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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

Andrew Sturrock,[1,2] Meaghan Grabrovaz ,[3] Laurna Bullock ,[4] Emma Clark,[5] Tracy Finch,[6] Shona Haining,[7] Toby Helliwell ,[8] Robert Horne,[9] Robin Hyde,[10] Ian Maidment ,[11] Claire Pryor ,[12] Louise Statham ,[13] Zoe Paskins [14]

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For numbered affiliations see end of article.

Correspondence to
Dr Meaghan Grabrovaz; meaghan.grabrovaz@northumbria.ac.uk

ABSTRACT

Introduction Adherence to medicines in osteoporosis is poor, with estimated 1 year persistence rates between 16% and 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 the 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 the 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, general practitioners, 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.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The project will draw on extensive evidence and empirical qualitative work with the perceptions and practicalities approach 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 and normalisation process theory; 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, more 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 the first-line therapy and are inexpensive, cost-effective and readily available.[4]

Medicine 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 1 year persistence rates of between 16% and 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', including 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 the 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 and unmet information needs, all of which are compounded by the absence of feedback and monitoring with osteoporosis care.[10–12] 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.[13–15]

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 the 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 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 medicine adherence guideline provides a framework for encouraging adherence through supporting and involving patients in decisions about the treatment.[21] This is based on the Necessity Concerns Framework, which describes adherence as a construct of patients perceived need for medications (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, general practitioners (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 while also addressing other outcomes related to medicine 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 medicine 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 patients' informed decision-making throughout treatment and (iii) candidate pharmacy interventions which have been proven clinically and cost-effective in other healthcare settings.

Second, the Improving update of Fracture Prevention Treatments (iFraP) study, funded by 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 medicine 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 learnt 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 that is, at the 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 the development of the intervention and emphasise the importance of understanding the 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 the 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 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 behavioural change. Developing a new intervention and changing the current practice requires behavioural changes of the relevant actors and mapping data to the TDF will enable a deeper understanding of implementation issues. The 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 medicine 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 pharmacist training.

Following this initial developmental project grant, the team plans 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 a start-up with stakeholders and the PPIE group to identify key learning from the ROS Bone Academy realist review. As 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 the UK primary care context and which components could be addressed using iFraP.

The planned project start and end dates are April 2023 to February 2025, respectively.

Work package 1 for 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 five to eight participants.

Recruitment of clinicians and patients from GP practices will be facilitated by the NIHR Clinical Research Network North East and North Cumbria (CRN NENC) and service commissioners through the North of England Commissioning Support (NECS) (via SH); patient inclusion criteria will include the 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 comorbidities 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 to choose the method of participation, while virtual options mitigate against any future COVID-19 disruption and facilitate 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, for example, in relation to shared decision-making and risk communication (see online supplemental files). The semi-structured nature will facilitate the 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 to map themes to both the TDF and NPT, providing a critical lens through which greater depth of understanding of current practice, 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; and (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.

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 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 pharmacist 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=approx0.10) 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.

PPIE

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 their implications 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 and be responsible for reviewing patients 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 by 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 affiliations
[1]NHS Education for Scotland, Edinburgh, UK
[2]University of Strathclyde, Glasgow, UK
[3]Nursing, Midwifery and Health, Northumbria University, Newcastle, UK
[4]Keele University, Stoke on Trent, UK
[5]Clinical Science at North Bristol, University of Bristol, Bristol, UK
[6]Nursing, Midwifery and Health, Northumbria University, Newcastle upon Tyne, UK
[7]NHS North of England Commissioning Support Unit, Durham, UK
[8]Research Institute for Primary Care and Health Sciences, Keele University, Keele, UK
[9]University College London, London, UK
[10]Northumbria University, Newcastle upon Tyne, UK
[11]Pharmacy, Aston University, Birmingham, UK
[12]School of Health & Society, University of Salford, Salford, UK
[13]University of Sunderland School of Pharmacy and Pharmaceutical Sciences, Sunderland, UK
[14]Arthritis Research UK Primary Care Centre, Research Institute for Primary Care & Health Sciences, Keele University, Keele, UK

X Tracy Finch @TracyLFinch and Ian Maidment @maidment_dr

Contributors AS conceived the study. AS, MG, LB, EC, TF, SH, TH, RHo, RHy, IM, CP, LS and 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 and be supported by AS and all other authors. All authors contributed to the refinement of the study protocol and approved the final manuscript. AS is the guarantor.

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Patient and public involvement Patients and/or the public were involved in the design, conduct, reporting or dissemination plans of this research. Refer to the Methods section for further details.

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ORCID iDs
Meaghan Grabrovaz http://orcid.org/0000-0002-0309-2890
Laurna Bullock http://orcid.org/0000-0002-4193-1835
Toby Helliwell http://orcid.org/0000-0003-3987-6045
Ian Maidment http://orcid.org/0000-0003-4152-9704
Claire Pryor http://orcid.org/0000-0003-0766-1357

Louise Statham http://orcid.org/0000-0002-4823-2295
Zoe Paskins http://orcid.org/0000-0002-7783-2986

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PHORM: The development and co-design of a (person-centred) primary care (clinical) pharmacist led osteoporosis review for optimising medicines

PHARMACIST FOCUS GROUP TOPIC GUIDE

Housekeeping

- Welcome and introductions
- Informed consent /& consent to audio record
- Payment expenses
- Ground rules (confidentiality, talk one at a time, respect each other's point of view)
- **Stress that there are no right or wrong answers**

Introduction

- You've all been invited here as pharmacists because we are developing a new model consultation to be delivered in primary care to support follow up and medicines optimisation with fracture prevention medication.
- We would like your thoughts and views on developing the intervention content, process/model of care, and training for pharmacists to deliver.

Lets start by exploring your role as a pharmacists in GP practices

- Can you share your experience of integrating into the GP practice team?
  - What things work well?
  - What things do not work well?
- What is your patient's understanding of GP pharmacists within your practice?
  - What are your experiences of GPs and patients confidence and trust in your decision making
- How are patients identified and/or referred to you?
- Do you make autonomous clinical decisions?
  - Around initiating medications and/or stopping medications
  - How is this communicated with the GP or wider care team?

Let's now explore your role current role as a pharmacist in prescribing and following up people prescribed fracture prevention medication

- Do you work specifically in an osteoporosis context in your practice or part of wider multimorbidity/polypharmacy work?
  - How does this fit with structured medication reviews?
- How do you see your role in fracture prevention?
- How does your role compare to GP, and those working in Fracture Liaison Services or other specialist roles?
- Whose role is it to discuss fracture prevention medication?
- Do you calculate fracture risk?
- If so, do you explain to patients their risk of possible broken bones in the future?

This study is funded by the Royal Osteoporosis Society (Ref 505)

- How? {what words? simple frequencies? pictures, graphs?}.
- How do you explain bone density scan results to your patients?

- How do you describe osteoporosis to your patients? Why do you describe it that way?
- What do you tell patients about the benefits and side effects of osteoporosis medications?
- Do you ever feel uncertain about whether osteoporosis medicine is needed or not?
- In what circumstance/why? What would help?
- How do you decide which osteoporosis drug treatment is most appropriate?
- Do you involve the patient in that decision?
- What does this choice include? {does it include alternative treatment? IV? HRT?}
- At what point {when} do you offer the patient a choice? {when treatment is indicated? only after first line is no longer appropriate?}
- Do you think that patients want a choice?
- Do you talk to the patient about lifestyle choices?
- If yes, how do these choices fit alongside osteoporosis medicines (is it an alternative or addition to medicines)?
- What are the training needs for pharmacists in this context?

Follow up

- After initiating fracture prevention medication how do you follow patients up? Or do you follow up patients after initiated by another clinician e.g., GP/FLS etc
  - When, how, who?
  - Does follow up focus specifically on osteoporosis and fracture prevention medication or is this a more holistic approach to follow up? Multimorbidity and polypharmacy etc?
  - What sort of questions, information needs, support do you find patients need on follow up?
  - How do you follow up patients initiated on medications by FLS or other specialists?
- Do you refer patients to other members of the team for follow up?
  - Who, when, how etc?

The PHORM Intervention

- What do you think is most important to include in this consultation?
- How do you see this fitting into existing practices?
  - How/who would identify and refer patients for this?
  - When should it take place? How frequently?
  - What information needs to be communicated back to the wider GP practice team

Demonstration of iFRAP computer decision support tool – Guide participants through tool

- Does the tool **make sense** to you? What does the term decision tool or decision aid mean to you?
- How would you **feel** about this tool being used to guide conversation with the patient when discussing osteoporosis medicines?
  - What are your thoughts?

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    - Are there any parts which you don't think are suitable for the pharmacist consultation?
- Do you feel confident that you and the patient could use this tool to discuss osteoporosis medicines?
- What problems do you think might occur when using the tool? What could help to overcome those problems?
- What additional experience or expertise might the pharmacist need to use the decision aid? Why?
- What additional skills might pharmacists need to use the decision aid? Why?

Closing Questions

- Do you think this tool and consultation would also be suitable for nurses to deliver in GP practice?
- Do you think this tool and consultation would also be suitable for community pharmacists to deliver?
    - Why, would what need to change?
    - Any other problems that would need to be addressed to use this ina community pharmacy?
- Is there anything else you would like to discuss.

Closing statement: On behalf of the research team and Northumbria University I would like to "Thank you" for participating in the PHORM patient focus group and for taking the time to share with us your views today.

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PHORM: The development and co-design of a (person-centred) primary care (clinical) pharmacist led osteoporosis review for optimising medicines

PATIENT FOCUS GROUP TOPIC GUIDE

Housekeeping

- Welcome and introductions
- Fire alarm and toilets (F2F only)
- Informed consent /& consent to audio record
- Payment travel expenses
- Ground rules (confidentiality, talk one at a time, respect each other's point of view)
- Collect demographics of participants
- **Stress that there are no right or wrong answers**

Introduction

- You've all been invited here because you have recently been started on fracture prevention medication. We are interested to find out more about your experiences when starting this medication and/or being followed up after starting.
- We would also like your thoughts, views, and feelings about any consultations you have had with pharmacists working in GP practices and the development of a new 'model consultation' to support follow up after starting fracture prevention medication that we are developing for pharmacists to deliver in GP practices.

Background questions related to initiation on fracture prevention medication

So first, we are going to explore your experiences of being started on fracture prevention medication.

- Was this done in primary care or in a hospital or specialist setting?
    - Who started it?
- What were you expecting from the appointment? Did the appointment meet your expectations?
- Do you feel that the health professional (who might have been a GP, consultant, nurse or pharmacist) explored what was important to you? How?
- Did the health professional provide you with enough information?
- Did you have unanswered questions/confusion/uncertainties?
    - During or immediately after the consultation
    - At some point following the consultation.
    - What were these unanswered questions/confusions/uncertainties?
    - What information or support did you want after starting on these medications?

Since being prescribed these medicines have you discussed these with any other healthcare professional?

- Have you discussed the recommendations with anyone else? {dentists, family, friends, helpline?}
- Did it change how you felt about medicines, why? why not?

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Background questions related to thoughts, views, and feelings about any consultations you have had with pharmacists working in GP practices.

- Did the pharmacist explain the purpose of the appointment to you?
- What were you expecting from these appointments? Did the appointment meet your expectations?
- Do you feel that the pharmacist explored what was important to you? How?
- Do you understand the different role of pharmacists working within GP practices compared to in a community pharmacy?
    - Was this explained to you?
    - Are your expectations for appointments different between the two?
- Did you feel confident and trusting in the pharmacist's advice and decisions?
    - What influenced your confidence/trust?
    - Do you still feel confident?

Questions for those that have seen the GP practice pharmacist for discussions on fracture prevention medication.

- What information were you given about osteoporosis medicines? (recommended/mentioned?)
- Did the pharmacist suggest there were medicine options? Which?
- Did you feel as though you had a choice of medicines? What made you feel this way?
- Would you have liked a choice?
- Did the pharmacist explain why osteoporosis medicine was important? (consequences)
- What did the pharmacist tell you about the benefits and side effects of the medicines?
    - How did you feel about this explanation?
- Did you feel confident about your decision to take, or not to take osteoporosis medicines?
    - What influenced your confidence?
    - Do you still feel confident?
- Did the pharmacist talk about lifestyle choices? For example: exercise, diet, smoking or drinking alcohol?
    - How did you feel about these choices?
    - Did you feel that lifestyle changes were an alternative to osteoporosis medicine or something to do alongside taking medicine?
- Did you have unanswered questions/confusion/ uncertainties?
- Since your appointment, have you discussed the recommendations with your GP or other healthcare professionals?
- Have you discussed the recommendations with anyone else? {dentists, family, friends, helpline?}
- Did it change how you felt about medicines, why? why not?

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PHORM Intervention:

Now we will discuss a new model consultation. A model consultation is a type of structured format (almost a script) for health professionals to use in appointments with patients to talk about their treatment options and helps them to remember to cover everything that might be helpful. Our aim is to support people with osteoporosis to take the medicine that is right for them and to take it in the way that works best for them. We want to make sure the consultation considers individual patient beliefs and address concerns about treatment. We want to make sure the new appointment is focused on what is important for the patient.

We are developing two things:

1) **training** for **pharmacists**
2) a **model consultation** that may use a **computer-based tool** that can be used to **guide** the consultation (which I will show you examples of in a minute).

- Thinking about when you started the fracture prevention medication at what point in time do you think you would have most benefited from an additional follow up consultation?
    - How would you suggest people are identified and invited to this consultation?
- What would you expect a follow up consultation with a pharmacist to include?
    - What would be important for you to discuss?
    - What would make you trust and have confidence in any recommendations made?
- From your experiences with GP practice pharmacists can you think of any additional training that might help them to better support people like you?

Demonstration of iFRAP computer decision support tool – Guide participants through tool

- Does the tool **make sense** to you? What does the term decision tool or decision aid mean to you?
- If this had been used in your appointments, how would it have changed the way you feel about osteoporosis medicines?
    - Is this tool suitable for both initiation (first appointment) and at follow up appointments?
- How would you **feel** about this tool being used to guide your conversation with the pharmacist to discuss osteoporosis medicines?
    - What are your thoughts?
    - Are there any parts which you don't think are suitable for the pharmacist consultation?
- Do you feel **confident** that you and the pharmacist could use this tool to discuss osteoporosis medicines?
- What **problems** do you think might occur when using the tool? What could **help** to overcome those problems?

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Closing Questions

- Do you think this tool and consultation would also be suitable for nurses to deliver in GP practice?
- Do you think this tool and consultation would also be suitable for community pharmacists to deliver?
    - Why, would what need to change?
    - Any other problems that would need to be addressed to use this ina community pharmacy?
- Is there anything else you would like to discuss.

Closing statement: On behalf of the research team and Northumbria University I would like to "Thank you" for participating in the PHORM patient focus group and for taking the time to share with us your views today

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PHORM: The development and co-design of a (person-centred) primary care (clinical) pharmacist led osteoporosis review for optimising medicines

GP FOCUS GROUP TOPIC GUIDE

Housekeeping

- Welcome and introductions
- Informed consent /& consent to audio record
- Payment expenses
- Ground rules (confidentiality, talk one at a time, respect each other's point of view

Stress that there are no right or wrong answers

Introduction

- You've all been invited here as GPs because we are developing a new model consultation to be delivered in primary care to support follow up and medicines optimisation with fracture prevention medication.
- We would like your thoughts and views on developing the intervention content, process/model of care, and training for pharmacists to deliver.

Let's start by exploring your role as a GP in prescribing and following up people prescribed fracture prevention medication

- How do you see your role in fracture prevention?
- How does your role compare to those working in Fracture Liaison Services or other specialist roles?
- Whose role is it to discuss fracture prevention medication?
- Do you calculate fracture risk?
- If so, do you explain to patients their risk of possible broken bones in the future?
    - How? {what words? simple frequencies? pictures, graphs?}.
    - How do you explain bone density scan results to your patients?
- How do you describe osteoporosis to your patients? Why do you describe it that way?
- What do you tell patients about the benefits and side effects of osteoporosis medications?
- Do you ever feel uncertain about whether osteoporosis medicine is needed or not?
- In what circumstance/why? What would help?
- How do you decide which osteoporosis drug treatment is most appropriate?
- Do you involve the patient in that decision?
- What does this choice include? {does it include alternative treatment? IV? HRT?}

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- At what point {when} do you offer the patient a choice? {when treatment is indicated? only after first line is no longer appropriate?}
- Do you think that patients want a choice?
- Do you talk to the patient about **lifestyle choices?**
- **If yes,** how do these choices fit alongside osteoporosis medicines (is it an alternative or addition to medicines)?

Follow up

- After initiating fracture prevention medication how do you follow patients up?
    - When, how, who?
    - Does follow up focus specifically on osteoporosis and fracture prevention medication or is this a more holistic approach to follow up? Multimorbidity and polypharmacy etc?
    - What sort of questions, information needs, support do you find patients need on follow up?
    - How do you follow up patients initiated on medications by FLS or other specialists?
- Do you refer patients to other members of the team for follow up?
    - Who, when, how etc?

Now we are going to focus on your views of pharmacists in GP practices

- Can you share your experience of integrating pharmacists into the team?
    - What things do they do well?
    - What things do they not do well?
- What is patient's understanding of GP pharmacists within your practice?
    - What is your confidence and patients' confidence and trust in their decision making
- How do you identify and/or refer patients to the GP practice pharmacist?
- Are they supported to make autonomous clinical decision?
    - Around initiating medications and/or stopping medications
    - How is this communicated?
- Do the pharmacists work specifically in osteoporosis in your practice?
    - How does this fit with structured medication reviews?
- What are the training needs for pharmacists in this context?

The PHORM Intervention

- What do you think is most important to include in this consultation?
- How do you see this fitting into existing practices?
    - How/who would identify and refer patients for this?
    - When should it take place? How frequently?
    - What information would you want to see back as the GP
- We've had suggestions that a drug counselling checklist would be helpful, - if you were designing this what would it include?

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Demonstration of iFRAP computer decision support tool – Guide participants through tool

- What do you think of this decision tool?
- Does the tool **make sense** to you? What does the term decision tool or decision aid mean to you?
- How would you **feel** about this tool being used to guide conversation between the pharmacist and patient when discussing osteoporosis medicines?
    - What are your thoughts?
    - Are there any parts which you don't think are suitable for the pharmacist consultation?
- Do you feel **confident** that you and the pharmacist could use this tool to discuss osteoporosis medicines?
- What **problems** do you think might occur when using the tool? What could **help** to overcome those problems?
- What additional **experience or expertise** might the pharmacist need to use the decision aid? **Why?**
- What additional **skills** might the pharmacist need to use the decision aid? **Why?**

Closing Questions

- Do you think this tool and consultation would also be suitable for nurses to deliver in GP practice?
- Do you think this tool and consultation would also be suitable for community pharmacists to deliver?
    - Why, would what need to change?
    - Any other problems that would need to be addressed to use this ina community pharmacy?
- Is there anything else you would like to discuss.

Closing statement: On behalf of the research team and Northumbria University I would like to "Thank you" for participating in the PHORM patient focus group and for taking the time to share with us your views today.

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PHORM: The development and co-design of a (person-centred) primary care (clinical) pharmacist led osteoporosis review for optimising medicines

SPECIALISRS FOCUS GROUP TOPIC GUIDE

Housekeeping

- Welcome and introductions
- Informed consent /& consent to audio record
- Payment expenses
- Ground rules (confidentiality, talk one at a time, respect each other's point of view)
- **Stress that there are no right or wrong answers**

Introduction

- You've all been invited here as osteoporosis specialist clinicians because we are developing a new model consultation to be delivered in primary care to support follow up and medicines optimisation with fracture prevention medication.
- We would like your thoughts and views on developing the intervention content, process/model of care, and training for pharmacists to deliver.

Let's start by exploring your role as a specialist in prescribing and following up people prescribed fracture prevention medication

- How do you see your role in fracture prevention?
- How does your role compare to those working in primary care/GP roles
- Whose role is it to discuss fracture prevention medication?
- Do you calculate fracture risk?
- If so, do you explain to patients their risk of possible broken bones in the future?
  - How? {what words? simple frequencies? pictures, graphs?}.
  - How do you explain bone density scan results to your patients?
- How do you describe osteoporosis to your patients? Why do you describe it that way?
- What do you tell patients about the benefits and side effects of osteoporosis medications?
- Do you ever feel uncertain about whether osteoporosis medicine is needed or not?
- In what circumstance/why? What would help?
- How do you decide which osteoporosis drug treatment is most appropriate?
- Do you involve the patient in that decision?
- What does this choice include? {does it include alternative treatment? IV? HRT?}
- At what point {when} do you offer the patient a choice? {when treatment is indicated? only after first line is no longer appropriate?}
- Do you think that patients want a choice?
- Do you talk to the patient about **lifestyle choices?**

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- **If yes,** how do these choices fit alongside osteoporosis medicines (is it an alternative or addition to medicines)?

Follow up

- After initiating fracture prevention medication how do you follow patients up?
    - When, how, who?
    - Does follow up focus specifically on osteoporosis and fracture prevention medication or is this a more holistic approach to follow up? Multimorbidity and polypharmacy etc?
    - What sort of questions, information needs, support do you find patients need on follow up?
- Do you refer patients to other members of the team for follow up?
    - Who, when, how etc?

Now we are going to focus on your views of pharmacists in GP practices

- Can you share your experience of working with pharmacists in primary care team?
    - What things do they do well?
    - What things do they not do well?
    - What is your confidence and patients confidence and trust in their decision making
- How do you identify and/or refer patients to the GP practice pharmacist?
- What are the training needs for pharmacists in this context?

The PHORM Intervention

- What do you think is most important to include in this consultation?
- How do you see this fitting into existing practices?
    - How/who would identify and refer patients for this?
    - When should it take place? How frequently?
    - What information would you want to see back as the GP

Demonstration of iFRAP computer decision support tool – Guide participants through tool

- Does the tool **make sense** to you? What does the term decision tool or decision aid mean to you?
- How would you **feel** about this tool being used to guide the conversation between the pharmacist and patient when discussing osteoporosis medicines?
    - What are your thoughts?
    - Are there any parts which you don't think are suitable for the pharmacist consultation?
- Do you feel **confident** that you and the pharmacist could use this tool to discuss osteoporosis medicines?
- What **problems** do you think might occur when using the tool? What could **help** to overcome those problems?
- What additional **experience or expertise** might the pharmacist need to use the decision aid? **Why?**
- What additional **skills** might the pharmacist need to use the decision aid? **Why?**

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Closing Questions

- Do you think this tool and consultation would also be suitable for nurses to deliver in GP practice?
- Do you think this tool and consultation would also be suitable for community pharmacists to deliver?
    - Why, would what need to change?
    - Any other problems that would need to be addressed to use this ina community pharmacy?
- Is there anything else you would like to discuss.

Closing statement: On behalf of the research team and Northumbria University I would like to "Thank you" for participating in the PHORM patient focus group and for taking the time to share with us your views today.

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PHORM: The development and co-design of a (person-centred) primary care (clinical) pharmacist led osteoporosis review for optimising medicines

SERVICE DESIGNERS/COMMISSIONERS FOCUS GROUP TOPIC GUIDE

Housekeeping

- Welcome and introductions
- Informed consent /& consent to audio record
- Payment expenses
- Ground rules (confidentiality, talk one at a time, respect each other's point of view)
- **Stress that there are no right or wrong answers**

Introduction

- You've all been invited here as service designers/commissioners because developing a new model consultation to be delivered in primary care to support follow up and medicines optimisation with fracture prevention medication.
- We would like your thoughts and views on developing the intervention content, process/model of care, and training for pharmacists to deliver.

Let's start by exploring your role as a service designers/commissioners in relation to developing and commissioning services using pharmacists in GP practices

- Can you share your experience of integrating pharmacists into primary care GP practice teams?
    - What things do they do well?
    - What things do they not do well?
- What things do you consider when developing services that are to be delivered by GP practice pharmacists?
    - How do you differentiate between services for GP practice pharmacists and community pharmacists?
    - What advantages do GP practice pharmacists provide?
- How do you assess the effectiveness and cost effectiveness in GP pharmacy-based services
- How do you identify training needs for pharmacists in newly commissioned services?

Current fracture prevention/osteoporosis services

- Do you currently run fracture prevention/osteoporosis specific services/interventions within your area?
    - Can you explain/elaborate on the detail
    - Do these utilise pharmacists – if so, how/why? if not, why?
- If there are no specific services
    - Why not?
    - Where does osteoporosis/fracture prevention fit in terms of wider service targets in your area?

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- What would make osteoporosis/fracture prevention a priority?

The PHORM Intervention

- What do you think is most important to include in this consultation?
- How do you see this fitting into existing services and roles?
  - How/who would identify and refer patients for this?
  - When should it take place? How frequently?
  - How could this be funded?
    - What sort of funding would this require?
    - Would this be a priority for commissioners?
      - How could it become a priority for commissioners?
    - What outcome measures would you need to see?
      - How could these be assessed to increase chances of future funding?

Closing Questions

- Do you think this model consultation would also be suitable for nurses to deliver in GP practice?
- Do you think this tool and consultation would also be suitable for community pharmacists to deliver?
  - Why, would what need to change?
  - Any other problems that would need to be addressed to use this in a community pharmacy?
- Is there anything else you would like to discuss.

Closing statement: On behalf of the research team and Northumbria University I would like to "Thank you" for participating in the PHORM patient focus group and for taking the time to share with us your views today.

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