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PARTICIPANT INFORMATION SHEET

Study Title: Missed Opportunities and Diagnostic Error (MODE) study.

You are invited to take part in an interview for a research study being run by the University of Oxford in collaboration with the University of Exeter and Queen Mary University of London. This sheet explains the purpose of the study and what we are inviting you to do. Please take time to read the following information carefully and discuss it with others if you wish.

Why is this research being conducted?

Cancer can be difficult to diagnose, especially as most patients with cancer present with non-specific symptoms that could be caused by other diseases. General practitioners (GPs) might first diagnose a non-cancer illness that matches the symptoms. In people who are later diagnosed with cancer, we call these “interim” diagnoses. Often interim diagnoses are good clinical practice, considering what was known at the time. Sometimes, they may be missed opportunities to test for cancer, leading to delayed diagnosis and poorer outcomes.

What is the purpose of the study?

The Missed Opportunities and Diagnostic Error (MODE) study aims to understand when interim diagnoses represent missed opportunities to diagnose cancer.

We would like to gain an in-depth understanding of interim diagnoses and when they may represent possible missed opportunities from the perspectives of healthcare providers. We plan to do this by carrying out interviews with healthcare professionals and non-clinical staff (e.g. receptionists).

We would like to find out:
(1) How do interim diagnoses happen, and how do they change over time?
(2) How are interim diagnoses recorded in the patient’s medical record, and why?
(3) What impact do primary care staff think interim diagnoses have on the chances that patients go back to their doctor and on their ongoing care?
(4) What could be done to reduce potential delays?
(5) What prompts healthcare professionals to rethink the interim diagnosis and consider cancer.

This study aims to define the situations where delays might occur, whether there are opportunities to reduce or avoid delays and, at a later stage, create a list of situations that could be the target for future interventions for reducing delays in cancer diagnosis.

Why have I been invited?

You have been invited because you work in primary care in a relevant role – whether clinically or through administering consultations, referrals, or follow-up. We aim to recruit up to 40 primary care staff for this study.

Do I have to take part?

No. It is entirely up to you to decide whether you want to take part. If you decide to take part, you are still free to stop at any time without giving a reason. No questions will be asked if you stop. Deciding whether or not to take part in the study will not affect your professional standing or your legal rights.

What will happen if I decide to take part?

If you would like to take part, please complete the expression of interest available here: https://app.onlinesurveys.jisc.ac.uk/s/oxford/mode-eoi. A member of the study team will then contact you to arrange an interview at a time that suits you. We intend to conduct all interviews remotely over Microsoft Teams. The researcher will be willing to answer any questions you may have about the study before you agree to take part. If, once you have spoken to the researcher, you would like to take part, the researcher will ask you to complete a consent form that will be available via a link sent to you by email. You will need to have completed this consent form before your interview.

At the interview, the researcher will make sure that you have completed the consent form and understand what the study is about. They will ask you if you have any more questions about the study before the interview begins.

With your permission, the interview will be audio recorded. The interview will be informal and will start with a discussion of a fictional scenario where a patient receives an interim non-cancer diagnosis, followed by a cancer diagnosis. You will then be invited to talk about your experiences of and thoughts on interim diagnoses in your own words.

The researcher will ask questions (as appropriate for your role) about:

- Times when you may have made an interim diagnosis before a cancer diagnosis.
- How certain you were of the interim diagnosis at the time it was made.
- Whether and how you recorded any uncertainty you may have had in the interim diagnosis.
- How patients are followed-up in your practice when there is uncertainty.
- What happened so that you reconsidered the interim diagnosis.
- Whether you think there is any way to reduce delays that might be caused by interim diagnoses.

How long would the interview take?

The time it takes for an interview varies, depending on how much you have to say, but we expect most interviews to last up to an hour. If the researcher believes that the interview is likely to run over an hour they will check whether you are able to continue. If you are they will complete the interview, if not, they will stop the interview on the hour. Remember, if you want to stop the interview at any time, you can do so without giving a reason.

What are the benefits/disadvantages of taking part?

We do not anticipate that you will benefit personally in any way. However, we hope that this research will benefit future patients and GPs. It may allow us to identify non-cancer illnesses that are commonly diagnosed in the interim, and ways in which the process of suspecting cancer following an interim diagnosis can be supported to reduce any potential delays.

Given the nature of this study it is highly unlikely that you will suffer harm by taking part. However, we appreciate that talking about care you have been involved in may be sensitive. If you feel this is the case you may ask to immediately pause or stop the interview. The researcher has experience of conducting qualitative interviews with health care professionals and you can decide to stop the interview at any time.

Expenses and payments

At the end of the interview we will reimburse you £60 to cover the interview time. We will not reimburse any other costs e.g. meals, childcare. We will email you with a link to an online form to enter your bank details for payment.

What information will be collected and why is the collection of this information relevant for achieving the research objectives?

The contact details provided on your expression of interest form will only be used to contact you about the study and arrange a time for the interview should you agreed to take part. We will permanently delete your contact details once the study findings have been published. Your bank details will be used to reimburse you for the interview time only and will be kept by the Nuffield Department of Primary Care Health Science’s (NDPCHS) finance team for 7 years for audit purposes. We will keep the identifiable information about you contained in your consent form for 10 years after the study has finished. We would like to use the data in future studies, and to share data with other researchers (e.g. in online databases). Data will have identifying information removed before it is shared with other researchers or results are made public. Your contact and bank details and consent form will be password protected and kept securely at the NDPCHS.

The interview recording will be labelled with a code number and given to a typist who will transcribe the interview. Field notes will be typed up by the researcher with identifiable data inadvertently included removed. The digital recording, transcription, and digital version of the field notes identified only by the code number, will be kept securely at the NDPCHS at the University of Oxford. The interview transcript will have all names of people, places, and organisations removed. A password-protected key will be kept separately from the interview files so that your data can be identified and removed, if you decide to withdraw from the study. However, it will not be possible to withdraw de-identified interview data once the study analysis has commenced. The digital audio recording of the interview will be destroyed once the analysis of the transcripts is complete.

Only members of the research team will have access to the folder where the interview materials are stored. The typist has signed an agreement to keep everything you say in the interview confidential. You may ask for a copy of your own de-identified interview transcript to be sent to you if you would like.

At your interview we will collect some background data about you including your age, gender, ethnicity, your role within your practice, and the approximate area where your practice is located (e.g. North West England). This is so that we can describe the individuals who participated in the study. Your background data will be password protected and stored on a secure drive at the NDPCHS. The information you provide in your interview will be analysed by the research team at the University of Oxford and, along with the information provided by other participants, used to answer the aims of the study described above.

The study researchers will maintain their duty of research confidentiality to participants as far as possible, however if very poor care or abuse is identified then the researchers will report this. We will be guided by national guidelines about what constitutes abuse.

Extracts from the de-identified study data may be looked at by members of our collaborative institutes (University of Exeter and Queen Mary University of London) for analysis purposes only. The study data may also be looked at by responsible members of the University of Oxford. This will only be for the purpose of audit and monitoring to ensure that the research is complying with applicable regulations.

Data Protection

The University of Oxford is the data controller with respect to your personal data, and as such will determine how your personal data is used in the research. The University will process your personal data for the purpose of the research outlined above. Research is a task that is performed in the public interest. Further information about your rights with respect to your personal data is available from the University's Information Compliance web site at https://compliance.admin.ox.ac.uk/individual-rights.

What happens at the end of the study?

At the end of this study, the findings from the research will be written up for publication in scientific journals, on our departmental website, and presented at medical conferences. We will also submit a report to our funder – the NIHR's School of Primary Care Research. With your permission, we would like to use direct quotations but without identifying you in research outputs.

We will not contact you again after your interview unless you tell us that you would like to receive a summary of the results of this study. If you would like to receive this summary, please indicate this on your consent form and provide us with an email address to send them.

Who is organising and funding the study?

The research is organised by researchers at the Nuffield Department of Primary Care Health Sciences, University of Oxford. The project is being funded via the National Institute of Health Research's (NIHR) School of Primary Care Research.

Who has reviewed the study?

This study has received ethics approval from a subcommittee of the University of Oxford Central University Research Ethics Committee (Ethics reference: R89542/RE001).

What if I decide to withdraw after the interview has taken place?

Your participation in this study is entirely voluntary. If you decide to withdraw after your interview has taken place, all recordings, transcripts and notes on your interview will be destroyed. However, it will not be possible to withdraw de-identified interview data once the study analysis is complete or the findings from the study are published.

Who do I contact if I have a concern about the research or I wish to complain?

If you have a concern about any aspect of this research, please contact PI/Acting PI on claire.friedemann@phc.ox.ac.uk and we will do our best to answer your query. We will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact the Chair of the Medical Sciences Interdivisional Research Ethics Committee at the University of Oxford who will seek to resolve the matter as soon as possible:

Email: ethics@medsci.ox.ac.uk; Address: Research Services, University of Oxford, Boundary Brook House, Churchill Drive, Headington, Oxford OX3 7GB

Contact for further information

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact: Dr Luke Robles on luke.robles@phc.ox.ac.uk.

Thank you for reading this information sheet.