

**Title:** A person-centred primary care pharmacist-led osteoporosis review for optimising medicines (PHORM): A protocol for the development and co-design of a model consultation intervention

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**ABSTRACT**

**Introduction:**

Adherence to medicines in osteoporosis is poor, with estimated one-year persistence rates between 16-60%. Poor adherence is complex, relating to combinations of: fear of side-effects, beliefs about medication being unnecessary; doubts about effectiveness and the burden of medication management. This is compounded by an absence of monitoring, as many patients are effectively discharged from ongoing care following initial prescription. Clinical pharmacists in general practice are a relatively new workforce in the UK NHS; this is an unexplored professional group that could provide person-centred, adherence-focused interventions in an osteoporosis context.

A model consultation intervention to be delivered by clinical pharmacists in general practice for patients already prescribed fracture prevention medications will be developed using existing evidence and theory and empirical qualitative work outlined in this protocol.

### **Methods and analysis:**

We will investigate current practice and barriers and facilitators to a clinical pharmacist-led osteoporosis intervention, including exploring training needs, through focus groups with people living with osteoporosis, pharmacists, GPs, osteoporosis specialists and service designers/commissioners. Framework analysis will identify and prioritise salient themes, followed by mapping codes to the Theoretical Domains Framework and Normalisation Process Theory to understand integration and implementation issues.

We will further develop the content and model of care for the new consultation intervention through co-design workshops with stakeholder and patient and public involvement and engagement group members. The intervention in practice will be refined in a sequential process with workshops and in-practice testing with people prescribed fracture prevention medication, pharmacists, and the multidisciplinary team.

### **Ethics and dissemination:**

Ethical approval was obtained from NHS North West - Greater Manchester South Research Ethics Committee (Ref 23/NW/0199). Dissemination and knowledge mobilisation will be facilitated through a range of national bodies/stakeholders. Impact and implementation plans will accelerate this research towards a future clinical trial to determine cost and clinical effectiveness.

## **Article Summary**

### **Strengths and limitations of this study**

- The project will draw on extensive evidence and empirical qualitative work with the Perceptions and practicalities approach (PAPA) as the overarching theoretical framework to ensure that the intervention is designed to understand patient's attitudes and beliefs that underpin non-adherence.
- The implementation element of the intervention will be informed by the Theoretical Domains Framework (TDF) and Normalisation Process Theory (NPT); both will underpin the exploration and understanding of the dynamics of implementing, embedding, and integrating a new complex intervention.
- This research will examine the practice development of primary care pharmacists in supporting people living with long-term disease; this is a relatively unexplored professional group that is rapidly expanding

- Extensive collaboration and co-design with patients and stakeholders will support the development of an intervention that is relevant and acceptable to users.
- The research will be conducted in the UK, with in-practice testing conducted in one geographical area only. Therefore, the relevance of our new intervention may vary across different context (health services structures) and geographical locations (nationally and internationally).

## INTRODUCTION

We have a growing and ageing population with increasing numbers of people accessing the NHS for care and support. (1) In the UK, greater than 3.7 million people are estimated to be living with osteoporosis, 78.3% women and 21.7% men. (2) Evidence indicates approximately 500,000 new fragility fractures occur annually leading to a significant impact on the quality of life for people as well as considerable healthcare spending, estimated to be around £5.4 billion. (3)

There is strong evidence to support prescribing of oral bisphosphonates for use in patients with osteoporosis, or in those at high risk of fracture; bisphosphonates are recommended by the National Institute for Health and Care Excellence (NICE) as first line therapy and are inexpensive, cost-effective and readily available. (4)

Medicines optimisation is defined as a 'person-centred approach to safe and effective medicines use, to ensure people obtain the best possible outcomes from their medicine'. This is a key focus in osteoporosis care, as adherence to prescribed medicines in osteoporosis is worse than many other long-term conditions, with estimates of one year persistence rates of between 16-60% with oral bisphosphonate therapy. (5)

Adherence can be defined as '*the extent to which the patient's behaviour matches agreed recommendations from the prescriber*' includes initiation, implementation and persistence and may be intentional or non-intentional. (6) Patients move along a path to active treatment, through (or between) stages of decision-making about treatment and strategies to tailor patient counselling with the appropriate stage of readiness can be used to support informed shared decision-making (7). Furthermore, approaches such as 'osteoporosis care gap' acknowledge that treatment is not suitable for or wanted by all and that informed decisions to not start or discontinue treatment should not be considered non-adherent (8).

Adherence/non-adherence is determined by many factors, both internal (intrinsic) and external (extrinsic) and which vary within individuals (eg through time or to different treatments/medications) and between individuals. The Perceptions and Practicalities Approach (PAPA) considers the effects of intrinsic and extrinsic factors on two key attributes, motivation and ability, which together determine adherence/non-adherence. (9) Thus, poor adherence may relate to a combination of modifiable factors, such as fear of side-effects, the burden of medication management and impact on daily living, beliefs about medication not being necessary or doubts about medication effectiveness, unmet information needs, all of which are compounded by an absence of feedback and monitoring with osteoporosis care. (10,11, 12) The absence of follow-up has been described by patients as a significant disincentive to persisting with treatment, and has therefore been highlighted as a priority area for osteoporosis research. (13,14,15)

Clinical pharmacists are different from community pharmacists; they work as part of the general practice team, typically employed by Primary Care Networks, or in some cases directly by practices. The published evaluation of the national clinical pharmacists in general practice pilot, found that patients benefited from increased lifestyle advice, and advice that improves medicines adherence and reduces the adverse effects of medication. (16) The NHS Long Term Plan outlines substantial expansion of the number of clinical pharmacists supporting general practice teams and primary care networks. (17) There is a target of one clinical pharmacist per practice by 2024, or approximately 7500 pharmacists, with NHS England funding 70% of costs. (18,19)

Clinical pharmacists typically work to help patients manage long-term conditions and support patients prescribed multiple medications. In January 2021 the General Pharmaceutical Council (GPhC) also published new Standards for the Initial Education and Training of

Pharmacists; the new Standards integrate the MPharm degree and Foundation Training and will train pharmacists in all clinical settings to be independent prescribers at the point of registration. (20) This is a significant step change for the pharmacy profession and the first cohort of pharmacists will join the register as independent prescribers in 2026, allowing new, more clinically focused interventions, to be delivered by pharmacists. This includes a greater role in clinical assessment and diagnoses, the initiation, optimisation and escalation of treatment, and supporting patients' information needs. In addition to developing an intervention to support people with osteoporosis, the work outlined in this proposal will explore training needs for pharmacists in this setting to deliver optimum care in an osteoporosis context.

The NICE medicines adherence guideline provides a framework for encouraging adherence through supporting and involving patients in decisions about treatment. (21) This is based on the Necessity Concerns Framework (NCF), which describes adherence as a construct of patients perceived need for medication (necessity beliefs) and concerns about their medication (concerns beliefs). (22)

An osteoporosis specific follow-up intervention, grounded in Perceptions and Practicalities Approach (PAPA) to facilitate tailored adherence support to address patient necessity and concern beliefs, and the application of the NICE medicine's adherence guideline, has never been developed in practice. With this study we will co-design an intervention to be delivered by clinical pharmacists in primary care, with people living with osteoporosis, pharmacists, GPs, osteoporosis specialists and service commissioners. The intervention will be person-centred, encompassing addressing the wider beliefs and concerns that are important to individuals to promote adherence, whilst also addressing other outcomes related to medicines optimisation, including safety and efficacy.

This study builds on two existing research studies in this area. First, we (AS/RH/IM/ZP) have published a rapid realist review of medicines optimisation interventions on behalf of the Royal Osteoporosis Society (ROS) Bone Research Academy; this focused on the interventions, contextual factors and mechanisms that support people with osteoporosis in taking (including adhering to) medications. (23) This rapid realist review identified i) that pharmacists appear to be the professional group most suited to further supporting patients on osteoporosis medicines, ii) the importance of supporting patient informed decision making throughout treatment and iii) candidate pharmacy interventions which have proved clinically and cost effective in other healthcare settings.

Second, the Improving update of Fracture Prevention Treatments (iFraP) study (funded by Royal Osteoporosis Society ROS/National Institute for Health and Care Research NIHR) has already developed a package of resources, underpinned by the evidence and theory in the NICE guidelines for medicines adherence, to help Fracture Liaison Service (FLS) clinicians discuss scientific information about osteoporosis and its treatments with patients, using evidenced health literacy and risk communication techniques, to support shared decision-making about medicines. (24) This study has already conducted an evidence synthesis to generate content for consultation resources, including clinician training and a web-based decision support tool in the context of FLS. The iFraP decision support tool and clinician training have been developed and undergone testing but need adaptation to be used with pharmacists (rather than FLS clinicians) and for a follow up context.

In this project, we will use what we have learned from the rapid realist review to develop an intervention that is grounded in evidence and fit for application and implementation in a UK

NHS context. This rapid realist review has produced key questions which will be explored as part of this project; including exploration of when pharmacists should see patients i.e., at initiation and/or follow up, whether consultations should be patient or clinician initiated, and tailored or generic. Further questions include what training needs are required for pharmacists to deliver the clinical consult, and what are the barriers and facilitators to conducting a consult and integrating this into practice. Our study will also map findings to key implementation science theories as articulated below to develop a sustainable model of care.

### **Underpinning theories**

Complex intervention development frameworks identify four phases of complex intervention including development of the intervention and emphasise the importance of understanding context, working with stakeholders in a dynamic iterative process. (25) In line with complex intervention development, the initial stages of exploring where and when the intervention will be delivered, alongside understanding key barriers to, and facilitators of, wider implementation and pharmacist training needs are key to long-term success. (26) This study therefore addresses key developmental work needed in order to design and implement such an intervention in line with the Medical Research Council guidance on complex intervention development. (27) The pharmacist intervention will, like iFraP, use the Perceptions and Practicalities Approach (PAPA) as the overarching theoretical framework, to ensure that the intervention is designed to understand patient's attitudes and beliefs that underpin non-adherence. The implementation element of the intervention will be informed by the Theoretical Domains Framework (TDF); (28) this is an overarching framework comprised of 14 domains, integrating constructs from multiple theories relating to health behaviour change. Developing a new intervention and changing current practice requires changes in behaviours of the relevant actors and mapping data to the TDF will enable a deeper understanding of implementation issues. Normalisation Process Theory (NPT) will also underpin the exploration and understanding of the dynamics of implementing, embedding, and integrating a new complex intervention. (29)

## **AIMS AND OBJECTIVES**

The overarching aim is to co-design a clinical pharmacist-led intervention to support medicines optimisation for people with osteoporosis that is designed to consider individual patient beliefs and address concerns about medicines. This will include mapping the model of care process/pathway, intervention content, and training for pharmacists.

Following this initial developmental project grant the team plan to seek further funding to undertake a pilot and feasibility study, randomised controlled trial (RCT) and economic evaluation of the intervention.

Study objectives:

1. To investigate current pharmacist practice related to osteoporosis care, exploring barriers and facilitators as well as patients' attitudes, perceptions and acceptance towards a pharmacist-led intervention.
2. To co-design the content and model of care for the pharmacist intervention, with Patient and Public Involvement and Engagement (PPIE) and including stakeholder groups (pharmacists, patients, GPs, osteoporosis specialists and service commissioners) informed by our prior development work, the existing iFraP intervention, theory, and qualitative research.
3. To conduct cycles of in-practice testing to refine the model intervention in advance of further funding applications for a full clinical and economic evaluation.

## METHODS AND ANALYSIS

**Pre-project** – the team will meet at start-up with stakeholders and the PPIE group to identify key learning from the ROS Bone Academy realist review. Where required further brief evidence synthesis will be undertaken of key papers in the review of existing pharmacy interventions to summarise key components of existing interventions using the template for intervention description and replication (TIDieR) checklist. (30) This checklist summarises key intervention information about who, where, when, what and why.

We will use this information (about existing successful interventions) as a starting point to inform focus group topic guides, identify key questions for the clinical pharmacist consult, including what would need to be adapted for UK primary care context and which components could be addressed using iFraP.

Planned project start and end dates are April 2023 – February 2025.

### **Work Package 1 – Focus Groups: exploring current clinical practice and context, the barriers and facilitators to change, and pharmacist training needs; study objectives 1 and 2.**

**Participants:** A series of focus groups (up to seven in total) will be held with patients prescribed oral bisphosphonates, clinical pharmacists, GPs, osteoporosis specialists, and service designers/commissioners involved with integrated care systems. Focus groups will consist of 5-8 participants.

**Recruitment of clinicians and patients from GP practices** will be facilitated by the National Institute for Health and Care Research Clinical Research Network North East and North Cumbria (NIHR NENC CRN) and service commissioners through the North of England Commissioning Support (NECS) (via SH); patient inclusion criteria will include current treatment with oral bisphosphonates and capacity to consent. An initial maximal variation sampling strategy will be adopted, with purposive sampling as appropriate to recruit patients with different characteristics and to include patients from underserved groups; this will include, age, gender, ethnicity, existence of co-morbidities and time since initiation of medicines. Osteoporosis specialists will be recruited via professional networks and the ROS.

**Focus group process:** Focus groups will be held face-to-face or virtually (MS Teams) allowing participants choice in method of participation, whilst virtual options mitigating against any future COVID-19 disruption and facilitating recruitment from a wide geographical area. Initial topic guides will be developed and informed by the overarching theories, rapid realist review, findings of the iFraP study, PPIE group and other stakeholders; this will include an exploration of current practices, views about the pharmacy intervention and the components identified in the pre-project evidence synthesis, perceived barriers/facilitators, and training needs for pharmacists e.g., in relation to shared decision making, and risk communication (see supplementary files). The semi-structured nature will facilitate exploration of concepts that develop during the focus group.

**Analysis:** Focus groups will be audio recorded and transcribed verbatim. Data will be analysed by (MG) with salient themes discussed, developed, and refined by the team and PPIE group. Framework analysis will provide a transparent and structured approach to the analysis of data. (31) Following the initial identification and prioritisation of salient themes a deductive process will be undertaken mapping themes to both the TDF and NPT, providing a critical lens through which greater depth of understanding of current practice, and barriers and facilitators to implementation and further investigation will be identified. (32) Findings will be discussed and refined by the project team and PPIE group.



**Work Package 2 – Co-design of the pharmacist intervention, adaptation of iFraP, and in-practice testing; study objectives 3 and 4.**

We will use co-design workshops with our stakeholder and PPIE group to build on the learning from the qualitative research in WP1 to: (1) further develop the model of care, process and pathway for the new intervention; including a focus on who, how and when patients will be able to access, be identified, or referred to, the intervention, and how this feeds back into current care pathways; (2) adapt and develop the content of the iFraP programme to fit the new context, including training and resources to support; (3) test and refine the intervention in practice with co-design workshops and in-practice testing leading to the iterative development and refinement.

Up to six workshops will be held with a mixed group of PPIE and clinical stakeholders. The first workshops will be held before the intervention is tested in-practice, with final workshops after in-practice testing is complete (see timeline appendix 1).

Workshops will be held face-to-face and virtually (see rationale in WP1). Initial workshops will focus on developing both the model of care process/pathway, including for example, how people would be identified, when/where the intervention will take place and how results will be communicated with the patient's GP. Subsequent workshops will focus on co-designing the content of the review and training for pharmacists; including reviewing and adapting content from the iFraP intervention to produce the model pharmacist consultation, which will then be further refined following in-practice testing. The final workshops will take place after in-practice testing as discussed below.

**In-practice testing:**

The content and prototype of the intervention, including pharmacists training and adapted decision support tools from the iFraP programme will be developed and the intervention will then be refined through 'in-practice' testing with patients and pharmacists.

**Design:** We will conduct an iterative process of intervention testing and refinement, with testing at GP sites in the North East of England. Site recruitment will be facilitated through the NIHR NENC CRN/NECS. Up to three pharmacists delivering the intervention will attend a training session with the research team before patients are recruited.

**Participants:** Participants (n= approx.10) will be recruited from the GP practice sites with the pharmacist conducting the intervention. Findings from WP1 and initial co-design workshops will inform the recruitment process, although this is anticipated to be undertaken by a search of medical records to identify patients recently started on oral bisphosphonates, who will then be invited to receive the intervention and participate in the study.

**Data collection and analysis:** With informed consent, patients will participate in the model intervention and evaluation, which will be observed and audio-recorded, followed by a 1-1 semi-structured interview with the researcher to allow participants to share their views. After the in-practice testing, interviews will also be conducted with the pharmacist, to explore their views and opinions on the intervention and explore potential implementation issues. Data will be analysed using the same approach described in WP1.

**Co-design Workshop**

The final co-design workshop with PPIE and stakeholder groups will review the findings of the in-practice testing and will refine the intervention to produce the final model that will be

ready for subsequent full evaluation in a proposed follow up pilot and feasibility RCT and economic evaluation.

### **Patient and Public Involvement and Engagement**

Patient involvement in the development of this work was provided at a workshop for patients with osteoporosis (n=6) from the University of Sunderland PPIE group in line with the UK Standards for Public Involvement. The aim was to obtain views on the aims, design, ethical considerations and ongoing PPIE plan.

Further PPIE work was undertaken with lay summaries reviewed by the NIHR NENC Consumer Panel. The recently published realist review integrated patient and public involvement through the ROS Bone Research Academy Effectiveness Working Group with three patient advocates contributing to a meeting, alongside members of the group to discuss and refine the findings of the review and the implications of these for clinical practice and future research. Two of the patient advocates joined the project team as patient co-applicants on this project, independent of their advocacy role with ROS. A further PPIE member joined the group and all will attend quarterly PPIE meetings and project management meetings, co-author outputs, be responsible for reviewing patient facing study resources/documentation, advising on emerging findings and dissemination strategy.

### **ETHICS AND DISSEMINATION:**

Ethics approval for the work outlined in this protocol was sought and obtained NHS North West - Greater Manchester South Research Ethics Committee (Ref 23/NW/0199).

The final output from this study will be the draft pharmacist intervention, including intervention content, manual and training package. The team will seek further funding to undertake a formal pilot and feasibility RCT and economic evaluation.

The team will work with the study PPIE group and the ROS on dissemination plans and next steps. Dissemination and knowledge mobilisation will be facilitated through national bodies and networks such as the ROS, journal papers and conference presentations.

### **Author Contributions:**

AS conceived the study. AS, MG, LB, EC, TF, SH, TH, RH, CP, LS, IM, ZP reviewed the study design and contributed to study implementation as part of the Study Management Group. MG will undertake all qualitative data collection and analysis, supported by AS and all other authors. All authors contributed to refinement of the study protocol and approved the final manuscript.

Andrew Sturrock is the guarantor.

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### **Competing interests:**

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