Greater Glasgow and Clyde Point of Care Testing Policy

Introduction

Point of care Testing (POCT) refers to any analytical tests performed for a patient, by a healthcare professional, outside the conventional laboratory setting in secondary or primary or other community setting.

Point of care devices can be categorised as:

i) Non-instrumental systems, disposable systems or devices which vary from reagent test strips for a single analyte to sophisticated multi-analyte reagent strips incorporating procedural controls [e.g. urinalysis test strips, pregnancy test kits].

ii) Small analysers, usually hand or palm-held devices which can vary in size [e.g. blood glucose meters, i-Stats, INR monitors].

iii) Desktop analysers are larger and include systems designed for use in clinics or satellite laboratories [e.g. blood gas analysers].

Recent advances in analytical and information technology have led to rapid growth in the availability and use of POCT. There may be considerable benefits to patients by using the latest methodology to carry out tests in close proximity to patients. The successful implementation of POCT is however still dependent upon the effective organisation and management of staff.

The appropriate use of POCT should be considered as a Clinical Governance Issue and subject to examination of clinical effectiveness. Users of POCT devices should have a sound understanding of the relevant analytical principles, quality assurance issues, interpretation of results, limitations to use and liability issues. To ensure reliable performance and to manage the risks associated with point of care testing, the relevant laboratory medicine department [or other relevant supporting department e.g. Clinical Physics] would be expected to have a key role in support, organization & management of such POCT devices.

This document outlines the Policy for point of care testing throughout primary and secondary care in NHS Greater Glasgow and Clyde. It has been updated following publication of new guidance from MHRA and standards from Clinical Pathology Accreditation (UK) Ltd [1-2].

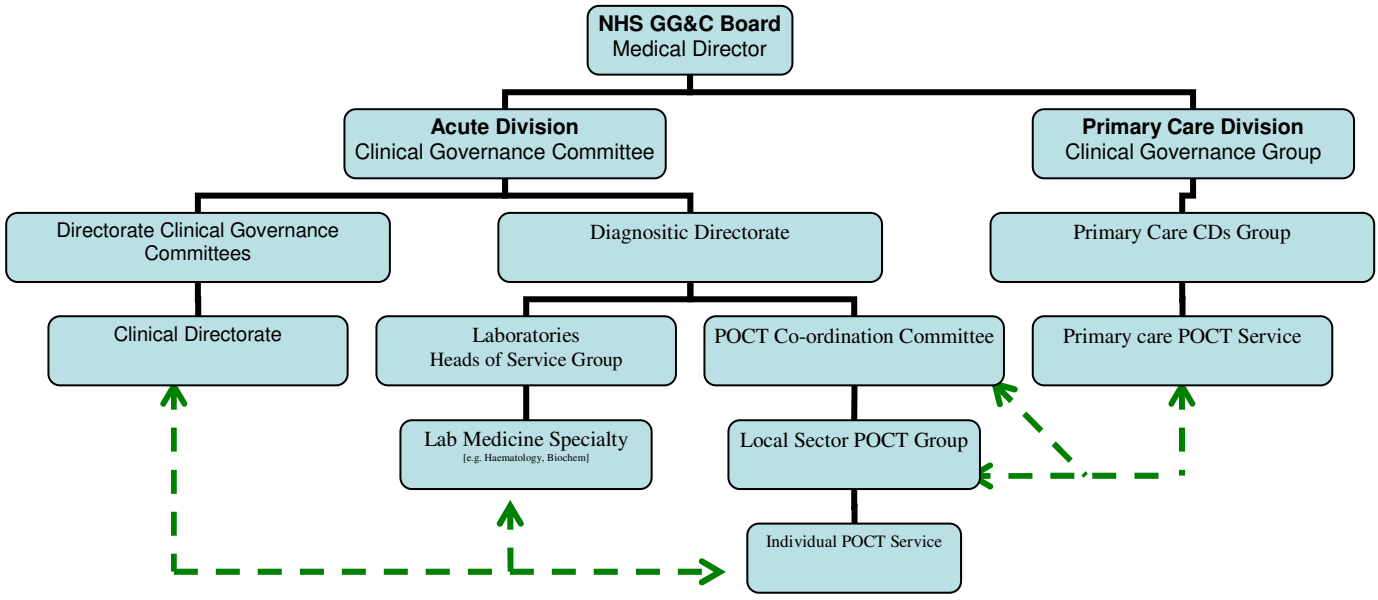
Clinical Governance of POCT in NHS GG&C

At the request of the Laboratory medicine Directorate a POCT Coordination Committee has been set up across NHS Glasgow and Clyde, with the role of devising policy on POCT, in line with current guidelines[1-4], 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 & Yorkhill 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 Coordination Committee and the Local Sector POCT Groups effectively constitute a POCT Management Group (as defined by CPA (UK) Ltd.[2]).

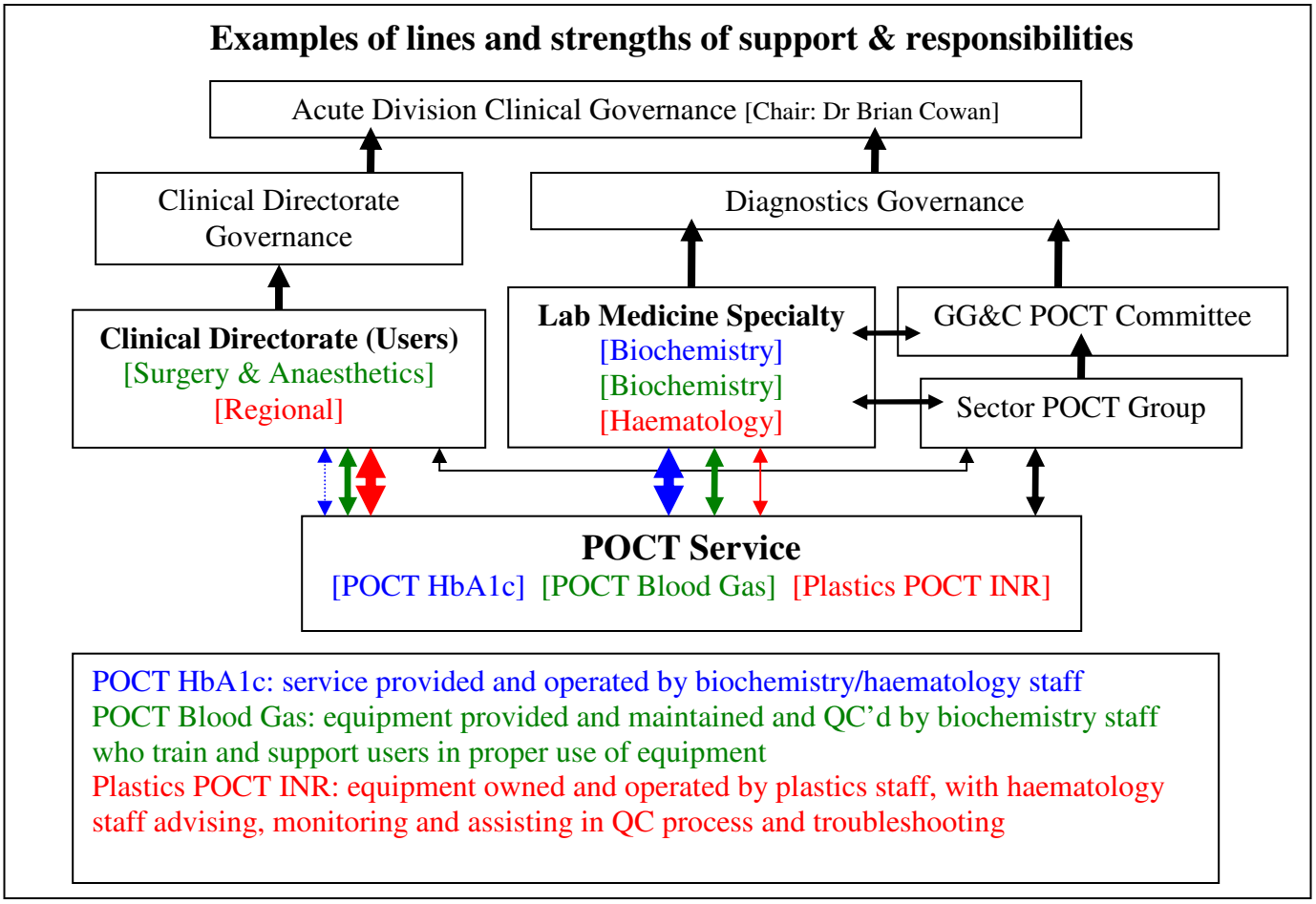
The Local Sector POCT Groups will ensure local implementation of POCT policy and monitoring of POCT activities on their hospital sites. A POCT Checklist document[5], will be used as a tool to facilitate compliance with the policy. A checklist should be completed for each POCT service and reviewed regularly 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 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 review biennial formal 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 an annual report to the POCT Co-ordinating 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. Under the European *In Vitro* Diagnostic Medical Device Directive, any device being considered must have a CE mark to ensure it is fit for purpose and of suitable quality.

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 Clinical Pathology Accreditation (CPA) UK Ltd. 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 and made available to Accreditation Agency Inspectors.

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 CPA 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 regularly 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 detailed audit exercise for each POCT Service should be undertaken at least biennially, and the report (and corrective actions) reviewed by the Local POCT Group. The audit should follow the POCT Audit Template[7].

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.

Any site providing a POCT service should undergo a relevant accreditation procedure and if the service is under the auspices of the local laboratory this will happen as part of their ongoing accreditation process by CPA (UK) Ltd. Users and managers of POCT outwith the responsibility of the local laboratory should contact Clinical Pathology Accreditation (UK) Ltd or UKAS directly or consult their local hospital laboratory for advice

References

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5. NHSGG&C POCT Checklist April 2010

6. The retention and storage of pathological records and archives (3rd edition). The Royal College of Pathologists 2005

7. NHSGG&C POCT Audit Template

8. Clinical Governance: implications for point-of-care testing. Freedman D B, Association of Clinical Biochemists 2002; 39: 421-423

9. Point of Care Testing Top 10 Tips. MHRA 2004

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