Greater Glasgow and Clyde Point of Care Testing Policy

Introduction

Point of Care Testing (POCT) refers to any diagnostic testing performed for a patient by a healthcare professional, outside the hospital laboratory within a secondary, primary care or other community setting. Technology advances mean that more and more laboratory equivalent tests are available closer to the point of need and it is likely that the demand for and scope of POCT will increase.

Purpose

The aim of this policy is to ensure that all POCT processes within the NHSGGC Health Board are appropriately managed and quality assured in accordance with national guidelines, local policies and accreditation standards and that all risk and governance issues are addressed.

It also sets a framework to support the safe and effective implementation and management of new and existing POCT devices to aid patient care within NHSGGC.

The policy seeks to ensure POCT is a value added activity and that no harm is rendered to any patient as a result of mismanagement or inappropriate use of a POCT device

The benefits to the organisation will include the medico-legal advantage of working within a system-wide procedure as well as access to Standard Operating Procedures (SOP), an operational POCT framework, appropriate training, potential savings on purchase price and maintenance of POCT devices. This policy is produced using recommendations from the documents: MHRA Management and use of IVD point of care test devices 2021, MHRA Guidance on the regulation of In Vitro Diagnostic medical devices in Great Britain 2023, ISO 15189:2022 standard which incorporates additional requirements for POCT, and Point of Care Testing: National Strategic Guidance for at Point of Need Testing (IBMS, RCPath, ACB).

The NHSGGC POCT policy aims to safeguard a high standard of care by ensuring that all areas performing POCT:

- Comply with all appropriate national guidelines and standards and applicable statutory directives

- Ensure the principles of best practice are followed.
- Promote safety, reliability and suitability of equipment and procedures.
- Adhere to uniform standards across all NHSGGC sites, reducing inappropriate variation
- Ensure that all staff are adequately trained and can demonstrate competence
- Ensure all POCT devices carry the relevant certification approval markings for their intended use
- Apply the principles of quality assurance and continuous improvement
- Maintain high quality records of all results and procedures
- Demonstrate compliance with the policy

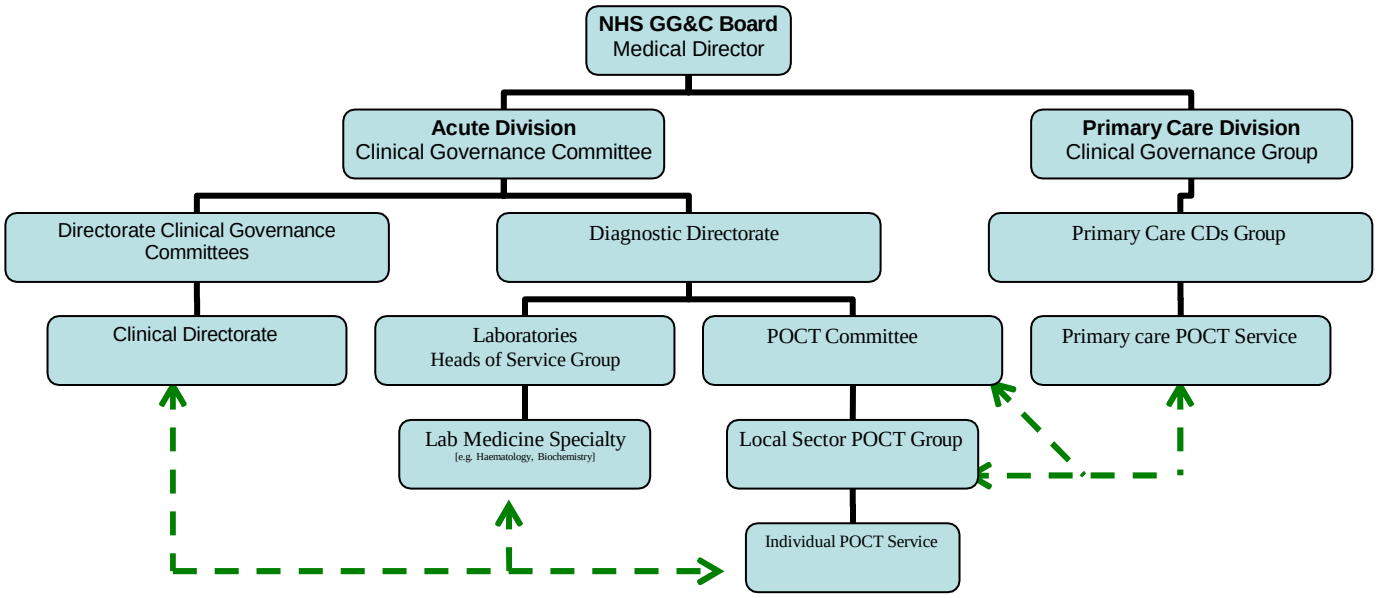
Clinical Governance of POCT in NHS GG&C

At the request of the Laboratory medicine Directorate a POCT Committee is set up across NHS Glasgow and Clyde, with the role of devising policy on POCT, in line with current guidelines[1-3], and facilitating compliance with this Policy across the Health Board. This committee is predominantly comprised of Laboratory Medicine representatives but also includes Health & Safety, General Practice, Pharmacy, Procurement and Management representation. Local Sector POCT Groups have also been established in the North, South and Clyde sectors under the auspices of this Glasgow and Clyde Committee. These groups are multidisciplinary and include representatives of laboratory staff and also clinical users. Together the POCT Committee and the Local Sector POCT Groups effectively constitute a POCT Management Group (as defined by UKAS[2]).

The Local Sector POCT Groups will ensure local implementation of POCT policy and monitoring of POCT activities on their hospital sites. A POCT Checklist document[4], will be used as a tool to facilitate compliance with the policy. A checklist should be completed for each POCT service and reviewed regularly by the relevant local POCT Group. A copy of the checklist should be held by this group and the POCT coordinator for that POCT service. Any new proposals for POCT services should be reviewed by Local POCT Group, prior to being established.

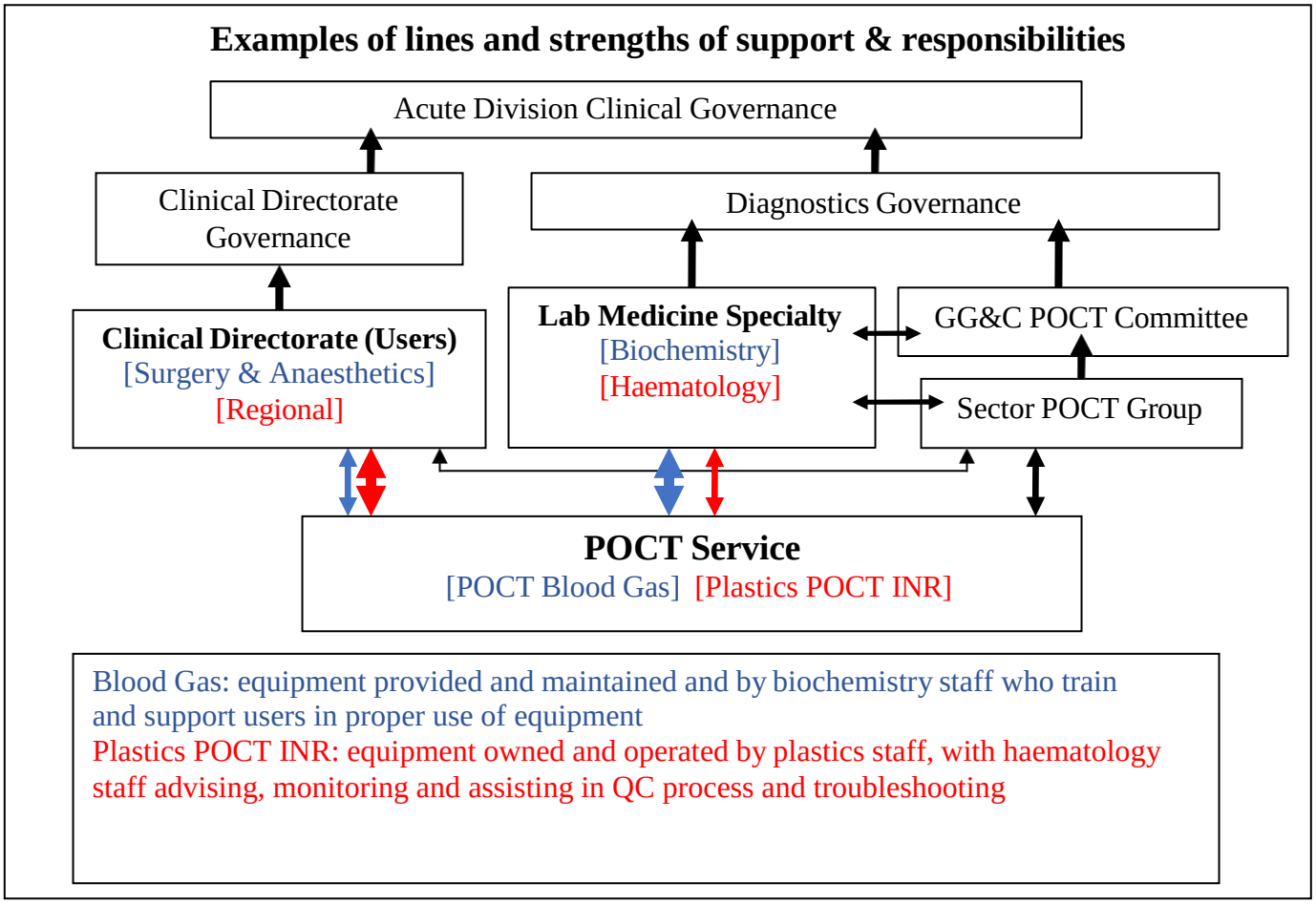
The relationships between the POCT Committee, Local POCT Groups, individual POCT services and the Health Board Governance Committee is shown below:

Relationships of POCT Co-ordination Committee within NHS GG&C



Laboratory medicine specialties hold a key strategic role in advising, facilitating, and in some cases delivery, POCT services. The level of input from the relevant laboratory specialty will vary between individual POCT services, however it is essential that whatever the level of support, it is fully recognised and resourced.

The following diagram serves to display some examples of differing levels of laboratory support for POCT services. Governance responsibility for an individual POCT service will primarily lie with the clinical user and their Directorate Governance Committee. However, where a laboratory has a major role in providing the POCT service then they will obviously share governance responsibility with the users.



Each POCT service will have identifiable key individuals, including:

- clinical lead (usually lead clinical user, or occasionally laboratory medical staff, with overall governance responsibility for that POCT service)
- POCT coordinator/link nurse
- supporting POCT/laboratory staff

Several of these roles may be undertaken by the same individual, but as a group they are responsible and accountable for maintaining a safe and high quality POCT service. Whilst the designated lead will have overall governance accountability, all individual users trained and approved for use of the POCT service will bear some responsibility for the results that they produce

The role of the Local POCT Group

These Groups will act as a resource to ensure that Health Board Policy on POCT is followed within their geographical area / hospital sites. Key activities will include:

- act as first point of contact for clinical services considering the potential need for a POCT service, and directing the clinical user to the appropriate laboratory medicine department
- authorise where appropriate, and in agreement with clinical user and relevant laboratory medicine department, development of any new POCT service
- ensure all POCT services in their sector are registered with the Group, and by satisfactory completion of the POCT Checklist demonstrate compliance with the Health Board Policy on POCT
- On behalf of Laboratory Management review each POCT service annually, specifically considering:
    - Ongoing clinical need for the POCT service (taking account of any changes which might affect its clinical- and cost-effectiveness)
    - Any failings in EQA exercises
    - Any adverse incidents relating to the service
- Facilitate and perform periodic audit of each POCT service
- Advise on any issues arising from POCT services, including: adverse incidents, re- training needs, QC issues, new guidelines or legislation
- Produce reports to the POCT Committee detailing POCT activities within their sector, any problems arising and summary of Service reviews and audits

The role of the Local Laboratory Medicine departments

The local hospital laboratory medicine departments should play a key role in the development and management of POCT services. This is particularly true for secondary care, and may also be useful for some primary care services. There should be close liaison between users and the relevant laboratory medicine department on all issues relating to a POCT service. These collaborations, particularly where there is cross-charging for resources or POCT support is provided to a separate organisation/legal entity, should be formalised in a service level agreement (SLA) defining the relationships and responsibilities.

The supporting local Laboratory Medicine department will have named individual with defined POCT responsibility, and will ensure that POCT policies and documents are embedded within its Quality Management system.

Any perceived problems arising with POCT services which fail to be addressed by the clinical users will be brought to the attention of the Laboratory Heads of Service Group and relevant Local POCT Group. Issues unresolved at this level will be reviewed by the Diagnostics Clinical Governance Committee so that appropriate guidance can be given.

Needs Assessment

Before deciding whether to implement a POCT service it is essential to establish a clinical need for such a service. This should be based on establishing that the perceived need is valid and that meeting it will be clinically effective. Consideration should also be made of whether it would be a cost-effective alternative to laboratory based testing, although in most cases an expedited laboratory solution (available through a 24 hour service) is likely to be safer and more cost-efficient. The Head of service for the relevant laboratory must be fully involved in all these discussions. New proposals for POCT services should be reviewed by the Local POCT Group, prior to being established. Furthermore, existing POCT services should re-assess their clinical need and clinical effectiveness on an annual basis.

Selection of Equipment

The selection of the appropriate instrument and consumables should be made by the laboratory medicine department, in partnership with the staff of the clinical service. The selection shall take into account the evaluation reports on the equipment produced by the Department of Health, MHRA or other evaluations as published in the literature. Other considerations include ease of use by non-laboratory staff, training issues, compatibility (including comparability of results) with laboratory based tests, connectivity (ie interfacing with hospital/laboratory information management systems), maintenance, vendor support and running costs. Any device being considered must have a UKCA/CE mark to ensure it is fit for purpose and of suitable quality[5].

Business case

The business case should demonstrate the clinical and economic benefits of POCT, together with details of all the financial costs of providing and maintaining the POCT service.

The relevant laboratory medicine department must be involved in the production and evaluation of the cost-benefit analysis. All direct and indirect costs must be considered, including full costs for laboratory involvement. There should be a clear definition of the problem that the device may solve so that a full examination of all possible solutions can be made.

Budgetary Arrangements

Prior to the procurement, there must be an agreement between the device's purchaser, its users, the Laboratory Medicine service and the Pharmacy department for the budgetary consequences of the purchase. Definitions must be put in place for the responsibility for the ordering of reagents, consumables, servicing, training, support, quality control and quality assessment.

Risk Management

Few devices are totally foolproof. It is essential that risk analysis should be carried out for both patients and staff. The identified risks associated with the use and interpretation of results must be properly managed by training and support from the appropriate Laboratory Medicine departments and the Local POCT Group.

To ensure the provision of a safe working environment in which staff can undertake required functions, premises within which POCT will be performed are required to be regularly re-assessed e.g. annually.

Adverse incidents in POCT devices may results from shortcomings in the device, its operating instructions, user practices or conditions of use. Each device-specific SOP should include arrangements for reporting adverse incidents according to local site policy. This will usually be through the DATIX reporting system, with any device-related adverse incidents also being reported to the MHRA. All incidents should also be reported to the Local POCT Group, by the POCT coordinator for the particular POCT service.

Health and Safety

POCT users and managers must be aware of the risks of transmission of infection between patients and recognise potential hazards of handling and disposing of body fluids and sharps, outside of a laboratory setting.

Operation of devices must be consistent with current legislation and guidance and comply with local Health and Safety and Infection Control Policies. Consideration of these issues should be made prior to implementation of a POCT service. This should involve liaison between safety officers for the testing site, staff of the clinical unit, the infection control team and the laboratory department. Where POCT is used to identify reportable infective diseases that have implications for public health and health protection, there must be formal reporting arrangements set in place.

Training

Only regulated healthcare professionals whose training and competence has been established and documented are authorised to use any POCT device. Training will be specified and supervised by the relevant laboratory department and provided by appropriately trained lead/link nurse, laboratory staff or device manufacturer. Training must cover maintenance of equipment, operation of equipment, record keeping, and interpretation of results, contraindications for and limitations of use, quality assurance and procedures to follow in the event of device breakdown/faults. A record of trained users should be held by the relevant POCT Service Co-ordinator and relevant laboratory department. The need for update training should be assessed on at least an annual basis and implemented as necessary.

Operation

Only authorised, trained users may operate POCT devices. There must be a comprehensive Standard Operating Procedure (SOP), produced in collaboration with the appropriate laboratory medicine department, which is written to the standard required by UKAS 15189:2022. This must be available, current and followed by all users of the device. The document will include instructions on safe working practice, maintenance procedures, interpretation of error messages, the recording of data and quality control procedures, and will usually include a copy of the manufacturer's instructions for use. The SOP master copy must be held by the relevant laboratory department.

Where appropriate, each POCT device should have a maintenance contract and details of local preventative maintenance and cleaning should be recorded in the SOP.

Documentation of results

All results for patients and quality control/quality assessment must be recorded. This record must include unequivocal patient identity, time of test, the result, relevant quality control (QC) results and user identity. The mechanism of transfer of results from the device to the patient's record (paper or electronic) must be unambiguous and stated in the SOP. An ideal system would be electronic transfer from POCT device directly to patient's electronic clinical or laboratory file, however it is appreciated that this is unlikely for the more manual POCT tests. All results from POCT devices should be identifiable in patient's records as being from a POCT service and distinguishable from a laboratory generated result.

All patients' results must be treated as confidential and kept in a secure place. If patients' results are stored in a computer system, local security rules on access to the system, whether stand-alone or networked, should be maintained. Users should have access to the system by password, which must be regularly updated. The storage of results should be in line with storage maintained by the laboratory and compatible with the Royal College of Pathologists guidelines[6].

Each device must have a log book in either paper or electronic form in which details are recorded of maintenance, faults, corrective actions and repairs by named individuals.

Interpretation of results must be properly managed by training and support from the Laboratory Medicine departments and the POCT implementation group.

Quality Assurance

Quality Assurance is an essential component of all analytical procures, including POCT, and includes all of the measures taken to ensure that testing is reliable. These include correct identification of patient, appropriate test selection, obtaining a satisfactory specimen, analysing it and recording results accurately and promptly, interpreting the results accurately, taking appropriate action and documenting all procedures for reference. It ensures optimal accuracy of results via continuous monitoring of operator performance, reagents and equipment.

The relevant laboratory department will ensure that the performance of the device is checked by appropriate internal quality control (IQC) and external quality assessment (EQA) procedures, as would satisfy the standards required by UKAS 15189:2022 inspection criteria. The IQC and EQA procedures must be clearly documented in the device SOP and adhered to by users.

Users of POCT have a duty to participate in an EQA scheme and perform adequately as part of clinical governance. The relevant laboratory is responsible for obtaining and reporting EQA and reviewing performance, along with the POCT co-ordinator, in the EQA scheme. For some POCT services, and in particular where no EQA scheme exists, consideration should be given to systematic parallel testing of a proportion of POCT samples (e.g. 1 in 10-20) in the relevant laboratory.

When the performance of a device falls out with acceptable limits, the relevant laboratory department may withdraw the device from use until the performance is resolved. As noted under 'Clinical Governance of POCT in NHS G&C', problems arising with POCT services which fail to be addressed by the clinical users will be brought to the attention of the Heads of Service group and Clinical Governance Group so that appropriate guidance can be given.

Audit

Each POCT service should be periodically audited to ensure that the quality of the service is being maintained to acceptable standards. This should include assessment of device performance (in terms of IQC and performance in EQA), health and safety aspects, adherence to SOP and quality assurance procedures, and the appropriate use of results. The reliability and clinical effectiveness of the tests being carried out should also be a part of this audit.

A formal scheduled audit exercise for each POCT Service should be undertaken at least biennially, and the report (and corrective actions) reviewed by the Local POCT Group.

Accreditation

Accreditation is assessment, by an external body, of the competence to provide a service to a recognised standard. By having this independently confirmed, POCT providers are able to give reassurance to users of their service.

The new ISO 15189:2022 standard for Medical Laboratories has been published which incorporates POCT into the standard[2]. It is more focused on risk and patient outcomes. It is a long term aim to work towards the standards required for POCT accreditation within the Health Board as part of continually improving POCT services and maintaining high level of patient care within NHSGGC.

References

1. Management and use of IVD Point of Care Test Devices. MHRA 2021

2. ISO 15189:2022 (Annex A – Additional Requirements for Point of Care Testing (POCT)

3. Point of Care Testing – National Strategic Guidance for at Point of Need Testing 2023 (ACB, IBMS, RCPath)

4. NHSGG&C POCT Checklist April 2024

5. Guidance on the regulation of In Vitro Diagnostic medical devices in Great Britain. MHRA 2023

6. The retention and storage of pathological records and archives (5th edition). The Royal College of Pathologists 2015