Patient Experiences of the Journey to Diagnosis Sub-Study

Participant Information Sheet

Invitation

We would like to invite you to take part in an interview. Before you decide whether you would like to, we want to tell you a bit more about why the research is being done and what it would involve for you. We have provided information below, including how the study will be conducted, to help you decide whether or not you wish to take part. Please take your time to read the information and ask us if anything is unclear.

What is this study about?

We want to better understand patient experiences of their journey to diagnosis with Inflammatory Bowel Disease (IBD - Crohn's or colitis).

Delays in the presentation, referral and diagnosis of IBD can be significant. The aim of the sub-study is to explore insights into patients' journeys to diagnosis of IBD, the barriers to gaining a diagnosis and the impact of delay on quality of life.

The 'diagnosis journey' covers the time from first experiencing symptoms, through the first consultation with any medical practitioner about those symptoms, up to the time of receiving a formal IBD diagnosis. In order to get more information about the diagnosis journey, we would like to invite you to take part in an interview as a participant. The interview will explore your experiences of the journey to diagnosis. We will also explore the possible challenges and barriers you may have come across.

Why have I been invited?

You have been invited to take part in an interview because you have experience of being diagnosed with Crohn's or Colitis within the last three years. It is up to you whether you take part and you can withdraw at any time.

What will be involved if I take part?

The research will take the form of an interview, during which we will ask you some questions about yourself and your experience of the journey to diagnosis. Before the interview, the researcher will need to reconfirm that you are willing to take part. The consent process and interview will last approximately one hour and will be audio-recorded.

The interview will take place online via video call using a secure facility called "Google Meet". If you prefer the interview can take place via telephone. We will ask you some questions about yourself and your experience of the journey to diagnosis.

Do I have to take part?

No. It is up to you to decide whether you agree to take part and you can change your mind at any time, without giving a reason. A copy of the consent form will be provided to you. This information sheet is for you to keep.

Will the interview be recorded and how will these recordings be used?

With your permission, the interview will be audio-recorded using encrypted electronic equipment. The recording will only be available to members of the study team and it will only be used to allow for the preparation of transcripts. Audio recordings will be transcribed by support staff within the University of Sheffield.

What will happen to the data and results from the interview?

The pseudonymised transcript of your interview will be analysed, by two university researchers. This means that your personal details will be removed from your data and replaced with a code number. Only authorised researchers will be able to associate your personal details with the transcript once the code number has been applied. At the end of the research study, we will destroy the audio recordings. The interview transcripts and consent forms will be stored securely for 10 years at the University of Sheffield.

If considered appropriate by the research team, the findings from the interviews may be shared in an anonymised form. This could be in written form in research publications or in presentations at conferences.

How will we use information about you?

We will need to use information from you and from your medical records for this research project.

This information will include your name and contact details. 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.

We will keep all information about you safe and secure.

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.
- 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 (aware-ibd@sheffield.ac.uk)
- by sending an email to the Data Protection Officer sth.InfoGov@nhs.net,

or

- by ringing 0114 226 5153

Will the information be confidential?

Any feedback that we collect during the interview will be treated as confidential and stored securely. The interview transcript may be read by other researchers within the process evaluation team for analysis, but your name will not be included on any

transcript. Quotes from the interview may be used in the final report; however, your name will not be included.

What are the potential benefits and disadvantages of taking part?

We hope that you will find an opportunity to reflect on your experiences of the journey to diagnosis beneficial and interesting. We do not anticipate any disadvantages to participation other than spending some of your time to complete the interview. We understand that you may need to take a break from, or leave the interview at any time. We will take the interview at a time, and conduct it at a pace, that suits you.

We hope that thinking about your experiences will not be distressing but, if that happens, we suggest seeking help from any one or more of the following sources of support and advice:

- Your GP;
- A member of your IBD team at Sheffield (**tel:** 01142 712209, **advice email:** ibdnurse@sth.nhs.uk);
- The Crohn's and Colitis UK Helpline (**tel:** 0300 222 5700; **email:** helpline@crohnsandcolitis.org.uk);
- NHS 111;
- The Samaritans (**tel:** 116 123; **email:** jo@samaritans.org)

Who is organising and funding this study?

This research is funded by Crohn's & Colitis UK (project number ???). The project is led by Crohn's & Colitis UK and the research study is organised by the University of Sheffield and Sheffield Teaching Hospitals.

Who has reviewed this project?

The study has been reviewed and approved by the Health Research Authority (HRA) and Wales Research Ethics Committee 3 (an independent group of people who protect your rights, well-being and dignity).

If you have any questions about this study, please feel free to contact:

Study manager: Elena Sheldon. Email: e.m.sheldon@sheffield.ac.uk

Chief Investigator: Professor Alan Lobo
Consultant Gastroenterologist
Gastroenterology and Liver Unit
P Floor, Royal Hallamshire Hospital
Sheffield Teaching Hospitals NHS Foundation Trust
Glossop Road, Sheffield, S10 2JF
Email: alan.lobo@net.net

If you would like to make a complaint about the study or have any issues that cannot be resolved with the research team directly, please contact the study's sponsor:

Clinical Research & Innovation Office, Sheffield Teaching Hospitals NHS Trust, Sheffield D Floor Royal Hallamshire Hospital Glossop Road Sheffield S10 2JF.

Tel:0114 271 2572.. **Email:** sth.researchadministration@nhs.net

Patient Services Team (PST), B Floor, Royal Hallamshire Hospital, Glossop Road, Sheffield S10 2JF. **Tel:** 0114 271 2400. **Email:** sth.pals@nhs.net

If you wish to make a report of a concern or incident relating to potential exploitation, abuse or harm resulting from your involvement in this project, please contact the project's Designed Safeguarding Contact (Daniel Hind, d.hind@sheffield.ac.uk). If the concern or incident relates to the Designated Safeguarding Contact, or if you feel a report you have made to this Contact has not been handled in a satisfactory way, please contact the University's Research Ethics and Integrity Manager (Lindsay Unwin; l.v.unwin@sheffield.ac.uk).

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Sheffield Teaching Hospitals but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

The University of Sheffield who are employing the researchers are liable for their employees' actions (undertaken as part of their job) and insure against the risk of claims relating to research studies that their staff design and undertake. This insurance covers both negligence and no-fault compensation.

Patients and doctors rely increasingly on the results of clinical studies, such as AWARE-IBD, to make sure they are offering the best possible service. Thank you for taking the time to read this information sheet, we hope that it has been helpful in deciding whether you would like to participate in the AWARE-IBD study.

This information sheet is for you to keep.