RESEARCH ARTICLE

Exploring the role of Patient and Public Involvement in Implementation Research using the Study of Implementation of Midwifery Continuity of Carer (SIMCA).

[version 1; peer review: 1 approved, 1 approved with reservations]

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Abstract

Background

Patient and Public Involvement (PPI) is a fundamental part of health research. The role of PPI in implementation research, which considers the transfer of evidence into practice, is often less well defined than in studies focussing on recruitment of individual patients and clinical outcomes, and there is limited guidance available. This paper uses an implementation research project, the Study of Implementation of Midwifery Continuity of Carer (SIMCA), to illustrate the types of activities, benefits, challenges and lessons learned to contribute to the development of this growing area.

Methods

The main aim of the PPI work in SIMCA was to embed the service user and community perspective in the study across all phases of the research, from preparation through execution and dissemination. Members of two organisations, one international and one community

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based, were core members of the study management team and PPI-driven activities were conducted throughout the study, incorporating both process and content focussed input.

Results

The key contributions of PPI to the study were identified as i) bringing experience and representation ii) providing connectivity between the team and the wider community iii) providing service user perspectives on study-related tasks iv) a developmental impact on the study team, improving awareness and challenging the dominant academic perspective. Several challenges are described, for example the ambiguity of the role.

Discussion

The SIMCA study has been used to illustrate the significant contributions that PPI can make to an implementation study and to the study team culture, in particular the value of having different perspectives within the team to ensure the study does not become too far removed from lived experience. Dilemmas related to the blurring between PPI and data collection and the need for more theoretical understanding of PPI in implementation research to make the findings more generalisable.

Plain Language Summary

Patient and Public Involvement (PPI) plays an important role in health research, but in implementation research—which focuses on turning research findings into practice—this role is less clearly described.

This paper uses a research project called SIMCA (Study of Implementation of Midwifery Continuity of Carer) as an example, to show how PPI can be integrated in an implementation research study, the benefits it brings, the challenges faced, and lessons learned.

The goal of PPI in SIMCA was to ensure the voices of service users and communities were considered throughout every stage of the study, from planning the funding application to delivering the study and sharing results. Two organisations—one international and one local—were actively involved in the research team, helping shape the study.

PPI contributed in many ways: it brought the context of the service users experience and connected the research team to the wider community in a meaningful way. The PPI team provided service users' perspectives on study-related tasks and helping the research team to listen to different viewpoints, rather than relying only on academic perspectives. There were some challenges including uncertainty around tasks for the PPI members which took time and discussion to work through, and important lessons were learned from the inclusion

of different perspectives in a research team. This can be especially valuable in implementation research, which can potentially lose sight of the real-life experiences of the people who will be ultimately affected by the findings. It also has a positive influence on how the team works together. Dilemmas during the project which are discussed, include being aware of the differences between PPI and data collection and concerns about the demands on PPI partners. There is a need for better theoretical understanding of the impact of PPI to develop PPI further in implementation research.

Keywords
Patient and Public Involvement, PPI, Implementation, Midwifery, Continuity

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Introduction

There is growing recognition of the importance of patient and public involvement (PPI) in health and social care activities, across service change, research and policy development (Ocloo *et al.*, 2021). In the context of research, this means conducting studies *with* or *by* patients and members of the public, rather than doing research *to*, *about*, or *for* them. (NIHR). In the United Kingdom, commitment to PPI in healthcare is enshrined in key legislation, and the six standards (inclusive opportunities, working together, support and learning, communications, impact, and governance) provide a framework for PPI in research (UK Standards for Public Involvement).

The terminologies used to describe PPI activities vary, often depending on the context (e.g., service users, lay people, research partners) and the nature or level of involvement, with specific definitions of some models of involvement, such as co-production and -design (Grindell *et al.*, 2022). In a health research setting, PPI is now well established in research that relies on the recruitment of patients or measuring clinical outcomes, but is much less well established in implementation research (IR) (Bauer & Kirchner, 2020), which investigates the processes and challenges of the transfer of evidence-based interventions or policies into practice. Implementation research questions commonly focus on understanding intervention delivery and changing behaviour at the professional provider and organisation levels. Patients are ultimately at the receiving end of this interactional chain but may not play a significant part in the data collected in IR to answer the research questions.

This study explores the role of PPI in Implementation Research using the Study of Implementation of Midwifery Continuity of Carer (SIMCA): By outlining the PPI focused activities throughout the project, the impact those activities had on the project, the challenges experienced, and the generalisable lessons learned, we hope to provide others with useful ideas for their own work, as well as building on work by Nicholas-Angl *et al.* (2024) and others, to contribute to the ongoing development of PPI in the context of IR.

What is PPI?

In health research, it is common to think of PPI as synonymous with lived experience, for example, of a particular condition, as a service user or caregiver. However, Barker *et al.* (2020) identified a much wider range of involvement roles taken on by public contributors, which broadly fall in three categories: i) experience, knowledge or skills ii) citizenship (to achieve a public good) or iii) being an outsider (for example as a "critical friend"). Their typology demonstrates how individuals can fill multiple roles, including where their lived experience may not be an obvious fit with the research questions, as may be the case in IR.

There have been many varied descriptions of the importance of, and rationale for, PPI in healthcare provision and research. As part of their systematic review of PPI frameworks in the research context, Greenhalgh *et al.* (2019) identified three arguments:

i) Normative/emancipatory perspective, which emphasizes researchers' moral duty to address power imbalances between patients and researchers, ensuring that patients have a meaningful voice in research about their condition.

ii) Consequentials/efficacy-oriented perspective, which focuses on the impact that a real-world perspective can have on the quality, efficiency, and value of the research, for example through greater relevance to patients, improved recruitment rates, and broader diversity of participation.

iii) Political/practical perspective, which positions PPI as part of "mode2 science" (Gibbons *et al.*, 1994): In this mode, the production of knowledge is more multidisciplinary, responsive to societal need and context-driven, compared to traditional "mode1 science" which is more hierarchically led by experts in one discipline, with little influence from outside.

As with the rationale for PPI, there have been several systematic reviews of factors that enable optimal patient engagement in the design, delivery, and evaluation of health services (eg Bombard *et al.*, 2018; Ocloo *et al.*, 2021). Key intra-team factors include establishing and maintaining a culture of respect, actively involving all team members, and facilitating effective communication (Witteman *et al.*, 2018). Understanding context is also of critical importance, necessitating a whole system approach to help overcome the barriers to effective PPI (Ocloo *et al.*, 2021), ranging from addressing individual circumstances of representatives to the impact of power dynamics in organisations. Context is also a crucial component in the relationship between engagement and the use of clinical effectiveness research findings, enhancing the relevance of findings and the strategic dissemination of results (Maurer *et al.*, 2024).

PPI in implementation research

Implementation Research in health settings is commonly focused on the work practices of healthcare providers and context. Ultimately, as with clinical outcomes research, patient benefit is at the heart of the endeavour: PPI is crucial in the real-world translation of research evidence into practice (Maurer *et al.*, 2024), and as such, is identified as one of the key domains in the implementation research development tool, ImpRes (Hull *et al.*, 2019). However, there is a greater risk of tokenism in asking patients to provide input on something, such as service delivery and implementation, for which they have less in-depth knowledge.

Therefore, what does PPI look like in implementation research? This was the question asked by Gray-Burrows and team who conducted a consensus exercise in relation to PPI roles in both implementation and clinical-outcomes focussed research (Gray-Burrows *et al.*, 2018) For the latter there was strong support for the majority of the 21 PPI roles in research identified

by the team, however for implementation research the views were much more divided: There was strong support for PPI roles in:

- priority setting,
- the planning research phase e.g. consent process, developing applications for funding
- conduct: e.g. governance within the research team
- sharing findings –e.g. taking part in dissemination and guiding future research

There was weaker support for other activities related to healthcare professionals, such as developing recruitment strategies, for example, and for interpreting findings, and no consensus on other areas such as intervention content. The study concluded that to ensure authentic PPI roles, the tasks need to contribute more clearly to answering the research questions, with more research needed on the best approaches to bringing patients' and professionals' perspectives together.

MacLeod *et al.* (2022) reflected on the activities of five knowledge transfer/implementation science teams to explore what lessons can be learned about engaging patients and the public in this type of study. As with the reviews of PPI across different types of research described above, there were intra-team processes such as sensitive, responsive leadership, and team-building, as well as ensuring an awareness of context and its impact on all team members. Alongside intra-team processes, the nature of the work - being more process-focused and exploratory with less concrete structure–meant that flexibility as the project progressed was crucial: leadership played an essential role in helping the team build a shared sense of endeavour, which might take more time when people are less clear about their role, particularly in the early stages.

In summary, what emerges from the existing research in this area is the more fluid and less linear nature of implementation research, which, combined with the focus on practice and delivery, results in a less clearly delineated and more responsive role for PPI partners. This requires the team and team process to accommodate uncertainty and change; it needs sensitive leadership to ensure equality of voice and it needs a much more open view on what types of "knowledge" we need to progress the field of implementation.

The SIMCA study

Implementation of the Midwifery Continuity of Carer (MCoC) model of care in England has been part of several policy directives designed to improve newborn and maternal health, coordinated within the Maternity Transformation Programme in England since 2016, (NHS England 2016, 2017, 2021). MCoC aims to ensure that women are cared for by a named midwife who coordinates and personally provides the majority of care supported by a small MCoC team (eight midwives or fewer) throughout pregnancy, birth, and the postnatal period. This represented a significant change in the operational model of maternity services, but there was limited knowledge about the factors, contexts, and conditions necessary for the successful implementation of MCoC, particularly within the context of the UK NHS. (Middlemiss *et al.*, 2024).

MCoC is a complex intervention, with multiple interacting components spanning macro, meso, and micro levels of organisations (Skivington *et al.*, 2021), making it inherently difficult to implement at scale. The aim of the SIMCA study was to explore the factors influencing the implementation of MCoC in England and to examine differences in how MCoC implementation had been operationalised, sustained, and experienced (Milton *et al.*, 2025). The study design incorporated a narrative review of the literature on MCoC implementation (Middlemiss *et al.*, 2024), six case studies of NHS sites, representing a mix of progress with MCoC implementation, and interviews with national and regional MCoC stakeholders. The results were intended to inform the ongoing implementation of MCoC in England and contribute to debates about future changes to maternity services ((See Milton *et al.*, 2025 for full protocol)

Methods

Patient and Public Involvement

The overall aim of PPI work in SIMCA was to enable the team to take a broad look at the context of maternity services from the perspective of communities and service users. The research questions of the study revolved around implementation of MCoC and the role of PPI was to help understand the relationships between national and regional decisions and systems, MCoC implementation, and individuals' experiences of maternity services. The PPI co-applicants were involved in the design and conduct throughout the study: The development of PPI within SIMCA was often an iterative process with the method leading to results that then informed the method; although these stages are reported separately for ease, the reality was more complex. The work reported here does not include the service user patient data collected during the study, this will be reported separately and the complexity of distinction between PPI and data collection is explored later in the discussion. Using Shippee's model of the stages of patient and service user engagement (Shippee *et al.*, 2015), the work is divided into Preparatory, Execution, and translational phases.

Preparatory phase

The first iteration of the research questions was generated through exploratory discussions by the academic members of the study team. Feedback on the topic and early development of the project was then sought from users of UK maternity services through social media posts on relevant accounts, including Maternity and Neonatal Voices Partnership (MNVP) and Tommy's Baby Charity ('Tommy's' through established links with the academic team and funded by a Research Design Service grant specifically for PPI activity.

This early engagement work led to connections with two contrasting but complementary organisations, providing the study with diverse sociodemographic, ethnic, and geographical

representation and reach: Tommy's run a UK-wide and international online midwifery-led pregnancy hub, supporting families through their pregnancy, reaching around two million people. The Mosaic Community Trust ('Mosaic') is a community based organisation which aims to empower diverse, socially and economically disadvantaged communities, to build community cohesion and break down health and social inequality barriers. One member of each organisation was identified as a co-applicant and the organisations involvement was costed into the project following the NIHR costing guidelines.

Execution phase

In the study design, PPI activities were described in four broad components:

Study Management Group (SMG): The study management group met monthly throughout the study period and included the two PPI co-leads as members, ensuring that service users' views were integrated in a timely manner throughout the lifetime of the project. Two other SMG members (SC and TP) were identified as having responsibilities for supporting and coordinating PPI activities.

Project Advisory Group (PAG): The PAG provided independent oversight of the study's conduct and progress. It comprised experts from the field of maternity services, including a PPI representative, who reviewed the PPI activities as part of their PAG role. The PAG was timetabled to meet every six months to advise the SMG on all aspects of work. Three representatives of the SMG were required to attend the PAG, including one PPI co-applicant (KD).

PPI Advisory Forum: The Forum was designed to provide a service-user-focused perspective to feed into the SMG for the duration of the study, meeting three times a year online or in person, each time with a focus on the current study activities. Examples given in the initial plan (with recognition that this would and did evolve with the study) were early work on the preparation of research materials, inclusive recruitment of service users from diverse communities, developing the data analysis, exploring findings, and dissemination. The core group members were the four SMG members with PPI in their study role description; other SMG members and PPI representatives outside the study team joined the forum and engagement activities (see below) where relevant to the specific activity.

Engagement and Dissemination Activities: Mosaic and Tommy's approaches to PPI engagement activities were designed to reflect their existing engagement models with their respective communities. In addition to LCS, Mosaic's public engagement and involvement throughout the project was to be coordinated by their health and well-being advocates, who work directly with vulnerable and disadvantaged Black, Asian, and minority ethnic women and communities. As part of their practice to encourage community participation and activism in health and social care issues, Mosaic regularly holds community events for people to share their experiences. The SIMCA protocol included plans and funding for such events, focussed on maternity services. For Tommy's where much of the work is UK wide and so conducted online, it was anticipated that these equivalent discussions would happen virtually, with funding allocated to attendees of virtual discussion groups.

Translation phase

The translation phase, including the dissemination plan, was not described in detail at the start of the study, to allow for development through the project timeline. However, as co-applicants and members of the SMG, the PPI representatives were identified as playing a key role in ensuring that the findings of the study include service users' perspectives and that dissemination of the project would have significant public reach through close involvement in the project of their organisations.

Results

Preparatory phase

Development work: The survey and discussion group before submission for funding identified priorities for the delivery of MCoC from the service users' perspective, including practicality, safety, and the potential knock-on effects to other parts of the service, with narratives of the lived experience of the impact of continuity and discontinuity of care. There was also advice on research processes, including the timing of engagement with service users, language, and potential routes for recruitment.

Getting to know the team: The roles of the two PPI partner organisations were identified during the development phase and included in the research plan, but the first face-to-face meeting of the study team members, hosted by Mosaic, took place between the funding decision and the study opening. This focused on building an understanding of Mosaic and Tommy's work and creating opportunities for informal personal introductions.

Execution

SMG: Study design, procedures, and recruitment. As members of the SMG, the PPI leads contributed to the discussions and decision-making in relation to all aspects of the study execution via their attendance at the monthly meetings and document reviews, which were part of the study management role. Specific contributions included the wording and selection of the images used in patient-facing materials, views on recruitment strategies for the recruitment of service users in the case sites, and suggestions of connections to local networks to assist with recruitment.

PPI forums

Memorandum of understanding

The first two PPI Forums, one hosted by Tommy's and one by the academic PPI member geographically closest to both PPI organisations (TP), were structured around developing a Memorandum of Understanding based on the PPI content of the application and deconstructing the study protocol to build a shared understanding of the study design and purpose. Formally, these meetings gave the team members a chance to review the plan for the PPI-focused work and to discuss expectations, meeting structures, logistics, etc. Informally, these in-person meetings helped further team familiarisation and

team building; they also offered opportunities to reflect on the early work as the study took shape.

Contextualising findings

A key aspect of the PPI work was contextualising emerging findings during the development of the data analysis, to ensure that the service user perspective was fully integrated into the work: This was part of the PPI contribution to the work of the SMG (see above) but there were also specific PPI events that contributed to the interpretation of findings:

i) Perspectives on Narrative Review

The PPI Forum convened to explore the draft findings of the narrative review of the evidence around the intervention, which was the first output of the study. The lead author summarised the main findings from the published literature and asked specific questions of the PPI group for discussion, including whether their perspectives, and those of service users generally, on CoC came through the findings: how women were or could be involved in planning Continuity of Carer and their reflections on the description of midwives' perspectives (who themselves are most likely to be women and may also be service users). The main themes that emerged from this work and were fed into the final paper were as follows:

- Limitations within the literature regarding different demographic groups and the failure to adequately differentiate between ethnicity, race, and class.
- The experience of being familiar with a group of midwives would be positive, but this would not necessarily equate to the description of MCoC, nor will women necessarily know that they were or were not receiving MCoC.
- Service users should contribute to policy changes, implementation, and evaluation, but this needs to happen at a community level, not at the level of individual feedback.
- One size will never fit all - no model of care can meet the needs of all women in the care pathway in all the different cultures and contexts.
- All services need strong community backup support and to create connections with that community.

Once the study moved into case-site work, the focus of the PPI forum turned to planning the community events, designed to provide a service user lens for the work.

ii) Contextualising services

The first Mosaic community event, attended by 19 women, was aimed at deepening the research teams' understanding of the service context by hearing from mothers and pregnant women what they know about local services and also to explore the relationship between the community and maternity services, in particular around service changes. The agenda included information from local service providers and a dialogue between service providers, researchers, and the community.

The themes that emerged were dominated by issues of communication between services and communities and between practitioners and pregnant women. When that communication went well, the woman felt compassionately supported, but when communication was poor, the woman felt that their experience was being dismissed, and there was a lack of exploration of knowledge and expectations. Service users are well aware of the pressure in the system and do not want to worsen a bad situation for the providers or themselves, so they often stay silent. In terms of service change, they were unaware of the mechanisms of influence that exist for people outside the service provider organisations (e.g., no one had heard of Maternity and Neonatal Voices Partnership) and most were unconvinced that their views would make a difference.

iii) Reflecting on the research interviews

As the study progressed, towards the end of case-site data collection and at the start of data analysis, the second round of community events was oriented to work with the study PPI community to reflect on the lived experiences of MCoC, from the perspective of service users primarily, but also the providers. Our approach to this was informed by Locock and team's work regarding PPI-led data analysis (Locock *et al.*, 2019). They focused on touch points (key interactions, both positive and challenging between service users and staff members) and also suggested that, rather than performing detailed transcript analysis "conversation, rather than data, is at the heart of user involvement in analysis." (P2). Therefore, these events were designed to utilise user reflections on their experiences of continuity and discontinuity of maternity care to direct the analytic gaze of the research team as they start the case site analysis.

There were three community events, one in person with Mosaic and two on-line discussions with the Tommy's community, each introduced and co-facilitated by the PPI leads in the research team from the respective organisations, alongside the qualitative researchers leading on the data analysis. Each session started with a brief description of the study and progress in data collection. In the Mosaic session, which was the first of the three, examples of the service user interview content were used as triggers for the discussion. It was clear from this event that the participants did not need much scaffolding content to describe their experiences. Therefore, in the Tommy's events, where the time was shorter, some simple open questions about their reflections on the important conversations in their care and moments where continuity was or would have been important were used instead to initiate discussion.

Each group had slightly different emphases because of their lived experiences, but there were some common themes:

"Above and Beyond" level of care: Some women had really positive touchpoint experiences where individuals (or some teams) provided the best kind of care, such that women felt understood and known by someone, that there was at least one person with their best interest at heart and the staff went above and beyond their duty of care. These were not necessarily

representations of the Better Births model of MCoC, with continuity including all three periods of maternity care. For many women, if they received good continuity in antenatal and postpartum care and were told that it was not feasible for that continuity to include intrapartum care, the situation was accepted, it was the knowledge and communication that was important.

Randomness of quality of care: Many had challenging experiences during their care, which led to a feeling of uncertainty permeating their experience of care: How will this appointment be? Am I getting what me and my baby need? These key touchpoint episodes were largely driven by poor communication. This might be at an organisational level (where services were unable or failed to communicate with each other), inter service-team communication (information not being passed on between staff members) or at the individual service-user and provider level (e.g. not knowing the persons history). The power of these touchpoint episodes resulted in distress, hypervigilance (to try and gauge the unspoken or hidden meaning in what the provider says), and potential disengagement with the service (avoiding asking questions or attending appointments).

There were strong resonances between these PPI-driven themes and the service user data in the case sites: The case site interviews with service users were primarily designed to elucidate the lived experience of receiving the services being explored in depth in the six case-sites. However, the compelling interplay between the PPI discussions and the service user interviews led the team to reflect on how this component of the research data was going to be used. As a result, rather than simply merging the service user data into the case-site narrative, the team decided to bring the service user data and the PPI reflections together for more detailed reflections on the lived experience, to be included in dissemination events and a separate publication.

iv) PPI impact

As part of the data analysis phase of the study, the Study Management Group attended the PPI Forum for a day workshop to reflect on PPI as part of the study. There were three main questions: 'What have been the key PPI contributions to SIMCA so far?' "What have the Challenges been?" and then a broader question to think about generalisable findings, "What have we learned about PPI during our work together?"

Key PPI contributions: The contributions identified spanned four main themes:

a. bringing experience and representation (e.g., personal and community knowledge, depth, and diversity of experience from across two very different organisations)

b. connectivity (this included hearing from real-world lived experiences but also improving the teams' communication with a wider audience).

c. Study-related tasks (co-development of materials, hosting events, document review, and ethical oversight)

d. Impact on the study team (improved knowledge and awareness, community voice as an equal partner in the discussions, challenging the dominant academic perspective)

The challenges identified ranged across individual, context specific and more broader structural challenges:

a. the boundary between data collection and public and patient involvement

b. positionality – PPI stakeholders' ability to represent will inevitably be based on their experiences and roles.

c. implementation research, for example, asking people about something they have not experienced and an ever-evolving context

d. time constraints from taking on PPI role in addition to other roles

e. PPI structures with funder requirements can create a formulaic approach and risk generating a feeling of a closed shop of PPI in research.

The generalisable lessons concerned the importance of meaningful connections within the team and between the team and the community:

a. Benefits of having PPI representation from organisations, with meaningful, trusted connections with the community

b. Learning from women that created a deeper understanding of the lived experience

c. Timing: Involvement is crucial throughout but particular importance of early engagement

d. Choice of PPI team: Breadth of representation and confident PPI co-investigators help build equality of voices in the SMG

Translational phase

A whole-system approach for planning the translation phase was developed. The central tenet was that all stakeholder groups would be involved in dissemination and that relevant information was disseminated across settings to ensure that everyone had an understanding of the results of the study, both in terms of its meaning for them personally or professionally, but also in the wider context. In the language of the (Gray-Burrows *et al.*, 2018) framework of PPI roles, this includes "sharing and using research knowledge" talking with researchers, and signposting and sharing learning with other relevant stakeholders.

The dissemination plan includes a wide range of target audiences from individual service users, service providers (individuals, organisational leads, and people with a national role),

policy makers, and academic advisors. The study was designed with the explicit aim of informing policy, so there is an unambiguous focus on ensuring that the key messages are received by NHS teams charged with implementation. The generalisable messages of the study make it relevant not only to those responsible for maternity care but also to those leading organisational change in the NHS more widely. Several events in the dissemination plan will follow the approach adopted in the first dissemination event in September 2024 (presenting and discussing the Narrative Review of the evidence underpinning the MCoC model), which was advertised to key stakeholders with an open invitation and held online to maximise access.

All service users and communities involved in the study will receive feedback in a variety of formats, including summary documents, social media information, and discussion events. The team will attend meetings with the national and regional leads for midwifery, and the study results will be written up with a practice and implementation focus for a midwifery-focused publication. The final Mosaic-led event will provide the opportunity to bring together the community, local midwifery teams, service leads, and policymakers to explore the meaning of the findings in the local context and implications for their shared future. There will also be academic-focused presentations at conferences, ranging from the British Sociological Association to the Health Service Policy Research conferences, to consider the study from a theory-building perspective.

Discussion

Patient and Public Involvement were woven into the study fabric of SIMCA to ground the research in the reality of the service user experience, to understand the context of maternity services from the perspective of communities, and to ensure that the outputs of the study had relevance and impact for service users in the future. As an implementation study with a focus on service providers, public involvement was particularly critical in increasing the diversity of participation, helping broaden the frame of reference. There were many lessons learned by the team, which will be used here to reflect on the work and discuss the broader implications for future work by the team, and hopefully of use to others working on Implementation Research studies.

PPI members of the team can take on multiple roles across the different phases: use the different strengths they bring to the study to shape the activities within the project

Reflecting on the roles played by the PPI team in the SIMCA study, using the Gray-Burrows *et al.* framework, there was a clear impact across the phases; in the planning phase, the survey and discussion groups provided feedback on the importance of the topic, and they gave the team a first-hand sense of the service user experience of continuity in midwifery care. In terms of study design, the team used PPI organisations' approaches as the blueprints for the model of involvement and engagement. In the conduct phase the PPI members helped shape the research materials for service user recruitment, they provided a context in which to understand the implementation of MCoC, and they were equal members of the study management team in terms of governance of the study.

Value the different, multiple perspectives across the team

The area where the impact of PPI was particularly strong was the consistent presence of the service user perspective. This may seem tautological – that is, after all, the overarching purpose of PPI and in keeping with the normative/emancipatory perspective identified by Greenhalgh *et al.* However, in some studies, this can be tokenistic and in practice, the impact of that function of PPI can be difficult to measure. In the SIMCA team, PPI representatives provided a counterbalance for the all-white, academic, and largely middle-class team, reorienting them to the reality of the lived experience, not just during the PPI sections on the meeting agenda, but threaded through the work of the study.

PPI involvement grounds work in lived experience but also impacts process and team culture

As a typical IR study, when so much of the focus is on policy, service providers, decision-making processes, etc., the importance of having team members who reflect on the meaning of discussions for service users cannot be overstated. In relation to the implementation of MCoC, this is particularly pertinent as much of the policy is built on the premise that "it is what service-users want" so the voice of service users is central. The Gray-Burrows *et al.* (2018) framework does not include a role that looks at the influence of PPI on team culture, something that comes through more strongly in MacLeod *et al.*'s (2022) discussion of the less concrete, more fluid nature of PPI in implementation research. Understanding PPI in this process-focused way and drawing on Laycock's ideas around PPI-led data analysis, using the idea of touch-points and conversations, made sense of the task, which enabled qualitative researchers to work with the communities and contextualise their work with diverse service user experiences.

There will be blurring between data collection and PPI activity in shaping the research process that needs to be managed sensitively

One of the dilemmas related to the PPI work was the distinction between "data collection " and "PPI activity," an issue that has been flagged (Ocloo *et al.*, 2021) particularly in qualitative work (Shippee *et al.*, 2015)) when there is often an iterative process between data collection and data analysis. This issue was most clearly evidenced by the synergy between the service user data in the case sites and work in the second community event. Rather than using these different narratives as a background, it was important to foreground the knowledge shared and create a separate report about the women's experiences and the common themes that emerged: This was a clear example of the importance of PPI and its power to influence the research process. However, the community input providing context was identified as helping with the analysis, not data collection per se. There are pragmatic differences, for example, not recording, not doing detailed thematic analysis of content, different consenting processes, etc: As Nollett *et al.* (2024) discussed, one key distinction is whether the activity is shaping the research

process (PPI) rather than answering the research question (data analysis). These are less-than clear areas that need ongoing sensitive exploration, particularly with the increasing use of co-design of research reflecting the political/practical argument for PPI as part of "mode2 science" that Greenhalgh identifies.

The term PPI doesn't adequately describe the complexity of representation, involvement and multiple roles that public partners take in implementation research

At each point, the PPI representatives were bringing their experience to the work and encompassing most, if not all, of Barker *et al.*'s (2020) nine PPI roles. In large studies such as SIMCA, it is not uncommon for PPI representatives to have a particular role within a community/third sector organisation; they are skilled in providing the bridge/interpretation from the user's voice to the research team. However, it was still critical for the researchers to hear directly from the communities, to explore the study data that is being presented in relation to their own experience, and to see where there are meaningful connections, if any, be they comparisons or contrasts. At both the individual and representative levels, the language of "Patient" and "Public" did not quite fit, but finding another term that fitted better for the majority proved impossible so the team stuck with "PPI" as at least a recognised shorthand.

PPI is crucial in implementation research to counteract the risk of an inward-looking, self-referencing policy and delivery focus

As described by Burton and Rycroft-Malone (2015), implementation is a complex system and not simply a linear unidirectional flow of knowledge. It could be easy in IR to get absorbed by the complexities of the service provider context and lose sight of the experience of the service user, which ultimately sits at the heart of all policies. One example of this was the service users' positive description of continuity, often not including intrapartum continuity (i.e., not achieving Better Births MCoC model) but with high-quality communication and knowledge of the intrapartum care provision: Thus, while policymakers are taking what can feel like an all-or-nothing approach to promoting continuity throughout the antenatal, intrapartum, and postnatal periods, service users might feel that if this approach compromises antenatal and postnatal continuity, then it is not justified.

In implementation research the PPI roles are inevitably less clear: Take time to build an understanding across the team and acceptance of the ambiguity

While there were many existing working relationships within the team, the SIMCA team as a whole was new, and there was a mix of experiences in IR across the team. Greater ambiguity of the work in IR means that the team process is potentially even more important. Early study meetings were vital for team building, and on reflection, there might have been a benefit in a clearer focus on the roles and relationships within the team. As a study management team (and co-applicants) with shared accountability and a non-hierarchical structure, the aim would be to achieve relational team accountability where team members develop a sense of "reciprocal responsibility, commitment, and shared purpose' (Stewart *et al.*, 2023 P692). This emerges from interactions between team members with key aspects of interdependence, mutual expectations, open communication, collective responsibility, and adaptive feedback. The work on community events in year two of the project highlighted the progress the team had made in forming a cohesive, resilient team, where team members supported each other and adapted to the ever-changing context (ranging from policy shifts to train strikes) that inevitably comes with real-world research. These relationships were built from working together with a shared purpose, but it might have been possible to focus more on this aspect at the start to enable a stronger sense of belonging from earlier in the project. All members of the team had extensive experience of collaboration, and each collaboration will have its own unique character; therefore, we could have worked more on understanding strengths, concerns, expectations, etc..

Ensure that the skills needed for sensitive data collection are equally applied to PPI work; adopt a trauma-informed approach

Reflecting back on the earlier phases of the work, some of the key touchpoints for the team have been when we were accepting and embracing the messiness of the work, times when there was no clear protocol and that needed more in depth discussion to resolve: This echoed themes from Nicholas-Angl *et al.*'s work on the roles of their lived experience advisors in implementation science: One point that felt particularly important from their work was to be really mindful both in the team process and the PPI work in general, to not replicate an experience of not being heard. While the discussions can be conducted with an ethical structure and ethos, the context of PPI is not in-depth individual interviews, so when people describe their lived experience, it can be very difficult to maintain the appropriate position. Alongside a clear route to support, taking a trauma-informed approach to PPI is important, regardless of the nature of your research inquiry; the guidance issued by the team at Imperial College London (Imperial College, 2024) provides a helpful framework to consider this from the start.

Professionalisation of PPI to fit the demands of the funding context and the role – does this set impossible requirements and undermine the process?

Finally, considering the context of research funding, application for funding, submission for ethical review, etc., there are inherent tensions between the lessons we have learned and the context in which we have learned them. When research-focused academic team members seek to engage community-focused members, there is a wish to convey professionalism, experience, and expertise, which often comes hand in hand with certainty and conviction about the way forward, which is reinforced by the funding application process and the formality required to convey ideas. Even in presenting an iterative process with a degree of developmental work, it will be couched in theoretical language privileging scientific expertise over lay language (Paylor & McKevitt, 2019), the co-applicants are all required to provide CVs, to sign off on-line forms etc, task which can be daunting and which inevitably privilege people with previous experience or from a particular background. There is an increasing sense of "professionalisation" of PPI to manage the demands of the role, so as with SIMCA it is really important

to ensure that the unfiltered lived experience doesn't get lost. Efforts have been made to reduce tokenism eg checklists and tools to measure impact of PPI; however as Pearce (2021) argues these potentially mask the importance of understanding the relational dynamic of collaboration. Creating those long-standing collaborations can be difficult in the context of short-term funding and some PPI costing models. The reality described here of uncertainty, the importance of a degree of informality, team-building, messiness of tasks and changing tack would be difficult to represent in the funding phase and are also not often seen in project write-ups.

There is a need for a more theory driven approach to PPI work that more fully captures the work of PPI within the research team itself

The SIMCA study used the Consolidated Framework for Implementation Research (CFIR) (Damschroder *et al.*, 2022) as the central theoretical model at the heart of SIMCA design and analysis. It offers a middle-range theory with wide applicability across different settings and it does include patient involvement: However, the PPI focus in CFIR is on the intervention under study and patient perspectives on implementation efforts (eg patient feedback loops to create a patient centered climate ("inner setting"), the use of patient champions ("characteristics of individuals"), co-design of an intervention ("intervention characteristics") etc). This does not address the role of PPI in the research team itself.

The lack of theory in relation to PPI activity has been identified (eg Ocloo *et al.*, 2021), a gap that undermines our ability to critically examine what we have learned and to ensure that learning is generalised to take the field of PPI forward. There is a multiplicity of frameworks for PPI, described in Greenhalghs *et al.* Systematic review (Greenhalgh *et al.*, 2019) and an ever-growing number since that review was published, but, as Greenhalgh identified, there seems to be little evidence of transferability: Whilst they might be useful as a design tool or as a checklist to ensure consideration is given to the multiple aspects of PPI, to what extent this progresses the field is debateable. There is a risk that this perpetuates a model of involvement that Beresford (2002) describes as the managerialist/consumerist approach, aiming to improve a service like a 'product' based on consumer feedback, rather than considering it more as a complex intervention (Fredriksson *et al.*, 2025).

Our experiences in SIMCA identified the impact that needs to be encapsulated in a more reflective, systemic model; for example, there were resonances with Rycroft-Malone *et al.* 's (2013) programme theory work in relation to collaborative action around implementation; this included mechanisms such as relationship building, motivation, knowledge exchange, etc., and incorporates features such as history of partnership and responsiveness. There are also parallels to be drawn from work on organisational culture that incorporates some of the important components relating to leadership and power (eg Tadesse Bogale & Debala, 2024). However, Erikainen and team's work, (Erikainen *et al.*, 2022) discussing engagement in health research from a feminist philosophical perspective, highlights some of the more fundamental systemic issues such as the institutional framing of knowledge production, how "value" of engagements is multifactorial, with academic impact being only one aspect of the value of the work. Their discussion, incorporating the notions of positionality (including knowledge production coming from multiple perspectives) and reflexivity, emphasising the importance of processes as well as products, has a closer fit with our experience of engagement as an organic process. Recognising the lack of emerging theories as a limitation of this study, work to bring the findings from this study into a more theorised model will be an ongoing project, structured around the lessons we have learned.

Conclusions

Implementation Research plays a central role in the translation of evidence-based research into practice, and PPI must be an integral part of that research process. The experience of SIMCA has shown how important it is for meaningful and trusted relationships to underpin that work, both across the team and between the team and community. The roles of patient and public partners in implementation research are often ambiguous and take time to develop, requiring a reflexive approach within the research team as they all navigate uncertainty, with sensitive leadership recognising the particular challenges this approach may bring for team members. Research teams would benefit from considering PPI in relation to their own functioning as a team, as well as the impact PPI can have on the external-facing aspects of the work, an area where a more well-developed theoretical approach is needed.

Statements and declarations

Ethical approval and informed consent

This study has been approved by NHS, East Midlands – Nottingham 2 Research Ethics Committee and Health Research Authority, REC reference 23/EM/0272, approval date 14th December 2023. All research participants in the SIMCA study provided full written consent for participation.

Data availability

This article relates to patient and public involvement in SIMCA and therefore there is no data associated with this article. The research participants of SIMCA did not give written consent for their data to be shared publicly, and the data cannot be deidentified sufficiently due to the nature of the participant roles and the sensitive nature of the research. However any requests to access data can be sent to the chief investigator Aled Jones (aled.jones@plymouth.ac.uk) and requests with suitable ethical approval will be considered where it does not contravene the conditions identified relating to participant consent.

Extended data

The extended data associated with the SIMCA study can be found at

Figshare Doi: https://doi.org/10.6084/m9.figshare.27831345.v1 (Milton, 2024)

Acknowledgements

Our grateful thanks go to the Mosaic Trust and Tommy's Communities who supported this project throughout, were generous with their time and trusted us with very personal stories of their experiences of maternity services: We hope you feel this description does justice to the work we did together. Our thanks to Lorraine Craig, Mandie Dorise and Penny Farthing who provided administrative support and also to the Project Advisory Group who reflected on the work and encouraged us throughout the project.

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Open Peer Review

Current Peer Review Status: ✔ ?

Version 1

Reviewer Report 29 October 2025

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?

Julie Abayomi
School of Applied Health and Social Care, Faculty of Health, Social Care and Medicine, Edge Hill University, Ormskirk, Ormskirk, UK

Thank you for asking me to review this well-written and thoughtful paper. I have some minor suggestions for improvement:

1. The plain English summary contains some complex words and could be revised to make it easier to understand for a lay audience (e.g. integrated, contributed, perspectives etc.).
2. For a PPI paper, the authors need to refer to the GRIPP2 reporting guidelines (Staniszewska et al., 2017 - ref 1) and ensure that the paper in written to meet these guidelines.
3. In line with GRIPP2, are the PPI representatives named as co-authors on the paper?

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Is the work clearly and accurately presented and does it cite the current literature?
Yes

Is the study design appropriate and is the work technically sound?
Yes

Are sufficient details of methods and analysis provided to allow replication by others?
Partly

If applicable, is the statistical analysis and its interpretation appropriate?
Not applicable

Are all the source data underlying the results available to ensure full reproducibility?

Yes

Are the conclusions drawn adequately supported by the results?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Maternal Nutrition

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Reviewer Report 16 October 2025

https://doi.org/10.3310/nihropenres.15228.r37579

Julie Roberts
University of Leicester, Leicester, England, UK

This is an interesting case study of patient and public involvement (PPI) in implementation research. The specific example explored is the implementation of midwifery continuity of carer, a topical and relevant issue in healthcare. The authors have conducted a narrative review and case studies at six maternity sites. A comprehensive and multi-faceted approach to PPI is presented, thoroughly described. Existing literature and frameworks are used effectively to frame the research approach and findings. The article makes the case that PPI is underutilised in implementation research and seek to promote interest and inform future practice in this field. The contribution made by PPI at each stage of the research is clearly set out, providing examples of how PPI can be beneficial. I enjoyed the reflexive approach and the acknowledgement of the inherent uncertainty, messiness and iterative nature of the research process.

I have a few suggestions to strengthen this interesting article.

The article would benefit from clearer positioning in the introduction. The early sections of the paper draw on literature about PPI in both research and healthcare services. I can see the relevance of both but this should be justified. A recent review of PPI in implementation research should be consulted and any additional insights added:
Mathieson, A., Brunton, L. & Wilson, P.M. The use of patient and public involvement and engagement in the design and conduct of implementation research: a scoping review. *Implement Sci Commun* **6**, 42 (2025). [Reference 1]

The role of PPI in this study is partly described as helping to ‘understand relationships between national and regional decisions and systems.’ The meaning of this is unclear to me and is not

connected to the roles for PPI described in the introduction. More information may be helpful.

The formal structures in place for PPI (SMG, PAG, PPI forum) are comprehensive. I would have liked to understand more about the thinking behind these structures and how they relate to each other and the research processes. Further justification of the approach would be a useful addition to the paper. A diagram may help the reader to see the overall picture.

The plain language summary should be edited for clarity with particular attention to sentence length.

References

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Is the work clearly and accurately presented and does it cite the current literature?
Partly

Is the study design appropriate and is the work technically sound?
Yes

Are sufficient details of methods and analysis provided to allow replication by others?
Yes

If applicable, is the statistical analysis and its interpretation appropriate?
Not applicable

Are all the source data underlying the results available to ensure full reproducibility?
No source data required

Are the conclusions drawn adequately supported by the results?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: qualitative research in maternity and neonatal care; PPIE

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.