INVITATION TO JOIN A RESEARCH PROJECT

ISCOMAT: Improving the safety and continuity of medicines management at care transitions

You are being invited to take part in a research study.

Before you decide whether to take part, it is important for you to understand why the research is being done and what is involved. Please take time to read this information carefully and discuss it with friends or relatives if you wish. You are entirely free to decide whether or not to take part in this study.

Your decision about taking part will not affect the standard of care you receive.

If there is anything that is not clear, or if you would like more information, please speak to the research nurse who gave you this information or to the study coordinator – who will be available on the ward to answer your questions. Or you can contact him her on 01274 233 6952.

We would like you to take part in three interviews lasting approximately 45 minutes each about your views about your medicines. Firstly on the day you are discharged, then after about two weeks after you are discharged, and finally after about six weeks. We also want you to keep a regular record of who you come into contact with about your medicines for about six weeks after you leave hospital. We also want your permission to obtain information about your medicines and your health conditions from your GP, community pharmacy and hospital records and from central organisations that hold information from all hospitals, GP practices and community pharmacies. The data will be sent to the Clinical Trials Research Unit at the University of Leeds for analysis. All information will be stored securely and only accessed by members of the research team.

The purpose of the research is to understand more about how medicines are managed after patients leave hospital so that patients and healthcare staff can come up with new and better ways of supporting other patients to manage their medicines.

Please turn over to find out more about what taking part will involve.

PATIENT INFORMATION

ISCOMAT: Improving the safety and continuity of medicines management at care transitions

We are inviting you to take part in our research study.

- Before you decide we would like you to understand why the research is being done and what it would involve for you. A research nurse will go through the information sheet with you and answer any questions you have. One of the team will return later in the day to ask if you will consent to take part in the study.

- Feel free to talk to others about the study if you wish.

- Ask if there is anything that is not clear.

About the study

Over half of the patients admitted to hospital will have changes to their medicines. This might be a new medicine that has been started in hospital, or a change to a medicine already being taken. The purpose of this study is to look into your experiences with your medicines when you are discharged and for approximately six weeks afterwards.

We want to find out your views about your medicines when you leave hospital and again once you are back at home. We also want to find out who you have contact with about your medicines once you are discharged from hospital and how you are supported in managing your medicines. We also want to develop a way of bringing together information about people's health conditions and the medicines they take that is held in different parts of the health system. Your medical records are held electronically by your GP practice and your hospital and your data flows between the different health and social care providers to ensure that professionals involved in your direct care have the most up-to-date information about you. We want to access this routinely collected data which the researchers think is relevant to your heart condition and your discharge from hospital. We want to link the data together and analyse these data so that in the future we will be able to see if changes

made to how people are supported with their discharge medicines has an impact on their health and the medicines they are taking.

Why have I been chosen?

You have been in hospital being treated for a heart condition for which a combination of medicines is known to benefit your heart and improve your health and wellbeing. It is important that you receive good information about your medicines, that you understand them, and that others involved in your care – your consultant, your nurse, your GP and your community pharmacist – communicate well with each other and with you about them.

Do I have to take part?

No, it is up to you to decide to join the study. We will explain the study and go through this information sheet with you. If you agree to take part, we will then ask you to sign a consent form. You are free to change your mind at any time, without giving a reason. This would not affect the standard of care you receive and you will not be treated any differently whether you decide to take part or not.

How do I take part?

If you decide to take part in this study you should complete the consent form and return them to us via the Research Nurse who introduced this study to you. We will post newsletters on the study website to keep you updated on the study (www.bradford.ac.uk/iscomat).

What am I being asked to do?

We would like you to take part in an interview on the day you leave hospital. This will be to find out your views about the medicines you are going home with. We'd also like to arrange to interview you after two weeks and then again six weeks after you have left hospital. Interviews will be with one researcher that will last around 30-45 minutes, during which we will ask you about your views about the different roles people and professionals play in helping you with your medicines and how well you have been taking your medicines. We will also ask you to answer questions about what you think about your medicines. The interview on the day you are discharged will be being audio recorded with your permission. The interviews after two weeks and after six weeks will be video recorded with your permission. If you do not wish to be video recorded then please let the researcher know. These interviews may be held at the hospital, in your own home, or in

another place of your choice – whichever you prefer. There are no right or wrong answers – we are just interested in your experiences and what you think.

We also want you to keep a record of who you have contact with about your medicines from the time you are discharged from hospital and receive your discharge medication until we have interviewed you after six weeks. On this sheet we want you to make a note of when you contact other people about your medicines and when they contact you. This contact might be a letter from the hospital, a conversation with a pharmacist, or a conversation with your GP or nurse.

We wish to use your accounts of your experiences to develop a film to show four small groups of patients and healthcare professionals so that together they can develop ways of improving the experiences of other patients. We would like you to be part of those groups too, and we will ask you at a later date if you wish to, although you can choose not to take part in them.

We would like to view hospital records about the care you have received, including the medicines you have been prescribed, those that have been stopped and those that have been adjusted. In order to help us better understand the impact of how your medicines use is supported and how they impact on your health, we would like to link up the health information your GP and your community pharmacy stores with the information the hospital supplies to national records about treatment and patients' health outcomes. We would do this using your identifiable data (for example, your NHS number, date of birth, postcode, sex and initials) to make sure that we have the right records.

With your permission, we will write to your GP to tell them you are taking part in this study. We will also inform you community pharmacist that you are taking part.

How will you access my data?

Your medical records are held electronically by your GP practice and your hospital. Different systems are used to hold the data and we would like to obtain certain data from these systems which researchers think is important to your heart condition. Some information may be duplicated in the different systems, but some data may only be on one which is why we need to use the different systems. If we cannot find the data in the

electronic systems, a researcher will go directly to the hospital or GP practice to try to obtain the data.

We will share your identifiable data with the following providers:

- *Hospital records:*

The Health and Social Care Information Centre (HSCIC) holds the records of all patients admitted to NHS hospitals in England – this data is known as 'Hospital Episode Statistics' or 'HES' and the National Institute for Cardiovascular Outcomes Research (NICOR) collects clinical information from hospitals across the UK on care received by heart disease patients for the purposes of clinical audit. The HSCIC collects cause of death from the Office of National Statistics (ONS) and we will obtain this information if it becomes available.

- *GP records:*

Most GP practices use a system provided by TPP (SystmOne) or EMIS Health.

- *Community pharmacy records:*

Most community pharmacies electronically store limited information about the medicines they dispense to you. They will send this information to the research team.

Will the information I give be kept confidential?

If you decide to participate, the information collected about you will be handled in accordance with the consent that you have given and also the 1998 Data Protection Act. Identifiable information (e.g. initials, data of birth, NHS number, sex, ethnicity, full name and address) will be collected on a paper form and entered by the research nurse or the ISCOMAT research fellow directly onto a secure web-based system hosted by the University of Leeds Clinical Trials Research Unit (CTRU). This information will be shared with the data providers using a Secure File Transfer System to obtain relevant data from your electronic health records and to obtain information about your health status.

Additional data about your heart condition and your stay in hospital will be obtained from your medical notes by the researcher nurse or the ISCOMAT research fellow and will be collected on paper forms and will be sent to the CTRU by standard post. You will be allocated a study number, which will be used along with your date of birth and initials to identify you on each paper form. Every effort will be made to ensure that any further information about you that leaves the hospital will have your name and address removed so that you cannot be recognised from it; this information will usually be removed by a

member of the study team at your hospital, but may also be removed by the CTRU upon receipt.

Data you give us will be processed by a data manager and statisticians at the University of Leeds Clinical Trials Research Unit and securely entered and stored on CTRU systems. Identifiable data sent to us will not be accessed by or shared with any third parties outside the ISCOMAT Research team. All the data you give us will be stored for up to 5 years after the end of the study and then destroyed.

Data we collect directly from you, for example audio and video recordings of interviews, will be stored on secure University computers and will be accessed by the research team in order to understand your experiences and compare them with other people's experiences. This information will be combined with other information we collect with other sources, for example hospital staff interviews, to help us better understand how patients with heart failure experience healthcare. Video footage of the interviews we conduct with you will be edited together with those we conduct with other patients to make a film to use to begin discussions about how the healthcare people received could be improved.
With your permission, we will audio or video record interviews but your name will not kept with the transcript or the recording / film of your interview. When we edit video recordings together to make a film, your name will not be included in any footage we use.

What are the benefits of taking part?

The information we get from this study may help the way other patients are supported with their medicines. This may contribute to improving their health through helping them better understand their medicines. It may also improve the way medical professionals work together to offer good standards of care to patients when they leave hospital. The information we get from this study will also help us to work out how best to collect relevant data on patients with heart failure when they are discharged from hospital. This will be used to develop a future trial which may help the way other patients are supported with their medicines.

What are the drawbacks of taking part?

You will need to regularly fill in your contact diaries for approximately six weeks and spare the time to be interviewed about your experiences. Researchers will store information about you, such as the medicines you are taking and your identifiable information, but that

information will be kept confidential at all times.

What happens at the end of the study?

Your role in this part of our research will end after your last interview approximately six weeks after you leave hospital. We will then take the information you and others have given us and use it during workshops with patients and healthcare staff to see if the way medicines are managed can be improved. The information will be used to develop data collection processes for a future trial. We will also write a report and develop a toolkit for patients and healthcare staff to use to improve the way that medicines are managed after someone with a heart condition has been in hospital. That toolkit will later be tested in the trial. We will also publish the study results in academic journals, but you will not be identified in any published report or journal article.

What if I decide during the research that I don't want to take part any more?

That's ok – just tell us that you don't want to take part any more or keep any more notes. You don't have to give a reason. There are several ways in which you can opt out of the study:

- If you are still in hospital you can tell the research nurse who will be available on the ward;
- You can telephone the ISCOMAT team on 01274 236952;
- You can email iscomat@bradford.ac.uk;
- You can write to us at ISCOMAT c/o School Pharmacy, University of Bradford, M24 Richmond Building; Bradford BD7 1DP.

What if I have worries about my medicines?

If you have worries about your medicines whilst you are taking part in the study you should talk to your doctor, nurse or community pharmacist (chemist). It is important that you speak to a qualified person if you are worried about your medicines for any reason.

Study organisation

This study has been funded by the National Institute of Health Research and is being managed by the Universities of Bradford and Leeds (the ISCOMAT research team). The Clinical Trials Research Unit at the University of Leeds is responsible for data processing, storage and analysis of data from your electronic and paper medical records. The

University of Bradford will be responsible for the analysis and storage of the data from your interviews. The study design has been reviewed and approved by independent NHS Research Ethics Committees.

What if I have questions about the study?

If there's anything you're not sure about, or if you have any questions, you can ask [Researcher Name] who will be available on the ward or by telephone on 01274 236952 or email iscomat@bradford.ac.uk.

What if I have a complaint about the study?

If you want to make a complaint at any point about any aspect of the study you can contact Professor Alison Blenkinsopp (01274 234290) or Professor Gerry Armitage (01274 236474) at the University of Bradford. If you want to complain at any point about any aspect of the study to an independent body you can contact your local Patient Advice Liaison Service (PALS) by telephoning [insert local PALS number].

Thank you for considering taking part.

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