Stakeholder involvement in the development of a new proactive clinical review of patients prescribed opioid medicines long-term for persistent pain in primary care

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Competing interests

Some members of the research team have roles with and/or other current grant funding from the National Institute for Health and Care Research (NIHR). CDM, MS and LD are NIHR Senior Investigators and CDM is Director of the NIHR School for Primary Care Research. CJ is a steering committee member of the NIHR Incubator for Applied Health and Care Methodology. CDM, CJ, NC and CW are part funded by the NIHR Applied Research Collaboration West Midlands. CJ and SW are NIHR funding panel members. SAH and CW are NIHR Research Support Service advisors. SAH, CJ, CW, LD, TH, RK, TP, MS, SW, CDM and JA have active and/or completed research awards from NIHR. RK is currently President and SAH is an elected council member of the British Pain Society. RK is a member of the UK Government Advisory Council on the Misuse of Drugs. Whilst we do not believe that the roles / funding mentioned above will present a conflict of interest, we acknowledge that they could potentially be perceived as such. All other authors have no competing interest to declare.

Data availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

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Abstract

Background

Stakeholder involvement is a core element of the Medical Research Council (MRC) framework for developing and evaluating complex interventions but approaches to involve stakeholders are not well- reported. We outline how stakeholders contributed to co-designing a **P**roactive clinical **R**eview of patients taking **O**pioid **M**edicines long-term for persistent **P**ain led by **P**harmacists working in primary care **T**eams (the PROMPPT intervention – a review and pharmacist training package).

Methods

We brought key stakeholders together to co-design the PROMPPT intervention using a person-based approach, alongside evidence from best practice guidance. We established a community of practice comprising of 3 complementary groups: a patient advisory group, a pharmacist advisory group, and a mixed stakeholder group. Patient stakeholders were identified from an existing patient involvement group. Professional stakeholders were identified using networks and social media. The 3 groups met in iterative workshops with predefined aims. We offered reimbursement for the stakeholders' time.

Outcomes

The patient advisory group (n=10), pharmacist advisory group (n=6), and mixed stakeholder group (n=16) each met for 2 or 3 workshops between April 2019 and February 2020. Stakeholders had expertise, often cross-cutting, in lived experience, persistent pain, opioids, delivering primary healthcare, and/or promoting behaviour change. Patient stakeholders provided their perspective of consulting about their pain and opioids. Pharmacist stakeholders provided their perspective on how pain reviews were happening in practice and on considerations for training (e.g., vignettes and experiential learning were considered important). The mixed stakeholder group provided a breadth of views highlighting current practice including: the value of engaging the wider GP practice team, issues around clinical responsibility for prescribing, and that international clinical guidance was not always relevant to UK primary care.

Conclusions

By understanding context of the PROMPPT intervention, stakeholders worked to develop a new pharmacist-led primary care review ahead of feasibility testing. We make recommendations for future developers of complex interventions.

Patient and Public Contribution

Patient stakeholders, including a lay co-applicant (CS) supported by a PPI support worker (AH), helped develop and refine the intervention. CS and AH read and contributed to the initial manuscript and approved the final manuscript.

Key words (up to 7)

Complex research intervention, service user involvement, methodology, community of practice, chronic non-malignant pain, implementation, primary care

Background

Opioid prescribing is common for people with persistent pain (pain lasting 3 months or longer and not caused by cancer), despite a lack of evidence for their long-term effectiveness in this population and growing evidence of harm (1-3). Best practice guidance recommends patients prescribed opioids should have a regular, comprehensive review (4-6), but this can be difficult to implement (7,8). In the UK, most opioid prescribing happens in primary care where a shift to multidisciplinary working has seen an expansion in pharmacists working in GP practices (9, 10). These practice pharmacists seem well-placed to take a proactive role in reviewing patients prescribed regular opioids for persistent pain. However, both patients and health care professionals often find conversations about opioids difficult (11) and there is no evidence about what an effective pharmacist-led primary care review for patients prescribed opioids should look like.

The Medical Research Council (MRC) framework is regarded as the gold standard for developing complex interventions (12). When developing new interventions, robust methodology across the whole development and evaluation pathway helps to give interventions the best chance of being effective and implemented, and of being acceptable to patients receiving the intervention and the health care professionals delivering it (12). Stakeholder involvement is a core element of the updated MRC framework (13) and in guidance by O'Cathain et al (14) it is considered a key action for researchers when developing complex health interventions.

Stakeholders are defined as individuals or groups who are responsible for or affected by health- and healthcare-related decisions that can be informed by research evidence (15). Key stakeholders include patients, health care providers, those with responsibilities to commission and pay for health care services, policy makers (for example, from professional associations) and researchers (15). Although stakeholder involvement is recommended by major funders of research (for example, the UK National Institute of Health and Care (NIHR)), approaches to involving stakeholders in the development of new interventions are not well reported (16).

One approach to enable meaningful involvement is to bring stakeholders together to build a community of practice (17). A community of practice is an organised group of people with shared interests and goals, with the key functions of peer problem-solving and generating new ideas (18). This paper describes how we used this approach to embed stakeholder involvement into the development of a new **P**roactive clinical **R**eview of patients taking **O**pioid **M**edicines long-term for persistent **P**ain led by **P**harmacists working in primary care **T**eams (the PROMPPT intervention). The aim of the PROMPPT intervention (a review and a pharmacist training package) is to support patients with persistent pain in primary care to reduce opioids, where appropriate, without increasing pain or pain-related interference. Our worked example illustrates how we established, built and maintained a community of practice to co-design the PROMPPT intervention with stakeholders. We have used the short form version of the Guidance for Reporting Involvement of Patients and the Public checklist (GRIPP2-SF) (19) checklist for reporting patient and public involvement throughout the manuscript (see table in supplementary information).

Methods

In line with the MRC Framework (12), we combined a person-based approach (20) combined with best practice guidance, theory and stakeholder involvement work. Before the award of funding, targeted stakeholder activity supported the development of the logic model (figure 1).

<< Figure 1 here >>

This paper describes the involvement work to optimise the logic model, design the PROMPPT intervention and refine it ahead of formal feasibility testing. The stakeholder activity was preceded by a synthesis of published guidance for guidelines of opioid management for persistent pain and carried out alongside primary qualitative data collection (interviews, online discussion forum, in-practice testing and focus groups) (21-23) and ahead of formal evaluation as illustrated in Figure 2.

<< Figure 2 here >>

We established 3 complementary stakeholder groups, specifically, a mixed stakeholder group and, to ensure adequate representation of the target population (those who will receive and deliver the intervention), a patient and a pharmacy advisory group. The groups met in iterative workshops, each with predefined aims. We offered reimbursement for the stakeholders' time (24). To keep the stakeholders up to date with the progress of the research programme, we created and distributed newsletters and posted regular updates on the study website (promppt.co.uk) and using social media. To capture the outputs of the workshops, a process of reviewing and personal reflections was embedded into the involvement work.

Patient Advisory Group

A group of patient stakeholders was convened with the aims of: 1) providing patient perspective on the design of personalised discussions about opioids and strategies to support self-management and, 2) co-designing patient resources. Patient stakeholders, with experience of taking opioid medicines for persistent pain, were recruited from the Research Users Group at the School of Medicine, Keele University. The patient stakeholders were supported by a dedicated Patient and Public Involvement (PPI) support worker (AH) before, during and after meetings (25). This group included co-author CS, who also had a link role with the mixed stakeholder group and the research team. The group, which was convened to support the funding application and continued postfunding to support intervention development, met for face-to-face workshops in buildings on the university campus.

Each workshop had a similar structure of starting with a researcher-led presentation, followed by a facilitated discussion, action planning, summary and next steps. The presentations were developed to outline the aims of the meeting; to provide some context in terms of how the research programme had moved forwards towards its goals; and to summarise key and complex issues (26). Meetings were audio-recorded, with consent, for the purposes of capturing the discussions accurately. A plain English summary of the discussions, the actions taken and those not taken forward (and why) was sent to stakeholders following each meeting. Written materials were in plain English and the use of jargon minimised (27).

Pharmacy Advisory Group

Pharmacists with experience of working in primary care teams and/or with experience of working with patients prescribed opioids, long-term for persistent pain were invited to join the pharmacy advisory group. The emphasis of the pharmacy advisory group workshops was placed on seeking the experiences and advice from members of the group with the aim of 1) providing pharmacist perspective on the design of personalised discussions about opioids and, 2) co-designing the pharmacist training package. Pharmacists were recruited from across the UK by advertising through professional networks and using social media. Meetings were held remotely (using teleconference services) and were audio-recorded with consent. To take account of scheduling difficulties, multiple workshops were held, with a minimum of two pharmacists per meeting. Workshops were facilitated by a member of the research team who was an academic pharmacist (SW). Documents outlining the background and aims of each of the workshops were circulated in advance of the meetings.

Mixed Stakeholder Group

The mixed stakeholder group was convened to: 1) review and prioritise techniques and strategies considered best practice in persistent pain management (for example, regarding prescribing, opioid reduction and supported self-management) identified in the synthesis of best practice guidelines, and 2) agree the content and structure of the PROMPPT review ahead of formal feasibility testing.

The mixed stakeholder group comprised patient stakeholders with relevant lived experience and healthcare professionals, with expertise regarding opioids, persistent pain, and/or delivering primary care services. Healthcare professional stakeholders were recruited through professional networks. Acknowledging the challenges of facilitating mixed groups, patients with experience of working alongside healthcare professionals (e.g. in project steering committees) were recruited from the Research User Group at Keele University. Patient stakeholders were accompanied by a PPI support worker during the workshop and afterwards, attended a debriefing session.

The mixed stakeholders convened for face-to-face workshops. The location, structure of the workshops and format of written information were as per the patient advisory groups. If stakeholders were not able to attend, individual meetings were scheduled. To disseminate findings from these workshops to the patient advisory group, the facilitating researchers subsequently met with patient stakeholders, co-author CS and the PPI support worker. Parallel sessions were held with a pharmacist stakeholder with the same purpose.

Outcomes

Characteristics of community of practice members

Patient advisory group

In the patient advisory group (n=10), all members had experience of opioids, either personally or by caring for others who had taken opioids regularly for persistent pain. Previous experience of involvement in research varied and three members of the group had no previous involvement. Most of the patient stakeholders were female (n=8) and they all came from the local area (Staffordshire, UK).

Pharmacy advisory group

The Pharmacy advisory group comprised of 6 pharmacists with cross-cutting experience of working in GP practices, community pharmacy, pain management and/or commissioning. The Pharmacy stakeholders expressed a wide breadth of professional interests in pharmacological and non-pharmacological pain management, decreasing dependence forming medicines, medicines optimisation, pharmacist education, research, non-medical prescribing, and/or having advised national clinical practice of pain management.

Mixed stakeholder group

The mixed stakeholder group (n=19) comprised; of two patient contributors, two GPs, one practice nurse, two pharmacists, two practice managers, one social prescriber, two physiotherapists and one clinical psychologist from a community pain service, one psychological therapist from a community mental health team, two psychiatrists from addiction services and one academic health psychologist. One of the GPs and one of the pharmacists had responsibility for commissioning of primary care services.

Stakeholder contributions to co-design and optimisation of the PROMPPT review

The stakeholder involvement work comprised 7 workshops between April 2019 and January 2020 (mixed stakeholder group n=3, patient advisory group n=2 and pharmacy advisory group n=2). The views and recommendations of stakeholders and the actions taken as a result are presented in Table 1.

<<Table 1 here>>

All 3 stakeholder groups started by discussing the overall principles for the new PROMPPT intervention and then moved towards discussing specific elements of the logic model. In the early stages, the views and recommendations of the stakeholders often fed directly into primary qualitative data collection (e.g., informing topic guides for the interviews). Other recommendations were carried forwards for further discussion in later workshops (e.g., to what extent the intervention should focus on pain self-management). Towards the end of the stakeholder consultation phase, recommendations (e.g., that online training would offer important flexibility and potential for scale up) fed directly into the PROMPPT intervention that was evaluated in the feasibility study. There were topics where there was uncertainty amongst the stakeholders and they did not always have clear recommendations (e.g., whether the review would result in a change in onward referrals and how to manage this). In these instances, the action taken by the research team was to check and confirm that the topic of referrals was scheduled to be discussed in the qualitative studies.

Patient stakeholders provided their views of consulting with healthcare professionals about opioids and non-pharmacological pain management strategies. They represented views of other groups of people (e.g., in elderly people and those taking high-dose opioids). Pharmacist stakeholders provided their views from the perspective of their profession (e.g., advising on how pain reviews were happening in current practice). The mixed stakeholder group provided their views relating to current GP practice (e.g., by highlighting the value in engaging the wider GP practice team), policy (e.g., identifying issues around who takes clinical responsibility for prescribing decisions), organisations (e.g., highlighting that different areas commission different services) and cultural factors (e.g., that international clinical guidance from outside the UK was not always relevant to UK primary care).

Discussion

Best practice guidance for the development of complex interventions highlights stakeholder involvement throughout the development process as a key action for intervention developers to consider (13, 14) but this is often under-reported. This paper provides detailed insight into stakeholder involvement in the design of a prototype PROMPPT intervention for in-practice testing and subsequent refinement of the review ahead of a formal feasibility study. Our worked example links stakeholder involvement to each of the key actions in O'Cathain's guidance for intervention developers (14) thus extending current thinking in this field.

Within a 12-month period, with a clear purpose of co-designing the new PROMPPT intervention, the PROMPPT community of practice comprised and involved many stakeholders, including a wide range of professionals. We set an ambitious agenda to incorporate the perspective of stakeholders and to learn from their experiences. We placed importance on having on-going dialogues, building and maintaining relationships. At each stage, we collected evidence (for example, emerging evidence from primary qualitative data collection) and took that to discuss with the stakeholders. We brought together a large team, the community of practice, where iterative group work and the interactions between the groups were of added value. A strength of our involvement work was the utility of the reflective approach, which helped us to better understand the views of the stakeholders and potentially helped us to make better decisions (28); for example, on the back of concerns from the patient advisory group about acceptability, we stopped work on a prototype shared decision-making tool. The impact of our work is that we have been able to outline recommendations, linked to the key actions (14), for researchers when planning stakeholder involvement in complex intervention development work (see table 2).

<< Table 2 here >>

We were clear from the outset that the research programme aimed to evaluate the new intervention and that it needed to be implementable in real world NHS settings. We worked together with stakeholders to understand the context, generate ideas (such as the importance of a holistic approach), and gain insights into practical aspects of delivering reviews. They anticipated barriers, like the feasibility of direct phone calls to specific staff members in primary care, and identified facilitators for future implementation, such as integrating lived experience into patient resources, which included issues around potential scale up (e.g., flexibility of including online training). We have demonstrated that the stakeholders' views and recommendations identified a breadth of features of context including those relating to the individual, profession, culture, service and organisation (29).

Identifying where there were gaps in the stakeholder's understanding was as important as taking onboard their views and recommendations. The gaps often reflected wider uncertainty about issues, e.g., because the role of the pharmacist in GP practices was an emerging one. In these cases, the strength of our work was that the stakeholder involvement ran alongside and subsequently informed the qualitative data collection and analysis. The effectiveness of complex interventions like PROMPPT is inextricably linked to implementation and context (30). Making sense of the complexity of the context in which the PROMPPT intervention was intended to be evaluated and implemented should give it the best chance of being successful in practice (29).

We set out to co-design the new intervention and planned the work before the onset of the global pandemic in 2020. It is likely that the things we did (e.g., involving stakeholders in the initial stages of PROMPPT, the role of the PPI support worker and the stakeholder debrief sessions) helped to foster a collaborative approach and address power differentials (31). The role and lived experience of the PPI support worker was key to promote trust and good working relationships with patient stakeholders and has been previously advocated in settings with under-served populations (25). The pandemic brought about a rapid change in how research was conducted and implemented. Having spent time building and maintaining relationships and having already identified that online training could be important to consider, the intervention was quickly modified for remote delivery given the need for social distancing.

There are some limitations to our work to consider. Whilst we involved many stakeholders representing people with different backgrounds, it is likely that some were not represented. The majority of our patient stakeholders, despite living with persistent pain, were still able to engage in valued activity such as participating in public involvement work, and we acknowledge that this is often not the case for many people from this patient population.

Most of the professional stakeholders completed their undergraduate training, and had gained most of their clinical experience, within the UK; and they were mostly in mid- to late- career stage. In the challenging context of the NHS, where there is a high turnover of staff and the proportion of the workforce moving from outside the UK is growing (32); we recognise that the voices of professionals who were either in the early stages of their career and/or were trained from outside the UK were not well-represented. In the future, intervention developers should plan approaches to reach, engage and involve diverse patient *and* professional stakeholders.

At the time of our involvement work, we did not record ethnicity of stakeholders and our observations were that our community was limited in ethnic diversity. It is now widely acknowledged that ethnic diversity of stakeholders and those who participate in research often does not reflect that of the wider population (33). Since the completion of our work the National Institute for Health and Care Research have taken action to improve the lack of representation from under-served groups in research through public partnership (34), development of guidance for researchers and funders (34), and the development and testing of a race equality framework (34,36). In the future, improving the diversity of all stakeholders and participants in research is vital (33,37).

Co-production, whereby stakeholders would have had equal decision-making powers with the research team (38, 39) was seen as a critical element of the change due to the pandemic (39) and key to broadening engagement of people with under-served characteristics. However, practical barriers of co-production are that it is time-consuming and expensive in terms of researcher time and resources (40). In the future, funders and intervention developers need to be realistic about the time and funding required for involving diverse stakeholders in robust and inclusive intervention development work.

Conclusion

We convened 3 complementary groups of stakeholders and brought them together in a community of practice approach to develop the PROMPPT intervention that is ready for testing in a feasibility study, ahead of a full-scale cluster randomised controlled trial. The community was greater than the sum of its parts. Stakeholder involvement was key to understanding the breadth and complexity of the context of the new intervention. We have provided evidence that stakeholder involvement extends to all of the key actions for researchers when developing complex interventions. Bringing together stakeholders alongside theory and research evidence provides a rigorous framework within which to operationalise intervention development. Specific to stakeholder involvement, we make our own recommendations for researchers when planning complex interventions.

List of abbreviations

MRC – Medical Research Council

NHS – National Health Service

NIHR - National Institute of Health and Social Care

PROMPPT - Proactive clinical Review of patients taking Opioid Medicines long-term for persistent Pain led by Pharmacists in primary care Teams

PPI – Patient and Public Involvement

UK – United Kingdom

GP - General Practitioner

Authors' contributions

SH led the work involving iterative stakeholder activity, supported by NC, CW, TH, SW and with oversight by JA and CJ. CS had the role of lay co-applicant, supported by AH (PPIE support worker). CM is the chief investigator of the PROMPPT research programme and JA is the principal investigator. JA, LD, CJ, RK, CM, TP, MS, CS and SW were grant holders and helped refine the development of the intervention. SH and CJ drafted the initial manuscript and all authors have read, contributed to further drafts and approved the final manuscript.

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Legend for tables and figures

Table 1. Work undertaken by stakeholders to co-design the PROMPPT intervention

Table 2. PROMPPT stakeholder involvement and recommendations for future work mapped to key actions for intervention developers (O'Cathain et al 2019)

Figure 1. The PROMPPT Logic model

Figure 2. Research & stakeholder activity in the development of the PROMPPT intervention