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# Point of care testing in community pharmacies

Guidance for commissioners and  
community pharmacies delivering NHS  
services

Version 1, January 2022

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# Foreword

As part of the Community Pharmacy Contractual Framework agreement of 2019, NHS England and NHS Improvement committed to explore point-of-care testing (POCT) by community pharmacists to help in the drive to conserve the use of antibiotics.

The impact of the COVID-19 pandemic and emergence of new POCT technologies that are more robust and less prone to error have now broadened the scope for the deployment of POCT in community pharmacies: to improve the quality and efficiency of the delivery of diagnostic services closer to home, supporting the recovery of primary care. This drive also reflects the NHS Long Term Plan focus on prevention of ill-health, making the best use of the clinical skills of pharmacists and providing more clinical services in convenient and accessible locations in the community.

Examples of NHS-commissioned POCT services that through technological advances can now be delivered in community pharmacies are:

- non-invasive blood pressure monitoring as part of the hypertension case finding and blood pressure checks
- urinalysis for possible urinary tract infections
- chlamydia screening for the under 25s
- carbon monoxide monitoring as part of smoking cessation services
- COVID-19 rapid antigen testing
- blood glucose measurements as part of diabetes prevention services
- oxygen saturation using oximeters to assess people presenting with breathing difficulties
- peak flow measurements for patients with asthma.

The successful implementation of POCT depends on commissioners understanding its application to community pharmacy service delivery, ensuring the right technologies are used to optimise patient care. Community pharmacies need to understand how to operate equipment correctly and how to maintain it in a safe and reliable condition.

This guidance covers:

- technology and equipment selection

- operational service delivery
- governance and assurance.

It describes the consistent standards and safe environment for the use of POCT equipment and devices for diagnosis, monitoring and screening in community pharmacy, to guide both commissioners of NHS services and community pharmacies

Increasing the availability of POCT in community pharmacy does carry the risk of medicalising self-limiting conditions that people would otherwise manage without consulting a health professional. This is a particular risk with infections, potentially increasing the unnecessary use of antimicrobials.

It is therefore imperative that this guidance is followed to establish effective clinical governance to scrutinise and authorise proposals for local enhanced services or advanced services and specifications for POCT for infection, ensuring only reliable point-of-care tests with high clinical utility are used in appropriate patient populations under the right circumstances.

As we look to recover from the impact of COVID-19, this guidance will help in the drive to expand primary care capacity by supporting new NHS community pharmacy POCT services and the communities they serve.

Professor Dame Sue Hill OBE  
Chief Scientific Officer

Dr Keith Ridge CBE  
Chief Pharmaceutical Officer

# Introduction

The [NHS Long Term Plan](#) highlights the importance of patients receiving care closer to home, shifting from a traditional model of hospital-based services toward a more community-based approach. To help make this shift, the [Community Pharmacy Contractual Framework 2019-2024](#) recognises that community pharmacies have the potential to deliver new prevention services that include testing and clinical services that incorporate monitoring that is timely, convenient to patients<sup>1</sup> and form part of an integrated pathway.

Rapidly developing healthcare technology and changes in clinical practice mean that increasingly complex medical devices and testing technologies can be and are being used in primary care. Good management systems appropriate to the care setting must be in place to ensure the safe and effective use of POCT devices, and these devices and their users must comply with relevant legal requirements.

This guidance supports commissioners and providers of community pharmacy clinical services to develop point of care testing (POCT) in the community pharmacy setting by setting out the key principles and signposting to essential resources, including [the relevant legislation and standards](#). The key principles are:

- identify best practice in the selection of equipment and technology that ensures adequate safety and quality to optimise cost and minimise risk
- describe an operational management system applicable to community pharmacy that ensures POCT technology is efficiently maintained and competently used by trained operators, risks are effectively addressed, medical device performance is optimised and a high standard of service is delivered
- establish a model of good clinical governance that satisfies independent regulators and meets applicable quality standards supporting commissioner assurance.

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<sup>1</sup> Including consideration of the impact on protected characteristic groups and others who experience health inequalities.

POCT technology is defined as any medical device<sup>2</sup> and/or system that enables diagnosis, monitoring or screening of patients at the time and place of care by appropriately trained users. It is already being applied in:

- community clinics
- community pharmacies
- GP surgeries
- health centres
- home (self-testing)
- independent sector
- industrial medical centres
- mobile units
- polyclinics – diagnostic centres
- sexual health clinics/GUM clinics
- dental surgeries
- rapid diagnostic and assessment centres
- residential settings.

POCT includes both quantitative and qualitative tests. Equipment can be divided into small, portable hand-held devices and larger bench-top or standalone devices. Some can be used by individuals in their home and others only by competently trained healthcare professionals. POCT technology can also be broadly categorised into the type of diagnostics it enables:

- screening and monitoring devices, eg:
  - non-invasive blood pressure (NIBP) monitors
  - pulse oximeters (SpO<sub>2</sub> monitors)
  - portable spirometers
- diagnostic test kits, eg:
  - blood glucose meters
  - urinalysis test strips
  - cholesterol tests.
  - Since point-of-care tests are carried out close to a patient, the time it takes to test and obtain the results can be significantly shorter compared to standard methods of testing in a laboratory and clinic environment. Potential benefits for NHS services and/or patients include faster decision-making and triage, reduced operating times, fewer outpatient

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<sup>2</sup> 'Medical device' is any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings ([https://ec.europa.eu/health/sites/default/files/md\\_sector/docs/md\\_mdcg\\_2019\\_11\\_guidance\\_qualification\\_classification\\_software\\_en.pdf](https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdcg_2019_11_guidance_qualification_classification_software_en.pdf))

clinic visits, increased access to and convenience of diagnostics,<sup>3</sup> optimal use of professional time and reduction in antimicrobial medication.<sup>4,5</sup>

This document has been developed in consultation with wider stakeholders, including but not limited to: General Pharmaceutical Council, Care Quality Commission, Pharmaceutical Services Negotiating Committee, Community Pharmacy Safety Group, and Medicines and Healthcare products Regulatory Agency.

# 1. Selection of equipment and technology

The selection of equipment and technology – the first step – is critical to the success of the service and needs careful planning. The stages to follow in planning are:

**i) Needs assessment** – establishing what is already available at the community pharmacy and what would be needed to deliver the patient service improvements.<sup>6</sup> POCT device considerations as part of service specification planning include:

- eligibility criteria
- specimen/measurement type
- turnaround time for results
- complexity of operations
- patterns of testing/measurement
- staff resources
- other resources (including IT systems) required to conduct POCT
- environmental requirements (eg space)
- requirements for additional equipment to undertake test

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<sup>3</sup> Including consideration of impact for protected characteristic groups and people who experience health inequalities.

<sup>4</sup> [In vitro diagnostic point-of-care test devices](#)

<sup>5</sup> [Point-of-care testing for respiratory viruses in adults: The current landscape and future potential](#)

<sup>6</sup> Including addressing barriers to access and trust in the services, and consideration of impact on protected characteristic groups and others who experience health inequalities.

- how results will be reported and any clinical consequences.

**ii) Options appraisal** – assessing whether POCT technologies on the market are suitable for the service and of good quality, and meet the identified needs. A risk assessment should be performed for each POCT technology under consideration: it is the key determining factor when deciding which options are suitable for the planned service. It should reflect the likely impact of each technology option and any further resources it might require, and can inform decision-making on aspects such as:

- Which POCT technology options are likely to be most acceptable to community pharmacy providers, to the target population and to commissioners?
- What might be the ‘knock-on’ effects or unintended consequences of implementing a particular POCT technology?
- The need for or exemption<sup>7</sup> from registering the service with the Care Quality Commission (CQC), depending on the type of sample and analysis the service will use.
- How will the results be delivered, and will onward clinical management or referral be required?
- Can any negative impacts be stopped or reduced? (eg over-testing, over-treatment)
- Are there any national or local frameworks or guidance setting out how risks can be mitigated?

Input from a multidisciplinary group of stakeholders can be very helpful in this task.

**iii) Budgeting and financing** – estimating the budget for equipment purchase and ongoing associated costs during its entire lifecycle. The source of funding for and the available acquisition of equipment need to be determined. The aim is to put a financial value on the lifecycle costs of the service for each option, to identify the most cost-effective POCT method.

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<sup>7</sup> Exemption from CQC registration under ‘the exemptions for the regulated activity of diagnostic and screening’ (<https://www.cqc.org.uk/guidance-providers/registration/diagnostic-screening-procedures>)

## 1.1 How to develop a desired device specification

A specification should be developed to ensure the equipment fulfils its purpose and is appropriate for use in the setting. The more detailed and clearly defined a specification, the easier it will be to narrow down the list of models for consideration. You may wish to divide your specification into a list of mandatory and desirable requirements. Where possible, standardisation of equipment (minimising the variety of models providing the same function in one clinical area) is advisable to improve safety of use from user familiarity, facilitate ease of training and take advantage of the economies of bulk purchasing.

The specification should address aspects such as:

- purpose of use (dedicated reader, laptop, smartphone)
- technical characteristics
- physical chemical characteristics
- utility requirements
- accessories,<sup>8</sup> consumables, spare parts
- other equipment needed to ensure end-to-end process
- environmental requirements
- training, installation and utilisation
- warranty and maintenance
- documentation
- decommissioning
- safety and standards.<sup>9</sup>

The earlier risk assessment will have defined many of these requirements. Stakeholders<sup>10</sup> opinion can be valuable in defining the requirements specific to the environment and the context in which equipment will be used. To ensure the POCT device's diagnostic performance is clinically acceptable compared to its 'gold

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<sup>8</sup> "An article which, while not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical devices specifically to enable the medical devices to be used in accordance with its intended purpose or to specifically and directly assist the medical functionality of the medical device in terms of its intended purpose." [Guidance on legislation: Borderlines with medical devices and other products in Great Britain](#)

<sup>9</sup> Medical devices must have CE marking, UKCA marking or CE UKNI marking by law. This mark means that, provided you use the device correctly, it will work properly and is safe (<https://www.gov.uk/guidance/medical-devices-information-for-users-and-patients#what-is-a-medical-device>).

<sup>10</sup> Engaging the target population (eg patients, public, voluntary sector), including conversations about the impact for protected characteristic groups and others who experience health inequalities.

standard', minimum acceptable values for at least four attributes should be verified as part of determining a device's technical characteristics in the specification:

- sensitivity
- specificity
- accuracy
- precision
- limits of detection (where relevant)
- reproducibility.

For genomic tests, [the evaluation criteria](#) are:

- analytical validity
- clinical validity
- clinical utility
- associated ethical, clinical, legal and social implications.

Minimum acceptable values for the above attributes/criteria should be defined using National Institute for Health and Care Excellence (NICE) guidelines, ISO standards and other scientific literature. If a POCT technology has been comprehensively evaluated by an accredited laboratory with a similar patient population, in similar testing environments and for the same clinical use, it may be appropriate to base decisions on fewer performance criteria. Where information is not easily available, especially for novel POCT technology, professional bodies and associations and accredited laboratories can help develop a minimum specification for a device.

## 1.2 How to assess and compare POCT devices

A manufacturer's performance claims for a device should be compared against the desired technical specification. (A record of claimed performance at the time of purchase should be kept.)

As part of your enquiries, it is a good idea to share your technical specification with suppliers of POCT technology when requesting evidence, data from clinical evaluations, documents and other information regarding their device's performance.

All aspects of the equipment offered should be compared with the requirements in the technical specification. Suppliers should provide evidence that their equipment meets the mandatory requirements or if the supplier confirms it does so but through

an approach different from that in the specification, further information and assessment may be required.

Suppliers/manufacturers should be able to provide much of the information you need to assess a device against the desired technical specification. Where possible, they should also provide sample equipment for practical testing and trials and/or contact details of UK-based organisations with similar equipment for their feedback.

An in-house evaluation form should include:

- purchase cost
- dedicated clinical consumable costs
- service support costs
- software upgrade and maintenance costs
- user support and training costs
- scheduled replacement parts costs
- costs to replace accessories
- user preferences and comments.<sup>11</sup>

The information you require for cost evaluation should be available from the suppliers. Increasingly, medical devices are provided ‘free of charge’ based on a ‘consumables contract’. In these circumstances, the cost implications for maintenance and lifetime costs should be considered in the same way as for the direct purchase of the medical device.

Devices that meet a mandatory technical specification can then be compared to choose the best available option that also meets desirable requirements. Your aim is to select the system with the lowest calculated whole-life cost that meets the minimum requirements, while taking into account user preferences and comments. As well as cost, the aspects to consider are:

- clinical performance
- patient comfort and acceptance
- design and usability
- quality of construction and robustness
- service and maintenance requirements
- [MD/IVD-MD UKCA, CE, UKNI marking](#)
- environmental impact/carbon footprint.

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<sup>11</sup> It should be recorded how user preferences and comments have influenced the overall assessment, including where applicable the rationale for varying from user comments and preferences.

# 2. Operational management system

## 2.1 POCT equipment installation, acceptance and commissioning

Most POCT equipment in community pharmacy settings will require nothing more than unpacking (eg single use testing kits). However, more complex devices will need to be assembled, set-up (eg activating specific software options for ambulatory blood pressure monitors) and validated through appropriate testing.

A trained technician – preferably the supplier’s representative – should carry out acceptance testing (or verification of performance); they will perform functional and safety tests (eg checking that the device is electrically safe to use). It is advisable to ask the technician to document the process on an ‘acceptance form’, which will serve as a reference document for users in case of any issues with equipment performance, associated consumables and spare parts. Acceptance procedures vary significantly depending on the complexity of a device and any risks associated with it.

Commissioning refers to the steps the end user, clinical engineer or company representative take to put the equipment into service, after installation and acceptance testing are complete. At this point a device information record should be established by a community pharmacy staff member and must be kept for future reference, eg in case of device failure or manufacture’s recall.

An information record of new POCT equipment should as a minimum provide the following information:

- contact information for the local representative and customer service
- serial number/LOT/batch number of the devices received
- warranty expiry date
- stocks of consumables, accessories and spare parts received
- results of inspection tests undertaken on commissioning

- frequency of planned preventive maintenance and/or calibration required
- details of any maintenance contract and maintenance contractor
- end of life/expiration date, if specified.

## 2.2 Staff training

Good training is the most effective factor in decreasing the risk of device-related incidents and is a necessary part of best practice. Furthermore, liability under the [Consumer Protection Act \(1987\)](#) will only remain with the manufacturer/supplier if the user can demonstrate that equipment has been used in strict accordance with the manufacturer’s instructions. Therefore, employers are responsible for ensuring that staff who use medical devices are appropriately trained and certified as competent. Equally, all healthcare professionals and support workers have a personal responsibility to ensure they are trained and competent in the safe use of any devices they use. Pharmacy professionals should also be able to advise patients on the safety and use of the self-care equipment they sell and help them recognise signs of malfunction or faults.<sup>12</sup> Training should be both theoretical and practical (Table 1).

**Table 1: What user training should cover**

<b>Pre-checks</b>	Ensuring a device is safe to use, performing any maintenance checks required
<b>Patient preparation<sup>12</sup></b>	Explaining to patients and giving them instructions on, for example, the correct use of consumables and preparation for taking samples
<b>General use</b>	Device capabilities, its intended clinical use, how to check it during use, consideration of all aspects of risk management, eg ensuring all sharps are disposed of appropriately
<b>Faults/alarms</b>	Common faults and errors in use and actions to take in the event of an alarm
<b>Cleaning</b>	Suitable decontamination processes between uses
<b>Troubleshooting</b>	Detecting and resolving the most frequent problems that occur when using equipment
<b>Consumables</b>	How to obtain device accessories

<sup>12</sup> Including consideration of the different communication needs of protected characteristic groups and others who experience health inequalities.

<b>Reporting incidents and concerns</b>	Process for reporting incidents, including through the MHRA Yellow Card Scheme, and any continuous faults and errors
<b>Contacts</b>	Numbers for routine and emergency contacts in case of faults and errors that cannot be resolved locally

Staff should be trained in use of equipment and procedure between installation and commissioning. There should be a plan for refresher training as well. Training may be provided by a manufacturer, a third-party provider or the facility staff trainers (who have undertaken ‘train-the-trainer’ training). Best practice recommends undertaking and documenting a competency assessment after training, including a written and practical assessment of the trainee’s understanding. What this entails will depend on the complexity of the test and seniority of staff performing it.

A record needs to be kept of staff training to identify who is competent to deliver the service. [The National Association of Medical Device Educators and Trainers \(NAMDET\)](#) offers free membership and support, including e-learning training modules and regular meetings about medical device safety and training.

The superintendent pharmacist for the pharmacy’s business should appoint a nominated lead in the pharmacy (eg responsible pharmacist) to be responsible for ensuring that POCT procedures are correctly implemented and followed.

Another crucial aspect of POCT user training is patient preparation for a procedure, including how to explain the testing/measurement process and discuss the results (with consideration of the different communication needs of protected characteristic groups and others who experience health inequalities).The [Health Education England \(HEE\) e-learning platform](#) offers free training modules on a range of topics that can assist with this, from medical conditions to how to undertake various aspects of professional practice. Regular participation by staff in external quality assurance schemes (EQA), if available, is recommended to ensure their practice can be benchmarked and any poor performance highlighted early enough to minimise risk to patients and staff.

## 2.3 Operation, maintenance and repair

The umbrella term ‘POCT technology’ encompasses medical devices with very different purposes, techniques of operation and maintenance requirements. However, some rules of good operation and maintenance practice apply to all medical

technologies. [The Health and Social Care Act 2008 \(Regulated Activities\) Regulations 2014](#): Regulation 15 places a legal responsibility on healthcare providers to ensure that equipment used to deliver care and treatment is:

- suitable for intended purpose
- used safely by trained people
- maintained and stored securely.

Equipment users are key to successful equipment operation and safety. They are accountable for their use of equipment and responsible for patient safety and quality of care. Community pharmacy professionals delivering POCT services are expected to:

- follow good practice and behaviour around the use of equipment
- ensure they have the necessary skills to operate and look after equipment correctly
- follow correct safety procedures for themselves and patients
- provide regular checks on the performance of equipment in use and ensure equipment is in a functional state
- validate performance of the device against the instructions for use (IFU) criteria when a new batch or lot number of consumables is put into use
- follow good practice around the withdrawal of equipment from service and its safe disposal
- monitor how effectively equipment is used and keep robust up-to-date records of each device's history and of patient results.

They are also expected to challenge poor practice.

Proper maintenance is essential to ensuring POCT equipment works safely and meets quality standards. It should also increase its working life. Manufacturers set out the specific maintenance requirements in user and service manuals; however, it is the responsibility of each health service provider to arrange how maintenance and repairs will be provided.

### **(a) Routine user maintenance**

Trained pharmacy staff should regularly perform routine user maintenance, according to the manufacturer's instructions. Regular cleaning, visual checks and performance verification enable users to check that a device is working properly and safely before it

is used on patients. Frequent performance checks and calibration (where relevant) helps staff identify when a device's performance is deteriorating and needs correcting. Regular maintenance is the most effective way of spotting faulty devices early and identifying a need to get it repaired.

### **(b) Planned maintenance/servicing**

The manufacturer or third-party engineers usually perform planned maintenance as part of a service level agreement. It generally comprises:

- a visual inspection
- detailed functional checks (including calibration where required)
- electrical safety testing
- periodic parts replacement (e.g. an internal battery, a filter element).

### **(c) Breakdown maintenance (repairs)**

Users can often be trained to perform some first-line fault finding and troubleshooting. However, if they cannot resolve an issue, faulty equipment should be removed from use and clearly labelled as 'faulty'. It should also be decontaminated in accordance with manufacturer instructions as soon as possible. Depending on the type of medical device, the ongoing support provided by an external engineering service may include a temporary loan of equipment to provide a back-up in case of faulty devices, ongoing servicing, calibration and maintenance.

## **2.4 Health and safety and infection control**

When a POCT service involves handling and disposing of biomedical waste (including bodily fluids and sharps), infection prevention and control, procedures and goods management policies must be in place to meet the requirements of regulators (eg General Pharmaceutical Council (GPhC), CQC). Good practice is for the nominated pharmacy lead to be responsible for managing relevant aspects of health and safety and infection control in the community pharmacy. [Health and Safety at Work](#) legislation requires provision of a written risk assessment identifying the hazards and infection control measures implemented in the workplace. These should include:

- staff training in correct hand hygiene (handwashing and disinfection)
- wearing protective personal equipment (PPE), such as gloves and face masks

- prevention of sharps injuries through selection of suitable lancing devices and appropriate training of pharmacy staff in their use and handling
- safe handling and disposal of biomedical waste through training and suitable waste collection arrangements
- safe handling and disposal of hazardous [Control of Substances Hazardous to Health \(COSHH\)](#) substances through training
- training users on the safe use and maintenance of medical devices, including decontamination of reusable devices
- provision of fit for purpose work and storage spaces free of clutter and trip hazards, with suitable ventilation, lighting and access to utilities
- storing POCT equipment securely and preventing its unauthorised use
- keeping POCT devices clean and fully charged, with the appropriate consumables available and ready to be used when required.

Further guidance is available on the [Health and Safety Executive website](#).

## 2.5 Decommissioning and disposal of POCT technology

Devices are condemned when identified as:

- clinically unsafe
- electrically unsafe
- mechanically unsafe
- beyond economic repair (cost >50% of replacement)
- withdrawn from use due to an instruction in a Hazard Warning or Patient Safety Notice issued by the MHRA or other authority
- obsolete
- unreliable in operation
- spare parts or consumables unavailable
- not compatible with current requirements for cleaning and decontamination
- increasing number of corrective maintenance procedures required may indicate imminent failure.

Decommissioning aims to remove unsafe or unusable devices with minimum damage to the environment. It is advisable to contact manufacturers for information on decommissioning. They should be able to provide details of any environmental,

disposal, recycling or structural requirements. If the manufacturer has ceased trading, contact the local authority for guidance on safe disposal.

Responsibility for arranging decommissioning and safe disposal of medical devices and/or consumables should be clearly defined and assigned in the service specification.

## 3. Clinical governance and assurance

Clear lines of responsibility and accountability are central to providing a quality service. The nominated pharmacy lead is responsible for ensuring the programme for clinical governance is in place and is monitored. They should be aware of their responsibility for clinical governance and of the medical and legal implications of an erroneous test result. As noted above, liability under the [Consumer Protection Act \(1987\)](#) 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.<sup>13</sup>

The POCT service's clinical governance structure should clearly define lines of accountability in its local policies and procedures, possibly including for the following areas:

- training
- instructions for use
- health and safety
- maintenance
- standard operating procedures
- record keeping
- clinical audit
- quality assurance
- risk management and adverse incident reporting
- clinical effectiveness
- accreditation
- national external quality assurance schemes.

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[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/957967/Management\\_and\\_use\\_of\\_IVD\\_point\\_of\\_care\\_test\\_devices.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/957967/Management_and_use_of_IVD_point_of_care_test_devices.pdf)

The [GPhC standards for registered pharmacies](#) set out the principles against which pharmacies are inspected. In particular, inspection encompasses the use of equipment and facilities to safeguard the health, safety and wellbeing of patients and the public.

### 3.1 Standard operating procedures

A nominated pharmacy lead in the community pharmacy should work under the direct supervision of the responsible pharmacist and will be appropriately trained and responsible for ensuring that staff using POCT devices follow the standard operating procedure (SOP) for each device. SOPs should be written in accordance with the manufacturer's instructions for use, and include:

- clinical relevance/purpose of examination
- underlying principles of the test
- correct preparation of the patient,<sup>14</sup> specimen requirements and means of identification
- equipment and special supplies
- storage of reagents, standards or calibrators and internal control materials
- equipment maintenance
- calibration and quality checks
- instructions for the performance of the procedure
- limitations of the procedure, including interferences, cross-reactions and reportable intervals
- reporting of range results, errors and incidents
- record keeping (including maintaining logs) and audit instructions.

A copy of the SOP should be available to all staff using POCT and kept close to the equipment being used. SOPs must be reviewed on a regular basis, at least every two years and always when procedures change. They should also be reviewed following an incident or poor audit result, when changes to improve processes and prevent future errors may be required. SOPs should be version controlled and maintained as part of an appropriate quality management system.

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<sup>14</sup> Including consideration of appropriate communication style and approach to protected characteristic groups and others who experience health inequalities.

## 3.2 Record keeping

Where tests are performed at the point of care it is crucial that the results are incorporated into a patient's health record. The [Professional Record Standards Body \(PRSB\)](#) has published a digital data standard for community pharmacy. The nature of consultation-related data records, including records of test results, will depend on the treatment pathway and should be defined by the commissioners as part of the service specification.

More POCT systems now allow full connectivity between the device (eg urine dipsticks, glucose meters) and patient data management systems. To help with ICT arrangements in community pharmacy, the Clinical and Laboratory Standards Institute published [POCT1-A2](#), a standard on point-of-care connectivity.

Robust POCT service records should enable community pharmacy to track its POCT devices, their maintenance records and associated history of staff user training.

## 3.3 Audit

The most significant risk associated with POCT is the failure of users to follow POCT [procedures](#). All elements of use, maintenance, repair, record generation and storage should be regularly audited to ensure the correct procedures are in place and being adhered to. Staff with appropriate knowledge and experience of POCT service delivery and management of POCT devices should carry out the audits. Audit results should be reviewed and acted on. Community pharmacies should also ensure there is a mechanism to obtain regular feedback from technical service contractors on the repair and maintenance process. This should include reporting even what appear to be minor problems, as without remedy these may lead to a major failure.

## 3.4 Quality assurance

POCT activities outside diagnostic laboratories are not subject currently to the same level of regulation and accreditation as conventional medical laboratories. This makes quality assurance all the more important.

Quality assurance covers all the processes that help ensure a test gives the correct result. It is an essential component of clinical governance and includes internal quality control (IQC) and external quality assessment (EQA). Each POCT SOP should detail

the specific IQC and EQA arrangements for associated equipment and procedures and these must be followed at all times.

## Internal quality control

IQC is checking that equipment results are reliable before it is used on patients. For POCT diagnostic tests, this usually involves analysing a sample of known concentration (often supplied by the manufacturer) and ensuring the result obtained falls within acceptable performance limits. IQC procedures for screening or monitoring POCT equipment are often built into the device, with a 'self-check' performed automatically when it is turned on. This provides reassurance as to the accuracy of results obtained and therefore helps to ensure patient safety. Analytical performance of the test/device and its acceptance ranges should be clearly specified in the SOPs.

Quality control checks should be carried out at regular intervals (as detailed in the SOP) and at least:

- on commissioning
- following major repairs
- for a new delivery of consumables/reagents or a new lot number of consumables
- when an operator lacks confidence in a patient result
- when the POCT result does not fit the patient's clinical presentation
- the device has suffered a mechanical impact
- at other times as specified by the manufacturer.

## External quality assessment

EQA involves analysing samples with unknown values from an external source or provider. The manufacturer or a dedicated EQA provider, such as a local acute hospital laboratory or [national external quality assurance provider \(NEQAS\)](#) may operate EQA schemes. The [MHRA recommends all POCT services participate in EQA](#) as part of clinical governance, but a pragmatic approach should be taken when deciding on participation in EQA for community pharmacy settings and for what type of diagnostic services. Judgement should be based on a risk/benefit assessment, taking into account the manufacturer's recommendations, the specific POCT technology and the user's capability.

## 3.5 Risk management and adverse incident reporting

Appropriate reporting of identified risks and an escalation process need to be established for all clinical services delivered by community pharmacies. This should cover any POCT device used as part of that service.

A device-related adverse incident is an event that produces, or has the potential to produce, unwanted effects for the safety of patients, users or other people.

An adverse incident can result from a shortcoming in:

- the device
- its accessories
- software failures
- the instructions for use
- user practice
- servicing and maintenance
- conditions of use.

An incident report should include the following information:

- date and time of the incident
- device settings, if relevant
- details of the incident (how it happened and any outcomes for the person affected)
- details of the device involved (type, make, model and serial number)
- details of any error message or failures observed
- root cause analysis of the fault from investigation.

Equipment involved in the incident should be removed from use and quarantined for further investigation, together with any packaging, consumables and accessories. Where user error is identified as causing the incident, training needs should be defined and appropriate re-training sessions arranged.

Incidents involving medical devices should be reported via the [MHRA Yellow Card Scheme](#). Community pharmacies are expected to register with the MHRA alert system to receive and act on safety alerts and recalls relating to medical devices.

## 3.6 Accreditation

Accreditation is available to providers of diagnostic services and tests through [the United Kingdom Accreditation Services](#) (UKAS). At present accreditation is not mandatory for community pharmacies delivering POCT.

Several international standards are used as the guiding framework for accreditation processes. These are internationally accepted and harmonised, and include [ISO 22870:2016](#) (requirements for quality and competence in POCT) and [ISO 13485:2016](#) (requirements for medical device quality management systems). Organisations turn to such standards when developing guidelines, definitions and procedures that help them:

- satisfy inspectors quality requirements
- ensure procedures and services are safe
- comply with regulations
- provide optimal storage and operation conditions for devices and reagents
- ensure that internal processes are defined and controlled.

Use of quality standards is also not mandatory but may be expected by certain stakeholders. In addition, some government agencies may require suppliers and partners to use a specific standard as a condition of doing business (eg manufacturers of medical electrical equipment must comply with [BS EN 60601](#) requirements).

# Appendix 1: Related regulations and guidance

Good medical device risk management and governance requires users of POCT technology to have an understanding of quality assurance (QA) processes, interpretation of test results, limitations of use and good record keeping. It is therefore important that users of POCT should have access to clear guidance on these and other matters relating to the management of POCT.

This list, while not exhaustive, gives the main regulations and guidance for medical device management and safe, high quality practice in community pharmacies.

## MHRA publications

- [Blood glucose meters guidance](#)
- [Buying medical devices for personal use](#)
- [Devices in practice](#)
- [Management and use of IVD point of care test devices](#)
- [Managing medical devices](#)
- [MHRA target product profile for Covid-19 related point of care tests](#)
- [Reporting problems with the device to MHRA using Yellow Card scheme](#)
- [Use and regulation of pulse oximeters](#)
- [What is a medical device?](#)

## Department of Health and Social Care publications

- [Consolidated pathology network - Clinical governance guide 2018](#)
- [Community Pharmacy Contractual Framework \(CPCF\) 2019-2024](#)
- [Health and Social Care Act 2012](#)

## Standards

- [EN 1041:2008 + A1:2013 - Information supplied by the manufacturer of medical devices](#)
- [EN ISO 13485:2016 Medical devices - quality management systems - Requirements for regulatory purposes](#)

- [BS EN ISO 14971:2019 - Medical devices. Application of risk management to medical devices](#)
- [BS EN ISO 15189:2012 - Medical laboratories. Requirements for quality and competence](#)
- [ISO/TS 22583:2019 - Guidance for supervisors and operators of point-of-care testing \(POCT\) devices](#)
- [BS EN ISO 22870:2016 - Point-of-care testing \(POCT\). Requirements for quality and competence](#)
- [BS EN 60601-1:2006+A12:2014 - Medical electrical equipment. General requirements for basic safety and essential performance](#)
- [BS 70000:2017 - Medical physics, clinical engineering and associated scientific services in healthcare. Requirements for quality, safety and competence](#)

## Other legislation

- [Consumer Protection Act \(1987\)](#)
- [CQC registration exemption under 'the exemptions for the regulated activity of diagnostic and screening'](#)
- [Health and Safety at Work Act](#)
- [Medical Devices Regulations 2002](#) (SI 2002 No 618, as amended) (UK MDR 2002)
- [Medicines and Medical Devices Act 2021](#)
- [The Health and Social Care Act 2008 \(Regulated Activities\) Regulations 2014:Regulation 15](#)

## Other publications

- [ACCE model process for evaluating genetic tests](#)
- [Diagnostic and screening procedures | Care Quality Commission \(cqc.org.uk\)](#)
- [GPhC standards](#)
- [MPACE accreditation FAQs](#)
- [NHS Long Term Plan](#)
- [Professional Record Standards Body \(PRSB\) has published a digital data standard for community pharmacy](#)
- [RCPA Chemical pathology analytical performance specifications](#)
- [UKAS Accreditation information leaflet](#)

- [User guide: WHO technical specification for medical devices](#)
- [WHO Good Clinical Laboratory Practice \(GCLP\)](#)
- [WHO Quality manual templates](#)

# Annex 1: A look into the future

## Pharmacogenomics

[Pharmacogenomics](#) is the study of how a patient's genome can influence their response to medicines. Variants in an individual's genome can determine whether they are likely to respond to a medicine or if they are at risk of side effects.

The [Genome UK](#) government strategy published in 2020 set out the ambition for the UK to be the most advanced genomic healthcare system in the world. This builds on the 2016 NHS England ambition set out in [Improving outcomes through personalised medicine](#) to improve the diagnosis, stratification and treatment of illness.

The use of genetic information to guide treatments is growing and will benefit patients by increasing the efficacy of their treatment and reducing the incidence and severity of adverse drug reactions. It will also contribute to the fight against antimicrobial resistance through increasing the overall efficiency of antibiotic prescription.

Accredited NHS [genomic laboratory hubs](#) currently perform all the genomic testing performed by the NHS in England. However, increasing numbers of private companies are offering direct to consumer (DTC) POCT genetic/genomic testing, including over the internet, and often targeted at healthy people.

The technology to analyse a person's DNA (genetic code) is now fast and affordable but the clinical validity, sensitivity and clinical utility of such testing may be variable. The Royal College of General Practitioners and British Society for Genetic Medicine issued a [joint statement](#) in 2019 to highlight that the chance of false positive and negative results is very high for some DTC tests.

NHS patients may present at community pharmacies requesting help with interpreting DTC genomic results. These results should not be taken at face value. Educational

resources<sup>15,16</sup> are available for pharmacists and pharmacy technicians that provide background on pharmacogenomics and the broader issues of genomic testing.

Seven [Genomic Medicine Service \(GMS\) Alliances](#) have formed in England, bringing together providers and organisations across their geographies to support the embedding of personalised medicine into pathways. These networks can provide advice on genomic testing, including for pharmacy leaders on implementing and interpreting pharmacogenomic testing.

## Multiparametric and multiplexed POCT analysers

Using multiple POCT kits and instruments to carry out several different tests on different samples is problematic and not very efficient. It increases training needs, volume of equipment, maintenance arrangements, quality management protocols, test supplies and required storage space.<sup>17</sup>

Multiparametric POCT analysers integrate several test types into a single instrument. This solution has the potential to improve patients' and healthcare professionals' experience. These devices are sufficiently accurate and precise to meet clinical needs, but smaller and less complex to use than standard laboratory equipment and as such can be operated by non-laboratory trained staff. They have a simple user interface and only a drop of whole blood needs to be added to a small cartridge or disc containing one or more test reagents. Cartridges are then slotted into the instrument and the analysis proceeds without the user's further involvement.<sup>18</sup>

Multiplexed POCT analysers are also available with the potential to undertake different biochemical and haematological tests on a single blood sample. Such analysers require a high throughput of tests is needed to justify investment in these analysers so they will not be suitable for all primary care and community settings.<sup>19</sup>

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<sup>15</sup> <https://www.genomicseducation.hee.nhs.uk/blog/tag/education-and-training/>

<sup>16</sup> <https://www.cppe.ac.uk/programmes/?t=Genomics-E-01&evid=51178>

<sup>17</sup> <https://bmjopen.bmj.com/content/4/8/e005611>

<sup>18</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4204237/>

<sup>19</sup> <https://www.nice.org.uk/guidance/dg26>

Contact us

[enquiries@england.nhs.uk](mailto:enquiries@england.nhs.uk)

NHS England and NHS Improvement  
Skipton House  
80 London Road  
London  
SE1 6LH

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