

Lee, Andrew ORCID: <https://orcid.org/0000-0001-8032-2170> , Thomas, Rachael, Chung, Bowen and Bont, Louis (2024) Listening to the voice of the patient in RSV research. *Pediatric Infectious Disease Journal* .

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LISTENING TO THE VOICE OF THE PATIENT IN RSV RESEARCH

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Abstract: Patient and public involvement in research refers to patients or caregivers with disease experience contributing to the design, conduct or dissemination of results from research. Patient and public involvement has given rise to new fields in healthcare-oriented research and has the potential to transform infectious diseases through interventional trials. Our recommendations and best practices from years of organizing respiratory syncytial virus parent networks are provided.

Key Words: patient engagement, patient and public involvement, RSV, clinical research

Accepted for publication July 19, 2024

A.W.L. has previously worked in the pharmaceutical industry, but was not employed in industry while the manuscript was authored and submitted for publication. B.C. is an employee of a for-profit company, Chorus Innovations, Inc. Louis Bont has regular interaction with pharmaceutical and other industrial partners. He has not received personal fees or other personal benefits. Other authors have no conflicts of interest to disclose

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DOI: 10.1097/INF.00000000000004512

Maybe you missed the New Yorker article,¹ but patient engagement in research is approaching wide public recognition. Patient engagement, or more broadly, patient and public involvement (PPI) in research refers to patients or caregivers with disease experience contributing to the design, conduct, or dissemination of results from research.

PPI in research arose out of the larger patient-centered healthcare movement, driven by the moral imperative that patients, as end-users of healthcare, need a voice in shaping their care. Patient-centered healthcare also seeks to address inequities in healthcare access (eg, for minorities, low socioeconomic class or other disadvantaged groups) by meeting patients where they are.

A major goal of PPI is to enhance public trust in publicly funded research and the uptake of health interventions or policies arising from this research. PPI has had sustained international support from established government institutions and policy groups. These include INVOLVE, founded in 1996 by the UK National Institute for Health Research (now NIHR Center for Engagement and Dissemination, <https://tinyurl.com/5dfd8p94>); and Patient-Centered Outcomes Research Institute (PCORI, <https://www.pcori.org/>), established by US Congress in 2010 within the Affordable Care Act.

Interest in PPI and its potential to improve healthcare-oriented research has exploded—for example, yearly PubMed citations on “patient engagement in clinical research” grew by over 6-fold between 2008 and 2023. The rapid growth of PPI has been driven in part by requirements from the UK’s NIHR to embed PPI as a key element in publicly funded healthcare and social sciences research. Funding applicants must have a PPI plan in place or explain why PPI will not be done. Similar requirements exist in the US (for PCORI and National Centers for Advancement of Translational Science grants), European Union, Canada and Australia. PPI

plans and patient advisory boards are gaining momentum within the pharmaceutical industry.

This perspective aims to help researchers who wish to collaborate with patients and public partners by providing practical recommendations. We share best practices from our experience over years of organizing respiratory syncytial virus (RSV) patient networks (eg, the RSV patient advisory board) to raise disease awareness, educate and facilitate patient input into research.

WHY PATIENT ENGAGEMENT IS BENEFICIAL TO RESEARCH

Patients or caregivers who commit to PPI are motivated to meet others who may have shared or similar experiences. “Afterwards, I looked for anything to do with RSV. I struggled to find any support anywhere. I wanted an awareness group, and then [years later] found the patient network. Being [involved] is cathartic because I feel like I’m doing something positive and meeting people and I don’t feel so alone.” Rachael, whose son died from RSV, PPI contributor. Patients and caregivers are naturally invested in raising awareness about the disease that has affected their lives. As experts in lived experience, patients can be powerful spokespeople to raise disease awareness and educate doctors and the general public.

PPI benefits the research as well. When patients share their life stories, they inspire research teams (who may have not met a patient before) while giving insights into challenges with existing treatments or other unmet medical needs. As part of a patient community, patient advocates are well-situated to aid patient recruitment and retention. In a review, clinical studies with PPI showed a modest but significant increase in the odds of enrollment.² Involvement of patient advocates as part of the research team is likely to bolster the community’s willingness to participate and may also support the patient’s relevance of a new treatment or prevention when it undergoes regulatory review.

Detailed guidance for engaging PPI in healthcare research is publicly available. PCORI in the United States has published foundational expectations for meaningful, effective and sustainable PPI (Table 1).³ Although these expectations are focused on comparative effectiveness studies, they are applicable to healthcare research generally. As one of the earliest proponents of PPI, the NIHR in the UK has published extensive rationale and guidance documents.⁴ They also provide a service to facilitate PPI for industry partners in life sciences research, where the NIHR serves as an intermediary between companies and PPI groups.⁵

Despite the availability of such resources, it appears that the PPI revolution within healthcare and social science research has not yet been widely adopted in pharmaceutical industry-sponsored randomized, controlled clinical trials that are foundational for the development of new treatments or preventions. A 2018 review found a very low number of published trials reporting PPI, “despite the presence and promotion of patient-oriented research across the globe.”⁶ It is also likely that low PPI is compounded by underreporting of PPI in trial publications.⁷

RECOMMENDATIONS AND BEST PRACTICES

Engage with Patients and Public Early and Throughout the Research Process

PPI may provide new areas for research, additional end-points or protocol modifications that may be incorporated while the program is in the planning phase. Early engagement also allows for additional time to build trust between researchers and partners.

In our experience over more than a decade, the RSV patient advisory board members have variously given input on whether

TABLE 1. Foundational Expectations

PCORI Foundational Expectations
Diversity and representation
Early and ongoing engagement
Dedicated funds for engagement and partner compensation
Build capacity to work as a team
Meaningful inclusion of partners in decision-making
Ongoing review and assessment of engagement

PCORI, Patient-Centered Outcomes Research Institute.

certain research questions are important to their community, posed research questions resulting in a new study, been applicants for research grants, written a letter of support to the Institutional Review Board for a research study, advised on the feasibility of procedures that resulted in trial design modifications, and given input on how study results should be shared with participants.

Document PPI in the Publication

In recognition of the inconsistent quality of reporting PPI within earlier published studies, standardized forms like the Guidance for Reporting Involvement of Patients and the Public 2 have been developed, with simple templates to collect the aims, methods, results, discussion and conclusions, and reflections/critical perspectives of PPI within the overall study.⁷ Such standardization will likely lead to increased quality, transparency and consistency of the PPI evidence base.

Reimburse for Expenses and Time Spent

Financial compensation of patient and public partners is recommended by PCORI and the NIH. Payment is a recognition of the expertise that patient and public partners bring to the table, and may also be an important tool to reduce barriers to participation that are more prominent for minority, lower socioeconomic class, or geographically remote partners. Payments should follow publicly accepted standard rates and should not affect eligibility for public services.⁸

Funding to support PPI from pharmaceutical companies sponsoring the overall research is controversial, because of the potential for private money to influence a group that by nature should be an independent voice. The potential for bias should be minimized by making private funds to support PPI unrestricted, adhering to standard payment rates, and forbidding mention of any specific products in educational/patient-facing materials. Even with these standards in place, however, it may be difficult for privately funded PPI to escape the perception of corporate influence. Accordingly, the RSV patient advisory board has never received private funds.⁹

Provide Training and Education

Providing training on disease, clinical symptoms, and research methods to patient and public research partners builds the capacity of the team and engenders trust between partners and researchers. “We as doctors should make more effort to try and explain scientific findings to the general public. Education is most successful if patients can directly engage with you. I think it’s important that patients are able to respond to what they’ve heard.” Lieke, physician and educator.

The ReSViNET foundation has made RSV education to the public a cornerstone of advocacy efforts, producing lay webinars on RSV signs and symptoms, research and emerging treatments/preventions.

Make PPI Interactions Flexible

In the spirit of meeting the patient and public partners where they are, nontraditional meeting schedules will lower barriers for

participation. “My only barrier [to participate] is that I can’t be at all the meetings. I have to do some of it in evening hours or on weekends. You need the internal drive, then you’ll prioritize to make the meetings.” Lisa, whose daughter was hospitalized with RSV, PPI contributor.

SPECIFIC CHALLENGES FOR RSV

With RSV and other acute infections, the illness is over relatively quickly, so parents who choose to get involved in patient advocacy are motivated by what they can do for other families, rather than affecting their own situation. “I’ve had parents message me, ‘because of you, I took my child to the doctor to have them checked [for RSV].’ If I can save one life, then I’ve achieved what I set out to do.” Rachael, PPI contributor. Advocating for the prevention of disease is more challenging than advocating for treatment, because of the more complex messaging around preventing cases in the future.

Patient-led advocacy in infectious diseases research can bring about major change. The HIV/AIDS community-led movement to speed regulatory approvals for new treatments amid the AIDS epidemic serves as a reminder of the power of the patient voice.

RSV also has a global reach, with many deaths occurring in the developing world. Ongoing efforts to broaden the reach of RSV research to include lower- and middle-income countries would surely benefit from increasing diversity of race, ethnicity, and socioeconomic class among the RSV PPI community. It will require dedicated recruitment efforts, and following the recommendations outlined here to achieve this important goal.

ACKNOWLEDGMENTS

The authors thank all of the PPI contributors interviewed for this article. We also thank Wendy Lo, and S. Fox for helpful early discussions.

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