



# The Royal College of Pathologists

## Guidelines on point-of-care testing

The following paper was commissioned from Dr R Cramb and approved by Council on 11 March 2004, subject to consultation. In accordance with the College publications policy, it was placed on the website for consultation between 26 March and 23 April 2004. Eight detailed items of feedback were received and taken into account in the preparation of this final document.

**Professor John A Lee**  
**Director of Publications**

### 1 SUMMARY

Point-of-care testing (POCT) encompasses a range of testing of many analytes across pathology. Most hospitals use POCT (though some may not recognise its use) on site. POCT is capable of delivering results in a timely manner that allows clinical decisions to occur quickly, potentially allowing better clinical (and/or economic) outcome. The Royal College of Pathologists welcomes the use of POCT into medical practice but has concerns that its widespread use must be considered carefully to ensure that it is used safely, effectively and economically.

### 2 BACKGROUND

The ability to deliver healthcare is under increasing pressure due to rising costs and increased community expectations. These pressures are changing the way in which care is provided, particularly through the increasing use of same-day procedures and the use of some community alternatives to hospital care. The use of diagnostic pathology procedures has a central role in the practice of medicine and it is possible that 60–70% of diagnoses depend upon laboratory tests.

Until the middle of the last century, some pathology tests were conducted close by the patient, either in a hospital ward side-room or in a general practitioner's surgery. As the range, complexity and clinical demand for tests increased during the 1960s, testing activities largely transferred to centralised pathology laboratories. In the last decade, diagnostic laboratories have concentrated on automation and information technology to accelerate services and reduce costs.

Pathology has a key role in medical decision-making and is not immune to changes in healthcare delivery. Some institutions have thought that pathology tests can be a rate-limiting

step in achieving further clinical and cost improvements in patient care, particularly when delayed clinical management decisions and follow-up consultations are imposed by test turn-around times. A modern pathology service will need to consider a wide range of technologies to provide its service and this may be achieved by linking disseminated laboratory services as part of an area of networked services, e.g. by remotely linking POCT with laboratories. The recognition that POCT can contribute to better healthcare is acknowledged in *Modernising Pathology Services*. POCT will also create new commercial markets for diagnostic technology and this is reflected in the increasing range and availability of tests that can be used by patients, their carers and the non-laboratory community in general.

### **3 TERMINOLOGY**

POCT already covers a broad range of both pathology and non-pathology testing, and this document is aimed at the application of diagnostic pathology, but many of the views expressed here are also relevant to other POCT applications. POCT is defined as follows:

*“An analytical test undertaken by a member of the healthcare team or by a non-medical individual in a setting distinct from a normal hospital laboratory.”*

The definition of POCT varies by test and equipment. This may comprise of:

- non-instrumental systems: disposable systems or devices that vary from reagent test strips for a single analyte to sophisticated multi-analyte reagent strips incorporating procedural controls
- small analysers: usually ‘hand- or palm-held’ devices, such as blood glucose meters, although they vary in size
- desktop analysers: they are larger and include systems designed for use in clinics or a small laboratory.

The numbers of tests that are available by POCT is not as comprehensive as a conventional laboratory, but may be similar to that available in many smaller laboratories.

### **4 USE**

POCT may be undertaken by diagnostic laboratory personnel, by non-laboratory trained healthcare professionals and by lay individuals, for personal or commercial purposes. The user may be a person responsible for the care of a patient or otherwise acting on the carer’s behalf.

Users of POCT should receive formal training in the operation of devices to ensure quality results are produced, and have an understanding of the results obtained appropriate to their medical use.

### **5 BUSINESS CASE**

Before any POCT device is purchased in a hospital or primary care setting, a business case must be produced. The cost of a test, including instruments and reagents for POCT, will exceed the cost within a routine hospital laboratory. Costs of POCT will not only include the costs of instruments and reagents, but will also include the hidden costs of support from a local (accredited) laboratory, the costs of training and of device maintenance. To justify this extra expense, the single most important issue of a POCT service is its clinical need. Clinical need, especially where there are good examples of evidence-based medicine, can show the need for innovative practice with POCT, but there are examples of POCT services implemented with the expectation of better clinical outcome where its use unmasked deficiencies in the clinical service.

Similarly, if there is a wish for POCT within general practice (administered by primary care Trusts), the clinical need must be established with an appropriate business case. Where patients are to use a device to monitor and change their treatment, the clinical need must be carefully assessed, taking into account the patient's needs, abilities and competence.

## **6 SELECTION**

Once a service need is accurately identified, test systems should be reviewed. A suitable test system should meet the service need using equipment that is simple and reliable, but which has the necessary accuracy and precision to deliver results that alter patient management and that are similar to those produced by the routine laboratory. The system must be able to be used by individuals within that healthcare setting who are using it on a regular basis and who are performing appropriate quality checks on their work.

## **7 IMPLEMENTATION**

The whole POCT package must be part of a clinical total quality assurance plan (TQA). Due to their experience and the needs of accreditation, local pathology laboratories should oversee all POCT. No single laboratory discipline has overall ownership of POCT; rather it is recommended, to meet the needs of clinical governance, that all disciplines should be under the auspices of a POCT committee that includes the users of the service, including those users in general practice. In some areas, POCT committees may exist in the hospital environment and in general practice (under the auspices of the local primary care Trust). Where this may occur, these two communities should not view each other in isolation and there should be representation of primary care within the hospital sector and vice versa. This will allow an overview of how devices can be introduced across the primary care and hospital sectors. Where individual patients are using their own POCT devices (e.g. for diabetic or anticoagulation monitoring), the responsibility for managing these should be from the site that initiated the introduction and training for the use of the device. The commitment to a POCT committee should not be underestimated for all interested parties and business planning should take due account of the time commitment as part of costing any service.

Management of a POCT service should take due account of several important areas, including clinical governance, the Consumer Protection Act (1987) and public health considerations. Poor use of POCT leading to the production of wrong results may have medicolegal implications, while under the terms of the Consumer Protection Act (1987) the use of instruments for purposes for which they are not intended will lead to liability transfer from manufacturer to user. Whilst there is a need for managerial responsibility of POCT devices and a designated individual who will take formal charge of any POCT programme, individual users trained and approved for POCT will have legal responsibility for the results that they produce. Finally, some tests that identify important infective diseases must have their results reported to the Health Protection Agency. Formal reporting arrangements therefore must be established where infections and infectious diseases have implications for public health and health protection.

## **8 TRAINING**

All users of POCT devices must be trained in the function and use of the devices as described in the standard operating procedure (SOP), and no user should be allowed to perform tests that will alter clinical management without the trainer being satisfied with the competence of the user. Upon completion of the training, all users must be registered and sign that they recognise the legal responsibilities of the tests that they undertake. They must adhere to an SOP, including the use of internal and external quality assurance material as detailed in a device-specific SOP. A list of trained and authorised users should be maintained with each device and updated training arranged as appropriate.

Where POCT is being used directly by patients or their carers, they must be provided with the necessary information to properly perform and interpret the test. The application of a test result to self-management by a patient must be taught by an individual who is judged competent by assessment within a teaching programme. Educational information must be specific to a patient's assessed needs, abilities and competence.

## **9 STANDARD OPERATING PROCEDURE (SOP)**

The POCT committee should ensure that an SOP, written to the standard of Clinical Pathology Accreditation (UK) Ltd or an equivalent accreditation organisation, is in place for each device. The SOP should cover:

- clinical background
- analytical principle
- health and safety including:
  - information on COSHH (Control of Substances Hazardous to Health)
  - safe disposal of waste
  - control of infection
  - adverse incident reporting
- pre-analytical considerations
- equipment
- reagents, standards, controls and quality assurance
- test procedure
- sample analysis
- calculation of results
- assay performance
- maintenance
- record-keeping.

Internal quality assurance (IQA) must be used to ensure that operators of the device and/or the tests used are performing to an acceptable standard to utilise the results for patient management. External quality assurance (EQA) of devices must be mandatory but, although there are EQA schemes available, they are not at present comprehensive enough to provide universal cover for all the devices and tests available.

Two important and often neglected points are maintenance and record-keeping of POCT devices. Many desktop devices now incorporate maintenance schedules into their software, preventing use until this is undertaken, and many now require valid user identification before they produce results. All analyses must be recorded in a record book or on laboratory IT and, where it is implemented directly, into an electronic patient record.

## **10 COMMERCIAL USE OF POCT**

There are examples of POCT used in commercial settings to provide tests to companies or individuals in non-profit or profit-making situations. The guidance for these organisations is similar to that of NHS organisations as directed above.

## 11 CONCLUSIONS

- Before any POCT service is considered, the clinical need should be clearly identified and, where appropriate, a business case made.
- The selection of POCT equipment should take due account of independent evaluation.
- To meet the needs of clinical governance, a POCT committee should be established in hospital practice and where necessary in primary care.
- The local hospital laboratory must be involved to provide management support to run an accredited POCT service.
- Lines of accountability for POCT must be clear and managers of the service and the end-users must take due notice of their responsibilities through clinical governance.
- Adherence to standard operating procedures must be followed, paying particular attention to training, management, quality assurance/control and health and safety policy, and must be reviewed at frequent specified intervals.
- Clear, comprehensive record-keeping and documentation is mandatory.

**Dr R Cramb**

**Approved by College Council  
11 March 2004**

(Reference 11 updated on 12 October 2004)

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