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# BMJ Open

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

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**Title**

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

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**Abstract**

Patient and Public Involvement (PPI) in clinical and healthcare research is an established practice in the United Kingdom. Recent developments in Europe and North America, such as the European Patients' Academy on Therapeutic Innovation (EUPATI) and the United States Food and Drug Administration's Patient-Focused Drug Development, promote the PPI approach internationally. However, it can be challenging to introduce PPI to research communities where there is limited prior knowledge, experience, or appreciation of PPI.

We describe strategies to promote the awareness, understanding, and uptake of PPI practices among the clinical and healthcare research community in Austria. Our activities address multiple levels, including information provision and practical support to individual researchers; provision of targeted funding streams; embedding of PPI practices within research organisational structures; and building consensus on how PPI practices are regulated within national research ethics and governance processes.

Our formative surveys of researchers and representatives of research ethics committees in Austria illustrate current perceptions of PPI and challenges in its implementation in research practice, such as conflation of PPI with qualitative research approaches; difficulties in differentiating PPI activities from formal data collection; and uncertainty about the need for review and approval of PPI activities by ethics committees.

Our experiences may provide useful examples to others who seek to introduce or strengthen PPI practices within their own research communities.

## BACKGROUND

Patient and Public Involvement (PPI) in research refers to the active involvement of citizens and patients in research processes and activities, with the aim that research is carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them.[1] The rationale for PPI includes a moral/ethical dimension, based on the argument that those who are affected by a particular healthcare issue should also have a voice in related research; and a methodological dimension, with claims that PPI leads to greater relevance and credibility of research funding proposals and improved study designs, for example with respect to acceptability of study procedures to research participants.[2]

PPI has largely originated in the United Kingdom (UK), where it was introduced during the 1990s and has been supported at the highest level of national research governance: the National Institute for Health Research (NIHR), the UK's largest publicly funded health research funder, has made PPI a requirement for research grant applications;[3] NIHR-sponsored national advisory organisation INVOLVE offers support to researchers for the implementation and advancement of PPI in healthcare research;[4] and regulator Health Research Authority (HRA) publishes clear regulatory and ethical guidance on PPI for researchers.[5]

Other recent international developments are also promoting the inclusion of patients' voices in research. The United States Food and Drug Administration (FDA) Center for Drug Evaluation and Research is working on a series of guidance documents to support stakeholders (patients, researchers, medical product developers and others) in collecting and submitting patient experience data for medical product development and regulatory decision making. The first document in this series, 'Collecting Comprehensive and Representative Input', was published in 2020.[6] In Europe, a multi-stakeholder public-private partnership, the European Patients' Academy on Therapeutic Innovation (EUPATI) was established by the IMI-EUPATI project (2012-2017). This programme provides education and training to increase the capacity and capability of patients and patient representatives to understand and meaningfully contribute to medicines research and development.[7] EUPATI National Platforms mirror the EUPATI partnership at national level and are currently set up in 22 European countries, including Austria.

In Austria, the independent non-profit research organisation Ludwig Boltzmann Gesellschaft (LBG) champions PPI in clinical and healthcare research as part of its Open Innovation in Science (OIS) strategy. OIS is an umbrella term that describes the 'opening up' of the scientific process through various strategies, including citizen science, open access to scientific outputs and data, open innovation approaches from business and industry, and PPI.[8] To promote PPI, the LBG OIS Center recently published a PPI guide for researchers in Austria,[9] and two newly established Ludwig Boltzmann Institutes for Digital Health have been tasked with incorporating PPI throughout their programmes of research.[10] Initial experiences of researchers at these two institutes, however, have surfaced challenges in implementing PPI practices, including lack of awareness and knowledge about the 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 conducted without formal ethical approval.

To successfully incorporate PPI into research in Austria, it appears that awareness and knowledge of PPI should be addressed, and clear guidance on research governance and ethical requirements should be provided for the national clinical and healthcare research community. To some degree, this requires a cultural shift and consensus building within the scientific community and among

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3 relevant stakeholders, such as funders, universities, research institutes and regional and federal  
4 medical research ethics committees.  
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## 10 **SCOPING PATIENT AND PUBLIC INVOLVEMENT PRACTICES IN AUSTRIA**

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12 In summer 2020, we conducted two formative online surveys to scope current PPI practices,  
13 experiences, and ethical and operational challenges with PPI. Our first survey was distributed among  
14 post-doctoral researchers, principal investigators and OIS managers at 21 LBG-funded research  
15 institutes/groups. Nineteen scientists from 9 different institutes/groups from disciplines across  
16 natural sciences, technical sciences, humanities, social sciences, and health sciences indicated  
17 generally positive attitudes toward the involvement of patients and the public in research (figure 1).  
18 Eleven had previously conducted PPI activities, 8 had not. Respondents were generally active in  
19 disseminating research findings to patients or the public, via traditional media, social media, popular  
20 science events, and other channels. Two thirds indicated they rarely or never involved patients or  
21 members of the public in consultant roles; three quarters indicated they rarely or never involved  
22 patients or the public in the development and conduct of research studies; and almost all indicated  
23 they rarely or never involved patients or members of the public in research lead or study oversight  
24 roles. With respect to ethical aspects of conducting PPI activities (especially when individuals are  
25 invited because of their 'patient' roles), those respondents who had prior experience with PPI  
26 indicated that they tend to seek guidance from ethics committees, but not submit formal ethics  
27 applications for PPI activities.  
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34 **FIGURE 1 ABOUT HERE**

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37 Our second survey addressed representatives from 23 medical and 9 university research ethics  
38 committees in Austria. We asked whether the committee was familiar with the concept of PPI, and  
39 how the committee dealt with queries regarding PPI. Eight committees responded. Two stated that  
40 they were familiar with PPI, and 6 that they were not. The 2 committees familiar with PPI reported  
41 that they offered information to researchers about PPI practices and provided statements to support  
42 the conduct of PPI activities. Seven committees expressed interest in joining a national working  
43 group, with the aim to foster PPI through co-ordinating research governance and ethical practices.  
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### 48 **Patient and Public Involvement**

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50 No patient involved.  
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## 56 **DISCUSSION**

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58 Our formative surveys showed that respondents have differing experience with PPI, from very  
59 limited experience to actively involving citizens and patients in several phases of the research cycle  
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3 and engaging with them through dissemination of research results. In our first survey, responses  
4 outline a gradient, whereby the implementation of PPI activities decreases with increasing level of  
5 involvement – from none to consultation to collaboration to control.[11] The sharing of decision-  
6 making and control over the research with PPI contributors is particularly rare. This snapshot  
7 encourages us to further promote PPI practices on various levels. In our second survey, most  
8 representatives from research ethics committees were not familiar with the PPI concept, but  
9 interested in discussing ethical aspects of involving citizens and patients as co-researchers.  
10 Acknowledging the potential for self-selection and social desirability bias in these surveys, our  
11 findings indicate a likely need for awareness raising, resources, and guidance for researchers on  
12 implementing PPI in research projects and dealing with ethical aspects of PPI.  
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### 18 **Points for attention**

19 Based on our survey findings and from our own experiences of introducing PPI practices at our  
20 Ludwig Boltzmann Institutes for Digital Health, we observe five points, which should be addressed  
21 with priority in Austria:  
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- 24 1. While there are researchers with considerable knowledge and experience of PPI, it appears that  
25 a large segment of the research community in Austria has limited awareness and knowledge of  
26 the PPI concept, let alone the necessary skills and experience for successfully conducting PPI.  
27 This has been highlighted as one of the main stumbling blocks to coproduction of research with  
28 patients and the public.[12] It will be helpful to signpost to other international descriptors of the  
29 same principal approach, such as ‘community engagement’[13] or ‘patient-focused drug  
30 development’,[14] to convey that this is a direction of travel across the international clinical  
31 research field; and that it is important for researchers to acquire adequate knowledge and skills.  
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- 34 2. We have encountered scepticism towards the usefulness and impact of PPI. Critics may ask for  
35 convincing evidence, especially when weighing up resources required for good quality PPI  
36 against expected outcomes. It is not straightforward to answer this point, as expected impacts of  
37 PPI are multifaceted, *e.g.*, benefiting research processes and outcomes, but also bringing about  
38 positive personal outcomes for PPI contributors and researchers.[15] A growing literature  
39 demonstrates these positive outcomes of PPI, although this evidence is also limited by  
40 methodological complexities.[16] A recent meta-analysis of seven randomised controlled trials  
41 demonstrated that PPI interventions modestly but significantly increased participant enrolment  
42 (odds ratio 1.16, 95% confidence interval 1.01 to 1.34).[17] Such high-level evidence will speak  
43 to proponents of the traditional hierarchy of evidence paradigm; but the value of evidence from  
44 qualitative and mixed methods reviews in describing nuanced and multifaceted impacts of PPI  
45 should not be neglected.[16]  
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- 48 3. There can be a conflation of PPI activities with qualitative research, which has also been  
49 reported by others.[18] Particularly among quantitative researchers, PPI conversations with  
50 individuals or groups can be misunderstood as qualitative data collection. Clearly, there is a need  
51 to raise awareness and understanding of patients’ different roles, *i.e.* patients as PPI  
52 contributors *versus* patients as research participants.  
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- 55 4. We have noticed uncertainty and sometimes considerable concern among clinical researchers  
56 who are unfamiliar with PPI about ethical aspects of PPI. This is grounded in the (valid) ethical  
57 imperative that patient information for clinical research purposes must not be collected before  
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3 ethical approval has been granted; but it neglects the difference between patients' enrolment as  
4 study participants *versus* patients' involvement as PPI contributors. Especially PPI at the study  
5 conceptualisation and design stage, which takes place before a research ethics application is  
6 submitted, can create anxiety and fear of unethical conduct. Authoritative guidance at national  
7 level could best allay these concerns, by stating unequivocally that PPI activities principally do  
8 not require formal review and approval by a research ethics committee. In the UK, for example,  
9 such guidance is provided by the HRA:  
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12 *'Do I need HRA ethical approval before I work with patients and the public? No.*  
13 *You do not need to submit an application to a Research Ethics Committee in order*  
14 *to involve the public in the planning or the design stage of research, even if the*  
15 *people involved are NHS [National Health Service] patients.'*[19]  
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18 At an international level and endorsed by the World Health Organisation, the International  
19 Ethical Guidelines for Health-related Research Involving Humans (Guideline 7: Community  
20 Engagement) provide a similarly helpful resource.[13] Although this does not clarify ethical  
21 requirements for PPI as explicitly as in the above example, the same message can be inferred:  
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24 *'Researchers and research ethics committees should be cognizant of the point at*  
25 *which the process of community engagement becomes a stage of formative*  
26 *research that itself requires ethics review.'*[13, p.26]  
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- 28 5. Lastly, there is uncertainty among researchers whether information collected through PPI  
29 activities should or could be published in peer-reviewed scientific articles. This could perhaps  
30 best be addressed by distinguishing three publication scenarios: the description of PPI in the  
31 methods section of scientific articles (this has recently been encouraged by the BMJ, signalling  
32 the importance attributed to PPI by a world-leading medical journal)[12]; the publication of PPI  
33 activities as research studies 'in their own right'; and the publication of research studies *about*  
34 PPI.  
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### 39 **Organisational, individual, and structural strategies for promoting PPI**

40 Building on existing initiatives of the LBG OIS Center that support PPI practices on an organisational  
41 and individual level, we used the momentum from our surveys to introduce PPI also on a structural  
42 level – working with Austrian research ethic committees.  
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45 On an organisational level, the LBG OIS Center initiated a multi-stakeholder process in 2019, to co-  
46 develop a Patient and Public Involvement and Engagement (PPIE) 'how to' guide with researchers  
47 from various disciplines, patient organisations, and citizen scientists.[20] This laid the foundation for  
48 a national PPI funding programme based on stakeholders' needs. Building on these needs, a PPIE  
49 grant scheme was introduced in 2020 (ppie.lbg.ac.at), supporting researchers to implement PPI  
50 activities in their research with up to EUR 60.000 over 12 months. This call is embedded in  
51 continuous consultation and training on PPI, and peer support for researchers and citizens to foster  
52 mutual learning. This addresses limited awareness and knowledge (above point 1) and further  
53 familiarises researchers with participatory methods and skills necessary to deliver PPI in practice.  
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56 With these measures, the LBG OIS Center functions as a national point of contact and competence  
57 centre, aiming to embed meaningful PPI practices in the Austrian research landscape also on an  
58 individual level. Besides the scientific impact of PPI projects and dissemination of best practices on  
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3 stakeholder conferences that are co-convened with citizens, we focus on impact case studies  
4 demonstrating the positive effects of PPI on citizens and patient-driven outcomes. We hope that  
5 these reflections on the quality of public involvement processes and methods may counter  
6 scepticism and address methodological complexities of demonstrating the benefits of PPI (above  
7 point 2) .  
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10 To further promote change on a structural level, and following on from our surveys, we initiated a  
11 dialogue with Austrian research ethics committees about PPI practices in research. Seven of 32  
12 medical und university research ethics committees indicated interest in this discussion, to explore  
13 and integrate ethical aspects of PPI in their portfolio and to widen their focus also to non-clinical  
14 studies. We view this as a crucial step to inform about PPI and its ethical challenges and to align our  
15 visions and address the conflation of PPI activities with qualitative research (above point 3) by  
16 outlining differences and ethical considerations of PPI also in ethics applications. Currently, we are  
17 working together with ethics committees to develop a guide for ethical aspects of PPI that could act  
18 as best practice example and may serve as a standard procedure for Austrian ethics committees in  
19 applying PPI in research projects. It will include a checklist based on existing ethics guidelines in  
20 research [9] and on the GRIPP-2 reporting checklist [21] which provides guidance on reporting PPI as  
21 integral part in research articles (above point 5). This would assure quality standards for  
22 implementing PPI practices and give researchers the opportunity to evaluate their ethical  
23 considerations around PPI activities (above point 4). To achieve this, applicants are, *e.g.*, asked to  
24 describe the citizens' and patients' roles in the research project, distinguishing between study  
25 participation and active contribution to research tasks and linking this to possible ethical issues. As in  
26 the UK, formal ethical review and approval of PPI activities is currently not required by Austrian law  
27 if citizens or patients act as co-researchers and not as study participants. In Austria, there is only a  
28 legal obligation for an ethical review from ethics committees in the case of clinical trial of drugs or  
29 medical devices and in the application of new medical methods and applied medical research to  
30 humans. National consensus and explicit guidance on this point would further contribute to the  
31 awareness of researchers applying participatory designs and PPI in its different forms – from none to  
32 consultation to collaboration to control – and their different ethical requirements.  
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## 43 CONCLUSION

44 In conclusion, this formative initiative for scoping and mapping PPI practices in research within the  
45 LBG research community in Austria has led to a wider discussion within the organisation and  
46 dialogue with multiple stakeholders on different levels. The recurring issues we encountered in  
47 survey responses and in exchanges with research ethics committees encouraged us to focus on  
48 sensitisation of researchers by providing support and guidance on an individual and structural level.  
49 With this initiative, we aim to promote cultural change and awareness for researchers and members  
50 of research ethics committees in Austria on how to successfully implement PPI practices in research.  
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### Author Contributions

In May 2020, the authors formed a working group to exchange experiences of introducing Patient and Public Involvement at their respective organisations. RK, STK, EK, MKP, ES and ASH conceived and planned the formative surveys of Ludwig Boltzmann Institutes and research ethics committees in Austria. RK, STK, EK, MKP, ES and ASH contributed to drafting the online questionnaires. The surveys were administered by RK and analysed by RK and STK. RK, STK, EK, MKP, ES and ASH contributed to the interpretation of survey findings. RK, STK, EK, MKP, ES and ASH contributed to the conceptualisation of this article. RK, STK and ES wrote the first manuscript draft. All authors critically reviewed the manuscript for intellectual content and approved the final version.

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### Competing Interests

The authors declare no conflict of interest.

### Data Availability Statement

Data (deidentified survey data) are available upon reasonable request from the corresponding author.

## References

- 1 Hayes H, Buckland S, Tarpey M. Briefing notes for researchers: public involvement in NHS, public health and social care research. Eastleigh, England: INVOLVE 2012.
- 2 Greenhalgh T, Hinton L, Finlay T, et al. Frameworks for supporting patient and public involvement in research: Systematic review and co-design pilot. *Health Expect* 2019;22:785-801. <https://doi.org/10.1111/hex.12888> (accessed 13 November 2020).
- 3 Wilson P, Mathie E, Keenan J, et al. Research with patient and public involvement: a realist evaluation – the RAPPORT study. *Health Serv Deliv Res* 2015;3(38). <https://www.journalslibrary.nihr.ac.uk/hsdr/hsdr03380/#/abstract> (accessed 11 November 2020).
- 4 INVOLVE. [website] <https://www.invo.org.uk/> (accessed 11 November 2020).
- 5 Health Research Authority (HRA). Public involvement [website]. <https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/> (accessed 11 November 2020).
- 6 Center for Drug Evaluation and Research (CDER). Patient-focused drug development: collecting comprehensive and representative input. Guidance for industry, Food and Drug Administration staff, and other stakeholders. Silver Spring, MD: U.S. Food and Drug Administration 2020. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-focused-drug-development-collecting-comprehensive-and-representative-input> (assessed 26 November 2020).
- 7 European Patients' Academy on Therapeutic Innovation (EUPATI). EUPATI: Patient engagement through education [website] <https://eupati.eu/> (accessed 26 November 2020).
- 8 Beck S, Bergenholtz C, Bogers M, et al. The Open Innovation in Science research field: a collaborative conceptualisation approach. *Ind Innov*, 4 August 2020. <https://doi.org/10.1080/13662716.2020.1792274> (accessed 6 November 2020).
- 9 Kaisler RE, Missbach B. Patient and public involvement and engagement in research – a 'how to' guide for researchers. *Zenodo* 2020. <http://doi.org/10.5281/zenodo.3515811> (accessed 6 November 2020).
- 10 Busch J, Leimueller G, Malfent L, et al. Best Open Innovation in Science practice for the establishment of interdisciplinary & inter-sectoral collaboration platforms for the implementation of PM [abstract]. *2nd ICPeMed Workshop – 'Best Practice in Personalised Medicine' Recognition 2019, Personalised Medicine for All Citizens and Patients within Sustainable Implementation, Madrid, 5 November 2019*. <https://www.icpermed.eu/en/icpermed-recognition-2019.php>
- 11 Oliver SR, Rees RW, Clarke-Jones L, et al. A multidimensional conceptual framework for analysing public involvement in health services research. *Health Expect* 2008;11:72-84. <https://doi.org/10.1111/j.1369-7625.2007.00476.x> (accessed 20 November 2020).
- 12 Wicks P, Richards T, Denegri S, et al. Patients' roles and rights in research. *BMJ* 2018;362:k3193. <https://doi.org/10.1136/bmj.k3193> (accessed 20 November 2020).
- 13 Council for International Organizations of Medical Sciences (CIOMS). International ethical guidelines for health-related research involving humans. 4<sup>th</sup> ed. Geneva, Switzerland: CIOMS 2016.
- 14 Center for Drug Evaluation and Research (CDER). CDER patient-focused drug development [website]. Silver Spring, MD: U.S. Food and Drug Administration.

1  
2  
3 [https://www.fda.gov/drugs/development-approval-process-drugs/cder-patient-focused-drug-](https://www.fda.gov/drugs/development-approval-process-drugs/cder-patient-focused-drug-development)  
4 [development](https://www.fda.gov/drugs/development-approval-process-drugs/cder-patient-focused-drug-development) (accessed 22 November 2020).  
5

6 15 Baldwin JN, Napier S, Neville S, et al. Impacts of older people's patient and public involvement in  
7 health and social care research: a systematic review. *Age Ageing* 2018;47:801-809.  
8 <https://doi.org/10.1093/ageing/afy092> (accessed 13 November 2020).  
9

10 16 Price A, Albarqouni L, Kirkpatrick J, et al. Patient and public involvement in the design of clinical  
11 trials: an overview of systematic reviews. *J Eval Clin Pract* 2018;24:240-253.  
12 <https://doi.org/10.1111/jep.12805> (accessed 13 November 2020).  
13

14 17 Crocker JC, Ricci-Cabello I, Parker A, et al. Impact of patient and public involvement on enrolment  
15 and retention in clinical trials: systematic review and meta-analysis. *BMJ* 2018;363:k4738.  
16 <https://doi.org/10.1136/bmj.k4738> (accessed 13 November 2020).  
17

18 18 Liabo K, Boddy K, Burchmore H, et al. Clarifying the roles of patients in research. *BMJ*  
19 2018;361:k1463. <https://doi.org/10.1136/bmj.k1463> (accessed 20 November 2020).  
20

21 19 Health Research Authority (HRA). Public involvement. What do I need to do? [website].  
22 [https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/what-](https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/what-do-i-need-to-do/)  
23 [do-i-need-to-do/](https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/what-do-i-need-to-do/) (accessed 11 November 2020).  
24

25 20 Kaisler RE, Missbach B. Co-creating a patient and public involvement and engagement 'how to'  
26 guide for researchers. *Res Involv Engagem* 2020;6:32. <https://doi.org/10.1186/s40900-020-00208-3>  
27 (accessed 6 November 2020).  
28

29 21 Staniszewska S, Brett J, Simera I, et al. GRIPP2 reporting checklists: tools to improve reporting of  
30 patient and public involvement in research. *BMJ* 2017;358:j3453. <https://doi.org/10.1136/bmj.j3453>  
31 (accessed 13 November 2020).  
32  
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**Figure 1.** Attitudes towards Patient and Public Involvement (PPI) among 19 researchers from 9 different research institutes/groups of the Ludwig Boltzmann Gesellschaft. Respondents rated 7 attitudinal dimensions on 7-point semantic differential scales. Shown are frequencies.

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Patient and Public Involvement refers to the involvement of patients and citizens in research. Involvement in research means that research is conducted *with* patients and citizens, so that they are not merely study participants (study subjects).

Those involved have a say in decisions about research questions, methods, conduct and analysis, so that research outcomes are relevant for patients and citizens.

**Have you *involved* patients and citizens in your research according to this definition?**

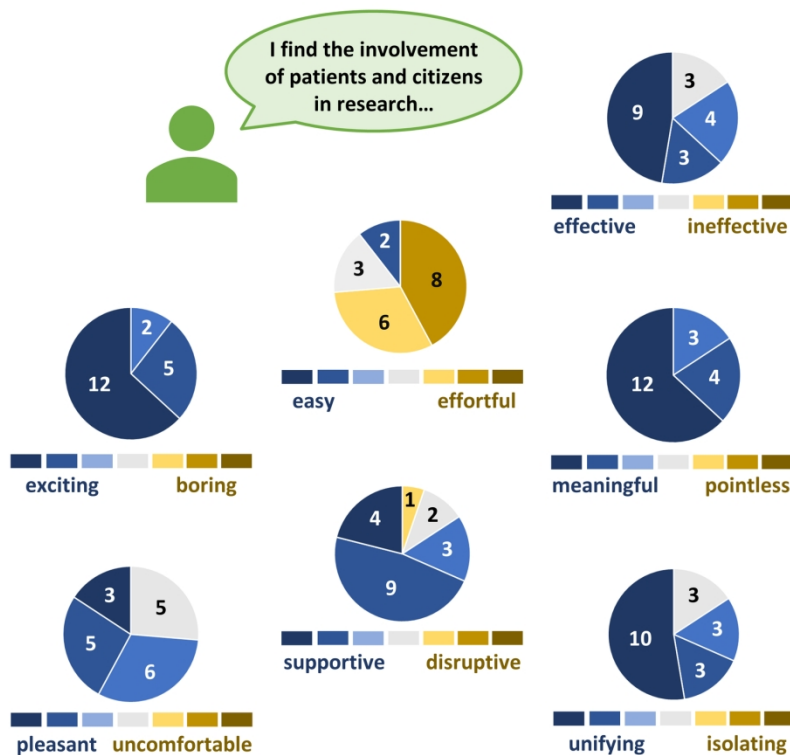


Figure 1. Attitudes towards Patient and Public Involvement (PPI) among 19 researchers from 9 different research institutes/groups of the Ludwig Boltzmann Gesellschaft. Respondents rated 7 attitudinal dimensions on 7-point semantic differential scales. Shown are frequencies.

154x205mm (300 x 300 DPI)



# BMJ Open

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

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3 **1 Title**

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5 2 Introducing Patient and Public Involvement practices to clinical and healthcare research in Austria:  
6 3 strategies for promoting change at multiple levels  
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5 Citizen Science, Community Engagement, Open Innovation in Science, Participation, Patient and  
6 Public Involvement, Service User Involvement

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3 1 **Abstract** (300 of max. 300 words)  
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7 3 **Background**  
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9 4 Patient and Public Involvement (PPI) in research is well-established in the United Kingdom. However,  
10 5 it can be challenging to introduce PPI to research communities where there is limited prior  
11 6 knowledge, experience, or appreciation of PPI.  
12

13 7 **Objective**  
14

15 8 In response to difficulties we experienced when setting up PPI activities at two new research  
16 9 institutes of the Ludwig Boltzmann Gesellschaft (LBG) in Austria, we sought to explore current PPI  
17 10 practices and challenges within our wider research community. The objectives were to gauge in how  
18 11 far our personal experiences might be reflected; and to inform strategies to strengthen PPI in Austria  
19 12 going forward.  
20

21 13 **Methods**  
22

23 14 We surveyed scientists at 21 LBG research institutes and representatives of 32 medical and  
24 15 university research ethics committees in Austria using online questionnaires; and we summarised  
25 16 five challenges around implementing PPI based on anecdotal evidence from our personal  
26 17 experience.  
27

28 18 **Results**  
29

30 19 Nineteen scientists from nine research institutes indicated generally positive attitudes towards PPI;  
31 20 however, the majority reported they rarely or never involved patients and members of the public in  
32 21 roles of consultation, collaboration, or control in research. Six of eight ethics committees were  
33 22 unfamiliar with PPI. From personal experience we have observed lack of knowledge and skills for PPI  
34 23 among scientists; scepticism about the usefulness of PPI; conflation of PPI with qualitative research;  
35 24 uncertainty about ethical requirements for PPI; and uncertainty about publishing PPI activities.  
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39 25 **Conclusions**  
40

41 26 We suggest that strategies addressing individual, institutional, and national structural levels are  
42 27 required to successfully implement PPI in the Austrian context. Building on a recently introduced PPI  
43 28 training and grant scheme offered by the LBG, our surveys have initiated a dialogue with ethics  
44 29 committees and the development of an ethics checklist for PPI. Our experiences may provide useful  
45 30 examples to others who seek to introduce or strengthen PPI practices within their own research  
46 31 communities.  
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## 1 BACKGROUND

2 Patient and Public Involvement (PPI) in research refers to the active involvement of members of the  
3 public in research processes and activities, with the aim that research is carried out 'with' or 'by'  
4 members of the public rather than 'to', 'about' or 'for' them [1]. The rationale for PPI includes a  
5 moral/ethical dimension, based on the argument that those who have lived experience of the  
6 phenomenon (e.g., a health condition) being researched should also have a voice in related  
7 research; a methodological dimension, claiming that PPI leads to greater relevance and credibility of  
8 research funding proposals and improved study designs, for example with respect to acceptability of  
9 study procedures to research participants; and a political dimension, based on citizens' rights and  
10 proposed advantages of alliances between researchers, patients and the public [2]. Typical examples  
11 for PPI activities are involvement of patients and members of the public in the setting of research  
12 priorities, as co-applicants on research grant applications, as members of study steering or advisory  
13 groups, and as co-researchers [1].

14 PPI has largely originated in the United Kingdom (UK), where it was introduced during the 1990s and  
15 has been supported at the highest level of national research governance: the National Institute for  
16 Health Research (NIHR), the UK's largest publicly funded health research funder, has made PPI a  
17 requirement for research grant applications [3]; NIHR-sponsored national advisory organisation  
18 INVOLVE [4] and other centres and support networks [5] offer expertise to researchers for the  
19 implementation and advancement of PPI in healthcare research; and regulator Health Research  
20 Authority (HRA) publishes clear regulatory and ethical guidance on PPI for researchers [6].

21 Other recent international developments are also promoting the inclusion of patients' voices in  
22 research. The United States Food and Drug Administration (FDA) Center for Drug Evaluation and  
23 Research is working on a series of guidance documents to support stakeholders (patients,  
24 researchers, medical product developers and others) in collecting and submitting patient experience  
25 data for medical product development and regulatory decision making. The first document in this  
26 series, 'Collecting Comprehensive and Representative Input', was published in 2020 [7]. In Europe, a  
27 multi-stakeholder public-private partnership, the European Patients' Academy on Therapeutic  
28 Innovation (EUPATI) was established by the IMI-EUPATI project (2012-2017). This programme  
29 provides education and training to increase the capacity and capability of patients and patient  
30 representatives to understand and meaningfully contribute to medicines research and development  
31 [8]. EUPATI National Platforms mirror the EUPATI partnership at national level and are currently set  
32 up in 22 European countries, including Austria.

### 33 Promoting PPI in Austria

34 In Austria, the independent non-profit research organisation Ludwig Boltzmann Gesellschaft (LBG)  
35 champions PPI in clinical and healthcare research as part of its Open Innovation in Science (OIS)  
36 strategy. OIS is an umbrella term that describes the 'opening up' of the scientific process through  
37 various strategies, including citizen science, open access to scientific outputs and data, open  
38 innovation approaches from business and industry, and PPI [9]. To promote PPI, the LBG OIS Center  
39 initiated a multi-stakeholder process in 2019, co-developing a Patient and Public Involvement and  
40 Engagement (PPIE) 'how to' guide with researchers from various disciplines, patient organisations,  
41 and citizen scientists [10, 11]. This laid the foundation for a national PPI funding programme  
42 introduced in 2020 (ppie.lbg.ac.at), which supports researchers to implement PPI activities with up  
43 to EUR 60,000 over 12 months. The call is embedded in continuous consultation and training on PPI,  
44 and peer support for researchers and members of the public to foster mutual learning. With these  
45 measures, the LBG OIS Center functions as a national point of contact and competence centre,

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2  
3 1 aiming to embed meaningful PPI practices in the Austrian research landscape and offering support to  
4 2 researchers on an individual level.  
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6 3 In another OIS initiative, the LBG established two new Ludwig Boltzmann Institutes for Digital Health  
7 4 which commenced work in 2019 and which were tasked with incorporating PPI throughout their  
8 5 programmes of research [12]. Initial experiences made by researchers at these two institutes (STK,  
9 6 EK, MKP, ES and ASH among others), however, have surfaced challenges in implementing PPI  
10 7 practices, including lack of awareness and knowledge about the PPI concept in the local scientific  
11 8 communities; lack of appreciation of the value of involving patients as 'experts by experience'; and  
12 9 fear of violating research ethics if PPI activities are carried out without formal ethical approval. We  
13 10 therefore undertook a scoping exercise and conducted surveys among researchers and research  
14 11 ethics committees in Austria. The aim was to explore current PPI practices, experiences, and ethical  
15 12 and operational challenges with PPI, to gauge in how far our personal experiences might be reflected  
16 13 within our wider research community; and to draw insights which may inform strategies for  
17 14 supporting PPI in research in Austria going forward.  
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## 23 16 **SCOPING PATIENT AND PUBLIC INVOLVEMENT PRACTICES IN AUSTRIA**

### 24 17 **Online surveys**

25 18 In summer 2020, we conducted two online surveys to scope current PPI practices, experiences, and  
26 19 ethical and operational challenges with PPI. Survey invitations were distributed by email and  
27 20 contained the access link, researcher contact details, and information about the study purpose and  
28 21 publication of anonymised data. The surveys were open for three weeks, and reminders were  
29 22 emailed twice.  
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34 23 The first survey was distributed among post-doctoral researchers, principal investigators and OIS  
35 24 managers at 21 LBG-funded research institutes and groups. The questionnaire consisted of 10 items  
36 25 which were structured according to three aspects (three roles a patient or member of the public  
37 26 may take on in relation to research): participation (i.e., entering a study as a study 'subject'),  
38 27 engagement/dissemination (i.e., engaging with information about research activities and findings),  
39 28 and involvement (i.e., making an active contribution to research processes and activities) [1, 9]. We  
40 29 formulated questions with Likert-scale response options to explore how frequently respondents  
41 30 undertook certain activities such as involving patients and members of the public in the  
42 31 conceptualisation of research proposals. Additionally, we formulated semantic differential scale  
43 32 items to gauge respondents' attitudes towards PPI, a multiple-choice item about ethical aspects, and  
44 33 two open questions about ethical aspects and general challenges around PPI.  
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48 34 The second survey addressed representatives (primary contact persons) from 23 medical and nine  
49 35 university research ethics committees in Austria. This was a short questionnaire consisting of three  
50 36 multiple-choice items with optional free text answers. We asked whether the committee was  
51 37 familiar with the concept of PPI, how the committee dealt with queries regarding PPI, and whether  
52 38 the committee was interested in joining a national PPI working group.  
53

54 39 In our first survey, 19 scientists from nine different institutes/groups from disciplines across natural  
55 40 sciences, technical sciences, humanities, social sciences, and health sciences indicated generally  
56 41 positive attitudes toward the involvement of patients and the public in research (figure 1). Eleven  
57 42 had previously conducted PPI activities, and eight had not (self-report). Respondents were generally  
58 43 active in disseminating research findings to patients or the public, via traditional media, social  
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3 1 media, popular science events, and other channels, which represents engagement/dissemination  
4 and not involvement. Two thirds indicated they rarely or never involved patients or members of the  
5 public in consultant roles; three quarters indicated they rarely or never involved patients or the  
6 public in the development and conduct of research studies; and almost all indicated they rarely or  
7 never involved patients or members of the public in research lead or study oversight roles. With  
8 respect to ethical aspects of PPI (especially when individuals are invited because of their 'patient'  
9 roles), those respondents who had prior experience with PPI indicated that they tend to seek  
10 guidance from ethics committees, but not submit formal ethics applications for PPI activities.  
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13  
14 9 In our second survey, eight of 32 committees responded. Two stated that they were familiar with  
15 PPI, and six that they were not. The two committees familiar with PPI reported that they offered  
16 information to researchers about PPI practices and provided statements in support of PPI activities.  
17 Seven committees expressed interest in joining a national working group, with the aim to foster PPI  
18 through co-ordinating research governance and ethical practices (figure 2).  
19

#### 20 14 **Points for attention**

21  
22 15 Our survey findings bring into focus, and to some extent corroborate, the anecdotal evidence from  
23 our personal experience of introducing PPI practices at our Ludwig Boltzmann Institutes for Digital  
24 Health. Based on this, we observe five challenges or 'points for attention':  
25

- 26 18 1. While some researchers have considerable knowledge and experience of PPI, it appears that a  
27 large segment of the research community in Austria has limited awareness and knowledge of  
28 the PPI concept, let alone the necessary skills and experience for successfully conducting PPI.
- 29 20 2. We have encountered scepticism towards the usefulness and impact of PPI among LBG  
30 researchers and Austrian ethics committees. Critics may ask for convincing evidence, especially  
31 when weighing up resources required for good quality PPI against expected outcomes.
- 32 22 3. There can be a conflation of PPI activities with qualitative research. Particularly among  
33 quantitative researchers, PPI conversations with individuals or groups can be misunderstood as  
34 qualitative data collection.
- 35 25 4. We have noticed uncertainty and sometimes considerable concern among clinical researchers  
36 who are unfamiliar with PPI about ethical aspects of PPI. This is grounded in the (valid) ethical  
37 imperative that patient information for clinical research purposes must not be collected before  
38 ethical approval has been granted; but it neglects the difference between patients' enrolment as  
39 study participants *versus* patients' involvement as PPI contributors. Especially PPI at the study  
40 conceptualisation and design stage, which takes place before a research ethics application is  
41 submitted, can create anxiety and fear of unethical conduct.
- 42 31 5. Lastly, there is uncertainty among researchers whether information collected through PPI  
43 activities should or could be published in peer-reviewed scientific articles.

#### 44 36 **Patient and Public Involvement**

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46 37 Members of the public were not involved in the design and conduct of the surveys, because the  
47 immediate barriers to PPI we encountered in our work seemed to relate to awareness, knowledge,  
48 and perceptions among researchers.  
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#### 50 40 51 41 **DISCUSSION**

52 42 Our online surveys showed that respondents have differing experience with PPI, from very limited  
53 experience to actively and competently involving members of the public in several phases of the  
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1 research cycle. In our first survey, responses outline a trend, whereby the implementation of PPI  
2 activities decreases with increasing degree of involvement (from no involvement to consultation to  
3 collaboration to control, [13]). The sharing of decision-making and control over the research is  
4 particularly rare. This snapshot encourages us to further promote PPI on individual level by offering  
5 training and facilitating exchange among researchers; and to introduce support structures on  
6 institutional and national level. In our second survey, most representatives from research ethics  
7 committees were unfamiliar with the PPI concept, but interested in discussing its ethical aspects.  
8 Acknowledging the potential for self-selection and social desirability bias in these surveys and  
9 limitations due to a low response rate from research ethics committees, our findings nevertheless  
10 indicate that awareness and knowledge of PPI should be addressed, and clear guidance on research  
11 governance and ethical requirements should be provided for the Austrian clinical and healthcare  
12 research community. To some extent, this requires a cultural shift and consensus building within the  
13 scientific community and among relevant stakeholders, such as funders, universities, research  
14 institutes and regional and federal medical research ethics committees.

### 15 **Addressing points for attention**

16 With respect to addressing the five challenges we formulate above, we offer the following  
17 considerations:

- 18 1. Researchers' limited awareness, knowledge and skills for PPI have been highlighted as main  
19 stumbling blocks in the active involvement of members of the public in research [14].  
20 Signposting researchers to international scientific communities in which PPI is an established and  
21 valued practice (also considering other descriptors which are used internationally to describe an  
22 approach that is similar to PPI in spirit, such as 'community engagement' [15] or 'patient-focused  
23 drug development'[16]) could stress the importance of PPI and increase motivation for  
24 researchers to acquire adequate knowledge and skills for PPI.
- 25 2. Demands for evidence of the usefulness of PPI are not straightforward to answer, as expected  
26 impacts of PPI are multifaceted, e.g., benefiting research processes and outcomes, but also  
27 bringing about positive personal outcomes for PPI contributors and researchers [17]. A growing  
28 literature demonstrates these positive outcomes of PPI, although this evidence is also limited by  
29 methodological complexities [18]. A recent meta-analysis of seven randomised controlled trials  
30 demonstrated that PPI interventions modestly but significantly increased participant enrolment  
31 (odds ratio 1.16, 95% confidence interval 1.01 to 1.34; [19]). Such high-level evidence will speak  
32 to proponents of the traditional hierarchy of evidence paradigm; however, the value of evidence  
33 from qualitative and mixed methods reviews in describing nuanced and multifaceted impacts of  
34 PPI should not be neglected [18] and should be considered for future research. PPI grant  
35 schemes should require that proposals incorporate processes for evaluating the impact of PPI.
- 36 3. The conflation of PPI activities with qualitative research has also been reported by others  
37 [20]. There is a need to raise awareness and understanding of patients' different roles, i.e.,  
38 patients as PPI contributors *versus* patients as research participants. Research institutions and  
39 ethic committees should provide guidance and training to support researchers in recognising  
40 these differences and in implementing PPI activities appropriately. Moreover, power  
41 differentials between researchers and PPI contributors need to be addressed [21], e.g., by  
42 providing PPI contributors with (monetary or other) compensation for their time and adequate  
43 training opportunities.

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3 1 4. Authoritative guidance at national level to address ethical concerns about PPI among clinical  
4 2 researchers is needed. This should state unequivocally that PPI activities principally do not  
5 3 require formal review and approval by a research ethics committee, including PPI at the  
6 4 conceptualisation and design stage of a research proposal. In the UK, for example, such guidance  
7 5 is provided by the HRA:

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10 6 *'Do I need HRA ethical approval before I work with patients and the public? No.*  
11 7 *You do not need to submit an application to a Research Ethics Committee in order*  
12 8 *to involve the public in the planning or the design stage of research, even if the*  
13 9 *people involved are NHS [National Health Service] patients' [22].*

14  
15 10 At an international level and endorsed by the World Health Organisation, the International  
16 11 Ethical Guidelines for Health-related Research Involving Humans (Guideline 7: Community  
17 12 Engagement) provide a similarly helpful resource [15]. Although this does not clarify ethical  
18 13 requirements for PPI as explicitly as in the above example, the same message can be inferred:

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21 14 *'Researchers and research ethics committees should be cognizant of the point at*  
22 15 *which the process of community engagement becomes a stage of formative*  
23 16 *research that itself requires ethics review' [15, p.26].*

- 24  
25 17 5. Uncertainty about publishing PPI in peer-review articles could be addressed by distinguishing  
26 18 three publication scenarios: the description of PPI in the methods section of scientific articles  
27 19 (this has recently been encouraged by the BMJ, signalling the importance attributed to PPI by a  
28 20 world-leading medical journal, [14]); the publication of PPI activities as research studies 'in their  
29 21 own right'; and the publication of research studies *about* PPI.

### 22 23 **Further developments**

24  
25 24 Following on from our survey findings, we identified the need for guidance about ethical  
26 25 requirements of PPI as a priority. As in the UK, formal ethical approval of PPI activities is currently  
27 26 not required by Austrian law if members of the public act as PPI contributors and not as study  
28 27 participants. In Austria, there is only a legal obligation for review by ethics committees in the case of  
29 28 clinical trial of drugs or medical devices and in the application of new medical methods and applied  
30 29 medical research to humans. National consensus and explicit guidance on this point would further  
31 30 awareness of researchers applying participatory research designs and PPI in its different forms –  
32 31 from consultation to collaboration to control – and their different ethical requirements.

32  
33 32 To initiate this national consensus and promote change on a structural level, we invited a dialogue  
34 33 with Austrian research ethics committees about PPI. To date, five committees have joined an  
35 34 informal working group coordinated by the LBG OIS Center and have supported the development of  
36 35 a checklist for ethical aspects of PPI [23]. We view this as a crucial step to inform about PPI and its  
37 36 ethical challenges, to align our visions, and to address the conflation of PPI with qualitative research  
38 37 by outlining differences and ethical considerations around PPI also in ethics applications. The  
39 38 checklist is based on existing ethics guidelines in research [10] and on the GRIPP-2 statement for  
40 39 reporting PPI in research publications [24]. The checklist could serve as best practice example and  
41 40 standard operating procedure for Austrian ethics committees in dealing with PPI. Applying the  
42 41 checklist to their own work, applicants may be asked to, e.g., describe the role of patients and  
43 42 members of the public in their project, distinguish between study participation and involvement and  
44 43 highlighting possible ethical issues. This could support quality assurance and implementation of

1 standards for PPI and give researchers an opportunity to self-evaluate their ethical considerations  
2 around PPI.

## 3 4 5 6 7 8 **CONCLUSION**

9  
10 This initiative for scoping PPI practices within the LBG research community in Austria has led to a  
11 wider discussion in the organisation and dialogue with stakeholders, including research ethics  
12 committees. With our recently published checklist we have made progress towards providing ethical  
13 guidance for PPI in the Austrian research context; but we suggest that addressing consensus on  
14 governance and ethics of PPI in research remains a top strategic priority at a national structural  
15 level. Further strategic priorities are the ongoing provision of support at individual and  
16 institutional/organisational levels through PPI training opportunities and grant schemes, to raise  
17 awareness and foster researchers' knowledge and skills; and the building of the evidence base for  
18 PPI in the Austrian context through impact evaluations and formal research about PPI. It will be  
19 opportune and important to increase the involvement of patients and members of the public in the  
20 decision-making and delivery of these strategic measures. We envisage that the LBG OIS Center will  
21 continue to lead this work in collaboration with researchers, ethics committees, patients and  
22 members of the public, with the aim to achieve authentic and beneficial implementation of PPI in  
23 the Austrian research community.  
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## 33 **Authors' Contributions**

34  
35 In May 2020, the authors formed a working group to exchange experiences of introducing Patient  
36 and Public Involvement at their respective organisations. RK, STK, EK, MKP, ES and ASH conceived  
37 and planned the formative surveys of Ludwig Boltzmann Institutes and research ethics committees  
38 in Austria. RK, STK, EK, MKP, ES and ASH contributed to drafting the online questionnaires. The  
39 surveys were administered by RK and analysed by RK and STK. RK, STK, EK, MKP, ES and ASH  
40 contributed to the interpretation of survey findings. RK, STK, EK, MKP, ES and ASH contributed to the  
41 conceptualisation of this article. RK, STK and ES wrote the first manuscript draft. All authors critically  
42 reviewed the manuscript for intellectual content, approved the final version, and agreed to be  
43 accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity  
44 of any part of the work are appropriately investigated and resolved.  
45  
46  
47

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50 for-profit sectors.  
51

## 52 **Competing Interests**

53 The authors declare no conflict of interest.  
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- 1 Hayes H, Buckland S, Tarpey M. Briefing notes for researchers: public involvement in NHS, public health and social care research. Eastleigh, England: INVOLVE 2012.
- 2 Greenhalgh T, Hinton L, Finlay T, et al. Frameworks for supporting patient and public involvement in research: Systematic review and co-design pilot. *Health Expect* 2019;22:785-801. <https://doi.org/10.1111/hex.12888> (accessed 13 November 2020).
- 3 Wilson P, Mathie E, Keenan J, et al. Research with patient and public involvement: a realist evaluation – the RAPPORT study. *Health Serv Deliv Res* 2015;3(38). <https://www.journalslibrary.nihr.ac.uk/hsdr/hsdr03380/#/abstract> (accessed 11 November 2020).
- 4 INVOLVE. [website] <https://www.invo.org.uk/> (accessed 01 March 2021)
- 5 National Institute of Health Research. Involve patients [website]. <https://www.nihr.ac.uk/health-and-care-professionals/engagement-and-participation-in-research/involve-patients.htm> (accessed 24 February 2021).
- 6 Health Research Authority (HRA). Public involvement [website]. <https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/> (accessed 11 November 2020).
- 7 Center for Drug Evaluation and Research (CDER). Patient-focused drug development: collecting comprehensive and representative input. Guidance for industry, Food and Drug Administration staff, and other stakeholders. Silver Spring, MD: U.S. Food and Drug Administration 2020. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-focused-drug-development-collecting-comprehensive-and-representative-input> (accessed 26 November 2020).
- 8 European Patients' Academy on Therapeutic Innovation (EUPATI). EUPATI: Patient engagement through education [website] <https://eupati.eu/> (accessed 26 November 2020).
- 9 Beck S, Bergenholtz C, Bogers M, et al. The Open Innovation in Science research field: a collaborative conceptualisation approach. *Ind Innov*, 4 August 2020. <https://doi.org/10.1080/13662716.2020.1792274> (accessed 6 November 2020).
- 10 Kaisler RE, Missbach B. Patient and public involvement and engagement in research – a 'how to' guide for researchers. *Zenodo* 2020. <http://doi.org/10.5281/zenodo.3515811> (accessed 6 November 2020).
- 11 Kaisler RE, Missbach B. Co-creating a patient and public involvement and engagement 'how to' guide for researchers. *Res Involv Engagem* 2020;6:32. <https://doi.org/10.1186/s40900-020-00208-3> (accessed 6 November 2020).
- 12 Busch J, Leimueller G, Malfent L, et al. Best Open Innovation in Science practice for the establishment of interdisciplinary & inter-sectoral collaboration platforms for the implementation of PM [abstract]. *2nd ICPeMed Workshop – 'Best Practice in Personalised Medicine' Recognition 2019, Personalised Medicine for All Citizens and Patients within Sustainable Implementation, Madrid, 5 November 2019*. <https://www.icpermed.eu/en/icpermed-recognition-2019.php>
- 13 Oliver SR, Rees RW, Clarke-Jones L, et al. A multidimensional conceptual framework for analysing public involvement in health services research. *Health Expect* 2008;11:72-84. <https://doi.org/10.1111/j.1369-7625.2007.00476.x> (accessed 20 November 2020).

- 1  
2  
3 1 14 Wicks P, Richards T, Denegri S, et al. Patients' roles and rights in research. *BMJ* 2018;362:k3193.  
4 2 <https://doi.org/10.1136/bmj.k3193> (accessed 20 November 2020).  
5  
6 3 15 Council for International Organizations of Medical Sciences (CIOMS). International ethical  
7 4 guidelines for health-related research involving humans. 4<sup>th</sup> ed. Geneva, Switzerland: CIOMS 2016.  
8  
9 5 16 Center for Drug Evaluation and Research (CDER). CDER patient-focused drug development  
10 6 [website]. Silver Spring, MD: U.S. Food and Drug Administration.  
11 7 [https://www.fda.gov/drugs/development-approval-process-drugs/cder-patient-focused-drug-](https://www.fda.gov/drugs/development-approval-process-drugs/cder-patient-focused-drug-development)  
12 8 [development](https://www.fda.gov/drugs/development-approval-process-drugs/cder-patient-focused-drug-development) (accessed 22 November 2020).  
13  
14 9 17 Baldwin JN, Napier S, Neville S, et al. Impacts of older people's patient and public involvement in  
15 10 health and social care research: a systematic review. *Age Ageing* 2018;47:801-809.  
16 11 <https://doi.org/10.1093/ageing/afy092> (accessed 13 November 2020).  
17  
18 12 18 Price A, Albarqouni L, Kirkpatrick J, et al. Patient and public involvement in the design of clinical  
19 13 trials: an overview of systematic reviews. *J Eval Clin Pract* 2018;24:240-253.  
20 14 <https://doi.org/10.1111/jep.12805> (accessed 13 November 2020).  
21  
22 15 19 Crocker JC, Ricci-Cabello I, Parker A, et al. Impact of patient and public involvement on enrolment  
23 16 and retention in clinical trials: systematic review and meta-analysis. *BMJ* 2018;363:k4738.  
24 17 <https://doi.org/10.1136/bmj.k4738> (accessed 13 November 2020).  
25  
26 18 20 Liabo K, Boddy K, Burchmore H, et al. Clarifying the roles of patients in research. *BMJ*  
27 19 2018;361:k1463. <https://doi.org/10.1136/bmj.k1463> (accessed 20 November 2020).  
28  
29 20 21 Di Lorito C, Godfrey M, Dunlop M, et al. Adding to the knowledge on Patient and Public  
30 21 Involvement: reflections from an experience of co-research with carers of people with dementia.  
31 22 *Health Expect* 2020;23:691-706. <https://doi.org/10.1111/hex.13049> (accessed 24 February 2021).  
32  
33 23 22 Health Research Authority (HRA). Public involvement. What do I need to do? [website].  
34 24 [https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/what-](https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/what-do-i-need-to-do/)  
35 25 [do-i-need-to-do/](https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/what-do-i-need-to-do/) (accessed 11 November 2020).  
36  
37 26 23 Kaisler RE. Checkliste für Forschungsvorhaben mit Bürger\*innen-Einbindung [Checklist for  
38 27 research projects with patient and public involvement activities]. *Zenodo* 2021.  
39 28 <https://zenodo.org/record/4573970> (accessed 4 March 2021).  
40  
41 29 24 Staniszewska S, Brett J, Simera I, et al. GRIPP2 reporting checklists: tools to improve reporting of  
42 30 patient and public involvement in research. *BMJ* 2017;358:j3453. <https://doi.org/10.1136/bmj.j3453>  
43 31 (accessed 13 November 2020).  
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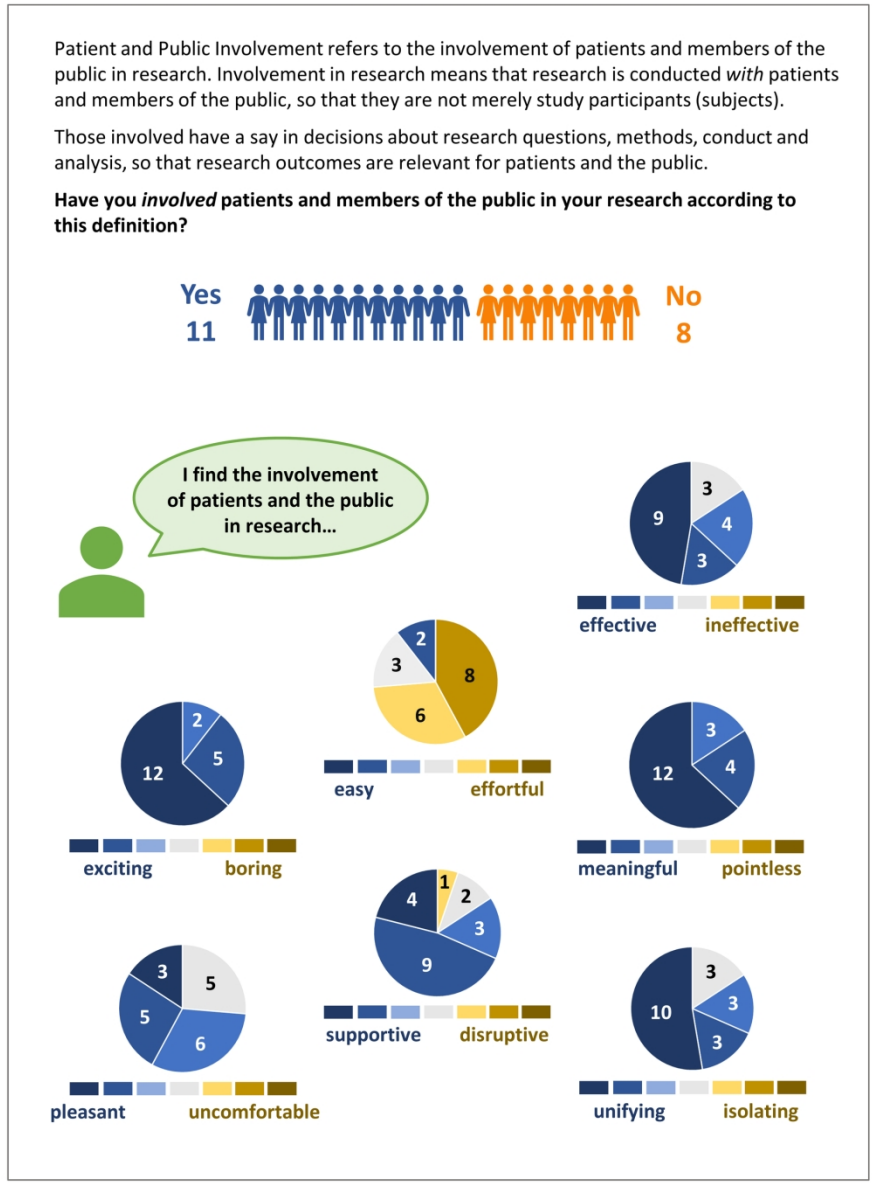
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1 **Figure 1.** Attitudes towards Patient and Public Involvement (PPI) among 19 researchers from nine  
2 different institutes/groups of the Ludwig Boltzmann Gesellschaft. Respondents rated seven  
3 attitudinal dimensions on 7-point semantic differential scales. Pie charts describe frequencies of  
4 ratings.

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6 **Figure 2.** Responses (frequencies) from representatives of eight research ethics committees in  
7 Austria.

8

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45 Figure 1. Attitudes towards Patient and Public Involvement (PPI) among 19 researchers from nine different  
46 institutes/groups of the Ludwig Boltzmann Gesellschaft. Respondents rated seven attitudinal dimensions on  
47 7-point semantic differential scales. Pie charts describe frequencies of ratings.

48 161x218mm (300 x 300 DPI)



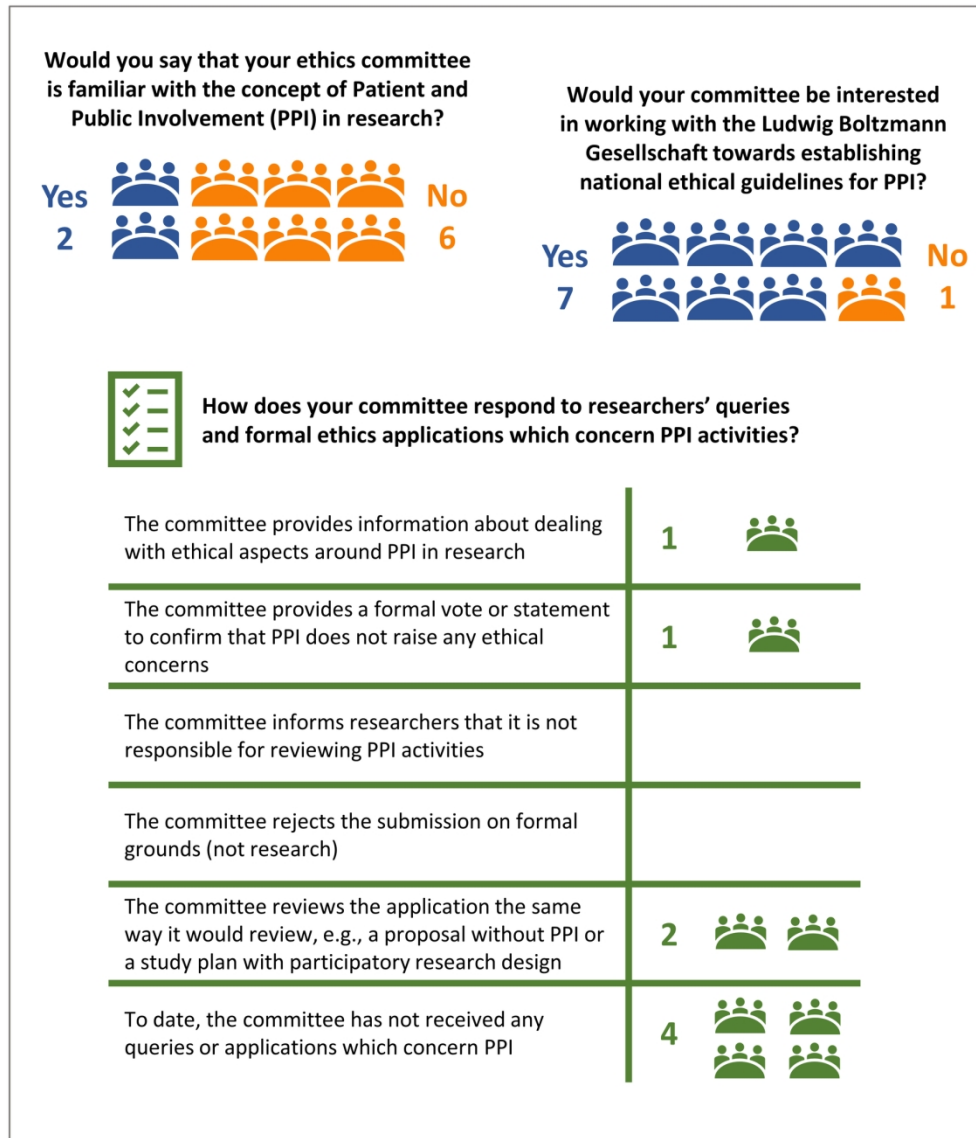


Figure 2. Responses (frequencies) from representatives of eight research ethics committees in Austria.

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# BMJ Open

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

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3 1 **Title**  
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5 2 Introducing Patient and Public Involvement practices to healthcare research in Austria: strategies to  
6 3 promote change at multiple levels  
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6 Involvement, Service User Involvement, Surveys and Questionnaires

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3 1 **Abstract** (300 of max. 300 words)  
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7 3 **Background**

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9 4 Patient and Public Involvement (PPI) in research is well-established in the United Kingdom. However,  
10 5 it can be challenging to introduce PPI to research communities where there is limited prior  
11 6 knowledge, experience, or appreciation of PPI. We aimed to explore current PPI practices,  
12 7 experiences, and ethical and operational challenges with PPI within our own research community in  
13 8 Austria, to inform strategies for supporting PPI in Austria going forward.

14  
15 9 **Methods**

16  
17 10 We surveyed scientists at 21 research institutes of the Ludwig Boltzmann Gesellschaft (LBG) and  
18 11 representatives of 32 medical and university research ethics committees in Austria using online  
19 12 questionnaires. We analysed quantitative data using descriptive statistics, and we collated textual  
20 13 responses to open questions. We combined survey data with anecdotal evidence from our personal  
21 14 experience to summarise current challenges around implementing PPI in Austria.

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23  
24 15 **Results**

25  
26 16 Nineteen scientists from nine research institutes indicated generally positive attitudes towards PPI.  
27 17 However, the majority reported they rarely or never involved patients and members of the public in  
28 18 roles of consultation, collaboration, or control in research. Six of eight ethics committees were  
29 19 unfamiliar with PPI. We discern five current challenges to implementing PPI in Austria: lack of  
30 20 knowledge and skills for PPI among scientists, scepticism about the usefulness of PPI, conflation of  
31 21 PPI with qualitative research, uncertainty about ethical requirements for PPI, and uncertainty about  
32 22 publishing PPI activities.

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35 23 **Discussion**

36  
37 24 We suggest that the provision of guidance about ethical requirements of PPI is a strategic priority. To  
38 25 address this, and following on from a recently introduced PPI training and grant scheme by the LBG,  
39 26 our surveys have initiated a dialogue with ethics committees and have informed the development of  
40 27 a checklist for ethical aspects of PPI.

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42 28 **Conclusion**

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44 29 Our experiences may provide useful examples to others who seek to introduce or strengthen PPI  
45 30 practices within their own research communities.  
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## 1 BACKGROUND

2 Patient and Public Involvement (PPI) in research refers to the active involvement of members of the  
3 public in research processes and activities, with the aim that research is carried out 'with' or 'by'  
4 members of the public rather than 'to', 'about', or 'for' them [1]. The rationale for PPI includes a  
5 moral/ethical dimension, based on the argument that those who have lived experience of the  
6 phenomenon being researched (e.g., a health condition) should also have a voice in related  
7 research; a methodological dimension, claiming that PPI leads to greater relevance and credibility of  
8 research funding proposals and improved study designs, for example with respect to acceptability of  
9 study procedures to research participants; and a political dimension, based on citizens' rights and  
10 proposed advantages of alliances between researchers, patients, and the public [2]. Typical  
11 examples for PPI activities are involvement of patients and members of the public in the setting of  
12 research priorities, as co-applicants on research grant applications, as members of study steering or  
13 advisory groups, and as co-researchers [1].

14 PPI has largely originated in the United Kingdom (UK), where it was introduced during the 1990s and  
15 has been supported at the highest level of national research governance. The National Institute for  
16 Health Research (NIHR), the UK's largest publicly funded health research funder, has made PPI a  
17 requirement for research grant applications [3]. NIHR-sponsored national advisory organisation  
18 INVOLVE [4] and other centres and support networks [5] offer expertise to researchers for the  
19 implementation and advancement of PPI in healthcare research, and regulator Health Research  
20 Authority (HRA) publishes clear regulatory and ethical guidance on PPI for researchers [6].

21 Other recent international developments are also promoting the inclusion of patients' voices in  
22 research. The United States Food and Drug Administration (FDA) Center for Drug Evaluation and  
23 Research is working on a series of guidance documents to support stakeholders (patients,  
24 researchers, medical product developers, and others) in collecting and submitting patient experience  
25 data for medical product development and regulatory decision making. The first document in this  
26 series, 'Collecting Comprehensive and Representative Input', was published in 2020 [7]. In Europe, a  
27 multi-stakeholder public-private partnership, the European Patients' Academy on Therapeutic  
28 Innovation (EUPATI), was established by the IMI-EUPATI project (2012-2017). This programme  
29 provides education and training to increase the capacity and capability of patients and patient  
30 representatives to understand and meaningfully contribute to medicines research and development  
31 [8]. EUPATI National Platforms mirror the EUPATI partnership at national level and are currently set  
32 up in 22 European countries, including Austria.

### 33 Promoting PPI in Austria

34 In Austria, the independent non-profit research organisation Ludwig Boltzmann Gesellschaft (LBG)  
35 champions PPI in clinical and healthcare research as part of its Open Innovation in Science (OIS)  
36 strategy. OIS is an umbrella term that describes the 'opening up' of the scientific process through  
37 various strategies, including citizen science, open access to scientific outputs and data, open  
38 innovation approaches from business and industry, and PPI [9]. To promote PPI, the LBG OIS Center  
39 initiated a multi-stakeholder process in 2019, co-developing a Patient and Public Involvement and  
40 Engagement (PPIE) 'how to' guide with researchers from various disciplines, patient organisations,  
41 and citizen scientists [10, 11]. This laid the foundation for a national PPI funding programme  
42 introduced in 2020 (ppie.lbg.ac.at) which supports researchers to implement PPI activities with up to  
43 EUR 60,000 over 12 months. The call is embedded in continuous consultation and training on PPI,  
44 and peer support for researchers and members of the public to foster mutual learning. With these  
45 measures, the LBG OIS Center functions as a national point of contact and competence centre,

1  
2  
3 1 aiming to embed meaningful PPI practices in the Austrian research landscape and offering support to  
4 2 researchers on an individual level.  
5

6 3 In another OIS initiative, the LBG established two new Ludwig Boltzmann Institutes for Digital Health  
7 4 which commenced work in 2019. Both institutes were tasked with incorporating PPI throughout  
8 5 their programmes of research [12]. Initial experiences made by researchers at these two institutes  
9 6 (STK, EK, MKP, ES, and ASH among others), however, have surfaced challenges in implementing PPI  
10 7 practices, including lack of awareness and knowledge about the PPI concept in the local scientific  
11 8 communities, lack of appreciation of the value of involving patients as ‘experts by experience’, and  
12 9 fear of violating research ethics if PPI activities are carried out without formal ethical approval. We  
13 10 therefore undertook a scoping exercise and conducted surveys among researchers and  
14 11 representatives of research ethics committees in Austria. The aim was to explore current PPI  
15 12 practices, experiences, and ethical and operational challenges with PPI, to gauge in how far our  
16 13 personal experiences might be reflected within our wider research community, and to draw insights  
17 14 which may inform strategies for supporting PPI in research in Austria going forward.  
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## 23 16 **METHODS**

### 24 17 **Study design**

25 18 In summer 2020, we conducted two online surveys to scope current PPI practices, experiences, and  
26 19 ethical and operational challenges with PPI. In the design and conduct of the surveys we followed  
27 20 standard ethical research guidelines.  
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### 31 21 **Data collection**

32 22 Survey invitations were distributed by email and contained the access link, researcher contact  
33 23 details, and information about the study purpose and publication of anonymised data. The surveys  
34 24 were open for three weeks, and reminders were emailed twice.  
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37 25 The first survey was distributed among post-doctoral researchers, principal investigators and OIS  
38 26 managers at 21 LBG-funded research institutes and groups. The questionnaire consisted of 10 items  
39 27 which were structured according to three aspects (three roles a patient or member of the public  
40 28 may take on in relation to research): participation (i.e., entering a study as a study ‘subject’),  
41 29 engagement/dissemination (i.e., engaging with information about research activities and findings),  
42 30 and involvement (i.e., making an active contribution to research processes and activities) [1, 9]. We  
43 31 formulated questions with Likert-scale response options to explore how frequently respondents  
44 32 undertook certain activities such as involving patients and members of the public in the  
45 33 conceptualisation of research proposals. Additionally, we formulated semantic differential scale  
46 34 items to gauge respondents’ attitudes towards PPI, a multiple-choice item about ethical aspects, and  
47 35 two open questions about ethical aspects and general challenges around PPI.  
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51 36 The second survey addressed representatives (primary contact persons) from 23 medical and nine  
52 37 university research ethics committees in Austria. This was a short questionnaire consisting of three  
53 38 multiple-choice items with optional free text answers. We asked whether the committee was  
54 39 familiar with the concept of PPI, how the committee dealt with queries regarding PPI, and whether  
55 40 the committee was interested in joining a national PPI working group.  
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### 58 41 **Analysis**

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3 1 We conducted descriptive statistical analyses for quantitative survey data and collated textual  
4 2 responses to open questions. Using survey data to contextualise our personal experiences, we  
5 3 articulated five current challenges to implementing PPI practices in Austria.

#### 7 4 **Patient and Public Involvement**

9 5 Members of the public were not involved in the design and conduct of the surveys, because the  
10 6 immediate barriers to PPI we encountered in our work seemed to relate to awareness, knowledge,  
11 7 and perceptions among researchers. Members of the public have been involved in the design and  
12 8 concept of the PPIE programme and funding model in 2019.

15 9

## 17 10 **RESULTS**

19 11 In our first survey, 19 scientists from nine different institutes/groups from disciplines across natural  
20 12 sciences, technical sciences, humanities, social sciences, and health sciences indicated generally  
21 13 positive attitudes towards the involvement of patients and the public in research (figure 1). Eleven  
22 14 had previously conducted PPI activities, and eight had not (self-report). Respondents were generally  
23 15 active in disseminating research findings to patients or the public, via traditional media, social  
24 16 media, popular science events, and other channels, which represents engagement/dissemination  
25 17 and not involvement. Two thirds indicated they rarely or never involved patients or members of the  
26 18 public in consultant roles. Three quarters indicated they rarely or never involved patients or the  
27 19 public in the development and conduct of research studies. And almost all indicated they rarely or  
28 20 never involved patients or members of the public in research lead or study oversight roles. With  
29 21 respect to ethical aspects of PPI (especially when individuals are invited because of their 'patient'  
30 22 roles), those respondents who had prior experience with PPI indicated that they tend to seek  
31 23 guidance from ethics committees, but not submit formal ethics applications for PPI activities.

35 24 In our second survey, we received responses from eight of 32 research ethics committees. Two  
36 25 respondents stated that committee members were familiar with PPI, and six that they were not. The  
37 26 two committees familiar with PPI reported that they offered information to researchers about PPI  
38 27 practices and provided statements in support of PPI activities. Seven respondents expressed interest  
39 28 in joining a national working group, with the aim to foster PPI by co-ordinating research governance  
40 29 and ethical practices (figure 2).

#### 43 30 **Points for attention**

45 31 Our survey findings bring into focus and contextualise, and to some extent corroborate, the  
46 32 anecdotal evidence from our personal experience of introducing PPI practices at our Ludwig  
47 33 Boltzmann Institutes for Digital Health. Based on this we observe five challenges or 'points for  
48 34 attention':

- 50 35 1. While some researchers have considerable knowledge and experience of PPI, it appears that a  
51 36 large segment of the research community in Austria has limited awareness and knowledge of  
52 37 the PPI concept, let alone the necessary skills and experience for successfully conducting PPI.
- 54 38 2. We have encountered scepticism towards the usefulness and impact of PPI among LBG  
55 39 researchers and Austrian ethics committee members. Critics may ask for convincing evidence,  
56 40 especially when weighing up resources required for good quality PPI against expected outcomes.
- 57 41 3. There can be a conflation of PPI activities with qualitative research. Particularly among  
58 42 quantitative researchers, PPI conversations with individuals or groups can be misunderstood as  
59 43 qualitative data collection.



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- 1 4. We have noticed uncertainty and sometimes considerable concern among clinical researchers who are unfamiliar with PPI about ethical aspects of PPI. This is grounded in the (valid) ethical imperative that patient information for clinical research purposes must not be collected before ethical approval has been granted, but it neglects the difference between patients' enrolment as study participants *versus* patients' involvement as PPI contributors. Especially PPI at the study conceptualisation and design stage, which takes place before a research ethics application is submitted, can create anxiety and fear of unethical conduct.
  - 2 5. Lastly, there is uncertainty among researchers whether information collected through PPI activities should or could be published in peer-reviewed scientific articles.

## 11 DISCUSSION

12 Our online surveys showed that respondents have differing levels of experience with PPI, from very limited experience to actively and competently involving members of the public in several phases of the research cycle. In our first survey, responses outline a trend whereby the implementation of PPI activities decreases with increasing degree of involvement (from consultation to collaboration to control [13]). The sharing of decision-making and control over the research is particularly rare. This snapshot encourages us to further promote PPI on individual level (i.e., offering training and facilitating exchange among researchers), and to introduce support structures on institutional and national level. In our second survey, most representatives from research ethics committees were unfamiliar with the PPI concept, but interested in discussing its ethical aspects. Acknowledging the potential for self-selection and social desirability bias in these surveys and limitations due to a low response rate from research ethics committees, our findings nevertheless indicate that awareness and knowledge of PPI should be addressed, and clear guidance on research governance and ethical requirements should be provided for the Austrian healthcare research community. To some extent, this requires a cultural shift and consensus building within the scientific community and among relevant stakeholders, such as funders, universities, research institutes, and regional and federal medical research ethics committees.

### 28 Addressing points for attention

29 With respect to addressing the five challenges we formulate above, we offer the following  
30 considerations:

- 31 1. Researchers' limited awareness, knowledge, and skills for PPI have been highlighted as main  
32 stumbling blocks in the active involvement of members of the public in research [14].  
33 Signposting researchers to international scientific communities in which PPI is an established and  
34 valued practice (also considering other descriptors which are used internationally to describe an  
35 approach that is similar to PPI in spirit, such as 'community engagement' [15] or 'patient-focused  
36 drug development'[16]) could emphasise the importance of PPI and increase motivation for  
37 researchers to acquire adequate knowledge and skills for PPI.
- 38 2. Demands for evidence of the usefulness of PPI are not straightforward to answer, as expected  
39 impacts of PPI are multifaceted, e.g., benefiting research processes and outcomes, but also  
40 bringing about positive personal outcomes for PPI contributors and researchers [17]. A growing  
41 literature demonstrates these positive outcomes of PPI, although this evidence is also limited by  
42 methodological complexities [18]. A recent meta-analysis of seven randomised controlled trials  
43 demonstrated that PPI interventions modestly but significantly increased participant enrolment  
44 (odds ratio 1.16, 95% confidence interval 1.01 to 1.34 [19]). Such high-level evidence will speak

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3 1 to proponents of the traditional hierarchy of evidence paradigm. However, the value of evidence  
4 2 from qualitative and mixed methods reviews in describing nuanced and multifaceted impacts of  
5 3 PPI should not be neglected [18] and should be considered for future research. PPI grant  
6 4 schemes should require that proposals incorporate processes for evaluating the impact of PPI.

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9 5 3. The conflation of PPI activities with qualitative research has also been reported by others [20].  
10 6 There is a need to raise awareness and understanding of patients' different roles, i.e., patients as  
11 7 PPI contributors *versus* patients as research participants. Research institutions and ethics  
12 8 committees should provide guidance and training to support researchers in recognising these  
13 9 differences and in implementing PPI activities appropriately. Moreover, power differentials  
14 10 between researchers and PPI contributors need to be addressed [21], e.g., by providing PPI  
15 11 contributors with adequate training opportunities and compensation (monetary or other) for  
16 12 their time.
- 17 13 4. Authoritative guidance at national level to address ethical concerns about PPI among healthcare  
18 14 researchers is needed. This should state unequivocally that PPI activities principally do not  
19 15 require formal review and approval by a research ethics committee, including PPI at the  
20 16 conceptualisation and design stage of a research proposal. In the UK, for example, such guidance  
21 17 is provided by the HRA:

22 18 *'Do I need HRA ethical approval before I work with patients and the public? No.*  
23 19 *You do not need to submit an application to a Research Ethics Committee in order*  
24 20 *to involve the public in the planning or the design stage of research, even if the*  
25 21 *people involved are NHS [National Health Service] patients' [22].*

26 22 At an international level and endorsed by the World Health Organisation, the International  
27 23 Ethical Guidelines for Health-related Research Involving Humans (Guideline 7: Community  
28 24 Engagement) provide a similarly helpful resource [15]. Although this does not clarify ethical  
29 25 requirements for PPI as explicitly as in the above example, the same message can be inferred:

30 26 *'Researchers and research ethics committees should be cognizant of the point at*  
31 27 *which the process of community engagement becomes a stage of formative*  
32 28 *research that itself requires ethics review' [15, p.26].*

- 33 29 5. Uncertainty about publishing PPI in peer-reviewed articles could be addressed by distinguishing  
34 30 three publication scenarios: the description of PPI in the methods section of scientific articles  
35 31 (this has recently been encouraged by the BMJ, signalling the importance attributed to PPI by a  
36 32 world-leading medical journal [14]), the publication of PPI activities as research studies 'in their  
37 33 own right', and the publication of research studies *about* PPI.

### 34 35 **Further developments**

36 36 Following on from our survey findings, we identified the need for guidance about ethical  
37 37 requirements of PPI as a priority. As in the UK, formal ethical approval of PPI activities is currently  
38 38 not required by Austrian law if members of the public act as PPI contributors and not as study  
39 39 participants. In Austria, there is only a legal obligation for review by ethics committees in the case of  
40 40 clinical trial of drugs or medical devices and in the application of new medical methods and applied  
41 41 medical research to humans. National consensus and explicit guidance on this point would further  
42 42 raise awareness of researchers applying participatory research designs and PPI in its different forms  
43 43 – from consultation to collaboration to control – and their different ethical requirements.

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3 1 To initiate this national consensus and promote change on a structural level, we invited a dialogue  
4 2 with Austrian research ethics committees about PPI. To date, five committees have joined an  
5 3 informal working group coordinated by the LBG OIS Center and have supported the development of  
6 4 a checklist for ethical aspects of PPI [23]. We view this as a crucial step to inform about PPI and its  
7 5 ethical challenges, to align our vision, and to address the conflation of PPI with qualitative research  
8 6 by outlining differences and ethical considerations around PPI also in ethics applications. The  
9 7 checklist is based on existing ethics guidelines in research [10] and on the GRIPP-2 statement for  
10 8 reporting PPI in research publications [24]. The checklist could serve as best practice example and  
11 9 standard operating procedure for Austrian ethics committees in dealing with PPI. Applying the  
12 10 checklist to their own work, applicants may be asked to, e.g., describe the role of patients and  
13 11 members of the public in their project, distinguish between study participation and involvement,  
14 12 and highlight possible ethical issues. This could support quality assurance and implementation of  
15 13 standards for PPI and give researchers an opportunity to self-evaluate their ethical considerations  
16 14 around PPI.  
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## 16 **CONCLUSION**

17 This initiative for scoping PPI practices within the LBG research community in Austria has led to a  
18 18 wider discussion in the organisation and dialogue with stakeholders, including research ethics  
19 19 committees. With our recently published checklist we have made progress towards providing ethical  
20 20 guidance for PPI in the Austrian research context, but we suggest that addressing consensus on  
21 21 governance and ethics of PPI remains a top strategic priority at a national structural level. Further  
22 22 strategic priorities are the ongoing provision of support at individual and institutional/organisational  
23 23 levels through PPI training opportunities and grant schemes to raise awareness and foster  
24 24 researchers' knowledge and skills, and the building of the evidence base for PPI in the Austrian  
25 25 context through impact evaluations and formal research about PPI. It will be opportune and  
26 26 important to increase the involvement of patients and members of the public in the decision-making  
27 27 and delivery of these strategic measures. We envisage that the LBG OIS Center will continue to lead  
28 28 this work in collaboration with researchers, ethics committees, patients, and members of the public,  
29 29 with the aim to achieve authentic and beneficial implementation of PPI in the Austrian research  
30 30 community.  
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## 34 **Authors' Contributions**

35 In May 2020, the authors formed a working group to exchange experiences of introducing Patient  
36 36 and Public Involvement at their respective organisations. RK, STK, EK, MKP, ES, and ASH conceived  
37 37 and planned the formative surveys of Ludwig Boltzmann Institutes and research ethics committees  
38 38 in Austria. RK, STK, EK, MKP, ES, and ASH contributed to drafting the online questionnaires. The  
39 39 surveys were administered by RK and analysed by RK and STK. RK, STK, EK, MKP, ES, and ASH  
40 40 contributed to the interpretation of survey findings. RK, STK, EK, MKP, ES, and ASH contributed to  
41 41 the conceptualisation of this article. RK, STK, MKP, and ES wrote the first manuscript draft. All  
42 42 authors critically reviewed the manuscript for intellectual content, approved the final version, and

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1 agreed to be accountable for all aspects of the work in ensuring that questions related to the  
2 accuracy or integrity of any part of the work are appropriately investigated and resolved.

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6 **Competing Interests**

7 The authors declare no conflict of interest.

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For peer review only

## 1 References

- 2 1 Hayes H, Buckland S, Tarpey M. Briefing notes for researchers: public involvement in NHS, public  
3 health and social care research. Eastleigh, England: INVOLVE 2012.
- 4 2 Greenhalgh T, Hinton L, Finlay T, et al. Frameworks for supporting patient and public involvement  
5 in research: Systematic review and co-design pilot. *Health Expect* 2019;22:785-801.  
6 <https://doi.org/10.1111/hex.12888> (accessed 13 November 2020).
- 7 3 Wilson P, Mathie E, Keenan J, et al. Research with patient and public involvement: a realist  
8 evaluation – the RAPPORT study. *Health Serv Deliv Res* 2015;3(38).  
9 <https://www.journalslibrary.nihr.ac.uk/hsdr/hsdr03380/#/abstract> (accessed 11 November 2020).
- 10 4 INVOLVE. [website] <https://www.invo.org.uk/> (accessed 01 March 2021)
- 11 5 National Institute of Health Research. Involve patients [website]. [https://www.nihr.ac.uk/health-](https://www.nihr.ac.uk/health-and-care-professionals/engagement-and-participation-in-research/involve-patients.htm)  
12 [and-care-professionals/engagement-and-participation-in-research/involve-patients.htm](https://www.nihr.ac.uk/health-and-care-professionals/engagement-and-participation-in-research/involve-patients.htm) (accessed  
13 24 February 2021).
- 14 6 Health Research Authority (HRA). Public involvement [website]. [https://www.hra.nhs.uk/planning-](https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/)  
15 [and-improving-research/best-practice/public-involvement/](https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/) (accessed 11 November 2020).
- 16 7 Center for Drug Evaluation and Research (CDER). Patient-focused drug development: collecting  
17 comprehensive and representative input. Guidance for industry, Food and Drug Administration staff,  
18 and other stakeholders. Silver Spring, MD: U.S. Food and Drug Administration 2020.  
19 [https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-focused-](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-focused-drug-development-collecting-comprehensive-and-representative-input)  
20 [drug-development-collecting-comprehensive-and-representative-input](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-focused-drug-development-collecting-comprehensive-and-representative-input) (assessed 26 November  
21 2020).
- 22 8 European Patients' Academy on Therapeutic Innovation (EUPATI). EUPATI: Patient engagement  
23 through education [website] <https://eupati.eu/> (accessed 26 November 2020).
- 24 9 Beck S, Bergenholtz C, Bogers M, et al. The Open Innovation in Science research field: a  
25 collaborative conceptualisation approach. *Ind Innov*, 4 August 2020.  
26 <https://doi.org/10.1080/13662716.2020.1792274> (accessed 6 November 2020).
- 27 10 Kaisler RE, Missbach B. Patient and public involvement and engagement in research – a 'how to'  
28 guide for researchers. *Zenodo* 2020. <http://doi.org/10.5281/zenodo.3515811> (accessed 6 November  
29 2020).
- 30 11 Kaisler RE, Missbach B. Co-creating a patient and public involvement and engagement 'how to'  
31 guide for researchers. *Res Involv Engagem* 2020;6:32. <https://doi.org/10.1186/s40900-020-00208-3>  
32 (accessed 6 November 2020).
- 33 12 Busch J, Leimueller G, Malfent L, et al. Best Open Innovation in Science practice for the  
34 establishment of interdisciplinary & inter-sectoral collaboration platforms for the implementation of  
35 PM [abstract]. *2nd ICPeMed Workshop – 'Best Practice in Personalised Medicine' Recognition 2019,*  
36 *Personalised Medicine for All Citizens and Patients within Sustainable Implementation, Madrid, 5*  
37 *November 2019.* <https://www.icpermed.eu/en/icpermed-recognition-2019.php>
- 38 13 Oliver SR, Rees RW, Clarke-Jones L, et al. A multidimensional conceptual framework for analysing  
39 public involvement in health services research. *Health Expect* 2008;11:72-84.  
40 <https://doi.org/10.1111/j.1369-7625.2007.00476.x> (accessed 20 November 2020).

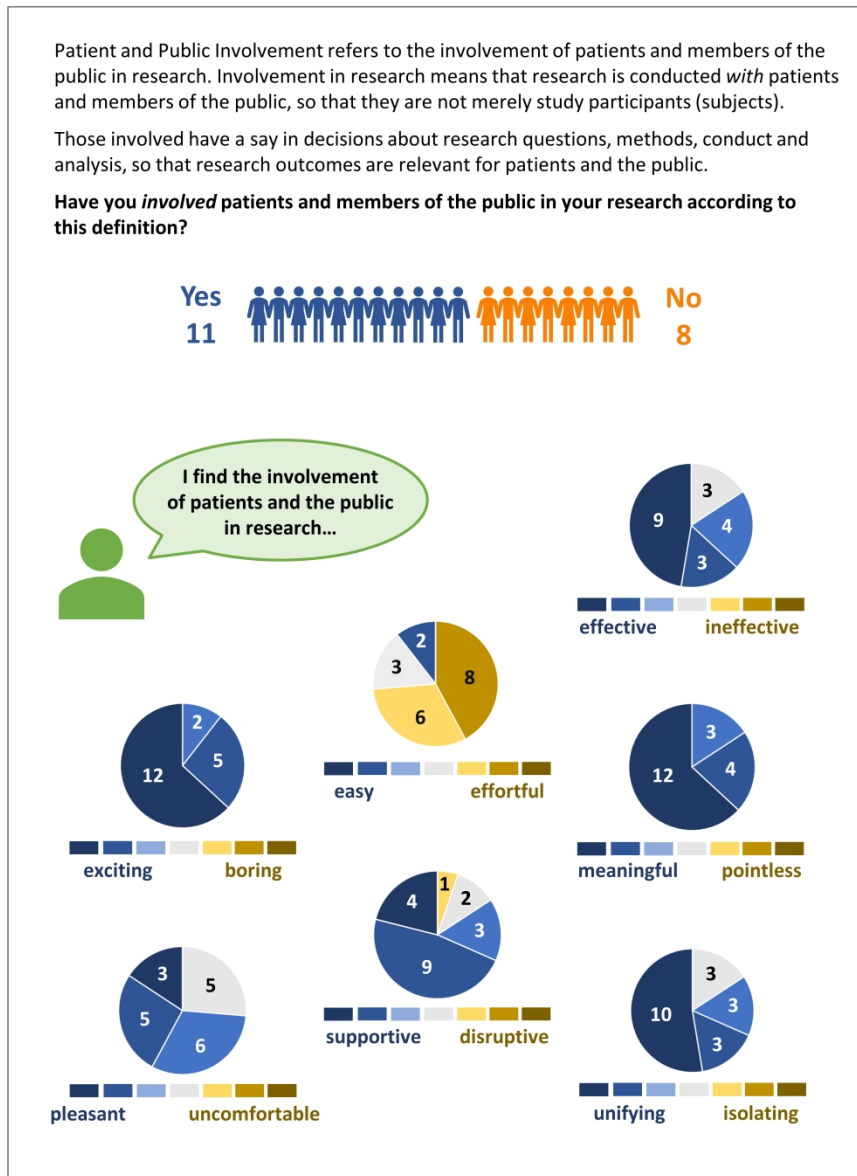
- 1  
2  
3 1 14 Wicks P, Richards T, Denegri S, et al. Patients' roles and rights in research. *BMJ* 2018;362:k3193.  
4 2 <https://doi.org/10.1136/bmj.k3193> (accessed 20 November 2020).  
5  
6 3 15 Council for International Organizations of Medical Sciences (CIOMS). International ethical  
7 4 guidelines for health-related research involving humans. 4<sup>th</sup> ed. Geneva, Switzerland: CIOMS 2016.  
8  
9 5 16 Center for Drug Evaluation and Research (CDER). CDER patient-focused drug development  
10 6 [website]. Silver Spring, MD: U.S. Food and Drug Administration.  
11 7 [https://www.fda.gov/drugs/development-approval-process-drugs/cder-patient-focused-drug-](https://www.fda.gov/drugs/development-approval-process-drugs/cder-patient-focused-drug-development)  
12 8 [development](https://www.fda.gov/drugs/development-approval-process-drugs/cder-patient-focused-drug-development) (accessed 22 November 2020).  
13  
14  
15 9 17 Baldwin JN, Napier S, Neville S, et al. Impacts of older people's patient and public involvement in  
16 10 health and social care research: a systematic review. *Age Ageing* 2018;47:801-809.  
17 11 <https://doi.org/10.1093/ageing/afy092> (accessed 13 November 2020).  
18  
19 12 18 Price A, Albarqouni L, Kirkpatrick J, et al. Patient and public involvement in the design of clinical  
20 13 trials: an overview of systematic reviews. *J Eval Clin Pract* 2018;24:240-253.  
21 14 <https://doi.org/10.1111/jep.12805> (accessed 13 November 2020).  
22  
23 15 19 Crocker JC, Ricci-Cabello I, Parker A, et al. Impact of patient and public involvement on enrolment  
24 16 and retention in clinical trials: systematic review and meta-analysis. *BMJ* 2018;363:k4738.  
25 17 <https://doi.org/10.1136/bmj.k4738> (accessed 13 November 2020).  
26  
27 18 20 Liabo K, Boddy K, Burchmore H, et al. Clarifying the roles of patients in research. *BMJ*  
28 19 2018;361:k1463. <https://doi.org/10.1136/bmj.k1463> (accessed 20 November 2020).  
29  
30 20 21 Di Lorito C, Godfrey M, Dunlop M, et al. Adding to the knowledge on Patient and Public  
31 21 Involvement: reflections from an experience of co-research with carers of people with dementia.  
32 22 *Health Expect* 2020;23:691-706. <https://doi.org/10.1111/hex.13049> (accessed 24 February 2021).  
33  
34 23 22 Health Research Authority (HRA). Public involvement. What do I need to do? [website].  
35 24 [https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/what-](https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/what-do-i-need-to-do/)  
36 25 [do-i-need-to-do/](https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/what-do-i-need-to-do/) (accessed 11 November 2020).  
37  
38  
39 26 23 Kaisler RE. Checkliste für Forschungsvorhaben mit Bürger\*innen-Einbindung [Checklist for  
40 27 research projects with patient and public involvement activities]. *Zenodo* 2021.  
41 28 <https://zenodo.org/record/4573970> (accessed 4 March 2021).  
42  
43 29 24 Staniszewska S, Brett J, Simera I, et al. GRIPP2 reporting checklists: tools to improve reporting of  
44 30 patient and public involvement in research. *BMJ* 2017;358:j3453. <https://doi.org/10.1136/bmj.j3453>  
45 31 (accessed 13 November 2020).  
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3 1 **Figure 1.** Attitudes towards Patient and Public Involvement (PPI) among 19 researchers from nine  
4 2 different institutes/groups of the Ludwig Boltzmann Gesellschaft. Respondents rated seven  
5 3 attitudinal dimensions on 7-point semantic differential scales. Pie charts describe frequencies of  
6 4 ratings.  
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10 6 **Figure 2.** Responses (frequencies) from representatives of eight research ethics committees in  
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45 Figure 1. Attitudes towards Patient and Public Involvement (PPI) among 19 researchers from nine different  
46 institutes/groups of the Ludwig Boltzmann Gesellschaft. Respondents rated seven attitudinal dimensions on  
47 7-point semantic differential scales. Pie charts describe frequencies of ratings.

48 161x218mm (600 x 600 DPI)



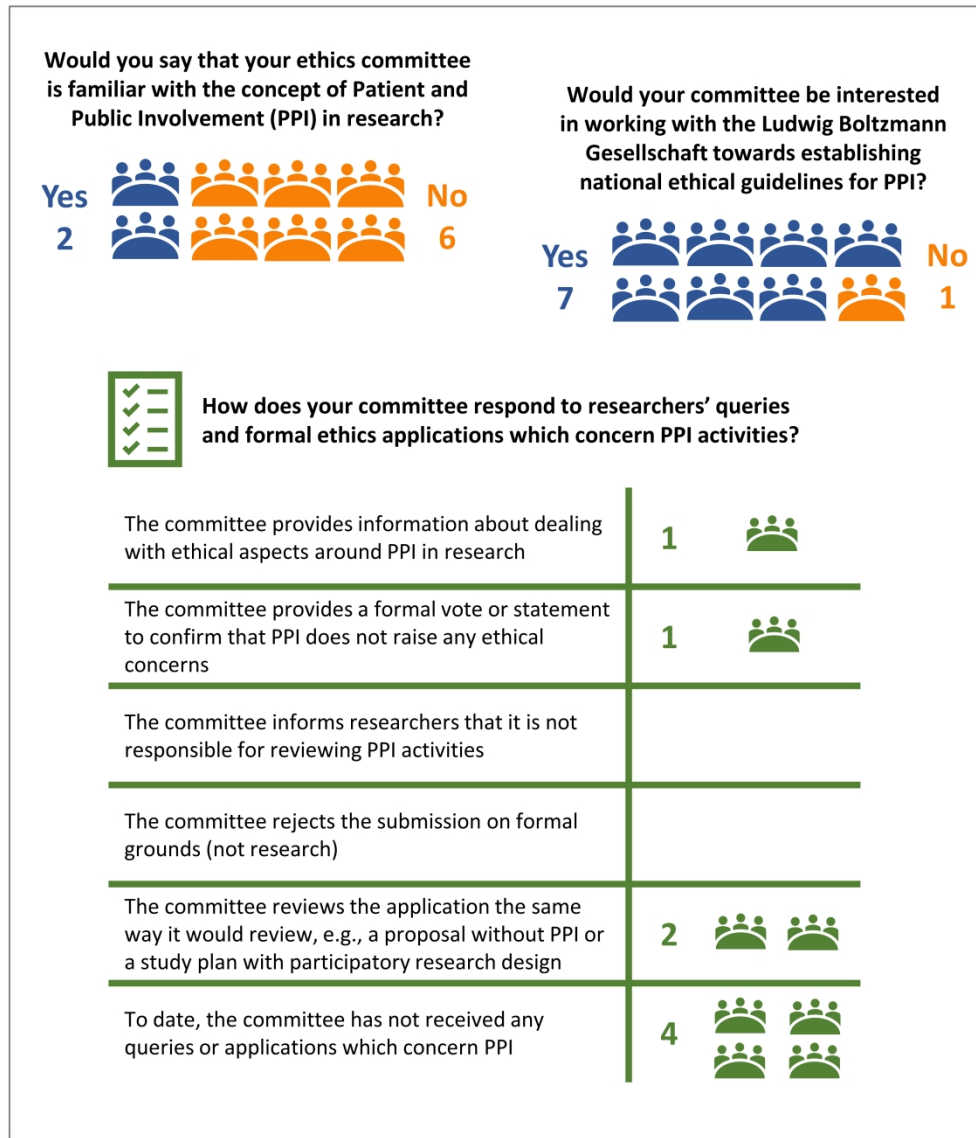


Figure 2. Responses (frequencies) from representatives of eight research ethics committees in Austria.

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