**Participant Information for cognitive interviews, phase 1**

**(V3PISci1)**

**Medication monitoring in general practice: clinical impact of implementing a nurse-led Adverse Drug Reaction (ADRe) Profile in older adults with 5 or more prescribed medicines**

*You are being invited to take part in an ADRe research study, conducted as part of a PhD project, under the supervision of Prof. Sue Jordan. Before you decide whether or not to participate, it is important for you to understand why the research is being conducted and what it will involve. Please read the following information carefully.*

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| **What is the ADRe Profile?** |
| The ADRe Profile is an instrument that a nurse or carer can use to recognise any problems or signs and symptoms patients may have that may relate to adverse effects of prescribed medicines. The structured ADRe profile works by recording patients’ observations and other relevant information about health and wellbeing. If problems are found, ADRe empowers the nurse to solve some of the concerns, while others may need to be shared with the prescribers of the medications. The ADRe Profile helps patients overcome bothersome problems and use their medications more effectively.  |
| **Why is the research being done?** |
| We know that some patients who take several medications are vulnerable to unwanted and preventable adverse side effects. We have already found that the ADRe Profile helps to identify and resolve these problems in nursing home residents and in patients who take respiratory or mental health medications. Now we would like to test the tool with patients in the community who take 5 or more medications. At this stage, we are trying to establish how well are the individual questions on the ADRe Profile understood by people. |
| **Who will be doing the research?** |
| This study is led by Professor Sue Jordan, working with a larger research team at Swansea University. The research will be done by Vera Logan (registered nurse) funded by a Swansea University centenary scholarship. We are inviting you, a service user at a general practice participating in our research, to take part.  |
| **What would taking part involve?** |
| If you agree to take part, we will arrange a mutually convenient date and time and use a video call to ask you about how you interpret the questions on the ADRe Profile. This will take about an hour of your time. |
| **What are the possible benefits of taking part?** |
| We cannot guarantee any benefits. By taking part, you will be helping us evaluate the ADRe tool. Research like this helps to continually improve the treatments and care provided to all patients now and in the future.  |
| **What are the possible disadvantages and risks of taking part?** |
| Our past studies have not identified any harm to participants. We do not anticipate any risks to participants’ physical or emotional health.  |
| **Do I have to take part?** |
| No, it is up to you whether or not you would like to take part in this research. |
| **Will taking part in this study be kept confidential?** |
| Yes, your data will be processed in accordance with the Data Protection Act 2018 and the General Data Protection Regulation 2016 (GDPR). No personal or health information about you will be collected. |
| **How will we use the information you provide?** |
| The information gathered will be used to adjust the questions on the ADRe Profile. Findings may be presented at seminars, conferences and published in academic papers. Your information will not be identifiable.  |
| **What are your choices about how your information is used?** |
| You can stop being part of the study at any time, without giving a reason, but we will keep any anonymized information about you that we already have.  |
| **Who has reviewed the study?** |
| All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by\_\_\_\_\_\_\_\_\_\_\_\_\_Research Ethics Committee.Swansea University is the sponsor of the study. |
| **What if there is a problem?** |
| If you should wish to make a complaint you can do this through Swansea University, Faculty of Health & Life Sciences (contact details are at the end of this information sheet). |
| **Where can I get more information?** |
| For more information about the ADRe Profile, please visit <https://www.swansea.ac.uk/adre/> , for information about how ADRe works, watch the video here: <https://www.swansea.ac.uk/adre/how-the-adre-works/>**You can find out more about how we use your information** • at www.hra.nhs.uk/information-about-patients/ • by sending an email to dataprotection@swansea.ac.uk (sponsor’s Data Protection Officer)• By contacting the research team on vera.logan@swansea.ac.uk• By ringing the research team on 01792 604721 |
| **What do I need to do next?** |
| If you do not wish to take part, there is no need to do anything. However, if you would like to be involved in this study, please contact Vera Logan or Prof. Sue Jordan (researcher contact details are below) or your general practice. If you decide to participate, you will be asked to sign a consent form. You are free to withdraw from the study at any point, without your care being affected. |

Thank you for taking the time to read this information.

Prof. S.E. Jordan, Faculty of Health and Life Sciences, Swansea University, Singleton Park, SA2 8PP. Tel: 01792 518541 s.e.jordan@swansea.ac.uk

**Further information is available from the researcher:**

Vera Logan, Faculty of Health and Life Sciences, Swansea University, Singleton Park, SA2 8PP. Tel: 01792 604721 email: vera.logan@swansea.ac.uk

**Swansea University research team**

Prof. S.E. Jordan, Prof. David Hughes, Dr Adam Turner (pharmacist) and Vera Logan (registered nurse)

**Contact for formal complaints:**

1. Data issues: GDPR Information Commissioner’s Office – tel. 0303 123 1113 or visit <https://ico.org.uk/make-a-complaint/>

2. Health issues: Community Health Council - tel: 01639 683490 or

email: complaints.advocacy@waleschc.org.uk

3. Management issues: Head of College – Prof. Jayne Cutter, tel. 01792 295790 or email: j.cutter@swansea.ac.uk