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# 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 relevant stakeholders, such as funders, universities, research institutes and regional and federal medical research ethics committees.

## SCOPING PATIENT AND PUBLIC INVOLVEMENT PRACTICES IN AUSTRIA

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

FIGURE 1 ABOUT HERE

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

### Patient and Public Involvement

No patient involved.

## DISCUSSION

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

## Points for attention

Based on our survey findings and from our own experiences of introducing PPI practices at our Ludwig Boltzmann Institutes for Digital Health, we observe five points, which should be addressed with priority in Austria:

1. While there are researchers with considerable knowledge and experience of PPI, it appears that a large segment of the research community in Austria has limited awareness and knowledge of the PPI concept, let alone the necessary skills and experience for successfully conducting PPI. This has been highlighted as one of the main stumbling blocks to coproduction of research with patients and the public.[12] It will be helpful to signpost to other international descriptors of the same principal approach, such as ‘community engagement’[13] or ‘patient-focused drug development’,[14] to convey that this is a direction of travel across the international clinical research field; and that it is important for researchers to acquire adequate knowledge and skills.

2. We have encountered scepticism towards the usefulness and impact of PPI. Critics may ask for convincing evidence, especially when weighing up resources required for good quality PPI against expected outcomes. It is not straightforward to answer this point, as expected impacts of PPI are multifaceted, *e.g.,* benefiting research processes and outcomes, but also bringing about positive personal outcomes for PPI contributors and researchers.[15] A growing literature demonstrates these positive outcomes of PPI, although this evidence is also limited by methodological complexities.[16] A recent meta-analysis of seven randomised controlled trials demonstrated that PPI interventions modestly but significantly increased participant enrolment (odds ratio 1.16, 95% confidence interval 1.01 to 1.34).[17] Such high-level evidence will speak to proponents of the traditional hierarchy of evidence paradigm; but the value of evidence from qualitative and mixed methods reviews in describing nuanced and multifaceted impacts of PPI should not be neglected.[16]

3. There can be a conflation of PPI activities with qualitative research, which has also been reported by others.[18] Particularly among quantitative researchers, PPI conversations with individuals or groups can be misunderstood as qualitative data collection. Clearly, there is a need to raise awareness and understanding of patients’ different roles, *i.e.* patients as PPI contributors *versus* patients as research participants.

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. Authoritative guidance at national level could best allay these concerns, by stating unequivocally that PPI activities principally do not require formal review and approval by a research ethics committee. In the UK, for example, such guidance is provided by the HRA:

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

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

> *'Researchers and research ethics committees should be cognizant of the point at which the process of community engagement becomes a stage of formative research that itself requires ethics review.'[13, p.26]*

5. Lastly, there is uncertainty among researchers whether information collected through PPI activities should or could be published in peer-reviewed scientific articles. This could perhaps best be addressed by distinguishing three publication scenarios: the description of PPI in the methods section of scientific articles (this has recently been encouraged by the BMJ, signalling the importance attributed to PPI by a world-leading medical journal)[12]; the publication of PPI activities as research studies 'in their own right'; and the publication of research studies *about* PPI.

### Organisational, individual, and structural strategies for promoting PPI

Building on existing initiatives of the LBG OIS Center that support PPI practices on an organisational and individual level, we used the momentum from our surveys to introduce PPI also on a structural level – working with Austrian research ethic committees.

On an organisational level, the LBG OIS Center initiated a multi-stakeholder process in 2019, to co-develop a Patient and Public Involvement and Engagement (PPIE) 'how to' guide with researchers from various disciplines, patient organisations, and citizen scientists.[20] This laid the foundation for a national PPI funding programme based on stakeholders' needs. Building on these needs, a PPIE grant scheme was introduced in 2020 (ppie.lbg.ac.at), supporting researchers to implement PPI activities in their research with up to EUR 60.000 over 12 months. This call is embedded in continuous consultation and training on PPI, and peer support for researchers and citizens to foster mutual learning. This addresses limited awareness and knowledge (above point 1) and further familiarises researchers with participatory methods and skills necessary to deliver PPI in practice.

With these measures, the LBG OIS Center functions as a national point of contact and competence centre, aiming to embed meaningful PPI practices in the Austrian research landscape also on an individual level. Besides the scientific impact of PPI projects and dissemination of best practices on stakeholder conferences that are co-convened with citizens, we focus on impact case studies demonstrating the positive effects of PPI on citizens and patient-driven outcomes. We hope that these reflections on the quality of public involvement processes and methods may counter scepticism and address methodological complexities of demonstrating the benefits of PPI (above point 2) .

To further promote change on a structural level, and following on from our surveys, we initiated a dialogue with Austrian research ethics committees about PPI practices in research. Seven of 32 medical und university research ethics committees indicated interest in this discussion, to explore and integrate ethical aspects of PPI in their portfolio and to widen their focus also to non-clinical studies. We view this as a crucial step to inform about PPI and its ethical challenges and to align our visions and address the conflation of PPI activities with qualitative research (above point 3) by outlining differences and ethical considerations of PPI also in ethics applications. Currently, we are working together with ethics committees to develop a guide for ethical aspects of PPI that could act as best practice example and may serve as a standard procedure for Austrian ethics committees in applying PPI in research projects. It will include a checklist based on existing ethics guidelines in research [9] and on the GRIPP-2 reporting checklist [21] which provides guidance on reporting PPI as integral part in research articles (above point 5). This would assure quality standards for implementing PPI practices and give researchers the opportunity to evaluate their ethical considerations around PPI activities (above point 4). To achieve this, applicants are, *e.g.*, asked to describe the citizens’ and patients’ roles in the research project, distinguishing between study participation and active contribution to research tasks and linking this to possible ethical issues. As in the UK, formal ethical review and approval of PPI activities is currently not required by Austrian law if citizens or patients act as co-researchers and not as study participants. In Austria, there is only a legal obligation for an ethical review from ethics committees in the case of clinical trial of drugs or medical devices and in the application of new medical methods and applied medical research to humans.  National consensus and explicit guidance on this point would further contribute to the awareness of researchers applying participatory designs and PPI in its different forms – from none to consultation to collaboration to control – and their different ethical requirements.

## CONCLUSION

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

## 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.

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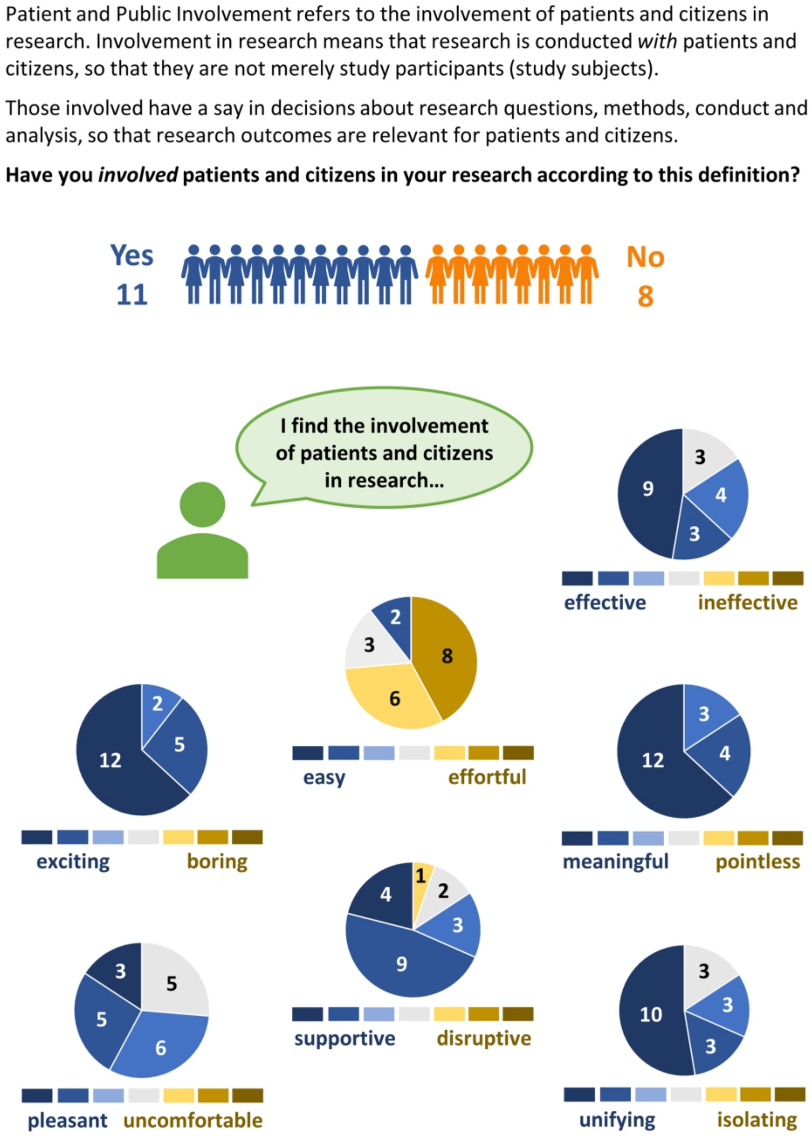
**Figure 1.** Attitudes towards Patient and Public Involvement (PPI) among 19 researchers from 9 different research institutes/groups of the Ludwig Boltzmann Gesellschaft. Respondents rated 7 attitudinal dimensions on 7-point semantic differential scales. Shown are frequencies.



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.

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**Abstract** (300 of max. 300 words)

**Background**

Patient and Public Involvement (PPI) in research is well-established in the United Kingdom. However, it can be challenging to introduce PPI to research communities where there is limited prior knowledge, experience, or appreciation of PPI.

**Objective**

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

**Methods**

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

**Results**

Nineteen scientists from nine research institutes indicated generally positive attitudes towards PPI; however, the majority reported they rarely or never involved patients and members of the public in roles of consultation, collaboration, or control in research. Six of eight ethics committees were unfamiliar with PPI. From personal experience we have observed lack of knowledge and skills for PPI among scientists; scepticism about the usefulness of PPI; conflation of PPI with qualitative research; uncertainty about ethical requirements for PPI; and uncertainty about publishing PPI activities.

**Conclusions**

We suggest that strategies addressing individual, institutional, and national structural levels are required to successfully implement PPI in the Austrian context. Building on a recently introduced PPI training and grant scheme offered by the LBG, our surveys have initiated a dialogue with ethics committees and the development of an ethics checklist for PPI. 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 members of the public 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 have lived experience of the phenomenon (e.g., a health condition) being researched should also have a voice in related research; a methodological dimension, claiming 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; and a political dimension, based on citizens’ rights and proposed advantages of alliances between researchers, patients and the public [2]. Typical examples for PPI activities are involvement of patients and members of the public in the setting of research priorities, as co-applicants on research grant applications, as members of study steering or advisory groups, and as co-researchers [1].

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 [4] and other centres and support networks [5] offer expertise to researchers for the implementation and advancement of PPI in healthcare research; and regulator Health Research Authority (HRA) publishes clear regulatory and ethical guidance on PPI for researchers [6].

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 [7]. 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 [8]. EUPATI National Platforms mirror the EUPATI partnership at national level and are currently set up in 22 European countries, including Austria.

### Promoting PPI in 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 [9]. To promote PPI, the LBG OIS Center initiated a multi-stakeholder process in 2019, co-developing a Patient and Public Involvement and Engagement (PPIE) ‘how to’ guide with researchers from various disciplines, patient organisations, and citizen scientists [10, 11]. This laid the foundation for a national PPI funding programme introduced in 2020 (ppie.lbg.ac.at), which supports researchers to implement PPI activities with up to EUR 60,000 over 12 months. The call is embedded in continuous consultation and training on PPI, and peer support for researchers and members of the public to foster mutual learning. With these measures, the LBG OIS Center functions as a national point of contact and competence centre, aiming to embed meaningful PPI practices in the Austrian research landscape and offering support to researchers on an individual level.

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

## SCOPING PATIENT AND PUBLIC INVOLVEMENT PRACTICES IN AUSTRIA

### Online surveys

In summer 2020, we conducted two online surveys to scope current PPI practices, experiences, and ethical and operational challenges with PPI. Survey invitations were distributed by email and contained the access link, researcher contact details, and information about the study purpose and publication of anonymised data. The surveys were open for three weeks, and reminders were emailed twice.

The first survey was distributed among post-doctoral researchers, principal investigators and OIS managers at 21 LBG-funded research institutes and groups. The questionnaire consisted of 10 items which were structured according to three aspects (three roles a patient or member of the public may take on in relation to research): participation (i.e., entering a study as a study 'subject'), engagement/dissemination (i.e., engaging with information about research activities and findings), and involvement (i.e., making an active contribution to research processes and activities) [1, 9]. We formulated questions with Likert-scale response options to explore how frequently respondents undertook certain activities such as involving patients and members of the public in the conceptualisation of research proposals. Additionally, we formulated semantic differential scale items to gauge respondents' attitudes towards PPI, a multiple-choice item about ethical aspects, and two open questions about ethical aspects and general challenges around PPI.

The second survey addressed representatives (primary contact persons) from 23 medical and nine university research ethics committees in Austria. This was a short questionnaire consisting of three multiple-choice items with optional free text answers. We asked whether the committee was familiar with the concept of PPI, how the committee dealt with queries regarding PPI, and whether the committee was interested in joining a national PPI working group.

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

In our second survey, eight of 32 committees responded. Two stated that they were familiar with PPI, and six that they were not. The two committees familiar with PPI reported that they offered information to researchers about PPI practices and provided statements in support of PPI activities. Seven committees expressed interest in joining a national working group, with the aim to foster PPI through co-ordinating research governance and ethical practices (figure 2).

**Points for attention**

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

1. While some researchers have considerable knowledge and experience of PPI, it appears that a large segment of the research community in Austria has limited awareness and knowledge of the PPI concept, let alone the necessary skills and experience for successfully conducting PPI.
2. We have encountered scepticism towards the usefulness and impact of PPI among LBG researchers and Austrian ethics committees. Critics may ask for convincing evidence, especially when weighing up resources required for good quality PPI against expected outcomes.
3. There can be a conflation of PPI activities with qualitative research. Particularly among quantitative researchers, PPI conversations with individuals or groups can be misunderstood as qualitative data collection.
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.
5. Lastly, there is uncertainty among researchers whether information collected through PPI activities should or could be published in peer-reviewed scientific articles.

**Patient and Public Involvement**

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

**DISCUSSION**

Our online surveys showed that respondents have differing 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 no involvement to 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 by 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 clinical and 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.

**Addressing points for attention**

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

1. Researchers' limited awareness, knowledge and skills for PPI have been highlighted as main stumbling blocks in the active involvement of members of the public in research [14]. Signposting researchers to international scientific communities in which PPI is an established and valued practice (also considering other descriptors which are used internationally to describe an approach that is similar to PPI in spirit, such as 'community engagement' [15] or 'patient-focused drug development'[16]) could stress the importance of PPI and increase motivation for researchers to acquire adequate knowledge and skills for PPI.

2. Demands for evidence of the usefulness of PPI are not straightforward to answer, as expected impacts of PPI are multifaceted, e.g., benefiting research processes and outcomes, but also bringing about positive personal outcomes for PPI contributors and researchers [17]. A growing literature demonstrates these positive outcomes of PPI, although this evidence is also limited by methodological complexities [18]. A recent meta-analysis of seven randomised controlled trials demonstrated that PPI interventions modestly but significantly increased participant enrolment (odds ratio 1.16, 95% confidence interval 1.01 to 1.34; [19]). Such high-level evidence will speak to proponents of the traditional hierarchy of evidence paradigm; however, the value of evidence from qualitative and mixed methods reviews in describing nuanced and multifaceted impacts of PPI should not be neglected [18] and should be considered for future research. PPI grant schemes should require that proposals incorporate processes for evaluating the impact of PPI.

3. The conflation of PPI activities with qualitative research has also been reported by others [20].There is a need to raise awareness and understanding of patients' different roles, i.e., patients as PPI contributors *versus* patients as research participants. Research institutions and ethic committees should provide guidance and training to support researchers in recognising these differences and in implementing PPI activities appropriately. Moreover, power differentials between researchers and PPI contributors need to be addressed [21], e.g., by providing PPI contributors with (monetary or other) compensation for their time and adequate training opportunities.

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

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

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

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

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

## Further developments

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

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

## CONCLUSION

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

## Authors' 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, approved the final version, and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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## Competing Interests

The authors declare no conflict of interest.

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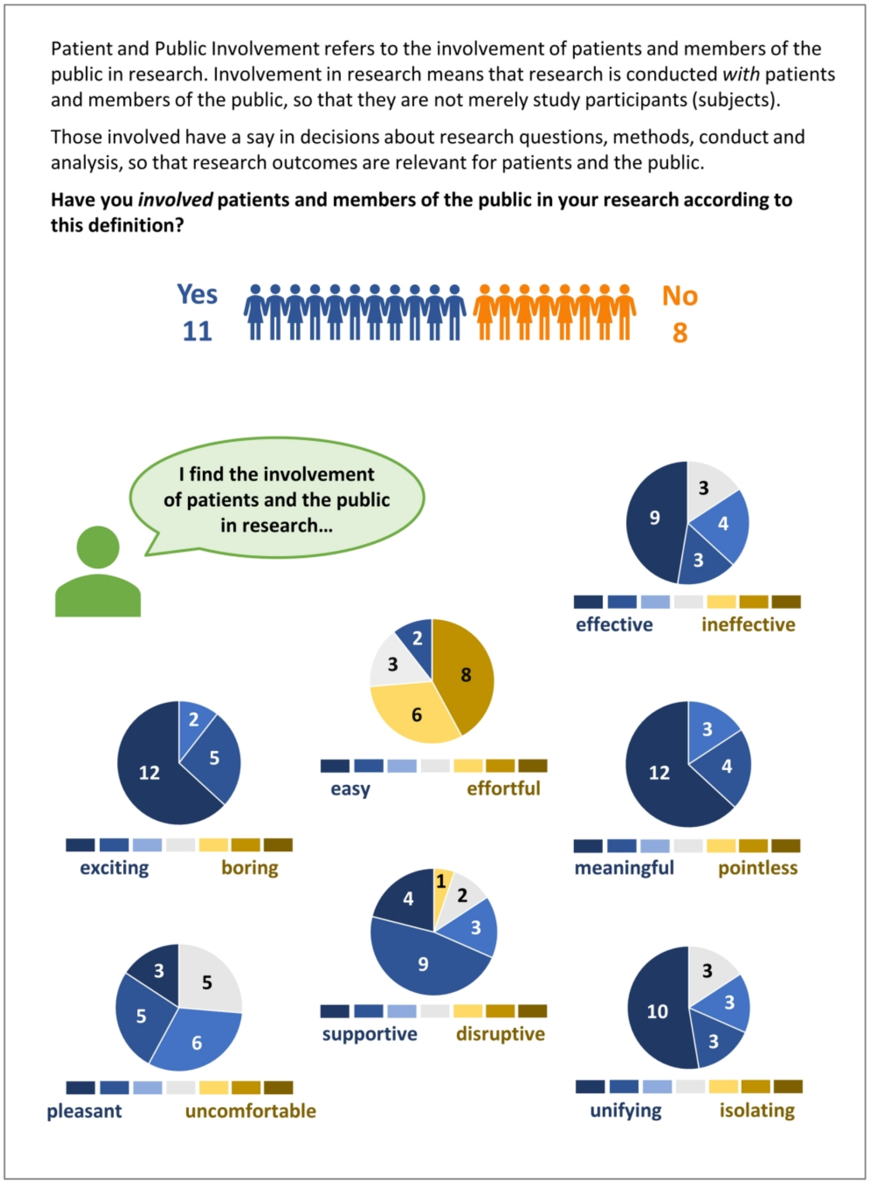
**Figure 1.** Attitudes towards Patient and Public Involvement (PPI) among 19 researchers from nine different institutes/groups of the Ludwig Boltzmann Gesellschaft. Respondents rated seven attitudinal dimensions on 7-point semantic differential scales. Pie charts describe frequencies of ratings.

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



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

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

**Have you *involved* patients and members of the public in your research according to this definition?**

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

161x218mm (300 x 300 DPI)

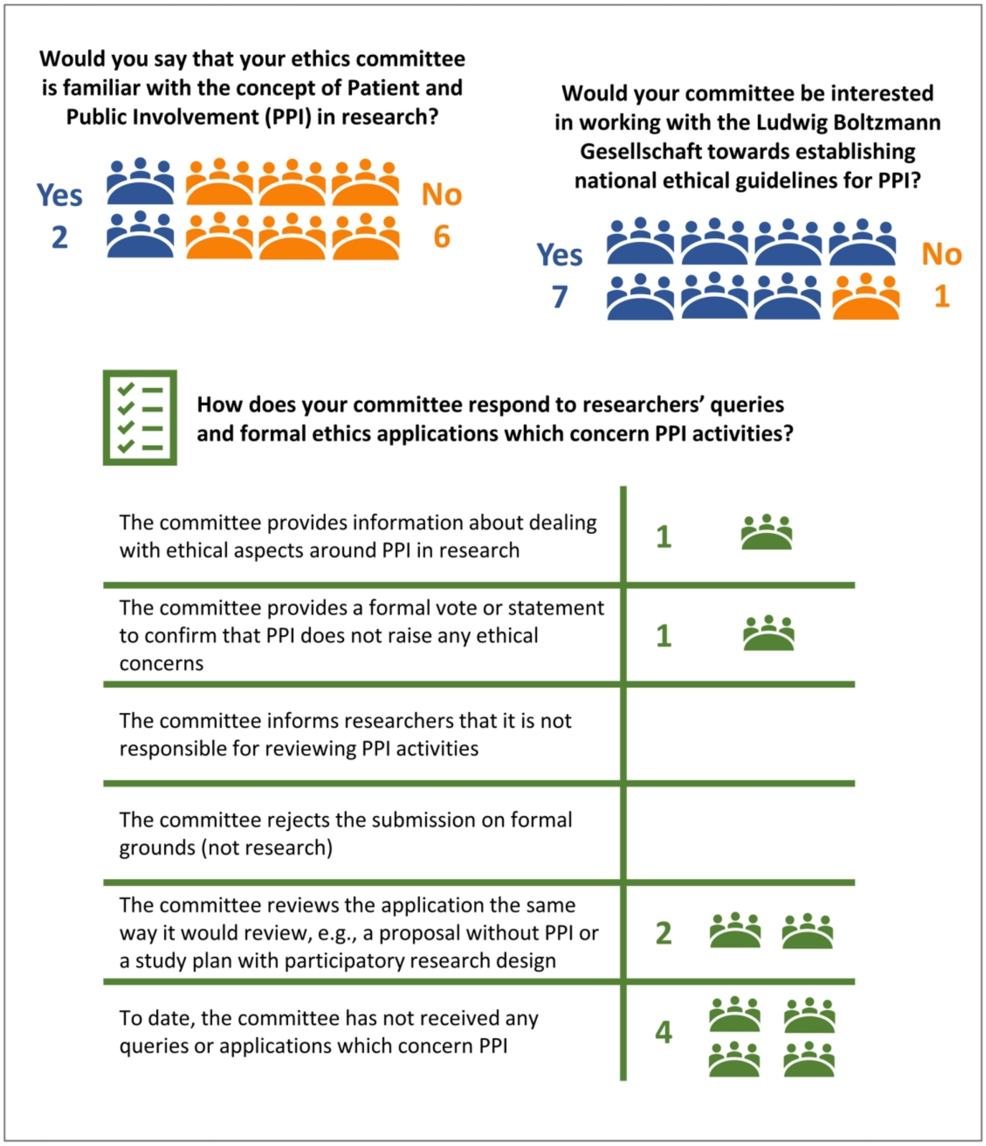


Figure 2. Responses (frequencies) from representatives of eight research ethics committees in Austria.

160x185mm (300 x 300 DPI)

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

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**Title**

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

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## Abstract (300 of max. 300 words)

### Background

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

### Methods

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

### Results

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

### Discussion

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

### Conclusion

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 members of the public 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 have lived experience of the phenomenon being researched (e.g., a health condition) should also have a voice in related research; a methodological dimension, claiming 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; and a political dimension, based on citizens’ rights and proposed advantages of alliances between researchers, patients, and the public [2]. Typical examples for PPI activities are involvement of patients and members of the public in the setting of research priorities, as co-applicants on research grant applications, as members of study steering or advisory groups, and as co-researchers [1].

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 [4] and other centres and support networks [5] offer expertise to researchers for the implementation and advancement of PPI in healthcare research, and regulator Health Research Authority (HRA) publishes clear regulatory and ethical guidance on PPI for researchers [6].

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 [7]. 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 [8]. EUPATI National Platforms mirror the EUPATI partnership at national level and are currently set up in 22 European countries, including Austria.

### Promoting PPI in 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 [9]. To promote PPI, the LBG OIS Center initiated a multi-stakeholder process in 2019, co-developing a Patient and Public Involvement and Engagement (PPIE) ‘how to’ guide with researchers from various disciplines, patient organisations, and citizen scientists [10, 11]. This laid the foundation for a national PPI funding programme introduced in 2020 (ppie.lbg.ac.at) which supports researchers to implement PPI activities with up to EUR 60,000 over 12 months. The call is embedded in continuous consultation and training on PPI, and peer support for researchers and members of the public to foster mutual learning. With these measures, the LBG OIS Center functions as a national point of contact and competence centre, aiming to embed meaningful PPI practices in the Austrian research landscape and offering support to researchers on an individual level.

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

## METHODS

### Study design

In summer 2020, we conducted two online surveys to scope current PPI practices, experiences, and ethical and operational challenges with PPI. In the design and conduct of the surveys we followed standard ethical research guidelines.

### Data collection

Survey invitations were distributed by email and contained the access link, researcher contact details, and information about the study purpose and publication of anonymised data. The surveys were open for three weeks, and reminders were emailed twice.

The first survey was distributed among post-doctoral researchers, principal investigators and OIS managers at 21 LBG-funded research institutes and groups. The questionnaire consisted of 10 items which were structured according to three aspects (three roles a patient or member of the public may take on in relation to research): participation (i.e., entering a study as a study 'subject'), engagement/dissemination (i.e., engaging with information about research activities and findings), and involvement (i.e., making an active contribution to research processes and activities) [1, 9]. We formulated questions with Likert-scale response options to explore how frequently respondents undertook certain activities such as involving patients and members of the public in the conceptualisation of research proposals. Additionally, we formulated semantic differential scale items to gauge respondents' attitudes towards PPI, a multiple-choice item about ethical aspects, and two open questions about ethical aspects and general challenges around PPI.

The second survey addressed representatives (primary contact persons) from 23 medical and nine university research ethics committees in Austria. This was a short questionnaire consisting of three multiple-choice items with optional free text answers. We asked whether the committee was familiar with the concept of PPI, how the committee dealt with queries regarding PPI, and whether the committee was interested in joining a national PPI working group.

### Analysis

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

### Patient and Public Involvement

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

## RESULTS

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

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

### Points for attention

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

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

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.
5. Lastly, there is uncertainty among researchers whether information collected through PPI activities should or could be published in peer-reviewed scientific articles.

## DISCUSSION

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.

### Addressing points for attention

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

1. Researchers' limited awareness, knowledge, and skills for PPI have been highlighted as main stumbling blocks in the active involvement of members of the public in research [14]. Signposting researchers to international scientific communities in which PPI is an established and valued practice (also considering other descriptors which are used internationally to describe an approach that is similar to PPI in spirit, such as 'community engagement' [15] or 'patient-focused drug development'[16]) could emphasise the importance of PPI and increase motivation for researchers to acquire adequate knowledge and skills for PPI.

2. Demands for evidence of the usefulness of PPI are not straightforward to answer, as expected impacts of PPI are multifaceted, e.g., benefiting research processes and outcomes, but also bringing about positive personal outcomes for PPI contributors and researchers [17]. A growing literature demonstrates these positive outcomes of PPI, although this evidence is also limited by methodological complexities [18]. A recent meta-analysis of seven randomised controlled trials demonstrated that PPI interventions modestly but significantly increased participant enrolment (odds ratio 1.16, 95% confidence interval 1.01 to 1.34 [19]). Such high-level evidence will speak

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

3. The conflation of PPI activities with qualitative research has also been reported by others [20]. There is a need to raise awareness and understanding of patients' different roles, i.e., patients as PPI contributors *versus* patients as research participants. Research institutions and ethics committees should provide guidance and training to support researchers in recognising these differences and in implementing PPI activities appropriately. Moreover, power differentials between researchers and PPI contributors need to be addressed [21], e.g., by providing PPI contributors with adequate training opportunities and compensation (monetary or other) for their time.

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

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

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

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

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

## Further developments

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

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

## CONCLUSION

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

## Authors' 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, MKP, and ES wrote the first manuscript draft. All authors critically reviewed the manuscript for intellectual content, approved the final version, and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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**Competing Interests**

The authors declare no conflict of interest.

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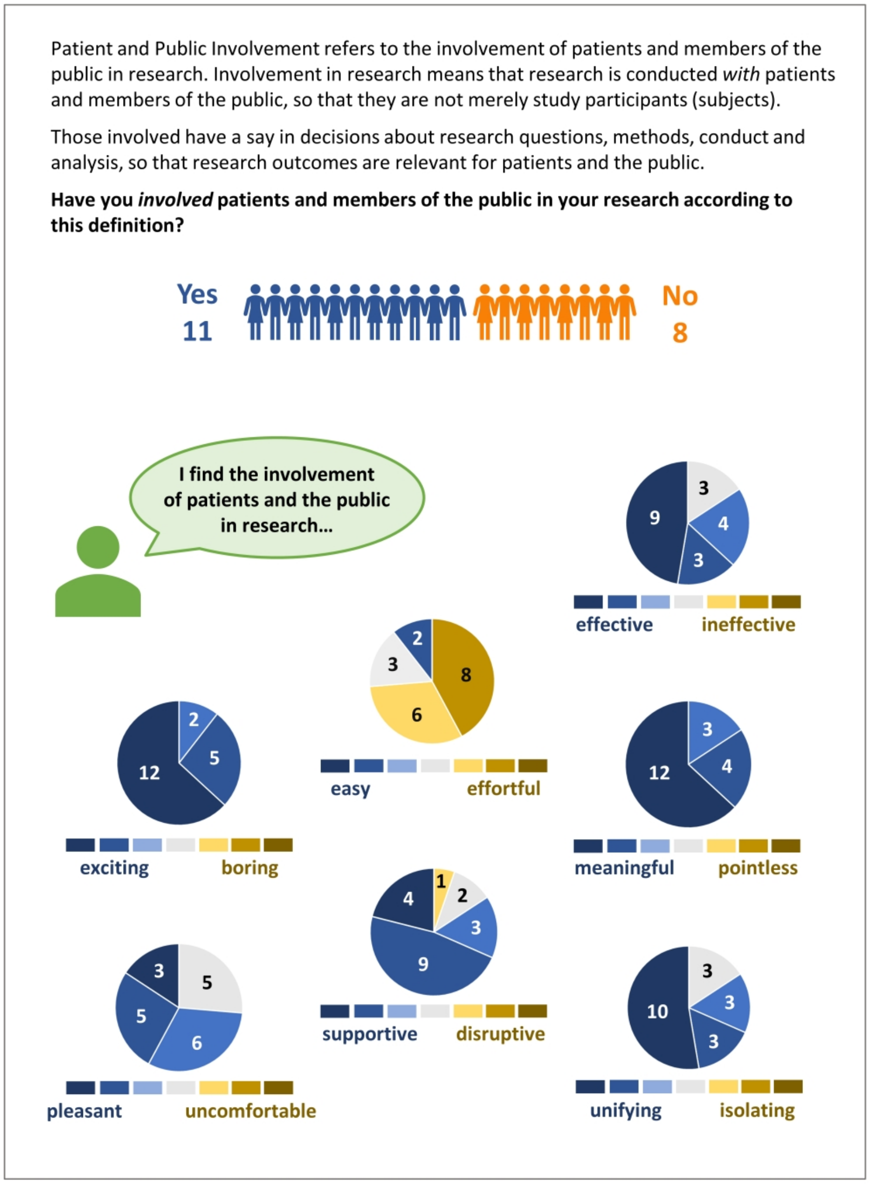
**Figure 1.** Attitudes towards Patient and Public Involvement (PPI) among 19 researchers from nine different institutes/groups of the Ludwig Boltzmann Gesellschaft. Respondents rated seven attitudinal dimensions on 7-point semantic differential scales. Pie charts describe frequencies of ratings.

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



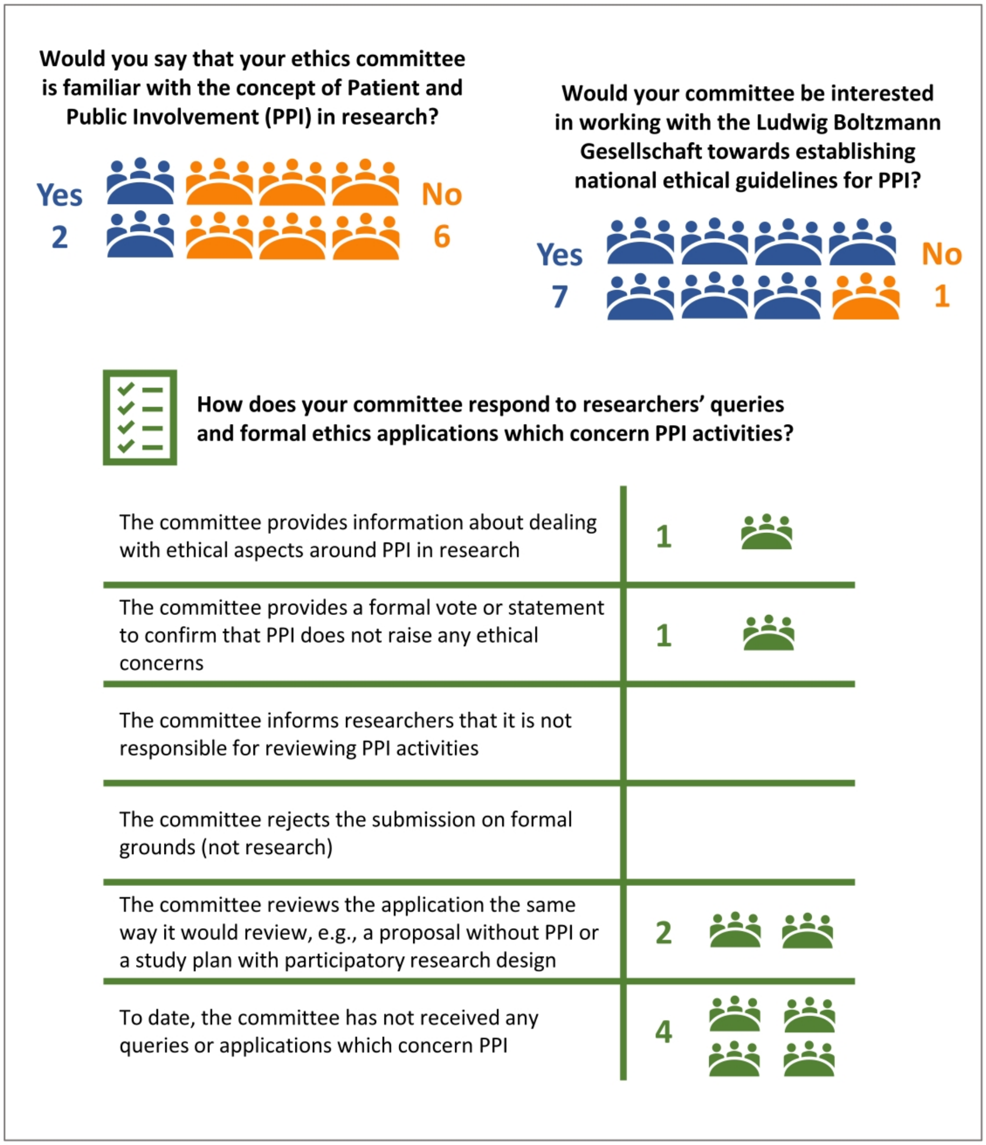
Patient and Public Involvement refers to the involvement of patients and members of the public in research. Involvement in research means that research is conducted *with* patients and members of the public, so that they are not merely study participants (subjects).

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

**Have you *involved* patients and members of the public in your research according to this definition?**

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

161x218mm (600 x 600 DPI)



Would you say that your ethics committee is familiar with the concept of Patient and Public Involvement (PPI) in research?

Would your committee be interested in working with the Ludwig Boltzmann Gesellschaft towards establishing national ethical guidelines for PPI?

How does your committee respond to researchers' queries and formal ethics applications which concern PPI activities?

| | |
|---|---|
| The committee provides information about dealing with ethical aspects around PPI in research | 1 |
| The committee provides a formal vote or statement to confirm that PPI does not raise any ethical concerns | 1 |
| The committee informs researchers that it is not responsible for reviewing PPI activities | |
| The committee rejects the submission on formal grounds (not research) | |
| The committee reviews the application the same way it would review, e.g., a proposal without PPI or a study plan with participatory research design | 2 |
| To date, the committee has not received any queries or applications which concern PPI | 4 |

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

160x185mm (600 x 600 DPI)