

# Gaining patient feedback on the use of finger prick blood tests at home

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<b>Registration date</b> 08/12/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 15/03/2024	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Up to 60% of the adult population live with a chronic condition and 40% have more than one. Many, if not most, require blood tests at intervals to track illness progression or to monitor for side effects of prescribed drugs. Alongside this, the wider use of remote clinics during the COVID-19 pandemic has led to a change in strategy whereby many patients now monitor their health status at home through home recording of blood pressure, oxygen saturation, weight, and exercise tolerance. There is also now the potential for this to be supplemented by home monitoring of blood tests. These tests are easy to undertake. Microsampling is similar to diabetic patients who check their own sugar levels. The primary aim of the study is to show that blood tests used in routine monitoring can be undertaken with a high level of accuracy and satisfaction by patients using microsampling test kits.

### Who can participate?

Adults who are under the care of a hospital clinic. People may be approached to participate if they are attending an outpatient appointment or if they are on a hospital ward.

### What does the study involve?

Participants will have their usual venous bloods taken and alongside this will be asked to take bloods themselves using one of three different microsampling kits. The researchers will determine the accuracy of these kits compared to the venous bloods and compare patient satisfaction with each of the kits using a feedback questionnaire. Clinical care pathways will not be changed.

### What are the possible benefits and risks of participating?

There are no clinical benefits to participating. Doing so will involve having to self-administer a sharp needle to the skin of a finger to draw blood. This may cause some temporary discomfort.

### Where is the study run from?

Salford Royal Hospital and Wythenshawe Hospital (UK)

### When is the study starting and how long is it expected to run for?

May 2022 to December 2023

Who is funding the study?  
Salford Clinical Commissioning Group (UK)

Who is the main contact?  
Prof. Darren Green, darren.green@nca.nhs.uk

## Contact information

### Type(s)

Principal investigator

### Contact name

Prof Darren Green

### ORCID ID

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

310182

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

21KID04-S, IRAS 310182

## Study information

### Scientific Title

Patient experience and accuracy of finger prick blood testing kits

### Study objectives

The aim of the study is to show that blood tests used in routine monitoring can be undertaken with a high level of accuracy and user satisfaction by patients using microsampling test kits. The secondary aim is to compare the accuracy of results and user satisfaction between three different types of microsampling devices.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 31/05/2022, London - Bromley Research Ethics Committee (Temple Quay House, 2 The Square, Temple Quay, Bristol, BS1 6PN, UK; +44 (0)207 104 8171; bromley.rec@hra.nhs.uk), ref: 22/LO/0379

## **Study design**

Observational cohort study

## **Primary study design**

Observational

## **Study type(s)**

Diagnostic

## **Health condition(s) or problem(s) studied**

Adult patients under the care of secondary care clinics who are having regular blood tests as part of usual care

## **Interventions**

Patients will be recruited from inpatient wards and outpatient clinics at the two hospital sites. After consent is taken bloods will be collected as follows:

Patients will be allocated to one of the three microsampling kits as per the flowsheet. For "limited bloods" patients will be allocated to either the Mitra or Captainer devices on an alternating basis. All patients requiring extensive blood panel or haematology tests will be allocated to the Microtainer system. The devices will be labelled with the patient study ID.

Patients will be given the microsampling kit and instructions and allowed to familiarise themselves with these. They will then have usual clinical bloods taken with the drawing of up to two extra bottles (max 10 ml). These bottles will be labelled with study ID only. Usual bloods will be sent to the local lab for analysis as per clinical care. The extra bottles will be kept by the study team and sent to the study lab with the microsamples.

After usual bloods are taken, the patients will be asked to take bloods themselves using the microsampling kit. The study team member will then put these with the study venous bloods for delivery to the reference lab. Bloods will not be retained for future research, samples will be destroyed in line with the disposal of clinical samples in usual practice. In the case of any spillages, standard infection control procedures should be followed as outlined in the Trust policy.

Patients will be given a feedback questionnaire to complete. This will be anonymous and can either be given to a ward staff member or retained by the patient for completion at a later date and posted back to us.

## **Intervention Type**

Device

## **Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

BD Microtainer microsampling kit

**Primary outcome(s)**

Bias between fingerprick and venous sampling for routine biochemistry assays measured using Bland-Altman analysis at single timepoint

**Key secondary outcome(s)**

Comparison of quantitative and semi-quantitative patient feedback between different fingerprick devices measured using a standardised feedback questionnaire at single timepoint

**Completion date**

31/12/2023

## Eligibility

**Key inclusion criteria**

1. Adult patients under the care of secondary care clinics having blood tests taken as an inpatient or outpatient as part of usual care
2. Patients must have the capacity to provide consent and be able to undertake finger prick testing themselves

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Needle phobia
2. Peripheral neuropathy or vascular disease affecting hands
3. Known infection with a blood-borne pathogen (HBV, HCV, HIV)

**Date of first enrolment**

01/01/2023

**Date of final enrolment**

31/12/2023

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Salford Royal Hospital**

Stott Lane

Eccles

Salford

United Kingdom

M6 8HD

**Study participating centre**

**Wythenshawe Hospital**

Southmoor Road

Wythenshawe

Manchester

United Kingdom

M23 9LT

## **Sponsor information**

**Organisation**

Northern Care Alliance NHS Foundation Trust

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Salford CCG

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

The data-sharing plans for the current study are unknown and will be made available at a later date

## IPD sharing plan summary

Data sharing statement to be made available at a later date

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No