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**IRAS ID: 299934**

# Feasibility and acceptability of a primary care liver fibrosis testing pathway centred on the diabetes annual review: PRELUDE1

## Patient Participant Information Sheet

Your GP Practice has been invited to take part in a research study to understand whether we should add monitoring tests for the liver in people living with type 2 diabetes (T2D). We have asked your GP practice to add a liver test to the annual diabetes monitoring bloods of everyone in the practice with T2D, and we have asked if we can look at these results and your clinical information so that we can help detect liver disease early in people with diabetes. So it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear or if you would like more information.

### Introduction

Changes in the liver are common among people with diabetes, and are mostly due to fat build up. This condition is called non-alcoholic fatty liver disease (NAFLD) and is found in up to two thirds of people living with T2D. In some cases patients with NAFLD are not at particularly increased risk of developing serious liver disease, but in some patients NAFLD can take a more progressive form that involves inflammation and scarring in the liver (non-alcoholic steatohepatitis or NASH) that can progress to cirrhosis, liver failure and liver cancer. Sadly people with diabetes are at increased risk of developing NASH and scarring in the liver. We want to identify people who will develop serious liver disease in the earlier stages, when something can be done to stop progression.

### What is the purpose of this study?

For most people, there are no symptoms of fatty liver, scarring or even cirrhosis until the latest stages of disease when treatment is less effective. Routine blood tests do not diagnose scarring or cirrhosis, but it is possible to calculate scores from these tests, such as the Fib-4 used in this study to accurately rule out significant disease. If Fib-4 is negative, we can be fairly confident that patients do not have significant fibrosis. If Fib-4 is positive, then patients should have further specialist investigations.

We will focus on people in GP practices with T2D because they have an annual review that includes blood tests, to which we will add a Fib-4 test. Patients who have positive test results will be referred for a liver fibrosis scan either at their local hospital or GP practice. If Fib-4 testing in the annual review identifies more patients with fibrosis and is cost-effective, we would introduce this test across the NHS to target treatment and reduce the number of people who develop liver cancer or liver failure.

### Why is my practice involved?

By agreeing to take part in this study, your practice is offering to add the Fib-4 liver scarring test to your routine diabetes blood tests, taken at the same time as the routine bloods (i.e. no extra needles). We have asked to access your practice's patient data – i.e. list of medications

and other medical conditions– so that we can find out more about people who test positive for liver fibrosis so we can target our testing more effectively.

**Do I have to take part?**
No, you do not have to take part; it is entirely up to you if you decide not you agree to adding this extra test to the bloods your practice is already taking or if you do not agree to the study team accessing your data anonymously after the tests are done. If you do decide to 'opt out' of this or withdraw from the study, please let your practice know at any time, even if this is after the bloods have been taken, without giving a reason. This will not affect the routine care you receive in any way.

**What will happen to me in this study?**
You will not experience anything different at your annual review and bloods will be taken in the normal way – you will only need one blood draw as normal for your annual review. Depending on the bloods your practice does as standard, you will either not need to give any extra blood. If the Fib-4 blood test cannot exclude significant liver scarring, you will be told and invited to have a special scan of the liver called a Fibroscan. This is a quick test (10 minutes) that involve applying jelly to the abdomen and running a probe over the liver. It is not painful and there are no needles involved. This might take place in your local hospital or at a location in or near your GP practice.

A small number of people will be asked to take part in an optional interview and/or focus group to explore people's thoughts about liver screening alongside the diabetes annual review and the experience of being involved in this study. This interview and/or focus group would take place either in person at your GP practice, other NHS sites, or alternatively online/by telephone. This should take less than 90 minutes of your time. We wish to audio or video record this interview/focus group to record what is said. These recordings will then be destroyed after transcription to a written record. Transcription of interviews will be undertaken by the study team in an anonymised format. Afterwards we may wish to contact you to ask follow up questions based on comments from other patient interviews before completion of the study. Direct quotes from interviews maybe published alongside the results of this study without any details that could identify you.

**The Study**
We hope that the discoveries from this research will lead to new and better tests of liver disease being developed. If this is the case, we will need to work with colleagues in other academic and commercial organisations, some of whom may be outside the United Kingdom or the European Union. We will only share anonymised data and/or samples with our collaborators and not any details that could identify you.

If the results of the examinations performed in this study identify any abnormalities with the liver then you will be referred to your local hospital liver clinic for routine clinical care.

**Who has reviewed this study?**
This study has been reviewed by the North Thames Diabetes Lay Panel and by Gilead Sciences, who are funding the work, but have not had any part in the study design or scientific conduct of the research. The study has also undergone ethics committee review.

**What happens if something goes wrong?**
If you have any queries about your diabetes or other medical matters, please contact your local diabetes nurse specialist or practice nurse, or consultant. For queries related to the study our contact details are at the bottom of this information sheet.

The insurance that Queen Mary University of London has in place provides cover for the design and management of the study as well as "No Fault Compensation" for participants, which provides an indemnity to participants for negligent and non-negligent harm.

**How will we use information about you?**
We will need to use information from your medical records for this research project.

This information will include your NHS number, name and contact details held by NHS sites only. 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 coded number instead. We will keep all information about you safe and secure. Some of your information will be sent to collaborators in the United States of America. They must follow our rules about keeping your information safe.

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.

**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.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records or your GP. If you do not want this to happen, tell us and we will stop.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

**Where can you find out more about how your information is used?**
You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team, or
- by sending an email to data-protection@qmul.ac.uk
- by ringing us on 020 7882 8610

**Who can I contact to withdraw from this study or find out more information?**
Information can be found on the study website: www.Prelude1.org

If you have any questions or wish to withdraw from this study please contact us:

**Study contact email:**
bartshealth.rlhprelude1@nhs.net

Study contact phone number: 020 7882 8610
**Study Investigators**:
Professor William Alazawi Study Chief Investigator; w.alazawi@qmul.ac.uk
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