



STUDY PROTOCOL

**REVISED**

# Evaluation of the Establishment of a Public and Patient Involvement and Engagement Group to Support Clinical Trials in Pakistan: Protocol for a Mixed-Methods Study

[version 2; peer review: 2 approved]

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## Abstract

### Background

Patient and public involvement and engagement (PPIE) in research is a collaboration between researchers, patients, and the public, enhancing research acceptability, relevance, and impact. There is a growing prevalence of PPIE in high-income country research; however, its integration in low- and middle-income countries (LMICs) remains poorly understood. Recognising this gap, the Ziauddin University Clinical Trials Unit in Karachi, Pakistan, launched a dedicated PPIE initiative in 2022. This study evaluates the engagement process and experiences of patient and public members and researchers to identify barriers and facilitators to participation within the PPIE group.

### Methods

The evaluation uses an explanatory sequential mixed-method design. First, the Public and Patient Engagement Evaluation Tool (PPEET) questionnaire will be administered online to group members, coordinators, and senior institutional leads. Insights from questionnaires will be further explored during semi-structured

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interviews, with questions guided by the Patient Engagement in Research (PEIR) framework, supplemented with analysis of project documentation. Study activities will be conducted in both English and Urdu. The study has been co-designed with PPIE members and is co-led with a public partner. Findings will highlight areas for improvement, inform best practices, and guide the development of more effective engagement strategies.

## Outcome

Although focused on a single group, this evaluation lays the groundwork for understanding PPIE practices in LMIC contexts. It provides valuable insights into developing equitable partnerships and improving patient-centred research. This study contributes to a growing body of knowledge, offering practical guidance for implementing PPIE in settings with unique socioeconomic challenges and cultural realities. The findings are expected to benefit the local research community and similar initiatives globally, particularly in regions with comparable challenges.

## Keywords

Patient and Public Involvement, Engagement, Critical Care, Clinical Trial, Low- and Middle-Income Countries, Mixed-Method Study, Co-design

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**REVISED Amendments from Version 1**

"In this revised version, we have improved clarity and coherence throughout the manuscript while making no changes to the title, authors, affiliations, figures, tables, datasets, or study design. The Introduction has been updated to replace outdated references and provide a clearer description of the PPIE initiative. In the Methods, we clarified that all individuals involved form an exhaustive population and refined the description of the evaluation tools and procedures. The Discussion now briefly outlines the planned next steps for follow-up evaluation and future development of PPIE activities. Minor edits were made across the manuscript to improve flow, reduce redundancy, and ensure consistency in terminology and tone."

**Any further responses from the reviewers can be found at the end of the article**

**Introduction**

Patient and public involvement and engagement (PPIE) represents a paradigm shift in research by empowering communities to actively shape the generation of evidence in healthcare. The National Institute for Health and Care Research (NIHR) defines it as conducting research "with" or "by" the public, rather than "to", "about" or "for" them<sup>1,2</sup>. By actively involving patients and public partners, and integrating their perspectives, PPIE enhances the relevance, acceptability, and impact of research, aligning it more closely with real-world needs and priorities<sup>3-6</sup>. Studies have shown that PPIE delivers ethical and practical benefits, such as influencing study design, improving recruitment by aligning practices with patient needs, guiding dissemination and ensuring greater accessibility of findings to the public<sup>7-9</sup>.

While PPIE has become increasingly established in high-research output countries such as Australia, Canada, New Zealand, the United Kingdom and the United States, its adoption in low- and middle-income countries (LMICs) remains limited<sup>10-13</sup>. A 2022 scoping review found that only one of 33 studies evaluating PPIE processes was conducted in an LMIC<sup>14</sup>. Reviewing engagement processes in these settings is essential, as lessons from high-income countries (HICs) may not directly apply to these contexts marked by structural inequities, social hierarchies, and limited public trust in research<sup>15</sup>. Furthermore, engagement in LMICs often relies on community leaders or gatekeepers, whose perspectives may not represent the wider community. These challenges are further compounded by social exclusion, gender inequities, and limited access to healthcare<sup>16</sup>.

Recognising this gap, the Ziauddin University Clinical Trials Unit (CTU) in Karachi launched Pakistan's first dedicated PPIE group in 2023, supported by an engagement bursary<sup>17</sup>. The initiative aimed to embed PPIE within research infrastructure and create a structured platform for community input into study design and review. Using tools such as the 'My Involvement Profile' template helped clarify members' expectations,

foster trust, and identify practical strategies for collaboration between researchers and local communities in a resource-limited context<sup>17</sup>.

During its first year, the group reviewed informed-consent processes, proposed improvements to public-facing materials, and developed mechanisms for sharing trial results with the wider community. It has also contributed to major international clinical trials, including REMAP-CAP (Randomised, Embedded, Multifactorial, Adaptive Platform trial for Community-Acquired Pneumonia) and Mega-ROX (Mega Randomised Registry Trial Comparing Conservative vs. Liberal Oxygenation Targets). Membership has evolved over time, reflecting the challenges of sustaining long-term involvement, although these changes have not affected the project's overall outcomes.

Research is often less prominent and less favourably perceived by the public in many LMICs compared to HICs, making engagement more challenging and necessitating different approaches<sup>18,19</sup>. Unfortunately, there are no best practice guidelines for PPIE in LMICs due to limited published experiences and a lack of research evaluating effective engagement methods. Accordingly, there is an urgent need to explore and develop strategies tailored to meet these realities<sup>7</sup>.

In line with NIHR guidance, this paper uses the term "patient and public involvement and engagement (PPIE)" to describe our work. "Involvement" refers to patients and public partners actively contributing to the research process (e.g. design, review of consent materials, dissemination); while "engagement" refers to researchers sharing information and research findings with the public. Our group primarily promotes involvement while also supporting engagement through public-facing activities.

To our knowledge, very few published studies from Pakistan explicitly describe patient or public involvement in research. This study aims to evaluate the engagement processes within the PPIE group, explore the experiences of its members, coordinators, and senior institutional leads, and identify barriers and facilitators to effective engagement. By addressing these objectives, the study contributes to the evidence base for PPIE practices in LMICs.

**Methods****Study design & setting**

The study employs an explanatory sequential mixed-method design combining quantitative and qualitative methodologies to evaluate patient and public engagement within the PPIE initiative<sup>2,20-23</sup>. Guided by the participatory action research approach, the study was co-designed with PPIE group members to ensure relevance, inclusivity and alignment with their needs and expectations. In the first phase the validated Public and Patient Engagement Evaluation Tool (PPEET) questionnaire will be administered to identify broad patterns of experience<sup>2</sup>. Results will then inform the qualitative phase, which includes semi-structured interviews and a review of project documentation.

Equal weighting is given to both methods which together provide measurable indicators and contextual understanding of engagement quality, offering a comprehensive view of engagement efforts. Findings will be reported using the Guidance for Reporting Involvement of Patients and the Public 2 (GRIPP2) checklist<sup>24</sup>.

### Study participants

Study participants include current (n=6) and past (n=3) members of the PPIE group, representing both patient and public representatives, as well as the PPIE coordinators (n=3) involved in establishing the group. Two senior institutional leads, including a department head and a CTU board representative, will be asked to share their experiences overseeing and integrating PPIE efforts into institutional practices and priorities. This sample (n=14) represents the full population of individuals directly involved since the inception of the initiative, making it exhaustive rather than sampled. The process evaluation aims to provide an in-depth understanding of engagement within this institutional setting, rather than achieve generalisability.

### Recruitment

Current PPIE members and coordinators will be introduced to the study during a regular PPIE group meeting or via WhatsApp if unable to attend. Senior institutional leads and past members will be contacted via email. All potential participants will receive the participant information sheet (PIS) in their preferred language (either English or Urdu), outlining the study's purpose, procedures, and confidentiality measures. Potential participants will have opportunities to ask clarifying questions in person, via WhatsApp or through email. Participants will be given a two-week window to complete the questionnaire, with reminders issued by the study lead after one week and two days before the deadline. Following this, all participants will be invited to participate in semi-structured interviews, regardless of whether they completed the questionnaire. The PIS will be re-shared at this stage.

All invitations will be made by the study co-leads who do not hold a hierarchical relationship with participants, to minimise any perceived pressure or undue influence.

### Data collection

The study involves three key components for data collection: a validated questionnaire, semi-structured interviews, and project documentation review.

#### ***Public and Patient Engagement Evaluation Tool (PPEET).***

The PPEET questionnaire, a widely used and validated tool developed by researchers at McMaster University, will be used to assess engagement effectiveness on a series of Likert scale items<sup>2</sup>. Participants will respond to statements on a 5-point Likert scale ranging from “Strongly disagree” to “Strongly agree,” with optional free-text fields allowing respondents to expand on their experiences.

The questionnaire will be administered through an online survey tool (Google Forms) in September 2024, 18 months

after the researchers started the PPIE project and one year after the first meeting of the PPIE group.

The PPEET is divided into three questionnaires tailored for different stakeholders: project participants, project coordinators, and organisational leads. These assess experiences and involvement at individual, project, and institutional levels, respectively, while providing valuable insights into the broader PPIE initiative. Responses from the survey will be used to identify areas for deeper exploration during interviews, e.g. lower scores in domains such as “impact and influence” will guide follow-up questions to understand underlying reasons.

*Participant Questionnaire* will employ Module B, focused on long-term engagement. The questionnaire comprises 22 questions addressing four key domains: communication and support for participation, opportunities for sharing views, impact and influence of the engagement process, and general reflections.

*Project Questionnaire* includes three modules designed to evaluate different phases of engagement: planning (Module A), implementation (Module B), and impact assessment (Module C). All three modules will be completed by the PPIE coordinators.

*Organisation Questionnaire* evaluates institutional engagement practices, providing insights into policies, participatory culture, collaboration, impact assessment, and organisational reflections. It is designed to identify trends, document improvements, and facilitate audits. This questionnaire will be completed by both senior institutional leads.

Demographic data, such as age, sex, education, ethnicity, and professional status, will not be collected through the questionnaire in order to ensure anonymity. Instead, demographic information previously recorded as part of routine project documentation will be reported. To ensure accessibility, the questionnaire will be translated into Urdu. The translation will be confirmed by the PI and co-PI, who are fluent in both English and Urdu. Prior to distribution, the translated version will be piloted for coherence. Additionally, the PPIE co-lead will be available to clarify terminology or content as needed.

All survey data will be handled and stored confidentially as detailed in the Data Analysis & Management section.

***Semi-structured Interviews.*** All participants will be invited to participate in semi-structured interviews lasting 30–60 minutes, at the university or their preferred location, conducted in English or Urdu based on their preferences. The interview guides are aligned with the Patient Engagement in Research (PEIR) framework<sup>25</sup> to explore the perceived benefits of engagement, challenges faced, and opportunities for improvement. Insights from the questionnaire will inform and refine the interview questions. The interview guide for senior institutional leads has been adapted to focus on organisational-level considerations using the PPEET domains, such as policies and strategies for PPIE, as the PEIR framework is not tailored to this

context. Interviews will be audio-recorded, transcribed verbatim, and translated into English if conducted in Urdu. Participants will have the opportunity to review and verify their transcripts to ensure accuracy.

The study lead and PPIE Coordinator (AH) will primarily interview researchers, while the co-lead and PPIE member (MK) will focus on interviewing PPIE members to manage any potential power imbalances during the interviews. While one facilitates the interview, the co-lead will observe to ensure consistency and capture additional thoughts. Both leads will interview each other first to mitigate bias in subsequent interviews, and this paired interviewer approach aims to create an open environment for participants to share both positive and critical reflections, particularly regarding power dynamics or institutional challenges.

**Project documentation.** A review of project documentation will be conducted to triangulate findings from interviews and questionnaires<sup>2</sup>. This document review will follow the completion of questionnaires and interviews to address any information gaps rather than shaping materials iteratively. Key documents include project logs, meeting minutes, debrief notes and member participation profiles recorded using the 'My Involvement Profile' template created by 'Shaping Our Lives'<sup>26,27</sup>. These documents, created at the beginning and throughout the PPIE project, provide further insights into the engagement process within the group and trials and help mitigate recall bias of interview participants<sup>22</sup>.

This document review will provide insights into member expectations and how they have been met, trends in participation, and the impact of flexible methods such as online and in-person meetings, by examining attendance patterns and other data. Process measures (e.g. number and type of events conducted, number and impact of materials created) from project logs will also be reported. Meeting minutes which document group discussions and debrief notes, as reflective summaries of these conversations will help in understanding evolving engagement patterns. Additionally, we will review the end-of-year funding report provided to the sponsor to gain an overview of the project's progress and outcomes.

Due to confidentiality reasons, as agreed upon by the members, meeting minutes and debrief notes will not be made publicly available. However, anonymised data, such as attendance percentages and overall project reports will be published.

### Data analysis & management

Responses from the PPEET questionnaires will be imported into Google Sheets and descriptive statistics will be used to summarise responses to the Likert scale questions. Responses to open-ended PPEET questions, transcripts of semi-structured interviews and project documents will be imported into qualitative data analysis software (NVivo, released in March 2020) for thematic analysis<sup>26</sup>. Data analysis will occur parallel to the administration of questionnaires and the conduct and transcription of interviews, allowing the interview guide to evolve and

guide deeper exploration of emerging themes. The constant comparative method will be used, with comparisons made within and across interviews, with particular attention paid to conflicting accounts and outliers<sup>27</sup>.

### Patient & Public Involvement

The study has substantial input from patient and public partners throughout. A PPIE member is a co-PI actively contributing to study design and will be involved in data collection and analysis. A preliminary draft of the protocol was shared with the wider PPIE group for input before finalisation and they will facilitate the dissemination of study findings to the community. This involves developing plain-language summaries, presentations, and other public-facing materials.

### Study timeline & management

The project will run from September 2024 to February 2025. Ethics applications were submitted in July 2024. The PPEET questionnaire will be administered in September and subsequent interviews will be completed by November 2024. Data analysis will be completed by January 2025. The study is led collaboratively by a public partner (MK) and one of the PPIE coordinators (AH), with input from a steering group consisting of other PPIE coordinators (NA, TT) and senior researchers (SM, AMD, MH) associated with the overall PPIE project that brings extensive research experience to ensure appropriateness of study procedures. Authors AH, MK, NA and MH also provide local expertise to ensure the study's relevance and appropriateness for the Karachi context and oversee local ethical approvals.

### Informed consent

For the online questionnaire, potential participants will be able to anonymously record their responses, indicating their voluntary consent to partake in the study. For the semi-structured interviews, individual written consent will be sought and documented. The consent form explicitly states that the interview will be audio-recorded and subsequently transcribed verbatim. Participants will have the opportunity to consider each point and indicate their understanding and agreement. The document also includes essential details such as confidentiality measures, participants' right to withdraw at any stage, contact information for the research team, and information about ethical approval.

### Benefits & risks

This study is a formative process evaluation of engagement within our PPIE group and will be used to identify areas for improvement and address any issues. By optimising engagement methods with our members, the group is more likely to work more efficiently, produce higher quality output and be motivated to sustain their involvement over a longer period of time. Improved engagement practices encourage relationship-building between researchers and public representatives, consolidating their commitment to bringing change in the realm of research. The participatory approach of this study fosters collaborative decision-making and builds research capacity in the evolving scientific field of PPIE, particularly for those with limited

prior experience. Insights gained may inform similar regions and offer insights to the global research community on best practices for patient and public involvement in LMICs. This is a minimal risk study, aimed to understand the experiences of engagement within a PPIE group. The questions are not of a sensitive nature and are not expected to evoke feelings of distress in the participants. The participatory action research approach additionally helps ensure that questions and topics of discussion are acceptable and relevant to participants.

### Participant confidentiality & compensation

All data collected during the study, including questionnaire responses, audio recordings and transcripts, will be stored securely for 10 years on an institutional designated shared drive accessible only to authorised personnel. All data will be anonymised prior to analysis, with participant identifiers replaced by unique numeric codes. The anonymisation key will be stored separately and accessible only to authorised personnel.

All members of the PPIE group, both current and former, will be compensated for their time and travel according to the existing compensation policy of the PPIE group, in the form of an honorarium and reimbursement for travel costs. Coordinators or senior leads will not receive compensation, as their participation will occur during their regular working hours. The PPIE members will review the protocol, results and manuscripts before finalisation, without access to identifiable study materials.

### Dissemination & publication policy

The study co-leads (AH, MK) will write the first draft of the manuscript, abstract, and any other publications resulting from the study. Our objective is to disseminate our findings effectively across Pakistan, ensuring relevance and accessibility to the target audience. Results will be shared with the Ziauddin University PPIE group through infographics, presenting key findings in both English and Urdu. We will share publication links with researchers in CTUs nationwide, existing PPIE groups and collaborators in the South Asian region interested in establishing or improving PPIE groups along with a toolkit containing useful checklists and documentation (e.g. terms of reference). Additionally, we aim to publish our results in academic journals like BMC Research Involvement & Engagement and present them at academic conferences such as the International Clinical Trial Methodology Conference 2026 and the Oxford Global Health and Bioethics International Conference scheduled for 2025.

### Discussion

This study improves understanding of effective engagement processes, which are not well explored in Pakistan or South Asia. Having a PPIE member as a co-lead ensures that the study design and documentation are appropriate for participants. The use of the validated PPEET tool and a framework-driven evaluation will generate results that are both generalisable and comparable. By incorporating feedback from both current and former participants, the study minimises risk of bias from

respondents who might view the initiative more favourably. Moreover, the findings have the potential to make a meaningful impact by informing and improving engagement practices for both researchers and members. Conducting the evaluation after the first year of a long-term initiative is beneficial as most evaluations occur post-project conclusion, when recall bias can affect responses and changes cannot be implemented to improve engagement practices<sup>21</sup>.

The sample size is small; however, it includes all involved groups within the institution, providing an exhaustive dataset to emphasise depth of understanding. This evaluation is not intended to produce externally valid and broadly generalisable knowledge, but insights from it will likely be useful for others, particularly in South Asia, to inform the development and refinement of PPIE initiatives. It offers a valuable baseline for engagement dynamics at our organisation and lays the groundwork for ongoing monitoring and evaluation by periodically administering the PPEET (i.e. annually), as recommended by the tool's creators<sup>2</sup>. Although resource constraints prevented formal back-and-forth translation of the PPEET tool, the translation will be reviewed by two researchers proficient in English and Urdu to ensure accuracy and fidelity.

The study co-leads (AH, MK) and nearly all protocol co-authors are planned participants for this study, in line with the participatory action research approach, introducing a potential response bias. However, the study aims to capture subjective responses. Furthermore, the involvement of senior researchers (ADM, SM), who are non-participants, in the interpretation of findings will mitigate such bias.

In the long term, this evaluation aims to contribute to the evidence base on PPIE in LMIC settings, providing lessons on how to sustain meaningful engagement and integrate community perspectives into institutional research practices.

### Conclusion

This study is an initial step to explore and understand engagement processes within our patient and public involvement and engagement group, to advance and improve public representation in research, especially in Pakistan. By utilising a participatory action research approach and robust evaluation methods, we aim to develop meaningful strategies and build capacity for sustained engagement with public partners. The findings can be used to inform local institutional practices, as well as contribute to the limited database on context-specific PPIE engagement in LMICs.

### Ethics and consent

Minimal risk ethical approval for this study was obtained from the Oxford Tropical Research Ethics Committee (OxTREC) (Reference: 562–24) on 4th September 2024. This approval is valid for the planned duration of the study and is subject to obtaining local ethical approval. Additionally, ethical approval was granted by the Ziauddin University Ethics Review Committee on 30th September 2024 (Reference: 9040824MHCCM).

This study adheres to the ethical principles outlined in the Declaration of Helsinki.

For the online survey, participants will record consent at the start of the survey. An introduction outlines the study's purpose, procedures, potential risks, and confidentiality measures. Participants are given the option to either continue with the survey if they agree to participate or select "No" to decline participation, which would immediately exit the survey.

For the semi-structured interviews, written informed consent will be obtained from each participant before the interview. The consent form explicitly states that interviews will be audio-recorded, transcribed and anonymised before analysis. Participants will have the opportunity to review and ask clarifying questions before providing consent.

## Data availability

No underlying data are associated with this article.

## Extended data

**Open Science Framework: Evaluation of the Establishment of a Public and Patient Involvement and Engagement Group to Support Clinical Trials in Pakistan,**

<https://doi.org/10.17605/OSF.IO/VQPZH>.

## This project contains the following extended data:

- Participant information sheets (in English and Urdu),
- Consent forms for the semi-structured interview (in English and Urdu),
- Questionnaires (in English for PPIE Coordinators and Senior Institutional Leads, in English and Urdu for Members),
- Interview guides for the semi-structured interviews (in English for PPIE Coordinators and Senior Institutional Leads, in English and Urdu for Members),
- Qualitative study protocol checklist (ObsQual).

Data are available under the terms of the Creative Commons Attribution 4.0 International license (CC BY 4.0).

## Software availability

The software used to analyse qualitative data in this study, NVivo, is a proprietary software. [QualCoder](#) is a free, open-source alternative that provides similar qualitative analysis functionalities. The Public and Patient Engagement Evaluation Tool has been licensed under a Creative Commons Attribution-NonCommercial-Share Alike 4.0 International License. ©2018, Julia Abelson and the PPEET Research-Practice Collaborative. McMaster University. All rights reserved.

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# Open Peer Review

Current Peer Review Status:  

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## Version 2

Reviewer Report 27 December 2025

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### Gwenda Simons

University of Birmingham, Birmingham, England, UK

I have reviewed the author response, and I believe that the authors have addressed my concerns and suggestions. I have no further reservations and would like to see the article approved as such. I am excited to see this work moving forward.

**Competing Interests:** No competing interests were disclosed.

**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.**

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## Version 1

Reviewer Report 03 September 2025

<https://doi.org/10.21956/wellcomeopenres.26131.r127089>

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### Gwenda Simons

University of Birmingham, Birmingham, England, UK

The paper describes the protocol for the evaluation of the establishment of a PPIE group to support clinical trials in Pakistan using a mixed method study. There is a growing prevalence of PPIE in health research, including clinical trials in high income countries. However, PPIE is less prevalent in low and middle-income countries. The study will use a mixed method design, asking

all the stakeholders (PPIE group members, PPIE coordinators and senior institutional leads) to complete the Public and Patient Engagement Evaluation Tool (PPEET)<sup>1</sup> at several time points, and conducting semi-structured interviews. In addition, the project documentation will be reviewed. The study will be conducted in two languages widening participation. Critically the study was co-designed with PPIE members and will be co-led by a public partner. This project is timely and worthwhile, and I have read the protocol with great interest.

**A few remarks regarding the INTRODUCTION section:**

\*The reference to INVOLVE website is rather old and INVOLVE no longer exists (ref 1). It would be better to for example refer to the Briefing notes for researchers - public involvement in NHS, health and social care research and in particular Briefing note two: what is public involvement in research?<sup>2</sup> which contains the same quote. Please update the reference.

\* I would have liked a little more background on the PPIE initiative that this study is evaluating. I realise that this has been published previously<sup>3</sup>, but a brief summary here would be welcome.

\*Furthermore, has the PPIE group been involved with any clinical trials and has the composition of the group changed since you set it up? Obviously, this will affect the outcomes of your evaluation exercise, and it would be worth mentioning this in the protocol.

\* Clarification around what you mean by 'engagement' in this context is needed to make the article scientifically sound. There is different terminology used by different people for PPIE. However, engagement often refers to researchers engaging with the public and sharing their findings, whereas 'Involvement' tends to refer to involving patients and members of the public in the actual research as research partners, e.g. when they co-design a study, help write lay summaries etc. From my reading of the current protocol and the terms of reference attached to your previous article, your PPIE group was set up to do more of the latter? See also the NIHR guidelines for PPI<sup>2</sup>

\*I was wondering how many studies incl. clinical trials conducted in Pakistan mention PPIE in their reports and publications? You refer to the review that only found 33 studies evaluating PPIE in a LMIC<sup>4</sup>, but surely there are more studies using input from patients and members of the public and describe this in the publications? I realise that this would be another review and I mainly ask out of interest, but if that information is readily available it might be of interest to the reader?

**A few remarks regarding the METHOD section:**

\*The mixed methodology seems well suited for the purpose of the study and I think you will get rich data from all 3 sections.

\*However, the sample size will be rather small, even if all PPIE members, both current and past, will take part. Do you think this will affect your study in any way? Please discuss here or in the analysis section.

\* Would it be an idea to use the PPEET answers of a participant as prompts in their interview? If you were only doing the PPEET and had a bigger sample, I think anonymity would be preferable, but since a) the sample is rather small and b) as they are completing the PPEET and asked to do an interview its likely you would be able to identify them anyway, so perhaps trying to 'combine' the two might be worthwhile?

\*This will be quite time intensive exercise for PPIE members and staff. Are they paid for taking part?

**A few remarks regarding the DATA ANALYSIS & MANAGEMENT section:**

\*The plans are clearly laid out and I don't have any major concerns.

**A few remarks regarding the DISCUSSION section:**

\*I believe you have highlighted the main impact of the study as well as any potential restrictions. Some further thoughts:

\*Are there future plans for evaluation of the group?

\*Are there plans for creating future PPIE groups at other hospitals/ Universities?

In Summary, I have read through this protocol with great interest and believe the study is worthwhile. PPIE in clinical trials in LMIC should be fully supported and effective PPIE groups set up. A few clarifications are needed as outlined in my report to make this publication and any follow-up publications more impactful and useful for your own and other PPIE groups.

**References**

1. Abelson J, Li K, Wilson G, Shields K, et al.: Supporting quality public and patient engagement in health system organizations: development and usability testing of the Public and Patient Engagement Evaluation Tool. *Health Expectations*. 2016; **19** (4): 817-827 [Publisher Full Text](#)
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**Is the rationale for, and objectives of, the study clearly described?**

Yes

**Is the study design appropriate for the research question?**

Yes

**Are sufficient details of the methods provided to allow replication by others?**

Yes

**Are the datasets clearly presented in a useable and accessible format?**

Not applicable

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Behavioural medicine, rheumatology, patient and public involvement

**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.**

Author Response 21 Nov 2025

**Arishay Hussaini**

We sincerely thank the reviewer for their constructive and encouraging feedback, which has helped strengthen the clarity, structure, and overall coherence of the manuscript.

In the Introduction, the reference to the now - discontinued INVOLVE website has been updated to the NIHR Briefing Notes for Researchers (2021). We have also expanded this section to briefly describe the establishment and aims of the Ziauddin University PPIE group, including its contributions to major international clinical trials (REMAP-CAP and Mega-ROX) and the evolution of its membership over time.

The distinction between “involvement” and “engagement” has been clarified in line with NIHR guidance, noting that our group’s work primarily centres on involvement while also supporting engagement through public-facing activities.

In the Methods, we clarified that all 14 individuals directly involved with the PPIE group will be included, making this an exhaustive rather than a sampled population. While the sample size is small, this is appropriate for a process evaluation that prioritises depth of understanding over generalisability.

The description of the PPEET tool has been refined to explain how scores will inform interview prompts, enhancing integration between quantitative and qualitative findings. The section on participant compensation now specifies that PPIE members receive an honorarium and travel reimbursement in line with the group’s policy, while coordinators and institutional leads participate within their regular institutional roles.

The Discussion has been expanded to outline next steps, including plans for longitudinal evaluation through annual PPEET assessments and exploration of similar PPIE groups at other institutions, contributing towards a potential national PPIE framework in Pakistan.

Finally, we carefully reviewed the full manuscript to improve flow, reduce redundancy, and ensure consistency in tone, terminology, and reference sequencing.

**Competing Interests:** No competing interests were disclosed.

Reviewer Report 22 April 2025

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**Michele Andrasik** 

Fred Hutch Cancer Center, Seattle, Washington, USA

What is presented here is a plan for future analysis of a community engagement process. I would advise the authors to develop a manuscript about the PPIE process focusing on how it was implemented, who was involved, barriers, challenges and factors that facilitated the process. That would be a great contribution to the literature as there are few examples of this focusing on LMIC in the literature. I would strongly encourage the authors to submit a manuscript once they have collected and analyzed the qualitative and quantitative evaluation data. What they have submitted here is a great beginning to the evaluation data manuscript. In its current state this manuscript is not appropriate for indexing. I want to underscore that this is a really interesting and exciting project, and the authors should definitely publish it. I hope my suggestions for future manuscript submissions are helpful.

**Is the rationale for, and objectives of, the study clearly described?**

Yes

**Is the study design appropriate for the research question?**

Yes

**Are sufficient details of the methods provided to allow replication by others?**

Yes

**Are the datasets clearly presented in a useable and accessible format?**

Not applicable

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** HIV and TB vaccines, social and structural determinants of health, trauma, mixed methods, community engagement

**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.**

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