# 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 who will be available on the ward to answer your questions. Or you can contact Dr Beth Fylan, the study co-ordinator – by telephoning 01274 233 6952.**

We would like you to be part of a project that finds out how people in hospital diagnosed with heart failure can be better prepared to manage their medicines after they are discharged. We want hospital staff to prepare an information "toolkit" about your medicines that is personal to you and spend some time talking with you about the pack before you leave the hospital. We are also asking you to allow the hospital to send a copy of your discharge advice note / letter to the community pharmacy (‘chemist’) that usually provides your medicines. The discharge advice note / letter includes why you have been admitted to hospital, what treatment you have received, follow-up care that will be arranged, instructions to your GP about your ongoing care and the list of medicines you are discharged with. Additionally we are asking you to fill in three questionnaires and we may ask you to take part in one interview lasting approximately 45 minutes approximately four weeks after you leave hospital to tell us what you think about the information pack.

The purpose of the project is: (1) to see how possible it is deliver more information to people about their medicines before they leave hospital, (2) keep healthcare professionals, such as community pharmacists, up-to-date with the changes to medicines made by the hospital and (3) to understand which healthcare professionals you have contact with after you are discharged.

***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 want you to understand why the research is being done and how you could be involved. A research nurse will go through this information sheet with you and answer any questions you have. One of the team will return later in the day or the next day to ask if you will consent to take part in the study.
* Feel free to talk to others – your healthcare team or friends and family or carers – about the study if you want to.
* 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 explore whether it is possible to improve the safety and use of medicines when people with heart failure leave hospital. We aim to do this through providing improved information about their medicines to them, and by ensuring their community pharmacist is aware of any medicines changes made by the hospital.

### 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 – such as your community pharmacist, your carer/family members – are aware of any changes made by staff in the hospital.

### 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, and you can also ask us not to use the information you have given us. 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 it to the Research Nurse who introduced this study to you.

### What am I being asked to do?

We would like you to spend time with a member of the healthcare team before you leave hospital. This would involve completing and discussing a “toolkit” called “My Medicines Toolkit”. This includes documents about your medicines that you then take home with you and use as an information source about your medicines. The toolkit has been developed by other patients like yourself and staff members and we want you to try it out so you can tell us how user-friendly and relevant it is to you.

We would like to contact you after you have been discharged to ask you to fill in three short questionnaires and to arrange for you to take part in an interview about four weeks after you leave hospital. The questionnaires and interview and will ask you about the following:

* Your experiences with your medicines in hospital and after leaving hospital.
* How your health affects your everyday life.
* Your experience filling in and using your medicines toolkit.
* The health services you have used since leaving hospital.

There are no right or wrong answers to any of the questions – we are just interested in your experiences and what you think.

The three questionnaires will take about ten minutes each to complete and the interviews will be with one researcher and will last around 45 minutes. The interview will be audio recorded with your permission. The interviews may be held at the hospital, in your own home, or in another place of your choice – whichever you prefer. The interview will be audio recorded with your permission.

With your permission, we will write to your GP and to your community pharmacist to tell them you are taking part in this study. With your permission we would also like to ask your community pharmacist (‘chemist’) for information about whether they invited you to use one of their medicines review services that aim to support patients like yourself with their medicines, such as a ‘Medicines Use Review’ (MUR) or the ‘New Medicines Service’ (NMS). We would also like your permission for the community pharmacist to tell us if you used one of those services.

We also want your permission for hospital staff to send a copy of the discharge advice note / letter that is sent to your GP to the community pharmacy that dispenses your medicines. The discharge advice note / letter includes why you have been admitted to hospital, what treatment you have received, the follow-up care that will be arranged, instructions to your GP about your ongoing care and the list of medicines you are discharged with. If you do not have a regular community pharmacy then staff in the hospital will help you choose one. On leaving hospital, we hope that the pharmacy will contact you to offer you help with your medicines.

### Will the information I give be kept confidential?

Yes. If you decide to participate, 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, which will be stored securely by the research nurse team. Copies will be transferred to the research team at the University of Bradford and stored securely in locked filing cabinets and on secure University file servers.

You will be allocated a study number, which will be used by the research team by the hospital to identify you. This along with other details such as you NHS number, gender, date of birth and address will be transferred to the University of Bradford and stored securely in a locked filing cabinet. A copy of your signed consent form will be sent to your GP and your nominated community pharmacist to confirm that you are taking part in the study. 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 research team upon receipt. Identifiable data sent to us will not be accessed by or shared with any third parties outside the ISCOMAT Research Team. All the identifiable and unidentifiable data you give us will be stored for up to 5 years after the end of the study and then destroyed.

Digital data we collect directly from you, for example audio 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. Paper-based data will be stored securely in locked filing cabinets and when it is transferred into databases any identifiable information will be removed.

With your permission, we will audio record interviews but your name will not be kept with the transcript of your interview.

### What are the benefits of taking part?

The information we get from this study may help us understand how hospitals can use our toolkit to improve 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.

### What are the drawbacks of taking part?

You will need to spend some time filling in information in the medicines toolkit and filling in three short questionnaires and to take part in one interview. Researchers will safely 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 interview approximately four weeks after you leave hospital. We will then take the information you and others have given us and use it to improve the medicines toolkit. The information will be used to develop a way of finding out if the medicines toolkit offers value for money to the NHS. We will publish the study results in academic journals, but you will not be identified in any published report or journal article. Anonymous quotes from you interview may be used in reports or research publications about the study

### What if I decide during the research that I want to stop taking part?

That’s ok – just tell us that you want to stop taking part and if you do not wish us to use the information you may already have given us. 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 Universities of Bradford and Leeds will be responsible for the analysis and storage of the data from questionnaire and 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 are not sure about, or if you have any questions, you can ask the study manager Dr Beth Fylan who will be available 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) at the University of Bradford or Dr Peter Gardner (0113 343 5719) at the University of Leeds. 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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*author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.*