PADRe Study Acronym

Short Title: Polypharmacy Adverse Drug Reactions (PADRe)

Long Title: Polypharmacy Adverse Drug Reactions (PADRe): Nurse-led intervention to minimise adverse drug reactions for older adults in care homes: a quality improvement process intervention

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Registration: For registration on the website 'clinicaltrials.gov'.

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Title

Polypharmacy Adverse Drug Reactions (PADRe)

Nurse-led intervention to minimise adverse drug reactions for older adults in care homes: a quality improvement process intervention

Introduction

Medicines' management is an area where innovation could improve delivery and outcomes of care and reduce unnecessary costs. However, widespread weaknesses in the monitoring and management of adverse drug reactions (ADRs) or side-effects, which can sometimes be fatal, means that preventable ADRs are responsible for 5-8% unplanned hospital admissions in the UK, costing the NHS £1.5-2.5bn pa (NICE 2015) – figures unchanged in the last decade. Between 2005 and 2013, 18% of 13,699 primary care patient safety incident reports, and 24% of 996 reports describing serious harm or fatalities were attributed to prescription medicines, particularly avoidable ADRs, mainly due to inadequate monitoring, communication or decision-making (Carson-Stevens 2016). Most ADRs are due to poor monitoring, not poor prescribing (Gabe 2011). These problems persist, despite new guidelines, computerised reminders, safety initiatives, and medication reviews, intimating the need for innovation.

Up to 50% of people in care homes are over-prescribed medicines, and many doses are too high, particularly for mental-health medicines (Banerjee 2009). ADRs can be life-threatening (e.g. haemorrhage, falls, cardiac arrhythmias, renal failure), debilitating (e.g. drug-induced Parkinsonism, ataxia, postural hypotension) or subtle, and mistaken for signs of ageing or underlying conditions. They can be overlooked, leading to hospitalisation, behaviour problems, loss of comfort and dignity (Howard et al 2007, Jordan 2008, Jordan et al 2014; Jordan et al 2015).

Polypharmacy presents a major threat to the patient safety of older adults internationally. There is widespread consensus that over-prescribing and failure to monitor are the underlying culprits (Banerjee 2009; Gabe et al 2011). However, there is less consensus as to how routine care should change to address inappropriate prescribing and suboptimal medicines' management.

Currently, there is no comprehensive, systematic assessment of problems potentially related to prescribed medicines, and doses are not regularly reviewed (Jordan et al 2016). Our intervention (Jordan et al 2014; Jordan et al 2015) offers a solution. We are seeking funding to extend the provision of an existing intervention for review of mental health medicines to: a) be inclusive of all commonly prescribed medicines to older adults; and, b) tested in a diverse range of care home contexts, including in new socio-economically deprived geographical area away from the current research centre.

Objectives

This new funding will test whether the intervention can identify adverse events in those without mental illness and prevent pain, nausea, vision and dental problems in care homes without academic research support, in an area of greater socio-economic deprivation.

This project aims to:

- Record how the PADRe Profile works during usual care.
- Record any changes to care or prescriptions.

- Record any benefits and harms to residents.
- Estimate changes in quality of life and costs emanating from the intervention.
- Make recommendations as to how the PADRe Profile can be sustained during usual care.

The ADRe Profile improved care and prevented serious adverse events in care homes and adult mental health teams in Abertawe Bro Morgannwg and Hywel dda UHBs, with the support of the author (SJ) and her students (Jordan et al 2015, Jones et al 2016). We are now extending the work to consider all medicines commonly prescribed in primary care: amongst older adults receiving nursing home care, the prevalence of potentially inappropriate prescribing is estimated to be 18.5%-82.6% (Dreischulte et al 2016).

Secondary research questions/objectives:

To document the extent to which the PADRe Profile fulfills its aims to:

- minimize adverse drug reactions without compromising the beneficial effects of medicines
- identify, monitor and ameliorate any possible adverse drug reactions associated with medicines commonly prescribed in primary care
- ensure problems are communicated to pharmacists and prescribers efficiently
- provide practical detail for implementation
- facilitate shared decision-making with residents and within the multi-disciplinary team

Methods

Study Design

We will undertake an observational study. This will involve the following:

- an analysis of polypharmacy-related reports in the National Reporting and Learning System (NRLS),
- a cognitive interview study with volunteers to review the PADRe Profile
- an eDelphi Study with experts to assess the modified PADRe Profile and
- a process evaluation (appendix – study flow diagram) to evaluate the practical use of the PADRe Profile with 182 care home residents within 7 care homes in the ABUHB area. This will involve debriefing interviews with care home nurses, a review of residents' medical and nursing notes and interviews with stakeholders.

Process evaluation Study

Setting*:* we plan to recruit nursing homes from the area of the Aneurin Bevan University Health Board.

Recruitment of nursing homes*:* care homes in AB UHB will be ordered by quality and safety performance indicators from Health Board inspection. Homes from the lower, middle and upper third tertials will be invited to participate. Those at the extremes will be approached initially. Eligibility of nursing homes for entering the study is as follows:

Inclusion criteria:

- Providing residential or nursing care or both to >30 residents meeting inclusion criteria below.
- Willing to use the PADRe Profile in routine practice
- Staff aware of the Mental Capacity Act 2005, and willing to take informed consent.

Exclusion criteria:

- <30 residents meet the inclusion criteria
- Unwilling or unable to volunteer to undertake nurse-led medicines' monitoring
- Unwilling or unable to volunteer a nurse to act as site lead
- Not using the services of ABUHB primary care professionals.

Care homes will initially be sent an approach letter (appendix – care home approach letter) and they will be asked to reply with their decision by way of an email or telephone call. If, after 2 weeks, the care home does not reply, then a telephone call will be made to the care home for their decision. Where a home declines, the next in order will be approached. If a care home would like more information about the study, an appointment will be made with the Matron/Care Home Manager for the researcher and Professor Sue Bale to visit the home to discuss further.

Recruitment of care home residents: the study nurses and the matron/care home manager will decide which residents will be approached. A list of names of residents who are eligible to take part in the study will be drawn up by the matron/care home manager and the study nurses from medicines administration records. The study nurses should discuss the study

with the resident and if they are happy, can provide more information about the study and answer any questions the resident may have. The resident will have sufficient time to consider the information, discuss with others if they wish, and decide whether to participate. The resident's GP will also be informed of their participation in the study by way of a letter to the GP surgery (app 5b).

Obtaining consent from residents: Where residents have capacity they will be asked to provide written informed consent. The care home staff, preferably a registered nurse if one is available, the researcher or a GCP-trained research team member, fully cognisant of the Mental Capacity Act 2005 and trained in study procedures, will take consent from the residents (appendix – care home residents PIS and consent).

For those residents who have physical difficulty signing the consent form, they will provide verbal consent which will be witnessed by another person using the same form (appendix - care home residents PIS and consent). Verbal assent will be obtained in the presence of and countersigned by a literate, impartial and independent witness confirming that all the relevant information was provided to the research participant in an understandable manner. She/ he will read the written information supplied to the resident and be present throughout the entire informed consent discussion. After the written PIS and informed consent form and any other written information to be provided to the resident, is read and explained to the subject, and after the subject has orally consented to the subject's participation in the study, the witness will sign and personally date the consent form. By signing the consent form, the witness will attest that the information in the consent form

and any other written information was accurately explained to, and apparently understood by, the subject and that informed consent was freely given by the subject.

Where residents lack capacity to provide consent: According to the Mental Capacity Act, residents will be assumed to have capacity unless it is established that they lack capacity, all practicable steps having been made to help them do so. Many of the residents we will work with have cognitive impairment or dementia, even if there is no formal diagnosis. Where there is a concern that a resident lacks capacity to provide informed consent for themselves to participate in the study, the resident will be assessed for mental capacity by delegated individuals (i.e. the care home staff or the researcher and this will be documented). Where a resident does not have capacity, a 'consultee' will be consulted who will provide assent. If a family member is too frail to be approached, the consultee may be a friend or unpaid carer. The consultee will be provided with information about the study (appendix – consultee PIS_Consent), and they will be asked their advice regarding what the person's views would have been about participating in the research, if they had capacity to make the decision for themselves. They will sign a consultee declaration form (appendix – consultee PIS_Consent).

In the event that a consultee who has an unpaid or non-professional role in caring for the person cannot be identified, or is not willing to act, a nominated consultee will be appointed and consulted prior to including the resident in the study. This may be a member of staff at the care home. They too will sign the consultee declaration form (appendix – consultee PIS_Consent).

Inclusion criteria:

- Resident at the care home and expected to continue to live there for 1 year;
- Currently taking >3 prescribed medicines daily. Vitamin and nutritional supplements and moisturising skin preparations will not be counted as 'medicines'. PRN medicines given regularly, according to MAR charts, will be included. PRN medicines with no records of administration will not be counted.
- Willing and able to give informed, signed consent themselves, or where capacity is lacking, a consultee (as above) who is willing to give advice and assent to the resident participating.

Exclusion criteria

- Not well enough to participate, as screened by their nurses;
- Aged <18;
- Prescribed <4 medicines daily;
- Receiving active palliative care.

Recruitment of nurses to administer the PADRe Profile*:* Care home nurses (with or without NMC registration) will be invited to take part in the study by the Matron/Care Home Manager. One study lead nurse and one deputy lead nurse will be required and both will need to read a participant information sheet and sign a consent form with the researcher (appendix - Health professionals PIS and consent).

Inclusion criteria

- Working in care home, and expected to continue in employment for at least 6 months
- Qualified to administer medicines in the care home, trained in medicines' administration (DH 2016), either through NMC registration or appropriate qualifications, including QCF (Qualifications and Credit Framework 2012) and
- Willing and able to administer the PADRe Profile monthly

Exclusion criteria

- Not trained in medicines' administration
- Not undertaking medicines' administration
- Unwilling or unable to administer medication monitoring

Recruitment of community pharmacists*;* The researcher will initially ask the care home for the names and contact details of the pharmacists who are aligned to them. Community pharmacists will then be invited to take part in the study by the study Consultant Pharmacists (TB, JH) using a PIS and consent form (appendix – Health Professionals PIS and consent) by letter and email. Pharmacists will be required to sign a consent form.

Inclusion criteria:

- Aligned to a study care home and expected to continue employed as a pharmacist for a t least 6 months
- Willing and able to administer the PADRe Profile monthly

Recruitment of stakeholders for interviews*:* Study stakeholders (1 GP, 1 pharmacist and 1 consultee per care home) will be invited to carry out an interview by the researcher (appendix – Health professionals PIS and consent; appendix – consultee PIS and consent), verbally or by way of an email. All stakeholders who undertake an interview will be required to sign a consent form with the researcher undertaking the interview.

Inclusion criteria

- GP aligned to a participating nursing home and caring for the recruited participants
- A Community pharmacist aligned to a participating nursing home
- A person who is representing a resident who is participating in the study

Exclusion criteria

- Not involved with residents in care homes
- Unwilling to consent to audio recorded interview

Training the care home nurses and community pharmacists

Nurses will receive training including a video as well as comprehensive guidelines. The researcher will visit the care home and provide the training at a time and date convenient to the care home. Community pharmacists and pharmacists who act as a 'back-up' for the study will receive training from the study consultant pharmacist. The research team will remain available for further training and guidance as required throughout the study period.

Using the PADRe Profile with care home residents

Nurse leads in 7 homes will implement the PADRe Profile. They will need to complete the PADRe Profile with each of the residents (up to 26) at least every month, for 3 months as part of normal care. To do this, they will take some observations and ask some questions. All observations and questions are those that are sometimes used as part of normal care and are not invasive. The PADRe Profile checklist will help to determine clinical signs and symptoms of adverse drug reactions. At this time, the nurses will also be asked to complete a record/log/diary of using the PADRe Profile to record how it works during usual care. Both use of the PADRe Profile and recording how it works will take approximately 10 to 25 minutes per resident. We ask nurses that they try to carry out PADRe Profile completion with residents and using existing documentation at least every month or more frequently if medicines are changed. They will then pass it to the prescribers and pharmacists caring for the residents, along with the medication administration records.

Use of the quality of life questionnaire

At the start and end of the study, study nurses will fill in a quality of life questionnaire (the EQ-5D-5L) (Euroqol Group 2009) with the participating residents (EQ-5D-5L English; EQ-5D-5L Welsh https://euroqol.org/eq-5d-instruments/eq-5d-5l-about/). This consists of 5 'tick box' questions and will take approximately 5 minutes. This will determine whether the use of the PADRe Profile has improved (or not) the quality of life of the residents.

Undertaking reviews of the care home residents' nursing and medical notes

Consent for researchers to view patient records will have already been obtained from the residents when they consent to take part in the process evaluation at the start of the study. The researcher will review these notes using a document review sheet (appendix – review

notes) before the start of the study and at the end of the study for evidence of use of the new PADRe Profile and any changes in care or outcomes of care.

Introductory and debriefing interviews with care home nurses

Before the implementation of the PADRe Profile, study nurses will be invited to take part in an introductory interview with the researcher who will ask them to discuss their views on medication monitoring and the potential of the PADRe Profile instrument. An interview guide will be used. Their knowledge of medications and adverse drug reactions will not be tested but rather, their views on these as well as their views on the PADRe Profile instrument to be used will be discussed. This interview will take place at the care home and will last approximately 30 minutes. Nurses will also receive a debriefing interview with the researcher at the end of month 2 of the implementation of the PADRe Profile (during its use) and at the end of month 3 of using the PADRe Profile. A separate interview guide will be used for debriefing the study nurses.

Undertaking interviews with the stakeholders

At the end of the study period where the PADRe Profile is used, the researcher will undertake qualitative interviews with stakeholders; 1 GP, 1 Community Pharmacist and 1 Resident Representative from each care home. They will be invited to discuss their experiences of participating in a study where the PADRe Profile is being used. This interview will take approximately 30 minutes and an interview guide will be used.

Study size

We shall introduce medicines' monitoring into 7 care homes, each with 26 residents prescribed >4 medicines (estimated ~90% residents (Jordan et al 2015). In previous work with participants acting as their own controls, de-prescribing occurred in 8.5% more participants (12.1% vs. 3.6%) when ADRe Profiles were used. We hypothesise that the new PADRe Profile will be twice as effective. Based on the reported intra-cluster coefficient (0.02) (Jordan et al 2015), 182 participants will detect this difference with 80% power & 5% significance, allowing for a 5% loss to follow up (Uitenbroek 1997, Killip et al 2004).

Analyses

Both quantitative and qualitative methods of analysis will be used and data will be triangulated.

Statistical analysis

Differences between before and after the intervention will be calculated for: problems addressed, prescription regimens, NHS use, and compared, adjusting for site (statistician AW). The impact of age, diagnoses, and medicines' use (numbers and types of medicines prescribed8) will be accounted. Resource use, costs, and health economic outcome measures will be described (JR).

Qualitative analysis

Interviews will be analysed by the team using the constant comparative method to identify predictors of successful adoption and any changes to the PADRe Profile, working

arrangements and oversight needed to embed use. This systematic, re-iterative method of comparing and contrasting emerging codes, categories and concepts ensures that theoretical perspectives are embedded in the description of change. Interviews will be coded, categorised, analysed and interpreted by at least two researchers and discussed at team meetings, with guidance and consistency checks.

Diaries/logs will also be analysed in association with interview transcripts.

Ethics

Permission to carry out this study will be given by an NHS Research Ethics Committee. Following approval, any subsequent amendments will be communicated to the Ethics Committee as well as the investigators, the study participants, and the trial registry.

Participation in the study is voluntary. All those participating will receive a participant information sheet (PIS) and will need to sign a consent form indicating their understanding of their role in the study. The researcher will also be available to discuss with the participants any questions that they may have.

All participants will be given sufficient time to decide whether they wish to take part. They will be informed that their participation in voluntary and that they are free to withdraw at any time without giving a reason for doing so. Those participants agreeing to be interviewed will be informed that their anonymised data and quotes may be used in any relevant publications.

Care home participants or their representatives will be informed that if they chose to withdraw from the study, their medical care or legal rights will not be affected. They will also be informed that

- sections of their care home health records may be looked at by individuals from Aneurin Bevan University Health Board, Cardiff and Swansea Universities and from regulatory authorities
- the completed PADRe Profile will be shared with the study pharmacist, together with a copy of their medication record
- their GP will be informed of their participation.

Declaration of interests: The chief investigator, principal investigator and all co-applicants and collaborators state they have no financial interests to declare in relation to the study and each study site.

Data storage

Case report forms (CRF) and audio devices will be stored in a locked cabinet in a locked office. The laptop/university computers used will be password protected. Any information transferred electronically will be anonymised.

All case notes will remain in the participant's organisation settings. Security & privacy of the case notes is maintained as per organisational routine practice.

We will ensure that signed consent forms will not be stored with participant data, including interview notes and transcripts. They are the only documents with identifiable data. They will be stored in a locked cabinet in a locked office for sole use of the CI.

Anonymised and de-identified data will be stored on password protected PCs for sole use of the researchers in locked offices for sole use of team members during the study. On completion, we shall store all current documents in locked tambour cupboards in AB UHB, and after 5 years documents will be sent to AB's archived files, into safe storage off site. AB UHB archives will be asked to destroy the data 5 years after the last publication from the study. This is to allow time for the research community to ask questions.

Data confidentiality

Participants will be given study numbers. Only the research assistant will keep a list linking numbers to care homes and names. This will be destroyed on completion of the study.

The study team will respect confidentiality of personal data and meet the requirements of the Data Protection Act, 1998. We will follow policies or guidance e.g. NHS Code of Confidentiality. The research team and staff are aware of and work to appropriate confidentiality standards. They have NHS backgrounds, and recognise the common law duty of confidentiality.

Any disclosures at interview will be treated in strict confidence. We shall avoid disclosure of attributable data in publications. Study numbers will be used throughout. Co-applicants will analyse redacted interview transcripts and field notes on password protected Swansea &

Cardiff University PCs. Most co-applicants are experienced qualitative researchers, with PhDs and academic publications. Dr. Carson-Stevens will oversee the qualitative analysis. De-identified numerical data will be and analysed by Dr. Alan Watkins and Professor Sue Jordan in their own secure offices. Quality of life (EQ-5D-5L), resource use and health economics data will be analysed by Dr. Jeffrey Round.

Confidentiality of de-identified personal data during data transfer via the University & UHB secure email network is assured. All pcs are password protected & require active log in. Additionally, the offices can only be accessed using own key. Only aggregated data will be reported. There are no plans to use the data outside the UK.

Dissemination

Letters will be sent to the participating care homes to inform them of the results of the study. Individual letters will also be sent to residents and their representatives. Other participants who have taken part in the study (for the e-DELPHI, the cognitive interviews and the stakeholder interviews - GP, Pharmacists) will receive results via postal letter or email.

This study will be a portfolio study for Health and Care Research Wales and will be recorded as such.

Translation of knowledge from evaluation of our implementation processes into steps and recommendations for establishing a national collaborative for ongoing quality improvement for prescribing in care homes. There is a developing community of practice involving

primary care professionals in Wales that would be a suitable mechanism for the spread of the innovation, in collaboration with Welsh Medicines Resource Centre (http://www.wemerec.org/Documents/Bulletins/optimisingmed2016online.pdf).
For example, the cost of hospitalization following a fall is $25k (~£20,000) (Burns et al 2016). Preventing one hospitalisation per year would more than pay for the annual costs of a prescribing quality improvement programme in each health care organisation (Health Board / CCG).

Previously, nurses continued using the ADRe Profile after completion of the research. Nurses will receive training and comprehensive guidelines, and the research team will remain available. If the benefit of the PADRe Profile can be demonstrated to the satisfaction of participants, we expect that current policy drivers to improve medicines' management will promote continuation.

Positive results would provide evidence for developing safer practice to safeguard against medication-related ill-health. There is potential to implement our intervention in both paper and electronic formats, with guidelines and audit/evaluation.

Results will be passed to the care homes' inspectorate, Older People's Commissioner and Welsh Government to inform consultation on antipsychotic use in older adults and the Wales Dementia Strategy.

Dissemination will complement our on-going work in engaging with care providers and policymakers around medicines' monitoring. They will target:

- Patients, patient-support organisations and the wider public
- Practitioners, including trainees e.g. further NICE case-study examples
- Policymakers
- The research community (academic papers)

The ultimate goal informing dissemination is policy-level introduction of medicines' monitoring based on the PADRe Profile across the UK.

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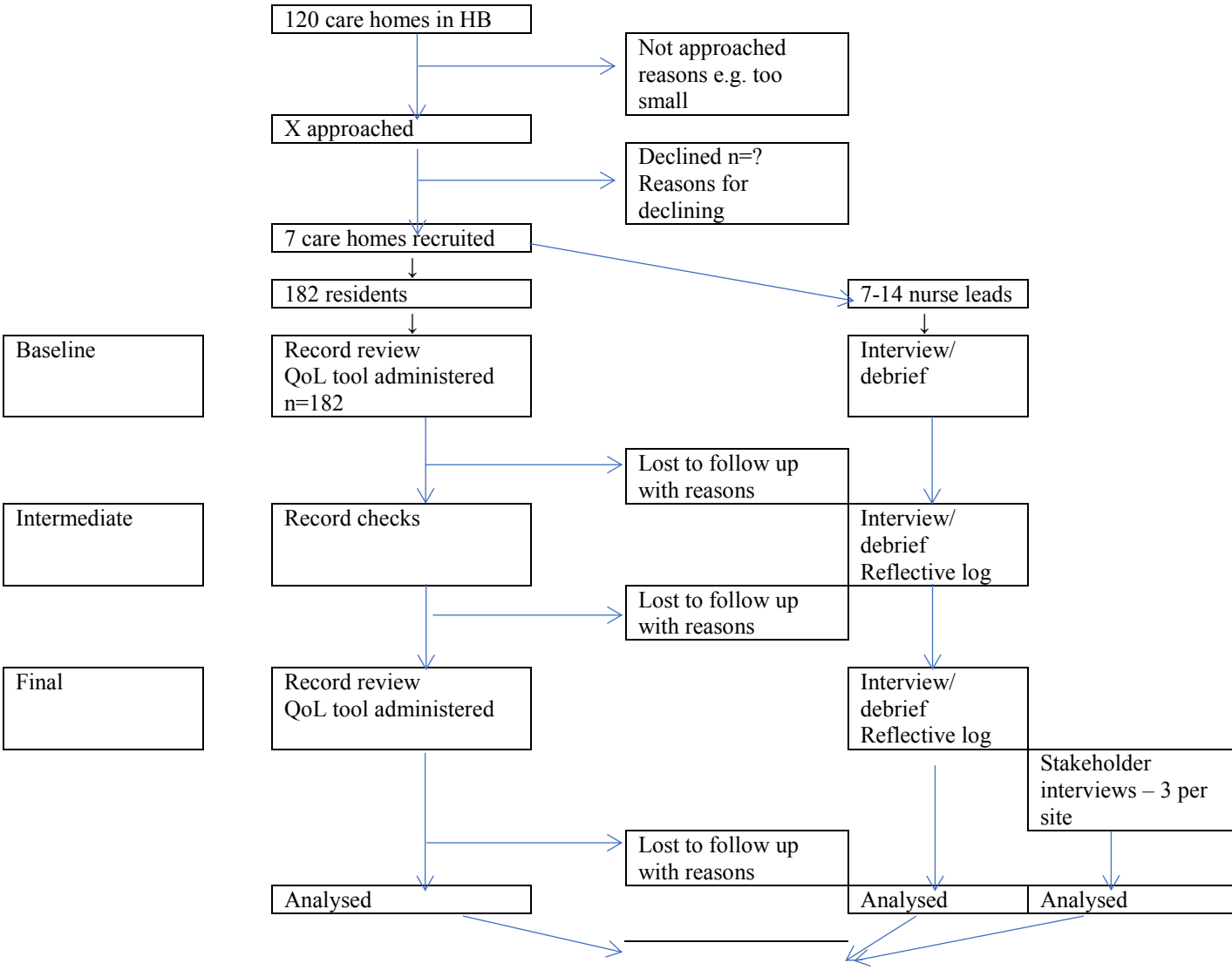
Appendix : Study flow Diagram



Care home approach letter Version 1.0

Care home address

DATE

Dear Care Home Lead,

Nurse-led intervention to minimise adverse drug reactions for older adults in care homes: a quality improvement process intervention

The PADRe Study (Polypharmacy Adverse Drug Reactions)

Aneurin Bevan University Health Board is working on an improvement initiative with Cardiff and Swansea Universities. We should like to invite your care home to work with us in nurse-led medication monitoring in care homes. The work is funded by the Health Foundation, and has the support of the Wales Centre for Primary and Emergency Care Research, the Centre for Aging and Dementia Research (CADR) and the Alzheimer's Society.

Many people who live in care homes take multiple medications (that is, 4 or more). This study aims to improve their safety by making it easier for nurses to identify any side effects that they may be experiencing. To do this, we will develop an existing intervention to monitor and manage medicines in care homes with the aim of improving identification of possible adverse drug reactions. This intervention will be in the form of a polypharmacy checklist Profile instrument that nurses can use and share with pharmacists and prescribers.

The earlier version of the intervention was tested in a clinical trial and a feasibility study in care homes in South West Wales. These provided evidence of the potential benefit of structured medicines' monitoring using an adverse drug reaction Profile. A copy of the previous medication monitoring profile and further information will be forwarded on request from http://www.swansea.ac.uk/adre/

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Our next step in the project is for care homes to use the Profile in routine care, and we should like to work with you in this.

A participant information sheet is attached to this letter which discusses the study in more detail including the role of participating care homes. If you are interested in this study or would like more information, Hayley Prout, the Researcher for this study and Professor Sue Bale, Research and Development Director for the Aneurin Bevan University Health Board can visit your care home to discuss the study further, if you wish.

If you agree to take part in this study, or would like more information, please could you contact us within 2 weeks of receiving this letter using the contact details set out below.

Thank you very much for taking the time to read this letter.

With very best wishes,

Dr Andrew Carson Stevens
Chief Investigator/Clinical Academic (GP)

For further information, you can speak to one of the study team:
Chief Investigator: Dr Andy Carson-Stevens or Study Researcher: Hayley Prout: 5th Floor, Neuadd Meirionydd, Heath Park, Cardiff. CF14 4YX. Telephone number: 029 20688907. Email address: Prouth@cardiff.ac.uk.

Principal Investigator / instrument author: Professor Sue Jordan: s.e.jordan@swansea.ac.uk / 01792518541
More information about the work in South West Wales can be found on the Swansea University website. http://www.swansea.ac.uk/adre/

PARTICIPANT INFORMATION SHEET: CARE HOME RESIDENTS

Nurse-led intervention to minimise adverse drug reactions for older adults in care homes: a quality improvement process intervention

The PADRe Study (Polypharmacy Adverse Drug Reactions)

We should like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it will involve. ***One of our colleagues will go through the information sheet with you and answer any questions you have.*** Feel free to discuss it with others if you wish. Please ask if there is anything that is not clear or if you want more information. Please take your time to read the following information carefully and decide if you wish to participate.

1. What is the purpose of the study?

Polypharmacy is the name given to the use of multiple or inappropriate medicines. It has the potential to harm older adults through adverse drug reactions (ADRs), including cognitive impairment (such as memory and thinking skills), falls and subsequent hospitalisations. Interventions led by nurses to engage with patients, check and record problems have previously demonstrated improved quality of care by identifying serious adverse drug reactions or side effects relating to prescribed medicines.

Many people who live in care homes take multiple medications. This study aims to improve their safety by making it easier for nurses to identify any adverse side effects that they may be experiencing. To do this, we will develop an existing intervention to monitor and manage medicines in care homes with the aim of improving identification of possible adverse drug reactions. This intervention is in the form of a polypharmacy checklist Profile instrument that nurses can use and share with pharmacists and prescribers.

2. Why have I been invited?

You have been invited to take part in our study because you are a resident at a care home within the area covered by Aneurin Bevan University Health Board, and currently taking 4 or more prescribed medicines daily. Twenty five other residents within your care home will also be invited to take part in this study. Residents from 6 other care homes within the area of Aneurin Bevan University Health Board will also be invited to take part in this study with a total of 182 residents taking part.

3. Do I have to take part?

No. Your participation in this study is entirely voluntary and you are under no pressure to take part. If you do decide to take part we shall ask you to sign a consent form. If you later change your mind, you are free to withdraw from the study at any time without having to explain why. If you do not wish to take part in this study, the standard of care that you receive will not be affected.

4. What will happen to me if I take part?

We should like you to take part in this observational study for the duration of up to 6 months. Before the start of the study, a nurse at your care home will ask you to sign a consent form to say that you agree to take part in the study. This will take approximately 10 minutes.

At the beginning of the study, a researcher or nurse will ask you to fill in a quality of life questionnaire of 5 'tick box' questions. This will take approximately 5 minutes. A researcher will also review your care home health records at this time.

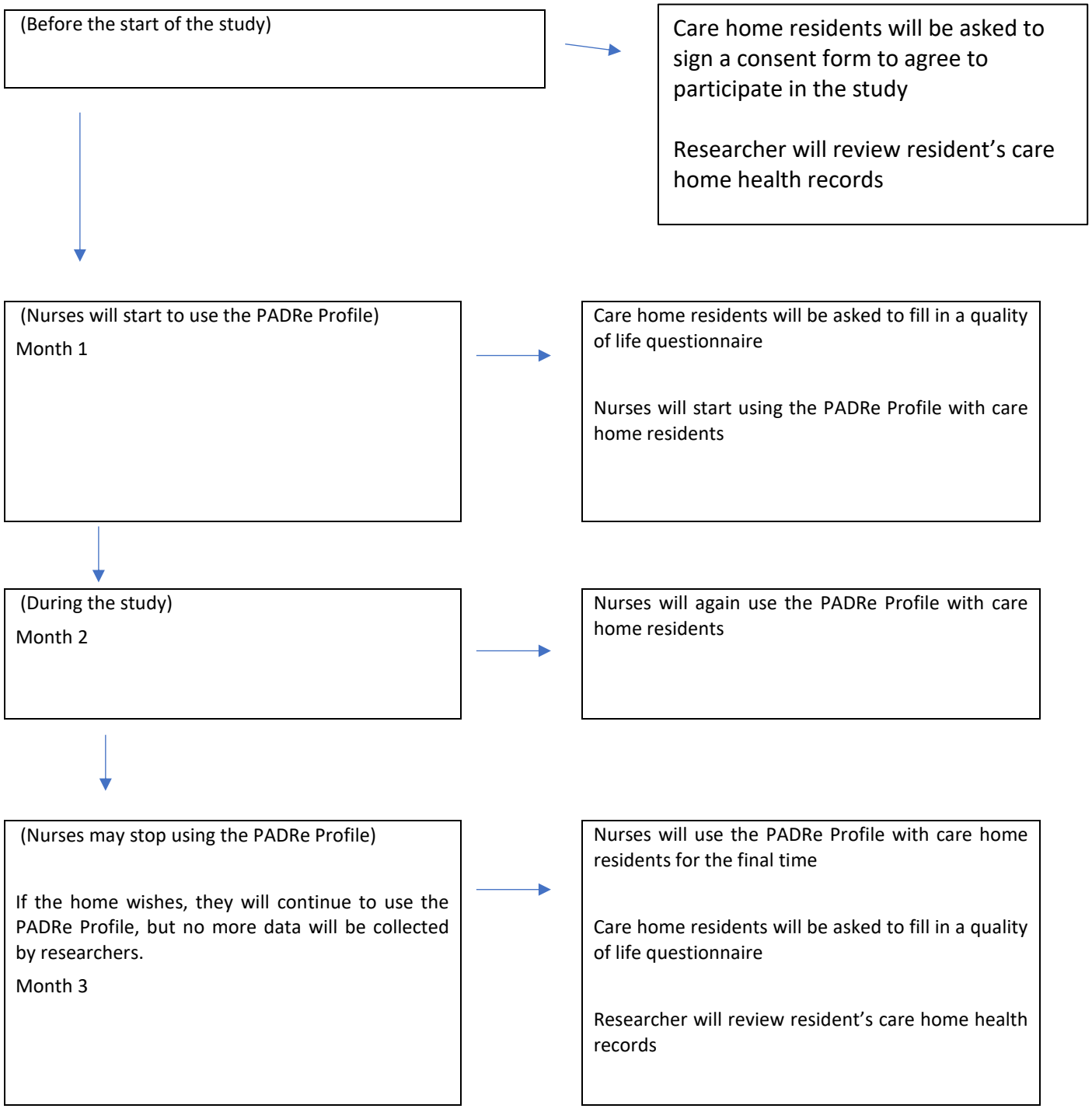
One of your nurses will then ask you to complete the PADRe Profile with them at least every month, for 3 months as part of normal care. To do this, they will take some observations and ask some questions. All observations and questions are those that are sometimes used as part of normal care, and are not invasive. This will take 10-20 minutes each time. The nurses will pass the checklist plus your medicines administration record (with all identifying details removed) to the prescribers and pharmacists caring for you.

After the 3 months, a researcher will review your care home health records again for evidence of use of the new checklist intervention, and any changes to your care or your health that may be related to this.

Finally, you may be invited to take part in an interview to discuss your experiences of taking part in this study. This will take approximately 10 to 20 minutes. We require one resident per care home to take part in this interview. If you would like to participate in the

interview, your name will be placed on the list of residents in your care home and a name will be randomly selected.

The following is a study flow diagram outlining your participation.



When the PADRe Profile instrument is no longer being studied

→

5.

You may be asked to take part in an interview with the researcher to discuss your experiences of participating in the study

Expenses and payments

There will be no payments to individual care home residents for taking part in the study, and no expenses are anticipated. However, the sum of £400 will be paid to each care home that participates. This is to help reimburse care homes for the time taken for the nurses to participate in the study.

6. What will I have to do?

You will need to sign a consent form before the study commences, answer questions in a quality of life questionnaire and complete the PADRe Profile with your nurse. This will take place at the care home in which you reside. As this study involves no more risk to you than a routine clinical examination, if you are not well enough to sign consent, your consultee (someone close to you who knows you well) will be asked to sign on your behalf.

7. What are the alternatives for diagnosis and treatment?

You will continue to receive the standard care of your care home.

8. What are the possible disadvantages and risks of taking part?

We do not anticipate any disadvantages to care home residents taking part in this study.

9. What are the possible benefits of taking part?

All patients in our previous studies have benefitted from our intervention. Interventions led by nurses to review medicines have previously demonstrated improved quality of care by identifying serious adverse drug reactions or side effects relating to prescribed medicines. The PADRe Profile improved quality of care by addressing physical health issues for all patients monitored and identifying and addressing serious adverse events in 10% of patients. We cannot promise the study will help you but the information we get from this study may help improve the treatment of care home residents who take 4 or more medicines.

10. What happens when the research study stops?

When the research study is finished, the researchers will analyse the data (the information) that they have collected from you. The results of the study will determine if the PADRe Profile is suitable to be used in other care homes. The matron and staff in your care home will decide if the intervention will continue to be used at your care home.

11. What if relevant new information becomes available?

We do not anticipate making any changes to the intervention during the course of this study. However, we shall revise our schedule if necessary.

12. What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time even though you have signed the consent form. If you wish, any data that can be attributed to you will not be used in the study.

13. What if there is a problem?

We do not anticipate there being a problem for you participating in this study. However, if you are concerned about any aspect of this study you should ask to speak to one of the researchers (contact details below) who will do their best to answer your questions.

The normal NHS complaints mechanisms will still be available to you.

14. Will my taking part in this study be kept confidential?

All information that is collected about you during the course of this study will be kept strictly confidential according to the Data Protection Act 1998. Information on paper will be kept in locked filing cabinets and behind security coded, locked doors. Electronic information will be kept on computers for the sole use of researchers that are protected by passwords.

The electronic data we store for this study will be kept on a database, but we will not keep any details of your name or address, the data will be stored only under your study number on a secure computer on university premises.

The results of the study will be made available to you and will be sent to your care home. Any information about you that leaves the home will be anonymous and anything that could identify you (name, date of birth, address, hospital number) will be removed and you will only be identified by a study code. When the study is reported to the funding body,

published in medical journals or presented at conferences it will not be possible to identify you personally.

Representatives from regulatory authorities may need to look at your medical records and the data collected in the study to check that the study was carried out correctly. All will have a duty of confidentiality to you.

15. Involvement of the General Practitioner

Your GP will be notified of your participation in this study.

16. What will happen to the results of the research study?

The results of this study will be written up in a report and they will be made available to you personally. The results will also be written up in a report and will also be published in a health- related journal but you will not be identified in any publication.

17. Who is organising and funding the research?

The study is being organized by Dr Andrew Carson Stevens who is a clinical academic working in general practice within Aneurin Bevan University Health Board, and Professor Sue Bale, Director of Research and Development, Aneurin Bevan University Health Board. The intervention has been developed by Professor Sue Jordan, Swansea University.

The study is being funded by the Health Foundation charity.

18. 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. The study was reviewed by the NHS Research Ethics Committee and the Research and Development Department.

19. Further information and contact details

For further information, you can speak to one of the study team:

Chief Investigator: Dr Andy Carson-Stevens: 5th Floor, Neuadd Meirionydd, Heath Park, Cardiff. CF14 4YX. Telephone number: 029 20688907. Email address: Prouth@cardiff.ac.uk.

Principal Investigator / instrument author: Professor Sue Jordan: s.e.jordan@swansea.ac.uk / 01792 518541

Research Fellow: Ms Hayley Prout: Cardiff University, 5th Floor, Neuadd Meirionydd, Heath Park, Cardiff. CF14 4YX. Telephone number: 029 20688907. Email address: Prouth@cardiff.ac.uk.

Alternatively, you can speak to an independent contact:

Thank you for considering taking part in this study.

If you decide to participate you will be asked to sign a consent form and will be given a copy of this information sheet and the consent form to keep.

Study title: The PADRe Study: (Polypharmacy Adverse Drug Reactions)

CONSENT FORM: Residents able to consent for themselves

Centre Number: Patient Identification Number:
Study Number: P0XXXX

Please initial box

1. I confirm that I have read and understood the information sheet dated XX (version XX) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that relevant sections of my care home health records, including my medicines administration records, and data collected during the study may be looked at by individuals from Aneurin Bevan University Health Board, Cardiff and Swansea Universities and from regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

4. I confirm that I have given permission for the completed medicines' monitoring PADRe Profile to be shared with the study pharmacist, together with a copy of my medication record. ☐

5. I agree to the use of anonymised data and quotes in any relevant publications. I agree to the use of a study number assigned to my details. ☐

6. I agree to my GP being informed of my participation in the study. ☐

7. I agree to take part in the above study. ☐

Name of Patient (PRINT) Date Signature

Name of witness to verbal consent (if needed) (PRINT)
Date Signature

Name of person taking consent (PRINT) Date Signature

Please tick box if you agree to a possible interview ☐

When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical / care home notes.

Study title:

Nurse-led intervention to minimise adverse drug reactions for older adults in care homes: a quality improvement process intervention

The PADRe Study: (Polypharmacy Adverse Drug Reactions)

Interview: CONSENT FORM FOR RESIDENT INTERVIEWS

Centre Number: Representative Id Number:
Study Number: P0XXXX to be allocated by REC

Please initial box

1. I confirm that I have read and understood the information sheet dated XX (version XX) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason. ☐

3.I am happy for the interview to be recorded and transcribed by the researchers, and the information used to inform development of medicines monitoring. ☐

4. I agree to the use of anonymised data and quotes in any relevant publications, and to the use of a study number assigned to my details. ☐

5. I agree to take part in the above study. ☐

Name of participant (PRINT) Date Signature

Name of person taking consent (PRINT) Date Signature

When completed: 1 for participant; 1 for researcher site file;

PARTICIPANT INFORMATION SHEET: Service User Representative/Consultee

Nurse-led intervention to minimise adverse drug reactions for older adults in care homes: a quality improvement process intervention

The PADRe Study (Polypharmacy Adverse Drug Reactions)

We should like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it will involve. ***One of our colleagues will go through the information sheet with you and answer any questions you have.*** Feel free to discuss it with others if you wish. Please ask if there is anything that is not clear or if you want more information. Please take your time to read the following information carefully and decide if you wish to participate.

1. What is the purpose of the study?

Polypharmacy is the name given to the use of multiple or inappropriate medicines. It has the potential to harm older adults through adverse drug reactions (ADRs), including cognitive impairment (such as memory and thinking skills), falls and subsequent hospitalisations. Interventions led by nurses to engage with patients, check and record problems have previously demonstrated improved quality of care by identifying serious adverse drug reactions or side effects relating to prescribed medicines.

Many people who live in care homes take multiple medications. This study aims to improve their safety by making it easier for nurses to identify any adverse side effects that they may be experiencing. To do this, we will develop an existing intervention to monitor and manage medicines in care homes with the aim of improving identification of possible adverse drug reactions. This intervention is in the form of a polypharmacy checklist Profile instrument that nurses can use and share with pharmacists and prescribers.

2. Why have I been invited?

You have been invited to take part in our study because you are thinking about being the consultee of a care home resident who currently takes 4 or more prescribed medicines daily. Twenty five other residents within this care home will also be invited to take part in this study. Residents from 6 other care homes within the area of Aneurin Bevan University Health Board will also be invited to take part in this study with a total number of 182 residents taking part.

3. Do I have to take part?

No. Your participation in this study is entirely voluntary and you are under no pressure to take part.

If you do decide to take part we shall ask you to sign a consultee declaration form on behalf of the resident, as consultee. If you or the resident later change your mind, you are free to withdraw from the study at any time without having to explain why.

If you do not wish to take part in this study, the standard of care that you or the care home resident (of which you are a representative) will receive will not be affected.

4. What will happen to me if I take part?

We should like the resident to take part in this observational study for the duration of up to 6 months. Before the start of the study, a nurse at the care home or the researcher will ask you to sign a consultee declaration form to say that you agree to the care home resident taking part in the study. This will take approximately 10 minutes.

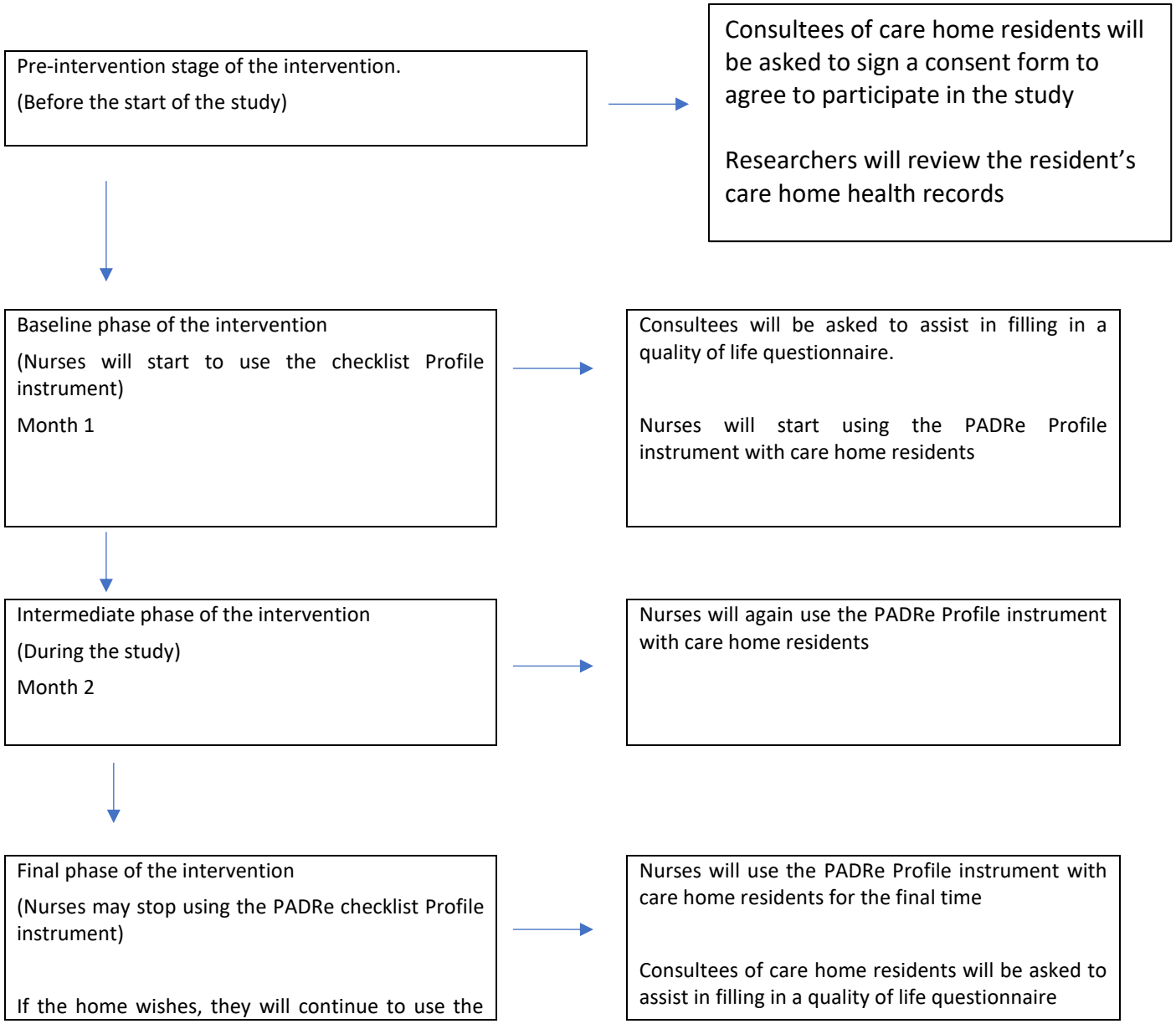
At the beginning of the study, a researcher or nurse will ask you to fill in a quality of life questionnaire on behalf of the resident. This consists of 5 'tick box' questions and will take you approximately 5 minutes. A researcher will also review the care home health records of the resident at this time.

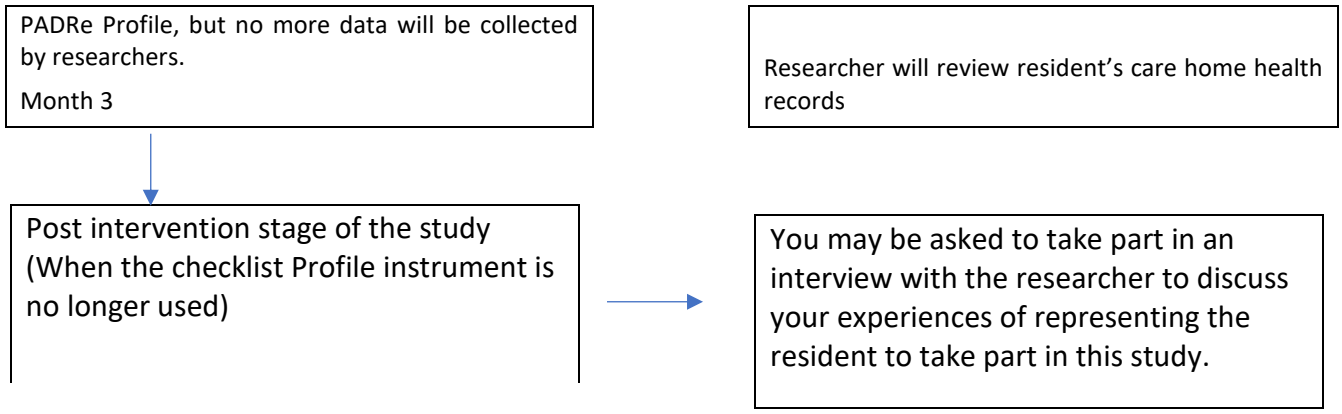
One of the nurses will then complete the PADRe Profile instrument with the resident at least every month for 3 months, as part of normal care. To do this, they will take observations and ask some questions. All observations and questions are those that are sometimes used as part of normal care, and are not invasive. This will take 10-20 minutes each time. The nurses will pass the PADRe Profile checklist plus the medicines administration record (with all identifying details removed) to the prescribers and pharmacists caring for the resident.

After the 3 months, a researcher will review the resident's care home health records again for evidence of use of the new checklist intervention, and any changes to care or health of the of the resident that may be related to this.

Finally, you may be invited to take part in an interview to discuss your experiences of being a consultee for the resident in taking part in this study. This will take approximately 10 to 20 minutes. We require one consultee per care home to take part in this interview. If you would like to participate in the interview, your name will be placed on the list of consultees in the care home and a name will be randomly selected.

The following is a study flow diagram outlining your participation.





5. Expenses and payments

There will be no payments to consultees of residents or to care home residents for taking part in the study, and no expenses are anticipated. However, the sum of £400 will be paid to each care home that participates. This is to help reimburse care homes for the time taken for the nurses to participate in the study.

6. What will I have to do?

As described in the flow chart above, you will need to sign a consent form before the study commences and, possibly, assist in answering questions on behalf of the resident in a quality of life questionnaire. This will take place at the care home.

7. What are the alternatives for diagnosis and treatment?

The care home resident will continue to receive the standard care of their care home.

8. What are the possible disadvantages and risks of taking part?

We do not anticipate any disadvantages to you acting as a consultee for a care home resident in this study or to the resident.

10. What are the possible benefits of taking part?

All patients in our previous studies have benefitted from our intervention. Interventions led by nurses to review medicines have previously demonstrated improved quality of care by identifying serious adverse drug reactions or side effects relating to prescribed medicines. The PADRe Profile intervention improved quality of care by addressing physical health issues for all patients monitored and identifying and addressing serious adverse events in 10% of patients. We cannot promise the study will help the resident but the information we get from this study may help improve the treatment of care home residents who take more than 4 medicines.

11. What happens when the research study stops?

Following the final phase of the intervention, the researchers will analyse the data (the information) that they have collected with you about the resident. The results of the study will determine if the PADRe Profile instrument is suitable to be used in other care homes. The matron and staff in the care home will decide if the intervention will continue to be used at the care home.

12. What if relevant new information becomes available?

We do not anticipate making any changes to the intervention during the course of this study. However, we shall revise our schedule if necessary.

13. What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time even though you have signed the consent form. If you wish, any data that can be attributed to you or the resident will not be used in the study.

14. What if there is a problem?

We do not anticipate there being a problem for you participating in this study. However, if you are concerned about any aspect of this study you should ask to speak to one of the researchers (contact details below) who will do their best to answer your questions.

The normal NHS complaints mechanisms will still be available to you.

15. Will my taking part in this study be kept confidential?

All information that is collected about the resident that you are representing during the course of this study will be kept strictly confidential according to the Data Protection Act 1998. Information on paper will be kept in locked filing cabinets and behind security coded, locked doors. Electronic information will be kept on computers for the sole use of researchers that are protected by passwords.

The electronic data we store for this study will be kept on a database, but we will not keep any details of you or the resident's name or address, the data will be stored only under your study number on a secure computer on university premises.

The results of the study will be made available to you and the resident and will be sent to the care home. Any information about you or the resident that leaves the home will be

anonymous and anything that could identify you or the resident (name, date of birth, address, hospital number) will be removed and you and the resident will only be identified by a study code. When the study is reported to the funding body, published in medical journals or presented at conferences it will not be possible to identify you or the resident personally.

Representatives from regulatory authorities may need to look at the resident's medical records and the data collected in the study to check that the study was carried out correctly. All will have a duty of confidentiality to them.

16. Involvement of the General Practitioner

The resident's GP will be notified of their and your participation in this study.

17. What will happen to the results of the research study?

The results of this study will be written up in a report and they will be made available to you and the resident personally. The results will also be written up in a report and will also be published in a health- related journal but you will not be identified in any publication.

19. Who is organising and funding the research?

The study is being organized by Dr Andy Carson Stevens who is a clinical academic working in general practice within Aneurin Bevan University Health Board, and Professor Sue Bale, Director of Research and Development, Aneurin Bevan University Health Board. The intervention has been developed by Professor Sue Jordan, Swansea University.

The study is being funded by the Health Foundation charity.

20. 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 participants' interests. The study was reviewed by the NHS Research Ethics Committee and the Research and Development Department.

21. Further information and contact details

For further information, you can speak to one of the study team:

Chief Investigator: Dr Andy Carson-Stevens: 5th Floor, Neuadd Meirionydd, Heath Park, Cardiff. CF14 4YX. Telephone number: 029 20688907. Email address: Prouth@cardiff.ac.uk.

Principal Investigator / instrument author: Professor Sue Jordan: s.e.jordan@swansea.ac.uk / 01792 518541

Research Fellow: Ms Hayley Prout: Cardiff University, 5th Floor, Neuadd Meirionydd, Heath Park, Cardiff. CF14 4YX. Telephone number: 029 20688907. Email address: Prouth@cardiff.ac.uk.

Thank you for considering taking part in this study.

If you decide to participate you will be asked to sign a consent form and will be given a copy of this information sheet and the consent form to keep.

Study title:

Nurse-led intervention to minimise adverse drug reactions for older adults in care homes: a quality improvement process intervention

The PADRe Study: (Polypharmacy Adverse Drug Reactions)

Consultee declaration form for research conducted under the Mental Capacity Act 2005

Centre Number: Study Number:

Participant Identification Number for this study:

Title of Project: PADRe:

Name of Researcher:

	Please initial box
I [name of consultee] have been consulted about [name of potential participant]'s participation in this research project. I have had the opportunity to ask questions about the study and understand what is involved.	☐
In my opinion he/she would have no objection to taking part in the above study.	☐
I understand that I can request he/she is withdrawn from the study at any time, without giving any reason and without his/her care or legal rights being affected.	☐
I understand that relevant sections of his/her care record and data collected during the study may be looked at by responsible individuals from Aneurin Bevan UHB and Caridff University, or from regulatory authorities, where it is relevant to their taking part in this research.	☐
I agree to their GP or other care professional being informed of their participation in the study.	☐

Name of Resident …….

Name of Consultee	Date	Signature

Consultee relationship to resident: ……

Researcher	Date	Signature

Please tick box if you agree to a possible interview ☐

When completed: 1 (original) to be kept in care record, 1 for consultee; 1 for researcher site file

PARTICIPANT INFORMATION SHEET: Health Care Professionals

Nurse-led intervention to minimise adverse drug reactions for older adults in care homes: a quality improvement process intervention

The PADRe Study (Polypharmacy Adverse Drug Reactions)

We should like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it will involve. ***One of our team will go through the information sheet with you and answer any questions you have.*** Feel free to discuss it with others if you wish. Ask us if there is anything that is not clear or if you want more information. Please take your time to read the following information carefully and decide if you wish to participate.

1. What is the purpose of the study?

Polypharmacy is the name given for the use of multiple or inappropriate medications. It has the potential to harm older adults through adverse drug reactions (ADRs) including cognitive impairment (such as memory and thinking skills), falls and subsequent hospitalisations. Interventions led by nurses to engage with patients, check and record problems have previously demonstrated improved quality of care by identifying serious adverse drug reactions or side effects relating to prescribed medicines.

Many people who live in care homes take multiple medications (that is, 4 or more). This study aims to improve their safety by making it easier for nurses to identify any side effects that they may be experiencing. To do this, we will develop an existing intervention to monitor and manage medicines in care homes with the aim of improving identification of possible adverse drug reactions. This intervention will be in the form of a polypharmacy checklist Profile (PADRe Profile) instrument that nurses can use and share with pharmacists and prescribers.

2. Why have I been invited?

You have been invited to take part in our study because your work is aligned to a care home which has agreed to take part in this study. You will either be a nurse (with or without NMC registration) working in a care home, or a community pharmacist or a GP. Seven care homes in total have been invited to take part in this study, all of which are located in the Aneurin Bevan University Health Board area. All care homes will have at least 26 residents residing with them.

3. Do I have to take part?

No. Your participation in this study is entirely voluntary and you are under no pressure to take part. If you do decide to take part we shall ask you to sign a consent form. If you later change your mind, you are free to withdraw from the study at any time without having to explain why.

4. What will I have to do if I take part?

We would like you to take part in this observational study for the duration of up to 6 months.

Section 1 (For Study Nurses)

Before the start of the study, you will be asked by the researcher to sign a consent form. You will then receive training in the use of the PADRe Profile. This will include comprehensive guidelines on using the PADRe Profile along with a video guide. This will take place at the care home and will take approximately half an hour. You will also decide whether to be either a lead nurse or the deputy nurse for the study duration.

Following this, you will be asked to undertake an introductory interview with the researcher who will discuss with you your views on medication monitoring and the potential of the PADRe Profile. It is important to note that your knowledge of medications and adverse drug reactions will not be tested but rather, your views on these as well as your views on the PADRe Profile to be used will be discussed. This interview will take place at the care home in which you work and will last approximately 30 minutes.

At the start of the study, you will fill in a quality of life questionnaire with the residents who are taking part in the study. This consists of 5 'tick box' questions and will take approximately 5 minutes. During this time, the researcher will review the care home health records of the residents who have consented to participate in the study.

You will then need to complete the PADRe Profile with each of the residents (up to 26) at least every month, for 3 months as part of normal care. To do this, you will take some observations and ask some questions. All observations and questions are those that are sometimes used as part of normal care and are not invasive. The PADRe Profile checklist will help to determine clinical signs and symptoms of adverse drug reactions. At this time, you will also be asked to complete a record/log/diary of using the PADRe profile to record how the Profile works during usual care. Both use of the PADRe Profile and recording how it works will take approximately 10 to 25 minutes per resident. We ask nurses that they try to carry out Profile completion with residents and using existing documentation at least every month or more frequently if medicines are changed. You will then pass the checklist to the prescribers and pharmacists caring for the residents, along with the medication administration records.

During the time that the PADRe Profile instrument is being used, nurses will be asked to take part in a 'debriefing' interview to discuss their experiences concerning its use. This will take approximately 45 minutes.

After the 3 months, the research intervention will be completed. You may decide to continue using the PADRe Profile instrument. You will need to fill in a quality of life questionnaire for the second time with the residents who are taking part in the study. A researcher will also review the care home health records of the residents once again for evidence of use of the new checklist intervention and any changes in care or outcomes of care.

Finally, you will be invited to undertake the final interview with the research where you will be asked to discuss experiences of implementing the PADRe Profile instrument following its use at the care home. This will take some 30 minutes.

Section 2 (For Study Pharmacists)

You will receive training in the use of the PADRe Profile. This will include comprehensive guidelines on using the Profile along with a video guide. This will take place with the Consultant Pharmacist at a location convenient to yourself and will take approximately half an hour.

During the Profile intervention study period, a nurse will be using the PADRe Profile with care home residents every month, for 3 months as part of their normal care. To do this, they will take some observations and ask some questions.

You will be asked to analyse the PADRe Profiles and medicines administration records from the 27 residents in the care homes that you are aligned to. These documents will have been developed by the study nurses using the checklist Profile instrument.

At the end of 3 months, the nurses will stop using the PADRe Profile for research, but may continue as part of normal care. You will then be invited to take part in an interview where you will be asked to discuss your experiences of participating in a study where the PADRe Profile is being used. This interview will take approximately 30 minutes.

Section 3 (For Study GPs)

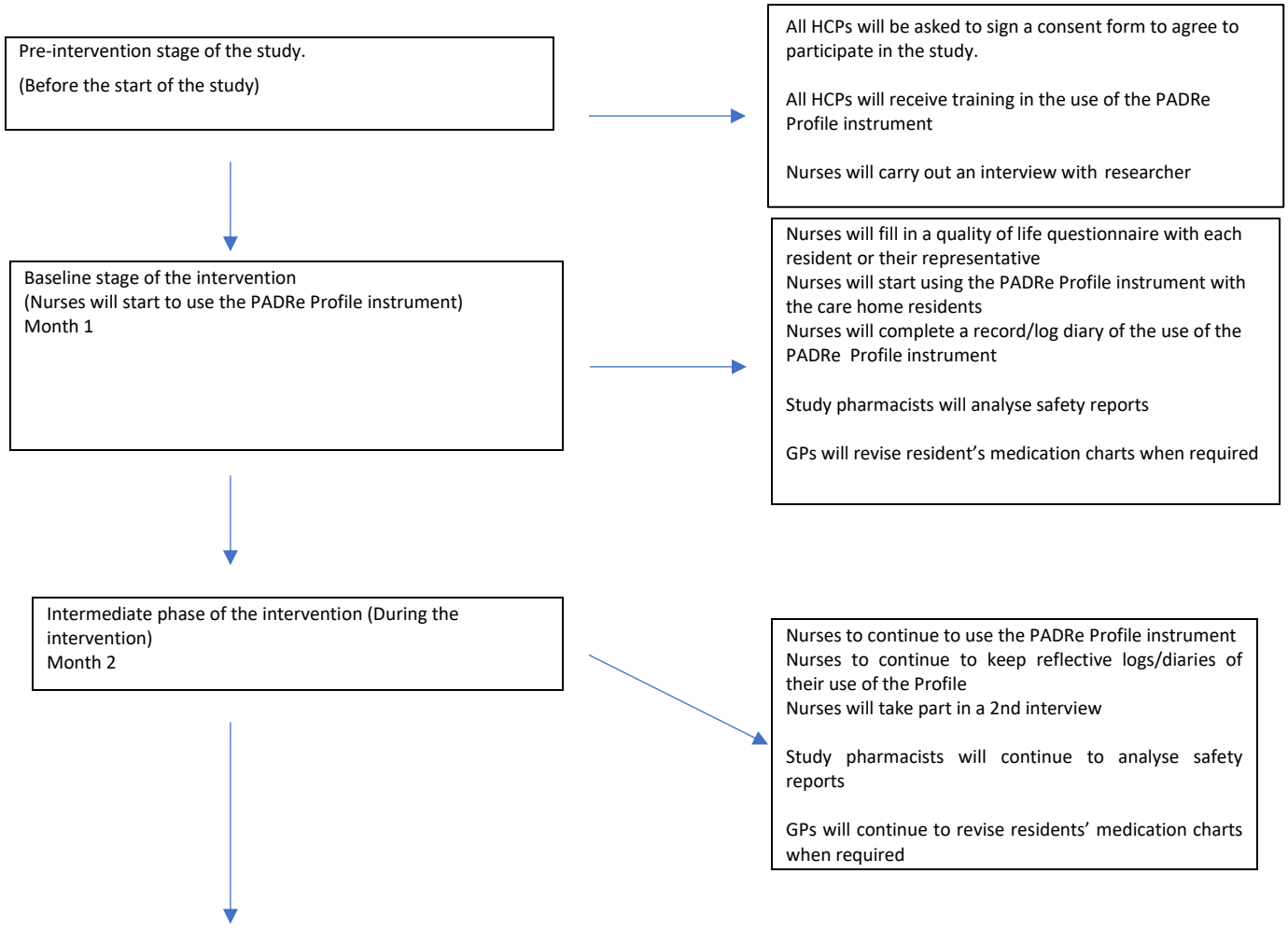
Study GPs will be offered training in the use of the PADRe Profile. This will include comprehensive guidelines on using the PADRe Profile along with a video guide. This will take place with the Study Researcher at a location convenient to yourself and will take approximately half an hour.

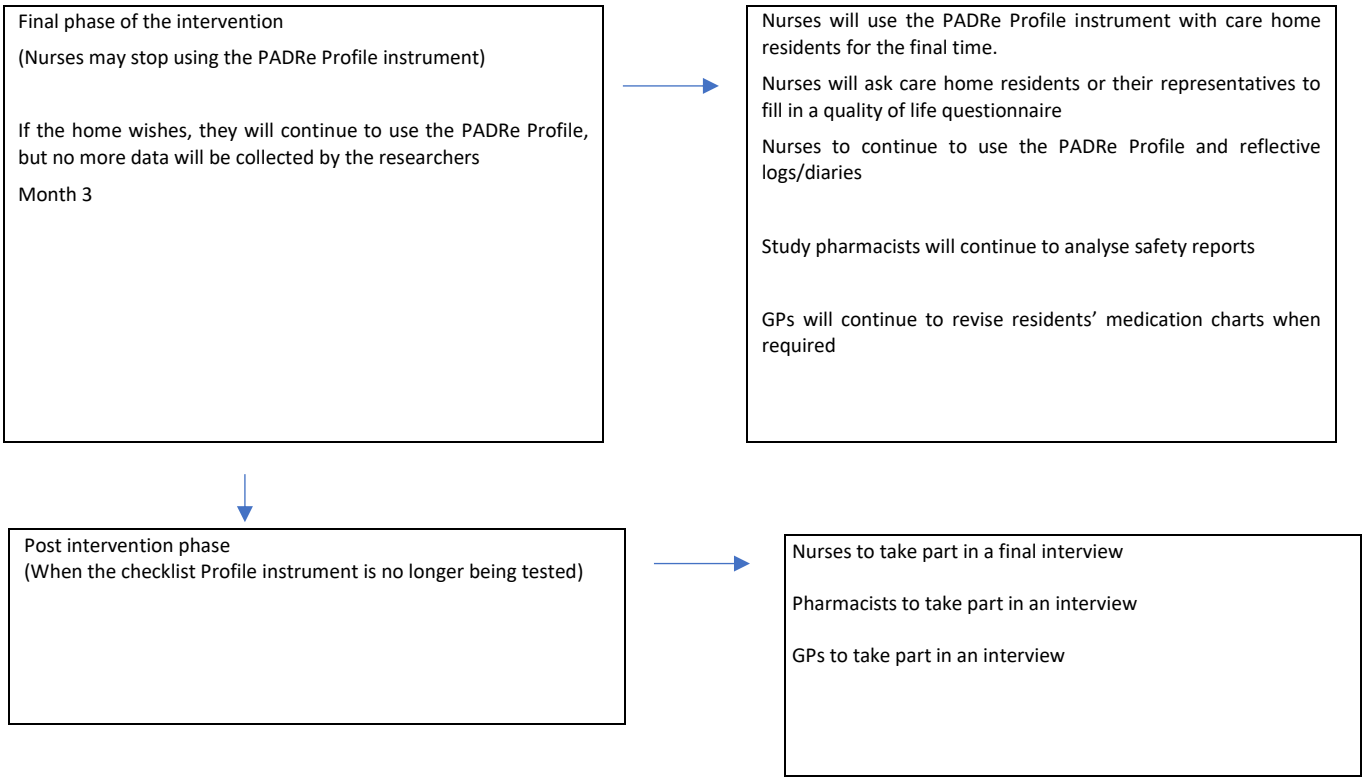
During the PADRe Profile intervention study period, a nurse will be using the PADRe Profile with care home residents every month, for 3 months as part of their normal care. To do this, they will take some observations and ask some questions. The nurses will pass the checklists and medicines administration records to you and the study pharmacists who are also caring for the residents.

These documents will have been developed by the study nurses using the PADRe Profile instrument. You may be asked by the care home study nurses to review residents' medication sheets based on safety reports that have been developed following the use of the PADRe Profile.

At the end of 3 months, the nurses will stop using the PADRe Profile for research, but may continue as part of normal care. You will then be invited to take part in an interview where you will be asked to discuss your experiences of participating in a study where the PADRe Profile instrument is being used. This interview will take approximately 30 minutes.

A flowchart of health care professional (HCP) participation in the study is shown below.





5. Expenses and payments

There will be no payments paid to individual health care professionals or care home residents for taking part in the study and no expenses are anticipated. However, the sum of £400 will be paid to each care home that participates. This is to help reimburse care homes for the time taken for the nurses to participate in the study.

6. What are the alternatives for diagnosis and treatment?

Care home residents will continue to receive the standard care of their care home.

7. What are the possible disadvantages and risks of taking part?

We do not anticipate any disadvantages of HCPs or home residents taking part in this study.

8. What are the possible benefits of taking part?

All patients in our previous studies have benefited from our intervention. Interventions led by nurses to review medicines have previously demonstrated improved quality of care by identifying serious adverse drug reactions or side effects relating to prescribed medicines. The PADRe Profile intervention improved quality of care by addressing physical health issues for all patients monitored and identifying and addressing serious adverse events in 10% of patients. We cannot promise the study will help residents but the information we get from this study may help improve the treatment of care home residents who take more than 4 medications.

Benefits to health professionals may include participating in this study as evidence of continuing professional development.

9. What happens when the research study stops?

Following the final phase of the intervention, the researchers will analyse the data (the information) that they have collected. The results of the study will determine if the polypharmacy intervention is suitable to be used in other care homes. The matron and staff in the care homes will decide if the intervention will continue to be used.

10. What if relevant new information becomes available?

We do not anticipate making any changes to the intervention during the course of this study. However, we shall revise our schedule if necessary.

11. What will happen if I don't want to carry on with the study?

Health care professionals and care home residents can withdraw from the study at any time even though they have signed the consent form. If you wish, any data that can be attributed to you will not be used in the study.

12. What if there is a problem?

We do not anticipate there being a problem for you participating in this study. However, if you are concerned about any aspect of this study you should ask to speak to one of the researchers (contact details below) who will do their best to answer your questions.
The normal NHS complaints mechanisms will still be available to you.

13. Will my taking part in this study be kept confidential?

All information that is collected about you during the course of this study will be kept strictly confidential according to the Data Protection Act 1998. Information on paper will be kept in locked filing cabinets and where possible behind security coded, locked doors. Electronic information will be kept on computers that are protected by passwords.

The electronic data we store for this study will be kept on a database, but we will not keep any details of your name or address, the data will be stored only under your hospital number on a secure computer on university premises.

The results of the study will be made available to you and will be sent to the care homes and individual residents who took part in the study. Any information about you that leaves the hospital will be anonymous and anything that could identify you will be removed and you will only be identified by a study code. When the study is reported to the funding body, published in medical journals or presented at conferences it will not be possible to identify you personally.

Representatives from regulatory authorities may need to look at residents' medical records and the data collected in the study to check that the study was carried out correctly. All will have a duty of confidentiality to you.

14. What will happen to the results of the research study?

The results of this study will be written up in a report and they will be made available to you personally. The results will also be written up in a report and will also be published in a health- related journal but you will not be identified in any publication.

15. Who is organising and funding the research?

The study is being organized by Dr Andy Carson Stevens who is a clinical academic working in general practice within Aneurin Bevan University Health Board, and Professor Sue Bale, Director of Research and Development. The intervention has been developed by Professor Sue Jordan, Swansea University.

The study is being funded by the Health Foundation charity.

16. Who has reviewed the study?

All research in the NHS is looked at by independent group of people, the Research Ethics Committee, to protect your interests. The study was reviewed by the NHS Research Ethics Committee and the Research and Development Department.

17. Further information and contact details

For further information, you can speak to one of the study team:

For further information, you can speak to one of the study team:

Chief Investigator: Dr Andy Carson-Stevens: 5th Floor, Neuadd Meirionydd, Heath Park, Cardiff. CF14 4YX. Telephone number: 029 20688907. Email address: Prouth@cardiff.ac.uk.

Principal Investigator / instrument author: Professor Sue Jordan: s.e.jordan@swansea.ac.uk / 01792518541

Research Fellow: Ms Hayley Prout: Cardiff University, 5th Floor, Neuadd Meirionydd, Heath Park, Cardiff. CF14 4YX. Telephone number: 029 20688907. Email address: Prouth@cardiff.ac.uk.

Thank you for considering taking part in this study.

If you decide to participate you will be asked to sign a consent form and will be given a copy of this information sheet and the consent form to keep.

Study title: The PADRe Study: (Polypharmacy Adverse Drug Reactions)

CONSENT FORM

Centre Number: HCP Participant Identification Number:
Study Number: P0XXXX

Please initial box

1. I confirm that I have read and understood the information sheet dated XX (version XX) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason or my legal rights being affected. ☐

3. I understand that input into this study will be used as data collection from the study and may be looked at by individuals from Aneurin Bevan University Health Board, Cardiff and Swansea Universities, and regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to this data. ☐

4. I agree to the use of anonymised data and quotes in any relevant publications. ☐

5. I agree to take part in the above study. ☐

Name of Participant (PRINT) Date Signature

Name of person taking consent (PRINT) Date Signature

Please tick box if you agree to a possible interview ☐

When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.

Study title:

Nurse-led intervention to minimise adverse drug reactions for older adults in care homes: a quality improvement process intervention

The PADRe Study: (Polypharmacy Adverse Drug Reactions)

Interview: CONSENT FORM

Centre Number: Representative Id Number:
Study Number: P0XXXX to be allocated by REC

Please initial box

1. I confirm that I have read and understood the information sheet dated XX (version XX) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason. ☐

3.I am happy for the interview to be recorded and transcribed by the researchers, and the information used to inform development of medicines monitoring. ☐

4. I agree to the use of anonymised data and quotes in any relevant publications, and to the use of a study number assigned to my details. ☐

5. I agree to take part in the above study. ☐

Name of participant (PRINT) Date Signature

Name of person taking consent (PRINT) Date Signature
When completed: 1 for participant; 1 for researcher site file

Process questions (review notes) to track use of PADRe.

We shall retrieve information for each PADRe Profile item (attached).

Q1.	How often are PADRe Profiles completed? N in ___ weeks
Q2.	Where stored? Notes / research file / other
Q3.	Note items omitted. LIST
Q4.	Other discrepancies y/n LIST
Q5.	Note which items copied from notes, if possible. LIST
Q6.	Guidelines used y/n
Q7.	Any equipment missing for vital signs? y/n
Q8.	If so, which
Q9.	Profiles juxtaposed with MAR charts? y/n
Q10.	Problems marked LIST n
Q11.	ACTIONS marked LIST n
Q12.	Professionals contacted LIST n
Q13.	Care plan changes LIST n
Q14.	Actions completed LIST n
Q15.	Evidence of pharmacist / prescriber review? y/n
Q16.	Changes in MAR charts LIST n
Q17.	Clinical changes LIST n
Q18.	Any other instruments used to record ADRs? y/n NAME