FULL TITLE OF THE STUDY

Optimising Structured Medication Reviews for Older People with Severe Frailty and Care Home Residents to Reduce Overprescribing and Associated Inequalities

SHORT STUDY TITLE / ACRONYM

Inequalities in SMRs for older people

PROTOCOL VERSION NUMBER AND DATE

Version 1.0 July 2024

STUDY IDENITFIERS

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STUDY SUMMARY

Study Title	Optimising Structured Medication Reviews for Older People with Severe Frailty and Care Home Residents to Reduce Overprescribing and Associated Inequalities
Internal ref. no. (or short title)	
Study Design	Mixed methods study involving co-production of resources for optimising Structured Medication Reviews (SMRs) for older people with frailty and care home residents. It will involve 3 work packages (WP), including quantitative analysis of data from Clinical Practice Research Datalink (CPRD) and Connected Bradford; qualitative observations and interviews with older people, their families and heath care professionals and co-production activities to iteratively develop and pilot a targeted training package for pharmacists and detailed guidance for commissioners.
Study Participants	• Older adults with severe frailty, care home residents and their families. • Health care professionals involved in the implementation and delivery of structured medication reviews.
Planned Size of Sample (if applicable)	<u>WP2 Sample:</u> <u>Working across 4 PCNs</u> • 32-40 older adults with severe frailty, care home residents and family members (8-10 from each of the 4 participating PCNs) • 32-48 healthcare professionals (8-12 from each of the 4 participating PCNs) <u>WP3 Sample:</u> • Up to 40 older adults and family members/ carers (workshops 1 and 2) • Up to 48 health and social care professionals (workshops 1 and 2) • 6-10 older adults, family members/ carers and health care professionals (co-production group) • 10 Pharmacists (pilot work)
Follow up duration (if applicable)	Not applicable
Planned Study Period	1st January 2024- 31st December 2026
Research Question/Aim(s)	Improve quality and accessibility of Structured Medication Reviews (SMRs) to reduce overprescribing for older people with severe frailty living in the community and care home residents, informed by intersectional characteristics and experiences.

KEY ROLES

Study Funder: NIHR Health and Social Care Delivery Research Programme

Our research was developed in line with the specification outlined in the HSDR Health Inequalities in Overprescribing call for further research to understand the links between overprescribing and deprivation, ethnicity, age and inequalities and the impact these have on the health of the population. This funding source had no other role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decisions relating to dissemination of results. The funder will however monitor progress of the study through annual study progress reports.

Study Sponsor: Bradford Teaching Hospitals NHS Foundation Trust (BTHFT)

BTHFT had no role in the design of the study but will ensure accountability for study conduct and procedures associated with the protocol. All records and documents regarding the conduct of the study will be managed and maintained in accordance with BTHFT information governance guidelines. BTHFT will also oversee the arrangements to initiate, manage, monitor and finance the study.

Project Management Group

The Project Management Group (PMG) will include the co-investigators and will be chaired by Andy Clegg, the Chief Investigator (CI). The PMG will meet on a 3-monthly basis across the duration of the study to oversee its implementation and management. Project monitoring and all mandatory reporting will be undertaken by the CI with support from the project Senior Research Fellow and wider research team.

Project Steering Group

We will establish a Project Steering Committee (PSG), chaired by Wasim Baqir (NHSE care homes medicines optimisation scheme lead) to oversee delivery of the project. We will work with Wasim to build our PSG membership strategically, focusing on involving key opinion leaders and representatives of our target audiences. This will help ensure that all our plans are aligned with contemporary policy and practice across the duration of the project, and help generate pull of our research findings into practice to maximise impact. We will aim to include strong representation from lay members across our diverse communities within the PSG.

Patient and Public Involvement Group

Our PPI co-applicant Manoj Mistry will work closely with our PPI lead Aseel Abuzour to ensure that the patient voice is heard throughout the research. In addition to strong PPI representation on our PMG and PSG, we will continue to work in full partnership with our diverse HDRUK PPI Medicines Optimisation Group, meeting regularly to ensure that all our plans are informed by older people and their families/carers who have lived experience of the challenges relating to overprescribing. Please see section 8.4 for further details about PPI in different aspects of the study.

STUDY FLOW CHART

WP1: Quantitative analysis of inequities in delivery and inequalities in outcomes of SMRs.

Outputs:

•Detailed quantitative information to inform sampling for planned qualitative work.

•Robust evidence on the scale of the problem and inequalities in delivery and outcomes of SMRs based on key intersectional characteristics to inform practice, commissioning and policy.

Connected Bradford

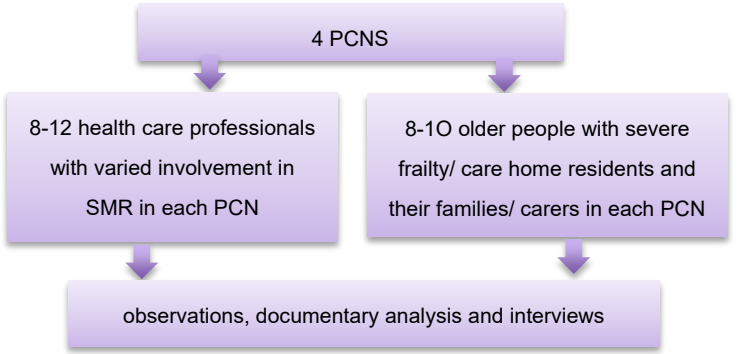
CPRD

WP2: Qualitative examination of implementation of SMRs and impact on equity of provision.

Outputs:

•Identification of structural and process factors, including the translation of training into practice, that shape access to and engagement with SMRs for a diverse group of older people with severe frailty and care home residents.

•Materials for use in coproduction work, based on a detailed examination of SMRs for older people with severe frailty and care home residents, taking into account intersectionality.

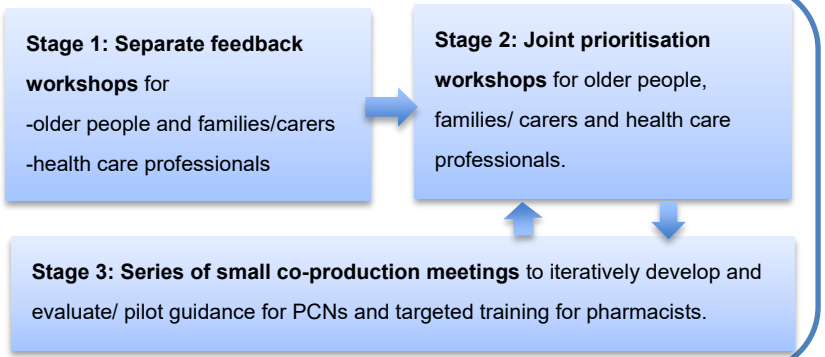


WP3: Using co-production methods to translate findings into actionable solutions.

Outputs:

•Targeted training on how best to operationalise and engage diverse older people with severe frailty and care home residents in SMRs.

•Detailed guidance for PCNs on how to maximise patient engagement across intersectional groups and reduce inequity in SMR provision, including an operating model of SMRs that can be tailored to local context and a toolkit to support change.



KEY WORDS: Older adults, Primary care, Polypharmacy, Ethnic minority, Socioeconomic deprivation, intersectionality

STUDY PROTOCOL

Optimising Structured Medication Reviews for Older People with Severe Frailty and Care Home Residents to Reduce Overprescribing and Associated Inequalities

1 BACKGROUND

Medicines provide considerable benefit for many patients, but overprescribing of medicines that people do not need or want, or where harms outweigh potential benefits, is estimated to account for at least 10% of all medicines prescribed in the NHS (1). The 2022 cost of community prescriptions in England was £9.69 billion, a rise of 8.4% (£746 million) from 2014/15 (2). It is estimated that 8% of all patients experience an adverse drug reaction (ADR), and ADRs account for 16.5% of all hospital admissions, with an estimated cost of £2.1 billion (3). The 2021 Overprescribing Review identifies that the overprescribing burden weighs heavily on older people, with 1/3 of people aged >80 taking more than eight medications (1). They are especially at high risk from overprescribing, with ADRs including falls, cognitive decline and loss of independence (4, 5), with related impact on the health and social care system. The impact of overprescribing on family members and carers who may be involved in organising and administering medications can also be considerable, yet is frequently overlooked.

Risk of harm from overprescribing increases with advancing frailty – a condition that is characterised by loss of biological reserves and failure of physiological mechanisms, with resulting impact on ability to respond to stressors, for example new medications (6, 7). Frailty is common, affecting around 10% of people aged 65 years and over, rising to around half of people aged 90 years and over (8, 9). The prevalence of frailty varies according to socioeconomic position and is increased in most ethnic minority groups, with three-fold increased risk in Bangladeshi and Pakistani versus White populations in the UK (10, 11). Care home residents are a societal group who are likely to be living with severe frailty and related risk of dependence in activities of daily living. Existing evidence indicates that older people with frailty living in the community, including care home residents, are at particularly high risk of overprescribing and experiencing harm through adverse effects of medications (12).

Most older people with frailty have multiple long-term conditions (multimorbidity) (13), so the physiological changes that accompany development of frailty are therefore exacerbated by a tendency for multiple medications to be prescribed (polypharmacy). Multiple medications can accumulate over many years without regard for ongoing benefit in the context of advancing frailty, or new harmful side effects. Consequently, dose adjustments that may be needed, or cessation of medications, may not happen. This can increase risk of ADRs from individual and multiple drug-drug and drug-disease interactions (12, 14), for example the cumulative effects of medications with anticholinergic (AC) effect, which are associated with mental and physical decline in older age (4, 5). Around 20% of older people are prescribed at least one medication with AC effects, with AC burden being greatest in people with severe frailty (15).

There is evidence of potential inequalities in overprescribing, with older people from most ethnic minority groups or with greater socioeconomic deprivation being more exposed to polypharmacy (16). However, the existing data on polypharmacy amongst people of different ethnicity and socioeconomic position has not taken account of how different characteristics of advancing age, frailty, ethnicity and socioeconomic position intersect with each other.

SMRs were introduced by the NHS in England in 2021 to target overprescribing as a contractual requirement for PCNs (17). Delivered through shared decision making and with a focus on deprescribing, SMRs are a comprehensive clinical review of a patient's medicines, supported in National Institute for Health and Care Excellence (NICE) guidance (18). The PCN contract specifies older people living with severe frailty (identified using the electronic frailty index (eFI) developed and implemented nationally by lead applicant Clegg (19)) and care home residents as two of the five populations who should be proactively targeted for SMRs. However, there is an evidence gap in current policy and practice regarding potential inequities in delivery and inequality in outcomes of SMRs for community-dwelling older people with severe frailty and care home residents, taking into account intersectional characteristics such as age, gender, ethnicity, and socioeconomic position. A 2022 review led by co-applicant Zaman identified only nine studies investigating medication management for older people from minority ethnic groups (20). All studies focused on single long-term conditions such as diabetes or hypertension - none considered intersectionality, people with frailty or care home residents.

SMRs are expected to be delivered by PCN pharmacists, but there is a broad range of experience and skills across this group. Some have limited experience of SMRs for older people with frailty in the community and care home residents, and receive limited training in this area. Frailty commonly co-exists with dementia, particularly in care home residents, but training is also lacking relating to how to approach this especially complex situation. The Primary Care Pharmacy Education Pathway (PCPEP) has been developed for pharmacists conducting SMRs (21) but includes very limited training on varying intersectional needs. Additionally, in practice, many SMRs are done by general practitioners (GPs) in parallel with long-term condition reviews and there are also recognised knowledge gaps relating to GP deprescribing in older people with frailty (22).

Our extensive work with policymakers, Integrated Care System (ICS) Overprescribing Leads, practitioners, patients and carers has identified key knowledge gaps relating to SMRs for the specified target groups of older people with severe frailty and care home residents, generating risk of inequalities. These include concerns about limited engagement with SMRs across ethnic and socioeconomic groups and how the family/carer perspectives are considered in SMRs. Potential gaps in training in inequalities and translation of knowledge relating to older people with severe frailty and care home residents were identified, whereby a tendency to not deprescribe if risks/adverse effects from medicines are not obvious, as often occurs in frailty, were highlighted. There were also concerns about the lack of necessary time allocated for ongoing follow-up to support deprescribing and that National targets for SMRs are potentially driving completion of less complex SMRs, with related inequalities for older people with severe frailty and care home residents.

2 RATIONALE

This study aligns with the specification for the HSDR Health Inequalities in Overprescribing call, for further research to understand the links between overprescribing and deprivation, ethnicity, age and inequalities and the impact these have on the health of the population. Incorporating quantitative and

qualitative methods our study will investigate inequity in delivery and inequality in outcomes of SMRs for community-dwelling[1] older people with severe frailty and care home residents.

Our study will address knowledge gaps, detailed in the earlier section, necessary for optimising quality and accessibility of SMRs for community-dwelling older people with severe frailty and care home residents across intersectional groups[2], taking account of age, ethnicity, gender and level of deprivation. Addressing overprescribing of medicines for this population has considerable potential to improve patient outcomes and generate NHS cost savings. Additional benefits include reduction in time spent on medicines activities by older people with severe frailty, informal carers, home care staff, and the estimated 50% of care home staff time spent on medicines management and administration (23). Fewer medicines means reduced risk of medication errors across all settings. Importantly, lower medication burden is associated with improved adherence (24, 25), increasing potential clinical benefits from necessary medicines and reduction in medicines waste.

The study design has been guided by our HDRUK North PPI Medicines Optimisation Group, comprising older people with lived experience of overprescribing as well as family members and carers of people living with frailty and dementia across multiple ethnicities. They emphasised the importance of developing better methods to engage older people with frailty and care home residents from different socioeconomic backgrounds and ethnicities in the SMR process, and an absence of ongoing support and follow-up after the SMR visit. These concerns have directly informed the design of our work packages and our key planned outputs.

3 THEORETICAL FRAMEWORK

We focus on intersectionality as a key theoretical framework – the recognition that social identities such as frailty, gender, ethnicity and socioeconomic position should be considered in combination, as certain intersectional subgroups may be more likely to experience inequities and health inequalities (26). A focus on the systems and processes of discrimination that underpin health inequalities means that intersectionality can be viewed as a useful theoretical framework for developing health policy that is more equitable (27). This is of particular relevance in relation to investigating the quality and accessibility of SMRs because there is considerable potential for inequity in delivery and inequality in outcomes of SMRs based on intersectional characteristics.

[1] We use the terms ‘community-dwelling older people with severe frailty’ and ‘care home residents’ in our research plan to indicate the two target groups of interest, aligned with the PCN SMR contract, recognising that care home residents are themselves part of the wider community.

[2] Intersectionality is a concept for understanding how aspects of a person’s identities (e.g. age, gender, ethnicity, socioeconomic position, frailty) combine to create different and multiple discrimination and privilege. Inequity refers to unfair, avoidable differences arising from poor governance or cultural exclusion (1). In the context of SMRs we use inequity to refer to the intersectional differences in SMR delivery that may result from the way SMR processes have been designed or are being implemented.

4 RESEARCH QUESTION/AIM(S)

Aim: To improve quality and accessibility of SMRs to reduce overprescribing for older people with severe frailty living in the community and care home residents, informed by intersectional characteristics and experiences.

Research questions (RQ):
1. Is there evidence for inequity in delivery and inequality in outcomes of SMRs for community-dwelling older people with severe frailty and care home residents as our target groups, taking into account intersectional characteristics and geographical location?
2. Does exposure to high-risk medications and related health and social care outcomes for our target groups vary according to intersectional characteristics?
3. How are SMRs for our target groups being implemented and delivered in practice, and what are the implications for access to and engagement with SMRs taking into account intersectionality?
4. Does experience of SMRs vary according to intersectional characteristics and geographical location?
5. What actionable solutions can be applied at key points to optimise implementation and delivery of SMRs for our target groups, fostering equity in access to and engagement with SMRs?

4.1 Objectives

- To use routinely available, linked health and care datasets that include ethnically diverse populations in areas of high socioeconomic deprivation to:
    - Analyse how SMRs for community-dwelling older people with severe frailty and care home residents are being delivered in NHS care, taking account of intersectional characteristics.
    - Investigate how exposure to high-risk medications (e.g. anticholinergic medications) and related health and social care outcomes are influenced by intersectional characteristics using routinely available, linked data?

- Using a qualitative observations and semi-structure interviews to:
    - Understand how the structures and processes employed to implement and deliver SMRs, including translation of pharmacist training into practice, shapes access and engagement for diverse groups of older people with severe frailty regardless of living accommodation.
    - Understand the intersectional experiences of SMRs from the perspectives of older people with severe frailty and care home residents, their families and informal carers, across different geographical locations.

- To work with older people, families, carers, health and social care professionals, commissioners, and policymakers to co-design resources to improve the quality and accessibility of SMRs for diverse groups of older people with severe frailty and care home residents, tailored to different settings, building on generated knowledge.

4.2 Outcomes

- Detailed quantitative information to inform sampling for planned qualitative work.
- Robust evidence on the scale of the problem and inequalities in delivery and outcomes of SMRs based on key intersectional characteristics to inform practice, commissioning and policy.
- Identification of structural and process factors, including the translation of training into practice, that shape access to and engagement with SMRs for a diverse group of older people with severe frailty and care home residents, highlighting existing strengths that support inclusion as well as factors that shape inequity.
- Materials for use in coproduction work (story boards, process maps, case summaries), based on a detailed examination of SMRs for older people with severe frailty and care home residents, taking into account intersectionality.
- Targeted training on how best to operationalise and engage diverse older people with severe frailty and care home residents in SMRs.
- Detailed guidance for PCNs on how to maximise patient engagement across intersectional groups and reduce inequity in SMR provision, including an operating model of SMRs that can be tailored to local context and a toolkit to support change.
- Detailed policy report for NHS England, summarising how the SMR framework should be refined to better account for the needs of older people with frailty and care home residents across key intersectional groups to reduce inequalities.

5 STUDY DESIGN

Our study design incorporates quantitative and qualitative methods, to investigate inequality in delivery and outcomes of SMRs for community-dwelling older people with severe frailty and care home residents, taking into account intersectionality as a key theoretical framework.

We plan three integrated work packages (WP):

- Using quantitative methods WP1 will involve analysis of routinely available health and care datasets to identify intersectional subgroups that are more likely to experience inequity and inequality relating to SMRs, including exposure to high-risk medications (RQ1 and RQ2). Ethical approval is already granted for CPRD/ Connected Bradford studies as part of the respective data applications.
- WP2 will build on the findings of WP1, using case study methods to sample people from intersectional subgroups identified in WP1 across four purposely sampled PCNs. Process Tracing techniques will be used to map structural and process elements in SMR implementation and delivery to understand how structural factors and processes shape access to and engagement with SMRs for diverse groups of older people with severe frailty and care home resident (RQ3 and RQ4).
- Building on co-production methods WP3 will integrate findings from WP1 and WP2 to develop and pilot a targeted training package for pharmacists and produce detailed guidance for PCNs and ICS Overprescribing Leads so that services can be designed or adapted to better meet the needs of intersectional subgroups of older people with frailty (RQ5).

Ethical approval will be sought for the recruitment of participants and conduct of research in WP2 and WP3.

5a. Data Collection Methods

WP1: Quantitative analysis of inequities in delivery and inequalities in outcomes of SMRs

Data from Clinical Practice Research Datalink (CPRD) Aurum and Gold, and Connected Bradford will be analysed to investigate inequities and inequalities in delivery and outcomes of SMRs for our target groups. CPRD is a database of de-identified coded primary care and linked records from UK patients. CPRD Gold will be used in addition to Aurum to provide a matched control group, where the SMR PCN contract was not rolled out. Connected Bradford has been selected as an additional data source to facilitate separate analyses of drug dose and home care packages, which would not be possible using CPRD. Connected Bradford includes prescription start and end dates, enabling estimation of daily drug dose for 98% of prescriptions, with cross-verification possible using the free-text prescription signateur. Connected Bradford links to social care data enabling identification of home care packages.

Following predictor variables, will be selected:

- Age (years)
- Gender (male, female).
- Ethnicity - ONS census Groups (Subgroups): White; Asian (Asian/Asian British); Black (Black/African/Caribbean/Black British); Mixed/Other (Mixed/Multiple ethnic groups/Other). Subgroups will be used for descriptive epidemiology and Groups for intersectional analysis.
- Socioeconomic position measured using Index of Multiple Deprivation (IMD)/Townsend score.
- Frailty (eFI score).
- Dementia (identified from primary care using validated codelists).
- Rurality (urban-rural, available direct from CPRD based on postcode).

WP2: Qualitative examination of implementation of SMRs and impact on equity of provision

A combination of observations, documentary analysis, and interviews will be used to investigate the implementation and delivery of SMRs, and the experiences of professionals, older people and their families/ carers. Researcher will:

- Review resources relating to how SMRs are operationalised for delivery (e.g. invitation letters, existing SMR guidance documents, procedures for follow-up). Observe relevant meetings (e.g. PCN pharmacy team meetings), where researchers will only take field notes.
- Undertake qualitative observations of SMRs (remote and face-to-face) conducted in general practices, pharmacies and care homes with consenting professionals and purposive sample of older people (approximately 8 observations at each PCN, total of 32 observations). When appropriate, the researcher will engage both professionals and older people in ethnographic style conversations before and after the SMRs to elicit ‘in the moment’ experiences (a technique we have successfully used in previous research in care home settings (28). These observations and conversations will examine the minutiae of how SMRs are conducted and experienced in practice.
- Conduct semi-structured interviews with a purposive sample of professionals involved in SMR implementation (including PCN Clinical Directors, Pharmacy Lead, senior and junior

pharmacists, GPs, admin staff, care home managers and staff, some of whom we will also observe). Participants will be offered the option of an in-person or remote (Microsoft Teams) interview. Topic guides will be devised drawing on existing literature on SMRs and will cover normalisation process theory domains (29). The guide will include: the structural context and decision making regarding the process for implementing SMRs and routine practices; their role in implementing SMRs; experiences, barriers and facilitators to inviting and delivering SMRs to older people with severe frailty or care home residents across intersectional groups; training content and how it has prepared them for their role, and related gaps. Each interview will last approximately an hour.

- Conduct semi-structured interviews with a purposive and diverse sample of older people with severe frailty/care home residents and their families/carers, including those whose SMRs we have observed, to further investigate SMR experiences. Some of these participants will also be older people who have declined the offer of a SMR. Participants will be offered the option to be interviewed alone or with a family member/carer. Ideally interviews will be conducted face-to-face (in their home / place of their choosing) to facilitate rapport, clear communication and to enable the researcher to better pace the interview and manage any potential distress. Participants will be offered the option to be interviewed remotely (telephone / MS TEAMS) when face-to-face interviews are not possible to ensure we do not unintentionally exclude groups of older people due to format of the interview. Topic guides will be developed in partnership with the PPI group and will cover topics such as: experiences of their/their relative's health and medication regimen prior to being offered the SMRs, why they accepted or declined the SMR, their expectations of the SMR, the impact of the SMR if appropriate, their experiences of their/their relative's current health and medication regimen and factors that shaped decision-making about medication/changes to medication, including high-risk medications. We plan for the interviews to last up to an hour but will take steps to ensure this is acceptable to participating older adults (for example, the interview may take place over multiple visits if more acceptable). Additionally, interviews will be conducted in the participant's first language when possible.

Researchers will record observations in field notes and, with permission, audio-record the interviews. Audio-recorded data will be professionally transcribed. Interviews conducted in a community language will be translated and transcribed by our researchers, who have previous experience of doing this. Identifiable information will be removed from transcripts and observation notes, prior to analysis.

WP3: Using co-production methods to translate findings into actionable solutions

Building on models of co-production (30,31), we will conduct a series of workshops and co-production meetings to iteratively develop and pilot a targeted training package for pharmacists and detailed guidance for commissioners. They will be grounded in lived experiences to ensure equitable access to and engagement with SMRs for diverse groups of older people with frailty. We will undertake this work in three stages:

<u>Stage 1: Feedback of the findings from WP1&2</u>

We will hold separate feedback workshops for older people, their families and carers, and for participating heath care professionals and representatives from PCNs in each PCN locality. It is important that these initial feedback events are held separately for the different stakeholder groups to

ensure they are all able to discuss the findings and voice their own perspective and priorities. All workshops will be co-facilitated by researchers and PPIE members.

Workshop facilitators will present data on inequalities in delivery of SMRs (WP1) and how the structures and processes employed to implement and deliver SMRs shape access and engagement for diverse groups of older people with severe frailty (WP2). Evidence of the experiences of professionals, older people and their families/carers will form a key element of this presentation. Findings will be presented in an accessible and engaging format. For example:

- At the workshop for older people and their families and carers, we will use vignettes presented as storyboards (31). Each storyboard will depict a fictional scenario devised from data collected in WP2 focusing on people's experiences of their medication regimen and SMR process. In addition to the storyboards, we will use a process map (flow diagram) to highlight the key stages in the implementation and delivery of SMRs based on the process tracing work in WP2.
- At the workshops for professionals involved in the implementation and delivery of SMRs and representatives from the PCN we will use visual displays of the findings from WP1, and anonymised case summaries from WP2 data supported by anonymised quotes and observation data, as well as the process map. Facilitators will then elicit participants' views on the data presented at the workshops and what works well, as well as what is hindering access and engagement to SMRs for this group (in relation to both service design and delivery).

The workshops will be audio-recorded and professionally transcribed, followed by de-identification of transcripts by the research team.

Stage 2: Joint prioritisation of the key elements that foster equitable provision of SMRs

At each PCN, we will hold a joint workshop with older people, their families and carers, professionals and PCN representatives who attended the stage 1 feedback workshop.

A summary of the key themes that impact on equitable provision of SMRs from the feedback workshops will be sent to participants in advance and will also be presented at the joint prioritisation workshop. Working in small groups older people, their families/carers and professionals will be asked to individually rank in order of importance the themes, which will be presented to them on cards. A small group discussion will be held to enable people to explain why they ranked their cards in the order they did, before the group jointly orders the cards from most to least important. The group will discuss their thoughts on the most highly ranked cards and what needs to happen to create the necessary change to implement their priorities to advance equitable provision (at an organisational level and in how SMRs are conducted in practice). These workshops will be audio-recorded and transcribed professionally. The ranking of the cards will be collated and compiled by the research team. The transcripts will be de-identified.

Stage 3: Co-production of targeted training materials and guidance for PCNs/ICSs.

In partnership with a group of 6-10 older people with lived experience, families/carers and other key stakeholders (health and social care professionals, commissioners, and policymakers), we will hold a series of six co-production meetings over eight months to iteratively develop guidance for PCNs and

targeted training for pharmacists and primary care staff. This will include resources (e.g. explanatory videos in community languages, leaflets, decision-aids) to support equitable access to and engagement with SMRs. We aim for the meeting membership to be stable (i.e. the same participants attend each meeting). The findings (e.g. theme summaries, priorities) from the feedback and prioritisation workshops will be presented and discussed with participants in the initial meeting. Based on these discussions, subsequent meetings will focus on drafting the content of the guidance for commissioners and targeted training and resources. We will iteratively evaluate and pilot the guidance and targeted training package. The draft guidance, targeted training and resources produced by the group will be taken back to the prioritisation workshop groups to gather feedback. The targeted training and supporting resources will be piloted using the think aloud method (32) with pharmacists. In think aloud interviews the pharmacists will be asked to work through the training and/or associated resources and articulate their thought processes while doing so. The researcher will then ask them questions allowing them to further elaborate on their experiences of using the training / resources. Feedback from the prioritisation workshop group and think aloud interviews with pharmacists will be audio recorded and transcribed for the co-production meetings. Guidance for commissioners, targeted training and resources will then be refined and finalised by the co-production group in the final meetings. To support the co-production process, discussions in co-production meetings will also be audio-recorded (including discussions concerning the ongoing evaluation and refinement of resources) and summarised.

5b. Data Analysis Methods

WP1: Quantitative analysis of inequities in delivery and inequalities in outcomes of SMRs

Intersectional analysis will be undertaken, whereby patients will be assigned to one of 120 intersectional subgroups, based on combinations of categories of: Age (65-74, 75-84, 85+); Gender (male, female); Ethnicity (Black, Asian, White, Mixed/Other); Socioeconomic position (quintiles)

We will investigate inequities in SMR delivery at 3 key stages of the SMR process, using the following process measures, all of which are included in the PCN SMR contract specification using standardised Systematised Nomenclature of Medicine Clinical Terms (SNOMED-CT) coding.

- Invitation of patients for SMR (using SNOMED CT code 1363201000000103).
- Decline of SMR by patients (using SNOMED CT code 1363191000000100).
- SMR receipt (using SNOMED CT code 1239511000000100).

We will estimate rates of SMR invitation/decline/receipt following PCN SMR contract implementation (1/10/21 onwards) according to intersectional characteristics using multilevel logistic regression, with SMR invitation/decline/receipt as the outcome in separate models. Intersectional subgroups will be represented by a random effect using the ‘Multilevel Analysis of Individual Heterogeneity and Discriminatory Accuracy’ (MAIHDA) approach (26). Predictors will additionally be incorporated into the fixed effects part of the model, with age included as a continuous variable. The model will produce precision weighted estimates of SMR invitation/decline/receipt for each intersectional subgroup with corresponding Bayesian credible intervals. To assess model performance, we will produce Harrell’s C-statistic (equivalent to the Area Under the Curve), sensitivity and specificity and Nagelkerke’s R2. We

will also assess calibration using calibration in the large and calibration plots. Internal validation will be undertaken using five-fold cross-validation. These models will be performed in CPRD only.

We will investigate medication-related outcomes focusing on:

- Number of medications (British National Formulary (BNF) subchapters).
- Number of medications of high-risk drug groups, including groups defined in PCN SMR guidelines (patients with >2 prescriptions over a 3 month period for 1) opioids, not including weak opioids, 2) gabapentinoid, 3) benzodiazepines, 4) z-drugs). We will develop an operational definition of high-risk drug groups to be considered for inclusion through an initial workshop with stakeholders at the start of the project.
- Anticholinergic Medication Index (ACMI) score, developed and validated by our WP leads Best and West in a Health Data Research UK (HDRUK) funded project led by lead applicant Clegg in partnership with team members Abuzour, Alldred, Lawton, Mistry, Pirmohamed, Todd and Walker (33).
- Estimated daily dose of medications (calculated in Connected Bradford only as the number of tablets prescribed divided by the exposure period and multiplied by the tablet strength).

We will also investigate health and social care outcomes, using:

- Hospital admission (all-cause; hospitalisation with delirium; hospitalisation with falls).
- Number of primary care consultations.
- Home care package (Connected Bradford only).
- Time at home (number of days living at home, taking into account hospitalisation/length of stay and mortality).
- Care home admission (determined using 49 clinical codes, used in previous CPRD study (34).
- Mortality, using linked ONS data.

Using CPRD Aurum, Interrupted Time Series (ITS) models will be performed to examine whether there were changes in the level and slope of all medication-related and health and social care outcomes, with the exceptions of drug dose and home care package, in England in the 2 years following the PCN SMR contract implementation. ITS will use the 5 years of pre-intervention trends to predict counter-factual post-intervention trends in the hypothetical scenario where SMR PCN contract was not implemented. Hypothetical trends will be compared to the actual post-intervention trend to determine whether any real changes were observed following intervention. By incorporating intersectional subgroups using random effects, we will also be able to examine whether the (pre-implementation) number of medications and the intervention effect varied according to intersectional characteristics. Using Connected Bradford, ITS models will similarly be fitted to analyse whether there were changes in the level and slope of the proportion of patients with a decrease in medication dose or home care package following the introduction of the PCN SMR contract.

Sensitivity analyses: The COVID19 pandemic may affect the reliability of counterfactual predictions so we will additionally introduce a comparator group of CPRD GOLD patients from Wales, Scotland and NI where the PCN SMR contract was not implemented, matched on the basis of intersectional characteristics.

WP2: Qualitative examination of implementation of SMRs and impact on equity of provision

Using process tracing techniques (35-37), all data will be analysed to produce in-depth understanding of how SMRs have been implemented and experienced by a diverse group of older people in the participating PCNs (supported by analytic frameworks, timelines and process maps). We have a track record of involving PPI members in the analysis of qualitative data (38-40). Our PPI members will represent the communities that face inequalities in accessing and engaging in SMRs as identified in WP1. They will be provided with anonymised sub-set of data and supported by researchers to review and discuss themes relating to how people experience SMRs evidenced in the data. These discussions will then inform the analytic frameworks used in ongoing analysis. Within/across case analysis will be used to generate explanations of how structural factors and processes shape access to and engagement with SMRs, taking into account intersectionality.

In parallel, discourse analysis (DA) of documentary and interview data will support the development of these explanations (41, 42). DA illuminates discourse that shapes policy and practice, including dominant beliefs and representations of social groups. Our PPI group will be actively involved by reviewing and discussing a subset of the data from a DA perspective highlighting how meaning is constructed through the wording of the text (policy, guidelines, interview transcripts) in relation to the delivery and receipt of SMRs. This discussion will inform the ongoing coding of data. Researchers will keep memos to capture reflections. Emerging analysis will be tested and refined through ongoing engagement with our PPI group and research team, and iterative data collection and analysis. This approach will support development of necessary materials for use in WP3, including story boards (working with a local artist who has particular skills in engaging older people with frailty and care home residents), process maps and case summaries.

WP3: Using co-production methods to translate findings into actionable solutions

Transcripts of discussions in stage1 workshop will be thematically summarised (43) to draw out the key themes that impact on equitable provision of SMRs for diverse groups of older people with frailty.

Transcripts of discussions in stage 2 workshops will be summarised thematically to identify key themes relating to the importance of different elements that foster equitable provision and how it is envisioned they could be implemented in practice.

Transcripts of feedback on the draft guidance, targeted training and resources provided by the prioritisation workshop group will be summarised to highlight key areas for improvement.

Similarly, transcripts from the think aloud interviews with health care professionals will also be thematically summarised to capture what aspects of the training works well and what can be further improved.

6 STUDY SETTING

This study will be conducted in the UK with participants (older people, their family members/ carers and health care professionals) recruited from PCNs in England.

WP1: Quantitative analysis of inequities in delivery and inequalities in outcomes of SMRs

CPRD Aurum covers a population of 13M patients in England (99%) and Northern Ireland (1%), whereas CPRD Gold covers 3M patients across all parts of the UK. Connected Bradford includes linked health care data from 900,000 residents of Bradford district and Craven (ethnically diverse, in areas of affluence/deprivation) including care home residence. Information on ethnicity is recorded for 90% of CPRD patients (44).

WP2: Qualitative examination of implementation of SMRs and impact on equity of provision

Four PCNs, differing in relation to location (inner city, rural and coastal), demographics of population served (ethnicity and socio-economic deprivation), and rates of SMRs undertaken will be purposely sampled to allow comparison between different services and a robust investigation of factors impacting on equitable provision.

Review of SMR documents and observations with staff and patients will be conducted in general practices, pharmacies, care homes and wherever implementation and delivery of SMRs and PCN meetings usually take place. Researchers will work with the pharmacy team and/or primary care team conducting SMRs to identify research participants (health care professionals and patients) and data collection opportunities (i.e. observations of team meetings and SMRs). The research team will also approach and discuss the research with care home managers, where we will be seeking to observe pharmacists conducting SMRs and conduct interviews with staff and residents. Interviews with older people and their families/ carers will ideally be conducted face-to-face in their home, care home or a place of their choosing. Remote interviews will be offered if face-to-face is not feasible. Similarly, interviews with health care professionals will be conducted at a place of their choosing or remotely.

WP3: Using co-production methods to translate findings into actionable solutions

Stage 1 and 2 workshops will take place (face-to-face or remotely) in each of the participating PCNs. We will aim for workshops involving older people and their families/ carers to be face-to-face to appropriately support them to engage in the process. However, health care professionals may find it more convenient to participate in the stage 1 workshop remotely. We will discuss the options with prospective participants to determine their preferred method. The co-production meetings will involve older people, their families/ carers and health and social care professionals. We will work in partnership with PCN stakeholders and local community groups to facilitate recruitment and to hold the workshops and meetings in accessible and familiar locations, to ensure maximum attendance.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria and Sampling

WP1: Quantitative analysis of inequities in delivery and inequalities in outcomes of SMRs

Inclusion criteria: Older people aged 65+ with severe frailty[3] living in the community, or care home residents, between 1/10/16 (5 years prior to start date for PCN contract of 1/10/21) and 31/9/23.

Sample size: There are 2.4M active patients in CPRD Aurum/GOLD aged 65+ residing in England and 527,000 in other parts of the UK, with 115,200 (4.8%) with severe frailty or care home residence. There are 80,000 patients aged 65+ contributing data to Connected Bradford, of whom 3,800 will have severe frailty or care home residence.

- *SMR delivery outcomes*- There will be approximately 92,160 CPRD patients available for each 5-fold cross-validation. This will enable adequate power to perform a single-level logistic regression with 131 predictor parameters (7 predictors (with 11 parameters) and 120 intersectional subgroups) with a conservative R^2 of 0.1, when SMR offer/ decline/ receipt is as low as 5% of the study population (45). We plan to increase parsimony and more robustly account for multiple interactions and small strata, by incorporating a random effect to model the 120 intersectional subgroups. Intersectional strata will vary in size from approximately 5 patients (males aged 85+ in the most deprived IMD quintile with Mixed/ Other ethnicity) to approximately 7078 patients (White females aged 65-74 in the least deprived IMD quintile), based on ONS demographic data. Should strata become smaller than 5 patients, strata will be combined. While some strata will be small in size, the MAIHDA down-weights unreliable rates (i.e. those from small strata) to the grand average.
- *Medication-related and health and social care outcomes*- ITS will be performed over 84 monthly time points with the post-intervention period accounting for approximately one third of time points. Simulation studies indicate that an ITS in this scenario will have over 80% power to detect small, medium and large effect sizes across all of our stated outcomes when autocorrelation remains below 0.3, 0.4 and 0.8, respectively. Based on previous policy evaluation studies, autocorrelation values usually lie in the range of 0.1-0.5 (46). Those with severe frailty have a median number of medications of 11, based on our previous research. A small effect size would be an average post-intervention decrease of one medication, with SD equal to 2, which is feasible with the anticipated sample sizes in both CPRD and Connected Bradford.

WP2: Qualitative examination of implementation of SMRs and impact on equity of provision

Purposive sample of older people and health and social care professionals will be identified from the four PCNs included in the study.

[3] Severe frailty will be defined as eFI score >0.36 (19), aligned with PCN contract guidance. Care home residence will be identified in CPRD Aurum and Gold using 49 clinical codes (28), and using linked social care data in Connected Bradford.

Inclusion criteria:

- Health and social care professionals who have differing involvement in the implementation and delivery of SMRs.
- Older people aged 65+ with severe frailty, living in their own home or in a care home setting who have been offered a SMR/ opportunistic medication review.
- Family members/ carers of older people participating in the study.

Sample of older people will be diverse in relation to intersectional characteristics (e.g. age, gender, ethnicity, and socioeconomic deprivation) and a detailed sampling strategy will be developed based on WP1.

Exclusion criteria:

- Older people with frailty who are on a palliative care pathway.

Size of sample:

- Approximately 8-12 health and social care professionals from each participating PCN (total of 32-48 health and social care professionals). This will include professionals in a variety of roles, for example senior and junior PCN pharmacists, individual general practice-employed pharmacists, PCN clinical director, GPs, and home care and care home staff.
- Approximately 8-10 older people with severe frailty (including those living in care home settings) from each participating PCN and their carers/family members will be included. We will conduct in-depth qualitative research with a total of 32-40 older people with frailty and family members/ carers across all sites.

WP3: Using co-production methods to translate findings into actionable solutions

Stage 1 and 2 workshops will involve WP2 participants and, if necessary, additional older people with frailty and their families/ carers from intersectional subgroups identified in WP1. The co-production group will comprise participants from WP2 and additional members will be recruited if necessary to ensure we have sufficient diversity and input from relevant health care professionals and experts. The pilot work will involve a separate sample of pharmacists. We will work in partnership with local community groups, our PCN contacts and professional networks to build our purposive sample for WP3.

Inclusion criteria:

- Stage 1 and stage 2 workshops- same inclusion criteria as WP2 (will mainly include the same participants from WP2).
- Stage 3 co-production group- Same inclusion criteria as WP2 and other key stakeholders (commissioners, and policymakers).
- Pilot of targeted training- pharmacists working in general practices and community pharmacies with different levels of seniority.

Exclusion criteria:

- Older people with frailty who are on a palliative care pathway.

Sample size:

- Stage 1 and stage 2 workshops- upto 28 older people and family members/ carers and upto 28 health and social care professionals across all four PCNs.
- Stage 3 Co-production group- 6 to 10 members (the same participants will attend all 6 meetings). Such a size group will allow diversity of members whilst ensuring everyone is able to engage in the discussions, planning and reflective work in a meaningful and inclusive manner.
- Review of materials developed by the co-production group will be conducted with upto 10 participants (older people, family members/ carers and health care professionals) who participated in the stage 1 and stage 2 workshops.
- Pilot of targeted training- up to 10 pharmacists who will be diverse in relation to experience of delivering SMRs and seniority, and experience of working within different settings/ service models to capture a range of perspectives.

7.2 Recruitment

7.2.1 Sample identification

WP1: Quantitative analysis of inequities in delivery and inequalities in outcomes of SMRs

Not applicable

WP2: Qualitative examination of implementation of SMRs and impact on equity of provision

Following discussions with the PCN Clinical Director the researcher will make contact with the PCN pharmacy team and work with them to identify other professionals (including GPs, home care and care home staff) who support the implementation and delivery of SMRs, to take part in the research. Identification of health and social care professionals will be based on their job roles, to enable recruitment of participants in a range of roles relating to implementation and delivery of SMRs in each PCN.

Once we have developed our detailed sampling strategy for older people with frailty (informed by WP1 findings), we will work with primary care/ pharmacy teams to devise searches for identification of eligible participants from their list of patients who have been/ due to be invited for a SMR. We will also work with primary care/ pharmacy teams to identify eligible older people who have recently been offered an opportunistic SMR as part of a routine appointment, to ensure inclusion of people who declined or did not receive a separate SMR appointment. When necessary, we will work with community groups as avenues for supplementary recruitment to recruit older people who may have previously declined a SMR. Researchers will in this case contact local community groups, when possible, attend meetings to discuss the research, and/or distribute posters. Potential participants who show interest from the community will need to contact the research team directly. They will be asked a number of questions by a member of the research team to determine their eligibility, before they are recruited to the study.

We will also ask older adults who agree to take part in the study, if they have any family members or carers who they would want to support them in the data collection process and who may be interested in taking part.

WP3: Using co-production methods to translate findings into actionable solutions

A purposive sample of participants (older people, family members/ carers, and health and social care professionals) from WP2 will be invited to participate in the stage 1 and 2 workshops in each of the participating PCNs. If necessary, to ensure diversity and inclusion, we will work with PCN teams and community groups (following the same method as in WP2) to identify additional older people with frailty with intersectional characteristics for the workshops.

Participants for the co-production group will include health care professionals and older people who are diverse in relation to their intersectional characteristics. We will involve participants from WP2 and identify additional participants, if necessary, through our contacts with community organisations and professional networks.. For the purpose of building a rapport between group members and supporting older people and their family members/ carers to meaningfully engage in discussions, we will aim to conduct the meetings face to face. Group membership will therefore depend on whether a person lives/ works locally to Bradford and Leeds, and able to attend meetings in person.

A purposive sample of participants (older people, family members/ carers and health care professionals) who took part in stage 1 and stage 2 workshops will be identified based on their intersectional characteristics/ professional role, to review materials developed by the co-production group. The purposive sample of pharmacists (diverse in relation to experience of delivering SMRs and seniority) to pilot the co-produced training materials will be identified working with PCN clinical directors and pharmacy leads. If feasible, we will broaden this sample to include pharmacists working outside of the four participating PCNs to capture as much diversity as possible in terms of their experience of working within different settings/ service models.

7.2.2 Consent

WP1: Quantitative analysis of inequities in delivery and inequalities in outcomes of SMRs

Not applicable. As patients cannot be identified from the data a GP practice sends to CPRD, the GP practice does not need to seek patient consent to share data with CPRD. Individual patients can opt-out of sharing their data for research in which case CPRD will not collect data for these patients.

WP2: Qualitative examination of implementation of SMRs and impact on equity of provision

Following discussion with the PCN clinical director and pharmacy lead, we will provide study information and consent form via email/ face-to-face, to health care professionals identified for the SMR observations

and/ or interview. They will be recruited by the researcher and will have the option of providing written consent (returned by post/ email or in person on day of data collection) or verbal consent (which will be audio recorded). The latter option will be appropriate for participants who may only participate in the study remotely, for example in an interview conducted via Microsoft Teams.

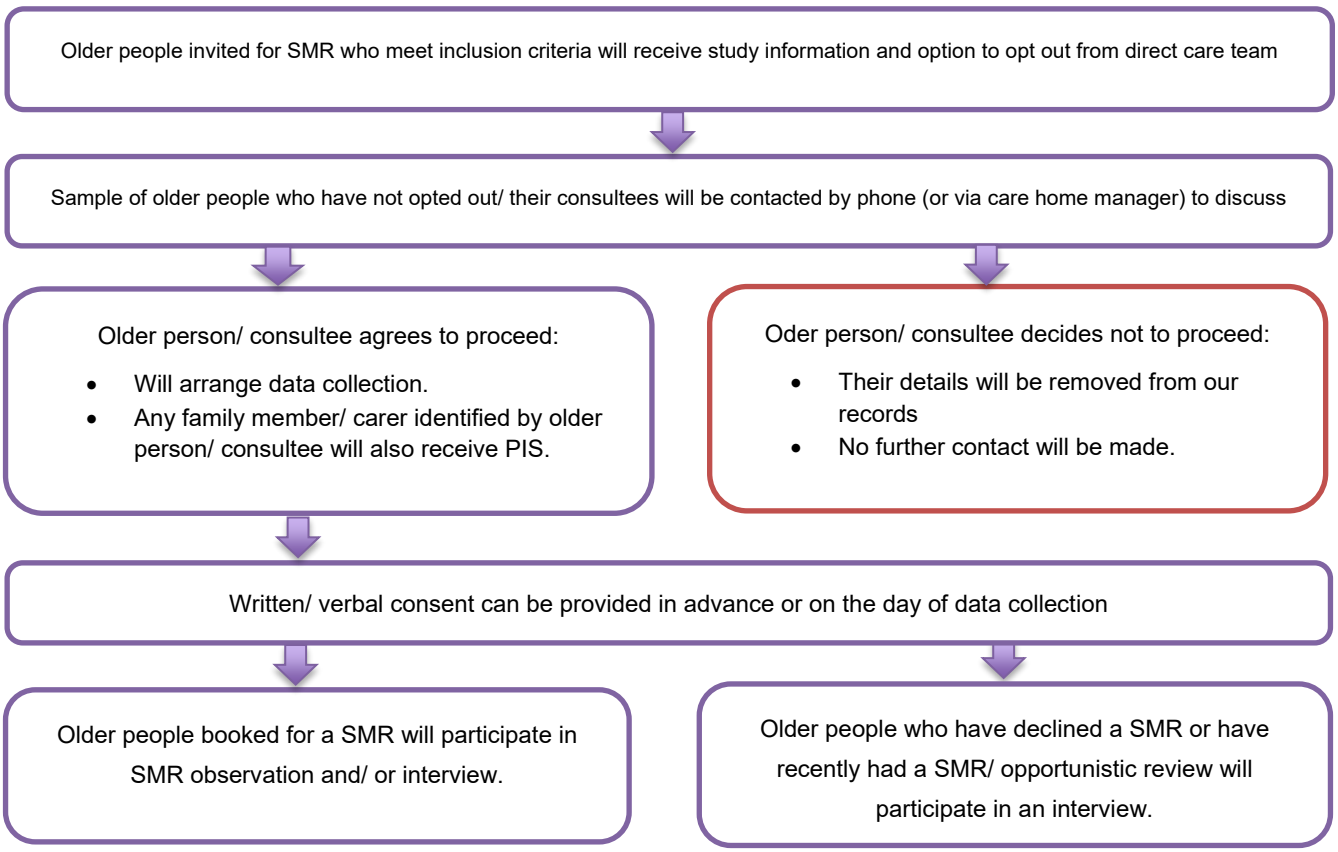
Observations of team meetings in participating PCNs will be arranged with PCN clinical director/ pharmacy lead. We will not seek to obtain individual consent from those in attendance as we will not be collecting/ recording any personally identifiable data or audio-recording the meetings. Information about the study, with an invitation to ask questions will be shared with staff via the PCN clinical director/ pharmacy lead at least a week in advance of the meetings.

For older people, members of the primary care/ pharmacy team responsible for booking/ conducting SMRs will provide patients (in the community and in care homes) with study information and consent form. The study information will inform patients that a researcher may contact them about the study in due course and provide instructions on how to opt-out of being contacted (we have used a similar approach effectively in earlier studies (47). Potential participants will be advised to contact their care provider to opt-out within 7 days of receiving the study information. If the older person lacks capacity to consent, study information will be provided to a relative or friend who may act as a consultee. The research team will discuss the research with care home managers within participating PCNs who will also be involved in engaging consultees of care home residents that lack capacity.

The primary care / pharmacy team will provide the research team with minimal of eligible potential participants information (name, contact telephone number, and confirm if they reside in a care home) a minimum of 7 days after sending out the study information. Details of eligible participants who have opted out of being contacted will not be passed to the research team. Researchers will contact potential participants / their consultee (via the care home manager if necessary) to discuss the study and answer any questions. If potential participants/ consultees wish to proceed, the researcher will arrange a time and date for data collection with them (SMR observation and / or interview) and obtain their postal address to send out a letter confirming this. Older adults who contact the research team after receiving a study leaflet via community group/ organisation, will be asked to provide their name and full postal address so that the participant information sheet and consent form, can be posted out to them, if they are eligible to take part.

Family members and carers who wish to take part in the study, will be provided separate study information and consent form.

Diagram 1: Recruitment of older people for WP2



All participants will be required to provide written or verbal consent before any data is collected from them. Some of our participants may be unable to read or sign the consent form. For example, some community languages do not have a written form, for example Mirpuri as a common community dialect in our older Bradford residents of south Asian ethnicity. Verbal consent will be obtained and audio-recorded for those who are unable to read and sign the consent form. In some cases SMR appointments may be offered to patients within a week or two of sending out the SMR invitation and initial study information, we will seek to obtain informed consent from participants in a timely manner. Participants will be able to provide informed consent in advance or on the day of data collection, depending on their convenience.

8 ETHICAL AND REGULATORY CONSIDERATIONS

We will follow legal and ethical guidelines to ensure we sample participants from diverse backgrounds, and that we collect, manage and use research data in an appropriate and sensitive manner.

Frailty in older age commonly co-exists with cognitive impairment and /or dementia, particularly in care home residents. This can make SMRs complex to conduct and result in inequalities. We will take steps to engage older people living with cognitive impairment and / or dementia, who may lack the capacity to provide informed consent, and their family members/ carers in our research, if the WP1 analysis finds

living with dementia to be a significant predictor of inequality in delivery and inequality in outcomes of SMRs. The inclusion of older people living with cognitive impairment and /or dementia in the study will be in line with the ethical principles underlying the Declaration of Helsinki.

The risks for patients participating in this study are minimal, there are also no direct benefits to the participants. We will manage the expectations of the study participants. When booking the SMR observation/ interview, we will explain that they have no clinical qualifications and therefore we are unable to give advice or information in this regard. We will also make sure that the participants understand we do not have direct contact to their medical records and unable to discuss their care with their care provider. We will confirm that the patient is willing to continue on this basis.

We also recognise that our participants may have frailty with co-morbidities. Our researcher will be able to read 'body language' and will offer breaks during the interview as needed. As previously described participants can also have a friend or family member present for support if they wish. If participants become fatigued, develop pain, or are distressed, an existing distress protocol will be followed, and interviews will be paused or terminated if necessary. It is possible that some participants may become emotionally distressed when talking about their health. They may have had a particularly bad experience or faced discrimination when accessing health care support. In such instances, we will offer to pause and/or stop the interview, and in all cases prioritise their emotional wellbeing. If appropriate we will offer to return another time to complete the interview. If the participant discloses any information relating to safeguarding issues during the interview, we will inform the participant that we are obliged to follow the Bradford Teaching Hospitals Foundation Trust (BTHFT) protocol. All matters of safeguarding will be reported to the CI as soon as possible (including outside of normal working hours).

If the researcher feels the participant is at risk or is a risk to others (including if malpractice is witnessed during observations), the researcher will inform the participant and disclose the issue without consent but in the interest of the participant using the following process: Details will be discussed with the Chief Investigator (CI). All details discussed will be kept strictly confidential. The CI will then agree a strategy to minimise harm whilst maintaining privacy. This is likely to involve discussing details of the disclosure with a local clinician and/or a safeguarding professional.

8.1 Assessment and management of risk

Participant capacity:

In line with the MCA (2005), we will assume that prospective participants have the capacity to consent, even when they have a diagnosis of a condition that may question that capacity, unless it is confirmed by their care provider or family member/ carer that they lack capacity. Study information will be provided in accessible language and format, including the option of a researcher discussing the information with potential participants and their family/ carer in person, to enable them to make their own decision. If it is established that a potential participant is unable to understand the study information and therefore lacks capacity to provide consent, information about the research will be provided to a relative or friend who may act as a consultee. We will seek advice from the consultee about an appropriate approach to data

collection and, if relevant, participants' fluctuating capacity. If any participants who were able to provide informed consent at the time of recruitment to the study, later loses/ has fluctuating capacity, They will continue to participate in the study unless they are unwilling or become distressed. If feasible, we will seek advice from their consultee on how we can better meet the needs of the participant during data collection.

Fluctuating health:

Older people's health may fluctuate during the course of the study. We will ensure, where possible, the same researcher conducts the telephone calls, consent, observation and interview so a trusting relationship is developed. If a participant becomes unwell or their health deteriorates, the researcher will liaise with the person directly or with their consultee about ongoing study participation.

The researcher will monitor for participant fatigue during interviews. Should a participant show signs of tiredness, the researcher will pause the interview and arrange to return or reconvene later the same day, or in the following days.

Risk of harm:

Consent will be obtained on the understanding that all information provided by the participant will be kept confidential unless the researcher witnesses something which they feel presents a potential or actual harm to the participant or others, or if a participant discloses information which the researcher feels has or may result in harm. In this case, the researcher will encourage the participant to raise this with a relevant professional, or raise it on their behalf.

If the researcher feels that the participant is at risk or is a risk to others, the researcher will disclose the issue without consent but in the interest of the participant using the following process. Details will be discussed with the Chief Investigator. All details discussed will be kept strictly confidential. The Chief Investigator will then agree a strategy to minimise harm whilst maintaining privacy. This is likely to involve discussing the anonymised details of the disclosure with a local clinician and/or safeguarding professional.

***Lone working policy*:**

Researchers will be required to conduct interviews and observations in study sites and in participants' homes or a place of their choosing. All staff will follow the Academic Unit for Ageing and Stroke Research *Lone Working Guidance for Researchers and Nominated Contacts (2019).* They will undertake regular risk assessments with the study lead, safety devices and a nominated contact who will monitor their safety whilst in a 'lone working' situation.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

Before the start of the study, a favourable opinion will be sought from an NHS Research Ethics Committee (REC) for the study protocol and research documents e.g. consent form, participant

information sheets and interview topic guides. Ethical review will be booked with a recognised REC once the IRAS application form is submitted and HRA approval validation is received.

Regulatory Review & Compliance

Before any site enrols patients into the study, the Chief Investigator or designee will ensure that appropriate approvals from participating organisations are in place. We will ensure specific arrangements on how to gain approval from participating organisations are in place and comply with the relevant guidance.

Amendments

Any amendments to the study, will be made following agreement between the research team and Chief Investigator. The Chief Investigator or designee, in agreement with the sponsor will complete and submit the online Amendment tool for the review body to issue approval for the amendment. Following submission of amendments, participating sites and local CRNs will be informed by email. The Chief Investigator or designee will work with sites (R&D departments) so they can put arrangements in place to implement the amendment, when necessary. Amendments will be uniformly implemented across all sites in accordance to the UK Policy Framework for Health and Social Care. Protocol identifiers and date swill be used, along with a record of amendments to track the history of amendments and identify the most recent protocol.

8.3 Peer review

The study proposal was reviewed and approved by the funding body (NIHR) and sponsor organisation (BTHFT), prior to research grant being awarded. The study protocol has been developed subsequently and only been reviewed internally by the study team and project investigators, it has not been externally peer reviewed.

8.4 Patient & Public Involvement

The research has been developed in full partnership with PPIE members (HDRUK North PPI medicines Optimisation Group). The study PPIE group will meet three times a year and will be actively involved throughout the duration of the study:

- Interpretation of data on SMR delivery and medication-related and health/social care outcomes.
- Preparation of study materials (e.g. Participant information sheet, interview topic guides)
- Agreeing a recruitment strategy.
- Analysis and interpretation of interview and observation data.
- Recruitment and co-facilitation of workshops.
- Preparation of workshop materials.
- Development of training package and PCN/ICS guidance.

8.5 Protocol compliance

Accidental protocol deviations can happen at any time. They will be adequately documented using relevant forms and reported to the Chief Investigator and Sponsor immediately. Deviations from the protocol found to frequently recur will be actioned immediately, following discussions between the Chief Investigator, research team and co-investigators.

8.6 Data protection and patient confidentiality

All study data and documents containing personal information will be stored on the BTHFT password protected server. Hard copies of informed consent forms will be kept in a secure filing cabinet at BTHFT. Personal data (eg, contact details and consent forms) will be stored separately to research data. They will only be accessible to the study staff team and authorised personnel.

The CPRD data will be stored in a cloud-based Trusted Research Environment (TRE) based at the University of Leeds, that provides a secure environment for researchers to store, handle, process and analyse sensitive and confidential data.

All data for WP2 and WP3 will be collected and retained in accordance with the Data Protection Act 2018 and General Data Protection Regulation standards.

- PCN Clinical Directors/ Pharmacy Leads will be asked to provide names, emails, and telephone numbers of staff members to be invited to participate in the study.
- PCN primary care/ pharmacy teams may share contact details of eligible older people to be contacted about the study in accordance with our recruitment process.
- This information will be stored at BTHFT in a password protected file. Details of those who decline will be deleted immediately. Details of others who are not recruited (cannot be reached/ not contacted) will be deleted from the record once the sample has been attained.
- Either written or verbal (audio recorded) consent will be obtained from study participants. Audio recordings and electronic (emailed) consent forms will be stored on the BTHFT server in a secure folder with controlled access.
- WP2 interviews will be conducted with consented participants, in person or on Microsoft Teams. Ethnographic style conversations with participants will also be conducted during observations of SMR. Interviews will be audio-recorded using encrypted digital recorders or MS Teams recording software and uploaded on to the BTHFT password protected server.
- WP3 workshops will take place in different locations (preferably in the locality of each PCN) and co-production meetings will ideally be in person (to allow us to appropriately support older people to engage fully in the co-production process). Discussions in the workshops and meetings will be audio- recorded using encrypted digital recorders.
- All recordings from audio-recorders will will be deleted as soon as the recordings are securely uploaded on to the BTHFT password-protected server. These audio files on the BTHFT server will be deleted once analysis is complete. Transcripts will be stored on the BTHFT password protected server.

- Participants will be given a participant identification number (ID) and only their participant ID will be used to identify their interview recordings and transcripts. A password protected excel file will link the participants name and ID.
- Only the Chief Investigator and the immediate research team will have access to personal data.

Once data analysis is completed, the study documents (paper and electronic) will be retained in a secure location for 5 years with a review of retention for up to a maximum of 20 years before being destroyed. This is in line with Record Management Code of Practice (research data), in compliance with Bradford Teaching Hospital NHS Foundation Trust (BTHFT).

8.7 Access to the final study data

The final study data collected in WP2 and WP3 will be accessible to the Chief Investigator and study team. The full data will not be made available to staff at any of the participating PCNs. Information about possible future use of study data will be included in the participant information sheet and participants will be asked if they consent for their data to be used for secondary analysis at the time of being recruited to the study. Anonymised data (e.g. interview transcripts) of consenting participants may therefore be shared with wider teams at BTHFT following a review and approval of its proposed use by the Chief investigator.

9 DISSEMINIATION POLICY

9.1 Dissemination policy

Our dissemination strategy has been developed to maximise uptake of our research findings. Our preparatory work with policymakers, commissioners, practitioners and PPI representatives means that our research plans will generate evidence that is grounded, relevant, accessible and useful.

Dissemination Objectives

Objectives	Plan
To inform NHSE policy on how the NHSE SMR framework should be updated to better account for the needs of older people with frailty and care home residents across key intersectional groups to reduce inequalities (target audience NHSE).	Develop detailed policy report for NHSE based on our findings, ensuring all policy-related outputs meet the needs of policymakers, for example using the standard policy structure of a 1 page executive summary/3 page overview/20 page detailed report.
To support ICSs and PCNs nationally to implement findings to ensure suitable operating model for SMRs for older people with frailty, taking into account the needs of key intersectional groups.	Develop and disseminate guidelines and necessary resources to support engagement of older people with frailty and care home residents across intersectional groups in the SMR process, and appropriate follow-up support (target audience ICSs/PCNs).

To support training needs for practitioners delivering SMRs for older people with frailty and care home residents.	Build on the training that is received through the Health Education England Primary Care Pharmacy Education Pathway (PCPEP) (target audience ICSs).

Dissemination to NHS, social care organisations and the wider population

We have already engaged many of our primary and secondary audiences to maximise pull of our research into practice (i.e. NHSE care homes medicines optimisation scheme lead, and the Overprescribing Lead for West Yorkshire ICS and Consultant Pharmacist for Older People, with extensive links across ICS Medicines Optimisation teams nationally). Working with the NHSE care homes medicines optimisation scheme lead, we will build membership of our Project Steering Group strategically to ensure that we maximise potential for pull of our research into practice. This will include wider representation across ICS Optimisation leads, PCN Clinical and Pharmacy leads, primary care pharmacy and GP representation, and PPI members. We have strong existing links to ICSs and PCNs across the North of England and will use these links to generate pull of research outputs into routine practice. Wider dissemination will be supported through the national NIHR ARC Ageing, Dementia & Frailty priority theme, for which CI Clegg is co-lead, working with co-applicant Lawton who leads the NIHR ARC Yorkshire & Humber Improvement Science theme.

Dissemination to academic audiences

We have a strong track record of academic publication in highly cited journals and dissemination will continue to target high impact journals alongside presentation at national and international conferences. Additionally, we will exploit non-academic channels, information intermediaries and networks including the NIHR Applied Research Collaboration (ARC) links and infrastructure to accelerate spread and adoption of the new evidence. We anticipate using a range of media: tailored and targeted summary briefings; engagement events; online communications (e.g. ARC websites); and mainstream and social media (e.g. twitter). Local, national and international dissemination will occur via patient, professional and research-orientated conferences and blogs.

Dissemination to and engagement of patients/service users and carers

Our longstanding, strong engagement with patient, carer and public representatives means that we are well-positioned to disseminate findings widely, informing the wider population about our work. The PPIE lead and PPIE co-applicant will lead on the development of newsletters, supported by the wider research team and external stakeholders. We will use a range of channels to share findings, including through social media, traditional media, voluntary sector publications (e.g. Age UK) and community organisations representing our diverse communities.

We will share progress of our research with participants through quarterly newsletters, summarising project developments in plain English, with translation into community languages as appropriate. We will aim to develop study progress newsletters that are inclusive, whilst remaining mindful of the likely needs of our range of study participants, which will span policy, practice and the wider public across diverse communities that extend into care home settings. We will seek consent from study participants

to include anonymised case studies in our reports as these can help illuminate findings and maximise impact. We will share study findings with participants through a lay summary report, applying the same principles to maximise inclusivity, accounting for diversity of study participants. The lay report will also be shared with policymakers and practitioners, as we have found that this is valued alongside provision of study outputs developed specifically for our target audiences.

9.2 Authorship eligibility guidelines

Decisions about authorship on any journal publication from this study will be based on International Journal of Medical Journal Editors conditions (ICMJE, 2020), which recommends the following four criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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