SCOTTISH GOVERNMENT
HEALTH AND SOCIAL CARE
DIRECTORATES

REVIEW OF THE USE OF POINT OF
CARE TESTING IN PRIMARY AND
SECONDARY CARE IN SCOTLAND

A Report by a Short Life Working
Group of the Scottish Medical and
Scientific Advisory Committee

The Scottish Government, 2011
POINT OF CARE TESTING REPORT

CHAIRMAN’S FOREWORD

Point-of-care testing (POCT), also known as near-patient testing, is the performance of a clinical investigation in the immediate vicinity of the patient, and away from the traditional laboratory environment. It may be used for screening, diagnostic, or monitoring purposes. Recent advances in technology mean that POCT is the most rapidly expanding field of diagnostic medicine. Available tests encompass almost all the major laboratory disciplines, and the repertoire is constantly expanding. POCT may be performed by laboratory or by non-laboratory NHS staff in primary and secondary care, or by non-NHS staff in community pharmacies or private commercial organisations. It is frequently performed by patients themselves, or by their relatives or carers.

The advantages of rapidly available test results are obvious, particularly in the rural areas of Scotland where the patient and their healthcare provider may be located many miles from their nearest NHS laboratory. However they are only of value if they are accurate and reliable. Tests performed for diagnostic or monitoring purposes can be immediately discussed with the patient. Tests performed for screening purposes are often performed in settings outwith primary or secondary NHS care, however, and require robust mechanisms for the confirmation, follow-up, and counselling of the patient if an unexpected or abnormal test result is found.

Guaranteeing that the POCT results are clinically useful requires a complex matrix of processes and procedures. Agreeing the need for a point-of-care test, and the selection of the appropriate test which is accurate and comparable with the local laboratory’s results, and which is cost effective, are only the first steps. The training and re-validation of staff, ensuring the accuracy of the results, and their correct interpretation in the context of a particular patient, all present their own challenges. Thus a robust system of clinical governance of POCT, which includes adequate and appropriate quality assurance, needs to be in place.

In early 2010 the Scottish Medical and Scientific Advisory Committee (SMASAC), recognised that there is a lack of overall standards for the performance of POCT across Scotland and that a national view was required. They therefore established a short-term working group to address these issues. It first met in October 2010. Its remit was to produce up-to-date guidance for NHS Scotland on POCT. While this guidance is primarily for POCT performed in primary care and secondary care within the NHS in Scotland, we would recommend that it is also adopted by POCT providers in community pharmacies and in the private sector.

I am grateful for the time and effort contributed by all the members of the working group, which it was my privilege to chair, and in particular for the efforts of the secretariat provided by the Scottish Government Health Directorate.

DR ALAN HUTCHISON
Consultant Clinical Biochemist
Southern General Hospital, NHS Greater Glasgow & Clyde
CHAPTER 1 - INTRODUCTION

Point of Care Testing (POCT) – also known as Near Patient Testing – involves the performance of a test in the immediate vicinity of a patient to provide a rapid result outside the conventional laboratory environment. POCT can range from a simple urine dipstick test performed in primary care, to an HbA1c level carried out in a clinical setting by laboratory staff. In 1996 the National Advisory Committee for Scientific Services in Scotland published a best practice statement on Near Patient Testing\(^1\), much of which remains relevant today. In the intervening years, with developments in analytical and information technology, there has been an exponential rise in the use of Point of Care Testing. In response, a number of organisations, including the Royal College of Pathologists\(^2\), MHRA\(^3\) Clinical Pathology Accreditation (CPA)\(^4\) and the Institute of Biomedical Science\(^5\) have produced guidance on POCT.

The Healthcare Quality Strategy for NHSScotland\(^6\), published in May 2010, is underpinned by 3 Quality Ambitions for the delivery of care in NHSScotland. All NHS services are expected to be

- Person centred – mutually beneficial partnerships between patients, their family and those delivering healthcare services ………
- Safe – no avoidable injury or harm to people from healthcare, advice or support they receive ……..
- Effective – the most appropriate treatments, interventions, support and services will be provided at the right time to everyone who will benefit, and wasteful or harmful variation will be eradicated.

Clearly all 3 ambitions are relevant to the delivery of POCT.

Against this background, the Scottish Medical and Scientific Advisory Committee (SMASAC) concluded that it would be timely to revisit this area and produce up to date guidance for NHSScotland on POCT. A Working Group was established under the Chairmanship of Dr Alan Hutchison, Consultant Clinical Biochemist, NHS Greater Glasgow and Clyde. The Group met on a total of 3 occasions between October 2010 and September 2011 to review current POCT provision in Scotland and in particular to advise on the future governance arrangements for POCT services in Scotland. The Group’s membership, remit and terms of reference are at Annex A.

Methods of Working

It was agreed that the scope of the Group’s work should include POCT being performed in primary care (with the exception of community pharmacies), and secondary care. However, the Group proposes that this guidance should be drawn to the attention of community pharmacies and any other private commercial companies performing POCT, with the recommendation that it should apply in those settings as well as in the NHS. The guidance does not cover patients using POCT to self manage their condition.

In addition to considering recently published guidance on POCT, a survey template was developed and distributed through Group members to gather information on the current level
of POCT across NHS Boards. The template (see Annex B) included specific questions on
the clinical areas and sites where POCT is being delivered, and whether the Board has an
overarching POCT Advisory Group or Committee. The Working Group was particularly
keen to learn what governance arrangements are in place to oversee POCT services, and
whether relevant laboratory disciplines were fully involved in these arrangements. In
addition, the survey asked Boards to undertake some “horizon scanning” in terms of new
POCT services being proposed. The information from the survey was supplemented by
further individual comments received from the field.

The survey returns (see summary at Annex C) from Boards, combined with the personal
experience of Working Group members, indicate that POCT is being provided in all NHS
Board areas, across a raft of clinical disciplines, and in various settings in general practice
and acute care. New technological developments and applications mean that POCT use will
continue to increase year on year, highlighting the need to develop and apply a proper
clinical governance framework for the use of these tests. The Working Group acknowledges
that some Boards already have well developed oversight arrangements in place for POCT,
but is concerned that in the majority of Boards, formal governance of POCT is either non-
existent or at a very early stage of development.

The key aims of this report are to:

- Describe current provision and governance of POCT in NHSScotland and “horizon
  scan” future needs.

- Make recommendations for future governance and quality assurance arrangements
  for NHS POCT services, taking account of existing guidance and standards, and any
  relevant regulatory and legal requirements in this area.
CHAPTER 2 - GENERAL ISSUES RELATING TO POCT

POCT has a number of potential associated advantages and disadvantages (see Box A)

<table>
<thead>
<tr>
<th>Box A</th>
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<tbody>
<tr>
<td><strong>Advantages and Disadvantages of POCT</strong></td>
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<tr>
<td><strong>Potential Advantages:</strong></td>
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<tr>
<td>• Improved access, particularly in remote areas, or for specific patient groups (eg the elderly)</td>
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<td>• More rapid turnaround times</td>
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<td>• Improved monitoring of conditions where frequent testing is required (eg diabetes)</td>
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<td>• Reduced clinic visits, with possible associated reduction in costs</td>
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<td>• Improved patient experience – (eg testing can be undertaken outwith core laboratory hours)</td>
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<td>• The ability to provide testing for infection to groups who would not attend conventional NHS clinics or hospital settings</td>
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<tr>
<td><strong>Potential Disadvantages:</strong></td>
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<tr>
<td>• Wide availability leading to potentially unnecessary or inappropriate testing</td>
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<td>• Duplication of effort through repeat testing in laboratory setting</td>
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<tr>
<td>• Poor quality of analyses and lack of result interpretation</td>
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<td>• Incompatibility with laboratory results (eg due to different methods and reference ranges)</td>
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<td>• Data recording/storage issues resulting in poor record keeping</td>
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<tr>
<td>• Consumables generally more expensive than laboratory based provision</td>
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<tr>
<td>• Legal/Health and Safety considerations</td>
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<tr>
<td>• Patient issues – anxiety, lack of understanding, and failure of delivery of follow-up information</td>
</tr>
<tr>
<td>• Potential problems in capturing data required for surveillance purposes or Public Health Act notification if patients do not have follow-up laboratory testing following a positive POCT</td>
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</tbody>
</table>
Legal Responsibilities

From the above, it is clear that while POCT may be more “person centred”, misuse of this kind of testing may result in a less safe, less effective and less efficient use of NHS resources. In addition, poor use of POCT which ends up with the wrong result(s) may have medicolegal implications. Laboratory staff are well aware that under the Consumer Protection Act (1987), use of instruments for purposes for which they are not intended results in liability transferring from the manufacturer to the user. Non-laboratory staff conducting POCT are quite likely to be unaware of this potential liability. Individual users of POCT, be they in primary or secondary care, need to recognise that they have a legal responsibility for the results that they produce. Box B is a Case Study taken from the MHRA Device Bulletin on the “Management and Use of IVD Point of Care Test Devices”\(^3\). This illustrates the potential legal liability to which individual users can expose themselves if they do not follow the manufacturer’s instructions for use.

Box B

Case Study
A known diabetic was admitted to a hospital intensive care unit and was on a complex regimen of treatments for a number of conditions. The patient’s blood glucose was measured at the point of care using a blood glucose meter. A high result indicated hyperglycaemia and insulin treatment was initiated. A separate sample sent to the hospital laboratory gave a markedly different result.

A thorough investigation, including a review of the manufacturers’ instructions, by the hospital and the MHRA revealed a number of contra-indications for use for the meter of which the users were unaware. These included that the POCT glucose meter should not be used on patients who were on treatments containing maltose. The patient suffered significant hypoglycaemia and complications because staff were unaware of this limitation.

Key Points

- Users should be aware of the manufacturer’s instructions and contra-indications for use
- Such information should be incorporated into training of all staff using such a device
- In this case, the device itself was not faulty, but was used contrary to the manufacturer’s recommendations
- The MHRA does not seek to apportion blame but instead to advise others on how to avoid similar problems
Health and Safety

Allied to the legal responsibilities are those relating to health and safety, which in Scotland are governed by the NHSScotland Code of Practice for the Local Management of Hygiene and Healthcare Associated Infection (2004), and Quality Improvement Scotland (now Healthcare Improvement Scotland) Standards on Healthcare Associated Infection. These were updated in March 2008 and are used by the Healthcare Environment Inspectorate in their assessments of NHS Boards. This underlines the need for POCT users and managers to give serious consideration to issues such as

- Standard (universal) infection control procedures
- Measures to prevent occupational exposure to blood borne viruses
- Measures to prevent cross infection between patients
- Safe handling and disposal of body fluids outwith the laboratory setting

Quality Assurance

Users must also recognise that Quality Assurance is an essential component of POCT, which encompasses proper training of those undertaking the test, and audit of overall performance. Quality Assurance consists of 2 elements – internal quality control and external quality assessment – which can help to ensure reliable results, but only when applied rigorously.

Internal quality control (IQC) means testing one or more samples (usually non-biological) which have known values or target ranges. This allows the user to be confident that the analytical system is performing to specification before it is used to test patient samples. It also allows users to assess the day-to-day precision of the system when results are compared over a period of time. Many manufacturers of POCT devices will provide solutions which can be used for IQC. If this is not the case, the local clinical laboratory will be able to advise on where appropriate IQC solutions can be obtained. In the context of quantitative POCT (mainly biochemistry and haematology) at least one IQC sample should be tested BEFORE patient samples are tested, and if the device is used every day, IQC should be performed as part of the daily routine. In situations where the POCT is qualitative (e.g. microbiology and virology) and where material for IQC is available, the minimum requirement is to follow the test manufacturer’s instructions.

External quality assessment (EQA) involves a number of users of similar devices testing a sample of unknown value which is circulated by the EQA scheme organiser. This allows the analytical system to be tested for bias and accuracy compared with users of similar devices, and may allow for comparison of performance of different methods used to measure the same analyte. EQA samples are circulated to users on a regular basis (often monthly) and the user is asked to analyse the sample in the same way as they would a patient sample and return the result to the scheme organiser. The EQA scheme may be organised on a local or a national basis, and the scheme organiser may be a local or distant clinical laboratory, or the device manufacturers themselves. Again, the local clinical laboratory will be able to advise on how POCT users can access an appropriate EQA scheme. However it should be noted that an EQA scheme is not available for every analyte which is measured as a point-of-care test.
The performance of IQC for POCT is mandatory when it is possible to do so, as is participation in an EQA scheme where one is available. If users are unsure how to perform IQC or how to access EQA schemes, advice should be obtained from the local clinical laboratory.

**Data Recording**

The Working Group identified a number of potential problems relating to recording and storage of POCT results. Users need to agree a minimum dataset (see Box C for suggested dataset) to be recorded. This should include user identity linked to a GMC or nursing registration number where relevant to identify the user, who should be a healthcare professional (a CPA requirement). CPA also requires that POCT results should be recorded in the patient’s medical record (Standard G2). In situations where there is a lack of concordance between POCT and laboratory results (i.e., the same investigation done by different methods), the potential for confusion on the part of both clinician and patients is obvious. Therefore POCT and laboratory tests should be specifically identified within IT systems. This also enables the often significant amount of quality control, training logs and access control data to be managed and stored on the relevant POCT system, with only the minimum dataset being required for the patient’s medical record.

Wherever possible POCT devices should be linked via a bi-directional interface to the LIMS (Laboratory Information Management System) and/or EPR (electronic patient record), to ensure good data quality and clinical governance, and to provide information for surveillance and Public Health Act purposes. The workload and costs associated with the data recording aspects of POCT testing should not be underestimated when evaluating whether or not to use a POCT test.
Box C

POCT – Suggested Minimum Dataset

- Patient CHI Number or other unique patient identifier
- Patient Name (given name and surname)
- Patient Date of Birth
- Patient Gender
- Test Date/Time
- Test Result(s) and units
- Test Reference Range/Interpretation (eg positive/negative)
- User identity linked to GMC/Nursing/HPC Registration Number where appropriate

Ethical Issues

The Working Group was keen to explore the potential ethical issues associated with point of care testing, and commissioned a paper on the subject (see Annex D) from Ian Donald, the patient representative on the Group. This covers the general issues of consent; the application of results; risks; and confidentiality. It also gives deeper consideration to patient centred issues such as informing the patient of test results; patient anxiety; convenience; confidence in the tester; and provision of follow-up information.
CHAPTER 3 - RECOMMENDATIONS

Safe and effective delivery of POCT is a clinical governance issue. However advanced and sophisticated the technology being applied, POCT cannot be implemented successfully in the absence of effective organisational and management arrangements. These should be part of and fully integrated with Boards’ overall risk management frameworks. An overarching POCT Committee should be established at Board level. In larger Boards it is likely that POCT sub-groups will be needed to cover the interests of particular geographical areas/hospital sites. These should report to the POCT Committee, which in turn should have a reporting line which leads ultimately to the Board Clinical Governance Committee or equivalent. Laboratory support should be in place to manage the introduction of any new POCT and an appropriate senior professional should be identified to act as POCT Coordinator (or Lead) for that service. This individual will have overall responsibility for the POCT service in question, from the beginning of the development process. Lines of accountability should be clearly defined in local policy documents.

Inevitably many people will be involved in the development, implementation and management of a POCT service. The advice of the relevant national Managed Diagnostic Network (these are currently in existence for pathology, microbiology/virology, and clinical biochemistry), may be useful, particularly at the service development stage.

Before any POCT service is considered, it is vital that the clinical need is clearly identified and articulated in a supporting Business Case. This should be comprehensive, covering all direct and indirect costs, including those of laboratory involvement in the establishment of POCT in areas outwith their normal sphere of responsibility eg primary care (but not excluding secondary care POCT services). (See the NHS Greater Glasgow and Clyde check list which is relevant in this context.) Laboratories will need to be appropriately supported and resourced in order to carry out this work.

Conclusion and Summary of Recommendations

As already stated, safe and effective delivery of POCT is a clinical governance issue. In order to make a reality of this statement, the Working Group makes the following recommendations for implementation by NHS Boards:

Recommendation 1

An overarching POCT Committee, fully integrated with Boards’ overall risk management and clinical governance frameworks, should be established at Board level, with appropriate sub groups as required, depending on the geographical areas/sites covered.

Recommendation 2

Before the establishment of any new POCT service, the clinical need should be clearly identified and articulated in the supporting Business Case, which needs to be comprehensive, covering all direct and indirect costs.
Recommendation 3

Laboratory advice and support should be available from the outset and documented procedures covering the following areas should be developed once agreement has been reached on the establishment of a given POCT service:

- Training (and retraining) of staff and testing of competence
- Instructions for use
- Standard operating procedures (SOPs)
- Health and safety
- Quality assurance
- Maintenance
- Accreditation
- Record-keeping
- Audit
- Adverse incident reporting
- Appropriate recording of data for surveillance and Public Health Act purposes

Recommendation 4

NHS Boards should consider undertaking a comprehensive audit to identify all POCT being undertaken in their area to determine the degree of regulation being applied to the introduction and maintenance of these services, and the value for money which they offer.

After setting up a new service providers should consider surveying users and patients to assess their satisfaction with it.

NHS Greater Glasgow and Clyde Point of Care Testing policy is included at Annex E. The development of this policy involved a large number of professionals and management staff over a prolonged period of time. Boards which are at an earlier stage in developing POCT policy may find this document helpful in that process.
REFERENCES

2. Guidelines on Point of Care Testing. The Royal College of Pathologists: March 2004
5. Institute of Biomedical Science, Point of Care Testing (Near-Patient Testing) Guidance on the Involvement of the Clinical Laboratory IBMS Professional Guidance www.ibms.org/publications
MEMBERSHIP

Chairman
Dr Alan Hutchison Consultant Clinical Biochemist, Southern General Hospital, NHS Greater Glasgow & Clyde

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Mr Ian Donald Patient Representative
Mr Frank Finlay Consultant Clinical Scientist, South Glasgow Biochemistry, NHS Greater Glasgow & Clyde
Mr Ian Gilbert Laboratory Manager, Western Isles Hospital, NHS Western Isles
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Mr Ewan McGregor Senior Biomedical Scientist, Haematology Laboratory, Ninewells Hospital, NHS Tayside
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Mr Hasmukh Pankhania Head of Laboratory and Diagnostic Services, NHS Orkney
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Dr Campbell Tait Consultant Haematologist, Department of Haematology, Royal Infirmary, NHS Greater Glasgow & Clyde

Officers
Dr Aileen Keel CBE Deputy Chief Medical Officer
Mr Andrew Smith POCT Secretariat
Remit

To consider other recently published reports in this area and provide key recommendations to SMASAC on the standards required for the use of POCT in primary and secondary care in NHSScotland.

Terms of Reference:

- To assess the degree of need for POCT currently, and “horizon scan” future need.
- To advise on what governance and quality assurance arrangements need to be in place, taking account of appropriate structures and standards for the management of POCT.
- To advise on the training, education and competencies required to carry out POCT.
- To advise on any implications for patient safety and the quality of care, in relation to NHSScotland’s Quality Strategy. This will include taking account of relevant regulatory processes and standards.
- To advise on the potential impact of POCT to e-Health, with specific reference to links to the electronic patient record.
- To make recommendations on the criteria to be used in assessing both the clinical and cost effectiveness of current and potential POCT.
Q1
Please list the clinical (specialty) areas and sites (primary or secondary care) where POCT is being delivered in your Board area.

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<tr>
<th>Clinical Area</th>
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Q2
Does your board have an overarching POCT advisory group / committee?

Q3
Please describe the governance arrangements which are in place to oversee POCT services in your Board area. Are relevant laboratory disciplines fully involved in these arrangements?

Q4
In cases where a new POCT service is proposed, are relevant laboratory disciplines involved in developing the required business?
### POCT SURVEY RESULTS JANUARY 2011

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"WHERE POSSIBLE" and "SHOULD BE" should be clarified.
ETHICAL ISSUES RELATING TO POINT-OF-CARE TESTING

Principal Ethical Issues

The working group has considered the principal ethical issues from the point of view of the users of healthcare services – patients, their carers, and families. There is general agreement under the following topics:-

Consent

For a patient to give informed consent it would be essential to ensure that the patient has a clear understanding of the reason that the test is suggested, which is something rather more than simple information upon its purpose. The purpose of a test might be to obtain a numeric result, but beyond that the test would then inform treatment options. For example, a patient presenting with symptoms which suggest Type 2 diabetes might have a blood glucose test, the purpose of which is to obtain a measure of blood glucose, but beyond that it might inform those involved in the diagnosis about treatment options, which could be as simple as diet and exercise, or might involve drug therapy for the remainder of the patient’s lifetime.

The working group recognise that in many cases the point-of-care test could represent a life changing experience for the patient concerned. Often a point-of-care test will not involve a new diagnosis, but in those cases where a new diagnosis is involved the practitioner should be aware of not simply the need to conduct the test to obtain a result, but also to have an understanding of the needs of the patient in the light of a diagnosis.

The working group considers that the practitioner, as well as the patient, would benefit from a short explanation from the practitioner to the patient about the test and its implications.

The working group does not consider that it will be necessary in every case to have the patient’s written consent for non-invasive testing, but a code of practice should be followed, and if universally adopted would provide protection to the practitioner as well as benefit to the patient.

Accuracy

The practitioner should have to hand, and be familiar with the degree of accuracy that will attach to the result of the test to be undertaken. Is there, for example, any room for false positives/false negatives? If so, what are the probabilities of such outcomes? If the patient receives a result which indicates a diagnosis is there any room for doubt? What follow on testing might be required to confirm a diagnosis? How long will it be before a confirming diagnosis test can be carried out?
Application of Results

The practitioner should be aware of the treatment options which will be indicated by the result of the test undertaken. Often the test might be required simply to confirm a diagnosis. Such testing with a high degree of reliability would then lead to a care pathway which the practitioner should be able to outline.

In cases where a test is inconclusive, or where the treatment options might require a more experienced practitioner’s opinion, then the patient should be made aware of the need for further interpretation, re-testing, or an alternative test which might be more accurate.

It is essential to avoid the patient interview being concluded without the patient completely understanding what the test has indicated, and what will happen next.

Risks

The practitioner should make perfectly clear to the patient the risks (if any) attaching to the test. A point-of-care test is not thought likely to involve any significant degree of risk, but there may be some cultural/religious implications arising out of the test process.

A practitioner should consider whether or not the particular patient might consider the test to be uncomfortable or painful. In the case of tests which have a duration of effect beyond the consultation the patient must be given, in advance, clear information about the effects of the test. For example, retinal screening will usually involve pupil dilation which will mean that the patient will be advised not to drive until the effects have dissipated. Additionally, a test which requires any preparation on the part of the patient should be accompanied by an information leaflet or a letter, providing clear information about the extent to which the patient needs to prepare for the test to avoid a misleading result.

Tests involving urine sampling might require the provision of a suitable receptacle, and instructions on use.

Confidentiality

In some conditions which have a social context the patient might be concerned about confidentiality, and whilst the working group feel that there is a high degree of confidence amongst patients in respect of confidentiality, where there is a wider public health interest the patient will wish to know that the results of tests will be kept in a confidential file to which only authorised healthcare staff would have access. Practitioners should not assume that will be understood by patients.

Is the test proposed particular to the needs of the patient, and will it inform treatment options? If the test is primarily intended to improve information about this disease/condition in the general population, then it should be made clear to the patient that this is the reason the test is being carried out.

Not all tests will be obviously medical; there might be, for example, a need for the practitioner to consider some psychological profiling. At its most basic level the patient questionnaire handed out at a general practitioner’s surgery might be regarded by some
patients as a point-of-care test, and in all such cases the purpose of the questionnaire/results of responses should remain either confidential or anonymised.

**Patient-Centred Issues**

**Information**

The practitioner should consider how the result of the test is to be given to the patient. Where there is printed guidance upon the meaning of the result then the practitioner should ensure that stocks are maintained to guarantee that the patient obtains information about the condition which has just been tested for. Will the patient receive a written confirmation of test results, and if so how long might the interval be before the results are made available?

The working group considers that in every case the practitioner conducting a test which will indicate a diagnosis should have available printed information to supply to the patient.

**Anxiety**

The practitioner who is to conduct the test should be prepared to deal with a patient displaying more than usual levels of anxiety. This might often be disease specific. In extreme cases is the practitioner aware of an alternative testing method that might be appropriate, and is the practitioner aware of those methods? Once the test has been conducted the practitioner should also be prepared to deal with questions about the interpretation of the test, and the anxiety that the patient will have should a diagnosis be confirmed.

Should a patient fail to attend an appointment made for a point-of-care test then a practitioner should consider whether or not that might be attributed to anxiety, and have available a routine to ensure that any tests necessary for treatment options can be conducted, thus preventing the patient avoiding necessary tests for any extended period.

**Convenience**

In cases where the patient might require to attend for more than one particular test the practitioner should consider how testing appointments might be arranged within a single visit to the clinic/hospital. Whilst the working group recognise that this might already be routine best practice, the practitioner should consider difficulties that might be experienced by the patient in attending an appointment for a test, and if there is a series of tests involved the practitioner should discuss beforehand with the patient what times would be suitable and involve the least inconvenience. Accommodating a patient’s work pattern/shift arrangements/childcare requirements wherever possible would assist in efficient use of practitioner time and resources.

**Confidence in Tester**

The practitioner should ensure that he/she has an acceptable competence in the testing process/equipment. The patient should be confident in the practitioner’s ability to conduct the test to ensure that there is confidence in its result. Peer review of practitioner competence should be mandatory.
Any introduction of new equipment/processes in a point-of-care testing setting should be preceded by necessary training of practitioners before the change occurs, to guarantee reliability in the test results, and assist patient confidence that the test has given the correct result.

**Follow-Up Information**

The practitioner should be prepared to deal with enquiries from patients and their carers about what will happen next. Whilst the provision of information available to be given to the patient at the testing appointment will give general guidance, the patient will wish to know the timetable of treatment options that might be indicated by the result of the test, where that treatment might be provided, and by whom.

The nature of the follow-up information will vary between conditions (acute/long term, etc), but the practitioner should ensure that the patient will leave the consultation at which the point-of-care test has been conducted with a clear understanding of what will happen next.
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 [eg 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 guidelines1,4, 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 document5, 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.

Examples of lines and strengths of support & responsibilities

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 result 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.

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 (eg 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 Template7.

**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.
ANNEX E

References

1. Management and use of IVD Point of Care Test Devices. Medical Devices Agency or MHRA DB2010(02) February 2010

2. Additional Standards for Point-of-Care testing (POCT) facilities. PD-LAB-POCT Additional Standards v1.00 Apr 10. CPA (UK) Ltd., 2010


4. Guidelines on point-of-care testing. The Royal College of Pathologists 2004

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


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

## MANAGEMENT AND ORGANISATION OF THIS POCT SERVICE

1. **There is a training policy & manual which will include:**
   - Name of designated trainer(s)
   - Details of training programme, including
     - The context and clinical utility of the POCT service
     - The analytical principles of the POCT system
     - Sample collection and handling
     - Reagent storage
     - Quality Control
     - Infection Control
     - Limitations of the Measuring Systems
     - Response to results outside predetermined limits
     - Documentation and reporting of results
   - Details of competency assessment
   - List of trained staff
   - Details of frequency and extent of training updates for staff

2. **There is a comprehensive Standard Operating Procedure (SOP) which will detail:**
   - Instructions for use of device (as per manufacturers guidance)
   - Summary of analytical principle of the device
   - Guidance on which patients should be tested and when
   - Specimen requirements
   - Limitations of device / analysis
   - Simple guidance on results acceptance, interpretation & action
   - Instructions for results documentation
   - Guidance on health & safety issues for the operator, to include details of COSHH (Control of Substances Hazardous to Health) and arrangements for disposal of waste reagent and clinical material
   - There is a documented procedure for decontamination / cleaning of equipment
   - All Infection Control risks & issues are addressed
   - Simple guidance on troubleshooting and contact details for advice
   - Details of agreed maintenance schedule

3. **There is a QA policy, which will include:**
   - Details of IQC requirements and actions required when IQC lies out-with designated limits
   - Details of EQA arrangements
   - Details of regular QA audit, and the individual(s) responsible for monitoring against the QA policy
   - Advice on the reporting of adverse incidents through the routine hospital system and to the Medicines & Healthcare products Regulatory Agency (MHRA) where a device shortcoming has been identified

4. **Record keeping.**
   - **a) Each device has a maintenance log detailing**
     - Date of equipment acquisition
• Appropriate safety checks (e.g. PAT testing)
• Results of any pre-installation, or subsequent, validation exercise
• Any relevant service/maintenance contract
• Results of calibration exercises
• Equipment failure & service/repair details

b) There is complete and confidential documentation of all analyses, to include:
• Date of test
• Identity of device
• Batch number of reagent (if applicable)
• Result obtained
• Identity of operator (for patient & QC samples)
• Identity of patient

(not all the above information need be stored in the same format/file/location)

c) Patient results are recorded in their medical record (i.e. secure hard copy medical case sheet or recognised electronic equivalent) and are distinguishable from results of the same analyte reported by the laboratory (i.e. by non-POCT methods).

d) IQC and EQA data are recorded and reviewed regularly