THE UNIVERSITY OF SYDNEY

**Discipline of Pharmacy Practice**
**Faculty of Medicine and Health**
**School of Pharmacy**

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# Can older people action pharmacist medication management recommendations after discharge?

## PARTICIPANT INFORMATION STATEMENT

### (1) What is this study about?

You are invited to take part in a research study about changes you may like to make to the medicines you take after having a conversation with the Hospital's pharmacist about their potential benefits and harms. These changes may be made by you (for non-prescription type medicines) or after talking to your General Practitioner.

You have been invited to participate in this study because you are over 65 years old, taking more than five medicines and your medical conditions have not affected your memory or thinking. We would like to do this research because of the opportunity to review your medicines. We know that the potential benefits and harms for many medicines change as one gets older and need to be regularly reviewed.

This Participant Information Statement tells you about the research study. Knowing what is involved will help you decide if you want to take part in the research. Please read this sheet carefully and ask questions about anything you don't understand or want to know more about.

Participation in this research study is voluntary.

By giving your consent to take part in this study you are telling us that you:
- ✓ Understand what you have read.
- ✓ Agree to take part in the research study as outlined below.
- ✓ Agree to the use of your personal information as described.

You will be given a copy of this Participant Information Statement to keep.

### (2) Who is running the study?

The study is being carried out by the following researchers:
- Dr Ben Basger, Clinical Pharmacist, Wolper Jewish Hospital
- Dr Nicholas Mills, Specialist in Geriatric Medicine, St Vincent's Hospital, Sydney
- Prof Tim Chen, Faculty of Pharmacy, The University of Sydney

- A/Prof Rebekah Moles, Faculty of Pharmacy, The University of Sydney

This study is being funded by Wolper Jewish Hospital to assess the results of a service already being provided. Most of the funding will provide the main researcher (Dr Ben Basger) with time to follow up, record and assess the results of speaking to all participants.

**(3) What will the study involve for me?**

As part of the care we provide and for which we already have a signed consent form, we ensure that the medicines you take home have been compared and checked with the medicines you took when you arrived. We discuss any new medicines started during your stay and check that they are a safe and appropriate treatment. Our clinical pharmacist reviews the medical records and writes out and discusses a list of their medicines with you before discharge. This discussion may include medicine issues that need to be considered and followed up after you leave. If you think the issues raised are important, you may decide that some medicine changes may be appropriate.

We are interested to know if this information was useful to you and what if any changes may have been made by you or your General Practitioner. To do this, we seek your consent to contact you 3-4 weeks after you leave hospital and have a conversation with you. We would do this at a time and place convenient to you. It may take up to 30 minutes of your time. The information we collect cannot be used to identify you. We are happy to share the results of this study with you when completed. We would like to publish this study so that people in other hospitals may benefit if this service is beneficial.

**(4) How much of my time will the study take?**

About 30 minutes of your time, depending upon the amount of information we need to collect and any further discussion we may have about your medicines. We will come to you – you will not need to travel anywhere.

**(5) Who can take part in the study?**

We are interested in people who are over 65 years of age and taking more than five medicines. This is because people may become more sensitive to the good and bad effects of medicines as they age. We know that the more medicines a person takes, the higher the likelihood of side effects. For example, medicine doses and medicine choice may need to be adjusted due to less robust brain, liver or kidney function. As part of the tests ordered for you by your doctor (such as vitamin D levels), the Montreal Cognitive Assessment (MOCA) will be performed. This is to see if your age or medical conditions have affected your thinking or memory. We have an ethical obligation to ensure that people who consent to our study fully understand it.

**(6) Do I have to be in the study? Can I withdraw from the study once I've started?**

Being in this study is completely voluntary and you do not have to take part. Your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at the University of Sydney or at Wolper Jewish Hospital. Whether or not you are a participant will have no effect on your in-hospital care during this admission or for any future admissions.

If you decide to take part in the study and then change your mind later, you are free to withdraw at any time. You can do this by notifying the clinical pharmacist, Dr Ben Basger, on 0412 852 828 or emailing ben.basger@sydney.edu.au. You may discontinue our home visit at any time. Any records obtained after your discharge will be destroyed.

**(7) Are there any risks or costs associated with being in the study?**

Aside from giving up your time, we do not think there will be any risks or costs associated with taking part in this study. However, if at any time or for any reason you would like to cancel or stop the interview or avoid certain issues, that is what will happen.

**(8) Are there any benefits associated with being in the study?**

We believe that the information given to you about your medicines will directly benefit you. A greater understanding of medicine effectiveness and possible side effects should occur, together with recommendations about possible reduction of cost and number of medicines taken.

This study also aims to show that, through making the patient the focus of care, medication management can be improved for older patients in other hospitals.

**(9) What will happen to information about me that is collected during the study?**

By providing your consent, you are agreeing to allow us to use the information collected while you were an inpatient at Wolper Jewish Hospital when we visit you. Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise.

Any paper-based information collected when we contact you will be stored securely with your medical records at Wolper Jewish Hospital, and your identity will be kept strictly confidential, except as required by law. Study findings will be reported to the Medical Executive Committee of Wolper Jewish Hospital. Study findings may also be published in a medical journal, but you will not be individually identifiable in these reports or publications. The information from this study will not be used for any other purposes. No one else will have access to this information. The results of this study will be archived with your medical records.

**(10) Can I tell other people about the study?**

Yes, you are welcome to tell other people about the study.

**(11) What if I would like further information about the study?**

When you have read this information, Dr Ben Basger will be available to discuss it with you further and answer any questions you may have. If you would like to know more at any stage during the study, please feel free to contact him on 0412 852 8238 or email ben.basger@sydney.edu.au.

(12) **Will I be told the results of the study?**

You have a right to receive feedback about the overall results of this study. Please let Dr Ben Basger know and he will arrange it. This feedback will be in the form of a one-page summary. You will receive this feedback after the study is finished.

If you would like personalised feedback, Dr Ben Basger will be happy to provide this as well.

**(13) What if I have a complaint or any concerns about the study?**

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the University of Sydney *[INSERT* protocol number once approval is obtained*].* As part of this

process, we have agreed to carry out the study according to the *National Statement on Ethical Conduct in Human Research (2007).* This statement has been developed to protect people who agree to take part in research studies.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number.

The Manager, Ethics Administration, University of Sydney:

- **Telephone:** +61 2 8627 8176
- **Email:** human.ethics@sydney.edu.au
- **Fax:** +61 2 8627 8177 (Facsimile)

*This information sheet is for you to keep*