling the risk. Department of Health, London

5 Health Services Advisory Committee (2003) Safe working and the prevention of infection in clinical laboratories and similar facilities. Health and Safety Executive, HSE Books, Sudbury.

6 Health and Safety Executive, Control of Substances Hazardous to Health (COSHH) 2002

7 Royal College of Pathologists and Institute of Biomedical Science. The Retention and Storage of Pathological Records and Archives, 4th edition (2009).

8 MHRA. Management and use of IVD point of care test devices, V1.2 (2021)

## Appendix 1: New or Replacement Point of Care Testing Proposal Form

### Introduction

The Trust policy for the management of POCT describes the principles of how the Trust will discharge its responsibilities with regard to the governance of POCT. One important aspect of this is the role of the POCT committee in assessing new and existing POCT applications within the Trust.

### Scope and purpose

This checklist is intended to prompt consideration of the various elements required for a new or replacement POCT application in order that the POCT committee can assess compliance with Trust policy and relevant guidelines. The information supplied should be supported by additional literature from peer reviewed publications and suppliers.

**It is recommended that Trust policy and referenced guidelines on POCT are reviewed and appropriate laboratory specialists are consulted in completing this pro forma.**

### 1. Baseline Information:

Proposed location of testing:

Directorate _____

Department _____

Contact Name _____

Proposed analyte(s)/test(s)

| |
|---|
| |

Purpose of test:
Diagnosis
Screening
Monitoring (disease or treatment)

| |
|---|
| |

Specimen requirements (circle or Bold)

| Whole Blood | | | Serum | Plasma | Urine |
|---|---|---|---|---|---|
| Capillary | Venus | Arterial | | | |
| If other provide details | | | | | |

Estimated test numbers: Daily ____ Weekly ____

Has a business case for capital and revenue costs been approved? What cost centre will be used? YES/NO

____

Do you have the resources to release staff for initial set up, implementation, daily QC, daily maintenance, EQA, regular training, cascade training, SAI investigation reagent stock control, record control, maintenance if training records, infection control and POCT Link Nurses duties? YES/NO

Do you have the resources to release staff to assist the POCT/Governance teams with Audit, quality assurance, quality improvement and trouble shooting YES/NO

**2. Clinical Benefits:**

What clinical benefits will this POCT proposal provide and what impact will it have on the clinical Pathway?

| |
| --- |
| |

Can you please provide evidence from trials to support claimed clinical and economic benefits? *Please attach*. YES/NO/NA

For which group of patients will this POCT proposal be used?

| |
| --- |
| |

Is this investigation currently provided by a different mechanism? If so how?

| |
| --- |
| |

Please state the limitations of current provision and what alternatives to POCT have been considered to try and rectify the problem?

| |
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| |

**3. Laboratory Evaluation**

Has there been a laboratory evaluation conducted on the proposed POCT test? Please provide either Laboratory or manufacturer's data.

| |
| --- |
| |

Please list the limitations highlighted by the manufacture.

| |
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| |

**4. Accommodation/Services**

| Candidate Instruments (circle) | Portable | Static | Device foot print | | Height | |
|---|---|---|---|---|---|---|

| Operator space required (circle) | Standing | Seated | PC workstation |
|---|---|---|---|

Do you have adequate storage space at the required temperature (room temperature or refrigerated) for reagents/calibrants/ QC material? YES/NO

Is the identified storage space temperature monitored? Room Temperature YES/NO
Refrigerated YES/NO

| Do you require estate installations? (power, IT port, water, refrigeration, computer): | |
|---|---|
| Are there any Health and safety issues to be addressed? | |
| Are there any control of infection issues to be addressed? | |
| Is there a service/maintenance contract in place? | |

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| Who will provide the training and competency assessment of users? | |
| Who will undertake the audit of the service and how frequently? | |
| How will Internal Quality control (IQC) be performed? | |
| Which External Quality Assurance (EQA) Scheme will you subscribe with? | |

| | | |
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| How will POCT data be recorded | Manual | Electronic |
| Is there a driver for connection to the Trust's POCT Data management system? | YES/NO | |
| Will result be transmitted to the electronic patient record? | YES/NO | |

**5. Finance**

Please complete the costing table below to ensure that the equipment takes into account the whole life costs (*life time usually 5year or expiration of regional contract*) –please note that not all of the considerations outlined below will be applicable:

| Procurement model | Regional Contract | NHS Supply Chain | Direct Award Contract | Loan/Trial |
|---|---|---|---|---|

| | |
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| Initial cost of purchasing the equipment (rental- multiply annual cost by 5): | £ |
| Ancillary Equipment (centrifuges, special collection kits etc): | £ |

Break down of consumable costs for quantity of equipment identified:

| | |
|---|---|
| | £ |
| | £ |
| | £ |
| | £ |
| | £ |

| | | |
|---|---|---|
| Total IT costs ( software, interfacing maintenance, patching etc): | £ | capital |
| | £ | annual |
| Total estate costs ( shelfing, power points, water supply, IT ports etc): | £ | |

| | |
|---|---|
| Additional Staff costs (consider resource required for training and testing): | £ |
| Decontamination costs: | £ |
| Internal Quality control costs: | £ |
| External Quality Assurance costs: | £ |
| Maintenance/Service contract costs: | £ |
| Waste Disposal costs: | £ |
| Total 5 year Cost: | £ |

## 6. References

| |
|---|
| |

Signature of Proposer _____ Date _____

Signature of Clinical Director (if different) _____ Date _____

Signature of Ward Manager _____ Date _____

Signature of Assistant Director _____ Date _____

**Please return to Chairperson POCT Committee, Laboratories**

**Appendix 2: Equality, Good Relations and Human Rights Screening**

Health and Social Care Board

# Equality, Good Relations and Human Rights SCREENING

The Health and Social Care Board is required to consider the likely equality implications of any policies or decisions. In particular it is asked to consider:

1) What is the likely impact on equality of opportunity for those affected by this policy, for each of the section 75 equality categories? (minor, major or none)

2) Are there opportunities to better promote equality of opportunity for people within the Section 75 equality categories?

3) To what extent is the policy likely to impact on good relations between people of a different religious belief, political opinion or racial group? (minor, major or none)

4) Are there opportunities to better promote good relations between people of a different religious belief, political opinion or racial group?

See Guidance Notes for further information on the 'why' 'what' 'when', and 'who' in relation to screening, for background information on the relevant legislation and for help in answering the questions on this template.

As part of the audit trail documentation needs to be made available for all policies and decisions examined for equality and human rights implications. The screening template is a pro forma to document consideration of each screening question.

**For information (evidence, data, research etc) on the Section 75 equality groups see the Equality and Human Rights Information Bank on the BSO website**: http://www.hscbusiness.hscni.net/services/1798.htm

Health and Social Care Board

# Equality, Good Relations and Human Rights
# SCREENING TEMPLATE

## (1) INFORMATION ABOUT THE POLICY OR DECISION

### 1.1 Title of policy or decision

The Northern Ireland Regional Point-of-Care Testing (POCT) Policy

### 1.2 Description of policy or decision

***Introduction***

In January 2019, the NI Pathology Network Board agreed that all HSC Organisations will adopt and implement new regional policies and procedures approved by the Network Board. This decision is in line with the Department of Health (DoH) policy on Pathology Transformation and approved by all HSC Trust Chief Executives.

The policy set out in this document also represents the strategic direction of travel for Pathology Services as a whole across Northern Ireland. A programme of regionalisation is currently underway, with numerous regional policies which may require equality screening. As part of this programme, the POCT Specialty Forum (which is a formal group of subject matter experts established by the NI Pathology Network) has identified the need for a regional POCT policy.

The policy has been drawn up and reviewed in light of the statutory obligations contained within Section 75 of the Northern Ireland Act (1998). In line with the statutory duty of equality, this policy has been screened against particular criteria. If at any stage of the life of the policy there are any issues within the policy which are perceived by any party as creating adverse impacts on any of the groups under Section 75, that party should bring these to the attention of the NI Pathology Network.

***Purpose of this Policy***

The purpose of the Policy is to ensure that POCT is effectively managed across all HSC Organisations so as to maximize the clinical benefit of POCT in patient care and to limit the risks to patients and staff associated with its use.

***Objectives / Elements of this Policy***

It will ensure that POCT systems in all HSC Organisations are managed in accordance with national/international best practice guidelines and accreditation standards, in particular ISO 15189:2012 (Medical Laboratories - Requirements for quality and competence)[2] and ISO 22870:2016 (Point-of-Care Testing [POCT] – Requirements for quality and competence).

***Scope of Policy***

This policy applies to all HSC staff undertaking or having responsibility for POCT and to all Departments and Services in which POCT is undertaken. This policy refers exclusively to POCT undertaken in a hospital or community using equipment procured by HSC Organisations and undertaken by HSC staff. Patient self-testing falls out with the scope of this policy.

***What is Point-of-Care Testing (POCT)***

Point-of-Care Testing (POCT) is any test performed for a patient by a healthcare professional outside the conventional laboratory setting.

Other terms commonly used to describe POCT include:

- near patient testing (NPT)
- bedside testing
- extra-laboratory testing
- disseminated / decentralised laboratory testing

Over the years there has been a continual rise in the use of POCT due to the drive to improve patient pathways and as a result of technological advances.

POCT may be performed in a variety of locations such as acute units in secondary care and, increasingly, in the community and primary care.

POCT must be performed by staff whose training and competence has

been established and recorded. The reason for this is to protect the patient, and ensure the quality of the service is appropriate to the clinical setting. This is applicable to all providers of POCT services.

As stated above, POCT can be carried out in a wide variety of settings. The following list is not exhaustive but serves to illustrate the variety of locations.

**Secondary care (in hospital):**

- A&E departments
- ambulance service
- cardiac units
- coagulation clinics
- dental clinics and hospitals
- diabetic clinics
- hospital wards
- intensive treatment units
- liver units
- neonatal units
- occupational health departments
- operating theatres
- out-patient departments
- renal units

**Primary care (in the community):**

- co-located commercial sites
- community clinics
- community pharmacies
- GP surgeries
- health centres
- independent sector
- industrial medical centres
- mobile units
- polyclinics – diagnostic centres
- sexual health clinics/GUM clinics
- dental surgeries
- residential settings

Before deciding whether to implement POCT it is essential to:

- establish a clinical need

- consider the benefit to patients of introducing POCT

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.

POCT must deliver an equivalent level of quality and clinical effectiveness as the alternative. Users should also keep under review the continuing clinical need for POCT.

**Main health conditions/applications where POCT is used:**
POCT can be performed for a patient by a healthcare professional outside the conventional laboratory setting for any health condition/application if deemed appropriate do to so, for example:

- Monitoring glucose and ketone levels in diabetics
- Testing urine for pregnancy
- Testing urine for protein, glucose, blood, leucocytes to screen for illness.
- Monitoring INR in those on warfarin
- Monitoring blood gas results in those with respiratory conditions (COPD, respiratory infection) or metabolic conditions (DKA) or investigation those acutely unwell

**Some benefits of POCT for the Organisation and Staff**

- Reduced number of clinic visits
- Earlier discharge from hospital
- Fewer unnecessary hospital admissions
- Optimised drug treatment
- More appropriate use of drugs
- Reduced use of blood products
- Reduced use of staff, equipment and space

**Potential advantages for the Organisation and Staff**

- Improved turnaround time – mainly by shortening the pre- and post-analytical steps.
- Potential for better monitoring of certain conditions and where frequent testing is desirable.
- Smaller sample and reagent volumes – POCT methods may be less clinically invasive.
- Advantageous in remote areas where access to a laboratory is

limited.
- POCT may offer an easier to access service e.g. for the elderly.
- Economic – although POCT is generally more expensive than laboratory testing, it may offer wider economic benefits with a reduced number of clinic visits, reduced length of stay in hospital and fewer hospital admissions.
- Greater patient involvement in their own care.
- Improved patient experience.
- Availability outside normal laboratory core hours.
- Opportunity for ward staff to develop additional skills and experience

**Potential disadvantages for the Organisation and Staff**
- Poor quality of analysis.
- Poor record keeping.
- Lack of result interpretation.
- Unnecessary duplication of equipment.
- Failure to detect erroneous results.
- The availability of an array of tests may tempt users to perform unnecessary or inappropriate testing.

**Benefits and disadvantages for the Patient**

Benefits
- Improved patient experience
- Quicker turnaround of results
- Reduce unnecessary anxiety / stress
- Reduced number of clinic visits
- Earlier discharge from hospital
- Fewer unnecessary hospital admissions

Disadvantages
- Poor quality of analysis which may result in repeat tests required or laboratory analysis and longer wait times for results. E.g. potassium may be due to haemolysed sample and falsely raised.
- False positive or false negative result e.g. pregnancy testing
- Result may not be on the patient electronic record if test not connected or patient identifier not used.

## 1.3 Main stakeholders affected (internal and external)

**Patients**

A POCT test can be performed on all patients and within all age ranges. As highlighted above there are various advantages and disadvantages for patients when considering a POCT test.

**Staff of POCT**

Users (i.e. doctors, nurses, pathology staff) of POCT should have a sound understanding of the relevant analytical principles, and of issues such as quality assurance (QA), interpretation of test results, limitations to use and liability issues. It is therefore important that users of POCT should have access to clear guidance on these and other issues relating to the management of POCT. This new regional policy will play a pivotal role in the management of POCT across Northern Ireland.

## 1.4 Other policies or decisions with a bearing on this policy or decision

All Trusts must develop, implement and enforce a policy for the control of POCT. The following list is not exhaustive but serves to illustrate the variety of other relevant guidance etc.

- MHRA - Management and Use of IVD Point of Care Test Devices
- British Standard EN ISO 15189:2012 (Medical Laboratories - Requirements for quality and competence)
- British Standard ISO 22870:2016 (Point-of-Care Testing [POCT] – Requirements for quality and competence)
- Department of Health Advisory Committee on Dangerous Pathogens (2003) Infection at work controlling the risk
- Department of Health, London, Health Services Advisory Committee (2003) Safe working and the prevention of infection in clinical laboratories and similar facilities
- Health and Safety Executive, Control of Substances Hazardous to Health (COSHH) 2002
- The Health and Safety at Work Act (1987)

## (2) CONSIDERATION OF EQUALITY AND GOOD RELATIONS ISSUES AND EVIDENCE USED

### 2.1 Data Gathering

**What information did you use to inform this equality screening? For example previous consultations, statistics, research, Equality Impact Assessments (EQIAs), complaints.**

- An extensive pre-consultation exercise was undertaken with key stakeholders from the POCT Specialty Forum (See Appendix 1).
- HSC Workforce Census
- HSC staff equality data
- Census 2011
- Further sources of data are referenced in 2.2 below.
-

**Provide details of how you involved stakeholders, views of colleagues, service users, staff side or other stakeholders.**

### 2.2 Quantitative Data

**Who is affected by the policy or decision? Please provide a statistical profile. Note if policy affects both staff and service users, please provide profile for both.**

| ***Category*** | ***What is the makeup of the affected group? ( %) Are there any issue or problems? For example, a lower uptake that needs to be addressed or greater involvement of a particular group?*** |
| --- | --- |

| | |
| --- | --- |
| Gender | Bearing in mind that in principle POCT can be performed for a patient for any health condition/application, in relation to some of the main examples outlined above (1.2), differential gender profiles of patients impacted can reasonably be assumed for the following:<br>• Monitoring glucose and ketone levels in diabetics.<br>• Testing urine for pregnancy - vast majority female (with potentially some transgender male patients).<br>• Monitoring INR in those on warfarin.<br>• Monitoring blood gas results in those with respiratory conditions (COPD, respiratory infection) or metabolic conditions (DKA) or investigation those acutely unwell.<br><br>**Gender information from NI HSC Workforce Census 2015**<br>• 74% of all HSC staff were female<br>• 54% of HSC staff (by headcount) work full-time<br><br>https://www.dhsspsni.gov.uk/publications/northern-ireland-health-and-social-care-hsc-workforce-census-march-2015<br><br>**Gender information from Pathology Services Section 75 Data**<br>• 64% are female<br>• 73% work full time<br><br>In comparison to the HSC as a whole, Pathology services have fewer female workers and fewer part time staff. Data on the number of female part time workers was unavailable. |

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|---|---|
| Age | Bearing in mind that in principle POCT can be performed for a patient for any health condition/application, in relation to some of the main examples outlined above (1.2.), differential age profiles of patients impacted can reasonably be assumed for the following:<br>• Monitoring glucose and ketone levels in diabetics.<br>• Testing urine for pregnancy.<br>• Monitoring INR in those on warfarin.<br>• Monitoring blood gas results in those with respiratory conditions (COPD, respiratory infection) or metabolic conditions (DKA) or investigation those acutely unwell.<br><br>**Age information from NI HSC Workforce Census 2015**<br>• 39% of all HSC Staff were under the age of 40<br>• 29% were aged between 40 and 49<br>• 32% were aged 50 and over<br><br>**https://www.dhsspsni.gov.uk/publications/northern-ireland-health-and-social-care-hsc-workforce-census-march-2015**<br><br>**Age information from Pathology Services Section 75 Data**<br>• 5% were under the age of 25<br>• 28% were under the age of 35<br>• 67% were aged 50 and over<br><br>In comparison to the HSC as a whole, Pathology services have a higher proportion of workers aged 50 and over. |
| Religion | **Religion information from 2011 census**<br>• 36% were Protestant<br>• 41% were Roman Catholic<br>• 23% were other or unknown<br><br>**Religion information from Pathology Services Section 75 Data**<br>• 44% were Protestant<br>• 39% were Roman Catholic<br>• 17% were other or unknown |

| | |
|---|---|
| | Pathology services are generally reflective of 2011 census data. |
| Political Opinion | **Political Opinion information from Pathology Services Section 75 Data**<br>• 10% were Broadly Unionist<br>• 7% were Broadly Nationalists<br>• 83% were other or unknown<br><br>There is no census data available to draw a comparison. |
| Marital Status | **Marital Status information from 2011 census**<br>• 47.6% of those aged 16 and over were married<br>• 36.1% were single<br>• 0.1% were registered in same-sex civil partnerships<br>• 9.4% were either divorced, separated of formerly in a same-sex relationship<br>• 6.8% were either widowed or a surviving partner<br><br>https://www.nisra.gov.uk/demography/default.asp11.htm<br><br>**Marital Status information from Pathology Services Section 75 Data**<br>• 53% were married<br>• 35% were single<br>• 12% were other or unknown<br><br>Pathology services are reflective of 2011 census data |

| | |
| --- | --- |
| Dependent Status | **Dependent Status information from 2011 census and CarersNI**<br><br>**Census 2011:**<br>• 11.81% (213, 863) of the usually resident population provide unpaid care to family members, friends, neighbours or others because of long-term physical or mental ill – health/disabilities or problems related to old age.<br>• 3.11% (56, 318) provided 50 hours care or more.<br>• 33.86% (238, 129) of households contained dependent children.<br>• 40.29% (283, 350) contained a least one person with a long – term health problem or a disability.<br><br>**Carers NI:**<br>• 1 in every 8 adults is a carer<br>• 2% of 0-17 year olds are carers, based on the 2011 Census<br>• There are approximately 220,000 carers in Northern Ireland<br>• One quarter of all carers provide over 50 hours of care per week<br>• People providing high levels of care are twice as likely to be permanently sick or disabled than the average person<br>• 64% of carers are women; 36% are men.<br><br>**Dependent Status information from Pathology Services Section 75 Data:**<br>• 25% reported Yes<br>• 24% reported No<br>• 51% were unknown<br><br>It is important to note that the available figures are not explanatory of the nature of the dependent (i.e. parent or carer) |

| | |
|---|---|
| Disability | **Disability information from 2011 census**<br>• 20.69% (374, 668) regard themselves as having a disability or long – term health problem, which has an impact on their day to day activities.<br>• 68.57% (1, 241709) of residents did not have long – term health condition.<br>• Deafness or partial hearing loss – 5.14% (93, 078)<br>• Blindness or partial sight loss – 1.7% (30, 785)<br>• Communication Difficulty – 1.65% (29, 879)<br>• Mobility or Dexterity Difficulty – 11.44% (207, 163)<br>• A learning, intellectual, social or behavioural difficulty - 2.22% (40, 201)<br>• An emotional, psychological or mental health condition - 5.83% (105, 573)<br>• Long – term pain or discomfort – 10.10% (182, 897)<br>• Shortness of breath or difficulty breathing – 8.72% (157, 907)<br>• Frequent confusion or memory loss – 1.97% (35, 674)<br>• A chronic illness (such as cancer, HIV, diabetes, heart disease or epilepsy. – 6.55% (118, 612)<br>• Other condition – 5.22% (94, 527)<br>• No Condition – 68.57% (1, 241, 709)<br><br>It can reasonably be assumed that the share of patients with a disability is significantly higher amongst those receiving POCT than in the general population.<br><br>**Disability information from Pathology Services Section 75 Data**<br>• 3% reported Yes<br>• 62% reported No<br>• 35% were unknown<br><br>It is important to note that the prevalence of disability amongst HSC workforce may be under reported. |

| | |
|---|---|
| Ethnicity | Bearing in mind that in principle POCT can be performed for a patient for any health condition/application, in relation to some of the main examples outlined above (1.2.), differential ethnic profiles of patients impacted can reasonably be assumed for the following:<br>• Monitoring glucose and ketone levels in diabetics.<br>• Testing urine for pregnancy<br>• Monitoring INR in those on warfarin<br>• Monitoring blood gas results in those with respiratory conditions ( COPD, respiratory infection) or metabolic conditions ( DKA) or investigation those acutely unwell<br><br>**Ethnicity information from 2011 census**<br>• 1.8% of the NI population belonged to a monitory ethnic group.<br><br>**Ethnicity information from Pathology Services Section 75 Data**<br>• 75% were White<br>• 2% were other which included minority ethnic groups<br>• 23% were unknown<br><br>Pathology services are reflective of 2011 census data. |
| Sexual Orientation | Accurate figures are not readily available but it is estimated that 5-7% of the population are from the gay and lesbian or bisexual community.<br><br>**Sexual Orientation information from Pathology Services Section 75 Data**<br>• 46% reported being attracted to the opposite sex<br>• 2% reported other<br>• 52% were unknown |

## 2.3 Qualitative Data

**What are the different needs, experiences and priorities of each of the categories in relation to this policy or decision and what equality issues emerge from this? Note if policy affects both staff and service users, please discuss issues for both.**

| *Category* | *Needs and Experiences* |
|---|---|
| Gender | **Patients**<br>There is no qualitative data to indicate there would be any impact. |
| Age | **Patients**<br>POCT may have benefits for certain age ranges e.g. children and elderly as it may mean less waiting times and hospital appointments. |
| Religion | **Patients**<br>There is no qualitative data to indicate particular needs on the basis of religion. |
| Political Opinion | **Patients**<br>There is no qualitative data to indicate particular needs on the basis of political opinion. |
| Marital Status | **Patients**<br>There is no qualitative data to indicate particular needs on the basis of marital status. |
| Dependent Status | **Patients**<br>There is no qualitative data to indicate particular needs on the basis of dependent status. |
| Disability | **Patients**<br>POCT may have benefits for certain disabilities e.g. Chronic illness or learning disability as it may mean less waiting times and hospital appointments. |
| Ethnicity | **Patients**<br>There is no qualitative data to indicate there would be any impact. |
| Sexual Orientation | **Patients**<br>There is no qualitative data to indicate particular needs on the basis of sexual orientation. |

## 2.4 Multiple Identities

**Are there any potential impacts of the policy or decision on people with multiple identities? For example; disabled minority ethnic people; disabled women; young Protestant men; and young lesbians, gay and bisexual people.**

The issues of multiple identities are important. In relation to this policy the Health & Social Care Board (HSCB) will ensure that equality categories are not considered in isolation.

## 2.5 Based on the equality issues you identified in 2.2 and 2.3, what changes did you make or do you intend to make in relation to the policy or decision in order to promote equality of opportunity?

| ***In developing the policy or decision what did you do or change to address the equality issues you identified?*** | ***What do you intend to do in future to address the equality issues you identified?*** |
|---|---|
| Based on the issues identified in 2.2. and 2.3, the POCT Specialty Forum did not need to change or address any issues that would indicate there would be any impact on patients or staff due to this regional policy. | The POCT Specialty Forum is committed to the promotion of equality of opportunity for staff and patients. In future and if deemed to do so, relevant groups will be engaged when monitoring and reviewing this policy.<br><br>If at any stage of the life of the policy there are any issues within the policy which are perceived by any party as creating adverse impacts on any of the groups under Section 75, that party should bring these to the attention of the NI Pathology Network. |

## 2.6 Good Relations

**What changes to the policy or decision – if any – or what additional measures would you suggest to ensure that it promotes good relations? (refer to guidance notes for guidance on impact)**

| *Group* | *Impact* | *Suggestions* |
|---|---|---|
| Religion | n/a | n/a |
| Political Opinion | n/a | n/a |
| Ethnicity | n/a | n/a |

## (3) SHOULD THE POLICY OR DECISION BE SUBJECT TO A FULL EQUALITY IMPACT ASSESSMENT?

A full equality impact assessment (EQIA) is usually confined to those policies or decisions considered to have major implications for equality of opportunity.

**How would you categorise the impacts of this decision or policy? (refer to guidance notes for guidance on impact)**

**Please tick:**

| | |
|---|---|
| Major impact | |
| Minor impact | |
| No further impact | |

**Do you consider that this policy or decision needs to be subjected to a full equality impact assessment?**

**Please tick:**

| | |
|---|---|
| Yes | |
| No | |

The information provided in section 2.1 to 2.5 above sets out potential equality implications for relevant Section 75 groups. The information also outlines the actions the POCT Specialty Forum has taken or plans to take to mitigate against any of the potential implications associated with the policy.

## (4) CONSIDERATION OF DISABILITY DUTIES

### 4.1 In what ways does the policy or decision encourage disabled people to participate in public life and what else could you do to do so?

| ***How does the policy or decision currently encourage disabled people to participate in public life?*** | ***What else could you do to encourage disabled people to participate in public life?*** |
|---|---|
| There are no additional measures considered relevant in the context of the policy over and above the considerations set out in relation to the Section 75 group on 2.2 & 2.3 above. | The POCT Specialty Forum is committed to the promotion of equality of opportunity for disabled people. In future and if deemed to do so, relevant groups will be engaged when monitoring and reviewing this policy. |

### 4.2 In what ways does the policy or decision promote positive attitudes towards disabled people and what else could you do to do so?

| ***How does the policy or decision currently promote positive attitudes towards disabled people?*** | ***What else could you do to promote positive attitudes towards disabled people?*** |
|---|---|
| There are no additional measures considered relevant in the context of the policy over and above the considerations set out in relation to the Section 75 group on 2.2 & 2.3 above. | N/A |

## (5) CONSIDERATION OF HUMAN RIGHTS

### 5.1 Are Human Rights relevant? Complete for each of the articles

| ARTICLE | Yes/No |
|---|---|
| Article 2 – Right to life | There is no evidence to indicate there would be any impact |
| Article 3 – Right to freedom from torture, inhuman or degrading treatment or punishment | There may be impact following the outcomes from incidents. |
| Article 4 – Right to freedom from slavery, servitude & forced or compulsory labour | There is no evidence to indicate there would be any impact |
| Article 5 – Right to liberty & security of person | There is no evidence to indicate there would be any impact |
| Article 6 – Right to a fair & public trial within a reasonable time | There is no evidence to indicate there would be any impact |
| Article 7 – Right to freedom from retrospective criminal law & no punishment without law | There is no evidence to indicate there would be any impact |
| Article 8 – Right to respect for private & family life, home and correspondence. | There is no evidence to indicate there would be any impact |
| Article 9 – Right to freedom of thought, conscience & religion | There is no evidence to indicate there would be any impact |
| Article 10 – Right to freedom of expression | There is no evidence to indicate there would be any impact |
| Article 11 – Right to freedom of assembly & association | There is no evidence to indicate there would be any impact |
| Article 12 – Right to marry & found a family | There is no evidence to indicate there would be any impact |
| Article 14 – Prohibition of discrimination in the enjoyment of the convention rights | There is no evidence to indicate there would be any impact |
| 1st protocol Article 1 – Right to a peaceful enjoyment of possessions & protection of property | There is no evidence to indicate there would be any impact |
| 1st protocol Article 2 – Right of access to education | There is no evidence to indicate there would be any impact |

*If you have answered no to all of the above please move onto to move on to **Question 6** on monitoring*

**5.2 If you have answered yes to any of the Articles in 5.1, does the policy or decision have a potential positive impact or does it potentially interfere with anyone's Human Rights?**

| List the Article Number | Positive impact or potential interference? | How? | Does this raise any legal issues?* Yes/No |
|---|---|---|---|
| Article 3 | Positive impact | Patients receive quicker access to pathology services which may result in improved patient pathways in terms of diagnosis and treatment. | No |

** It is important to speak to your line manager on this and if necessary seek legal opinion to clarify this*

**5.3 Outline any actions which could be taken to promote or raise awareness of human rights or to ensure compliance with the legislation in relation to the policy or decision.**

| |
|---|
| N/A |

## (6) MONITORING

### 6.1 What data will you collect in the future in order to monitor the effect of the policy or decision on any of the categories (for equality of opportunity and good relations, disability duties and human rights?

| Equality & Good Relations | Disability Duties | Human Rights |
|---|---|---|
| POCT SF will consider collecting relevant data in the future in order to monitor the effect of the policy or decision on any of the categories (for equality of opportunity and good relations, disability duties and human rights). For example, patient experience in relation to gender, age and disability. | N/A | N/A |

Approved Lead Officer: Dr Derek McKillop

Position: NI Pathology Network POCT Specialty Forum Chair & Consultant Clinical Scientist, SEHSCT

Policy/Decision Screened by: …….

Signed:
Date:

**Please note that having completed the screening you are required by statute to publish the completed screening template, as per your organisation's equality scheme. If a consultee, including the Equality Commission, raises a concern about a screening decision based on supporting evidence, you will need to review the screening decision.**

**Please forward completed template to:**
**Equality.Unit@hscni.net**

**Template produced November 2011**
If you require this document in an alternative format (such as large print, Braille, disk, audio file, audio cassette, Easy Read or in minority languages to meet the needs of those not fluent in English) please contact the Equality Unit:

> 2 Franklin Street; Belfast; BT2 8DQ; email: Equality.Unit@hscni.net; phone: 028 95363961 (for Text Relay prefix with 18001); fax: 028 9023 2304

**POCT Specialty Forum Stakeholders**

| Name | HSC Trust |
| --- | --- |
| Derek McKillop (Chair) | South Eastern HSC Trust |
| Marnie Dodd | South Eastern HSC Trust |
| Jenny Hamilton | Southern HSC Trust |
| Ciara Strain | Southern HSC Trust |
| Elinor Hanna | Northern HSC Trust |
| Gerard Duffy | Northern HSC Trust |
| Emma Reilly | Belfast HSC Trust |
| Gareth McKeeman | Belfast HSC Trust |
| Jeremy Neely | Belfast HSC Trust |
| Kathy Ryan | Western HSC Trust |
| Mark Lynch | Western HSC Trust |