Author’s response to reviews

Title: The Maudsley Biomedical Research Centre (BRC) Data Linkage Service User and Carer Advisory Group: Creating and Sustaining a Successful Patient and Public Involvement Group to Guide Research in a Complex Area

Authors:

Amelia Jewell (amelia.jewell@slam.nhs.uk)
Megan Pritchard (megan.pritchard@kcl.ac.uk)
Katherine Barrett (jabarrett@hotmail.com)
Patrick Green (pad.green@zen.co.uk)
Sarah Markham (sarah.markham@kcl.ac.uk)
Sharon McKenzie (s.j.mckenzie@btinternet.com)
Roger Oliver (ro3746@aol.com)
Maria Wan (mwoz03@yahoo.com)
Johnny Downs (johnny.downs@kcl.ac.uk)
Robert Stewart (robert.stewart@kcl.ac.uk)

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Author’s response to reviews:

Response to Reviewers

Thank you for the opportunity to revise our manuscript “The Maudsley Biomedical Research Centre (BRC) Data Linkage Service User and Carer Advisory Group: Creating and Sustaining a Successful Patient and Public Involvement Group to Guide Research in a Complex Area” (RIAE-D-19-00006) to BMC Research Involvement and Engagement.

We appreciate the time and detail provided by each of the reviewers, and we have revised our manuscript accordingly. We are grateful for these very helpful comments and suggestions and believe that the manuscript is substantially improved after making the suggested modifications.

We hope that you will consider this revised article for publication.
Please find our response to each of the reviewer’s points below:

Reviewer 1:

1. ABSTRACT: You highlight the single result of breaking down barriers between service users/carers and researchers. The abstract would benefit from adding findings from the Advisory focus groups and researchers in this section.

RESPONSE: We agree with the reviewer and have amended the abstract, in particular adding more details to the results section, which is now written as follows (page 3):

‘Results: Evaluation revealed that the group succeeded in promoting dialogue between service users/carers and researchers. Factors that contributed to the success of the group’s first year included the opportunity it provided for researchers to involve service users and carers in their projects, the training provided to group members, and the openness of researchers to receiving feedback from the group.’

2. PLAIN ENGLISH SUMMARY: Line 38 - 39: You state this conclusion in several locations in the document, yet the results, as presented, do not specifically demonstrate this. I recommend including a stronger discussion of how the results establish the conclusion of barriers being broken down between researchers and patients/carers.

RESPONSE: In light of the reviewers suggestion we have added a paragraph in the Discussion section of the manuscript considering the barriers in PPI identified by previous research and how the group has contributed to breaking down some of these barriers (page 21):

‘Previous research has identified a number of potential barriers to PPI in health research, including the scientific language used in research, lack of support for PPI from research funders, the perception that members of the public have biased views, and the attitudes of researchers to relinquishing power and control [30]. Based on the feedback from group members and researchers, our view is that the group has succeeded in breaking down some of these barriers. For example, during the discussion group it was agreed that researchers had explained their projects clearly and had been happy to explain difficult concepts. The meetings permitted group members to seek clarification from the researchers, to the point where all were satisfied that the project purpose were clear, providing evidence that the group had addressed issues of the use of scientific language in research. Furthermore, it does not cost researchers to attend the group, meaning that support from research funders is not required.’

3. BACKGROUND: You provide a general description of the reason for PPI in data linkage research. What is not discussed is the importance of engaging stakeholders in research question
development and design to the relevance of the research to the people who will ultimately be impacted by it? Could you include information about this.

RESPONSE: We agree with the reviewer that it is important to engage stakeholders in research question development and design in order to ensure that the research that is conducted is relevant to those that are ultimately impacted by it. In fact, one of the aims of the Data Linkage Service User and Carer Advisory group is to identify research priorities in data linkage research. Indeed, during the presentations given by researchers, members of the data linkage group have suggested possible research questions and further areas of research work and the researchers have been receptive to suggestions. We have amended the Background section to include this (page 5):

‘Furthermore, engaging stakeholders in the development and design of data linkage projects and research questions is an important way of ensuring that the research conducted is relevant to those who are most impacted by it.’

4. METHODS: The methods section is lacking some information that will be of interest to the readers. I have highlighted some points below: Provide more information about the consent process for participants. Were they compensated?

RESPONSE: We have added additional information to the Recruitment section of the Methods to clarify the joining process for new group members (page 7):

‘An Involvement Register Activity Criteria was completed, including a brief description of the group, details on the frequency and duration of meetings, training provided, and whether or not any specific skills or abilities were required; this was circulated to members of the SLaM Involvement Register.’

Group members were compensated for their time and reimbursed for travel expenses to meetings. We have amended the Recruitment section of the Methods to reflect this (page 8):

‘Group members were offered payment for their time in line with SLaM Involvement Register payment rates as well as reimbursement for travel costs.’

5. Can you provide more detail on what researchers were told about the function of the advisory group?

RESPONSE: The group is advertised to researchers on the Maudsley Biomedical Researcher Centre (BRC) website (www.maudsleybrc.nihr.ac.uk/patients-public/support-for-researchers/), through posters located in the main office, and via word of mouth. Researchers are informed that the group is a regular meeting of people with lived experience of mental health conditions, all of whom have an interest in mental health research involving data linkage. With regards to the
function of the group, potential presenters are informed that the group can provide feedback and advice on their project and that the group are happy to review projects at a variety of stages - from identifying research priorities and preparing grant applications right through to disseminating findings. We have updated the manuscript to include this detail (page 9):

‘The group was advertised to researchers via word of mouth, posters, and the Maudsley BRC website. Prior to meetings researchers were advised by the group facilitators on the function, aims and objectives, and the level of knowledge of the group to ensure that presentations were appropriate and could be pitched at the right level.’

We have also included additional information describing the Maudsley BRC as we felt it would be helpful to readers to provide further context (page 6):

‘The Maudsley BRC is a partnership between SLaM and the Institute of Psychiatry, Psychology and Neuroscience at King’s College London, funded by the National Institute for Health Research (NIHR). It is one of several national centres set up to bring academic and healthcare institutions together in order to foster translational research [25].’

6. Training: You provided a description of the training the advisory group received about data linkage. Can you provide information on what they were told about their role as an advisory group?

RESPONSE: During the initial training session group members reviewed and agreed Terms of Reference, which included the aims and objectives of the group (described in the Background section - page 6, line 151). The Terms of Reference were drafted prior to the first meeting by the two staff members who coordinated the group. They were discussed and reviewed by all group members in the initial meeting. We have amended the Training section in the Methods to reflect this (page 9):

‘Terms of Reference for the group were drafted prior to the initial training sessions. These included the aims and objectives of the group as well details on frequency, location, and record keeping. During the initial session the Terms of Reference were reviewed, discussed, and approved by the group.’

7. Frequency of Meetings: Did you document what happened during the researcher presentations?

RESPONSE: During meetings formal minutes were taken, these provided an overview of the researcher presentation and detailed the discussion that took place. Minutes were then circulated
to both group members and the presenters’ following the meeting. We have clarified this in the manuscript (page 9):

‘During the meetings formal minutes were taken detailing the researcher presentation and the subsequent discussion that had taken place, these were then circulated to both group members and attendees.’

8. Did you evaluate if the group's recommendations to the research being discussed was acted upon? Was this communicated to the advisory group?

RESPONSE: During the 12 month formative evaluation we examined whether or not the group’s recommendations were acted upon within the survey sent to presenters. Specifically, we asked: ‘What impact did your visit to the group have on your project?’ The responses received from researchers indicated that that feedback from the group had been acted on in a number of different ways, for example, prioritising some research questions over others, including factors that had not previously been considered, and amending patient information sheets.

Following presentation to the group, researchers are encouraged to provide updates on their projects; these are communicated to the group via the newsletters (sent directly to members and available on our public facing website - www.maudsleybrc.nihr.ac.uk/cris-data-linkages/) and during future meetings.

We have updated the manuscript to include details of the survey questions asked to researchers (Table 2) and have included additional information within the ‘Impact of the Group’ section of the Results (page 18).

9. Evaluation: Provide more detail about the focus group: Detail the lines of questioning (particularly interested if you asked about their perspectives on the researchers acting upon their advice). Who led the focus group? Was it recorded and transcribed? Notes taken? How was the data analyzed?

RESPONSE: Following consideration of the reviewers’ feedback with co-authors, we feel that, as we did not conduct a formal qualitative evaluation of the group or collect data, it would be more appropriate to refer to the discussion which took place with the group as a ‘Discussion Group’ rather than a focus group. This is consistent with guidance from Doria et al. (2018) and captures the formative nature of the evaluation. We have updated the manuscript to reflect this.

The discussion group was led by the group facilitators, the session was recorded and notes were taken. Themes for discussion were agreed a priori and included the aims of the group, information provided prior to meetings, format of meetings, researcher presentations, and general
feelings towards mental health research using data linkage. Following the discussion group session, the group facilitators transcribed the recording and summarised the feedback. We have amended the Evaluation of the Group section of the Methods to provide further detail (page 10):

‘At the end of the pilot year a formative evaluation took place. A discussion group [28] led by the group facilitators was conducted with all six group members with the aim of obtaining feedback on different aspects of the group. The purpose of the discussion was to evaluate the group as well as make decisions to shape the future of the group. Themes for discussion were agreed a priori and included the aims of the group, information provided prior to meetings, format of meetings, researcher presentations, and general feelings towards mental health research using data linkage. The discussion group was recorded and transcribed. A questionnaire was also emailed to all members with specific questions about the format and administration of the meetings (Table 1).

Researchers who attended the group during the trial year were sent an online survey (Table 2) to complete. A review of the minutes from the meetings which took place during the trial year was also conducted. Feedback from the discussion group and surveys was summarised by the group facilitators in an evaluation report which was circulated to group members for discussion and approval.’


10. Provide more information about the research survey contents.

RESPONSE: In light of the reviewer’s comments we have included two tables within the manuscript describing the questions asked within the questionnaire to group members (Table 1) and presenting researchers (Table 2).

11. RESULTS: Need more description of the people that composed the Advisory group - how many service users and carers, age, etc.

RESPONSE: At the time of the formative evaluation the group consisted of six working age adults (18+) who were all either current or past service users of NHS mental health services or carers of NHS mental health service users. We did not collect detailed demographic information (e.g. age, ethnicity, diagnosis) from group members as it was not relevant to joining the group and it was agreed that it would be intrusive for sensitive information such as diagnosis to be collected. The level of detail to provide on the demographics of the group within the manuscript was discussed with group members/ co-authors and it was felt that it would not be appropriate
for statistical disclosure reasons, arising from the small group size, to include detailed demographic information. We have added additional information to the Results section (page 11):

‘At the time of the evaluation the group consisted of six working age adults (18+) all of whom had personal experience of mental illness, either as a service user or carer, and who were all either current or past service users of NHS mental health services.’

We have also commented on this in the Discussion (page 24):

‘Detailed demographic information on group members, e.g. ethnicity, age, etc., was not collected as it was not felt that it was relevant to membership of the group. We therefore cannot comment on the diversity of the group and the group may not be representative of the diverse community of SLaM service users and carers.’

12. Line 214, should this read "…aware of the OBJECTIVES (rather than objections)…"?

RESPONSE: We are grateful to the reviewer for drawing this to our attention; this has now been amended in the manuscript.

13. I am wondering if you had some a priori expectations for what the information coming from the advisory group would be used for by researchers? Did this align with what they indicated they used it for in the survey?

RESPONSE: We did have some expectations on what the information coming from the group would be used for due to prior discussions with researchers and with coordinators of existing service user advisory groups. We anticipated that the majority of researchers would want to obtain service user and carer feedback at the beginning of their projects either at the point where they were applying for the necessary legal and ethical approvals to conduct data linkages or when applying for fellowships/ grants. Generally we found this to be true from the feedback given within the survey and from the individuals requesting to present to the group.

14. DISCUSSION: Line 303 - 307 - This summary statement is not based on any information in the results sections. Can you provide a little more detail in the results that substantiates this statement. Providing more detail about the questions asked during the focus group in the methods section would also help the reader understand the source of this conclusion.

RESPONSE: We agree with the reviewer that more detail on the evaluation would help the reader to understand the source of our conclusions better. We have therefore updated the
‘Evaluation of the Group’ section of the Methods to include further detail on the discussion group held (page 10) and the survey’s sent to both group members and researchers (please see Tables 1 and 2 in the updated manuscript). We have also updated the paragraph in the Discussion (page 21):

‘From the perspective of the group’s members, the factors that contributed to the success of the group’s first year included the opportunity it provided for researchers to involve service users and carers in their projects, the level of training provided to the group prior to meetings, and the openness of researchers to receiving suggestions and feedback from the group.’

15. Line 345 - 347 - I am not sure that you have adequately substantiated this statement. On what basis are you concluding that setting up this advisory group broke down barriers between these two groups, or “improving” perceptions of data linkage research. This might be inferred by the fact that the two groups talked to each other, and each felt they got something out of the interaction, however, you have not outlined what the “barriers” were initially and how you measured them to know that you have broken them down. The trainings certainly did increase the advisory group's understanding of data linkage research, but I am not sure you have demonstrated that participants improved their "perceptions" of data linkage. You provide no information about what their perceptions were before and after the project.

RESPONSE: As soon as interested service users and carers come together with researchers to share knowledge and views, there is the potential for any perceptual barriers to be broken down. The fact that there was such strong mutual interest exhibited within the group meetings facilitated this process. In light of the reviewer’s helpful suggestion we have added a paragraph in the Discussion section of the manuscript considering the barriers in PPI identified by previous research and how the group has contributed to breaking down some of these barriers (page 21):

‘Previous research has identified a number of potential barriers to PPI in health research, including the scientific language used in research, lack of support for PPI from research funders, the perception that members of the public have biased views, and the attitudes of researchers to relinquishing power and control [30]. Based on the feedback from group members and researchers, our view is that the group has succeeded in breaking down some of these barriers. For example, during the discussion group it was agreed that researchers had explained their projects clearly and had been happy to explain difficult concepts. The meetings permitted group members to seek clarification from the researchers, to the point where all were satisfied that the project purpose were clear, providing evidence that the group had addressed issues of the use of scientific language in research. Furthermore, it does not cost researchers to attend the group, meaning that support from research funders is not required.’

With regards to group members perceptions of data linkage, we agree with the reviewer that it is difficult to conclude that the group improved members perceptions of data linkage as we did not
gather information on what their perceptions were before and after the project; therefore we have amended this in the manuscript to ‘improving the awareness of data linkage’ as we feel this better captures what was achieved.

16. CONCLUSION: Line 350 - I am not sure that this paper provides much of a description of the groups experience with setting up the Advisory Group. Rather, it presents a description of how the Advisory group was set up operationally, and the experience of group members and researchers.

RESPONSE: This has been amended in the manuscript as follows (page 25):

‘The paper provides a description of how the Data Linkage Service User and Carer Advisory Group was set up operationally within the Maudsley BRC, a joint partnership between a university and healthcare provider. Evaluation of the group after the first year was overwhelmingly positive with the experience being valued by both group members and the researchers who attended the group.’

17. Line 356 - 357 - Theoretically, an Advisory group whose opinions are sought and applied can maximize legitimacy of research designs and priorities. This project, however, has not provided evidence that the information gathered from the Advisory group was actually applied to the research design. Can you add further specific evidence that the engagement actually impact the research design or methods such that it increased its legitimacy?

RESPONSE: We have amended the Results section to further highlight how the information gathered from the group was applied to the research design (page 18):

‘Survey responses indicated that the feedback received by researchers had had an impact on their projects in a number of different ways, from highlighting particular priority areas to focus on within the analysis to informing information to be included in public information sheets and fair processing notices:’

Reviewer 2:

1. The statement: "Evaluation after a trial period of 12 months revealed that the group succeeded in breaking down barriers between service users/carers and researchers" is rather too bland, even for good news. What exactly was 'revealed'?

RESPONSE: We have amended the abstract to provide more accurate conclusions. We have also added a paragraph in the Discussion section of the manuscript considering the barriers in PPI
identified by previous research and how the group has contributed to breaking down some of these barriers (page 21):

‘Previous research has identified a number of potential barriers to PPI in health research, including the scientific language used in research, lack of support for PPI from research funders, the perception that members of the public have biased views, and the attitudes of researchers to relinquishing power and control [30]. Based on the feedback from group members and researchers, our view is that the group has succeeded in breaking down some of these barriers. For example, during the discussion group it was agreed that researchers had explained their projects clearly and had been happy to explain difficult concepts. The meetings permitted group members to seek clarification from the researchers, to the point where all were satisfied that the project purpose were clear, providing evidence that the group had addressed issues of the use of scientific language in research. Furthermore, it does not cost researchers to attend the group, meaning that support from research funders is not required.’

2. There is no reference to the National UK Standards and whether or not an audit of the project and its use of PPI was audited against the Standards.

RESPONSE: We did not audit the project or its use of PPI against any National UK Standards. Following a suggestion by reviewer 3 we have since used the GRIPP2 checklist criteria to ensure that the manuscript meets the international guidance for reporting of PPI in health and social care research. Going forward we intend to audit the group against National UK PPI Standards, e.g. INVOLVE National Standards for Public Involvement, and we have updated the Discussion section of the manuscript to reflect this (page 24):

‘Going forward, a more in-depth evaluation, including evaluating the group against recognised PPI standards such as the INVOLVE National Standards for Public Involvement [34], would be useful to ensure the on-going relevance of the group to both the group members and the researchers attending.’

3. Avoid the use of words, and concepts, such as "believe", especially as in the last sentence of the article. Research should be more about proof than belief and there is more assertion than proof in this article.

RESPONSE: In light of the reviewer’s comments we have amended the manuscript throughout to remove use of the word ‘believe’.
Reviewer 3:

1. Considering the PPI nature of this article, was the GRIPP2 checklist criteria used? If it was, please add it to the Introduction and References. (Stanišewski S, Brett J, Simera I, Seers K, Mockford C, Goodlad S, et al. GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research. BMJ (Clinical research ed). 2017;358:j3453).

RESPONSE: We would like to thank the reviewer for bringing the guidelines to our attention. We have now used the checklist and have included it as Supplementary Material. The Methods (page 10) and References sections have also been updated to reflect this:

‘Findings are reported in line with the Guidance for Reporting Involvement of Patients and the Public (GRIPP2) checklist [28], for the full checklist please see the Supplementary Material.’

2. The word "appropriateness" used in the Abstract, Introduction, Discussion, and Conclusion is a very subjective term and lends itself more towards ethical considerations of the research project. The word should be removed or exchanged for another word such as "relevance".

RESPONSE: In light of the reviewers comments were have removed the word ‘appropriateness’ in relevant sections of the manuscript.

3. Abstract

Background: The aims need to be described here.

Method:
Describe the steps followed to achieve your aims.

Briefly describe how the advisory was set up and how the service users and carers were recruited.

Results: What barriers were broken down? It would be easier to follow if it said, for example, "the group promoted dialogue between service users/carers and researchers”.

Conclusion:
"Pool" does not fit a group of 6 people.

Is it an "expert" group? If I were to read only the abstract, I would think of a group of experts in data linkage (i.e. professors, researchers) and not service users/carers.
RESPONSE: We have amended the abstract based on the above recommendations, it is now written as follows (page 3):

‘Background: Patient and Public Involvement (PPI) in health and social care research has been shown to improve the quality and relevance of research. PPI in data linkage research is important in ensuring the legitimacy of future health informatics initiatives, but remains sparse and underdeveloped. This article describes the setting up and evaluation of a service user and carer advisory group with the aim of providing feedback and advice to researchers developing or making use of database linkages in the field of mental health.

Aim: The aim of this study is to describe the creation and formative evaluation of the service user and carer advisory group after a trial period of 12 months.

Method: Six individuals were recruited to the group all of whom had personal experience of mental illness. A formative evaluation was conducted after a trial period of 12 months.

Results: Evaluation revealed that the group succeeded in promoting dialogue between service users/carers and researchers. Factors that contributed to the success of the group’s first year included the opportunity it provided for researchers to involve service users and carers in their projects, the training provided to group members, and the openness of researchers to receiving feedback from the group.

Conclusion: The group encourages the incorporation of PPI in data linkage research which helps to ensure the legitimacy of data linkage practices and governance systems whilst also improving the quality and relevance of the research being conducted using linked data.’

4. Introduction.

Line 87-89: the flow of the sentence seems interrupted at "and a systematic review". For example, this part could be written as "... contributes to feelings of empowerment and value"

Line 88: I suggest the authors add "awareness" before "acceptance of research". It is very difficult for the public to accept research they are not aware of or implications/science not properly understood.

Line 93: A new sentence can begin at "for example, health data..."

Line 98: Remove "public acceptance". It is PPI in data linkage which ensures legitimacy rather than public acceptance.

Line 119-123: This sentence is too long and not easy to follow. It could be broken down into 2 sentences.
Line 126: Following "service users,..." the sentence would be clearer if it said "with their perspectives being considered..."

RESPONSE: We would like to thank the reviewer for highlighting these points; they have now been amended in the manuscript.

5. Methods: A description of the demographic information of advisory group is needed. Of the 6 service users/carers how many were men and how many were women? What was the age range? Which mental illnesses did the group have experience with (either as patient or carer)? How many years of experience did they have as service users/carers in mental health?

RESPONSE: At the time of the formative evaluation the group consisted of six working age adults (18+) who were all either current or past service users of NHS mental health services or carers of NHS mental health service users. We did not collect detailed demographic information (e.g. age, ethnicity, diagnosis) from group members as it was not relevant to joining the group and it was agreed that it would be intrusive for sensitive information such as diagnosis to be collected. The level of detail to provide on the demographics of the group within the manuscript was discussed with group members/ co-authors and it was felt that it would not be appropriate for statistical disclosure reasons, arising from the small group size, to include detailed demographic information. We have added additional information to the Results section (page 11):

‘At the time of the evaluation the group consisted of six working age adults (18+) all of whom had personal experience of mental illness, either as a service user or carer, and who were all either current or past service users of NHS mental health services.’

We have also commented on this in the Discussion (page 24):

‘Detailed demographic information on group members, e.g. ethnicity, age, etc., was not collected as it was not felt that it was relevant to membership of the group. We therefore cannot comment on the diversity of the group and the group may not be representative of the diverse community of SLaM service users and carers.’

6. The authors need to restate that the data linkage research projects were in the area of mental health. For example, sentence 177 just mentions "data linkage projects" which might lead to confusion in terms of data linkage projects in other areas. Similarly, did the email newsletter feature only mental health data linkage research (line 188)?

RESPONSE: Thank you for bringing this to our attention. We have amended the manuscript where appropriate to clarify that research projects were in the area of mental health.
With regards to the email newsletter, this does focus on mental health research that uses data linkage. We have clarified this in the manuscript (page 9):

‘The newsletter included information on project or group updates/ news and also highlighted recent publications featuring data linkage research in the area of mental health.’

7. The methods successfully address aims i, ii, and iii, however, the authors do not mention how or if the group assisted in designing studies, preparing grant applications, disseminating findings, or identifying research priorities.

RESPONSE: The aims and objectives of the group were agreed with group members at the initial meeting. Throughout the trial year the group were not involved in all of the activities set out in the aims as they were not required by the presenting researchers. However, these remain the aims and objectives of the group going forward and group members are happy to be involved in these activities as required by researchers presenting to the group. We have updated the Results section to clarify this (page 12):

‘The aims and objectives of the group were agreed with group members at the initial meeting. Throughout the trial year the group were not involved in all of the activities set out in the aims as they were not required by the presenting researchers. Projects presented during the first year included brand new mental health linkages at the start of the approvals process, e.g. a linkage between mental health data and a national audit of heart attacks, and projects being conducted using existing linkages, e.g. a project looking to improve end of life care in dementia using a linkage between mental health and general hospital data.’

8. If research priorities were identified, what methodology was used to identify them?

RESPONSE: After the initial 12 months of the group we found that group members regularly advised presenters on specific priorities within their projects which had perhaps been previously overlooked within researchers proposals. We have updated the manuscript to include examples of the feedback given to researchers (Table 3).

9. Results.

Please provide examples of:

Questions, feedback, or opinions from the advisory group to the researchers.

Other frequent questions that the researchers asked the group.
Please provide 1-2 more examples of the research projects presented to give the reader a better idea of the type of studies reviewed by the advisory group. For example, did the researchers present new studies or were some of these on-going studies with researchers seeking ideas for improvement?

RESPONSE: We agree with the reviewer that it would be helpful for the reader to have more examples within the manuscript. In order to provide examples of questions, feedback, and opinions from the advisory group, frequent questions from the researchers, and examples of the research projects presented we have reviewed the formal minutes from the meetings conducted over the initial trial year. We have now added a section to the Results, detailing this and providing examples (page 12):

‘The minutes of the meetings were reviewed; during the trial year six data linkage projects were presented to the group. The aims and objectives of the group were agreed with group members at the initial meeting. Throughout the trial year the group were not involved in all of the activities set out in the aims as they were not required by the presenting researchers. Projects presented during the first year included brand new mental health linkages at the start of the approvals process, e.g. a linkage between mental health data and a national audit of heart attacks, and projects being conducted using existing linkages, e.g. a project looking to improve end of life care in dementia using a linkage between mental health and general hospital data. Frequent questions from researchers to the group included “do you think it is acceptable to use patient identifiable information in order to conduct this data linkage?”, “are there any factors which you think I should be focusing on in this analysis?”, and “how can I best communicate these findings to relevant stakeholders?”. Examples of questions, feedback, and opinions from the advisory group to the researchers are presented in Table 3.’

10. Line 214: "objections (objectives) and purpose of the group".

RESPONSE: We are grateful to the reviewer for drawing this to our attention; this has now been amended in the manuscript.

11. Discussion. Line 328: What are possible ways to measure the group's impact on research studies? Could it be measured, for example, by the number of accepted ethics applications or grants won?

RESPONSE: The reviewer raises an important point and gives some useful suggestions. During the formative evaluation we found it very difficult to measure quantitatively the impact of the group on research studies, particularly due to the fact that each of the projects presented to the group were at varying stages of the research process. For instance, those projects using existing
CRIS linkages were not required to apply for separate ethics approval, as these linkage had already obtained the necessary legal and ethical approvals. For projects at the very initial stage of planning and applying we found that the group had a positive effect in shaping and supporting applications for the necessary legal approvals required to conduct respective data linkages (known as Section 251 approval in the UK), as demonstrated in the Results section of the manuscript (page 18). However, for those projects which had already achieved all necessary approvals and were perhaps presenting on their findings, we found it difficult to identify a quantitative way of measuring the groups’ impact. We have amended the Discussion to acknowledge this limitation further (page 23):

‘Beyond qualitative responses from researchers, the extent to which the group is considered to have had a tangible impact on the research being conducted was difficult to assess. The projects presented to the group were at widely varying stages in the research process, and therefore it was not possible to accurately measure the impact by quantitative means, for example the time to reach ethical approval.’

12. Line 335: Very briefly explain the reasons why a formal qualitative evaluation was not conducted.
RESPONSE: It was agreed with group members that a formative evaluation, as opposed to a formal qualitative evaluation would be conducted as it was felt by all involved that this would be the most appropriate way to ensure that the group was meeting its aims and objectives whilst also evaluating the administration and design of the group. Given the small size of the group and the novelty of focusing specifically on data linkage projects, with no precedents on which to base the setting-up and implementation of the group, a formative evaluation enabled us to evaluate the group and also make any necessary improvements going forward. We have added further detail to the Discussion section to clarify this (page 24):

‘During discussions with group members it was felt that a formative evaluation would provide the necessary feedback to ensure that the group was meeting its aims and objectives and to evaluate the design of group in order to make any necessary improvements going forward.’

13. Line 345: Include specific barriers between researchers and service users/carers identified in the literature.
RESPONSE: In light of the reviewer’s helpful suggestion we have added a paragraph in the Discussion section of the manuscript considering the barriers in PPI identified by previous research and how the group has contributed to breaking down some of these barriers (page 21):
‘Previous research has identified a number of potential barriers to PPI in health research, including the scientific language used in research, lack of support for PPI from research funders, the perception that members of the public have biased views, and the attitudes of researchers to relinquishing power and control [30]. Based on the feedback from group members and researchers, our view is that the group has succeeded in breaking down some of these barriers. For example, during the discussion group it was agreed that researchers had explained their projects clearly and had been happy to explain difficult concepts. The meetings permitted group members to seek clarification from the researchers, to the point where all were satisfied that the project purpose were clear, providing evidence that the group had addressed issues of the use of scientific language in research. Furthermore, it does not cost researchers to attend the group, meaning that support from research funders is not required.’

Reviewer 4:

1. ABSTRACT AND PLAIN ENGLISH SUMMARY: The Abstract and Plain English Summary are the same. The abstract should be written in scientific terms, e.g. method: goal, design, participants, data collection and analysis. In the results section the main categories should be provided. Concerning the Plain English Summary the conclusion should be simplified.

RESPONSE: In light of the reviewer’s comments with have amended the abstract (page 3) and simplified the conclusion (page 2) within the Plain English Summary, which now reads as follows:

‘We found that the group encouraged researchers to incorporate PPI in their data linkage research and this helps to improve the quality and relevance of the research being conducted using linked data in the area of mental health.’

2. BACKGROUND. The authors refer to very few systematic reviews about the positive impact of PPI. However, there have been more than 20 systematic reviews on PPI in research. It would strengthen the background to cite more of them (or at least most cited ones), for example Shippee and colleagues (2015) Patient and service user engagement in research: a systematic review and synthesized framework, HEX, Domecq and colleagues (2014) Patient engagement in research: a systematic Review, BMC Health Service Research. Also the following review might be suitable to cite Manaf and colleagues (2018) Patient engagement in Canada: a scoping review of the 'how' and 'why' of patient engagement in health reserach. Health Research Policy and Systems.
RESPONSE: We are grateful to the reviewer for their suggestion and for bringing these systematic reviews to our attention. We have reviewed these and others, and have added references to the manuscript where applicable.

3. There should be reference to the theoretical background of PPI such as the ladder of participation by Sherry Arnstein (1969).

RESPONSE: We have amended the Background section of the manuscript to make reference to Arnstein’s Ladder of Citizen Participation (page 4):

‘As observed in Arnstein’s Ladder of Participation [6], there are many degrees of PPI within health and social care services from non-participation (manipulation or therapy) to tokenism (consultation or placation) to citizen control (partnership or delegated power). Patients and the public can be involved at different stages in the research process which span the full ladder of participation; including identifying research priorities and setting agendas, helping to develop patient information, collecting data, and informing policy [7].’

4. The authors might also provide a definition of PPI so that it is clear for an international readership.

RESPONSE: We have amended the Background section to include a definition of PPI (page 4):

‘Patient and Public Involvement (PPI) is defined in the United Kingdom (UK) as research which is carried out ‘with’ or ‘by’ members of the public (including patients and carers) rather than ‘to’, ‘about’, or ‘for’ them [1].’

5. Line 112, page 2, the authors state that there is very little guidance on how to set up and sustain PPI groups concerning data linkages. This statement is barely supported by the literature. There should be a strong identification of the knowledge gap. If there is no literature on PPI in data linkage research - this is great to do new research - but there should be a review of proxy literature to provide the current state-of-the-art of scientific knowledge which should lead to the knowledge-gap. Then the research question should follow - which is missing. Please add it.

RESPONSE: We have updated the Methods section and included additional references. We have not added a research question as the aim of the paper was to describe the creation and formative evaluation of the group and therefore we did not have a research question as such.
6. METHOD.

In the method the process of PPI is in detail described. However, this should be one heading within the method section. It improves the manuscript if you follow the authors guidelines.

Please start with aim, design and setting.

Continue with the characteristics of participants. As it is written now a lot of information is provided on recruitment but only patients are described not the researchers who participated in the survey. What were the inclusion and exclusion criteria for participation in this study?

Process and data collection. Here the authors might want to integrate the working process with the advisory group (in a shorter way). As I understand it there is a qualitative (patients/focus group discussion) and a quantitative part (researchers/survey) please provide all relevant information timing, construction of questioning route for the focus group discussion, construction and validation of the survey, etc. Please provide the focus group questioning route and survey in a box. How did you deal with data saturation/recording/transcription/data entry?

Information about the analysis and trustworthiness is completely missing. How do you secure credibility and transferability and validity?

RESPONSE: We have updated the Methods section to include further detail. We have decided to keep the initial headings as we feel that they are more suited to the description of the set-up of the group, although, we have added an ‘Aim’ and a ‘Patient and Public Involvement’ heading.

Following consideration of the reviewers’ feedback with co-authors, we feel that, as we did not conduct a formal qualitative evaluation of the group or collect data, it would be more appropriate to refer to the discussion which took place with the group as a ‘Discussion Group’ rather than a focus group. This is consistent with guidance from Doria et al. (2018) and captures the formative nature of the evaluation. We have updated the manuscript to reflect this.

The discussion group was led by the group facilitators, the session was recorded and notes were taken. Themes for discussion were agreed a priori and included the aims of the group, information provided prior to meetings, format of meetings, researcher presentations, and general feelings towards mental health research using data linkage. Following the discussion group session, the group facilitators transcribed the recording and summarised the feedback. We have amended the Evaluation of the Group section of the Methods to provide further detail (page 10):

‘At the end of the pilot year a formative evaluation took place. A discussion group [28] led by the group facilitators was conducted with all six group members with the aim of obtaining feedback on different aspects of the group. The purpose of the discussion was to evaluate the group as well as make decisions to shape the future of the group. Themes for discussion were agreed a priori and included the aims of the group, information provided prior to meetings, format of meetings, researcher presentations, and general feelings towards mental health research
using data linkage. The discussion group was recorded and transcribed. A questionnaire was also emailed to all members with specific questions about the format and administration of the meetings (Table 1).

Researchers who attended the group during the trial year were sent an online survey (Table 2) to complete. A review of the minutes from the meetings which took place during the trial year was also conducted. Feedback from the discussion group and surveys was summarised by the group facilitators in an evaluation report which was circulated to group members for discussion and approval.

With regards to the surveys sent out to group members and presenting researchers we have added two boxes to the manuscript describing the contents of the surveys (Table 1 and 2).


7. There is little information about research ethics. Was it reviewed by a research board, did participants sign informed consent etc.

RESPONSE: Group members who took part in the meetings did so as patient and public involvement partners, and were paid an honorarium for their time. They were given written information about the purpose of the meetings and evaluation as well as verbal explanation and training. The National Institute for Health Research (NIHR) INVOLVE organisation advises that “Members of the public actively involved in research are acting as specialist advisors, providing valuable knowledge and expertise based on their experience of a health condition or public health concern. Therefore ethical approval is not needed for the active involvement element of the research (even when people are recruited via the NHS), where people are involved in planning or advising on research, for example helping to develop a protocol, questionnaire or information sheet, being a member of an advisory group or co-applicant”. This information has been included in the ‘Ethics Approval and Consent to Participate’ section of the Declarations (page 26).

8. I was also wondering what was the involvement of the group, especially patients and carers in writing this manuscript? Where they involved besides providing information?

RESPONSE: The manuscript was written in collaboration with group members and group members are listed as co-authors. The formative evaluation of the group was conceived by AJ and MP and conducted in collaboration with group members. The initial draft was written by AJ and all authors critically revised the manuscript.
9. RESULTS. This section should start with a description of the participants in the study. The first heading does not really cover the meaning of the results. It might be helpful to work with a main category and sub-categories. Next, it is a summary but not really a description of experiences. Short quotes or only words are used, but they are used as result and not to illustrate results. The quotes used should be longer and context rich to provide meaningful information. The second heading is about a survey with researchers. The survey instrument and analysis is not explained, as a consequence, it is not easy to understand the quotes. It seems that in the survey open questions were used and no measurements, right? Since there is fragmented information about data collection, data collection tools and no information about the analysis it is very hard for the reader to 'get' the results.

RESPONSE: In light of the reviewer’s comments we have expanded the results section, added more context to the illustrative quotes provided, and included headings. We have also included two tables within the manuscript describing the questions asked within the surveys to group members and presenting researchers.

With regards to a description of the group members and researchers who took part in the formative evaluation we have included a short paragraph at the start of the results section (page 11):

‘At the time of the evaluation the group consisted of six working age adults (18+) all of whom had personal experience of mental illness, either as a service user or carer, and who were all either current or past service users of NHS mental health services. All members took part in the discussion group. Following the discussion group a survey was emailed to members (Table 1), only one response to the survey was received.

During the 12 month trial, seven researchers presented at meetings. All presenters were researchers at the Maudsley BRC who were undertaking or planning to undertake projects using mental health data from the CRIS system linked to data from an external source. Five researchers responded to the request to feedback.’

The level of detail to provide on the demographics of the group and researchers within the manuscript was discussed with group members and it was felt that it would not be appropriate for statistical disclosure reasons to include detailed demographic information.

10. DISCUSSION.

The discussion should start with the goal and then summarize the main results. As the first paragraph it is written now it seems a kind of conclusion. Line 303, page 12 the sentence 'From the perspective of the group members, the factors….' This sentence is not supported by the
results. Is it a new results or already conclusion? Line 328 - it seems new results are presented because it is not positioned in current scientific literature.

The findings of the survey are rarely discussed and positioned in current scientific literature. Please add.

The authors make an interesting difference about the monetary costs and non-monetary benefits. However, the benefits as stated here are not supported by the results - please add the missing data in the results section. It would be interesting to reflect on what the literature says about value of PPI to bridge costs and benefits?

It might strengthen the manuscript if the authors reflect on the level of actual participation in research about data linkage using Arnsteins ladder of participation and what might be the theoretical implications of this study to develop the ladder further. In addition, the authors should reflect about what is necessary to move to the partnership or control level and is it necessary?

A methodological reflection is missing: what are the strengths and what are the weaknesses of this study and how did you compensate?

It would strengthen the discussion if the authors show what is the 'new scientific knowledge' and how does it contribute to advance PPI. Also recommendations for research and for researchers, who want to start PPI in a complex scientific area would improve the discussion.

The last sentence of the conclusion might be left out since it has already been proven in many publications. It reads as a personal commitment.

RESPONSE: We are grateful to the reviewer for their helpful suggestions; we have amended the Discussion section of the manuscript accordingly.

11. REFERENCES. Be aware that no [] should be used when citing the assessment date of online data.

RESPONSE: Thank you for drawing this to our attention; this has now been amended in the manuscript.

Assistant co-editors' comments:

1. We would like in particular a focus on providing additional methodological detail on how you carried out their evaluation, for instance:

How did you analyse data from the focus group and the survey?
RESPONSE: Following consideration of the reviewers’ feedback with co-authors, we feel that, as we did not conduct a formal qualitative evaluation of the group or collect data, it would be more appropriate to refer to the discussion which took place with the group as a ‘Discussion Group’ rather than a focus group. This is consistent with guidance from Doria et al. (2018) and captures the formative nature of the evaluation. We have updated the manuscript to reflect this.

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2. Were negative views sought when analysing the data? (It seems that no negative views are reported but were any expressed?) Data excerpts are welcome but should be given unique identifiers so that the reader can have some idea of how many different people’s views are being represented here.

RESPONSE: We have amended the manuscript throughout to provide unique identifiers for the quotes. Views were sought during the evaluation with no specific emphasis on positive or
negative views; however, no negative views were expressed and the summaries provided in the manuscript provide a true reflection of the discussion that took place.

3. We would also like you to remind the reader of the particular problems of using PPI in data linkage research and if these vary when considering mental health applications.

RESPONSE: One of the particular problems of using PPI in data linkage research revolves around the level of understanding of what might be seen as complex technical processes. Data linkage is challenging and members of the public may not be naturally versed in this area of research. This is something that we considered prior to setting up the group and the reason why we decided to conduct training sessions. We included further detail about this particular problem within the Discussion section of the manuscript (page 22).