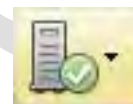


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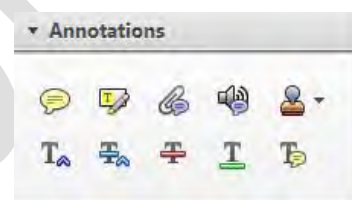


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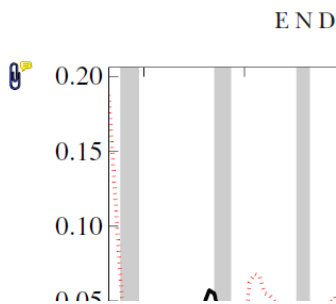
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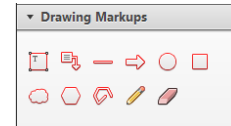
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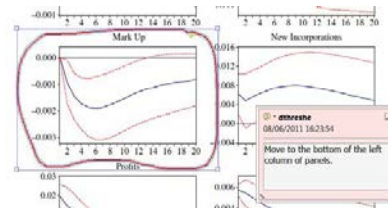
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Involving pregnant women, mothers and members of the public to improve the quality of women's health research

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Applied clinical research should be for the sake of society, not solely for the sake of a scientific endeavour. Accepting this principle also requires us to reconsider the paternalistic approach that dominates medical research. To conduct research in response to and in harmony with the patient and public voice represents a strong cultural shift. For its proper implementation, beyond paying lip service, researchers need a new mind-set and a new work ethic. How can they incorporate patient engagement in their work from design and conduct of studies to interpretation and dissemination of findings? This is not an easy task. In this commentary, drawing on our experience of developing Katie's Team, a patient and public advisory group for pregnancy and childbirth research,¹ we outline how meaningful collaboration can be fostered in every step of the research lifecycle (Figure 1).

What is patient and public involvement (PPI)?

Put simply, PPI is the encouragement of health service users to engage actively in research, policy development and service delivery.² Emerging data demonstrate the positive benefits of PPI initiatives, including improved quality of targeted research, wider dissemination of its findings and better integration of findings into healthcare policy and practice.^{2,3} Hence, research funded by taxpayers' monies increasingly demands active PPI.⁴ National and international organisations are beginning to harness the power of health service user involvement, advocating for public participation in research planning, technical consultations with consumers, and the development of resources

and information to support PPI, e.g. The International Association for Public Participation,⁵ The European Patients' Forum⁶ and The INVOLVE initiative.⁷ As things stand, researcher-led investigations sometimes prove irrelevant, often are too small in sample size or fail to achieve target size,⁸ only infrequently complete on time or within budget,⁹ suffer poor dissemination,¹⁰ and take too long to permeate into practice. PPI may help in responding to these challenges.³ Women's health researchers and publishers need to develop the best ways to work closely and effectively with patients and public.

Asking the right people to come up with the research questions

PPI initiatives in pregnancy and childbirth research differ from those in chronic conditions, not least because motherhood is a transient health experience in a woman's life. PPI representatives can have a variety of lived experiences of pregnancy and childbirth, ranging from low-risk, intervention-free home birth to prolonged hospitalisation with lasting morbidity.¹¹ This variation can shape their attitudes and will inevitably influence their contribution to research. At the outset researchers need to ensure that their questions are shaped by the input of PPI representatives when designing a research project (Figure 1). For example, PPI may clarify the priority areas of health service users such as impact of a condition on quality of life, rather than laboratory measures, as outcomes.¹² PPI consultations can provide insight into how to tackle emotive subjects in a sensitive manner, e.g. domestic abuse and stillbirth.¹³ The transient nature of pregnancy and the lifestyle changes that ensue, mean that accessing individuals to participate in

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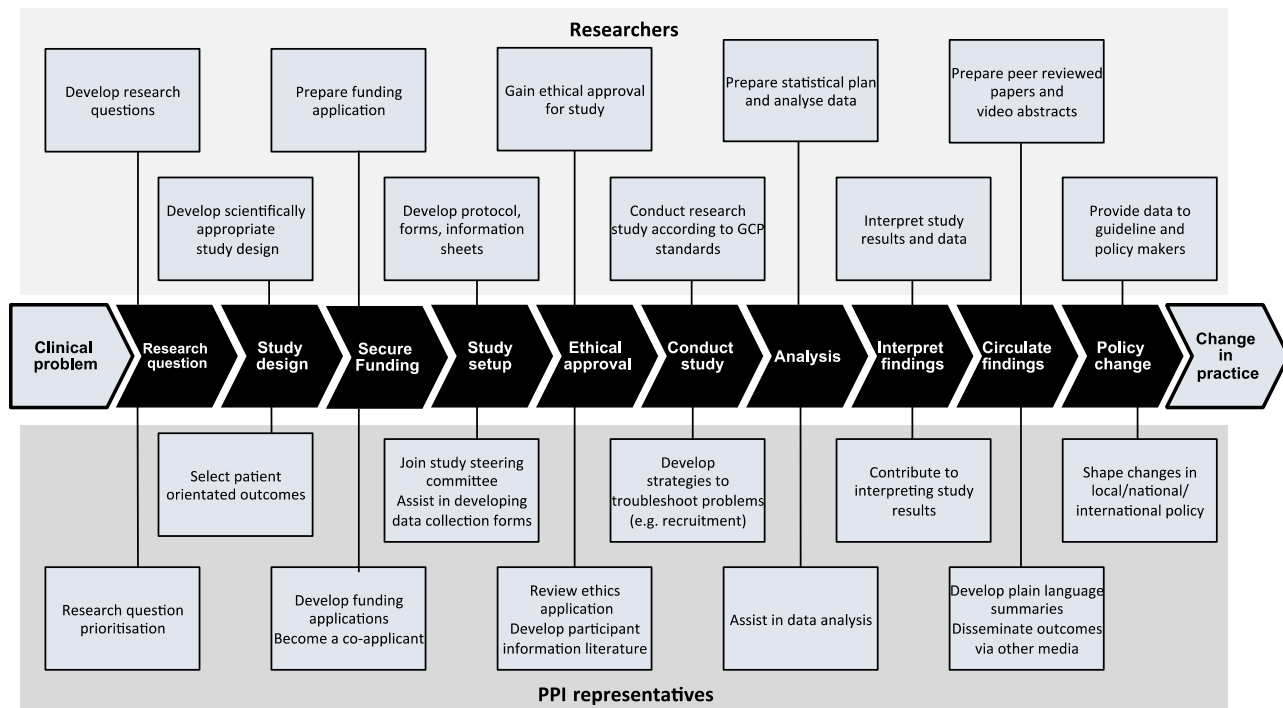


Figure 1. The life cycle of a research project and areas where PPI representatives can contribute to the processes that researchers are undertaking. GCP, good clinical practice; PPI, patient and public involvement.

pregnancy-specific PPI initiatives is challenging.¹¹ Approaching study participants with face-to-face invitations, recruiting participants through local community support groups and nurseries,¹² and using online announcements are useful ways of identifying interested audiences. National research funding calls are increasingly being based on the input of patient support groups to prioritise research questions, rather than being investigator-led, to ensure that publically funded research is of the greatest relevance to health service users.¹⁴

Input in study design

A diverse group of individuals in terms of socio-economic background, varied experiences of pregnancy and family members and carers of pregnant women can provide alternative perspectives which can impact on the merits and feasibility of various design options when planning a study (Figure 1). PPI representatives can provide insight into how an intervention will be used by people in real life and what outcomes matter when assessing effects.¹¹ In our consultations on a proposal of lifestyle interventions for gestational diabetes prevention in pregnancy, it was relatives of pregnant women who emphasised the importance of including family support mechanisms in any studies of lifestyle interventions, to ensure these are followed by participants throughout the study. When we discussed the timing

of antenatal and postnatal visits for a proposed study, those PPI representatives who had a personal history of gestational diabetes highlighted the importance of the timing of postnatal follow up, which they recommended should be after the routine 6-week visit. PPI input when integrated into the proposal makes for a more feasible study, reducing the risk of failure to recruit.

Securing funds and approvals

There can be many misconceptions about pregnancy research among patients and public.¹⁵ Equally there are misconceptions about patients' readiness to participate in research among academic members of committees that grant funds and permissions, e.g. ethical approval. Both are detrimental to research. Pregnant women can be fearful of the potential side effects of new interventions, particularly with prevalent stories in the media.¹⁶ Active engagement with PPI representatives can help dispel these myths.¹⁵ PPI representatives can be a source of knowledge in identifying areas within a project that may generate debate or confusion. Women with a lived experience of pregnancy complications provide helpful practical insight into ethical issues, for example regarding emergency care research such as that during labour,¹⁷ which cannot necessarily be comprehended by armchair committee members. In one of our studies,¹⁸ PPI representatives provided solutions that

helped us and our ethics committee balance the arguments for advance versus retrospective signed consent for a study of an obstetric haemorrhage intervention. Interested and motivated PPI representatives have recently been co-applicants and will be co-authors on some of our research projects, allowing deeper PPI engagement in the research process and providing formal recognition of their contributions.

Study conduct

Inclusion of PPI representatives in research conduct has traditionally been limited to joining trial steering committees, often as a token representative or as an after-thought. Figure 1 demonstrates that PPI input can be critical for trouble-shooting issues such as recruitment and participant retention, as well as being a point of contact external to the scientific research team. PPI representatives should have a formal role in research promotion, raising awareness and increasing engagement in the relevant communities. Traditionally, PPI input has heavily involved writing and reviewing participant information sheets. Involvement can be wider than this: N.M. contributed to a recruitment drive on a study on epilepsy in pregnancy through a video testimony, motivating and engaging researchers and potential participants. From her personal experience as a trial participant, she provided insight into how to use patient questionnaires judiciously in this study. Researchers should bear in mind that this level of involvement may require specific ethical approval.¹⁹

Data analysis and interpretation

Once statistical analyses have been completed and results known, involving PPI representatives can be beneficial in providing alternative interpretations of observed findings. The Pregnancy Sickness Support group has discussed themes emerging from a systematic review of studies of nausea and vomiting in pregnancy with women with lived experiences of these issues and found these women drew different conclusions on results than those published.²⁰ Systematic reviews and qualitative study designs naturally lend themselves to including PPI representatives in the analysis, by allowing for the discussion of overall themes. In our opinion, quantitative primary research can be similarly discussed with PPI representatives, ensuring their interpretations are included in the final publication of the results.

Dissemination, not just publication in journal articles

Publication in current formats typically for medical publishing does not lend itself to diffusion beyond a limited scientific readership. Involving PPI representatives (Figure 1) provides new, previously underutilised avenues for research dissemination increasing the potential reach of research output. For example, using varied social media

channels and providing video summaries of completed projects can reach women who would likely benefit most from the research findings. N.M. has been involved in disseminating the key recommendations of new national guidelines on the management of epilepsy in pregnancy to her local clinical care commissioning group.²¹ Including PPI representatives on scientific papers, not just as regards refining a plain language summary, is an area researchers should seriously consider. Medical publishing should encourage reporting of the role of PPI formally as a subsection of the Methods section of a paper. Medical journals are beginning to acknowledge the added value of patient involvement and include PPI experts within their peer review processes.^{22,23}

Research training for PPI

PPI representatives, whether acting as co-investigators or sitting as independent members on committees, can face several challenges. Learning the principles underpinning trial conduct and governance can address some of these challenges.² There are arguments for and against training in research methods for PPI representatives. Understanding basic ethical and research principles prior to engaging in discussions can develop a common language useful for consultations.²³ For researchers, appreciating the varied skill mix that PPI brings is important. Some PPI representatives may already be very familiar with research principles; when this is not the case, some prior guided learning can be useful. In our experience, providing short guided learning (e.g. via e-learning) on basic scientific principles and research processes (e.g. study design and research ethics committee review) prior to discussing a new project is valuable. This enables an even playing field between PPI representatives with and without prior knowledge of research processes to engage in meaningful discussions when meeting face-to-face. The argument against training for PPI representatives is centred on the clouding of PPI representatives' perception and bringing lay people into a medical mould. This can easily make their opinions unrepresentative of most patients and members of the public. Although this has not been our experience, this area needs further consideration and research in its own right.

Making PPI representative

It is necessary to use a variety of strategies to engage a broader group of individuals in research, otherwise PPI risks becoming biased toward particular interests. Ensuring that remote communities and hard-to-access ethnic groups can take part in PPI initiatives is challenging. From work we have conducted, diagrammatic representations of research questions¹² can allow for a dialogue to be developed between researchers and PPI participants with limited literacy or language skills. Many existing PPI

representatives in our own group have brought in new members, widening access by bringing in disengaged and often marginalised local women.²⁴

Conclusion

Active collaboration between researchers and members of the public and patients is now recognised as best applied clinical research practice.² For women's health research, if investigators ensure that pregnant women and mothers are included in planning, conducting and disseminating studies, there is a stronger potential effectively to influence practice than has been possible in the past. The goal of transforming healthcare outcomes through relevant, quality patient-oriented research is achievable through PPI.

Disclosure of interests

Full disclosure of interests available to view online as supporting information.

Contribution to authorship

JD conceived the idea for the commentary. NM, JD and DL wrote the first draft of the manuscript and contributed to arguments presented. ST and KSK contributed to the arguments presented in this manuscript and in designing the figure.

Details of ethics approval

None required.

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