PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Introducing Patient and Public Involvement practices to healthcare research in Austria: strategies to promote change at multiple levels
AUTHORS	Kaisler, Raphaela; Kulnik, Stefan; Klager, Elisabeth; Kletecka-Pulker, Maria; Schaden, Eva; Stainer-Hochgatterer, Andreas

VERSION 1 – REVIEW

REVIEWER	Di Lorito, Claudio University of Nottingham, Division of Rehabilitation, Ageing and Wellbeing
REVIEW RETURNED	15-Jan-2021

GENERAL COMMENTS	Thank you for your manuscript, which I read with great interest, given my previous experience with PPI. I commend your commitment and the initiative you have undertaken to further PPI practice in your country. However, I feel that at this stage, your manuscript requires further work before it is ready for publication. I have provided extensive points for improvement in the attached PDF, which I would invite you to carefully address, before I recommend publication to the Editor. Other than several other issues, as it stands, the main problem with the manuscript is how it is structured. To me, you have two distinct elements to your work : 1. The surveys; 2. The anecdotal evidence based on personal experience (currently entitled "points for attention"). At present, you have structured the paper as if the surveys are the only and core element of your data collection, but it does not work, because the current discussion is mostly unrelated to the survey findings. In fact, the discussion presents new data/findings and introduces new concepts based on your personal experience. I would re-structure the manuscript so that the results section includes the surveys and anecdotal personal experience. The discussion can then focus on the initiative you have been working on to advance PPI in Austria. This should be also reflected in the abstract and Aims and Objectives section which you need to include at the end of the introduction. Looking forward to seeing these comments addressed. Best Wishes and good luck

REVIEWER	Evans, Catherine King's College London
REVIEW RETURNED	01-Feb-2021

GENERAL COMMENTS	It is very encouraging to see the development of PPI in research in Austria and for this to be undertaken in a strategic way informed by surveying researchers and ethical committee members. The points for attention in the discussion state clearly the priorities for PPI informed by the survey findings and research evidence on PPI. The manuscript reporting is difficult to follow. This compromises the robust reporting required for publication of a communication. Although this is a communication, greater clarity is needed on what you did, why and how. The abstract is difficult to follow to understand the why PPI is important, the methods used with two surveys and the results should report the participants and the findings. BMJ Open recommend a structured abstract style in communication pieces. Using the structured abstract format would enable clearer presentation of the salient points of the importance of PPI in research, the aim of the study, methods and results, and the conclusions informed by the results detailing the key messages such as state the useful examples to introduce PPI - what are the strategic priorities. This PPI strategic work is undertaken with the Ludwig Boltsmann Institute (LBG) e.g. sampling their researchers. What is unclear is how this survey work of researchers and ethical committees links with the LBI stakeholder consultation in 2019 to develop PPI 'How to Guide'. This laid foundation for investment in research on PPI for researchers to apply for grants to support implementation. This initiative is detailed towards the end of the discussion. To set the context of PPI this detail would be better reported in the background, then aim of this work. In the discussion helpful to consider the organizational/national level initiatives needed to drive change. The background could be reduced to salient points re what is PPI, what is the importance for research and the situation in Austria to set context for the importance and relevance of the communication aim and findings reported. Greater detail is needed on how you scoped PPI practices for example the survey design - from the findings series of closed questions with a ranked scale, but key words state qualitative research. Use of open questions in the survey is not detailed. Also important to reference the underpinning evidence that informed the focus of the questions e.g. national guidance INVOLVE guidance on standards for PPI, systematic reviews on impact of PPI. Sampling and participants - detail is very limited. Limitations of the work - Response from the ethical committee members very low 8/32, clearly this weakens the findings especially to understand that ethical committee members indicating limited experience, yet researchers indicating seek advise from ethical committee members. Clearly a priority is to engage ethics committee members to develop the strategic priorities e.g. as members of the national network on PPI You make important conclusions about how this work mapping PPI practices in research in the LBG community in Austria has led to wider discussions. Important to state clearly in the abstract and background that this work intended to map (or scope both terms

	are used in the manuscript) PPI in research in Austria to inform what ? In the conclusion - state the main strategic priorities that detailed in the discussion. What are the main messages from the priorities detailed. This would strength the message in the conclusion about the priorities, rather than detailing the aim of the study.

REVIEWER	Barker, Jacqueline University of the West of England Bristol, Faculty of Business and Law
REVIEW RETURNED	08-Feb-2021

GENERAL COMMENTS	This is an interesting paper. I think the following needs to be addressed: 1. There is no clear research question, therefore it is hard to judge the methods. 2. The methods are not completely described (eg how was the survey administered, how were the questions developed etc). 3. In research about PPI, it is accepted practice to have involved the public. It looks as if the public were not involved in this paper so it is important to say why. 4. The UK organisation INVOLVE has been replaced - see this link https://www.nihr.ac.uk/news/nihr-launches-new-centre-for-engagement-and-dissemination/24576 so some of your wording may need to be updated. 5. You seem to use the term 'levels' in 2 different ways: 1) to describe levels of PPI from consultation to control and 2) in your abstract and elsewhere in terms of levels of organisation e.g. the individual, the organisation, the governance structures. You may need to clarify and flesh out these two different concepts and how they interact in your paper. 6. Proofing point: there is one use of 'und' instead of 'and' 7. In the background section, you mention the reasons for PPI but only list 2 items. I think you are missing arguments about citizens' rights 8. Towards the end of your paper you use the term 'co production' which has specific meaning and for many people is not interchangeable with 'involvement'. I think you need to either stick to involvement or reflect the debate around involvement and co production in your paper.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Dr. Claudio Di Lorito, University of Nottingham

Comments to the Author:

Dear Authors

Thank you for your manuscript, which I read with great interest, given my previous experience with PPI. I commend your commitment and the initiative you have undertaken to further PPI practice in your country. However, I feel that at this stage, your manuscript requires further work before it is ready for publication. I have provided extensive points for improvement in the attached PDF, which I would invite you to carefully address, before I recommend publication to the Editor. Other than several other issues, as it stands, the main problem with the manuscript is how it is structured. To me, you have two distinct elements to your work : 1. The surveys; 2. The anecdotal evidence based on personal experience (currently entitled "points for attention"). At present, you have structured the paper as if the surveys are the only and core element of your data collection, but it does not work, because the current discussion is mostly unrelated to the survey findings. In fact, the discussion presents new data/findings and introduces new concepts based on your personal experience. I would re-structure the manuscript so that the results section includes the surveys and anecdotal personal experience. The discussion can then focus on the initiative you have been working on to advance PPI in Austria. This should be also reflected in the abstract and Aims and Objectives section which you need to include at the end of the introduction.

Looking forward to seeing these comments addressed.

Best Wishes and good luck

Thank you for your suggestions and the specific feedback provided in the annotated PDF file. We have addressed all comments, which we have listed below referring to the comment sequence and page number in the annotated PDF file:

Comment 1, page 4: We have re-written the abstract, which is now in a structured format and follows the order in which we have presented information in the main text: survey, anecdotal evidence, strategies to promote PPI.

Comment 2, page 4: We fully acknowledge the reviewer's point that survey findings and observations from our personal experience need to be explicitly distinguished in the abstract and main text. We have re-structured and re-worded accordingly, and we have also explicitly described our personal observations as anecdotal evidence.

Comment 1, page 5: Thank you for noticing this, and we changed "citizens" to "members of the public" throughout the manuscript.

Comment 2, page 5: We thank the reviewer and have added examples of PPI activities (revised manuscript page 4, lines 10-13):

"Typical examples for PPI activities are involvement of patients and members of the public in the setting of research priorities, as co-applicants on research grant applications, as members of study steering or advisory groups, and as co-researchers [1]."

Comment 3, page 5: Thank you for pointing this out, and we have amended the wording (manuscript page 4, lines 5-7):

"…based on the argument that those who have lived experience of the phenomenon (e.g., a health condition) being researched should also have a voice in related research;…"

Comment 1, page 6: We thank Reviewer #1, and also Reviewers #2 and #3, for suggesting these improvements to the structure of our manuscript.

We restructured the manuscript according to the suggestion: first, reporting the surveys, second, the anecdotal evidence (see Scoping section, page 5ff), and last, the strategies for promoting PPI in Austria (see Discussion section, page 6ff).

We have added an explicit statement of the problem and the survey aims at the end of the Background section (manuscript page 5, lines 3-14):

"In another OIS initiative, the LBG established two new Ludwig Boltzmann Institutes for Digital Health which commenced work in 2019 and which were tasked with incorporating PPI throughout their programmes of research [12]. Initial experiences made by researchers at these two institutes (STK, EK, MKP, ES and ASH among others), however, have surfaced challenges in implementing PPI practices, including lack of awareness and knowledge about the PPI concept in the local scientific communities; lack of appreciation of the value of involving patients as 'experts by experience'; and fear of violating research ethics if PPI activities are carried out without formal ethical approval. We therefore undertook a scoping exercise and conducted surveys among researchers and research ethics committees in Austria. The aim was to explore current PPI practices, experiences, and ethical and operational challenges with PPI, to gauge in how far our personal experiences might be reflected within our wider research community; and to draw insights which may inform strategies for supporting PPI in research in Austria going forward."

We disentangled results of the survey and anecdotal evidence from the initiative with the working group representing ethics committees (see Discussion, page 8).

We further added information to the initiative with Austrian ethics committees (page 8, line 32, to page 9, line 2):

"*To initiate this national consensus and promote change on a structural level, we invited a dialogue with Austrian research ethics committees about PPI. To date, five committees have joined an informal working group coordinated by the LBG OIS Center and have supported the development of a checklist for ethical aspects of PPI [23]. We view this as a crucial step to inform about PPI and its ethical challenges, to align our visions, and to address the conflation of PPI with qualitative research by outlining differences and ethical considerations around PPI also in ethics applications. The checklist is based on existing ethics guidelines in research [10] and on the GRIPP-2 statement for reporting PPI in research publications [24]. The checklist could serve as best practice example and standard operating procedure for Austrian ethics committees in dealing with PPI. Applying the checklist to their own work, applicants may be asked to, e.g., describe the role of patients and members of the public in their project, distinguish between study participation and involvement and highlighting possible ethical issues. This could support quality assurance and implementation of standards for PPI and give researchers an opportunity to self-evaluate their ethical considerations around PPI."*

Comment 2, page 6: We deleted "formative" throughout the manuscript, as it does not add information to the manuscript.

Comment 3, page 6

We added further detail on the survey design, sampling, and distribution (page 5, lines 18-38)

Comment 4, page 6: We clarified that dissemination does not actively involve members of the public and therefore is not considered PPI (page 5, line 42, to page 6, line 2):

"Respondents were generally active in disseminating research findings to patients or the public, via traditional media, social media, popular science events, and other channels, which represents engagement/dissemination and not involvement."

Comment 5, page 6: We have added Figure 2 describing the results of the second online survey to research ethics committees.

Comment 6, page 6: We thank the reviewer for this comment, and we admit that there is some irony in not including any PPI in a manuscript about PPI. We hope that the manuscript does convey our good faith intentions to realise a genuine PPI approach in our research community, and that it provides some useful real-world insights into the types of difficulties we have encountered. Input and feedback from members of the public would undoubtedly be valuable; however, in this first scoping step we did not include members of the public in the study design or procedure. Our perception was that the immediate barriers we encountered in our work related to lack of awareness and understanding among researchers, and we therefore intended to scope current PPI practices among this group. For the reviewer's information, members of the public have been involved in the design and concept of the PPIE programme and funding model in 2019. We rephrased the sentence (page 6, lines 37-39):

"Members of the public were not involved in the design and conduct of the surveys, because the immediate barriers to PPI we encountered in our work seemed to relate to awareness, knowledge, and perceptions among researchers."

Comment 1, page 7: We removed the sentence here, and we have clarified the distinction between active involvement (PPI) and dissemination earlier in the manuscript (see above, your comment 4, page 6).

Comment 2, page 7: Thank you for the suggestion, we changed "gradient" to "trend" (page 7, line 1):

Comment 3, page 7: Thank you for the comment. We expanded the statement (page 7, lines 4-6):

"This snapshot encourages us to further promote PPI on individual level by offering training and facilitating exchange among researchers; and to introduce support structures on institutional and national level."

Comment 4, page 7: Thank you for this comment. We rewrote the sentence in more general terms not focusing on co-researchers (page 7, lines 6-7):

"In our second survey, most representatives from research ethics committees were unfamiliar with the PPI concept, but interested in discussing its ethical aspects."

Comment 5, page 7: Thank you for this comment. We moved the "anecdotal evidence based on personal experience" to the Scoping section (page 6, lines 18-35) and the "organisational, individual, and structural strategies" to the Background section (page 4, line 34, to page 5, line 2). We further discuss the initiative and working group with Austrian ethic committees in the Discussion section (page 8, line 24, to page 9, line 2).

Comment 6, page 7: We rephrased the sentence (page 7, lines 20-24):

"Signposting researchers to international scientific communities in which PPI is an established and valued practice (also considering other descriptors which are used internationally to describe an approach that is similar to PPI in spirit, such as 'community engagement' [15] or 'patient-focused drug development'[16]) could stress the importance of PPI and increase motivation for researchers to acquire adequate knowledge and skills for PPI."

Comment 7, page 7: We added detail to this statement (page 6, lines 21-22):

“We have encountered scepticism towards the usefulness and impact of PPI among LBG researchers and Austrian ethics committees.”

Comment 8, page 7: Thank you for the suggestion. Indeed, these are very relevant considerations also in our institutes, whereby the discussions we are having are differentiated, e.g., some PPI contributors value donating their time and would prefer not to receive financial remuneration. For the reviewer’s information, at one of our institutes we have advertised a salaried PPI contributor (“patient researcher”) position and found that the purpose and background to this role is challenging to convey, partly, undoubtedly, because such a position is rather unusual in the Austrian research landscape; but also because the particular contribution and added value of a researcher with lived experience to an institute such as ours takes some explaining of background, history and epistemology of PPI. The latter could be provided in training events, to create some equity in power by sharing knowledge about the value and purpose of PPI contributors’ work.

We have included the suggested statement about power differentials and the suggested reference [21] (page 7, lines 40-43):

“Moreover, power differentials between researchers and PPI contributors need to be addressed [21], e.g., by providing PPI contributors with (monetary or other) compensation for their time and adequate training opportunities.”

Reviewer: 2

Dr. Catherine Evans, King's College London

Comments to the Author:

It is very encouraging to see the development of PPI in research in Austria and for this to be undertaken in a strategic way informed by surveying researchers and ethical committee members. The points for attention in the discussion state clearly the priorities for PPI informed by the survey findings and research evidence on PPI.

Thank you for this encouraging comment.

The manuscript reporting is difficult to follow. This compromises the robust reporting required for publication of a communication.

Thank you for the comment. We restructured the manuscript as follows: first, reporting the surveys, second, the anecdotal evidence (see Scoping section), and last, the strategies for promoting of PPI in Austria (see Discussion section).

Although this is a communication, greater clarity is needed on what you did, why and how.

We thank the reviewer and appreciate this comment, which is also mirrored by comments from Reviewers #1 and #3.

We restructured the manuscript: first, reporting the surveys, second, the anecdotal evidence (see Scoping section, page 5ff), and last, the strategies for promoting PPI in Austria (see Discussion section, page 6ff).

We have added an explicit statement of the problem and the survey aims at the end of the Background section (manuscript page 5, lines 3-14):

"In another OIS initiative, the LBG established two new Ludwig Boltzmann Institutes for Digital Health which commenced work in 2019 and which were tasked with incorporating PPI throughout their programmes of research [12]. Initial experiences made by researchers at these two institutes (STK, EK, MKP, ES and ASH among others), however, have surfaced challenges in implementing PPI practices, including lack of awareness and knowledge about the PPI concept in the local scientific communities; lack of appreciation of the value of involving patients as 'experts by experience'; and fear of violating research ethics if PPI activities are carried out without formal ethical approval. We therefore undertook a scoping exercise and conducted surveys among researchers and research ethics committees in Austria. The aim was to explore current PPI practices, experiences, and ethical and operational challenges with PPI, to gauge in how far our personal experiences might be reflected within our wider research community; and to draw insights which may inform strategies for supporting PPI in research in Austria going forward."

We disentangled results of the survey and anecdotal evidence from the initiative with the working group representing ethics committees (see Discussion, page 8).

We further added information to the initiative with Austrian ethics committees (page 8, line 32, to page 9, line 2):

"*To initiate this national consensus and promote change on a structural level, we invited a dialogue with Austrian research ethics committees about PPI. To date, five committees have joined an informal working group coordinated by the LBG OIS Center and have supported the development of a checklist for ethical aspects of PPI [23]. We view this as a crucial step to inform about PPI and its ethical challenges, to align our visions, and to address the conflation of PPI with qualitative research by outlining differences and ethical considerations around PPI also in ethics applications. The checklist is based on existing ethics guidelines in research [10] and on the GRIPP-2 statement for reporting PPI in research publications [24]. The checklist could serve as best practice example and standard operating procedure for Austrian ethics committees in dealing with PPI. Applying the checklist to their own work, applicants may be asked to, e.g., describe the role of patients and members of the public in their project, distinguish between study participation and involvement and highlighting possible ethical issues. This could support quality assurance and implementation of standards for PPI and give researchers an opportunity to self-evaluate their ethical considerations around PPI."*

We have provided more detail on the survey distribution and content of questionnaires (page 5, lines 18-38).

The abstract is difficult to follow to understand the why PPI is important, the methods used with two surveys and the results should report the participants and the findings. BMJ Open recommend a structured abstract style in communication pieces. Using the structured abstract format would enable clearer presentation of the salient points of the importance of PPI in research, the aim of the study, methods and results, and the conclusions informed by the results detailing the key messages such as state the useful examples to introduce PPI - what are the strategic priorities.

We apologise for providing an unstructured abstract and have re-written the abstract in a structured format, also taking into account comments from Reviewer #1.

This PPI strategic work is undertaken with the Ludwig Boltzmann Institute (LBG) e.g. sampling their researchers. What is unclear is how this survey work of researchers and ethical committees links with the LBI stakeholder consultation in 2019 to develop PPI 'How to Guide'.

We appreciate the reviewer's comment and realise that in our first manuscript version information about the 'How to Guide' was introduced after the surveys, when in fact this work had preceded the surveys. We have now moved this passage to the Background and hope that this provides a better description of the sequence of events; and how the activities conducted by the LBG OIS Center to foster PPI in Austria dovetailed with the practical experiences of researchers at the two Ludwig Boltzmann Institutes for Digital Health, which in turn sparked the surveys and led to further work with ethics committees.

This laid foundation for investment in research on PPI for researchers to apply for grants to support implementation. This initiative is detailed towards the end of the discussion. To set the context of PPI this detail would be better reported in the background, then aim of this work. In the discussion helpful to consider the organizational/national level initiatives needed to drive change.

We thank the reviewer and have moved the description of the PPI grant scheme to the Background. We have added a new statement of the aims of this work at the end of the Background section. We have kept the discussion of initiatives at organisational/national levels in the Discussion section.

The background could be reduced to salient points re what is PPI, what is the importance for research and the situation in Austria to set context for the importance and relevance of the communication aim and findings reported.

We have restructured the Background to present some of the details which were previously given in the Discussion section. We feel that the passages on PPI governance in the UK and on international developments in PPI (FDA and EUPATI) provide important context, as they situate PPI on an international landscape of research and signal to (Austrian) readers that PPI is in line with the international medical scientific community's direction of travel. In our national discourse this offers a helpful, sometimes very impactful argument. We therefore hope that the reviewer will agree that these points offer meaningful content to the Background.

Greater detail is needed on how you scoped PPI practices for example the survey design - from the findings series of closed questions with a ranked scale, but key words state qualitative research. Use of open questions in the survey is not detailed. Also important to reference the underpinning evidence that informed the focus of the questions e.g. national guidance INVOLVE guidance on standards for PPI, systematic reviews on impact of PPI. Sampling and participants - detail is very limited.

Thank you for this comment. We added details on the study design, sampling, and participants in the surveys (page 5, lines 18-38) and underpinning evidence that informed the focus of the questions.

We apologise for including the keyword "qualitative research", which we realise could be misleading. There were some qualitative findings in our surveys from open questions, and we highlight the issue of researchers confusing/conflating PPI conversations with qualitative research, so the keyword was meant to refer to these two aspects; but we realise that it is better removed.

Limitations of the work - Response from the ethical committee members very low 8/32, clearly this weakens the findings especially to understand that ethical committee members indicating limited experience, yet researchers indicating seek advise from ethical committee members. Clearly a priority is to engage ethics committee members to develop the strategic priorities e.g. as members of the national network on PPI

Thank you for the comment. We agree on the argument and the limitation of the second survey. This was the reason why we asked the ethics committees to continue as a working group exploring ethical aspects in PPI in research. We expanded our previous acknowledgement of limitations in the Discussion section (page 7, lines 8-9) and highlighted the importance of engaging ethics committee members in developing strategic priorities for PPI (page 9, lines 7-10 and lines 15-18).

You make important conclusions about how this work mapping PPI practices in research in the LBG community in Austria has led to wider discussions. Important to state clearly in the abstract and background that this work intended to map (or scope both terms are used in the manuscript) PPI in research in Austria to inform what ?

We appreciate the reviewer's comment (which is also echoed by the other reviewers) regarding the lack of a statement of aims in the abstract and background, which we have now added:

"We therefore undertook a scoping exercise and conducted surveys among researchers and research ethics committees in Austria. The aim was to explore current PPI practices, experiences, and ethical and operational challenges with PPI, to gauge in how far our personal experiences might be reflected within our wider research community; and to draw insights which may inform strategies for supporting PPI in research in Austria going forward."

For consistency in wording, we have removed "map"/"mapping" from the manuscript and only use "scope".

In the conclusion - state the main strategic priorities that detailed in the discussion. What are the main messages from the priorities detailed. This would strength the message in the conclusion about the priorities, rather than detailing the aim of the study.

Thank you for this comment. We rewrote the conclusion specifically highlighting strategic priorities for PPI in Austria and the view going forward, rather than re-stating the aim of our surveys (page 9, lines 5-18).

<u>Reviewer: 3</u>

Dr. Jacqueline Barker, University of the West of England Bristol

Comments to the Author:

This is an interesting paper. I think the following needs to be addressed:

1. There is no clear research question, therefore it is hard to judge the methods.

We thank the reviewer for raising this point, which we have addressed by formulating a statement of the problem as it presented itself to us, and the aims of our online surveys. This passage is provided at the end of the Background section (page 5, lines 5-14):

"…Initial experiences made by researchers at these two institutes (STK, EK, MKP, ES and ASH among others), however, have surfaced challenges in implementing PPI practices, including lack of awareness and knowledge about the PPI concept in the local scientific communities; lack of appreciation of the value of involving patients as 'experts by experience'; and fear of violating research ethics if PPI activities are carried out without formal ethical approval. We therefore undertook a scoping exercise and conducted surveys among researchers and research ethics committees in Austria. The aim was to explore current PPI practices, experiences, and ethical and operational challenges with PPI, to gauge in how far our personal experiences might be reflected within our wider research community; and to draw insights which may inform strategies for supporting PPI in research in Austria going forward."

We hope that through restructuring the manuscript as advised by all 3 reviewers, this passage contributes to a more apparent and coherent thread through the manuscript, linking problem statement, aims, methods, results, discussion, and conclusion.

2. The methods are not completely described (eg how was the survey administered, how were the questions developed etc).

Thank you for this comment. We added further detail on the survey design, sampling, and distribution (page 5, lines 18-38).

3. In research about PPI, it is accepted practice to have involved the public. It looks as if the public were not involved in this paper so it is important to say why.

Thank you for this comment, which has also been raised by Reviewer #1.

We admit that there is some irony in not including any PPI in a manuscript about PPI. We hope that the manuscript does convey our good faith intentions to realise a genuine PPI approach in our research community, and that it provides some useful real-world insights into the types of difficulties we have encountered. Input and feedback from members of the public would undoubtedly be valuable; however, in this first scoping step we did not include members of the public in the study design or procedure. Our perception was that the immediate barriers we encountered in our work related to lack of awareness and understanding among researchers, and we therefore intended to scope current PPI practices among this group. For the reviewer’s information, members of the public have been involved in the design and concept of the PPIE programme and funding model in 2019. We rephrased the sentence (page 6, lines 37-39):

“Members of the public were not involved in the design and conduct of the surveys, because the immediate barriers to PPI we encountered in our work seemed to relate to awareness, knowledge, and perceptions among researchers.”

4. The UK organisation INVOLVE has been replaced - see this link:

https://www.nihr.ac.uk/news/nihr-launches-new-centre-for-engagement-and-dissemination/24576 so some of your wording may need to be updated.

Thank you for this information. We updated the wording in this passage (keeping the reference to INVOLVE, since the INVOLVE webpage remains active and appears to have been updated recently in 2021), and we added a reference to the NIHR website “Involve patients” which includes a link to NIHR Evidence (page 4, line 18).

5. You seem to use the term 'levels' in 2 different ways: 1) to describe levels of PPI from consultation to control and 2) in your abstract and elsewhere in terms of levels of organisation e.g. the individual, the organisation, the governance structures. You may need to clarify and flesh out these two different concepts and how they interact in your paper.

We appreciate this point and thank the reviewer. For clarity, we have revised the use of ‘levels’ in the manuscript, so that ‘levels’ is now only used to indicate levels of organisation; and we use the term ‘degree’ to describe the concept of ‘how much’ involvement is afforded to patients and members of the public (no involvement – consultation – collaboration – control, as outlined in the discussion and with reference to Oliver et al. 2008).

6. Proofing point: there is one use of 'und' instead of 'and'

Thank you for noticing this mistake, we corrected it.

7. In the background section, you mention the reasons for PPI but only list 2 items. I think you are missing arguments about citizens' rights

Thank you for highlighting this, and we have added this point to the opening paragraph (page 4, lines 9-10):

"…;and a political dimension, based on citizens' rights and proposed advantages of alliances between researchers, patients and the public [2]."

8. Towards the end of your paper you use the term 'co production' which has specific meaning and for many people is not interchangeable with 'involvement'. I think you need to either stick to involvement or reflect the debate around involvement and co-production in your paper.

Thank you for this comment. We are aware and appreciate the debate around involvement and co-production, and we realise that our use of "co-production" did not consider this discourse. Upon reflection, we feel that this discussion is somewhat outside the remit of our manuscript, and to avoid misinterpretation we decided to use "involvement" throughout the manuscript.

VERSION 2 – REVIEW

REVIEWER	Di Lorito, Claudio University of Nottingham, Division of Rehabilitation, Ageing and Wellbeing
REVIEW RETURNED	19-Mar-2021

GENERAL COMMENTS	Thank you for addressing the comments previously provided and for improving sensibly the quality of the manuscript. I only have the following two points that I would like to see addressed before I am happy to recommend publication of your manuscript: 1. The body of the manuscript should follow the structure of the Abstract. At the moment, it is difficult to understand in the text which section corresponds to which section of the abstract. Please use the same heading of the abstract (i.e. introduction, methods, results, discussion, conclusion) in the text; 2. I am sorry but I do not quite understand your current justification as to why you did not use PPI to design the survey: "Members of the public were not involved in the design and conduct of the surveys, because the immediate barriers to PPI we encountered in our work seemed to relate to awareness, knowledge, and perceptions among researchers." Could you please rephrase to clarify? It would be worth mentioning in the paper that "members of the public have been involved in the design and concept of the PPIE programme and funding model in 2019" as this is evidence of good practice. Looking forward to seeing these comments addressed. Good Luck.

REVIEWER	Evans, Catherine King's College London
REVIEW RETURNED	06-Apr-2021

GENERAL COMMENTS	Thank you for revising this paper following detailed comments from the three peer-reviewers. The paper is improved, but could be strengthened to convey the methods of data analysis, detail on the checklist in the discussion and greater clarity in the abstract to report the aim and the results.

	The title could be improved with correct use of prepositions for a verb– to promote and noun – for clinical. Can you state either clinical research or healthcare research? Stating both seems to duplicate Introducing Patient and Public Involvement practices for to clinical and healthcare research in Austria: strategies to promote change at multiple levels Keywords – please can you check that you are using the most appropriate MeSH terms to describe the research. For example, use MesCH term 'Surveys and Questionnaires' to indicate research methods used. Using 'Ethics' only is sufficient, 'Ethics, Medical' is a MeSH term within the 'Ethics' MeSH tree Abstract: This is clearer with the structured format. The aim stated in the main paper is very clear. Please state in the abstract we aimed to – and give detail as stated in the main paper. Background and aim – Background two sentences. We aimed to ….. Detail on response to difficulties could be removed or reduced, to increase word count to report the methods. This detail can be given in the main paper background to set the context for the work. Detail is needed in the methods about data analysis of the survey findings, and how you 'summarise five key challenges' from personal experiences. What is the relationship between the survey findings and your personal experiences? The objective is stated as to gauge the extent your personal experiences were echoed (or not) by other researchers in Austria. The abstract results need to report against this – were your experiences echoed in the survey? Or not as the surveyed researchers rarely involved PPI. The detail on the results in the main paper could be better reflected in the abstract. For example, researchers experience of PPI was limited to dissemination of research. You want to present key results in the abstract that speak to the conclusions drawn. The conclusions need to relate to the results reported. The conclusions state development of checklist for ethical committees. Which findings inform this? The main paper reporting on this is clearer – a checklist for ethical aspects of PPI. In the abstract better to state the findings inform checklist for ethical aspects of PPI. Main manuscript Methods – detail is needed on methods of data analysis. Stating for example, descriptive statistical analysis and collation of textual responses to open questions. Throughout: Please carefully proof read the manuscript to correct typos and grammatical errors. Best to avoid use of semi-colons or use minimally. Abstract results line 20 clearer to use a full stop and new sentence starting However, Throughout the manuscript please review use of semi-colon. In most instances a comma, or full stop and new sentence would be clearer.

	Research ethical committees, members of research ethical committees is correct not ethics committee, which implies belonging to. Line 36 – should state vision

REVIEWER	Barker, Jacqueline University of the West of England Bristol, Faculty of Business and Law
REVIEW RETURNED	23-Mar-2021

GENERAL COMMENTS	Congratulations on this major rewrite. Your paper is now very clear on all the points raised last time. I think there is only 1 very small revision now required: please can you briefly describe the ethical permission you received for your research (sorry if it's there and I missed it) and/or what you did about informed consent and withdrawal from the study.

VERSION 2 – AUTHOR RESPONSE

Reviewer: 1

Dr. Claudio Di Lorito, University of Nottingham

Comments to the Author:

Dear Authors

Thank you for addressing the comments previously provided and for improving sensibly the quality of the manuscript.

We thank the reviewer for the positive feedback on our revision.

I only have the following two points that I would like to see addressed before I am happy to recommend publication of your manuscript:

1. The body of the manuscript should follow the structure of the Abstract. At the moment, it is difficult to understand in the text which section corresponds to which section of the abstract. Please use the same heading of the abstract (i.e. introduction, methods, results, discussion, conclusion) in the text;

We thank the reviewer and have amended the headings in the abstract and main text, so they correspond. (We also took into account the further comments regarding the abstract by Reviewer #2.)

The headings used in both abstract and main text are now: Background, Methods, Results, Discussion, Conclusion.

2. I am sorry but I do not quite understand your current justification as to why you did not use PPI to design the survey: “Members of the public were not involved in the design and conduct of the surveys, because the immediate barriers to PPI we encountered in our work seemed to relate to awareness, knowledge, and perceptions among researchers.” Could you please rephrase to clarify?

Apologies for not being more explicit in the description of the reason why we did not use PPI in the design of the surveys. We would like to request that the text in the manuscript may remain unchanged, as we thought very carefully about this passage to provide a wording that is truthful (we did not use PPI to design the surveys) but also appropriately sensitive and diplomatic to the readership in our community.

(For the reviewer's information, we might re-iterate that in our attempts to implement PPI we encountered barriers related to awareness, knowledge, and perceptions among researchers; and one might consider a scenario in which senior medical scientists who are unfamiliar with PPI forbid researchers to engage with patients unless this has been formally approved by a research ethics committee.)

It would be worth mentioning in the paper that "members of the public have been involved in the design and concept of the PPIE programme and funding model in 2019" as this is evidence of good practice.

Amended

Looking forward to seeing these comments addressed. Good Luck.

We thank the reviewer.

Reviewer: 3

Dr. Jacqueline Barker, University of the West of England Bristol

Comments to the Author:

Congratulations on this major rewrite. Your paper is now very clear on all the points raised last time.

We thank the reviewer for the positive feedback.

I think there is only 1 very small revision now required: please can you briefly describe the ethical permission you received for your research (sorry if it's there and I missed it) and/or what you did about informed consent and withdrawal from the study.

We thank the reviewer for raising this point. We have completed the section on research ethics approval in the ScholarOne online system, indicating that "This study involves human participants but was not approved by an Ethics Committee(s) or Institutional Board(s)" and specifying the reason why formal ethics approval was not obtained:

"In Austria, online surveys which are considered low-risk are commonly conducted without formal review and approval by a research ethics committee. Our surveys were considered low-risk, due to the target group (scientists and research ethics committee representatives, who may be assumed to be familiar with processes and governance in research), and we therefore did not formally submit these survey projects for ethical review. We followed ethical research practice as outlined in the Declaration of Helsinki (i.e. voluntary participation; assurance of anonymity, data protection and confidentiality; advance information of purpose and content; provision of contact details of the research team; and full disclosure of involved organisations). This information was summarised in the survey invitation email and described in the opening pages of the online questionnaires.”

and:

“In line with common practice in online survey research, completion of the online questionnaire was understood as implied consent for participation. We followed standard practice for ethical research. The online surveys included opening pages which provided participants with the relevant information about the project (content and purpose of the questionnaires, voluntary participation, assurance of no disadvantage in case of non-participation, assurance of anonymity and data protection, dissemination plans, contact details of researchers and involved organisations). Participants' answers were registered only after the final questionnaire page had been completed. If a participant exited the questionnaire before completing the final page, the entries they had made up to that point were not stored by the online survey platform. Participants were informed that, should they wish to withdraw their data after having completed the questionnaire, they should contact us and we would do our best to accommodate this, but that this may be difficult due to the anonymised dataset.”

We have added one sentence to the Methods section: “In the design and conduct of the surveys we followed standard ethical research guidelines.” We would ask the Editor for guidance whether additional detail should be provided within the main manuscript.

Reviewer: 2

Dr. Catherine Evans, King's College London

Comments to the Author:

Thank you for revising this paper following detailed comments from the three peer-reviewers. The paper is improved, but could be strengthened to convey the methods of data analysis, detail on the checklist in the discussion and greater clarity in the abstract to report the aim and the results.

We thank the reviewer for the positive feedback on our revision and for their further suggestions to improve the manuscript.

The title could be improved with correct use of prepositions for a verb– to promote and noun – for clinical. Can you state either clinical research or healthcare research? Stating both seems to duplicate

Introducing Patient and Public Involvement practices for to clinical and healthcare research in Austria: strategies to promote change at multiple levels

We thank the reviewer and have amended the title to: “Introducing Patient and Public Involvement practices to healthcare research in Austria: strategies to promote change at multiple levels”.

Keywords – please can you check that you are using the most appropriate MeSH terms to describe the research. For example, use MesCH term ‘Surveys and Questionnaires’ to indicate research methods used. Using ‘Ethics’ only is sufficient, ‘Ethics, Medical’ is a MeSH term within the ‘Ethics’ MeSH tree

We thank the reviewer for highlighting this and agree that careful selection of keywords is important for the work to be easily discoverable and helpful to others.

We think the reviewer is referring to the 3 keywords listed on the cover page of the PDF proof ("ETHICS (see Medical Ethics), STATISTICS & RESEARCH METHODS, MEDICAL ETHICS"). These are keywords required by the ScholarOne online system, and a minimum of 3 need to be selected from a given list which is not equivalent to the MeSH catalogue. It is not possible to enter other keywords and most of these terms specify medical conditions or interventions. There is no keyword "Survey" or Questionnaires", but we have replaced "Medical Ethics" with "Qualitative Research", which could fit the aspect of qualitative (free text) responses in our survey.

Please note that in the main manuscript, we have also defined our own 6 keywords: "Citizen Science, Community Engagement, Open Innovation in Science, Participation, Patient and Public Involvement, Service User Involvement", and we have double-checked these terms against the PubMed MeSH catalogue. We have subsequently amended this list of keywords to:

- Citizen Science (MeSH term)
- Community Participation (MeSH term)
- Open Innovation in Science (not a MeSH term, but a relevant term in the context of our research community in open innovation)
- Patient and Public Involvement (not a MeSH term but relevant in the UK PPI context)
- Service User Involvement (not a MeSH term but relevant in the UK PPI context)
- Surveys and Questionnaires (MeSH term, as suggested by the reviewer)

We thank the reviewer for this prompt.

Abstract:

This is clearer with the structured format.

The aim stated in the main paper is very clear. Please state in the abstract we aimed to – and give detail as stated in the main paper. Background and aim – Background two sentences. We aimed to ….. Detail on response to difficulties could be removed or reduced, to increase word count to report the methods. This detail can be given in the main paper background to set the context for the work.

Amended

Detail is needed in the methods about data analysis of the survey findings, and how you 'summarise five key challenges' from personal experiences. What is the relationship between the survey findings and your personal experiences?

Amended

The objective is stated as to gauge the extent your personal experiences were echoed (or not) by other researchers in Austria. The abstract results need to report against this – were your experiences echoed in the survey? Or not as the surveyed researchers rarely involved PPI. The detail on the results in the main paper could be better reflected in the abstract. For example, researchers experience of PPI was limited to dissemination of research. You want to present key results in the abstract that speak to the conclusions drawn.

We have revisited the results section of the abstract to address these points:

With the revised aim/objective statement, the aspect of personal experiences echoed in the survey is now removed from the abstract.

The key findings have been re-worded, to highlight the five current key challenges.

(In the previous round of review, the point has been made that dissemination activities are not involvement, so we would prefer to avoid the wording that “PPI was limited to dissemination of research”, as this could be understood to imply that dissemination activities do constitute PPI.)

The conclusions need to relate to the results reported. The conclusions state development of checklist for ethical committees. Which findings inform this? The main paper reporting on this is clearer – a checklist for ethical aspects of PPI. In the abstract better to state the findings inform checklist for ethical aspects of PPI.

Amended

We thank the reviewer for these comments and hope that we have successfully incorporated all suggestions in the revised abstract.

Main manuscript

Methods – detail is needed on methods of data analysis. Stating for example, descriptive statistical analysis and collation of textual responses to open questions.

We have added the following passage to the Methods section:

“We conducted descriptive statistical analyses for quantitative survey data and collated textual responses to open questions. Using survey data to contextualise our personal experiences, we articulated five current challenges to implementing PPI practices in Austria.“

Throughout:

Please carefully proof read the manuscript to correct typos and grammatical errors.

We have proof-read and corrected throughout the manuscript.

Best to avoid use of semi-colons or use minimally. Abstract results line 20 clearer to use a full stop and new sentence starting However,

Amended

Throughout the manuscript please review use of semi-colon. In most instances a comma, or full stop and new sentence would be clearer.

We thank the reviewer and have reduced the use of semi-colon throughout the manuscript.

Research ethical committees, members of research ethical committees is correct not ethics committee, which implies belonging to.

Apologies, but we are unsure whether the reviewer is suggesting that we should use the wording of “research ethic*al* committee” rather than “research ethic*s* committee”?

To our knowledge the common wording is “research ethic*s* committee”, e.g., on the HRA website, in the WHO International Ethical Guidelines for Health-Related Research Involving Humans, and on the BMJ Open ScholarOne online system. We would be more than happy to follow editorial guidance.

Line 36 – should state vision

Amended

We thank all reviewers for their further helpful comments.

VERSION 3 – REVIEW

REVIEWER	Di Lorito, Claudio University of Nottingham, Division of Rehabilitation, Ageing and Wellbeing
REVIEW RETURNED	29-Jun-2021

GENERAL COMMENTS	Thank you for revising the manuscript and for addressing the remaining comments I provided. In relation to your statement as to why you did not have PPI input, I think that the explanation provided for me is much more understandable. Could you please reword into: "In our attempts to implement PPI, we encountered barriers related to awareness, knowledge, and perceptions among researchers". I would suggest adding the very illustrative example; "one might consider a scenario in which senior medical scientists who are unfamiliar with PPI forbid researchers to engage with patients unless this has been formally approved by a research ethics committee". But I would leave the decision to this last sentence to you.