

Participant Information Sheet

(1a) Evolving Patterns of Patient-Professional Interaction

Funded by NHS Service Delivery and Organisation

Thank you for considering participation in this NHS-funded research. Before you commit it is important for you to understand why the research is being done and what it will involve. This information sheet (no. 1a, version 8, 4/7/07) tells you about the project. Please read this sheet carefully and ask us if there is anything that is not clear or if you would like more information. The research is confidential and your anonymity will be protected at all times.

Part One

What is the purpose of this study?

The aim of this study is to understand how patients (and carers) use the Internet to get health information and how this changes experiences with doctors, consultants or other healthcare professionals. The part of the study you have been asked to participate in will look at how the patient-professional relationship changes over time and whether being able to get health information from the Internet has any influence over these changes.

Why have I been asked to take part?

You have been asked to take part because you have approached the doctor with a health issue and will be having or have had diagnostic tests to rule out or confirm one of the following conditions: diabetes, depression, and cancer (breast or prostate), and you have agreed to have your contact details given to us. We are asking up to 60 patients from different practices in the Stockport area to take part in the research.

Do I have to take part?

No, it is entirely up to you. This information sheet should help you to decide and we are happy to answer any questions. We will normally ask you to decide whether to participate within five working days. If you decide to take part you will be asked to sign a consent form. You can leave the study at any time without having to give a reason. A decision to leave the study or a decision not to take part will not affect your standard of care.

What will happen to me if I take part?

This part of the study will take place over 12-18 months. During this time a researcher will be present at 5 consultations (e.g. with GPs, Consultants, Nurses) to observe and audio record what happens. This person will take notes throughout the period that they are with you (including waiting times outside the consultation). You will also be asked to keep a written diary and take part in 2-3 interviews.

What do I have to do?

A researcher will observe and record discussions with your consultant, and make notes throughout the

time that they are with you (including waiting periods). The researcher will NOT be present at physical examinations. You can ask the researcher to leave the consultation room at any time. You will be asked to take part in 2/3 interviews and complete a questionnaire. You will be asked to keep a diary of your day-to-day experiences related to your condition. You will also be invited to take part in further parts of the study. If you do not wish to take part in further research please let us know.

What are the possible benefits of taking part?

The information will be used to help improve future health services by understanding how Internet sources of health information can be used and improved to help patients and carers. The study may not have any immediate benefits for you.

What are the possible inconveniences or disadvantages of taking part?

Although we will do our best to minimise intrusion, a researcher will be present at consultations where your health and personal information will be discussed. You will need to set time aside to take part in the interviews and to complete the diaries.

What happens when the study ends?

The findings from this study will show how health information from the Internet can help to improve patient care, and will be used by the NHS to improve health service delivery. Findings will be made available for participants.

What if I have a concern?

Any concerns about any aspect of the research or any possible difficulties you may have will be addressed (details in Part 2).

Will my involvement remain confidential?

Yes. All information about your participation in this study will be kept confidential by the research team. In the unlikely event that there is a need to disclose information, this will be done with your consent (details in Part 2).

Contact details:

Dr. Diane Speier, Tel: 0161 2756327

Dr. Debbie Keeling, Tel: 0161 2756569

Manchester Business School, The University of Manchester, Booth Street West, Manchester M15 6PB

This completes part 1 of the information sheet. If you are considering taking part in the study, please continue to read the additional information in part 2 before making any decision.

Part Two

What if relevant new information becomes available?

During this study your course of treatment or consultation might change. If this happens, you are free to decide whether to continue or leave the study. Your course of treatment or consultation might end. If this happens, it may be necessary for you to leave the study. You are free to discuss this with the research team at any time. You might also be asked to withdraw from the study on the advice of a healthcare professional, researcher or carer. If this is the case you will be kept fully informed and the reasons for advising your withdrawal explained. If the study stops for any other reason you will be told why. If you leave the study your standard of care will not be affected.

What will happen if I don't carry on with the study?

You can withdraw from the study at any time without your standard of care being affected. Information collected during the time that you took part in the study will still be used, but your anonymity and confidentiality will be protected. However, you can request that we delete all or part of the data that we hold about you.

What if I have a concern?

If you have a concern about any aspect of the study, you should ask to speak with the researchers who will do their best to answer your questions (Dr. Diane Speier 0161 2756327 or Dr. Debbie Keeling 0161 2756569). If you remain unhappy and wish to complain formally, you can do so through the University of Manchester Complaints Procedure. Details can be obtained from the University.

In the event that something does go wrong during the research that affects you there are no special compensation arrangements. If you are affected and this is due to someone's negligence then you may have grounds for a legal action for compensation against The University of Manchester but you may have to pay legal costs. The normal University of Manchester complaints mechanisms will still be available to you.

Will my taking part in this study be kept confidential?

Yes, all information that is collected about you during the course of the research will be kept strictly confidential. You should be aware of the following:

- 1) We are required to comply with the Data Protection Act 1998 in terms of handling, processing, storage and destruction of the information that we collect from you.
- 2) We will collect data from you by interview, questionnaire, observation, note taking, audio recordings and written diaries. We will also ask you to sign a consent form on which your name will appear.
- 3) Code numbers will be used in place of names of people so that all information collected for the study can be kept strictly confidential. Consent forms will be kept separately from other data collected.
- 4) All patient-identifiable data will be kept by the research team in the research office at the University of Manchester. It will be stored securely in locked cabinets.

Anonymised data will be kept on secure, password protected servers/computers/DVDs.

- 5) Access to data is restricted to research staff and named team members. The research team have access to coded information for the purpose of analysis, writing reports and presentations. All have a duty of confidentiality to you and nothing that could reveal your identity will be disclosed outside the research site (see point 9 below).
- 6) Anonymised data will be kept for a period of 5 years from data collection. All paper forms of data (completed questionnaires, signed consent forms, diaries and transcripts) will be destroyed at the end of the funded period for this project.
- 7) As we are observing and recording your meetings with healthcare professionals, they will be aware of your participation in this part of the study. However, the interviews and written diaries are entirely confidential (see point 9 below).
- 8) You can request a review of the data that the research team hold in relation to your case only.
- 9) The only reason that we might have to break confidentiality is if anything you told us suggested that you or another person was at serious risk of harm. Depending on the circumstance, health researchers are required by law to co-operate with designated authorities to prevent or minimise harm in line with legislation or guidance (especially to children – Children Act 1989). This might mean informing someone else about our concerns, **AFTER DISCUSSING THIS WITH YOU FIRST.**

What will happen to the results of this study?

The results of this study will be used to guide NHS policy and practice for future health services. In particular, how the Internet can be used and improved to help patients, carers and healthcare professionals. To do this, guidelines and workshops will be developed for healthcare professionals and website designers to let them know how the Internet is used for health information and how it could be improved in the future. We will also make our suggestions for using and improving the Internet for health information available to healthcare academics, healthcare professionals, patient groups and the public through published reports. A project conference will be organised to which participants will be invited. The results of this study may be used as a basis for future research.

Who is organising and funding the research?

The research is funded by NHS Service Delivery and Organisation and organised through the Universities of Manchester and Glasgow. Research Team members are based at the University of Manchester, University of Glasgow, Open University and University of Strathclyde.

Who has reviewed the study?

This study has been reviewed through the NHS SDO, Central Office for Research Ethics Committees and the University of Manchester Ethics Committee.