# ICSH Guideline for worldwide point-of-care testing in haematology with special reference to the complete blood count

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## SUMMARY

These guidelines provide information on how to develop and manage a point-of-care (POCT) service so that reliable haematology results are produced regardless of where the test is performed. Many of the issues addressed here are relevant to POCT within hospitals or health centres; however, the principles are equally applicable to care in the community and doctors' offices. Other aspects discussed in this guideline are the initiation of the service (including indications for and limitations of a POCT service), staff training, type of haematology equipment selected, the blood results, monitoring of quality, accreditation, safety and cost. Equipment selected should generate results that are comparable to those of the local reference laboratory. If a complete independent evaluation of the POCT device has not been performed, the purchaser should perform a local assessment according to the protocol in this document. A literature search should also be undertaken to find independent peer reviewed evaluations on POCT equipment. Often the ideals discussed here may not be achievable in some developing countries but long-term training and education of POCT workers needs to be supported and constantly kept on government agendas to reach the recommendations advised here. Users should interpret these recommendations for their particular POCT needs and setting.

 

## INTRODUCTION

The International Council for Standardization in Hematology (ICSH) has prepared these international guidelines for worldwide access recognising the increasing need for a complete blood count analysis in many different clinical settings. Consensus has been sought from practising laboratory haematologists from all continents of the modern world. Point-of-care (POCT) may be defined differently by different users in different contexts. For these guidelines POCT is defined as any analytical test performed for a patient by a healthcare worker, or potentially by a carer or the patient themselves, outside the laboratory setting and where the result is available without the sample being sent to a laboratory for analysis. For the purpose of this document POCT includes what is sometimes termed as alternative site testing or near patient testing, which is testing that remains under the jurisdiction of the health facility but outside the traditional laboratory setting.

The purpose of POCT is to improve the quality of patient care by providing rapid laboratory test results to clinicians or other healthcare workers to contribute to immediate patient management decisions. Technological advances mean that newly developed improved devices are now available for performing diagnostic tests with increasingly simple methods, shorter processing time and better analytical performance. POCT is becoming more common with average yearly increases of >15% being reported in the USA (Scalise, 2006). The expansion was initially restricted to selected hospital environments such as operating theatres, intensive care units, emergency units and outpatient clinics, particularly where same day procedures are being carried out, but POCT has become increasingly important in primary care, especially in the USA, where up to 20% of laboratory tests are now performed within primary healthcare settings (Hilton, 1990; U.S. Hospitals POCT Survey, 2001). In the future, the sophistication and availability of POCT for rapid blood count analysis is likely to expand globally. There is good evidence that implementation of POCT in UK hospitals can result in dramatic improvements in turn around time and contribute to meeting government waiting time targets (Leman *et al.*, 2004).

To ensure safe practice in POCT in haematology the British Committee for Standards in Haematology (BCSH) published guidelines for POCT in both General Haematology and Thrombosis and Haemostasis (England *et al.*, 1995). In 2007, an updated guideline for POCT testing in haematology was published (GH/016, 2007. http://www.bcshguidelines.com), which is intended to replace the previous guideline. The BCSH guidelines only encompass the regulations and requirements for haematology laboratories and POCT services in the UK. These ICSH guidelines have been written to apply to international health facilities and community haematology services where the existence of different national regulations has been taken into consideration.

## SCOPE

The scope of the present guideline relates to the management philosophy for complete blood count (CBC), including the differential leucocyte count, the venues where POCT for CBC may be undertaken, the range of results, the qualifications of the personnel involved in testing and interpretation of results 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. Accordingly, the main purpose of this guideline is to provide healthcare professionals with a clear guidance on the management of a POCT service. Often these ideals may not be achievable in some developing countries but long term training and education of all healthcare workers needs to be supported and constantly kept on government agendas to reach the recommendations advised here. Users should interpret these recommendations for their particular POCT needs and setting.

These guidelines are intended to provide information and suggestions for good laboratory practice and for producing reliable results, regardless of where the test is performed, including general practitioner surgeries, community clinics, pharmacies, health centres or other testing centres. In under-resourced countries, clinical laboratory services may be considered at three levels according to their size, staffing, and the work they undertake. These are (i) rural and outpatient facilities including health centres; (ii) district hospitals; and (iii) central, regional and teaching hospitals (Laboratory services for primary health care: requirements for essential clinical laboratory tests. WHO/LAB 1998).

The level i 'laboratory' generally provides outpatient testing, including services to maternal and child health clinics, and is usually operated by qualified or locally trained technicians. The haematology equipment available may include a simple method for estimating haemoglobin and a microscope for examination of blood slides for blood cell morphology or malaria infection, sputum for tuberculosis, and stool and urine examinations (laboratory services for primary health care: requirements for essential clinical laboratory tests, Health Laboratory Services in support of primary health care in developing countries SEARO Regional Publication, 1999).

As the final aim is to provide a safe and efficient service for patients, there is a need for defined operational details for the POCT including the staff involved and how to address abnormal results. As in the Guideline for POCT in Haematology (GH/016) this document embodies the philosophy agreed by the Joint Working Group (JWG) on Quality Assurance (1999), the national standards required for clinical pathology accreditation (Clinical Pathology Accreditation 2007) and the International Standards Organisation (ISO) 22870 POCT Requirements for Quality and Competence (2003).

## INDICATIONS, LIMITATIONS AND ALTERNATIVES FOR POCT FOR CBC

Before selecting and implementing a POCT analyser for complete blood count (CBC), careful consideration must be given to the indications for POCT haematology analysis and the currently available alternatives. In general, a CBC performed in the central haematology laboratory with the availability for blood film review by qualified personnel is preferable to POCT, provided that the turnaround time (TAT) is satisfactory for the specific clinical setting. Possible indications for the introduction of POCT in haematology might include where a faster TAT is necessary for rapid patient management decisions, the availability, or nonavailability, of skilled personnel or cost considerations. Some clinical questions should be considered before deciding to implement a POCT service such as:

- What is the clinical indication for the POCT CBC?
- What is the desirable TAT and what is an acceptable TAT?
- Which parameters are necessary for patient management?
- Is a complete white blood cell (WBC) differential necessary, or will a partial differential be sufficient?
- How will flagged results be reported and what follow-up action will be taken?
- What are the consequences of an erroneous WBC haemoglobin or platelet count?
- Will transfusions of blood or blood components be based on these results?
- Will chemotherapy be given based on these results?
- Which personnel will be performing the tests and do they understand the clinical significance of the results?

This list does not include cost/benefit analysis.

An informed decision should be made that recognizes possible limitations in accuracy and precision for a faster TAT. The extent of these limitations will depend on the type of analyser chosen and the training and competency of the testing personnel and will affect the clinical utility of the POCT service. Some examples of limitations of the POCT haematology analyser that could affect the clinical utility of the POCT service might be:

- Sample size limitations.
- Number of reported parameters (e.g. no platelet count or limited differential).
- Reportable ranges.
- Limited abnormal cell flagging capabilities.
- Detection of analytic interferences.
- Data storage and retrieval capabilities.

The clinical care-givers who will make treatment decisions based on these results, must understand the limitations of the methodology. In general, the limitations of the testing personnel are usually related to competency. For these reasons, it is important to have clear and detailed procedures that include preanalytical, analytical, and postanalytical steps. The procedure must define, which abnormal or flagged results require further evaluation and how those results are to be reported. Failure to take appropriate action on flagged results or abnormal results may cause patient harm.

However, the use of a POCT CBC analyser is preferable to the use of blood gas analysers for the measurement of haemoglobin or haematocrit. The use of

blood gas analysers that use conductivity for the measurement of haemoglobin concentration or haematocrit is not recommended because of reported differences in values when compared to laboratory analysers (McNulty *et al.*, 1995). Haemoglobin and haematocrits determined by this method are subject to error in hyperosmolar patients and in patients who experience plasma dilution with protein free electrolyte solutions, as commonly occurs in cardiac by pass surgery (Hopfer *et al.*, 2004). A downward bias has been demonstrated when the haematocrit value is below 30% (Steinfelder-Visscher *et al.*, 2006) and 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 spectrophotmetric/co-oximetry to measure haemoglobin, results have been demonstrated to compare well with standard CBC analysers (Hinds, Brown & Clark, 2007) but these instruments should only be used if there is appropriate internal and external quality control available. Despite these limitations haemoglobin and haematocrit results from blood gas analysers are widely used worldwide in the intensive care and surgical operating room environment.

## POSSIBLE SITES FOR POCT, CBC TESTING OR HAEMOGLOBIN ALONE

The POCT tests can be performed in multiple areas of medical care in hospitals but also outside hospitals.

### Sites for hospital POCT

- Intensive care units.
- Accident and emergency departments.
- Operating theatres and postoperative care units.
- Renal dialysis units.
- Neonatal units.
- Outpatient departments.
- Research laboratories (undertaking clinical tests).

### Sites for outside hospital POCT

- Ambulances.
- General practitioners' surgeries and health centres.
- The workplace.
- Healthcare screening clinics.
- Independent treatment centres.
- Pharmacies.
- Chronic care facilities.
- Geriatric homes.
- The homes of patients in primary care.

## POINT-OF-CARE COMMITTEE

A POCT committee should be established in every hospital to take responsibility for all POCT and ensure it is appropriate and accreditable. Ideally there should also be a local POCT committee to oversee the service when it is in the nonhospital setting. In smaller sites, an individual POCT coordinator may be responsible but a committee structure is preferable for larger institutions. Documents published by various accreditation and regulatory agencies propose that an interdisciplinary committee be constituted at any site performing POCT (Medical Devices Agency 2002; ISO 22870 2006; The National Academy of Clinical Biochemistry Laboratory Medicine Practice Guideline 2007). The committee should be multidisciplinary including laboratory staff, clinicians, nursing staff and other nonlaboratory staff. If the POCT extends to the community a representative from the primary healthcare sector should also be included. A patient representative, acting as an advocate for users of the service, may also participate.

In hospitals with POCT services a person responsible for the POCT clinical governance should be appointed as POCT co-ordinator (Department of Health 1999; Gray, 2000; Freedman, 2002). Clinical governance is defined as a framework through which organizations 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. Recommendations for POCT clinical governance have been well documented in the 2007 Guideline for POCT in Haematology (GH/016).

The committee should appoint a person with appropriate training and experience as quality manager for POCT. A quality manual should be prepared and requirements related to POCT reviewed (ISO 22870, 2006). Standard operating procedures (SOP) must be written and regularly reviewed and include details of procedures relating to service performance,

information on actions to be taken on the basis of results and action to be taken in the event of a fault on the instrument, including the reporting of adverse incidents. Protocols must also be produced for training of staff, monitoring performance of equipment, safety regulations and handling of results.

The committee is responsible for the overseeing of selection and procurement of the most appropriate equipment for the task in hand and assessing the infrastructure of the on-site environment.

## EQUIPMENT SELECTION AND IMPLEMENTATION

Implementation of POCT devices requires regulatory and accreditation compliance. This guideline aims to assist personnel (laboratory, management and information technology staff) responsible for the evaluation and selection of POCT equipment and provides an overview of important considerations when comparing POCT devices.

Any equipment for haematology POCT tests should deliver rapid results to provide clinicians with timely information to guide immediate patient management. There are two types of technology to support POCT for general haematology, small bench top analysers and hand-held devices. The bench top systems are often smaller versions of laboratory analysers providing a complete blood count (CBC) with red cell indices and either a five-part white cell differential or a partial three-part differential. 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 will 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 and do not use instrumentation that involves dilution of whole blood in the preanalytical phase. The most widely used test using a hand held device is the measurement of haemoglobin concentration; however, a device, using a disposable cartridge, has recently been introduced that measures haemoglobin, leucocytes and a three-part differential on capillary blood. Table 1 lists examples of currently available haematology tests suitable for POCT, however, the range of equipment will inevitably expand. Not all the parameters or indices reported by the central laboratory may be needed in a given clinical setting and it may be desirable to have the ability to suppress parameters at some locations.

Table 1. Examples of currently available tests and test profiles available on POCT devices

| Tests profiles available |
|---|
| 26, 22, 18 or 13 parameter CBC |
| Five-part differential |
| Three-part differential granulocytes, lymphocytes and monocytes or neutrophils, lymphocytes and mixed cells (monocytes, eosinophils and basophils) |
| Leucocytes, haemoglobin and three-part differential |
| Haemoglobin alone |

The POCT devices should generate results that are comparable to those of the local reference laboratory, and the reference ranges should match those of this haematology laboratory. Where several instruments are required at different sites within a single institution ideally only one specific instrument type will be selected so that reference ranges and results generated are the same wherever the patient is tested. This also simplifies training, ordering and storage of reagents and servicing and maintenance contracts.

If a complete independent evaluation has not been performed, the purchaser should perform a local assessment according to the protocol in this document. The suitability of the equipment, imprecision, and comparability to a reference method must all be studied. A literature search should be undertaken to find independent peer reviewed evaluations on POCT equipment. The Food and Drug Administration (FDA) of America requires a description of the design and results of studies conducted to demonstrate that the device has insignificant risk of erroneous results in the hands of the intended user (FDA guidance 2005). A nationally accredited external quality assessment (EQA) programme and internal quality control (IQC) system must be established for the POCT device; this must be documented and archived. If an appropriate national scheme is not available assessment schemes

must be sought from larger regional centres. Manufacturers promoting POCT devices/instrumentation designed for nonlaboratory sites should provide initial training as well as ongoing training and annual competency assessment, if possible using a web-based system.

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, including voltage stabilization, and network ports. Advice should be sought from the central 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 written SOP for the use of instrument. These should include the following.

- Principle of operation.
- Health and safety.
- Specimens required, request form identification criteria and specimen handling.
- Preparation of reagents and other materials.
- Calibration.
- Quality control procedures.
- Sample analysis procedures.
- Reporting of results, including abnormal results.
- Documentation/transmission of results.
- Criteria for referral of samples.
- Limitations of the procedure.
- Reference values.
- Specimen storage and stability.
- Disposal of reagents and materials.

Troubleshooting and backup arrangements if instrument is inoperable.

## 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 some type of request form is appropriate and these requests should include name of requesting practitioner and patient identity details (complete name, medical record number, date of birth, sex, location, date, and time). It is strongly recommended that POCT instruments are connected to the laboratory information system (LIS) but 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 internal quality control (IQC) materials used at the time of processing that particular sample (providing an audit trail in the event of faulty or out of date reagents).

Operator authorized results should be returned to the clinician in a printed or written format, with appropriate 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 (Guidance from 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. When the instrument is connected to the LIS or hospital information system (HIS) the POCT results should be integrated into the patients results electronically but their origin should be appropriately identified and the record should distinguish between POCT results and those from the central laboratory (ISO 22870, 2006). If the POCT analyser is connected to the LIS an expert rules system such as the ISLH consensus rules (Barnes *et al.* 2005) 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 HIS must comply with the ISO 11073 (2004). 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 results that are outside the normal range must be available. Advice on interpretation and clinical matters should be available from consultant staff in the haematology laboratory.

## QUALITY CONTROL

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.

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 (National Academy of Clinical Biochemistry Laboratory Medicine Practice Guidelines 2007) and ending with the integration of results into the patient's case notes. All aspects of quality must be considered, including personnel, training, equipment, reagents and appropriateness and timeliness of the service. POCT equipment should be accredited as meeting acceptable performance standards for its clinical purpose (see section on operational evaluation in this document). Users of POCT must ensure there is an appropriate level of continuous internal quality control (IQC) that will detect significant deviations from acceptable performance. There must also be an objective external method of quality assurance, external quality control (EQA), to guarantee POCT meets its own national quality standards.

### 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 and results of IQC should also be recorded correctly in accordance with national requirements. It is recommended that there is a lock-out function that does not allow output of patient results if IQC or certain system checks are not completed (FDA guidance 2005). Parallel testing of a patient sample may be carried out at the POCT site and the supporting laboratory to ensure comparable results.

### External quality assessment

External quality assessment is the term mainly used in Europe, in the USA it is referred to as Proficiency testing. The WHO aim is for EQA to become mandatory for central laboratories throughout the world. It is also a requirement for POCT in many countries. Users of POCT also have a duty to participate in an EQA scheme as part of clinical governance. EQA 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 from accredited national schemes, which are recognized by the JWG (1999), Clinical Pathology Accreditation (2004), and Clinical and Laboratory Standards Institute (1999). 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/pathologists should encourage general practitioners and other POCT users to participate in the supervising laboratory's EQA scheme as POCT results are used for clinical purposes in just the same way as those from the supporting laboratories.

### Internal audit

Clinical Pathology Accreditation (2004) and ISO 15189 (2003) will also require evidence that the POCT quality management system is audited and that preanalytical, analytical and postanalytical processes are audited on a scheduled basis. Such regular audit activities should also be incorporated into specified clinical activity, including appropriate patient care plans.

## 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 the basic principles of obtaining the correct specimen, sample preparation, sample measurement, maintenance and calibration of the equipment, appropriate use of the equipment and consequences of inappropri-

ate use, stability of sample and reagents, knowledge and preliminary interpretation of normal and abnormal results, the importance of documentation of IQC, EQA and safety procedures. A list of authorized users must be drawn up and approved by the head of the supervising laboratory. Staff must have a clear understanding that they must not allow persons to operate the equipment without undergoing a formal training process and participation in intermittent competency testing. Retraining intervals, competency/proficiency testing and a continuing education programme should be established and POCT operators' performance monitored as part of the quality assurance programme (ISO 22870 2006). Secondment of POCT staff to the supporting laboratories may be an appropriate method of training and continuing staff development.

## ACCREDITATION

In most countries, all laboratory services are subject to accreditation and in many cases this extends to POCT. The Clinical Laboratory Improvement Amendments of 1988 (CLIA) legislation in the USA stipulates that all POCT must meet certain standards. By having the POCT service independently inspected and compliance to regulations confirmed, the POCT service offers reassurance to users. If it is not possible for the POCT site to undergo accreditation, it is highly desirable that the supervising haematology laboratory support and validate the local POCT service and their accreditation application by mentorship. Under such a scheme, a haematology laboratory may be contracted by the POCT service to assist in monitoring quality management protocols including staff training, maintenance, safety, internal quality control and quality assurance and troubleshooting. The haematology laboratory could provide identical schemes to several POCT services, and during the laboratory's own national accreditation inspection, the assessors may choose to randomly inspect any of the several POCT services monitored by that laboratory. The haematology laboratory clinical governance would then cover POCT used in other settings, including primary healthcare units such as health centres, or individual general practitioner surgeries. However, POCT raises the possibilities of litigation if erroneous results are reported and acted upon. It needs to be established locally who would bear legal responsibility, and so require appropriate insurance cover, if this situation should occur.

## SAFETY

Risk assessments should be carried out before equipment is commissioned, according to national legislation. SOP 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 the UK Department of Health Advisory Committee on Dangerous Pathogens (2003) or other relevant policy. Ideally, specimen analysis should be by closed-vial sampling. 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 complete control of substances hazardous to health (COSHH) assessment, for example, if cyanide reagents are used in the determination of haemoglobin. All procedures should conform to the appropriate legislation (HMSO 1999; Department of Health 2003; Health Services Advisory Committee, 2003; CLSI 2005).

## FINANCE

In some circumstances a cost-benefit analysis may need to be undertaken, as it may be that the cost per test of the POCT instrument is more expensive than sending the sample to the main laboratory. There is reduced efficiency in low volume activity and higher quality control costs. However, this potential for an increase in cost needs to be balanced against a possible reduction in other costs such as those resulting from delays in receiving results from the main laboratory or the transport costs of patients or samples reaching 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 maintenance and documentation 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.

## SUMMARY OF RECOMMENDATIONS FOR IMPLEMENTATION AND MANAGEMENT OF POCT IN HAEMATOLOGY

- The purpose and benefits of POCT at a particular site should be defined before initiating the service.
- The advice and involvement of an accredited clinical laboratory should be sought to achieve optimum quality and cost-effectiveness. This is also the recommendation for nonhealth facility sites (doctor's offices or pharmacies for example). The haematology laboratory should play a key part in maintaining standards for patients in their catchments area. Uniformity of POCT equipment within institutions and across countries allows simplification of training, storage and supply of reagents, servicing and maintenance.
- A hospital POCT committee should be established and take responsibility for all POCT to ensure it is appropriate and accreditable. The committee should involve laboratory staff but also other relevant staff, as appropriate. Where necessary there should also be a local POCT committee to oversee the service when it is in a nonhealth facility setting.
- The POCT committee should investigate the complete costs of the service, including purchase costs, revenue costs and the cost of staff training before initiating the service.
- A technical and practical performance evaluation of POCT devices should be carried out based on structured and appropriate assessments in the POCT environment involving intended users, which may be nonlaboratory staff.
- The POCT environment should be clean, well lit and may need temperature control. Service managers must perform a risk assessment of testing procedures. Space must be available for the storage of reagents, refrigerated if necessary, and for retained samples that have been tested but may require retesting or further tests.
- Written standard operating procedures for all process for the POCT must be available, from receipt of specimen, analysis on the instrument and reporting of results. It is recommended that there is a quick reference guide is available covering the key operating procedures for the instrument/device. This should be kept near to the POCT instrument.
- Staff must recognize that only trained operators may use the equipment. An up-to-date list of trained operators and competency training should be maintained. Training should include an awareness of the clinical utility of the parameters being measured, sample stability for the parameters being measured and the reference and critical values for the parameters being measured. Training relating to the POCT instrument should include calibration and quality control, cleaning, maintenance and reagent expiry, and interpretation of abnormal cell flags and error codes.
- 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 same time as the analysis. Patient results should be transmitted to the laboratory or hospital information system, if possible, or sent to be stored in the patient's notes. A record of any maintenance and repair on the instrument and should also be kept and an 'error log' to assist in any investigation of potential incidents.
- Internal quality control (IQC) and external quality assessment (EQA) programmes must be established.
- POCT raises the possibilities of litigation ensuing from erroneous results. There is a need to establish locally who bears this legal responsibility and encourage them to seek the appropriate insurance cover.

## OPERATIONAL EVALUATION

In Australia, the Therapeutic Device Evaluation Committee is responsible for advising on the safety, quality, efficacy, use and availability of therapeutic

devices. The USA has the Food and Drug Administration (FDA) approval system that encompasses all diagnostic devices, and Europe has its own 'In vitro diagnostic devices directive'. The Australian Therapeutic Goods Administration is seeking to harmonise its decision making with that of overseas authorities including the FDA. This may offer an opportunity to harmonise a diagnostic device approval system with overseas authorities.

Manufacturer claims of the performance of POCT devices may be overestimated because of testing in optimal conditions in nonclinical environments. Therefore the performance attributes of the device should be obtained from the environment where the instrument will be sited and by the staff that will be operating the instrument so that its ease of operation by nonscientific staff can be confirmed. It has been previously demonstrated that the experiences of skilled *vs.* unskilled users can be different, and usually the experience of the POCT user and the testing quality is worse than that of laboratory staff, (Skeie *et al.*, 2002).

### A complete national evaluation

This should be performed by an official organization at an approved national evaluation centre carried out in accordance with the protocol for the evaluation of blood analysers produced by the International Council for Standardization in Haematology (ICSH., 1994). 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 Medicines and Healthcare products Advisory Agency (MHRA, 2006). Where there has not been a national evaluation an evaluation performed to a similar standard should be sought by performing a literature search of peer-reviewed publications.

### Local evaluation

The local purchaser should perform a less extensive assessment, which appraises certain aspects of the equipment in its intended location and user dependent steps. Recommendations for Evaluation of Coagulation Analysers (Gardiner *et al.*, 2006; Clinical and Laboratory Standards Institute, 2007) 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.
- Information concerning instrument maintenance requirements should be obtained and ease of troubleshooting investigated. It is important to confirm that the instrument is compatible with the POCT service, for which it is intended, and to this end the following should be obtained: the range of tests available, complete 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 the evaluation must be calculated.
- Ensure that there is appropriate documentation and a record is kept of the down time and reason for breakdown, service response time, maintenance schedules, reagent and control usage (batch number, expiry dates, storage conditions, etc).
- The haematology laboratory organizing the evaluation and/or the equipment supplier should provide the training. Refer to the training section in the main guideline.
- Ensure safety by a COSHH, microbiological, electrical and mechanical assessment. 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 should also be made.

### Operational aspects

*Random and systematic errors*

Imprecision, inaccuracy, linearity, carry-over and drift, etc. will have been assessed during the national 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).

*Comparison of imprecision*

Thirty patients' specimens, covering the expected clinical range (low, normal, high) should be analysed in triplicate by a user-evaluator and by a competent laboratory scientist. Thirty IQC samples should be run on different days by a user-evaluator and by a competent laboratory scientist. The mean, standard deviation and co-efficient of variation of the results need to be calculated. These experiments will provide estimates of optimal (laboratory staff) and achievable (POCT user) levels of between run and total precision.

*Assessment of comparability*

During the trial period a minimum of 40 samples, normal and abnormal, including some samples with potential interfering substances such as lipids or cold agglutinins, 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 Protocol for evaluation of automated blood cell counters' (ICSH., 1994). This should be repeated, comparing a user-evaluator and competent laboratory scientists on the POCT equipment alone, to provide an estimate of achievable levels of comparability in a near-patient location. The number of abnormal cell flags generated and 'vote-outs' (inability of the analyser to provide a result) should be documented.

*Sample identification and data handling*

When available the reliability of bar-code readers should be monitored throughout the evaluation but manual input of patient identification should also be available for flexibility and assessed during the trial period. 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.

## 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 ICSH nor publishers can accept any legal responsibility for the content of these guidelines.

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