Guidelines for point-of-care testing: haematology

Summary

This guideline provides a framework for the arrangement of point-of-care testing (POCT) services, previously known as near patient testing (patient self-testing not covered). POCT is defined as any analytical test performed outside the laboratory. Primary users are often non-laboratory healthcare workers. The guidance applies to units within hospitals as well as general practitioner surgeries, community clinics and pharmacies. The head of the haematology laboratory or a point of care coordinator must take responsibility for all aspects of the POCT service, including quality and training. Depending on the size and nature of the POCT practice, a local POCT manager may also be required. Equipment selected should have received a successful independent performance evaluation. If an independent evaluation has not been performed the purchaser should assess the device according to the protocol in this document. POCT devices should generate results that are comparable to those of the local laboratory. An accredited external quality assessment programme and internal quality control system must be established. Manufacturers promoting POCT devices designed for non-laboratory sites, e.g. pharmacies, should undertake training and annual competency assessment, perhaps using a web-based system. A diagram to illustrate the stages for the implementation of a POCT service is illustrated.

Keywords: point-of-care testing, point-of-care committee, accreditation, external quality assurance, instrument evaluation.

The purpose of these guidelines is to provide a framework for the proposal of appropriate local arrangements for point-of-care testing (POCT) and to protect patients and staff. The guideline provides information and suggestions for good laboratory practice and for producing reliable results, regardless of where the test is performed. POCT may be defined as any analytical test performed for a patient by a healthcare worker outside the laboratory setting. This document is an update to the British Committee for Standards in Haematology (BCSH) guideline for Near Patient Testing: haematology (England et al., 1995) and embodies the philosophy agreed by the Joint Working Group (JWG) (1999) on Quality Assurance, the national standards required for clinical pathology accreditation (Clinical Pathology Accreditation (CPA) (UK) Ltd, 2007, revised Burnett et al., 2002) and the International Standards Organisation (ISO) POCT requirements for quality and competence (International Standard Organisation, ISO, 2004a). There have been several evaluations carried out on the views of general practitioners (GPs) to POCT and quality control procedures (England et al., 1995; Murray & Fitzmaurice, 1998). GPs do not always find POCT a useful addition to their resources and the challenges presented by community environments may mean that it is more difficult to adequately address all quality control issues (Department of Health, 1987; Hilton et al., 1994). Other important factors for consideration are the efficacy of the procedures being undertaken, medico-legal and safety aspects. As well as clear clinical procedural protocols, it is also essential that clear clinical guidelines to guard or gate keep access to POCT tests are in place. This is because any inadequacy in such protocols or guidelines for POCT is likely to lead to significantly increased activity in test usage for no clinical gain. Not only will the POCT then not provide "value for money" for the commissioners, but more importantly patients may have inappropriate tests and as a result find themselves subjected to further costly tests which may even carry a morbidity risk.

Recent advances in technology have made it possible to move laboratory tests closer to the patient. POCT is intended to provide a more rapid service than can be achieved in the hospital laboratory. There are a number of National Health Service (NHS) initiatives in England that are centred around high street testing (Wieringa, 2005a,b). The growth of POCT over the last 5 years, both within and outside the hospital, has been substantial. There is good evidence that implementation of POCT in UK NHS Trusts can result in dramatic improvements in turn around time and contribute to meeting government waiting time targets (Leman et al., 2004).

Scope

POCT refers to any testing performed outside the hospital laboratory. The scope of these guidelines relates to the management philosophy of POCT, the venues where POCT may be undertaken, the range of tests, the qualifications of the personnel involved and the timeliness of the service. Other aspects discussed in this guideline are initiation of the service, training, equipment, results, monitoring of quality, accreditation, safety and cost. The guidelines focus on the delivery of an on-site service within a hospital environment, e.g. an intensive-care unit. The guidelines do not specifically encompass...
community testing, however, much of the information could be applied to these other POCT sites and they should be encouraged to adhere to the guidelines as far as possible. Specific and detailed POCT guidelines for haemostasis are being prepared for BCSH in a separate document (Mackie I, 2006, personal communication). BCSH guidelines on patient self-testing and self-management of oral anticoagulation are already available (Fitzmaurice et al, 2005). Sites for POCT could include:

1. intensive care units,
2. accident and emergency departments,
3. operating theatres,
4. renal dialysis units,
5. neonatal units,
6. out-patient departments,
7. research laboratories (undertaking clinical tests),
8. general practitioners’ surgeries and health centres,
9. independent treatment centres,
10. pharmacies,
11. in the home of patients in primary care,

Other non-accredited commercial institutions may also wish to avail themselves of the professional expertise available in the CPA accredited clinical laboratories.

The new community pharmacy contractual framework from the Department of Health introduced in 2005 (http://www.dh.gov.uk/en/Publicationsandstatistics/) is very pertinent in that it will provide opportunities for what is considered to be an underused resource in the NHS. Numerous pharmacy located schemes have already been established across the UK and this will integrate and enhance the contribution of pharmacies to managing the increasing demands for healthcare placed on general practice. Six million people visit a pharmacy every day and there is clearly scope for pharmacists to both develop and deliver local POCT services. The Royal Pharmaceutical Society of Great Britain has published guidelines for testing body fluids (The Royal Pharmaceutical Society of Great Britain 2003); these cover training, identification of suitable areas and facilities for POCT, quality assurance, referral criteria and pathways, insurance, consent, health and safety and data protection.

Range of equipment and tests

Full blood counts/haemoglobin concentration

There are two types of technology to support POCT, small bench top analysers and hand-held devices. The bench top systems are often smaller versions of laboratory analysers providing a full blood count (FBC) with red cell indices and either a 5-part white cell differential or a partial 3-part differential. The bench top analysers are equipped with automated calibration and quality control; however they may be too large for use at the patient’s bedside and are designed for use in clinics or small laboratories. Most bench top analysers have the ability to generate flags in the presence of abnormal cells or interfering substances; however the range of alert flags available on these instruments is limited and their sensitivity and specificity may not be as good as those on the main laboratory haematology analysers. For blood counts, it is strongly recommended that near-patient investigators use only instrumentation that employs primary sampling (automated systems) and do not use instrumentation that involves dilution of whole blood in the pre-analytical phase (semi-automated systems). The most widely used test using a hand-held device is the measurement of haemoglobin concentration, but a device that utilizes a disposable cartridge has recently been introduced that measures haemoglobin, leucocytes and a three-part differential on capillary blood. Table I lists examples of currently available haematology and coagulation tests suitable for POCT; the range of equipment will inevitably expand.

Coagulation tests

POCT methods for prothrombin time (PT) and activated partial thromboplastin time (APPT) may be performed by semi-automated and fully automated, self-contained systems (Table I). The former approach typically uses mechanical coagulation end-point detection; although a turbidometric method is also available. They require pipetting of the test sample and reagents into disposable plastic cups. These systems usually require citrated plasma, which must be

<table>
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<tr>
<td><strong>Haematology</strong></td>
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<tr>
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<tr>
<td>5-part differential</td>
</tr>
<tr>
<td>3-part differential; granulocytes, lymphocytes and monocytes or neutrophils, lymphocytes and mixed cell (monocytes, eosinophils and basophils) counts</td>
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<tr>
<td>Leucocyte count, haemoglobin concentration and 3-part differential</td>
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<td><strong>Coagulation</strong></td>
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<td>PT, INR, APPT, Thrombin time</td>
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<td>Tests to monitor Low Molecular Weight Heparin Platelet factor 4 heparin antibodies (heparin-induced thrombocytopenia) Thrombelastography/Thrombelastometry (clotting time, rate of clot formation, tensile strength of clot, clot lysis rate)</td>
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<td>d-dimer</td>
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FBC, full blood count; PT, prothrombin time; INR, International Normalized Ratio; APPT, activated partial thromboplastin time.
platelet poor, requiring centrifugation at 2000 g for 15 min. Users should be aware that the citrate concentration and type of blood collection tube might influence the International Normalized Ratio (INR) value (van den Besselaar et al, 2000).

The majority of POCT users perform the PT for anticoagulant control, using analysers where the reagent system is enclosed in a disposable test strip, cuvette, or cartridge and blood is applied to a sample reservoir. These devices often have a built in internal quality control (IQC) system and are most often used with non-anticoagulated capillary blood. Some systems are available that can use venous blood, citrated blood or citrated plasma. These devices use a variety of coagulation end-point detection methods. Some methods are available for APTT, thrombin time and activated clotting time, but these are end-point detection methods. Some methods are available for a built in internal quality control (IQC) system and are most often used with non-anticoagulated capillary blood. Some systems are available that can use venous blood, citrated blood or citrated plasma. These devices use a variety of coagulation end-point detection methods. Some methods are available for APTT, thrombin time and activated clotting time, but these are end-point detection methods. Some methods are available for

\( \text{n-dimer tests} \)

Several devices are available for \( n \)-dimer measurement that can be used in a POCT setting. These devices were originally intended for the measurement of \( n \)-dimer levels as an indicator of increased fibrinolysis and disseminated intravascular coagulation, but some are claimed to be suitable for the negative prediction of deep vein thrombosis (DVT). The manufacturer’s intended purpose should be examined in detail before using these devices for any particular clinical purpose. Reagent- and analyser-specific normal reference ranges and clinical cut-off values must be used. When used for the exclusion of DVT, \( n \)-dimer methods should be combined with clinical assessment of pre-test probability and should have a negative predictive value equivalent to that of established methods of detecting proximal DVT, i.e. >98% (BCSH Guidelines, Keeling et al, 2004).

\( \text{Blood gas analysers} \)

The use of blood gas analysers that use conductivity for the measurement of haemoglobin concentration or haematocrit is not recommended due to reported differences in values when compared to laboratory analysers (McNulty et al, 1995) with discrepancies of up 20 g/l for haemoglobin and 4% for haematocrit occurring when the plasma protein is low (Hopfer et al, 2004). A downward bias has been demonstrated when the haemtocrit value is below 30% (al-Odeh et al, 1994; Steinfelder-Visscher et al, 2006). Reproducibility of results for the haematocrit has also been demonstrated to be poor with a co-efficient of variation of 21% (Papadea et al, 2002). For analysers that use spectrophotometric/co-oximetry to measure haemoglobin results have been demonstrated to compare well with the laboratory (Hinds et al, 2007), but these instruments should only be used if there is appropriate IQC and external quality assessment (EQA) available.

\( \text{HbA1c} \)

Some HbA1c POCT instrument manufacturers claim that the HbA1c results are not affected by the presence of Haemoglobin S in the heterozygous state or in combination with beta-thalassaemia. However several studies (Kosecki et al, 2005; Haliassos et al, 2006) have reported discrepant HbA1c results in some cases of haemoglobinopathy, thus HbA1c results from patients with haemoglobinopathies should be interpreted with caution when tested using some POCT instruments. Patients who may have a haemoglobinopathy and who require HbA1c measurements should be investigated for variant haemoglobins by an accredited laboratory.

\( \text{Philosophy} \)

The aim is to provide a safe and efficient service for patients, which also ensures staff safety. This should be achieved by close co-operation between the haematology laboratory and the service. There is a need for a carefully drafted service level agreement (SLA) that defines operational details, including the staff involved and the time for which support is available. The agreement must cover what is to be done with abnormal results, and what is to be done in the out of hours situation.

\( \text{Management} \)

While the hospital staff may understand the day-to-day operation and provision of results, the professional head of the supervising laboratory must take responsibility for all aspects of this service, after discussion with the clinicians concerned. In smaller sites, an individual POCT coordinator may be responsible (http://www.ihbs.org/pdf/point_of_care_testing.pdf) but a committee structure is preferable for larger institutions. Any POCT coordinator should be accountable to the professional head of the supervising laboratory. Documents published by various accreditation and regulatory agencies propose that an interdisciplinary committee be constituted at any site performing POCT (Medical Devices Agency 2002; International Standard organisation, ISO, 2004a). The committee should be multidisciplinary to include all stakeholders such as:

- Clinical staff representatives
- Laboratory staff representatives
- Nursing staff representatives
- Quality manager (pathology staff member)
- Training officer (pathology staff member)
- Finance representative
- POCT Co-ordinator.

If the POCT extends to the community, a representative from the primary care sector should also be included. This could be a GP or practice nurse and if pharmacies are to be used as community sites then a clinical pharmacist should also be involved. The committee is responsible for the overseeing of selection and procurement of the most
appropriate equipment for the task in hand, assessment of the infrastructure of the on-site environment, which must meet basic laboratory standards. The group should also be responsible for implementation, monitoring and audit of process-related protocols that shall cover all aspects of the institution’s POCT programme. Appendix 2 graphically demonstrates the role of the Point of care committee in the setting up, running and monitoring of the service. The POCT co-ordinator is defined as the person responsible for the POCT clinical service and should be aware of their responsibility for clinical governance (Department of Health 1999; Gray, 2000; Freedman, 2002) and the medico-legal implications of reporting an erroneous result. Clinical governance is defined as a framework through which organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish. Clinical governance is the responsibility of the institution and this responsibility also devolves onto the POCT committee. Accountability and leadership are crucial in the implementation of clinical governance and the onus is on laboratories to take the lead for POCT and ensure that there is a risk management strategy to protect both the patient and staff. For a high quality POCT service to be delivered, fulfilling the requirements of clinical governance, a multidisciplinary local group must be established with recognized accountability, appropriate resources and, importantly, management support. The committee should appoint a person with appropriate training and experience as quality manager for POCT quality. A quality manual should be prepared and requirements related to POCT reviewed (International Standard organisation, ISO, 2004a). Standard operating procedures (SOPs) must be written and signed by a designated member of the POCT committee; these SOPs must be published with a future review date and must be regularly reviewed.

They should include details of procedures relating to:

1. Service performance
2. Information on actions to be taken on the basis of results
3. Information on action to be taken in the event of a fault on the instrument, including the reporting of adverse incidents to the Medicines and Healthcare products Regulatory Agency (MHRA) (Medical Devices Agency, 2002)
4. Safety regulations recognising potential hazards (HMSO 2002; Department of Health Advisory Committee on Dangerous Pathogens 2003, Health Services Advisory Committee2003)
5. Training of staff, monitoring performance of equipment and handling of results.

Ideally, the coordinator on the POCT committee would be from a CPA-accredited haematology department but this is not always feasible and there may need to be a local POCT manager e.g. in a GP surgery or independent treatment centre. In these circumstances it is essential that the CPA-accredited supporting laboratory would support the local POCT service for the purposes of training, quality assurance and compliance with standards, and provide formal clinical supervision. The commissioners contracting such a service should ensure this arrangement is clearly stated and resourced within the SLA. Competency needs to be assessed as well as certification and ongoing assessment. The supporting laboratory could then accredit the POCT service. The primary care trust, or individual GP surgery, would then be covered by the haematology laboratory clinical governance arrangements. The recent Independent Review of Pathology Services (Lord Carter of Coles 2006) makes very similar recommendations. The management arrangements should be clearly documented, together with appropriate lines of accountability.

Training

Training protocols must be established and all potential operators must achieve an adequate level of competence. The content of the training programme and the knowledge/skill level assessment should be documented in a training manual.

This should include:

1. Sample requirement and specimen collection,
2. Sample preparation,
3. Stability of sample and reagents,
4. Analyte measurement,
5. Maintenance, calibration and cleaning of instruments,
6. Appropriate use of equipment and consequences of inappropriate use,
7. Reporting of results,
8. Knowledge of normal and abnormal results and actions in the event of an abnormal result,
9. Performance of quality control,
10. Documentation of test and quality control results.

Safety

The basic principles of obtaining the correct specimen, sample preparation, analyte measurement, maintenance and calibration of the equipment, appropriate use of the equipment and consequences of inappropriate use, stability of sample and reagents, knowledge of normal and abnormal results, the importance of documentation of IQC, EQA and safety procedures. There should also be an SOP for the reporting and recording of results. Trainees should also be awarded a certificate of competence by the supervising haematology laboratory and a list of authorised users must be drawn up and approved by the head of the central laboratory. Recertification of this ‘competency certificate’ should occur annually. Staff must have a clear understanding that they must not allow others access to tests without undergoing a formal training process. Retraining intervals and a continuing education programme should be established and POCT operator
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performance monitored as part of the quality assurance programme. It may be useful to make trainees aware of the code of conduct for POCT (Council for Professions supplementary to Medicine, 1994; Health Professions Council, 2007). Arrangements must also be in hand for continuing professional development of the staff delivering the service, with regular training updates. Secondment of on-site staff to the supporting laboratories may be an appropriate method of training and continuing staff development.

Equipment selection and implementation

Equipment selected for on-site investigations will ideally have been evaluated by the Centre for Evidence-based Purchasing (CEP), which is part of the Purchase and Supply Agency (or its predecessor, the MHRA), at the Department of Health. Appendix 3 outlines the information needed and methods used for a local operational evaluation of a POCT device. Evaluation reports from 2002 onwards are published on the CEP website (http://www.pasa.nhs.uk/cep). Requests for an instrument/device evaluation can also be submitted via the website. Where there has not been a CEP evaluation a literature search should be undertaken to find independent peer-reviewed evaluations; these should be applicable to UK practice. A detailed specification should be prepared to include the number of samples to be processed, sample preparation requirements, the footprint of the instrument, maintenance requirement, consumables storage, power supply and network ports. A decision on equipment procurement should only be made after evaluation of the options in consultation with the Pathology and Supplies departments. Potential users must ensure that equipment is safe, that results are comparable with those from instruments in the supporting laboratory and that suitable precision is achieved. Advice should be sought from haematology laboratory staff who, in conjunction with the manufacturer of the device, should take responsibility for the initial installation, setting up and calibration of equipment and providing a written SOP for the use of instrument. This should include:

1 Principle of operation,
2 Health and safety requirements,
3 Specimens required, patient sample and request form identification criteria and specimen handling,
4 Preparation of reagents and other materials,
5 Calibration,
6 Quality control procedures,
7 Sample analysis procedures,
8 Reporting of results, including abnormal results,
9 Documentation/transmission of results,
10 Criteria for referral of samples,
11 Limitations of the procedure,
12 Remedial action for instrument problems,
13 Reference values,
14 Specimen storage and stability,
15 Disposal of reagents and materials,
16 Action if instrument is inoperable.

It is also essential that equipment has a preventive maintenance schedule and a service contract, together with a logbook documenting operational details, faults, repairs or other corrective action. Appropriate backup arrangements for equipment must be made.

Reagents should be procured in a cost-effective manner to the clinical unit concerned. A logbook of the shelf life of reagents and batch numbers used must be maintained by on site staff, providing an audit trail in the event of faulty or out of date reagents. In those community sites where the same clinical space is shared by a wide range of clinical staff it is essential that reagent fridges are identified and kept secure so that they cannot be opened by unauthorised persons.

Safety

Risk assessments must be carried out before equipment is commissioned. SOPs must be available for the collection, transportation, processing and disposal of specimens. Advice on the safety of the instrument should be sought from the manufacturer and is usually included in the operator’s manual for the instrument. A safety manual should be available for containment of spillages and a clearly identified policy for containment of ‘high-risk’ samples must be defined. All procedures must conform to the policy for Department of Health Advisory Committee on Dangerous Pathogens (2003). Ideally, specimen analysis should be by closed-vial sampling. Dilution of whole blood in the pre-analytical phase is not recommended in a POCT environment. Staff performing POCT must be aware of the microbiological hazards of samples, the chemical hazards of reagents and the physical or electrical hazards of equipment.

Protocols must also be available for the disinfection and decontamination of equipment and laboratories. Each procedure must have undergone a full control of substances hazardous to health (COSHH) assessment, for example, if cyanide reagents are used in the determination of haemoglobin concentration. All procedures should conform to the appropriate legislation (HMSO 1999; Department of Health 2002; Health Services Advisory Committee, 2003).

The POCT environment should be clean and well lit. Many clinical areas in community clinics are still carpeted and such flooring should be replaced with healthcare-grade hard flooring. Appropriate sink(s) with lever taps must be in place in each clinical room, and in the case of community clinics sited in adapted residential dwellings, it is important to have all proposed areas assessed by the health and safety team of the Trust Estates Department. Any SLA for such a service must make it clear who has responsibility for providing the test environment, and should specify clearly the type of clinical space required.
Documentation and transmission of results

Quality assurance requires that the recording of analytical data is satisfactory. It is essential that the results of tests be documented including the operator identification. For most investigations, for example blood counts, some type of request form would be appropriate and these requests should include the name of requesting practitioner and full patient identity details (full name, medical record number, date of birth, location, date, time). In the absence of appropriate computer systems, results must be documented in a logbook, which also identifies reagent batch Lot numbers and the name of the operator; as well as the Lot numbers of any calibrants and IQC materials. Results must be returned to the clinician in a printed or written format, with appropriate biological reference ranges. The patient’s name, medical record number, date of birth and date and time of analysis must be given on all printed or written results. The POCT results should be permanently stored in the patient’s medical record. All results from POCT should be retained for at least 2 years (The Royal College of Pathologists and Institute of Biomedical Science, 2005) in such a way that they can be linked with other quality assurance data. A system must be in place to ensure that results are comparable with the supporting haematology laboratory results and integrated with these in the case notes of the patient. When computers are available, for example, for order communications systems, POCT results must be integrated with central laboratory results in the clinical computer but their origin should be appropriately identified; the record should distinguish between POCT results and those from the central laboratory (International Standard organisation, ISO, 2004a).

When the POCT analyser is connected to the laboratory information system an expert rules system can be used to determine whether the results can be automatically released or whether further investigations are needed. All results stored on computer systems should be password protected. Instruments connected to the hospital information system must comply with the ISO 11073 document (International Standard organisation, ISO, 2004b). The units used for reporting results must be the same as those in the supporting laboratory.

A system should also be defined where results are validated by satisfactory performance in IQC and EQA schemes. Abnormal results must be appropriately flagged. Moreover, mechanisms must be agreed for appropriate referral to the supporting laboratory of out-of-limits results for further investigation. A SOP for dealing with results that are outside of the normal range must be available. Advice on interpretation and clinical matters must also be readily available from consultant staff in the haematology laboratory.

Quality

The principles of total quality management must be adhered to, beginning with the correct identification of the patient, appropriate test selection, sample collection, analysing and recording the results, interpreting the result correctly, taking appropriate action, documenting all procedures and ending with the integration of results into the patient’s case notes. All aspects of quality should be considered, including personnel, training, equipment, reagents and appropriateness and timeliness of the service. The quality manager is responsible for the design, implementation and operation of quality control that ensures POCT conforms to the quality standards of the central supervising laboratory.

Internal quality control

All trained operators should be involved so that the quality of the analytical team as well as the instrument is monitored. The analysis of control material before analysing patient samples can provide reassurance that the system is working correctly, results of IQC should also be recorded correctly in accordance with standard CPA requirements. Parallel testing of a patient sample may be carried out at the POCT site and the supporting laboratory to confirm comparable results.

The type of IQC and EQA system used in coagulation testing depends on the operating system of the device. Some devices have an electronic QC system, where an electronic device is inserted instead of a test strip and produces a signal that tests the optical/electronic systems and mimics the analysis of a real test sample. Some devices have an integral IQC system, which is performed as part of each test sample analysis. Where available, the manufacturer’s liquid QC materials should be used, to provide verification of performance independent of the device. In the latter case, the target values should be in the appropriate range (e.g., for oral anticoagulation, INR 2–4) and the accepted variability of QC results should reflect the required accuracy (e.g., ±0.5 INR units). IQC should be performed at regular intervals, the frequency of which will be influenced by the nature of the device, pattern of testing and number of tests performed. Where electronic IQC is available, it should be performed each time the monitor is used. Liquid controls should be used at least on a weekly basis and also when there is a new lot number of a test strip, a new delivery of strips, any doubt about the storage condition of strips, or unexpected high or low analytical values. If the IQC result is outside the target range, a new IQC sample should be prepared and tested. If the second result is also out of range, no further clinical tests should be performed on the device until the problem has been identified and corrected.

External quality assessment

QA involves the analysis of samples received from an accredited external source with undisclosed values; this could be from the supervising laboratory itself, from a manufacturer or accredited schemes such as the UK National External Quality Assessment Scheme (UK NEQAS), which is recognised by the Joint Working Group (JWG) (1999) on Quality
Assurance and CPA (UK) Ltd (2004). Results are subject to peer group assessment and statistical analysis to compare results across different sites. All providers of laboratory services have access to a range of EQA schemes and it is expected that both POCT and the supervising laboratory should subscribe to an accredited EQA scheme. Results should be recorded and retained in the same way as IQC. POCT should not be seen as a secondary type of testing service and subjected to less rigorous EQA. Local haematologists should encourage general practitioners and other POCT users to participate in the supervising laboratory’s EQA scheme (where such exists) because POCT results are used for clinical purposes in just the same way as those from the supporting laboratories. Results must be recorded with the date, time and operator identification. They should be retained as long as recommended by The Royal College of Pathologists and Institute of Biomedical Sciences (2005).

For coagulation testing, EQA may be available through UK NEQAS and other accredited bodies, for certain devices, but these EQA samples are not suitable for all methods. Where this difficulty arises, EQA may be achieved by the parallel testing of citrated venous blood samples sent to the host laboratory. Alternatively, the device may be periodically taken to the host laboratory, where capillary blood may be tested on the local device as well as on a similar device residing at the host laboratory (which would itself be controlled by occasional parallel testing of capillary and citrated venous blood samples, using a traditional method). Further information on these approaches is detailed elsewhere (Fitzmaurice et al, 2005).

Internal audit

CPA standards (CPA (UK) Ltd 2007) and International Standard organisation, ISO (2003) will also require evidence that the POCT quality management system is audited and that pre-analytical, analytical and post-analytical processes are audited on a scheduled basis.

Accreditation

The Independent Review of Pathology (Lord Carter of Coles, 2006) was also quite clear in its recommendations for POCT providers to be accredited with a suitable national accreditation process. In addition the requirements to comply with this process should also meet the standards set across the entire healthcare sector by the Health Care Commission (2006), having this independently confirmed the laboratory offers reassurance to users of the services. If it is not possible for the POCT site to undergo CPA accreditation it is highly desirable that the supervising haematology laboratory support and validate the local POCT service and their accreditation application. The haematology laboratory clinical governance would then cover the primary care trust, or individual GP surgery.

Finance

In some circumstances a cost-benefit analysis may need to be undertaken, because it may be that the cost per test of the POCT instrument is higher than the cost of sending the sample to the main laboratory. The overall cost will include the equipment costs (purchase or rental) and service and maintenance contracts. Running costs will include reagents (which may depend on the number of tests per year), quality control material and miscellaneous items, such as lancets, needles and syringes. Administration costs will include troubleshooting, staff training and competency assessment, quality control, the time taken for staff to analyse samples and carry out maintenance and documentation. In addition to assessing the costs of POCT, the benefits (averted costs) must be assessed. The direct and indirect elements of both costs and benefits must be assessed for the local health economy rather than just from the perspective of the laboratory. Furthermore, the impact on costs and benefits to the patient must also be considered.

It is essential that the clinical utility of results produced from POCT devices are subject to a formal risk analysis.

Key recommendations

1. The purpose, nature and potential benefits of POCT at a particular site should be defined before initiating the service.
2. An NHS Trust POCT committee should be established and take responsibility for all POCT and ensure it is appropriate and accreditable. The committee should involve laboratory staff and other relevant staff as appropriate. Where necessary, there should also be a local point-of-care committee to oversee the service when it is in a non-hospital setting.
3. The advice and involvement of an accredited clinical laboratory should be sought in order to achieve optimum quality and cost-effectiveness. This is also the recommendation for non-NHS sites (pharmacies for example). The haematology laboratory should play a key part in maintaining standards for patients in their catchment area.
4. The POCT committee should be clear as to the purpose of the test: is it for diagnosis, screening for occult disease, monitoring disease or treatment?
5. The POCT committee should investigate the full costs of the service including purchase costs and revenue costs including the cost of staff training.
6. The POCT environment should be clean and well lit and may need temperature control. Service managers must perform a risk assessment of testing procedures. Equipment must be provided for the safe disposal of blood and contaminated consumables; staff must be trained in the use of this equipment.
7. Documentation must include the name of the operator, date, patient identity details, results, lot number of calibrant, reagents and quality control materials. This must be recorded at the time of analysis. A record of any
As the problems arising from POCT are not inconsiderable, POCT equipment should be uniform to allow simplification of training, storage and supply of reagents, servicing and maintenance.

11 Internal quality control (IQC) and EQA programmes must be established.

12 As the problems arising from POCT are not inconsiderable, but can usually be overcome, the local haematologist and laboratory staff should be co-opted into the POCT service and involved in the ongoing provision of POCT.

**Disclaimer**

While the advice and information in these guidelines is believed to be true and accurate at the time of going to press, neither the authors, the British Society for Haematology nor the publishers can accept any legal responsibility for the content of these guidelines.

**Guideline update**

This guideline is an update to Guidelines for near patient testing: haematology, (England et al, 1995) and is to replace the previous guideline.

The guideline group was selected to be representative of UK based clinical experts. For this updated guideline PubMed, MEDLINE and EMBASE were searched systematically for publications in English 1995 to 2006 using the key words ‘near patient testing’ and ‘point of care testing’. The writing group produced the draft guideline that was subsequently revised by consensus by members of the General Haematology Task Force of the BCSH. The guideline was then reviewed by a sounding board of approximately 100 UK haematologists, the BCSH and the British Society for Haematology Committee and comments incorporated as appropriate.

The objective of this guideline is to provide healthcare professionals with clear guidance on the management of point of care testing in haematology, in all cases individual patient circumstances may dictate an alternative approach.

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**References**


Clinical Pathology Accreditation (UK) Ltd (2004) Standards for the Medical Laboratory. CPA Ltd, Sheffield, UK.


Joint Working Group (JWG) on Quality Assurance Near to Patient or Point of Care Testing guidelines. (1999) Available from JWGEQA, c/o Mast House, Derby Road, Liverpool, L20 1EA.


Appendix I

Diagram to illustrate the stages of implementation of a point-of-care service:

Appendix II: Operational evaluation

POCT equipment requires evaluation at three levels.

A full, national evaluation by the CEP at one of the national evaluation centres. This is still necessary, even now that all medical devices in the European community carry a CE mark indicating that the performance claims have been validated by the manufacturer (MHRA 2006). Where there has not been a national CEP evaluation an independent, UK-based, evaluation performed to a similar standard, should be sought by a literature search of peer-reviewed publications. If a CEP operational evaluation or equivalent has not been undertaken, the local purchaser should perform an evaluation to the same standard. If a CEP operational evaluation has been undertaken, the local purchaser may wish to perform a less extensive assessment, which appraises certain aspects of the equipment in its intended location and user dependent steps. The national evaluation should be carried out in accordance with the protocol for blood counters produced by the International Council for Standardization in Haematology (ICSH 1994) or for coagulation, protocols based on Gardiner et al (2006) and Giddings et al (1989). Reports of these evaluations are readily available from the CEP website and they assess the following: general operational aspects, the effects of dilution, precision, carry-over, accuracy, comparability (relative accuracy), linearity, sensitivity, specificity, safety and reliability.

Preliminary evaluation

Recommendations for Evaluation of Coagulation Analysers (Gardiner et al, 2006) provide some general advice relevant to haematology and POCT analysers.

The evaluator should obtain the following information: name, manufacturer and distributor of the instrument, list price including options for rental or leasing, reagent and consumable costs, and terms of service contracts. Service response times and general frequency of service calls should also be sought. Regular instrument maintenance requirements should be obtained and ease of troubleshooting investigated. It is important to confirm that the instrument is compatible with the laboratory for which it is intended, and to this end the following should be obtained: overall dimensions, weight, power requirements (AC/DC, voltage, current etc.), area of bench space required and operational environment (temperature and humidity). Information on methodology and principles of operation should be available. This should include the tests available, full technical specifications, measurement principles, and minimum sample volume. Many instruments now offer closed-tube sampling, which may be a requirement for local health and safety regulations. The ability of the instrument to be interfaced with the laboratory/hospital information system should also be sought at this stage.
A plan should provide a realistic time-scale for the evaluation. Such a plan is particularly important when the instrument is loaned or leased. The quantities of reagents and consumables required for this evaluation must be calculated.

**Documentation**

Ensure that there is appropriate documentation and a record is kept of the following.

1. Down time and reason for breakdown, service response time.
2. Maintenance schedules.
3. Reagent usage (batch number, expiry dates, storage conditions, etc.).
4. Use of appropriate control materials.

**Training**

The haematology laboratory organizing the evaluation and/or the equipment supplier should provide the training. Refer to the training section in main guideline.

**What the evaluation should assess**

**Safety.** A COSHH, microbiological, electrical and mechanical assessment will normally have been undertaken during the national CEP evaluation.

It is important to ensure that staff using the equipment can adhere to appropriate control of infection standards. An assessment should be made of microbiological risks arising from, for example, contamination of equipment/surfaces by patient specimens, together with an assessment of appropriate decontamination and waste-disposal procedures.

A risk assessment of any potential mechanical and fire hazards (e.g. is the equipment continuously powered?) should also be made.

**Operational aspects.** These aspects should be assessed by completion of questionnaires. One questionnaire should be compiled for user-evaluators and a separate questionnaire for the main laboratory staff.

**Random and systematic errors.** Imprecision, inaccuracy and drift, etc. will have been assessed during the national CEP evaluation. The purpose of this section is to assess imprecision under routine conditions. These performance characteristics should be assessed in accordance with ‘Protocol for evaluation of automated blood cell counters’ (ICSH 1994) and recommendations for evaluation of coagulation analysers (Gardiner et al, 2006).

**Blood-count analysers**

**Comparison of imprecision.** Twenty to thirty patients’ specimens, covering the expected clinical range (normal, high, low), should be analysed in triplicate by a user-evaluator and by a competent Biomedical scientist (BMS). These experiments will provide estimates of optimal (BMSs) and achievable (POCT user) levels of precision (mean, standard deviation and co-efficient of variation. If these data are not significantly (clinically) different, the equipment should be judged appropriate for use in the operational evaluation (ICSH 1994).

**Between-batch imprecision.** During the trial period (over a period of days), several user-evaluators should analyse patients’ samples in triplicate, from different batches, to achieve a total of 20–30 patients’ samples. The samples must cover the expected clinical range (normal, high, low). This must be undertaken under routine conditions to provide an estimate of routine between-batch variance (ICSH 1994).

**Assessment of comparability.** During the trial period, a minimum of 40 samples (ICSH 1994) should be analysed both by the POCT instrument and by the instrument in the hospital laboratory and comparisons made in accordance with the protocol from the (ICSH 1994). This should be repeated, comparing a user-evaluator and BMS on the POCT equipment alone, to provide an estimate of achievable levels of comparability in a near-patient location. The number of ‘vote-outs’ (inability of the analyser to provide a result) should be documented.

**Carry-over/interfering substances.** These aspects will have been fully assessed during the national CEP evaluation. During this operational evaluation, the assessment should be limited to determining whether staff are aware of carry-over from, for example, high white-cell counts and the effects of interfering substances, such as lipids or cold agglutinins. During the course of the evaluation, some samples of these types should be included in each evaluator’s assessment and their ability to take appropriate action should be assessed.

**Sample identification and data handling**

Positive sample identification achieved through the use of a bar-code reader is a major advantage but manual input of patient identification should also be available for flexibility. The reliability of bar-code readers should be monitored throughout the evaluation. The following should be commented upon: the clarity and format of the data and graphics, the validation processes, quality control programs and data storage capacity, ease of use, and speed of retrieval of stored data.

**Coagulation devices**

**Imprecision.** The methods for performing imprecision exercises will depend on the sample type that can be applied to the device (e.g. capillary blood, citrated venous blood) and
whether suitable lyophilised QC materials are available. Where citrated venous blood or lyophilised QC samples can be used, within-run imprecision may be assessed by performing at least 12 replicate tests and calculating the coefficient of variation (CV), which should be <5%. Lyophilised QC samples may also be used to assess between-day variability, with daily measurements for at least 10 days. An acceptable CV would be <10%. Where imprecision or comparability studies are to be performed using citrated venous blood and the normal means of clinical testing will be with capillary blood, it is appropriate to first ensure that there are no clinically relevant differences between the two types of blood sample. This can be achieved by testing paired capillary and citrated venous blood samples from six normal subjects and 12 patients and analysing the data by 1-way analysis of variance (ANOVA).

When it is only possible to use capillary blood, three replicate capillary samples should be tested from at least two normal subjects and three patients (e.g. receiving oral anticoagulants). Overall imprecision is then assessed by calculating the mean percentage CV. A similar approach can be used for between day variability, by testing three replications of one normal subject and two patients (abnormal samples) daily for 5 d and calculating the total imprecision as the mean percentage CV. Obviously this will usually be different patients on each of the days for practical purposes.

Variability of devices and test strips. When a large number of POCT analysers are to be used in the practice, it is desirable to check for between analyser variability. Blood samples from 10 normal subjects and 20 patients should be assessed on three POCT device units, using the same lot number of test strips/cartridges. Variation between the analyser can be assessed by 1-way ANOVA. A similar approach can be used for studying between lot variability of the test strips/cartridges. If there are no significant differences between analysers, each unit can be used with a different lot number of test strip/cartridge and the significance of any differences assessed as above.

Comparability. At least 20 samples from healthy normal subjects and 50 samples from a relevant patient group should be studied. In the case of INR measurement, the samples should be selected to achieve an even spread of results across, and just above, the target therapeutic range (i.e. equal groups with INR 2–0–2.5, 2.5–3.0, 3.5–4.0, 4.0–6.0). The results for the POCT device should be compared to those obtained using a paired, citrated venous blood sample; with an established reference method (this will usually be a coagulometer in routine use in a hospital coagulation laboratory, which has itself received an independent evaluation). For INR testing, it is essential that the International Sensitivity Index (ISI) value used for the reference method is verified using ISI/INR calibrated plasma samples (Adcock & Johnston, 2002; van den Besselaar et al, 2004). If there are no clinically significant differences (e.g. 90% of INR values are within ±0.5 INR units of the reference method), then the POCT method is comparable.

Interfering substances and carryover. Carryover is not usually an issue with coagulation POCT devices, since there is no automated pipetting of samples or reagents. Potential POCT users may wish to assess the impact of extreme haematocrit and platelet count, where these are likely to influence the detection principle. This can be accomplished by studying suitable samples from patients with a range of values. Some POCT methods (e.g. APTT) may be influenced by heparin contamination or the presence of lupus anticoagulant and the impact of these must sometimes be assessed.