Developing a role for patients and the public in the implementation of health and social care research evidence into practice: the PIPER study (Pathways to Implementation for Public Engagement in Research) realist evaluation protocol

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Research Involvement and Engagement

PROTOCOL

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Abstract

Background While patients and the public are routinely involved as active collaborators in health and social care research, they are rarely involved in the implementation of research. The PIPER (Pathways to Implementation for Public Engagement in Research) research questions are:

1. How can patients, carers, service users and the public be involved in the implementation of health and social care research evidence into practice?

2. What types of roles, contributions and impact can patients, carers, service users and the public make to the implementation of health and social care evidence into practice?

3. How can we support patients, service users, carers and the public to contribute to the implementation of health and social care evidence into practice?

4. How can we co-produce the knowledge that explores a greater role for patients, carers, service users and the public in the implementation of health and social care evidence into practice?

Methods Our overarching methodological framework is realist evaluation. This study includes four work packages with a cross-cutting co-production theme.

•Work Package 1: A realist review of published literature, grey literature and sources such as blogs.

•Work Package 2: Interviews with 40–60 people using a realist approach.

•Work Package 3: A series of workshops to co-design the PIPER Toolkit.

•Work Package 4: Pilot evaluation of the PIPER Toolkit.

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Results The scoping of the literature will be informed by the development of an initial programme theory that identifies the potential breadth of the field of public involvement in implementation. Data from the WP2 interviews will be used to iteratively refine the development of the context, mechanism and outcomes (CMOs). This will inform the PIPER Toolkit, which will consist of a set of *'Guiding Principles'* supported by *'Practical Resources.'* The PIPER Toolkit will enable an individual or a group to plan and undertake implementation activities. More specifically, the Guiding Principles will enable the Practical Resources to be tailored to specific implementation strategies for an individual or group.

Discussion Patient and public involvement in implementation is an emerging area of practice and is likely to significantly strengthen over the next decade. The PIPER Toolkit will recognise this early stage of development, identifying the key system enablers that organisations need to have in place to support this activity. The Toolkit will support patients and the public and implementation teams to navigate the field of implementation practice. The PIPER study will challenge the field of implementation and knowledge mobilisation research to develop clearer forms of partnership with patients and the public in both research and practice.

Keywords Patient and public involvement, Public engagement, Implementation, Knowledge mobilisation, Realist evaluation

Plain English Summary

Background Why are we doing this study?

Patients and the public are often involved in research studies about health and social care, contributing to how research is designed, conducted and shared. However, they are rarely involved in moving the research evidence into practice. This is called implementation. The PIPER (Pathways to Implementation for Public Engagement in Research) research questions are:

What we want to find out

1. How can patients, carers, service users and the public be involved in the implementation of health and social care research evidence into practice?

2. What types of roles, contributions and impact can patients, carers, service users and the public make to the implementation of health and social care evidence into practice?

3. How can we support patients, service users, carers and the public to contribute to the implementation of health and social care evidence into practice?

4. How can we co-produce the knowledge that explores a greater role for patients, carers, service users and the public in the implementation of health and social care evidence into practice?

Methods What we plan to do

We plan to use a research approach (realist evaluation) that focuses on finding out what works, for whom, why and in what way, in four work packages:

- Work Package 1: We will review relevant research and sources of knowledge including both peer-reviewed and grey literature.
- Work Package 2: We will interview 40-60 people with either experience of or interest in PPIE in implementation.
- Work Package 3: We will use a series of workshops to co-design the PIPER Toolkit, a set of resources, which will help with PPIE in implementation.
- Work Package 4: We will pilot the PIPER Toolkit to make sure it works.

Results The initial review of literature helped early mapping to identify the potential breadth of the field of public involvement in implementation. This will inform the PIPER Toolkit. PIPER will consist of a set of *'Guiding Principles'* supported by *'Practical Resources'* that will help an individual or a group to get involved in implementation activity.

Discussion What we aim to achieve

Patient and public involvement in implementation, rather than in research is new and is likely to evolve in the future. The PIPER Toolkit will support patients and the public who wish to be involved in implementation and individuals who are involved in moving research findings into practice. It will also help organisations understand what needs to be in place to support patient and public involvement in implementation.

Background

The potential for the public to enhance the implementation of health and social care evidence into practice is a key gap in our evidence base. Over the last two decades, our understanding of the contribution and impact of public involvement in health and social care research has grown internationally [1–5]. However, this progress has not generally been reflected in the field of implementation research and practice and there are few resources around to enable this. This is a large, complex, theoretically diverse body of literature. It has predominantly focused on studying approaches or strategies that close the gap between evidence and practice, which is vital for high quality, effective and acceptable services [6–11].

The involvement of people, whether they are patients, public contributors, or service users, has become increasingly important in health and social care research and service provision. Terms are used differently with health using 'patient,' or 'public; commonly, while social care has used 'people who draw on care and support'. We use the term 'public involvement' to include people involved in health and social care research and practice [1]. While many studies have explored the role of health professionals in implementation, few have considered the potential for the public to create transformative change in how evidence is put into practice [7, 8, 10–17]. The importance of exploring the potential public role in implementation [18–21] was highlighted by Burton and Rycroft-Malone [16] who stated patient and public involvement has potential significance to change the debate and practice, but "as yet this resource remains largely untapped." As one public contributor involved with the development of this project stated,

> *"Whether a piece of evidence gets used in practice or not can have a huge impact on my well-being and quality of life. I want to make sure there are opportunities for me to work with health care professionals to make sure things change when they need to, for me and for others."*

This study will be undertaken at a pivotal point in the emerging field of public involvement in implementation and will add new knowledge to understanding of the role the public can take in implementation activities of health and social care evidence into practice [22] and transform that knowledge into practical guidance and resources that lead to practice change. The potential for evidence to be implemented also depends on the mobilisation of knowledge to the right place. We will use the National Institute of Health Research (NIHR) definition of involvement developed by INVOLVE as research "carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them." This reflects a more active focus compared to engagement, which often involves researchers presenting their findings, and participation where patients are subjects of research, for example, participants in a clinical trial [23].

As Burton and Rycroft-Malone [16] highlight, *"co-production has the greatest potential to provide a new ontological platform with which to progress the ambition of (patient and) public involvement in implementation."* Based on our initial theorisation, we view the potential for involvement according to key conceptual levels of patient as supporter, patient as partner or co-leader, and patient as leader of the implementation activity. These levels could operate at an individual level, an institutional or collective level or at a broader health system level. We use this initial conceptualisation to inform the research questions, which are:

1. How can patients, carers, service users and the public be involved in the implementation of health and social care research evidence into practice?
2. What types of roles, contributions and impact can patients, carers, service users and the public make to the implementation of health and social care evidence into practice?
3. How can we support patients, service users, carers and the public to contribute to the implementation of health and social care evidence into practice?
4. How can we co-produce the knowledge that explores a greater role for patients, carers, service users and the public in the implementation of health and social care evidence into practice?

Based on the research questions, we identified the following research objectives:

1. To co-produce theories of how, why, in what context, and with what impact, patients, service users, carers and the public can be involved in the process of implementation of evidence into health and social care practice.
2. To co-produce the Pathways to Implementation for Public Engagement in Research (PIPER) Toolkit (to include guiding principles, recommendations and practical resources) to guide best practice in how patients and the public are involved in implementation of evidence into practice, that consider scalability (expansion within a broadly similar context) and transferability (expansion to different contexts).
3. To pilot the Pathways to Implementation for Public Engagement in Research (PIPER) Toolkit and produce a final version ready for use by patients, the public and other stakeholders.

4. To evaluate this study's co-production process, to understand how it works for patient and public involvement in the implementation of health and social care evidence into practice.

Methods

Our overarching methodological framework is realist evaluation because it helps us to understand the mechanisms that drive outcomes in a particular context, enabling rich explanations of what works, in what context, for whom, and why, and because realist methods are particularly well suited to emerging 'green shoots' areas where there is limited evidence [24].

The framing of realist evaluation as context, mechanism and outcome configurations aligns theoretically with PPIE and implementation as it takes into account the different aspects of the context we are working within, identifies the mechanisms of how and why an intervention might work, and identifies the potential outcomes [2, 3, 25]. Previous studies of PPIE have used realist evaluation to develop rich theories of how and why public involvement works in particular contexts [16, 25]. As realist evaluation is iterative, project plans can change in response to evolving theory. While this protocol provides an important foundation for the study, it may change as theory evolves. Any changes will be reported in future papers to ensure transparency and support critique.

The study includes four work packages (WPs), with each building on and integrated within the previous one to address each of the research objectives, with a cross-cutting co-production theme exploring and evaluating the contribution co-production makes to the study, illustrated in Fig. 1.

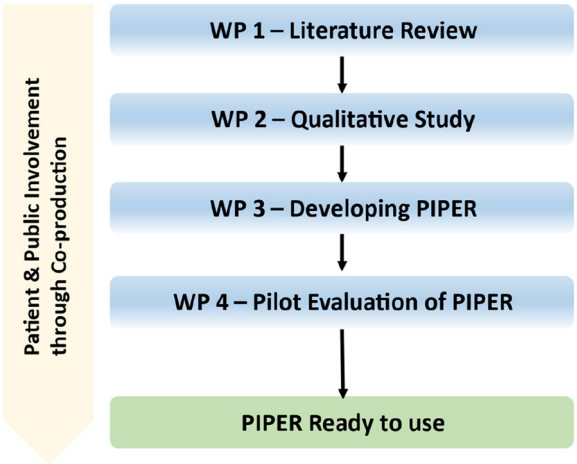

Fig. 1 Study Flow Chart

Ethical approval

Ethical approval was received for the study from Warwick Medical School BSREC Ethics Committee BSREC 45/22–23. We considered key ethical considerations including protecting anonymity, ensuring participants felt able to decline participation and ensuring we did not overburden participants, and they felt able to withdraw from the study at any point.

Patient and public involvement and engagement (PPIE)

Our key focus will be to embed co-production as a cross-cutting theme across the four work packages, using the NIHR approach to co-production [26] and reflecting the importance NIHR places on co-production as a core concept in PPIE [1]. The key principles of co-production include sharing of power, including all perspectives and skills, respecting and valuing the knowledge of all those working together, reciprocity and building and maintaining relationships.

To address all the research objectives, we will establish a diverse Co-Production Group ranging in ethnicity, sex, and background experience of research and implementation, that will meet flexibly at least five times a year with email contact in between. The Group will be co-chaired by one of the research team and one of the public contributors to minimise power disparities. To ensure we connect across work packages, especially with WP4, two members of the Keele LINK group, a dedicated PPIE group focusing on knowledge mobilisation and implementation activities, will join the Co-Production Group. We anticipate some of the meetings will be virtual to ensure they are accessible to all, and public contributors will be renumerated at NIHR rates. We intend these meetings to be opportunities for rich deliberative discussion (based on the provision of key information), sometimes called a deliberative knowledge space, where members will develop their knowledge of implementation and discussion is facilitated to enable co-production of thinking, and where the Co-Production Group are encouraged to discuss the approaches to the component work packages.

The Co-Production Group will work alongside the Research Team to decide how we implement each principle of co-production throughout each work package and how to evaluate each element so current plans may be slightly refined, as is the ethos of co-production. Our discussions will focus on how each principle of co-production will work in each work package.

Evaluation of co-production

To address objective 4, in each work package we plan to use the reflection tool developed by co-applicant Hickey as part of NIHR Research Support Service, to guide reflection, based on the coproduction guidance [26].

We will record and transcribe each meeting and work together with the Co-Production Group to co-produce our analysis, drawing on realist evaluation to identify the mechanism of co-production in this study, the contexts required and the resulting outcomes on the four work packages [27, 28].

Work Package 1: Realist review of literature

A realist synthesis will support the development of a theory driven understanding of how, why, in what context, and with what impact, patients, service users, carers and the public can be involved in the process of implementation (e.g. introducing a new intervention, or practice) and where appropriate, de-implementation (e.g. stopping a routinely used intervention, or practice) in health and social care, thus addressing objective 1.

Step 1: Scoping

The scoping stage will establish which areas of literature we will include in the literature review. The Principal Investigator (PI) (SS) and the Research Fellow (JW), in collaboration with an information specialist, working collaboratively with the Co-Production Group (10 Public contributors) and the Research Team, will scope the literature to start building an initial programme theory. We intend to use key databases to scope literature that has explored PPIE, implementation, PPIE in implementation and other adjacent areas, including grey literature. Papers and documents (e.g. policy reports) will be searched for initial ideas ('theories') relating to how we understand the role, contribution and impact of patients, service users, carers and the public in the implementation of evidence into practice in health and social care. We will use the idea of theoretical layers or levels of PPIE [29] to help us to look for concepts.

Step 2: Searching

Building on Step 1, we will search, MEDLINE, EMBASE, CINAHL, SCOPUS, CENTRAL, ASSIA, Web of Science, AMED, DH, NICE Guidelines, Cochrane, EPPI-Centre, Google Scholar, and UK healthcare websites and patient organisation websites. Search dates will include 2009 to 2025 to capture key developments in public involvement and in implementation. Both electronic and manual searching will be undertaken. In addition, manually checking of reference lists, 'cited by' searching and contacting experts will also be undertaken. In the original funded plan submitted to the funder, we stated 2021 as the end search date, but during the review we recognised that key studies of relevance were likely to report during 2021–25 so did not want to exclude them. The intention of the search strategy is not to be exhaustive, but to provide a large enough overview of the literature and sources to be meaningful in developing an initial programme theory [24, 28].

Step 3: Selecting documents

Drawing on papers, reports and articles identified in Step 2, our next key step will be to select documents and papers to include in the review that contain information or data relevant to the programme theory [27, 28, 30]. Data screening and selection will be undertaken by the Research Fellow, with the PI acting as second reviewer, checking 10% for consistency [31] using Covidence. Reasons for all exclusions will be noted and disagreements discussed with a third research team member to reach consensus. Included papers will include those that either describe how PPIE have been involved in implementation projects, or those that are from either PPIE or implementation that contain relevant concepts that we can hypothesise from. Excluded papers will be those that are not written in English, earlier than 2009, or related purely to PPIE or implementation.

Step 4: Data extraction

Data extraction forms will be developed and piloted. The initial programme theory developed in Step 1 will guide the annotation of documents, enabling the development of theory/theories in the form of context-mechanisms-outcome configurations [24] using Logseq. Annotations will be discussed by the Research Fellow and the PI, the wider Research Team and the Co-Production Group. The quality of documents relevant to theory generation will be assessed to judge whether their methods are credible and trustworthy [32].

Step 5: Data synthesis

This stage will bring together the evidence from the literature review with the PI in collaboration with the Research Fellow, the Research Team and the Co-Production Group. We will draw on our previous experience of realist review and build on the principles of realist enquiry [32, 33]. We expect the synthesis and refining stages to be iterative.

Step 6: Refining the PPIE Implementation theory

The final step involves refining the theory that will be expressed as a set of context, mechanism and outcome configurations. These configurations will be tested in the WP2 interviews and will continue to be refined throughout WP2 and WP3. We will do this by holding discussion groups with research team members and the Co-Production Group to discuss the context-mechanism-outcome configurations to increase their relevance and practicability.

When Step 6 is completed, the Research Team will review whether we need to revisit any of the review steps to further refine the PPIE Implementation theory in order to achieve 'theoretical saturation', when the repetition of steps is not adding further knowledge [28].

Work Package 2: Realist interviews

The initial theories developed in Work Package 1, based on the literature, will form the basis of Work Package 2. Work Package 2 will collect realist qualitative data to strengthen our theory and help us to understand the different ways in which patients and the public can be involved in implementation. WP2 addresses research questions 1 and 2 and objective 1, to co-produce a theory driven understanding of how, why, in what context, and with what impact, patients, service users, carers and the public can be involved in the process of implementation and where appropriate, de-implementation (stopping using an intervention). We will use a particular type of interview, a realist semi-structured interview, that enables us to continue exploring whether the PPIE Implementation theory 'holds' for an individual, enabling refining and confirmation as the interviewee adds their interpretation [34]. The outcome of this work package will provide a final realist theory that will underpin Work Package 3, the development of the Guiding Principles, Recommendations, and Practical Resources (PIPER), although we acknowledge that theory development is likely to continue during Work Package 3.

Sample and sampling

Using the principles of realist sampling, we will select interviewees based on their potential contributions towards further developing, refining and testing the programme theory, based on their knowledge and experience [24]. We theorise different types of respondents with different characteristics, such as age, ethnicity and experiences, will have different experiences and perspectives and could make different contributions to the programme theory.

Using our research team and wider networks we will recruit potential interviewees to include patients, service users, carers, public, implementation researchers, health and social care professionals, agencies, public involvement leads in agencies such as Social Care Institute for Excellence (SCIE), National Institute for Health and Care Excellence (NICE), Applied Health and Care Research Collaborations (ARCs), Health Innovation Networks (HINs), research commissioners and funders, health and social care managers, policy and decision makers and patient organisations.

We will collect personal data including age, ethnicity, gender, region the person is from, role and background (including any health conditions and their experience in research and implementation) how they would describe themselves. Our Co-Production Group added this last category to ensure we capture the way an individual wishes their identity to be understood, in response to a suggestion from one of our public contributors (RG). This collection of data is important because we need to know whether we are achieving our sampling intention and also important for us to understand how diverse our sample is.

Realist interviews

We predict we will need to undertake 40–60 interviews, reflecting the sample diversity required to develop high quality programme theories, ensuring up to 20 interviews at each of the micro, meso and macro levels that we have theorised as important in how implementation works [29]. The exact number will depend on the point at which we feel there has been adequate theory testing and refinement and when no new ideas are being generated. Interviews will be virtual or face-to-face, depending on the COVID-19 situation and participant preferences. If virtual, we will use Microsoft Teams to maximise the potential for interaction, using the Teams recording function, with their consent.

During the interviews, we will test and refine the PPIE Implementation theory by adopting the *teaching–learning* function and the *conceptual focusing* function proposed by Pawson and Tilley [24]. Within each realist interview, the researcher will present the respondent with the theory for examination (teacher-learning function) and ask the respondent to explain and clarify the thinking of the researcher based on their (respondent) ideas (conceptual focusing function). In 'teaching' the interviewee in this way, the response should be 'yes, I understand the general theoretical ground you are exploring, this makes your concepts clear to me, and applying them to me gives the following answers' [24].

Analysis

Interviews will be recorded and transcribed verbatim. Data analysis will be organized in relation to initial context-mechanism-outcome configurations, identifying patterns, exploring mechanisms and analysing contexts in which mechanisms worked [30] within a wider explanation [24, 35, 36] using NVivo, with input from the Co-Production Group.

Testing the theory workshop

At the end of Work Package 2, we will hold a theory testing workshop to enable us to interrogate the evidence (specifically the CMOs configurations), to take stock, and to ensure the theory is ready for Work Package 3. Participants will include the Research Team, the Co-Production Group and key external experts.

Work Package 3: Developing pathways to implementation for public engagement (PIPER)

In Work Package 3, we will use theory developed in Work Packages 1 and 2 to co-produce the Pathways to Implementation for Public Engagement in Research Resource (PIPER). Thus, Work Package 3 will address research question 3 and objective 2.

PIPER will consist of a set of *'Guiding Principles'* supported by *'Practical Resources'* and *'Recommendations'* that will enable an individual or a group to plan and undertake implementation activity. More specifically the Guiding Principles will enable the Practical Resources to be tailored to specific implementation strategies, using filtering to identify and select most appropriate strategies and then adapting and refining them to suit specific idiosyncrasies. For example, selecting strategies based on the types of interventions being implemented, and refinement to suit contexts of implementation.

At this stage, we make no assumptions about what the detailed elements of these Guiding Principles, Practical Resources and Recommendations will look like – this is to be defined by the programme theory from Work Packages 1 & 2 and the co-production process. However, based on our experience, we have an idea of the types of principles and resources that might be produced. The principles may include elements such as responsiveness and reflexivity. The practical resources may include process maps, decision trees, and templates for expectations and 'rules of engagement', implementation planning and strategy prompts. We anticipate that there are likely to be different resources or variations of the same resources for different stakeholder groups to ensure accessibility. For example, a set of practical resources to support academics, another to support patients and public, perhaps others for funders, policy makers or organisational managers.

From a wide range of other frameworks supporting implementation or knowledge mobilisation (moving knowledge to the right place), we can also anticipate that implementation processes are likely to follow common steps that will inform the development of our resources [8]. They include engagement of stakeholders, understanding the intervention and evidence, understanding individuals and context(s), tailoring of intervention or evidence, developing implementation strategies, ensuring logistics and support resources are in place to support adoption or use, setting up reflective feedback systems etc.

Originally, pre-COVID-19, this would have been a series of four face-to-face workshops planned with the research team and the Co-Production Group, used effectively in a previous realist synthesis by co-applicant Langley [37–40]. Langley and others evolved co-production practises in response to the pandemic. Learning from these projects [40, 41] suggests there is value in hybrid approaches that combine some mix of synchronised 'face-to-face' and asynchronous, individual or remote forms of co-production (Fig. 2).

For this project, we propose a hybrid method that combines postal and face-to-face (via screen or real world, co-production interactions, as illustrated in Fig. 3 overlaying the four phases of the Double Diamond, and as used effectively in previous NIHR funded research by co-applicant Langley [42].

Sample and sampling

Together with the Co-Production Group and the Research Team, we will invite a sample of our WP2 participants to be co-production partners in WP3 because they have built up a relationship with the project and will have some knowledge of the topic and should represent all the various stakeholders we want to include in the co-design work. In total, we expect WP3 to include 25–35 people. This will consist of a small number (5–10) of participants from WP4 to ensure connection across the WPs and between 20 and 25 co-production partners from our WP2 participants with equal representation between public stakeholders (including patients, services users, carers) and professional stakeholders (including health and social care professionals, agencies, implementation leads in agencies such as SCIE, NICE, ARC, HIN (formerly AHSN), research commissioners/funders, health and social care managers, policy and decision makers and patient organisations). We will support individuals to ensure they do not feel overburdened. The design process will enable new people to join during the four-step process and for people to leave without it affecting the integrity of the work package.

We will offer training and support to reduce barriers to partners engaging in the process. E.g. Training/orientation sessions/tutorial videos in using Zoom/MS Teams/MIRO (online digital collaboration workspace). If we cannot secure enough participants from our planned approach, we will draw on our wider networks to recruit additional participants, ensuring they are well briefed and supported.

The co-design process includes four key steps, each with a key role in development:

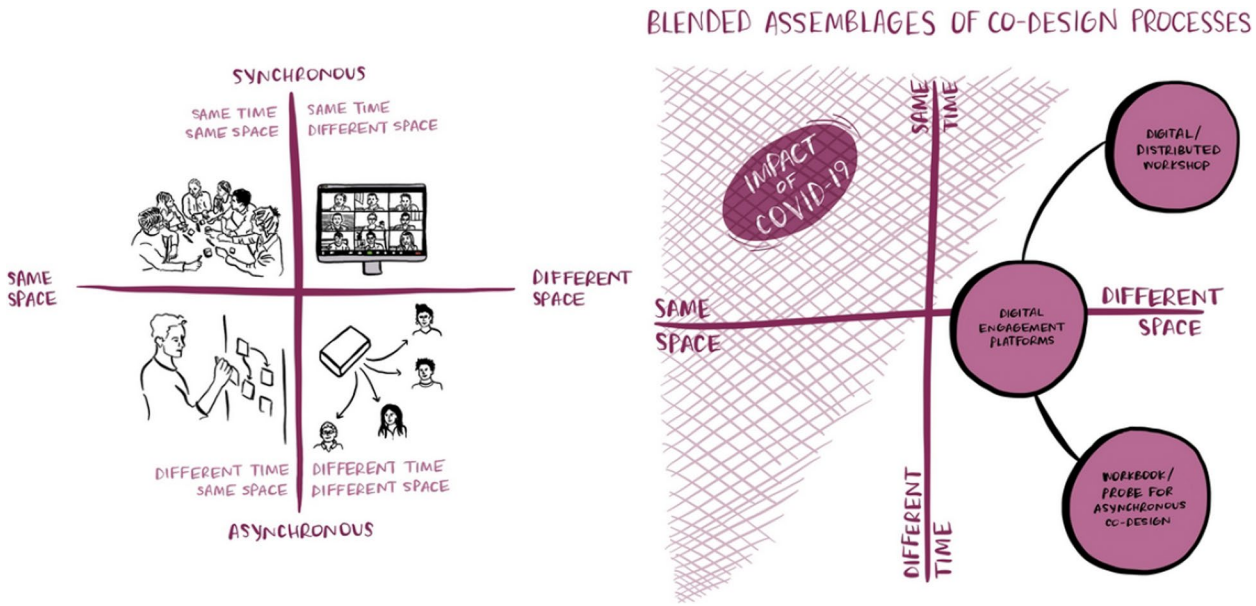

Fig. 2 Re-conceptualising co-production interactions across variations in space and time and considering hybrid combinations of interactions (38)

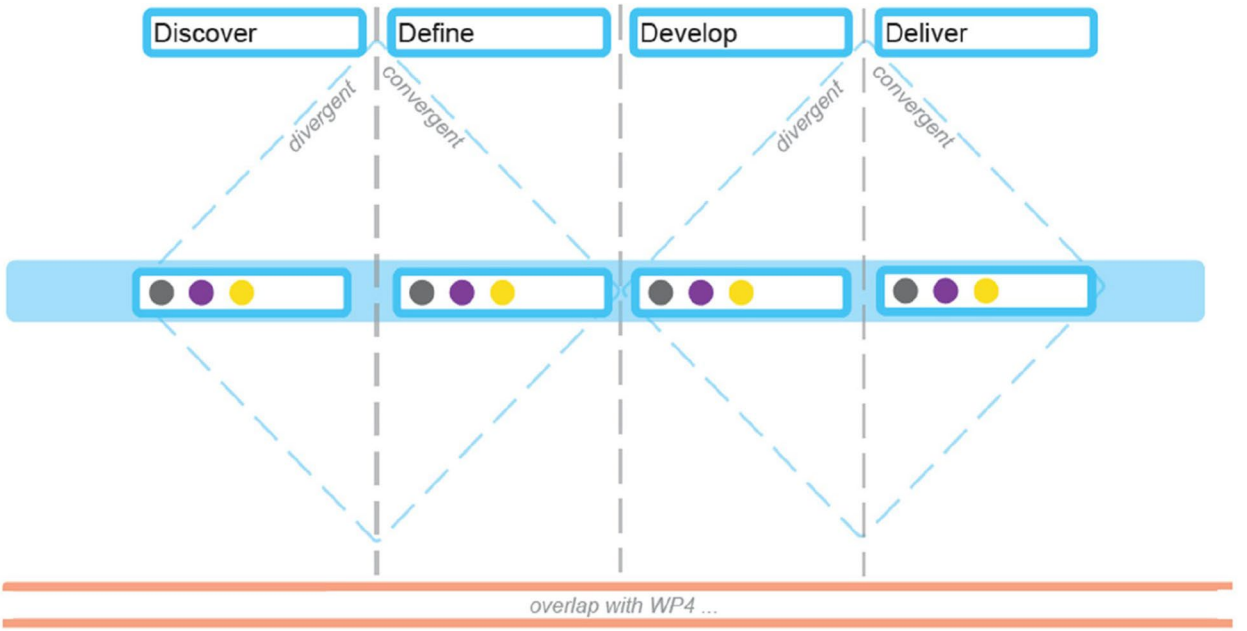

Fig. 3 Our proposed postal and face-to-face co-production, supported throughout by online shared design spaces and overlaid onto the Design Councils Double Diamond design process

Stage 1: Discover: Evidence from WPs 1 and 2 will be synthesised into creative interactive formats such as the 'If this – then that' card format [40, 41] or the 'Rebuilding Investigations Kits' (NIHR funded project 18/10/02). These will be combined with vignettes refined in our 'Testing the Theory' Workshop at the end of WP2. Component elements of the vignettes (for example, target beneficiaries, type of intervention and context of implementation, implementation resources) will be divided up to make them interchangeable between vignettes. This will allow us to invite participants to choose from these various elements to 'build their own', inviting a critical reflection of what combinations might work (or not work) for different people in different settings. This builds critical familiarity with emerging programme theories. Individual experiences will be drawn out through LEGO® SERIOUS PLAY® [sic] and six-picture storyboarding methods. The creative media generated will be used by participants to create models and images that reflect their combined knowledge of program theories and experiential knowledge [43], that represent shared understandings of the evidence, experiences, practices and contexts relevant to PPIE in implementation.

Between Stages 1 and 2, the designers will combine and digitise data from Stage 1 to create a digital exhibition of the PPIE Implementation theories. This exhibition will be produced as a (low cost) printed catalogue that can be shared with those with limited digital access. Detailed Stage 2 plans will be developed with the Co-Production Group.

Stage 2: Define and Develop: Using the outputs of Stage 1, our co-production partners will draw out key themes and develop these into draft Guiding Principles. The artificial implementation scenarios created by the Research Team will be used by co-production partners to create hypothetical scenarios to which they will then apply the Guiding Principles, exploring how these might be enacted in different scenarios. This will be repeated 3–4 times, refining the Guiding Principles and Recommendations identifying nuanced variations related to different implementation scenarios. In each case, we will identify what Practical Resources, would be required. Variations will be visually mapped against each other, beginning to frame the 'core' (consistent, immutable) elements across all cases and 'adaptable' (tailored) elements that are required to address different implementation situations.

Each criterion above will apply a filter to make some resources non-applicable and perhaps other resources more important. These will be a set of filters that will both 'rule out' and 'rule in' sub-sets of the Guiding Principles and Practical Resources. At this stage, we expect these filters might be based on factors such as the type of intervention being implemented or the implementation context. For example, a drug intervention being implemented in acute care settings might require slightly different resources to a drug intervention being implemented in mental health, primary care or social care.

Deliverables

a) Generation of a set of Guiding Principles. b) Generation of a set of case specific filters to support the selection of relevant Practical Resources (c) Generation of a set of ideas about Practical Resources to tailor and apply specific implementation activities and (d) details of stakeholder specific variations of these (e) initial framework of 'core' and 'tailored' elements of PIPER.

Between Workshops 2 and 3 the designers will develop low-resolution prototypes of the Guiding Principles, tailoring and selection filters and Practical Resources, including the stakeholder specific variations. The initial framework of 'core' and 'tailored' elements will be shared with the wider Research Team and Co-Production Group, drawing on their expertise to gain insights about possible classifications or typologies of implementation scenarios.

Stage 3: Develop – continued: All participants will test the draft unified framework of Guiding Principles and Practical Resources through application to more hypothetical scenarios, drawing on the implementation vignettes once again. They will use the low-resolution prototypes and annotate them for further refinement. The participants will present the framework and resources to an invited panel of experts. This panel will be drawn from WP2 participants who have not been involved in the co-production process and Knowledge Mobilisation Fellows through the NIHR Knowledge Mobilisation Alliance. Recommendations for real world practice will be discussed focusing on the distinction between 'core' and 'tailored' elements of the resources.

Stage 4: Deliver (or 'Knowledge mobilisation'): This workshop will focus on 'knowledge mobilisation' to ensure PIPER is relevant, useable and accessible to stakeholders. The knowledge mobilisation event will refine content for dissemination. In this event, participants create plans and content to support training, distribution and dissemination of PIPER. We will include participants recruited to three Case Studies from WP4 to ensure they start becoming familiar with PIPER.

WP3 will have early input from researchers involved with WP4 to ensure there is synergy in thinking and development through knowledge mobilisation at each stage. This is described more fully in WP4.

Work package 4: Pilot evaluation of PIPER for different stakeholders

Work Package 4 will address research question 3 and objective 3, to evaluate the use of PIPER in three pilot case studies (focused on relevance, usability, accessibility). This work package will also develop an implementation strategy for scaling PIPER up to be used beyond this study and produce a final refined version of PIPER ready for use by patients, the public, carers, service user organisations, patient organisations, health and social care staff, NICE, SCIE, and the NIHR Centre for Engagement and Dissemination (CED). We plan to house and update PIPER with the NIHR.

Case study context

Work Package 4 will be delivered by The University of Keele's Impact Accelerator Unit (IAU) with the Research Team and the Keele LINK group, a dedicated patient and public group for Knowledge Mobilisation and implementation activities. The IAU has a significant track record of working with a range of stakeholders to support the implementation of innovation across health and care, particularly in Northwest Midlands in the UK (over 19 different health and care providers covered by two Integrated Care Systems). Deprivation across the Midlands is high (urban and rural Shropshire and Staffordshire) with areas of high rates of health inequalities. The IAU is advised by its Race Equality Ambassador for Public Involvement in Research on PPIE coproduction and co-design with Black African, Asian and Caribbean heritage communities. As such, the IAU is very well placed to provide access to a range of projects from which a selection of case studies for WP4 will be made. Initial discussions of potential case studies will start during Work Package 2 and final case study selection will be made during WP3.

Case studies

We will evaluate the experiences of the individuals and teams using PIPER in three case studies using realist evaluation to continue our focus on understanding of what works, for whom, why and in what context, guiding the analysis of the data.

Case study selection

In terms of the process of selecting case studies, we will identify potential cases from the portfolio of active innovation and implementation projects within the IAU portfolio. We will work closely with our Co-Production Group in the review and selection of case studies and in designing materials to recruit people to take part, as we know this can be vital in successful recruitment. Initially, we will make informal approaches to possible case studies by team members KD and AM to gauge interest. Those who express an interest will be asked to submit information (focusing on our criteria below). Each potential project and their submitted project information will be reviewed.

Criteria for selection

Case studies will be selected according to criteria that will be refined through preceding work packages although we already have some expectation of what they might include: Implementation projects that already have an innovation or product to implement, that fit the programme theory to ensure we include different levels of implementation, that have a clear time-line aligning with PIPER, and that participants will consent to take part. We are confident that opportunities for identifying case studies are sufficient because of the current and projected through-put of projects through the IAU.

Sample and sampling

We expect the sample in the case studies to include teams from different settings (health, care, community, primary care, social care); will involve multidisciplinary teams; will involve underrepresented communities; will include dedicated patient and public contributors; and can be in different stages of progress of implementation of their innovation. We will ensure feasibility of the case studies with volunteers, health and care professionals, and quality improvement leads.

Implementation will be supported by individuals drawn from individuals from the IAU at Keele who work in usual practice contexts to support implementation. In each case study, 8–12 people will be asked to participate (n = an estimated 36 participants in total) and each case study will be nested in routine practice in health and social care. Case studies will be selected towards the end of WP3, so WP3 deliberation can inform the types of case studies selected in WP4. Each member of each case study will be asked to consent to being part of the study. There will be three key stages to the pilot evaluation of PIPER, outlined below and a final stage to refine PIPER ready for dissemination and use.

Stage 1. PIPER pre-implementation interview

Prior to the introduction of PIPER in Stage 1, participants in each case study will be interviewed.

We will collect personal data including age, ethnicity, gender, region the person is from, role and background (including any health conditions and their experience in research and implementation) and how they would describe themselves. Our Co-Production Group added this last category to ensure we capture the way an individual wishes their identity to be understood. This collection of data is important because we need to know whether we

are achieving our sampling intention and also important for us to understand the diversity of our sample.

They will be introduced to implementation vignettes (a brief evocative description or account of PPIE and implementation) to judge how much they know about PPIE. The vignettes will be developed with public contributors drawn from the LINK group members towards the end of WP3. The discussion about the vignette will determine whether they favour an approach where patients and the public are consulted, or where patients and clinicians work together, or where patients and public lead. Our intention is that each case study represents each of these three approaches. Each participant in each case study ($n = 8–12$ in each case study, n max = 36 in total) will be invited to participate in an interview (face to face or virtual) to address key questions that will focus on (i) their reasons and drivers for why they might use PIPER and (ii) the perceived benefits and challenges of PPIE in implementation drawing on the vignettes developed in WP3 to illustrate theory and understand context.

Analysis of qualitative data

Data from the interviews will be entered into NVIVO 12 software to aid analysis. We will draw on the programme theory developed in WP2 to analyse the reasons for using PIPER and the benefits of PPIE in implementation, reflecting on the extent to which findings reflect theory. The research team will undertake the analysis in collaboration with the Co-Production Group.

Stage 2. PIPER Implementation

PIPER will be introduced to each case study and its participants (face to face or virtually) at a launch meeting. The WP3 design team and members of the LINK group will introduce PIPER, presenting the principles that sit behind it, the Guiding Principles, Recommendations and Practical Resources with implementation advice to guide its use in a case study. Implementation support will be provided by a project team that includes a knowledge mobilisation expert, a patient and public contributor, (representatives from Keele's IAU) and a member of the wider stakeholder group involved in WP3. The project team will work flexibly with each case study over three months, to champion and support the use of PIPER within each case study, meeting regularly and supported by mentoring and coaching by the Keele IAU (sounding board, challenger, and thinking partner) to help each case study use PIPER. The use of PIPER will be captured using an evaluation template. Each case study will decide how they wish to use the evaluation template to capture the implementation of PIPER. For example, some may prefer to complete it individually, while for some teams, an individual will complete the template on behalf of the team.

Analysis of qualitative data

Each case study will record key discussions and interactions to capture the process of implementation in the implementation template.

Stage 3. Post-Implementation Interview or Focus group

Following a three-month implementation phase in each case study, participants from each case study and the project teams who worked with them will be invited to participate either in focus groups or interviews to ascertain: whether PIPER is acceptable and feasible in practice (usability, design); refinements needed; barriers and facilitators for adoption (successes and failures); the perceived benefits (for health and care practice, for the organisation, for their project, for their own role etc.); how the process of coproduction worked and the elements for future implementation. Interviews will help us understand their experiences of using PIPER and their views of PPIE in implementation.

Analysis of qualitative data

The analysis will focus on a) whether PIPER resonates with the context, mechanism and outcomes (CMOs), (b) whether PIPER (and therefore the CMO's) enables PPIE in implementation, (c) whether this makes a difference to implementation and (d) how has co-production worked in the implementation of PIPER?

Stage 4. Refining PIPER and planning for implementation

The final step in Work Package 4 will be to determine any further refinements, including planning the strategy for scaling up the implementation of PIPER across health and social care settings, and dissemination. The results of the focus groups and interviews will direct the refinements made to PIPER, ensuring the learning from Work Package 4 is fully utilised in the final version. Refined vignettes will be produced based on findings.

Discussion

The initial review of literature helped early conceptual mapping to identify the potential breadth of the field of public involvement in implementation. The early mapping captured three types of involvement: patient support (an interest in and desire to be part of implementation), patient partnership or co-leadership (working together to deliver implementation activities) and patient leadership (the patient leading the implementation activity). For each of these types of involvement, the mapping then considers three levels of involvement; the individual level (patient/service user or individual carer/family member/friend or advocate or PPIE facilitator enabling some level of patient involvement in implementation), the institutional or collective level (semi formal or formal

patient groups/Trust/research team initiatives around implementation) and the broader health system level (other health or social care organisations, local authority/patient advocacy groups/online groups/international patient groups). Within each of the conceptual areas, we have identified potential examples that might reflect an individual or group were working at that intersection of the level and type of involvement.

In addition to helping us develop our initial conceptual understanding of the field, the mapping also identified the significant breadth of literature which may contain concepts of relevance in the fields of public involvement and in implementation. With a realist review there is always a balance of trying to ensure conceptual saturation while maintaining pragmatic boundaries.

In reviewing our early theorisation, we were also aware that the field of public involvement in implementation is very new and will evolve over the next decade. As such, key system enablers required for patients and the public to be involved in implementation may not yet be present as important contextual factors or mechanism that support involvement. In addition, we may propose forms of involvement that will take place within a complex and pressured health and social care systems that may have limited flexibility to adopt new ways of working. In addition, since the COVID-19 pandemic, working practices have changed significantly and people may want to interact in different ways. The implications of this for the practice of public involvement in implementation are less clear, but may be important, particularly if public contributors are in vulnerable groups or groups that choose to work in different ways.

Although the PIPER study will focus on public involvement in implementation practice, there may also be lessons for the field of implementation research. For example, the many theories and frameworks that exist to guide practice rarely mention the potential role of patients and the public. Through the PIPER study, we hope to challenge the field of implementation research, encouraging it to review its conceptual and theoretical stance by starting to build a patient and public element. As such, we hope PIPER represents a marker in the ground for the implementation community, a signal for the need to change direction, towards clearer forms of partnership, for patient benefit in both implementation research and practice.

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Authors' contributions
SS, JW, JL, KD, AM, NA, CB, LB, PB, TG, RG, GH, RL, JRM, KS, MS, DS, LW and MR contributed to the conception of this protocol. SS drafted the manuscript with input from JW, JL, KD, AM, NA, CB, LB, PB, TG, RG, GH, RL, JRM, KS, MS, DS, LW and MR. All authors critically revised the manuscript and approved the final version for submission.

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Data availability
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
Ethical approval was sought form the University of Warwick Medical School Biomedical and Scientific Research Ethics Committee (BSREC) [BSREC 59/20–21]. All participants will complete a consent form approved by BSREC.

Consent for publication
All participants will consent to the use of anonymised quotes from the work packages in publications.

Competing interests
Sophie Staniszewska is co-editor of the Research Involvement and Engagement journal.

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