THE UNIVERSITY OF SYDNEY

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Can older people action pharmacist medication management recommendations after discharge?

INFORMATION STATEMENT: PERSON RESPONSIBLE

(1) What is this study about?

The person under your guardianship/care is invited to take part in a research study about changes to the medicines they take, after you have both had a conversation with the Hospital's pharmacist. There may be new medicines that have been started or medicines that have been stopped.

The person under your care has been invited to participate in this study because they are over 65 years old and taking more than five medicines. You are asked to participate because their medical condition(s) have affected their memory or thinking. We would like to do this research because of the opportunity to review their medicines. We know that the potential benefits and harms for many medicines change as one gets older and need to be regularly reviewed.

Participation in this research study is voluntary.

By giving your consent you are telling us that you:
- ✓ Understand what you have read.
- ✓ Agree for the person under your guardianship/care to take part in the study as outlined below.
- ✓ Agree to the use of their personal information as described.

You will be given a copy of this 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?

As part of the care we provide and for which we already have a signed consent form, we ensure that the medicines the person under your care takes home have been compared and checked with the medicines they took when they arrived. We discuss any new medicines started during their 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 both of you before discharge. This discussion may include medicine issues that need to be considered and followed up after they leave. If you think the issues raised are important, both you and the person under your care 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 for the person under your care or by their General Practitioner. To do this, we seek your consent to contact you and the person under your care 3-4 weeks after they leave hospital and have a conversation with both of 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 or the person under your care. 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 time will the study take?

About 30 minutes, depending upon the amount of information we need to collect and any further discussion we may have about the 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 that comes with age. As part of the tests ordered for the person under your care (such as vitamin D levels), the Montreal Cognitive Assessment (MOCA) was performed. This showed that the persons medical conditions have affected their thinking or memory. This test identifies a special group of people who need assistance to get the most benefit from medicines. We wish to include such patients in our research by asking for your cooperation. We have an ethical obligation to ensure that people who consent to our study fully understand it.

(6) Does the person have to be in the study? Can they withdraw from the study once they've started?

Being in this study is completely voluntary and the person under your care does not have to take part. The decision whether to participate will not affect any current or future relationship with the researchers or anyone else at the University of Sydney or at Wolper Jewish Hospital. Participation or non-participation will have no effect on their in-hospital care during this admission or for any future admissions.

If you or the person under your care decide to take part in the study and then change your mind later, withdrawal may occur 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 discharge will be destroyed

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

Aside from giving up your time and the time of the person under your care, 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 or the person under your care 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 the person under your care about their medicines will directly benefit them. 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 collected during the study?

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

Any paper-based information collected when we contact you will be stored securely with the medical records at Wolper Jewish Hospital, and the 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 the person under your care 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 their medical records.

(10) Can we tell other people about the study?

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

(11) What if we 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 we be told the results of the study?

You and the person under your care 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 or the person under your care 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