PATIENT AND CARER INFORMATION LEAFLET
IMPROVING MEDICINES USE IN PEOPLE WITH POLYPHARMACY IN PRIMARY CARE (IMPPP)

Can you help us to improve care for people who need to take lots of different medicines by taking part in our research study?

We are inviting you because your general practice is taking part and has it on record that you take multiple medicines or you care for someone who does.

If you take part we will ask you to share your experience of using lots of medicines. This will include questions about your health, the medicines you take and your situation. Your answers will be used to help improve care for people who take lots of different medicines. Answering the questions should only take about 30 or 40 minutes and you can fill in a form and send it back to us (no stamp needed) or do it online. After a few months we will ask you some more questions, and then again, a few months after that, to see if things have changed.

As well as answering questions you may be invited to come in to the surgery to see one of the doctors or a pharmacist for 20-minutes to discuss the medicines you are taking and how you are getting on with them. We call this a medication review and about half the people taking part will be invited. If you are invited to a medication review you are welcome to bring a friend or relative with you. We will also send you some questions afterwards so you can tell us about the appointment. Offering a medication review to only half the people who are taking part in the research means we can compare the experience of the people who receive one with those who don't.

If you agree, we will collect information about your medicines from your doctor and the local hospital if you are also being seen there. The information will only be used to help us improve care for people like you who take lots of medicines and anything with your name or other personal details will be kept strictly private.

Interviews and observations - an optional extra

Some people taking part in the research will be chosen later to be invited to take part in interviews so that we can find out in more detail about the care they have received and their experiences during the research.

We will also ask up to 30 people whether they would be willing to have their medicines review appointment observed by a researcher. If you are one of this small number of people we would like to invite we will contact you with an invitation and more information later and you can choose then whether or not you would like to take part in this extra bit.

If you wish to help, please read all the information on the next pages and sign the consent form included to say you agree to take part. You don't have to take part if you don't want to and you can stop any time and it won't make any difference to the care you get or the medicines you are taking.

Please note: If you are moving to another surgery in the next 6 months, you won't be able to take part in the research.

Please ask us if anything is not clear or if you would like more information

Contact us via telephone on 0117 331 3901 or via email on imppp-study@bristol.ac.uk

Frequently asked questions and other information

What is the purpose of the study?

We are interested in how GP surgeries can better support people taking multiple medicines. We have developed a new General Practice approach for reviewing medicines in people who take lots of different medicines. We are running this study to test this new approach by comparing it with usual/normal care for people taking multiple medicines.

Do I have to take part?

It is up to you to decide if you want to take part. If you do take part, you are free to stop at any time without giving a reason. Deciding to stop will not affect the quality of health care you get.

What are the benefits and disadvantages of taking part?

There might be a benefit to you from receiving a medication review but this is not certain. The answers you give to the research could help other people in the future**.** There should be no disadvantages from taking part. We follow the same NHS guidelines as your normal care.

Why are you asking for my agreement to collect information from my NHS hospital records?

We would like collect data from your hospital records because we want to find out whether the new IMPPP approach to medicines review improves medicines safety and results in less use of hospital services. To enable us to collect information about your hospital care, we need you to agree to us sharing your identifying information, (specifically; your date of birth, NHS number, postcode and gender) with NHS Digital. NHS Digital is responsible for making sure that NHS patient information is only used to support the delivery of health care... If you agree, NHS Digital will link your identifying data to your NHS records so that it can be used for the purposes of this medical research. Hospital data will be collected for a period of 18 months to include the 6-month period before you started the study up until the point that you complete the final study questionnaire. All information collected about you for the study will kept in strict confidence.

What if new information becomes available?

If new information about health care and medicines use becomes available, your GP will talk to you about changes to your care and whether you should carry on or drop out.

What happens when the research stops?

Nothing will change and you will continue with your usual care as before. Your GP practice will decide whether to make any changes to the care they provide. The study results will be published in reports for use by the NHS, researchers, health professionals and NHS managers. It will not be possible for you to be identified in any reports.

What will happen to the information I give?

If you decide to stop the information you have already given will still be used. All information collected about you will be kept strictly private. Your information will be stored securely at the University of Bristol. Your name and other personal details will only be used to help improve care. The University of Bristol is the sponsor for this study and the data controller. Universities in the UK have a duty to ensure that it is in the public interest to collect and use person details from people who have agreed to take part in research. This means that when you agree to take part in a study, we will only use your data in the ways needed to conduct and analyse the study. Your rights to access, change or move your information are limited, as we need to manage

your information in specific ways for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally-identifying information possible. All personal information collected will be removed from your study records so that you cannot be identified and will be securely destroyed within 3 months of study completion. Your study consent form, study questionnaires and anonymised records will be securely stored for 5 years in line with the University policies.

Will my data be used by any other authorised people?
In addition to the research team, people from the NHS authority whose job it is to check the conduct of research will be allowed to see your study information.
We will make study information, with the personal details removed (anonymised information) available on request to authorised researchers who are working on other related studies. Anonymised information will only be shared with researchers who request access, pass checks to show that they are genuine researchers and have ethical approval for use of research information. Authorised researchers will also be required to sign a data sharing agreement before they can have access to any data.

What if there is a problem?
If you are concerned about any part of the study, please contact, Debbie McCahon, IMPPP Trial Manager at the University of Bristol via telephone on 0117 331 3901 or email on imppp-study@bristol.ac.uk. If you are still unhappy and wish to make a formal complaint, you can (a) contact your GP who will advise on local NHS complaints procedures, or (b) Patient Advice and Liaison Service (PALS), the patient support and complaints service who can provide general advice about taking part in research. PALS can be contacted on Tel: 0117 414 4569, 0117 414 4568, 0117 414 4571 or Email: complaints@nbt.nhs.uk.

If you wish to make a complaint about how the researchers handle your personal data, you can contact our Data Protection Officer who will investigate the matter. You can contact our Data Protection Officer at the University of Bristol on data-protection@bristol.ac.uk or you can complain to the Information Commissioner's Office via telephone on 0303 123 1113. Please see www.ico.org.uk for further information about making a complaint.

Other Information about the study
The research is being run by the Centre of Academic Primary Care at the University of Bristol, with the Universities of Dundee and Keele.
This study is funded by the NHS National Institute for Health Research (NIHR).
All research in the NHS is looked at by an independent group of people called a Research Ethics committee, to protect your safety, rights, well-being and dignity. This study has been reviewed and approved by the Wales REC 6, NHS Research Ethics Committee (REC reference 19/WA/0090).

More information about the study is available on the IMPPP study website:-
http://www.bristol.ac.uk/primaryhealthcare/researchthemes/imppp/

Thank you for taking time to read this information