Title:

The role of Participatory Action Research in developing new models of healthcare: perspectives from participants and recommendations for ethical review and governance oversight

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HIGHLIGHTS

- Practical guidance for using a Participatory Action Research (PAR) to develop and evaluate new models of healthcare is lacking.
- Participants in a PAR study of a new model of community respiratory care highlighted ethical and governance challenges to implementation.
- Recommendations for researchers intending to incorporate PAR methods in clinical research within the ethics and governance structures of the UK are proposed.

Abstract

Background: Participatory Action Research (PAR) is a methodology often used in social sciences, which involves groups of people in action, reflection and iterative change. In PAR, 'traditional' researchers become participants, and people who comprise 'traditional' participants become researchers, facilitating cohesiveness and communication within the team. However, PAR is less used in healthcare, despite the . complexity of providing and receiving health and social care. Development and testing of the delivery of new models of care is an area with increasing service-user participation, but often with no structured or formalised framework to embed end-users. This may be due in part to the complex ethical and governance systems in healthcare research, and the lack of practical guidance on using PAR as a research method within this context.

Methods: We carried out a PAR project to develop and evaluate the implementation of a new model of care for the assessment and management of respiratory conditions in the community (MISSION ABC). The care model delivered a community-based multidisciplinary clinic involving healthcare staff from both primary and secondary care. Regular sessions were held for participants (including patients, healthcare staff, research staff) to discuss observations, reflections and suggestions for the development and delivery of the care model. At the end of the project, meetings were held with representatives from the different groups of participants to discuss overall views about the study and ethics and research governance challenges specifically.

Results: We present key perspectives from various stakeholders involved in the PAR process, highlighting benefits and challenges. Specific challenges relating to ethical and governance approvals encountered in the set-up and delivery of the project are described. These include the design of the study protocol, approaches to consent, presentation of study information within the current ethical and regulatory frameworks and maintaining the flexibility of study methods and roles of participants throughout the study period. Recommendations for improvement in the research pathway that PAR researchers could adopt to enable a meaningful and successful PAR approach are made, in addition to suggestions for overarching ethics and governance frameworks.

Conclusions: Developing new models of healthcare benefits significantly from collaboration with stakeholders so that the design and delivery are feasible and acceptable to all. However, the current UK research approvals and governance frameworks present challenges to design and successfully deliver PAR studies in healthcare; we present possible solutions.

Keywords

Participatory action research, plan-do-study-act, new model of care, healthcare research ethics, healthcare research governance

Introduction

Participatory Action Research (PAR) is a research approach which has developed from action research and participatory research concepts and ideologies. [1] It is an approach which aims to effect context-specific change or development, through shared decision-making and promotion of equality of the voices of the participants. Key features of the approach include the cycles of activity designed to develop, act and reflect on activities or services, and the inclusion of a wide range of participants with the intention of empowering the people for whom the research is intended to benefit. [2] PAR involves groups of people in action, reflection, and iterative change. Throughout the process, an academic or clinical researcher may also become a participant, for example, by delivering healthcare within the study context, and the people (or communities of patients) involved in the research, traditionally defined as 'participants', may become 'researchers'. [3] In PAR, the research is designed and delivered by the whole group - 'researcher' and 'participant' roles are inextricably entwined in influencing the data collected, the design of the next stage of care and the research that needs to be done. PAR is an emergent research model where many aspects, e.g. methods and content of data collection, iterate and evolve during implementation, rather than having a formal beginning and end. PAR is a common approach in education, social care and social sciences [4, 5] but is still under-utilised in healthcare. [6]

Healthcare systems are complex, and various research methods to develop and embed new care models are needed. Primary care is designed to be the first point of access for many health problems, in addition to providing health promotion activities, and as such interventions designed for primary care should aim to improve healthcare access, quality, health outcomes and equity in health. [7] Primary care services are delivered within a broader framework of linked secondary, community, emergency and social care services. New interventions, particularly those which draw on resources from different services, need evidence that they will be successfully delivered and provide value to patients and their carers', as well as improving health outcomes. To achieve this, it is essential to involve all stakeholders in the development and testing of interventions and services. One approach is to employ experience-based co-design (EBCD) methods, which provide a mainly qualitative framework for data gathering from patients, carers and healthcare staff with the intention of identifying priorities for improving services, taking quality improvement beyond simplistic patient experience surveys.[8] Although such methods have been shown to be impactful to enhance patient-centred care, they do not necessarily enable questions about the impact of new interventions or services on patient clinical outcomes to be answered, nor facilitate service users to be fully integrated within the research process. Commonly used quality improvement methodologies, such as the Plan-Do-Study-Act cycle, are designed for small, incremental changes, usually of an existing service, [9] but do not by themselves constitute a process which would be considered as formal research.

PAR challenges traditional notions of knowledge creation and ownership in clinical research settings by placing patient participants on an equal footing with researchers, thus acknowledging the validity of their contribution to the knowledge creation process. It may also address current gaps in diversity and inclusivity in the research process. [10] Although PAR is intensive and requires significant input and commitment from all parties, it increases equity and ownership of the research by service users, giving the methodology the potential to provide truly co-created knowledge and effective services. However, the extension of PAR methods into health service research poses challenges for ethical

review and the ethics and clinical research governance oversight. Considerations for ethical review of PAR projects involving health promotion activities suggest items that may be incorporated into the Research Ethics Boards (REB) review. [1] These include ensuring an understanding of the PAR goals and methodological tools by REB members, inclusion of wider communities in the review and evaluating the ethical implications of the proposal in a way suitable to encompass the variety of approaches that may be taken, rather than in a list-oriented way. Whilst this is a good suggestion, the iterative nature of PAR projects may require more intensive involvement from an REB, working hand-in-hand with clinical research governance structures to enable the rigid structure of clinical research processes and documentation to incorporate a more flexible PAR approach. Practical guidance on how to achieve this is currently lacking.

Existing regulatory frameworks do not accommodate PAR very well, as we have found during our experience of developing and delivering such a study. In this paper, we intend to begin to address this issue by highlighting the constraints imposed by regulatory demands and expectations and providing practical solutions which are novel and could be taken into consideration by researchers planning a PAR project in a healthcare setting. The paper summarises the difficult path negotiated by researchers including standard constraints such as an expectation of a fixed protocol, front-loaded ethics review, fixed participant information sheets and informed consent forms, narrow definitions of recruitment and patient public involvement as a one-off consultation. Our aim is to provide an account of action research with the intention of providing advice and recommendations on how to steer PAR projects through ethics and governance structures for approving and delivering clinical research in the UK.

Methods:

Context of the MISSION ABC healthcare model and the role of PAR

MISSION ABC designed, developed and delivered a new model of care for people with respiratory conditions. [11] The project implemented an integrated care model for patients with airways disease and undifferentiated breathlessness, assessing, diagnosing and treating patients with a multidisciplinary team of general practitioners and specialist respiratory health professionals from secondary care. The care model was delivered in clinics based in a primary care setting to enable maximum accessibility for patients. A PAR approach was adopted to allow the clinic format and delivery to be adapted throughout the process in response to feedback to ensure the resulting model was patient-centric, feasible and successful. Patients attending the clinics who consented to be part of the research project were involved as researchers, evaluating processes, experiences and clinical outcomes to establish the best way to deliver the clinics and collect data to evaluate clinical outcomes.

Data collection relevant to this article

After each clinic, all research group members obtained critical feedback and direction, including the patients and carer participants who were engaged as researchers. The group analysed and discussed qualitative feedback with quantitative outcomes for service implementation and patient factors (e.g. uptake of the service, clinical benefits realised in-session) to adapt the project during the delivery phase. Viewpoints were shared, and solutions were implemented directly into clinical practice, e.g. reducing the number of pre-clinic comorbidity and quality-of-life questionnaires, changing the order

in which the multidisciplinary team were arranged in the 'carousel clinic', and ensuring there was a respiratory physiotherapist present.

At the end of the project, several meetings were held with a group of participants involved from different backgrounds (i.e. patients, clinicians, research nurses, ethics, research governance, research methodologists) with the purpose of reflecting on their experiences from different perspectives and identifying areas for change in future work and potential barriers to change. Minutes from these meetings constituted data collected as part of the PAR process. The issues raised in these meetings were categorised into themes relating to each type of perspective, and a thematic document was produced. This was used as the basis for subsequent meetings, when the participants decided that it would be useful to share the results, with a focus on the PAR approach overall, and the implications of using this approach in healthcare in relation to clinical research governance and ethics.

Results

This section firstly presents viewpoints from individuals with different roles within the PAR process, as written by the participants. These include contextualisation of their experience and thus references to the wider literature are included, as they arose as discussion points during the meetings. It then summarises specific ethics and governance areas which raised challenges for the research team, with pragmatic suggestions for improvements and further considerations generated from the discussions.

1. ***Viewpoints***

From a patient representative:

Patient and Public Involvement (PPI) is now a staple of clinical research and stems from an ethical position that "those who the research is for should have a stake in how it is done". [12] PPI members are potential participants in research, and we can influence the research design and delivery by giving essential context from a service user's perspective. Usually, PPI advisors or advisory groups are separate from the research process, e.g. sitting on an external advisory group or as lay members in a panel of academic or clinical researchers, rather than being integral to the research process. Incorporating concepts and methods from PAR may provide a more holistic approach to ensure that our engagement is are not seen as a tokenistic 'add-on' to the research process. PAR facilitates the integration of PPI to maximise the applicability, sincerity and veracity of the research.

From a patient's perspective, PAR can be a very positive experience. Being involved as researchers means we can take part in steering group meetings, provide feedback and interpret data collected, provide solutions and adaptations for the services provided, and share information with other patients. This approach is in addition to the direct benefits of participating in research, with the potential to improve our health and wellbeing. Patients have a unique opportunity to work alongside clinicians and academics, embedding their voice in the research and directly influencing outcomes. We gain insight into all aspects of the project and share in the team's success, having their contributions recognised in nominations for awards and dissemination outputs.

From a clinician delivering care during the project:

The increasing challenge of providing healthcare drives the development and testing of new models of delivery. PAR is an important methodology to generate and dynamically evaluate new models of care, allowing the implementation of proposed improvements whilst concurrently evaluating the process and rapidly adapting to achieve the desired outcomes. [13] Within MISSION ABC, PAR enabled the evaluation of the impact of roles provided by the wider multidisciplinary team (MDT) within a service, prompting changes and re-evaluation, as per the 'plan-do-study-act' cycle. [14] The use of PAR in MISSION ABC enabled the translation of knowledge from developing new health technologies to appropriate and effective use in clinical care. Evidence of front line implementation of new technology often arrives late in the innovation process – meaning that neither the needs of the end-user nor the innovator are met when barriers are encountered. [15, 16] Opportunities for iterative innovation could be facilitated much earlier if PAR was used routinely, particularly with the involvement of the end-user (i.e. patient, clinician or policymaker) as a research participant and embedded evaluation of contextual and capability factors that influence the successful adoption of new technology. [13, 17]

From a researcher involved in the methodological design:

A research study protocol which includes a PAR approach should describe the improvement or innovation, i.e. the newly introduced model of care or the changes to the current system. This enables readers to judge its potential application to other healthcare systems, the importance of which is discussed widely in improvement literature. [18-24] Ethical considerations and pragmatic delivery issues may have dissuaded researchers from choosing PAR, e.g. by measuring only those aspects that would be regarded as 'service evaluation', avoiding the need to interact with a Research Ethics Committee (REC). However, this deters a deeper study of the context and process of implementation, which might result in otherwise well-designed programmes being abandoned. [23-25] PAR allows for adoption at pace and scale, meeting the urgent need for healthcare innovation. [18, 25] Generalised adoption of a PAR approach by commissioners and health policymakers could discourage the blanket implementation of programmes that are later abandoned due to a lack of acceptability and engagement from patients. Furthermore, a PAR approach may lead to cost-savings as the comprehensiveness of a consensus approach may avoid nugatory traditional research efforts which do not result in successful change.

PAR is a valuable technique to use as healthcare provision increasingly seeks a larger role for patients in managing their conditions and moves away from the traditional prescriptive medical model. However, this technique requires sustained, integrated input from patients and their families and carers as co-researchers to design and evaluate patient-centred services. Empowering NHS patients to understand better the process of developing and delivering research is essential to generate more patient and carer-led research projects in areas that are more likely to impact care directly.

From a member of the research ethics committee involved in ethical review, project approvals and monitoring:

A PAR design is ethically desirable. The non-hierarchical approach and the blurring of researcher/participant roles challenge the standard approach to review, which focuses on the researcher's intentions and the consequent impact on the participant's welfare: participants are viewed as data sources, protected through mechanisms of consent and confidentiality

arrangements. The checks and balances of an iterative approach, together with constant review of outcomes and establishing a team consensus, make PAR a more 'ethical' approach than traditional research models. PAR engenders close relationships within the researching community as a whole, where mutual respect and shared goals replace standard hierarchical pseudo-contractual relationships. By its nature, PAR needs to be highly reflexive and will only be effective in a climate of mutual respect.

Ethics committees might not view PAR as research, as the protocol may not include formal hypotheses or clear scope for generalisability at the outset, falling outside the scope of NHS ethics review. This problem is equally seen in examples of exploratory, iterative, qualitative research, where hypotheses and a requirement for generalisability associated with standard research designs are neither possible nor appropriate. However, most qualitative research retains the key roles of researcher and research participant, so the ethical review can still centre on familiar ethical domains, including fair recruitment, consent and confidentiality; PAR necessarily obfuscates these domains. There is also the risk that the REC will see PAR as service evaluation; PAR provides an excellent framework for service development and innovation, which should be contrasted with evaluating an *existing* service.

What should RECs consider? A virtue ethics approach might be adopted, [26] where the focus of the review is on the probity of the researcher, seeking evidence of ethical dispositions. The tendency to seek evidence of good research conduct in documents including protocols, information sheets, consent forms and applications for ethical review should be balanced with equally compelling evidence gained by considering the intentions of the researcher – their character and moral dispositions. Examples include courage, respectfulness, resoluteness, sincerity, humility and reflexivity. [27] These virtues characterise PAR better than traditional preoccupations with consent, confidentiality, and compliance with codes and principles. In demonstrating the probity of research, applicants could emphasise resonance with these virtues by appropriate referencing throughout the documentation presented to RECs.

From a member of the NHS Governance team providing project oversight and approvals:

Fitting PAR projects into existing NHS governance structures for clinical research can be challenging. In a culture of applying rules and metrics to all studies, blurred lines between traditional researcher and participant roles can make it tricky for a reviewer to fit the study into standard categories. There can be a tendency to steer the project towards service evaluation – "if it doesn't look like a research study, maybe it isn't?" The fluid nature of the labels attributed to people involved in PAR studies also complicates other standard research procedures; for example, who should be put on the delegation log if the study participants are also researchers and vice versa? It can be difficult to register the project if it doesn't fit categories used in research approval systems, e.g. the Integrated Research Approval System (IRAS), and providing pre-specified primary and secondary endpoints on publicly available registers, e.g. https://clinicaltrials.gov/. The current guidance for research studies in the NHS may lead to steering projects which look like PAR towards service evaluation, hence why PAR may not yet be a commonly used approach. However, from the NHS perspective, the main purpose of research is to lead to positive changes for patients and improve the delivery of care. [28] The ethos of PAR fits this aim when used to evaluate interventions or models of care. It ensures the

inclusion of all perspectives and contributions, so adjustments must be made to make approval of such projects more straightforward.

2. Recommendations for consideration when implementing PAR in healthcare contexts

Based on our experience delivering MISSION ABC, we propose ideas and practical solutions for challenges that researchers may encounter in delivering a PAR project within the NHS.

1. The team, research protocol and sponsor

Take an inclusive approach to the formation of the research team, taking time and effort to identify key stakeholders, including diverse representatives of the population under study (Table 1). The protocol should be clear on the benefits of involving "participants as researchers" and why it is ethically important to be involved to an appropriate level. The study Sponsor should be identified and engaged early in the process, and facilitators from the Sponsor team involved in defining the protocol. The background to the overarching aim of the research and the study objectives, links and buy-in from the relevant health services should be ascertained and agreed upon, and the level of vulnerability of participants (including the researchers). [29] The Sponsor can then adequately assess capability, capacity and feasibility, perform the required risk assessment, and establish that the project is research (rather than service evaluation). To aid the Sponsor, a multidisciplinary group with external, impartial members could be convened to review and approve the protocol and provide additional oversight during study delivery, including an ethics advisor, patients, and professionals with philosophy or legal backgrounds.

Table 1 Recommendations for developing a research protocol with a PAR approach

Recommendations
• Include potential participants, such as current patients, researchers, clinicians, managers, ethical oversight steering group, and Sponsor representatives in developing the protocol. • Build flexibility into the protocol to include new members during the study delivery and within sponsor governance processes to recognise the entry/exit of new members. • Include overarching aims and the structure of the research in the protocol, for example, diagrams of the people, groups or services involved and the nature of the relationships between them, and terms of reference for the delivery of the research, including confidentiality considerations. • Develop a document or 'charter' for researchers, detailing the purpose and functions of the research overall which is aligned with the study protocol, and the roles, rights and responsibilities of the researchers, including what they will consent and commit to as researchers and participants. • Convene an Expert Advisory Group to monitor the research progress and provide an independent view for the research team and the Sponsor.

2. Approaches to Consent

Current approaches to consent to participate in research draw clear distinctions between researcher and research participant, reflected in the style of key documentation such as the participant information sheet (PIS) and informed consent form (ICF). There are inherent assumptions about participant vulnerability and researcher power within this system, reflecting a philosophy of individualism rather than a communitarian approach with the common good at its heart. [26] A more suitable approach in PAR could be a consensual charter, shared by equals with a common goal. This contract captures the nature of relationships within the 'researching community', and is framed around key virtues, including mutual respect, solidarity, critical reflection, resoluteness and sincerity (Table 2).

According to the Consensual Charter, what constitutes consent in PAR may be as simple as being clear that if a person is participating in the research, they are consenting. The content and participants of the research may be continuously changing, so it is not feasible to adopt the traditional model of signing a form to consent to a pre-determined series of activities. Fundamental issues such as confidentiality of medical data and the ability to withdraw at any time should be clear in the consensus agreement, signed when work starts. This agreement may evolve during the research process but does not need to be updated for minor details as long as all participants are involved in the decision-making. The current requirement for formal consent to 'count' towards recruitment through Research Networks may be overcome by clearly identifying what procedures will be used to record participation in the protocol. As with all research projects, consent should be re-affirmed by all participant-researchers at regular intervals and iteration that they have the option to withdraw at any time or choose to modify their role in the research.

Table 2 Recommendations for consent to PAR

Recommendations
• Establish in the protocol what constitutes consent and how participation will be recorded or reflected in the results, for example, signing up to the researchers' 'charter'. • Ensure that explaining the research to potential participants/researchers and adding to the research team are agreed upon, and guidelines for how this will be reviewed and adapted during the project if required. • Establish the circumstances which constitute continued consent and withdrawal through consensus agreement. • Consider using a consensual agreement to reflect the research structure and relationships as a basis for participation.

3. Completing the Integrated Research Application System (IRAS) form and preparing for Health Research Authority (HRA) and Ethics review

Researchers are often reluctant to approach the HRA Research Ethics Service before submitting an IRAS form for validation and subsequent review. However, early dialogue with a REC manager or a REC Chair can help prepare the ground for more unusual projects such as PAR and will not be viewed as an attempt to compromise the independence of the REC but rather as an opportunity for early advice and support. For example, such discussions on how PAR differs from service evaluation can be summarised in the cover letter accompanying the application.

The UK HRA Research Ethics Service aims: "*to protect the rights, safety, dignity and wellbeing of research participants*" and "*to facilitate and promote ethical research that is of potential benefit to participants, science and society".* [30] The application should indicate how these aims are addressed for researchers, participants and all members of the researching community. The application should be framed to make the best use of the IRAS form (Table 3). Such questions are likely to share commonality with application forms for ethical review to clinical research review systems in other countries.

Table 3 Recommendations for completion of IRAS form

Recommendations for completion of IRAS form
• Ensure that the study title includes 'Participatory Action Research' – thus avoiding confusion with service evaluation. • Study design (Filter question 2): if there is no category that identifies PAR or allows PAR to be a distinct entity within the study design, tick 'other' and describe the study design in full. • 'Summary of the study' (Question A6-1) comprises the summary which will appear on the HRA website – identify the study as PAR. • 'Summary of main issues' (Question A6-2) provides an opportunity to identify the unique ethical and legal perspectives on PAR. Point out the blurring of 'researcher' and 'participant' and highlight 'researching community'. Refer to specific elements of the contract relating to data sharing and confidentiality within and beyond the community. Identify the community's shared values, e.g. mutual respect, a shared resolution to work together and a commitment to share reflections on the project. Refer to the consensual contract substituting for information sheets and consent forms. Explain how the contract establishes an ethical framework overseen by an expert advisory group, permitting the project's continuing development, thus obviating the need for further ethical review. • 'Select the appropriate methodology description for this research' (Question A7): select 'other' and provide detail about the unique nature of PAR. • 'In which aspects of the research process have you actively involved, or will you involve, patients, service users and/or carers, or members of the public?' (Question A14-1) provides an excellent opportunity to show how PAR extends the idea of Patient Public Involvement from patient consultation to full patient involvement and user-led research.

When preparing to attend the REC meeting, the representatives of the research team who are going to present the proposal need to include a cross-section of the researching community (Table 4). This

description provides the REC with a clearer idea of how the team is organised and will conduct the research and allows them to assess how the team will successfully work together.

Table 4 Recommendations for Research Ethics Committees and research applicants

Recommendations
• The initial HRA assessment should focus on data confidentiality, data protection, and whether it is appropriate to run the research in the NHS. • RECs who have been trained in the characteristics of PAR could be identified by a 'flag' (such as those used for RECs specialising in other study designs) so that proposals including PAR can be reviewed appropriately. • The initial research team should attend the ethics committee meeting, reflecting the PAR structure, so that the committee can observe the nature and cohesion of the relationships within the group. • Ethics committees should include assessment of the research team in their evaluation of the project, including elements such as training, values, established relationship with PAR group, quality, supervision, trust between members. • Data storage and access should be discussed and agreed upon by the group in a consensual manner, including how confidential data will be shared and how different types of data will be dealt with, for example, medical data vs participant feedback.

4. Research Delivery

Before the study starts, it is challenging to provide the defined endpoints or clinical outcomes required to register the project on research databases, as they may change during the PAR study delivery. (Table 5). The ongoing relationship with the REC, who issued the initial favourable opinion, is vital. With a traditional clinical research design, initial favourable opinions are received, and formal amendments would be required for changes in endpoints. The natural development of a PAR project does not lend itself to this formal, structured process, so a different approach is needed to communicate changes to the REC. This communication could be via logs provided following the plan-do-study-act (PDSA) cycles or including an ethical advisor in the research team.

It is advisable to discuss who counts as a 'recruit' within the project with local research network facilitators during study set-up and state this clearly in the protocol. For example, one suggestion from colleagues at the Wessex Clinical Research Network was to have the researching community sign up to a set of ideals for the project and thus count as recruited participants.

Clinical research studies are usually run within a governance framework which includes a process called 'monitoring' (which may be absent in other disciplines). This is to verify that the rights and well-being of participants are protected, that the data are valid, and that the study has been conducted in accordance with the protocol. Monitoring is usually performed by a member of the governance team, often using prescribed check-lists which do not change during the study process. A pragmatic approach was taken for MISSION ABC to allow self-monitoring whilst ensuring the study was run within Good Clinical Practice principles. This allowed the researcher and the study monitor to operate in an adaptive way, including new forms and data sources as the project progressed.

When reporting results of PAR, participant confidentiality must be carefully considered when deciding the contents of dissemination. This assurance may be facilitated by formally agreed writing and a clear publication plan that considers all stakeholders' interests.

Table 5 Recommendations for study delivery

Recommendations
• A solution needs to be developed to allow for easy inclusion of PAR studies on publicly available databases, e.g. on www.clinicaltrials.gov , data from which also feeds the UK Clinical Trial Gateway site. • Ethics process to be updated to include either "iterative review", allowing for discussions following major changes in the direction of the project (in preference to a repeated amendments process), or details on how a different ethics advisory group for the project will be set up and managed. • Engage with Clinical Research Networks early to ensure clear communication and agreement around recruitment attribution. • Early engagement of the Sponsor representative to ensure full comprehension of the project so appropriate risk can be ascertained and pragmatic monitoring arrangements put in place. • Timely communication with the ethics committee regarding the development of study delivery. • Whilst the project is in process, ongoing dialogue with all researchers/participants should take place to decide how, and to whom, study results will be disseminated, creating a 'living' dissemination plan, as styles of dissemination, e.g. talks at patient group meetings, may also bring in further ideas to shape the research, thus incorporating 'real-time engagement'. • Record the impact of dissemination – who was present, what was said, what impact did the dissemination have on the remainder of the project. • Provide options for anonymity in publication (e.g. pseudonyms).

CONCLUSIONS

PAR is a valid and important method of research in healthcare and is particularly valuable in evaluating new models of care, healthcare innovation and technology and engaging with people living with long-term conditions. Collected perspectives from a team who worked on delivering a PAR approach to facilitate the implementation of a new model of community respiratory healthcare highlight the benefits of this approach and confirm its place in clinical research. This paper established that there are important issues to consider to be able to steer PAR research through regulatory frameworks and provides advice and recommendations relevant to the UK clinical research framework, which are likely applicable to other settings. Delivery of PAR within healthcare systems requires an appropriate ethical approach, enabling the involvement of patients and healthcare staff as researchers on an equal footing. To ensure success, close communication and collaboration are essential between researchers, ethics committees, research departments and institutional sponsors. Although PAR may be resource intensive, the benefits of healthcare design

with patients and staff at its centre reflects the aspirations of a public healthcare system and the democratic principles on which it is built.

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