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# Self-sampling at the point-of-care – enhancing access, improving care

Read about the latest developments in self-sampling.

**Published:** 17 July 2025
**Author:** Gilbert Wieringa, Dr Julia C Smith, Alyson Bryant, Sarah Duffin, Dr Karen Perkins, Professor Andy Bacon, Joseph Burt
**Read time:** 12 Mins

**Self-sampling has the potential to catalyse ownership of healthcare, as well as offering choice and convenience for patients (and sometimes their carers) who might otherwise not have access to clinical services. Here, speakers and participants in a February 2025 conference organised by th Association for Laboratory Medicine report on the benefits, latest developments and available guidance on introducing self-sampling devices.**

# The clinical perspective

Self-sampling as an alternative to venepuncture has proven to be a popular means of enhancing clinical outreach and improving patients' experience, particularly during the COVID-19 pandemic when access to central testing was restricted.[1–4] Innovative devices range from dried blood spot cards, capillary blood collectors and upper arm devices able to collect up to 3mL of blood.[5] Adoption of self-sampling in NHS clinical practice has, however, been slow, despite the opportunity it offers to support patients in hard-to-reach or remote locations.

A case history describes the experience of June, a participant in an ongoing project implementing touch-activated phlebotomy for people with learning disabilities in Carnforth and Milnthorpe, Cumbria:

> *"June is a 30-year-old lady with Down's syndrome and hypothyroidism, who is cared for by her brother, Darren. Concerns had been raised over June's welfare due to her significant recent weight loss at her annual health checks with her general practitioner. Despite multiple attempts over a few years, blood sampling had never been successful, causing increasing distress due to anxiety. Her levothyroxine medication dose could therefore not be monitored appropriately. The introduction of the touch-activated phlebotomy device has transformed the situation and her thyroid function tests are now regularly carried out and thyroxine dose adjusted as appropriate.*
>
> *Darren commented: "They tried to do the blood test with a needle but as soon as they go to the 'pump' on her arm, she knew what was going to happen and she would refuse. My little sister has been scared for over 8 years and that is how long we have been waiting for a blood test. Since we have had this [new method], she has done maybe 4 or 5 of these and sits there good as gold. I would say it is absolutely brilliant!"*

The repertoire of literature-cited tests is growing and typically reflects clinical interest in supporting specific patient groups, for example monitoring of diabetes,[6] lipid levels[7] and tumour markers for cancer patients,[8,9] offering people home sampling for full blood counts and anti-coagulation monitoring,[10] measuring auto-antibody levels in patients with auto-immune-mediated rheumatic diseases,[11] and monitoring immune-suppressive drug levels.[12]

# The patient's perspective

Although not an exhaustive list, individuals who may benefit from self-sampling include:

- patients with needle phobias or those unable to tolerate venepuncture
- patients for whom venepuncture is not an option
- children
- patients with long-term conditions – for example, patients who need to monitor diabetes/lipids, cancer patients who need to monitor tumour marker levels, or patients with hypothyroidism
- people with learning disabilities or mental health issues for whom venepuncture provokes misunderstanding and anxiety
- participants in screening programmes and clinical trials
- patients reluctant to attend appointments – for example, due to a fear of clinical locations, or those who need to attend a sexual health clinic

- patients unable to access care – for example, due to hard-to-reach locations, immobility or economic barriers
- patients' carers
- under-represented, under-served patient populations.

The advantages that self-sampling can bring to patients include:

- release of patient, carer, phlebotomy and clinician time/money
- the offer of choice and convenience
- better clinical care through enhanced compliance/concordance with treatment
- enhanced patient participation in their care, encouraging self-management, empowering patients.

However, patient self-sampling poses some disadvantages, including:

- the potential for sample tampering and substitution
- waste and the impact of disposable single-use devices and their associated packaging on the environment
- risk of infection/bleeding/haemolysis if instructions for use are not followed.

# The laboratory perspective

Traditional sampling activities undertaken by trained personnel at centralised locations (e.g. a phlebotomy clinic or a GP practice) often come under the responsibility of the laboratory. While responsibility cannot extend to sampling activities undertaken by patients, laboratories are well placed to take a leadership role to support those wishing to adopt this new way of working. Furthermore, for United Kingdom Accreditation Service (UKAS)-accredited laboratories, there is a vested interest in doing so if the subsequent testing is included as an extension to scope (see the following section on accreditation).

Training in self-sampling – whether hands-on or distance learning (video guides, written instructions, tutorials) – is key to ensuring that high-quality samples of adequate volume are received in the laboratory. Engagement with clinical leads, patients and their representative groups benefits this process and provides the baseline for future relationships.

Self-sampling is the early, vulnerable step and can render all subsequent processes redundant if not appropriately carried out. In practice, while first-time self-sampling failure is not uncommon, it is usually followed by second-time and subsequent successes.[11] Tracking from the point of device purchase/issue to the collection of a sample, its dispatch, transport, receipt in laboratory and analysis, and the issue and receipt of a report allows the chain of responsibility to be shared

among all stakeholders and provides the data for regular audit. Tracking options include bespoke systems linked to real-time alerts, adaptation of laboratory information and management systems, app-based information sharing and messaging. In the simplest form of tracking, self-collected samples can be mediated through the laboratory for dispatch and receipt.

Reduced sample volumes may restrict testing to a smaller number of analytes, each of which needs to be validated from point of sampling to point of analysis, to take into account time and temperature stability issues, matrix differences (e.g. capillary versus venous, anti-coagulant differences), potential interferents not usually encountered during phlebotomy (e.g. hand creams, biotin, altered blood-to-gel ratio in collection devices). The higher level of risk of receiving haemolysed samples may also preclude some analyses, e.g. potassium.

Within the laboratory, the new way of working may necessitate altered work patterns: responsibility for purchase, distribution and monitoring the journeys of devices, if not being undertaken by fellow stakeholders; consideration of options for direct test requesting by patients; the need to adapt centrifuges to accommodate self-sampling devices; ensuring capability of analysers to handle micro-samples; and providing suitable environments for receipt, storage and disposal of devices.

# Accreditation

While sampling activities carried out by patients cannot be accredited, ISO 15189:2022 puts patient welfare and consideration of clinical risk/impact at the forefront of medical laboratory accreditation.[13] In the UK, accreditation to ISO 15189:2022 by UKAS provides independent assurance of the quality and safety of medical laboratory services.

UKAS accreditation can cover traditional laboratory-based testing, point-of-care testing and tests performed in a laboratory on a sample taken by a patient using a self-sampling device. For tests from self-sampled devices to be included in the scope of UKAS accreditation, laboratories must demonstrate compliance with ISO15189:2022 for the pre-examination, examination and post-examination stages.

# Pre-examination

Self-sampling will likely be the highest risk area on the validity of all subsequent processes. Laboratories must provide clear, relevant, up-to-date information to patients regarding the self-sampling process, including patient preparation (e.g. fasting, not taking medication for a period of time before providing the sample), type and amount of sample to be taken, sample labelling requirements, sample transport/packaging requirements (e.g. choice of courier versus mail, consideration of temperature/stability issues) and criteria for acceptance/rejection of samples.

## Examination

Laboratories must assure themselves that the tests are clinically fit for purpose. Samples taken using self-sampling devices might differ from the samples taken by healthcare professionals (e.g. capillary blood sample vs venous blood sample). Accredited laboratories must ensure that the test methods used have been validated and verified for the applicable sample types, that they have defined appropriate clinical decision limits and reference ranges for all sample types, and that there are appropriate quality control and quality assurance processes in place as applicable to all sample types.

## Post-examination

When test results are released, they must include the type of primary sample and the date it was collected, plus comments on sample quality and suitability that can compromise the clinical value of the examination result. Laboratory services must clearly define by whom and to whom they will release results (e.g. will they go directly to the patient via a text message or app notification; will they only be released to the patient's GP?). Consideration should be given to the need for special counselling should a result have serious implications for the patient.

# Regulation

Self-sampling devices are regulated medical products. The Medicines and Healthcare products Regulatory Agency (MHRA) is the regulator of medicines, medical devices and blood components for transfusion in the UK, ensuring safe access to medical devices for patients and the public. Manufacturers must register self-sampling devices with the MHRA before they can be used across the UK. Registration requires a declaration or certificate of conformity, ensuring the devices are safe and effective, and they must have either a UKCA (UK Conformity Assessed) or a CE (Conformité Européenne) marking to indicate they meet relevant regulations.

For most specimens like urine, blood or tissue, which might be infected with a disease or virus (category B samples), postal regulation UN3373 applies and allows transport at up to 30°C. For infectious samples that pose a high risk to humans (category A samples), postal regulation UN2814 requires specialised handling and transport means.

# Starting a service

A recommended approach to starting a self-sampling service is for the innovation to be seen as part of a system enhancement/pathway development, rather than a purchase of devices. This is also a safer solution, as responsibility and risk can be shared.

Given that the population who would benefit may not be numerically significant, it is unlikely that cost-releasing resources (e.g. phlebotomy time) will be released in the first instance. Hence, a start-up business case for a local conurbation might focus on the relatively low investment required or the impact on healthcare/outcomes for those patients who would benefit. The strength of any business case is multi-stakeholder demonstration of investment in new ways of working for mutual gain. A check list of other issues to be considered is shown in Table 1 below.

## Table 1. Issues to be considered in a business case for a self-sampling service.

| Topic | Issues |
|---|---|
| Selection of technology | Range of fit-for-purpose, MHRA-registered, UKCA- or CE-marked self-sampling devices<br>Choice of 'postal pathology' provider able to meet UN3373 postal regulations<br>Selection of sample device-tracking infrastructure provider |
| Stakeholder involvement | Local patient interest groups, GP surgeries, secondary/primary/community care clinicians, primary care networks, device suppliers, laboratories, 'postal pathology' providers, telehealth providers (for device tracking/telecommunications), clinical trials leads |
| Potential funding sources | Local/trust R/D and innovation funds, national research, development and innovation funds, self- sampling device providers, telehealth providers, 'postal pathology' providers, independent sector healthcare providers, GP surgeries, patients and/or local patient interest groups, charities, emerging providers – diagnostic hubs, community diagnostic centres |
| Funding requirements | Device costs<br>Tracking infrastructure<br>Postal/transport services<br>Laboratory adjustments<br>Training |

| | |
|---|---|
| Alignment with local/national healthcare priorities | The 2025–2026 NHS priorities to improve patient experience of access to general practice, reducing inequality of care, providing better care closer to or in people's homes, preventing people spending unnecessary time in hospital or care homes, providing patients with more choice and control. The 2023 NHS Equality, Diversity and Inclusion improvement plan |
| Governance/risk management | Coordination of and responsibility for training, postal chain and liaison with end users. Quality assurance across the pre-analytical, analytical and post-analytical chain |

# Sustaining services

Having established a pilot, the next stage could be the procurement/commissioning of a service for recurrent funding (rather than for a one-off grant). Ideally, the pilot report can provide the outcome measures and will have developed stakeholder ownership and buy-in (as well as the momentum that helps justify a sustained service). However, the challenge to secure sustained funding, especially on a larger footprint, may remain.

The commissioning of new services in England is undergoing restructuring. Currently, commissioning functions come under the remit of the 42 regionally based integrated care systems or boards and their local area 'place-based partnerships', which populations of around 250,000–500,000 people. Therefore, it is suggested that, instead of a top-down and funder-led project, the new service is developed as a provider collaboration with service users that starts from the grassroots (GP practice/primary care network), then grows and spreads. This method of service development can be achieved by direct engagement with localised neighbourhoods of multi-agency (primary care, community services and acute outreach) teams and may reap greater rewards.

In Scotland, regional commissioning responsibility lies with the 14 health boards. Delegation to place-based, integrated health and social care planning perhaps draws parallels with NHS England's approach of place-based partnership models. In Wales, responsibility lies with the 7 local health boards, but these work in conjunction with coterminous regional partnership boards and public service boards to implement joint area plans for the benefit of local populations. In Northern Ireland, 5 local commissioning groups, coterminous with the 5 health and social care

trusts, work with 17 integrated care partnerships to review how care is provided, particularly for frail, elderly people and those with long-term conditions. However, as with England, a community-based approach should also be considered.

# Discussion

Self-sampling is not new – colorectal cancer screening starts at home; evidence increasingly shows that self-collected vaginal samples can be an acceptable approach to cervical cancer screening;[14] and a national framework for HIV self-sampling has been in place since 2015.[15] Self-sampling of blood, urine, saliva or other bodily fluids via recent advances in technology represents another step on the way to more user-friendly diagnostics that begin and end at home.

While the immediately identified beneficiaries may be smaller patient populations, the new way of working perhaps opens a window to meeting society's wider expectations from their healthcare services. Society is moving towards online services from home, like shopping and banking, that are delivered quickly at a time that suits the consumer.

Healthcare resources and professionals' time continue to be stretched as populations get older, while more individuals are in a position to choose who provides their healthcare. As such, the choice to request a test from home – knowing that the result that comes back is accurate, reliable and actioned – represents an effective and convenient use of resource from all the contributors along the on-line journey of the sample.[16] The advent of artificial-intelligence-driven algorithms to the chain will likely only add to its safety and assurance.

References available on our website.

## Meet the authors


GILBERT WIERINGA

CONSULTANT CLINICAL SCIENTIST

DR JULIA C SMITH

GP PARTNER, PARK VIEW SURGERY


## ALYSON BRYANT

ACCREDITATION SPECIALIST, UNITED KINGDOM ACCREDITATION SERVICE



## SARAH DUFFIN

SENIOR LECTURER LEARNING DISABILITY NURSING, UNIVERSITY OF CUMBRIA



## DR KAREN PERKINS

PRINCIPAL CLINICAL SCIENTIST, UNIVERSITY HOSPITALS OF MORECAMBE BAY NHS FOUNDATION TRUST



## ANDY BACON

UNIVERSITY OF CHESTER, POLICY LEAD FOR NHS ENGLAND (RETIRED)



## JOSEPH BURT

HEAD OF DIAGNOSTICS & GENERAL MEDICAL DEVICES, MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY


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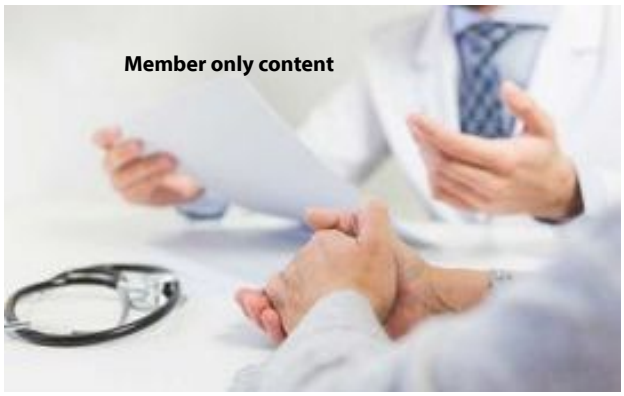


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The Royal College of Pathologists
6 Alie Street
London E1 8QT
Map and directions
Tel: +44 (0) 20 7451 6700

Email: info@rcpath.org