

Participant Information Sheet for Patients at the GP practice

TARGET-ID pilot implementation study

Study Title: Digitally enhanced targeted testing for HIV, hepatitis B and hepatitis C in primary care (TARGET-ID): Feasibility study

Principal Investigator:

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Co-Principal Investigators:

Professor Chris Griffiths; Dr John Robson, Reader, Queen Mary University of London

In this research study we will use some of your information from your general practice medical records that has had all your identifying details removed. With their consent, we will also interview some staff and patients about their experience of the study.

We will make sure no-one can work out who you are from the reports we write. All research study reports are fully anonymised, and no one can be identified from these reports or will know who you are. Everyone involved in this study will keep your data safe and secure. We will follow all privacy rules.

At the end of the study, we will save some of the data for a limited period in case we need to check it. The information pack tells you more details about this.

Study Summary:

Your GP practice is taking part in research project, called TARGET-ID.

TARGET-ID is a study looking for better ways to help people who might be at risk of three virus infections (HIV, hepatitis B and hepatitis C) get tested quickly and easily. If these viruses are found early, people can get the advice and treatment they need to stay healthy.

What is the purpose of this study?

This study aims to see if a pre-defined computer search at your GP practice can help find people who might be at high risk of these infections. Across six GP practices, up to 1800 patients may be offered a test, including around 300 patients at your practice. If the search suggests that you may be at risk, you will be offered a simple blood test to check for these viruses.

Why have I been chosen to take part?

The practice is inviting some patients at risk of carrying one or more of these three viruses to get tested for these viruses.

Do I have to take part?

No. Your GP practice has decided to take part in the study. The practice will offer these tests routinely to patients at risk of these viruses. If you do not wish to share your data for the research, please let the GP or practice nurse know.

By agreeing to have a blood test, you are giving consent to take part in the study. If you've provided consent to take part now but then change your mind later, you can withdraw your consent at any time during the study by contacting a member of the study team at Queen Mary University of London using this email: Target-ID@qmul.ac.uk. Once you've withdrawn your consent, we will only use data collected before the withdrawal.

You will have at least seven days to review the study information before deciding whether to have a blood test. If you need help with translation, your GP can arrange a phone conversation with an interpreter.

What will happen to me if I take part?

If you decide to take part, the practice will arrange an appointment for you to have a blood test. This can be done either at the practice or at a nearby community phlebotomy centre, depending on your practice's phlebotomy policy.

During the appointment, a nurse or healthcare assistant will take a small sample of blood (one to two teaspoons) from your arm. This sample will then be sent to the hospital for testing using their routine courier service.

If it is not possible to take blood from your arm, or you are uncomfortable having blood taken from your arm, a finger-prick blood test may be arranged at a local community centre or hospital.

If you feel emotionally distressed, anxious, or uncertain, your GP can provide support. If you agree that this would be helpful, a peer supporter may also be available to answer your questions and guide you through the next steps.

How long will I be in the study, and what happens next?

If your blood test result is negative, your GP will send you a text message to let you know. With a negative result, your part in the study ends after your blood test appointment with the nurse or healthcare assistant.

If your result is positive, your GP will advise that you should be referred to a specialist clinic for further advice and treatment. Testing positive for HIV, hepatitis B or hepatitis C can feel overwhelming, and it may affect you emotionally or practically. Your GP will explain the result, answer your questions, and guide you through the next steps. Close contacts or family members may also be offered testing or support if needed.

You will not be alone — peer supporters are available to talk things through, offer reassurance, and help with any changes you may face.

If the test is positive, patient participation in the study ends at the point of referral to the specialist clinic. Your routine care will continue with the specialist.

Patients who have had a blood test, both those who test positive or negative, along with GP staff, may be invited to take part in a post-study interview. During blood testing, the healthcare assistant or nurse may inform patients about the opportunity to participate in a qualitative interview later in the study. Taking part in the interview is completely optional. If you do not wish to participate, please let your nurse or healthcare assistant know.

Venous blood samples will be collected by a trained nurse or healthcare assistant. Samples will be securely transported to the local laboratory and after testing, samples will be disposed of at the local laboratory in accordance with standard laboratory procedures and HTA-compliant clinical waste protocols.

Hepatitis B and hepatitis C are notifiable diseases in the UK. If you are diagnosed with either infection, your GP or the laboratory is required by law to report this to the UK Health Security Agency (UKHSA). This helps monitor and control the spread of infection. Your identity will be protected, and the information will be handled confidentially in line with public health regulations.

Will my taking part in the study be kept confidential?

Yes, we will keep information about your participation confidential. All the information collected about you will be handled in confidence and we will follow strict ethical guidelines. All information will be stored on password-protected computers at the Clinical Effectiveness Group (CEG), Queen Mary University of London. The CEG is an established GP data service provider in North East London.

How will we use information about you?

We will need to use information from your GP records for this research project. This information will include your NHS number, local GP patient identifier, your name, your date of birth and your de-identified, unique patient research identifier held by your GP.

Only your de-identified, unique patient research identifier will be held by the sponsor for the research.

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

Queen Mary University of London (QMUL) is the sponsor of this research. QMUL is responsible for looking after your information. We will share your information related to this research project with the following organisation:

- The Big Data Institute, University of Oxford.

We will keep all information about you safe and secure by:

- Storing your records on the secure Barts Cancer Institute server, London
- Controlling access to data using password protection and encryption
- Backing up data regularly to prevent data loss.

International transfers:

- Your data will not be shared outside the UK.

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of five years. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

Where can you find out more about how your information is used?

- You can find out more about how we use your information, by contacting:
- The Health Research Authority (HRA) website:
www.hra.nhs.uk/patientdataandresearch
- The Queen Mary University of London Data Protection Officer: data-protection@qmul.ac.uk.
- The research team: TARGET-ID@qmul.ac.uk

If you're unhappy about how your data is used, you can contact the UK Information Commissioner's Office: <https://ico.org.uk/concerns>.

What will happen to the data collected?

If you choose to take part in this study, your anonymised data will be securely stored at the CEG until the study is completed. All data will be securely stored in line with the Data Protection Act 2018.

What will happen to the results of this study?

No participant's identity will be disclosed in the fully anonymised results of this study. The results of this study will be shared in several ways. They will be posted on our website (<https://bit.ly/3MyOyZU>), presented at scientific meetings and conferences, and published in academic journals. Additionally, the findings will be shared with our professional networks, including NHS England, the UK Health Security Agency (UKHSA), the Fast-Track Cities Initiative, and the London Joint Working Group for Substance Use and Hepatitis C. Importantly, you will not be identifiable in any report or publication.

What are the possible disadvantages of taking part?

We do not expect any serious health risks from taking part, but you may experience minor pain, slight bruising or light-headedness when we draw your blood. Talking about past

experiences could make you feel uneasy or upset, and it's normal to feel anxious before or during the test. Aside from these minor discomforts, there are no other known disadvantages to joining this study.

What are the benefits of taking part?

While there may not be an immediate personal benefit to participating in this research, the information gathered from this study will help us improve the intervention. This, in turn, could enhance the identification and management of HIV, hepatitis B, and hepatitis C among high-risk groups in primary care.

Who is organising and funding the research project?

This research is being led by Dr Werner Leber at the Queen Mary University, London. Dr Leber is a practicing GP in the London borough of Newham and a Senior Clinical Lecturer in Primary Care at the Wolfson Institute of Population Health, Queen Mary University. His research focuses on the early identification of infectious diseases in primary care.

The research is being funded by the National Institute for Health and Care Research (NIHR) School of Primary Care Research (SPCR).

Who has reviewed the study?

All research that involves NHS patients, information from NHS medical records or uses NHS premises must be approved by an NHS research ethics committee. This research was approved by the relevant Research Ethics Committee and has the following reference: IRAS 326061. Approval means that the committee is satisfied that your rights will be respected and that you will be given sufficient information on which to make an informed decision.

Complaints:

If you have a concern about any aspect of this study, you should ask to speak to Mr James Patterson, Research Integrity And Assurance Officer, james.patterson@qmul.ac.uk, at Queen Mary University of London.

Further study information:

Video link to our research study: <https://bit.ly/4lw1U9r>

Our website: <https://bit.ly/3MyOyZU>



Thank you very much for taking the time to read this information.

