

Management and use of IVD point of care test devices

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Revision history

This version	Date published	Changes
V1.1	Dec 2013	New MHRA logo
V1.2	Jan 2021	Reflects regulatory changes resulting from the end of the transition period with the EU

1 Executive summary

The aim of this document is to provide advice and guidance on the management and use of point of care testing (POCT) in vitro diagnostic (IVD) devices. It is a revised edition of the version first published in 2002 as DB 2002(03).

The key issues addressed in this guidance include:

- A clinical need must be identified before the implementation of a POCT service.
- Consider involving the local hospital laboratory in the management of POCT services.
- Lines of accountability for POCT management must be clear.
- Managers of POCT services must be aware of their responsibilities under clinical governance.
- Arrangements for training, management, quality assurance (QA) and quality control (QC), health and safety policy and the use of standard operating procedures (SOPs) must be made and reviewed at frequent specified intervals.
- Assessment of the service by an external accreditation body is recommended.
- You should consider the available evidence for the performance of the test.
- Adverse incidents must be reported to the MHRA.
- Clear, comprehensive record keeping and documentation is vital.
- Everyone involved in POCT should know what to do in the event of any abnormal result or unsatisfactory QC result.

This document is written for people involved in the management and use of POCT services in primary and secondary care including managerial, scientific, technical, clinical and nursing staff. While many of the issues addressed are relevant to the performance of POCT in a hospital environment, the principles are applicable to their use in outpatient clinics, community care, GP practices and other community providers and primary care settings.

Although primarily not intended for people who use self-testing devices and 'direct to consumer testing' at home, this document may be useful to healthcare professionals involved in advising them.

2 Introduction

Since the publication of the first edition of this Device Bulletin in 2002 there has been a continual rise in the use of POCT due to the drive to improve patient pathways and as a result of technological advances. Developments in fluid handling, microchip and miniaturisation technology and improved manufacturing processes are producing POCT devices which are more robust and less prone to error than previous generations. However, despite improvements in technology, the successful implementation of POCT is still dependent on the effective organisation and management of staff.

The importance of the management of POCT was emphasised in the 2006 'Report of the review of NHS pathology services in England' which was an independent review for the Department of Health chaired by Lord Carter of Coles [1]. Throughout this bulletin references have been made to key points from Lord Carter's review relating to POCT.

POCT may be performed in a variety of locations such as acute units in secondary care and, increasingly, in the community and primary care. POCT must be performed by staff whose training and competence has been established and recorded. The reason for this is to protect the patient, and ensure the quality of the service is appropriate to the clinical setting. This is applicable to all providers of POCT services.

From a clinical governance perspective users of POCT should have a sound understanding of the relevant analytical principles, and of issues such as quality assurance (QA), interpretation of test results, limitations to use and liability issues. It is therefore important that users of POCT should have access to clear guidance on these and other issues relating to the management of POCT.

Guidelines for POCT have been produced by a number of organisations and the purpose of this document is to provide a check-list of questions that potential users of POCT will need to consider when implementing and managing POCT.

This document is intended to complement existing guidance on the management of in vitro diagnostic medical devices [2].

For the purpose of this document, POCT is defined as any analytical test performed for a patient by a healthcare professional outside the conventional laboratory setting. Other terms commonly used to describe POCT include:

- near patient testing (NPT)
- bedside testing
- extra-laboratory testing
- disseminated / decentralised laboratory testing.

2.1 Sites for POCT

POCT can be carried out in a wide variety of settings. The following list is not exhaustive but serves to illustrate the variety of locations.

Secondary care (in hospital)

- A&E departments
- ambulance service
- cardiac units
- coagulation clinics
- dental clinics and hospitals
- diabetic clinics
- hospital wards
- intensive treatment units
- liver units
- neonatal units
- occupational health departments
- operating theatres

- out-patient departments
- renal units.

Primary care (in the community)

- co-located commercial sites
- community clinics
- community pharmacies
- GP surgeries
- health centres
- independent sector
- industrial medical centres
- mobile units
- polyclinics – diagnostic centres
- sexual health clinics/GUM clinics
- dental surgeries
- residential settings.

2.2 Examples of POCT

- analysers and kits for HbA_{1c}
- bilirubinometers
- blood gas analysers
- blood glucose meters
- cardiac testing: BNP, troponin, D dimer
- cholesterol tests
- coagulometers
- electrolyte analysers
- MRSA screening test
- pregnancy tests
- rapid test kits for infectious disease markers
- urinalysis test strips.

Systems can be categorised as:

- non-instrumental systems; disposable systems or devices. These 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, which can vary in size e.g. blood glucose meters
- desktop analysers are larger and include systems designed for use in clinics or small laboratories.

3 Before implementation of a POCT service

This section deals with issues and questions that need to be considered before deciding whether to adopt a POCT option. The principles outlined here are equally applicable to existing POCT services.

This section covers some aspects of purchasing that may influence the safety, quality and performance of the devices. However, it does not attempt to address wider issues of best procurement practice, such as regulations implementing EU purchasing requirements, financial evaluations and purchasing specifications. Advice on such matters can be obtained from the Centre for Evidence Based Purchasing (CEP).

3.1 Role of the local hospital pathology laboratory

The local hospital pathology laboratory should play a key role in the development and management of a POCT service. This is particularly true for secondary care and may also be useful for some primary care services. The pathology laboratory can provide advice on a range of issues including the purchase of devices, training, interpretation of results, troubleshooting, quality control, quality assessment and health and safety. There should therefore be close liaison between users and the local hospital pathology laboratory on all issues relating to POCT. Wherever possible this liaison should be formally defined e.g. by a service level agreement specifying the range of products, services, operational details and the responsibilities of the central laboratory and the POCT user.

Excerpt from the Report of the Review of NHS Pathology Services in England [1].
Part 1: Summary and recommendations: 13 'We have identified a number of factors which impede the delivery of an efficient and effective service. These include: ...the fragmentation of parts of the service, particularly point-of-care services which are increasingly being undertaken by other members of the health care team, often with no reference to pathology services.'
Part 2: Findings: 131 'In pathology we also see the need for accreditation of POCT (irrespective of site of provision) with this preferably being integrated with that of the laboratory service because of the close synergies – from the patient's perspective – between the two modes of testing.'

3.2 Identifying the need for POCT

Before deciding whether to implement POCT it is essential to:

- establish a clinical need
- consider the benefit to patients of introducing POCT.

In many cases improving the patient pathway and experience could be major considerations when introducing POCT. As regards clinical need, this should be based on establishing that the perceived need is valid. POCT must deliver an equivalent level of quality and clinical effectiveness as the alternative. Users should also keep under review the continuing clinical need for POCT.

Benefits to patients and identifying a need

The following questions should help in assessing the clinical need for POCT:

- How is the service currently provided and does it adequately meet the clinical need?
- If clinical need has not been met, what has been done to try to rectify the problem?
- Which groups of patients need testing and what test(s) need to be performed?

- Is access to a laboratory service difficult for patients with conditions requiring frequent monitoring? Has this been discussed with the laboratory?
- Will POCT enable more rapid or effective diagnosis or treatment?
- Can you provide evidence that POCT will provide a measurable clinical benefit?
- Will POCT provide a cost-effective alternative to laboratory testing?
- How does the POCT service compare to current service in terms of quality?
- Will any change in quality be appropriate for best management of the patient?
- What will be the benefits to patients of providing the service in a different way?

3.3 Advantages and disadvantages of POCT

Users should be aware of some of the potential advantages and disadvantages of POCT before accepting the need for POCT. Examples of potential advantages and disadvantages are listed below:

Potential advantages

- Improved turnaround time – mainly by shortening the pre- and postanalytical steps.
- Potential for better monitoring of certain conditions and where frequent testing is desirable.
- Smaller sample and reagent volumes – POCT methods may be less clinically invasive.
- Advantageous in remote areas where access to a laboratory is limited.
- POCT may offer an easier to access service e.g. for the elderly.
- Economic – although POCT is generally more expensive than laboratory testing, it may offer wider economic benefits with a reduced number of clinic visits, reduced length of stay in hospital and fewer hospital admissions.
- Greater patient involvement in their own care.
- Improved patient experience.
- Availability outside normal laboratory core hours.

Potential disadvantages

- Poor quality of analysis.
- Poor record keeping.
- Lack of result interpretation.
- Unnecessary duplication of equipment.
- Failure to detect erroneous results.
- The availability of an array of tests may tempt users to perform unnecessary or inappropriate testing.
- Data recording may be complex and less robust – less recording of results in patient records.
- Incompatibility with laboratory results – reference ranges and results may differ from those used by the established laboratory service making comparisons difficult.
- Without the economies of scale that come from centralised laboratory testing, POCT can be expensive.

3.4 Costs

As well as the clinical and economic benefits there are financial costs of providing a POCT service to consider. These may include:

Capital costs

- Initial purchase cost.
- Accessories e.g. centrifuges and incubators.
- Provision of a safe environment e.g. health and safety improvements.
- Site alterations to accommodate POCT e.g. operator and storage space.
- Depreciation.
- Interfacing with information management systems.

Other fixed costs

- Routine and preventative maintenance e.g. external service contracts with manufacturers.
- Internal quality control material and participation in external quality assessment scheme.
- Accreditation scheme compliance.

Variable costs

- Consumables.
- Record keeping e.g. data-handling system.
- Waste disposal.
- Cleaning.
- Demand.

Professional costs

- Indemnity insurance and legal liability.
- Laboratory support.
- Management of the POCT programme.
- Operator time.
- Staff training.

3.5 Choosing the right equipment

Once a need has been established, the next step is to identify the most suitable device. Accuracy and precision of results, robustness of the device and a record of results all need to be evaluated and documented before acquisition. An accredited laboratory should be able to assist in the selection process. A local evaluation could be important to ensure compatibility of POCT with local reference ranges and clinical practice.

Excerpt from the Report of the Review of NHS Pathology Services in England [1].
Part 2: 60 Minimising variation in results through standardisation of processes

'This is particularly relevant at a time when opportunities for greater access and choice may result in patients attending a range of health care facilities during their journey along the care pathway. Greater standardisation would help to reduce the fragmentation of services, repeat testing and the consequent errors that occur. In addition there is a growing demand for point-of-care testing and patients may be managed using a combination of laboratory and point-of-care testing systems. There is also a growing market in do-it-yourself testing, which from a patient safety perspective should be considered in the same way...What is clear however is that these developments in near-patient testing must be safe, accurate – and foolproof.'

What equipment will meet your needs?

The following questions need to be considered.

- What is the expected workload?
- Who is going to use the equipment?
- What are the manufacturer's claims for performance? What level of performance is required for the service? (Manufacturer's performance claims might include: sensitivity, specificity, accuracy, repeatability, reproducibility, measurement range etc.)
- Where will the equipment and consumables be sited?
- Is there adequate space, with appropriate services e.g. power, water, refrigeration?
- What evaluations of the equipment are available? e.g. independent, manufacturer's, hospital's own.
- Are the results comparable to those of the local hospital pathology laboratory?
- What are the limitations of the equipment?
- Will the POCT service work satisfactorily with existing data handling systems and IT infrastructure?
- Has consideration been given to health and safety issues such as the safe disposal of clinical waste and sharps (see section 4.5)?

Users and managers of POCT should consider the benefits of equipment standardisation, such as minimising variation in results, cost-effectiveness for capital purchases and consumables (larger discounts), benefits for staff training (when staff move around different clinical settings etc.) and also for those staff who support the equipment.

3.6 Clinical governance

Clinical governance covers the organisation's systems and processes for monitoring and improving services, and is an essential part of any POCT service including:

- consultation and patient involvement
- clinical risk management
- clinical audit
- research and effectiveness
- staffing and staff management
- education, training and continuing personal and professional development
- use of information to support clinical governance and healthcare delivery.

The use of POCT as an alternative to laboratory testing should be considered as a clinical governance issue and subject to examination of clinical effectiveness. Such considerations may best be achieved through the setting up of a POCT committee (see Section 4).

4 Management and organisation of POCT

4.1 Responsibility and accountability

There will be many people involved in the creation, implementation and management of a POCT service. It is vital that an appropriate senior professional is identified to act as a 'POCT co-ordinator' and given the authority and overall responsibility for the service at the beginning of the development process. This individual will have responsibility for both the results that are generated and the correct use of the devices that generate those results.

Managers of POCT should also be aware of their responsibility for clinical governance and of the medico-legal implications of an erroneous result. Liability under the Consumer Protection Act (1987) [3] will only remain with the manufacturer or supplier if the user can demonstrate that the equipment has been used in strict accordance with the manufacturer's instructions.

Lines of accountability should be clearly written into local policies and procedures and should cover the following areas:

- training
- instructions for use
- standard operating procedures
- health and safety
- quality assurance
- maintenance
- accreditation
- record keeping
- audit
- adverse incident reporting.

Responsibility and accountability – questions to consider

- How will the service quality be maintained?
- Does the management structure include designated deputies capable of assuming the necessary responsibilities?
- Is a laboratory able and willing to provide the necessary support for the POCT service, including interpretation of results? If so, is this supported by a service level agreement with the laboratory?

Establishment of a POCT committee

In addition to the appointment of a POCT co-ordinator, the establishment of a multidisciplinary POCT committee to oversee POCT whether in the hospital setting or in some elements of primary care is recommended as good practice. All stakeholders should be represented in a POCT committee e.g. laboratory staff, clinicians, nursing staff, specialist nurses, pharmacists, IT and finance.

POCT in the community requires similar stakeholder representation; input from a clinical scientist or a biomedical scientist may be helpful.

The role of the POCT committee may include the following:

- determining if POCT is justified at a particular location. This would include a clear demonstration of increased clinical effectiveness
- establishing a system for the continuing audit and assessment of POCT
- ensuring that no POCT device is used unless it has been looked at by the POCT committee
- setting up a quality hierarchy to ensure that there is a direct link between the person performing the analysis and the POCT committee
- establishing the presence of a link nurse or other healthcare professional at the point of service delivery
- including representatives from primary care and the community where necessary
- ensuring that users have documented training in the use of POCT devices and that they are fully aware of all contra-indications and limitations
- ensuring that internal quality control (IQC) and external quality assessment (EQA) schemes are applied to POCT in the same way as they would be for the established laboratory service.

4.2 Training

Only staff whose training and competence has been established and recorded should be permitted to carry out POCT. They should also receive continued support and regular updates.

The Department of Health is working with the [United Kingdom Accreditation Service \(UKAS\)](#), [Skills for Health](#) and [e-Learning for Healthcare](#) to develop a flexible and robust accreditation service for POCT. The three main elements of the work are around accreditation, competence and the development of learning materials. e-Learning for Healthcare is responsible for the creation of the e-learning materials that will equip organisations and individuals with the skills to carry out point of care testing to the standards and competences defined by the assessment and accreditation approaches.

Questions to consider

- Who is able to provide the necessary support for staff training?
- Have core competences been assessed by a competent individual
e.g. a POCT co-ordinator or through an accredited learning package?
- Does the hospital laboratory, other provider or manufacturer offer a comprehensive training programme for the device(s)?
- Can staff carrying out POCT be released for the appropriate length of time to complete training, and are relevant training materials available?
- Does the training manual identify operator-dependent steps?
- Who will be responsible for compiling a training programme certification programme in order to assess staff competence?
- Is there a continuing professional development (CPD) programme for the staff delivering the service?
- How will the requirement for training updates be carried out and how will it be assessed?

4.3 Instructions for use

All staff performing POCT must be familiar with the manufacturer's instructions for use, with particular reference to:

- the intended purpose of the device
- performance characteristics
- interpretation of results
- limitations of use
- sampling requirements, including sample type
- storage of reagents and samples
- expiry dates
- quality assurance procedures
- health and safety issues.

Case study

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

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

Key points

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

4.4 Standard operating procedures (SOPs)

We recommend having a standard operating procedure (SOP) in place wherever POCT is performed. It is essential that the SOP include a copy of the manufacturer's instructions for use and that all existing copies are updated as appropriate.

Questions to consider

- Have SOPs been produced and written in accordance with a recognised quality standard?
- Are the SOPs made readily available to users and combined with other relevant information e.g. instructions for use, manufacturer updates, and safety warnings?
- Do they include infection control procedures, where appropriate?
- Have the manufacturer's instructions been included in these procedures?

- Are SOPs regularly reviewed to ensure that they follow the latest version of the manufacturer's instructions?
- Do the SOPs contain information on actions to be taken on the basis of the result?
- Do the SOPs contain information on actions to be taken in the event of a fault or instrument breakdown, including the reporting of adverse incidents to the MHRA?

Case study

The MHRA received several reports of false positive results from a pregnancy test used in hospitals. Reports also indicated that there was seemingly conflicting information regarding at what time the pregnancy test should be read and that staff were unsure where to find the correct information.

The manufacturer of the test issued a Field Safety Notice (FSN) updating the instructions for use (IFU) with regards to read time but a number of sites had not implemented it. The MHRA issued a Medical Device Alert to support the manufacturer's FSN and inform test users of the correct read time and the need to be aware of the IFU.

Key points

- Ensure that SOPs are readily available.
- Ensure SOPs are kept up to date and reflect the manufacturer's current instructions for use.
- Ensure device users know where to find up-to-date information regarding correct use of the test device.

4.5 Health and safety

POCT users and managers must recognise the hazards of handling and disposing of body fluids and sharps outside a laboratory setting.

Questions to consider

- Will provision of the POCT service comply with current health and safety policy?
- Who will be responsible for ensuring that staff are aware of the current health and safety legislation and guidance, including the medico-legal implications of transmission of infection due to lack of safe specimen handling or spillage?

4.6 Infection control

POCT users and managers should be reminded of the importance of:

- standard (universal) infection control precautions
- the prevention of occupational exposure to blood-borne viruses, the wearing of gloves and other protective clothing, and the prevention of sharps injuries
- prevention of cross infection with blood-borne viruses, including selection of appropriate lancing devices
- safe handling and disposal of healthcare waste, including sharps
- safe medical device use, including decontamination of reusable devices.

Further detail is available in the Health and Social Care Act 2008: Code of Practice of the NHS on the prevention and control of healthcare associated infection and related guidance [4].

This Code of Practice applies to NHS bodies for 2009/2010. For 2010 and 2011 a revised version of the code covering independent health care and social care will be available.

Case study

Outbreaks of hepatitis B were reported from several environments where blood glucose monitoring was being carried out for multiple patients. Thorough investigations identified that care workers were found to be using lancing devices intended for self-use (by one patient only) to take blood samples from multiple patients. This use of the wrong sort of lancing device was implicated in the transmission of the virus.

Key points

- Be aware that employing the wrong sort of lancing device can cause cross infection.
- Use a disposable single-use lancing device where the entire device is thrown away after use, or employ a reusable lancing device that is intended, by the manufacturer, for taking samples from more than one patient.
- Users should review current practice to ensure that appropriate devices are provided and used.

4.7 Quality assurance (QA)

Quality assurance is an essential component of POCT and includes all the measures taken to ensure that investigations are reliable. These will include:

- correct identification of the patient
- appropriate test selection
- obtaining a satisfactory specimen
- analysing it and recording the results promptly and correctly
- interpreting the result accurately
- taking appropriate action
- documenting all procedures and maintaining accurate records.

Quality assurance also encompasses proper training and review of overall performance. Two components of quality assurance, internal quality control and external quality assessment, can help ensure reliable results, but only if they are applied rigorously. The local hospital laboratory or accredited QA provider should be consulted for advice.

Case study

The MHRA received a report regarding a number of spurious results obtained on a blood gas analyser situated in a neonatal ward. The reported cases involved blood samples taken from fetal scalp during delivery and concerns were raised as crucial treatment decisions could be made on the basis of test results. On this occasion treatment decisions were not affected as a trained member of staff had spotted the incorrect results. An investigation by the MHRA and the manufacturer revealed that the analyser was relatively new and not all staff using it had been trained in its use. In addition some staff were not aware of the pre-analytical factors necessary to obtain a high quality good sample (e.g. not to use Vaseline on fetal scalp, not to transfer from syringe to capillary tube). The MHRA asked the manufacturer to visit the hospital, provide further training and to

ensure that information was provided on pre-analytical factors. The MHRA also facilitated liaison between staff involved in this area (nurses, midwives, ward managers, biochemistry laboratory and POCT co-ordinator).

Key points

- Ensure that all users are trained in the use of a new device.
- When a new device is put into service ensure that SOPs are updated.

4.7.1 Internal quality control (IQC)

This is a means of checking that patient results are reliable before they are issued. The analysis of an appropriate control material (often supplied by the manufacturer of the POCT device) before analysing a set of specimens can provide reassurance that the system is working correctly. It is essential that the results of QC be recorded appropriately. Readers should note that some POCT devices incorporate electrical or optical checks, which form part of IQC.

Questions to consider

- Is there a procedure in place to ensure that IQC is performed at an appropriate frequency and that the results are recorded appropriately and in accordance with manufacturers' recommendations?
- Is the manufacturer of the POCT device or the hospital laboratory able to provide appropriate QC material?
- Is the POCT manufacturer or hospital laboratory able to provide support to ensure that any results outside of acceptance limits are investigated?
- Is there a procedure in place for acceptance testing for both single-use devices and instrumentation?
- Are there guidelines in place that define responsibilities for interpretation of results?
- Are there procedures in place to deal with QC results that fall outside the specified limits for the QC material being used?

Acceptance testing involves testing to check that the device or new batch of consumables is working properly and is within acceptable controls. This can provide an invaluable quality control measure before dispatch to testing sites.

4.7.2 External quality assessment (EQA)

EQA involves the analysis of samples with unknown values from an external source. Results are then subject to peer group assessment and statistical analysis to compare results across different sites. EQA schemes may be operated by the manufacturer or by dedicated EQA providers. The hospital laboratory may be able to recommend an appropriate EQA provider or may be able to act in this capacity itself in relation to POCT in the hospital and primary care settings. Users of POCT are strongly recommended to participate in an EQA scheme and perform adequately as part of clinical governance.

Questions to consider

- Is the central laboratory able to provide or recommend appropriate EQA schemes for the POCT service?
- Who will be responsible for co-ordination of the EQA programme within the POCT service?
- Are there procedures in place to ensure that specimens are analysed appropriately and results are returned to the scheme provider and also recorded as for IQC?
- Who will review EQA performance?
- Who will provide the necessary support in the event of inadequate performance in an EQA scheme?
- Is the local hospital pathology laboratory able to provide an alternative EQA tool such as 'parallel testing' if enrolment on an external scheme is impracticable?

Parallel testing

Parallel testing of a patient sample in the laboratory can provide a QA tool. This needs to be well planned and the comparative data recorded and scrutinised. It has the advantage of using patient samples which avoids possible matrix effects of control material but it may have the disadvantage of requiring more blood, which might be collected differently to that normally used for the POCT device. POCT managers also need to take into account possible ethical considerations (including patient consent and confidentiality) when planning parallel testing.

4.8 Maintenance

Planned preventative maintenance should follow the manufacturer's guidance, which is essential for the safe and effective use of POCT devices

Questions to consider

- Who will provide preventative maintenance and 'troubleshooting'?
- Is a maintenance record kept for each device used in the POCT service, and does it include a record of all faults and repairs?
- Are procedures in place to ensure that weekly and monthly maintenance checks are performed and that reagent records are kept in line with the manufacturer's instructions?
- Is there a procedure in place that defines when and how the manufacturer should be contacted in the event of a technical problem or breakdown?
- Do you need a maintenance contract for call-out or support engineers?
- Report adverse events to MHRA (see also section 4.12).

4.9 Accreditation

Accreditation is assessment, by an external body, of the competence to provide a service to a recognised standard. By having this independently confirmed, POCT providers are able to give reassurance to users of their service.

Any site providing a POCT service should undergo a relevant accreditation procedure. Users and managers of POCT should contact [Clinical Pathology Accreditation \(UK\) Ltd](#) or [UKAS](#) directly or consult their local hospital pathology laboratory.

Excerpt from the Report of the Review of NHS Pathology Services in England [1].

Part 1: 24 (x)

'all pathology providers, including point-of-care testing providers, are accredited in accordance with a national independent accreditation process which is responsive to changes in the nature, scope and delivery of pathology (and the wider health care system) and which requires full participation in external quality assurance schemes'

4.10 Record keeping

It is **imperative** to keep accurate records of patient results from POCT devices. These records should include: date; device type; batch numbers; result; operator identity; patient identity.

Case study

A hospital laboratory alerted the MHRA to a problem of false negative pregnancy tests. The MHRA investigation revealed the need for a recall of affected devices (of a particular batch) and retesting of certain patients. Difficulties arose for hospitals when trying to identify which patients to recall and retest as central records had not been kept of test distribution and local records did not detail who was tested, when tests were performed or batch numbers of test kits used. In some cases an advert was placed in local papers requesting people to contact their GP if they had had a pregnancy test done at the hospital. The manufacturer issued a Field Safety Notice recalling affected batches and the MHRA issued a Medical Device Alert to ensure that all users of the devices were aware of the problem.

Key points

- A recall of patients would have been much more refined had records been kept. Many people were contacted unnecessarily as some trusts were not able to identify who was tested with the affected batch.
- Record keeping is essential especially where you need to review patient results in the event of a device failure.

Questions to consider

- Stock control – who is responsible for issuing or dispensing testing devices? Is there a system in place to record who receives the devices, when they are received and what the batch numbers are?
- Are operator ID and patient ID properly recorded?
- Can laboratory staff access QA/QC results?
- Are records kept of the batch numbers of the test kits used, including date opened and use-by dates for all reagents?

- Have arrangements been made with the hospital laboratory to provide support to ensure that abnormal results and out-of-limit results are confirmed and referred to the relevant pathology consultant?
- Are the results expressed in the same stated units as used by the hospital laboratory? (e.g. SI units)
- Are staff aware of the confidentiality aspects of patient results? Are results stored on computer systems password protected?
- How are results stored within the POCT system and for how long?
- How are computer records stored and backed up?
- Are results returned to the clinician and placed in the patient's notes in a written format (with their POCT source identified), with appropriate reference ranges for the POCT device or electronically recorded on the hospital information system?

4.11 Information technology and connectivity

There are many areas to consider with regard to POCT and information technology, particularly the connecting of POCT devices to external data systems such as management workstations and laboratory information systems. It is recommended that POCT devices are integrated into laboratory information management systems (LIMS) and hospital information management systems (HIMS) wherever possible.

In 2006 the second edition of a standard on point of care connectivity for device manufacturers was published by the Clinical and Laboratory Standards Institute (CLSI) 'POCT1-A2' [5]. There are an increasing number of systems available that allow full connectivity of POCT devices e.g. urine dipsticks, glucose meters, with data management systems.

Excerpt from the Report of the Review of NHS Pathology Services in England [1].

Annex C.2

'The scope of IT needs in pathology extends beyond the individual patient's request reporting cycle...Specifically these need to cover: connectivity for point-of-care systems running within primary and secondary care and extending outside into the wider community including pharmacies and other non-NHS providers.'

Part 2: 45

'Developments in point-of-care testing, where laboratory equipment can be located in a number of hospital and community settings (for example a GP's surgery or a health centre), are especially dependent on good IT links with the parent laboratory as the only means of maintaining a complete record of the patient's results.'
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4.12 Adverse incident reporting

An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users including patients or other persons. The MHRA has [two](#)

[parallel reporting systems for device-related adverse incidents](#) – one for manufacturers and another for users. These can be accessed via the [Yellow Card Scheme](#).

We strongly encourage device users to report all adverse incidents to us. It really does make a difference to the work of the MHRA in ensuring POCT devices are fit for purpose.

If in doubt – report!

Additionally, manufacturers of IVDs are obliged, under the UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended) [6], to report certain adverse events to the MHRA.

By reporting to us we can:

- enable manufacturers to find solutions to device-related problems
- disseminate advice to the healthcare professions to prevent adverse incidents and promote good practice for use and maintenance of devices
- collate information to identify trends in device safety and performance.

An essential part of POCT management is a system for reporting adverse incidents to the MHRA. We publish an annual document that contains details on how to report incidents (available on our website www.mhra.gov.uk).

5 References and bibliography

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PD 6461-1:1995 General metrology Part 1: Basic and general terms (VIM).

BS EN ISO 13485:2003 Medical devices. Quality management systems. Requirements for regulatory purposes.

BS EN ISO 14971:2007 Medical devices. Application of risk management to medical devices.

BS EN ISO 22870:2006 Point-of-care testing (POCT). Requirements for quality and competence

BS ISO 15190:2003 Medical laboratories. Requirements for safety
Clinical laboratory testing and in vitro diagnostic systems ISO 15189 (2003)

Available from BSI: <http://www.bsigroup.co.uk>

For a list of standards designated to the UK MDR 2002, please see:
<https://www.gov.uk/guidance/designated-standards#healthcare-engineering>

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Contacts

Centre for Evidence Based Purchasing (CEP) <http://www.pasa.nhs.uk/PASAWeb/NHSprocurement/CEP/>

Clinical Pathology Accreditation (UK) Ltd <http://www.cpa-uk.co.uk/> e-Learning Can

MHRA
<http://www.mhra.gov.uk>

Skills for Health <http://www.skillsforhealth.org.uk/>

United Kingdom Accreditation Service (UKAS) <http://www.ukas.com>

Appendix Regulation of POCT devices

In order for an IVD medical device to be placed on the UK market it must meet the requirements of the UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002).

Part IV of the UK MDR 2002 details regulatory requirements for manufacturers of IVDs, which deal specifically with the safety, quality and performance of IVDs. In outline, it is intended to ensure that IVDs:

- do not compromise the health and safety of patients, users and others when used for their intended purpose
- are designed and manufactured so that they are suitable for the purpose specified by the manufacturer
- achieve the performances stated by the manufacturer.

Part IV of the UK MDR 2002, Annex I (as modified by Part 3 of Schedule 2A to the UK MDR 2002) lists various 'essential requirements' with which IVDs must comply before being placed on the market or put into service. Not all the essential requirements will apply to all devices and it is for the manufacturer of the device to assess which are relevant to the particular product. In determining this, account must be taken of the intended purpose of the device.

Extract from Annex I

Essential Requirement 8: Information supplied by the manufacturer.

8.1 Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer.

This information comprises the data on the label and in the instructions for use.

8.7 Where appropriate the instructions for use must contain the following particulars:

(h) the measurement procedure to be followed with the device including as appropriate:

- principle of the method,
- the specific analytical performance characteristics...
- the indication whether any particular training is required

The CE, CE UKNI or UKCA marking on an IVD represents the declaration by the manufacturer that the device meets all of the relevant provisions of the UK MDR 2002.