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Automatic for the people: an introduction to self-collected capillary blood testing

Timothy Woolley*[,1,2], Emma Rutter[1], Leanne Fitzgerald[1], Sophie Hepburn[2,3] & Karen Perkins[2,4]

[1]Inuvi Diagnostics, Churcham, Gloucestershire, UK
[2]LabMed UK Patient Centred Testing and Sampling (PaCTS) Interest Group, UK
[3]Blood Sciences, Raigmore Hospital, Inverness, IV2 3UJ, UK
[4]Blood Sciences, University Hospitals of Morecambe Bay NHS Foundation Trust, Burton Rd, Kendal, LA9 7RG, UK
*Author for correspondence: timothy.woolley@inuvi.co.uk

Venepuncture is traditionally considered the gold standard for blood sample collection and remains one of the most common procedures in clinical practice. However, the need for specialised personnel and resources is a limiting factor that affects the efficiency of downstream clinical pathways. Self-collected capillary blood sampling has emerged as a practical alternative to venepuncture in various settings, potentially promoting a patient-centred, personalised, and cost-effective healthcare model. Nonetheless, several operational challenges remain, including limited data on analyte stability and laboratory automation. Despite these challenges, the incorporation of self-collected capillary blood sampling into patient pathways seems inevitable, and routine clinical laboratories should consider adopting this approach to deliver blood services from the hospital to the community. Here, we introduce capillary blood testing, summarise its potential role in healthcare provision, and provide an overview of the areas to consider for its successful implementation.

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Interest in self-collected capillary blood testing (CBT) with back-to-laboratory analysis increased during the COVID-19 pandemic, in part due to the clinical constraints of the time [1–3]. Since then, there has been a notable shift toward this more patient-centred technology [4–8].

The UK-based patient charity, The Patients Association, recently reported that 77% of patients would be interested in self-collecting blood samples; this preference is driven in part by a desire for quicker, more convenient testing options [9]. It is also estimated that approximately a third of patients miss blood collection appointments due to inconvenient testing locations [10], suggesting that self-collection may also reduce non-attendance rates. Hettiarachchi *et al.* found that when comparing hospital-based and at-home sampling, patients preferred capillary self-collection, and return rates were higher for self-collected samples than for clinic-collected venous samples [3]. Furthermore, self-management pathways for chronic disease have been shown to improve health-related quality of life [11].

Given this, self-collected capillary blood with back-to-laboratory testing offers a promising alternative to standard in-clinic venous collection. This delivery model could be an effective way to deliver traditional diagnostics, enabling sample collection to move from the clinic to the community. Due to its patient-centric nature and lower cost [3], CBT is ideally suited to support at-home and community testing, virtual wards, large-scale population screening initiatives and preventive healthcare services [2]. Similar improvements have already been seen with other patient-centric programs, such as HPV testing [4].

While healthcare providers have recently expressed interest in the potential benefits of CBT [5], many laboratory scientists and medical professionals have limited knowledge of this technology. Here, we introduce the reader to the areas that may need to be considered for its successful implementation. This paper concentrates on the

Table 1. Summary of CE-marked capillary blood testing devices & tubes

Self-sampling device	Max volume (µl)	Matrices	Manufacturer	Ref.
CE-marked transdermal device				
TAP II	600	Capillary whole blood	YourBio Health (using BD Microtainer®)	[16]
Tasso+	600	Capillary whole blood	Tasso Inc. (using BD Microtainer)	[17]
Capillary blood tube options				
Microtainer®	600	Capillary whole blood	BD	[18,19]
MiniCollect®	1000	Capillary whole blood	Greiner	[20]
Microvette®	500	Capillary whole blood	Sarstedt	[21]

BD: Becton Dickinson.

self-collection of 'wet' capillary blood. Other sample types and methods, such as dried blood spot testing and self-collected swabs, are not covered here.

Traditional challenges with CBT, such as ease of use and painless collection, have been largely addressed by transdermal self-sampling devices [12,13]. These devices are easier for laypersons to use, streamline logistics by including all consumables in a single pack, simplify sample collection, and produce samples of sufficient quality and volume to enable a large number of assays to be performed with minimal operational changes for the laboratory [13]. In addition to improving patient usability, they address regulatory challenges by being registered for self-use, removing the need for additional validation studies.

However, challenges to the widespread adoption of CBT remain, including the need for whole blood sample stability data and the lack of off-the-shelf laboratory automation [14]. In addition, very few manufacturers have included capillary blood in their assay instructions for use (IFU), although this is changing, and a recent claim extension from Roche Diagnostics (Burgess Hill, UK) has included capillary blood as an approved matrix for urea, uric acid, ALP, GGT, total protein, total bilirubin and ferritin [15]. While examples of total laboratory automation for capillary samples exist, off-the-shelf options remain limited, which will undoubtedly slow the initial widespread deployment of this technology [14].

Pre-analytical considerations

Capillary blood sample collection

Although CBT has been used for decades, most consumables are based on earlier pediatric sample-collection applications that have been available for many years, and many are still intended for professional use only. These consumables, however, have been successfully co-opted for self-collection. Recent innovations in the sample collection space include transdermal devices, which have improved both access and usability and are approved for self-collection [13]. Although they are more expensive than simple finger-prick consumables, they allow the layperson to produce a higher-quality sample [13] (Table 1).

Finger-prick capillary blood testing

Capillary blood sampling is routinely performed using the fingertips of the middle and ring fingers. A lancet with sufficient depth is used to open the finger capillary network; the first drop of blood is wiped away, and subsequent drops are collected into the blood tube. Although straightforward, the self-collection process may be challenging for some patients, particularly those with limited dexterity. To make collection easier, many kit suppliers now provide a sample holder integrated into the packaging; however, other options are also available. The recently released SelfSafeSure Blood Collection Assist Device (BCAD)™ includes both a sample funnel and a secure tube base [22]. The collection process has been successfully tested with self-collected samples across a range of analytes [23].

Becton Dickinson (BD) has also released the BD MiniDraw™ Capillary Blood Collection System, which has shown promising results [24]. This innovative collection device combines a finger sleeve and a new tube format. The sleeve acts as a tourniquet, a lancet guide, and a tube holder, whereas the new tube type is designed for upside-down centrifugation. The finger sleeve gently pools blood in the fingertip, helps the user position the lancet, and allows the blood tube to slide into place during collection. Unfortunately, each device is designed for single-use with one tube, and the finger sleeve must be sized to fit the patient's finger (available in small, medium, large, and extra-large). Likewise, the MiniDraw is approved for professional use only.

Table 2. Tube types and corresponding collection volumes available from manufacturers of capillary blood/pediatric tubes.

Tube type	Greiner MiniCollect® (max whole blood µl)	BD Microtainer® (max whole blood µl)	Sarstedt Microvette® (max whole blood µl)
EDTA	K3: 500–1000 K2: 500	K2: 500	K3: 200 K2: 500
SST	1000	600	300
Plain serum	1000	500	NA
Lith Hep (plain)	1000	400	300
Lith Hep (Gel)	1000	600	NA
References	[20]	[18]	[21]

A summary of the maximum sample volumes from different capillary collection tubes.
EDTA: Ethylenediaminetetraacetic acid; K2: Dipotassium; K3: Tripotassium; Lith Hep: Lithium heparin; SST: Serum separator tube.

BD Microtainer®, Greiner MiniCollect® and Sarstedt Microvette®

Although CE-marked for professional use only, both BD's Microtainer [18] and Greiner's MiniCollect series [20] are popular self-sampling solutions, and the BD Microtainer tubes have become the standard for use with transdermal devices (see Table 1).

Additionally, all three manufacturers offer pressure-activated lancets with sufficient depth (e.g., 2 mm) to obtain a high-quality sample. However, key differences between the tubes may affect their operational suitability. This is especially important when large sample volumes are required, as the Greiner MiniCollect tube enables the collection of larger blood volumes.

The Microvette by Sarstedt [21] offers a lower-volume capillary tube for serum and lithium heparin plasma, which may limit its use in some cases; however, the Microvette EDTA automated processing tube (APT) can be handled directly on some haematology analysers and, as such, can be treated in the same way as venous tubes (Table 2).

Transdermal devices

Recent advances in self-collection methods have led to the introduction of several new transdermal devices [13,14]. Some, however, are either not yet available for commercial use or, when going to press, did not have CE marking; these include the Onflow from Loop Medical (Lausanne, Switzerland), ezdraw™ from Preci-Health (Neuchâtel, Switzerland), ImPress from LetsGetChecked (Dublin, Ireland), and RedDrop from RedDrop Dx (Fort Collins, USA). Although the RedDrop device is commercially available and widely used in the USA [13]. Those that do have a CE mark include the TAP II (YourBio Health, Medford, USA) and Tasso+ (Tasso Inc., Seattle, USA). Given the additional validation steps required for using non-CE-marked devices, we will focus on those already approved for use in the EU/UK marketplace.

TAP – YourBio health

The Touch Activated Phlebotomy (TAP) device is a minimally invasive, transdermal blood-collection device that uses a gentle vacuum and microneedle HALO array technology to collect capillary blood samples.

The TAP device is placed on the upper arm, and a peel-off self-adhesive seal secures the device in place before activation. The device is then activated by pressing the plunger, which forces a microneedle array into the upper dermal layer. Negative pressure is created, increasing blood flow from the skin into the collection tube. TAP device utilises BD Microtainer tubes and is available in the following varieties: EDTA, serum, serum gel, heparin plasma and heparin plasma gel. This device has been evaluated in several studies, including immune-mediated rheumatic disease, Anti-Müllerian Hormone, and carcinoembryonic antigen (CEA) [25–27].

Tasso+ – Tasso Inc.

The Tasso+ device is also placed on the upper arm and secured with a self-adhesive seal. After activating the lancet by pressing the red button, negative pressure is created, drawing blood from the skin into a BD Microtainer. The Tasso+ has also been used in several studies, including assays for COVID-19 antibodies, autoantibodies, liver, kidney and lipid markers [28–31].

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User instructions & patient support

The pre-analytical phase of self-collected capillary blood is primarily outside the laboratory's control. It is therefore critical that collection kit IFUs are tested with the user cohort in mind; a patient may not be using a self-collection device for the first time and may only need a reminder, whereas a patient unfamiliar with the collection process will require more detailed instructions and/or additional guidance.

A delicate balance needs to be achieved between hard-copy instructions, in-person training and online content. The patient cohort will inevitably influence this. Engagement with patient-representative groups and caregivers would be advantageous here. For example, instructions in relevant languages or tailored for patients with learning disabilities or pediatric scenarios can be better designed when the end users are involved in their development.

Sample logistics & transport conditions

Although self-collected CBT was designed for samples to be returned to the laboratory via the postal network, this need not be the route in every case. Delivering samples in person to a designated drop-off point, such as a primary care clinic, will ensure they are collected alongside samples taken within the clinical setting. In this case, sample stability may be within those listed in the assay IFU. For samples returned via the postal service, analyte stability in whole blood will need to be evaluated over expected timeframes and transit temperatures.

There is a growing body of published work on CBT using standard capillary tubes and finger-prick collection. Published data include comparisons between capillary and venous blood for full blood count [32], enzymatic creatinine [33], urea, liver function tests [7,34], lipids [31], C-reactive protein (CRP), HbA1c [7,8], enzymatic creatinine [33], prostate-specific antigen [35], Anti-Müllerian Hormone, luteinising hormone, follicle-stimulating hormone, oestradiol, testosterone, prolactin, dehydroepiandrosterone sulphate (DHEA-S), sex hormone-binding globulin, thyroid-stimulating hormone and free thyroxine (FT4) [36]. Some of these analytes are highly robust, whereas others can be affected by even low levels of degradation [37]. Given this, it is advised that the laboratory undertake whole-process verification, including sample stability experiments using whole blood stored at the expected temperatures over a set period.

In the UK, samples must be shipped via Royal Mail Tracked 24. It has been found that over 95% of samples are returned within 72 h using this service (own unpublished data). Therefore, it is advisable to conduct stability studies relevant to the observed transit time.

Ideally, each sample kit would include a temperature logger. Although temperature damage usually results in haemolysis and is therefore detected by the serum indices assay, this is not always the case, and some analytes are unstable at higher temperatures, e.g., HbA1c [37].

Unfortunately, temperature loggers can be challenging for laypeople to use. However, several options are available, including the Varcode Smart Tag [38], the Tive Tag [39] and the TimeStrip [40].

The Varcode Smart Tag uses a barcode made of thermolabile ink that changes in response to temperature and duration. The Tive Tag is a passive temperature data logger that the user activates and collects real-time data via an online application. Data are then available on the cloud once the parcel is re-scanned at the laboratory. Simpler and cheaper options include liquid-based irreversible temperature indicators such as the Timestrip. These are manually activated and read, but they only indicate temperature breach and do not provide data points. They are, however, easy to use and inexpensive, and have a long track record in blood product monitoring, although only limited temperature ranges are available.

Analytical considerations

Sample processing

Currently, CBT utilises repurposed paediatric tubes, which in most cases were not designed to be placed directly onto automated laboratory analysers. To protect the analyser probes from short samples or gel contamination, a secondary tube may be required. As yet, there are limited off-the-shelf total laboratory automation solutions for capillary blood samples, and modern pre- and post-analytical units struggle to process capillary tubes [14].

Adequate labelling of secondary tubes is also often problematic in a routine hospital laboratory. Despite this, incorporating self-sampling CBT into the routine diagnostic pathway is relatively straightforward, and laboratories require minimal additional resources to integrate these samples seamlessly into their standard workflow [14].

Depending on the requested tests, capillary samples may need to be manually checked. Although most haematology analysers can process capillary samples [41], the collection process itself raises concerns about clotted samples.

In such cases, to prevent analyser downtime, it may be necessary to check each sample, which can hinder rapid throughput. Clotting is not an issue for most chemistry analyses, but the small sample volume obtained may be.

Analysers with fixed-sample probes risk blockage if the probes enter the gel of the serum separator tube or the cellular layer. When disposable pipette tips and sample reaction vessels are used, this is generally not a concern, and it may be possible to sample directly from the primary tube. If this is not the case, it may be necessary to aliquot the sample into a secondary analyser cup. Without automation, this process is likely to be manual, but it does allow for a physical sample check before analysis. At that point, samples that are insufficient in volume or grossly hemolyzed can be rejected.

Once the sample is placed in an analyser cup, it can be treated much like any other sample. However, the number of tests available to the clinician will depend on the sample volume obtained, the efficiency of serum/plasma recovery, and the laboratory's analyser methodology.

Although most chemistry analysers use similar sample volumes for basic chemistry profiles (e.g., liver and kidney function, lipids), much larger volumes are sometimes required for immunochemistry assays, e.g., the Roche e801 uses 12 ul for Total PSA (not including dead volume), while the Beckman Dxl uses 25 ul.

Post-analytical considerations

Sample contamination

Due to the nature of this technology, the sample collection process is literally in the hands of a layperson and, as such, difficult to fully control. Result interpretation, therefore, must also account for sample contamination from various sources, including the collection site (e.g., skin). With CBT, anything on the skin or within the capillary network at the collection site is likely to be transferred to the blood tube. High concentrations of biotin (vitamin B7) have been detected in the capillary network following topical cream use [42], and although many assays have recently been reformulated to include biotin scavengers, biotin interference could still be an issue in some immunoassays [43]. Given this, other potential interfering substances are likely to emerge as CBT becomes more widely used across various patient cohorts. For example, creams containing large amounts of coconut oil would be expected to falsely increase triglyceride results, and patients using topical hormone replacement therapy may exhibit falsely high hormone levels. These issues may be overcome by including additional guidance in user instructions.

It has also been found that serum separator tubes may falsely lower some analyte results compared with plain serum tubes when testing is delayed, as seen with postal samples [36]. This has been reported for oestradiol and testosterone and is believed to result from these hormones binding to the gel, an effect exacerbated by the higher gel-to-blood ratio in serum separator capillary tubes than in venous tubes. The decrease may be more pronounced with extended contact times [36]; therefore, it is critical to verify comparability between venous and capillary samples using realistic stability timelines, and laboratory scientists must have an appreciation that interference from unknown substances with capillary blood may come from both the site and the collection process, as well as other well-known routes such as EDTA contamination.

CBT applications & patient groups

The use of capillary blood self-sampling devices has the potential to benefit several patient cohorts. These include patients with learning disabilities, needle-phobia, those with poor venous access, patients in remote or underserved areas, and those requiring regular long-term monitoring (e.g., therapeutic drug and chronic disease monitoring).

In some instances, a business case for CBT applications may be required to implement the service. The savings from the introduction of CBT are spread across the whole patient journey, and it is appreciated that health services do not always allocate budgets in this manner. However, a business case should include the costs of devices, administration, transport, environmental impact, workflow changes (including pre- and post-analytical processing requirements), as well as the cost-benefit to the patient [3]. The early involvement of patient groups will be essential when introducing a CBT service.

Applications have been demonstrated for prostate disease monitoring [35], immunosuppressant and creatinine measurement in transplant recipients [44–48], therapeutic drug monitoring for inflammatory bowel disease [49], and anti-psychotic drug monitoring [50]. In addition, CBT has been used for HbA1c analysis [51], C-peptide testing for classification of diabetes subtype [52], chronic respiratory disease monitoring [4] and steroid monitoring [36,53]. For a more comprehensive list, see Schröder *et al.*, who recently conducted a meta-analysis comparing capillary and venous samples with relevant stability data [54].

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ISO 15189 accreditation

Most clinical laboratory tests are verified for use only with venous blood. Therefore, validation is necessary for non-conventional sample types, including CBT. The Medicines and Healthcare products Regulatory Agency (MHRA) has stated that unless the manufacturer has explicitly listed the sample type being used (e.g., capillary blood), the assay is being used off-label [55]. Therefore, concordance between venous and capillary blood must be evaluated using a suitable analytical method. The Clinical and Laboratory Standards Institute EP35 guideline (Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures) [56] offers recommendations for assessing clinically equivalent performance across similar-matrix specimen types. It is also noted that the LabMed UK Patient-Centred Testing and Sampling (PaCTS) Interest Group is in the process of publishing its recommendations on the validation and adoption of CBT in routine clinical laboratories, which will no doubt help laboratories navigate the complexities of validation versus verification.

Conclusion

Venepuncture remains the gold standard for blood sampling and is one of the most performed medical procedures in clinical practice. However, the need for specialist personnel and equipment can be a limitation. In addition, up to 90% of laboratories' carbon footprint comes from the sample collection process [57].

Self-collected capillary blood sampling has been proven to be a viable alternative to venepuncture for a number of analytes [54] and could be a significant contributor to a more patient-centric, cost-effective healthcare system, focused on access and patient participation.

Importantly, this patient-centric approach can help drive health equity for populations that struggle to access blood testing. As an example, Morecambe Bay NHS Foundation Trust has successfully piloted capillary sampling among patients with learning disabilities, in whom 45% had been unable to provide a blood sample over 5 years (15% have never had blood taken), mostly due to needle phobia (own unpublished data).

Recent interest from government agencies [5], the successful application of transdermal collection devices in clinical practice [13], the wider availability of whole-blood stability data [54], and the addition of capillary blood as an approved matrix in some manufacturers' IFUs [15] will lead to the widespread adoption of CBT.

However, issues remain. While early innovation focused on patient-centric collection methods, these new devices still use pediatric tubes that have been available for decades. These tubes were designed before most pre- and post-analytical platforms and large central laboratories became the norm [14]. As such, primary tube compatibility with laboratory analysers is a major limiting factor. It is therefore critical that transdermal device, tube and analytical platform manufacturers come together to rethink the end-to-end process.

Executive summary

- Taking blood from a vein with a needle is the usual way doctors collect blood for tests, but this process can be expensive and inconvenient because people have to go to a clinic or hospital, and trained staff are required to perform it.
- A new, simpler way uses a device that sticks to the upper arm and draws blood painlessly from beneath the skin (transdermal or upper-arm device). Patients and carers can use these devices themselves at home, kits can be sent by mail, and samples can be returned by post, so there is no need to visit a medical facility. This makes it easier and more comfortable for patients to get their blood tested.
- However, this technology is still new, and some challenges need to be solved before it can be used everywhere. This article explains how this new method works, its possible benefits, and what needs to be considered for it to be widely used.

Author contributions

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