



Embracing the Patient Voice Within Publications

**Cross-Functional
Perspectives Toward Better
Patient Partnerships**

The biopharmaceutical sector continues to recognize the value of integrating the voice of the patient community into its activities.

Despite growing recognition of the importance of patient partnership within publications, uncertainty remains regarding how best to involve patients and where in the process this involvement should happen. Furthermore, although many of our colleagues working in Medical Affairs and publications have established the goal of engaging patients in publications, possibly as authors, their own internal guidance on publication development may create roadblocks. Compliance and regulatory concerns can limit opportunities to partner with patient communities, and the occasional reluctance of physician authors to include patients as co-authors further exacerbates the situation. Additional barriers arise from the general uncertainty in the scientific communications community as to how and when to engage patients in an appropriate manner that ensures a positive experience and recognizes the resource challenges of advocacy groups.

This paper will explore multidisciplinary perspectives on how we can better engage patient communities in publications to optimize the value of their contributions, while navigating any uncertainties and reluctance from internal and external stakeholders. We recognize that we are all learning together, with the shared goal of evolving our practices to fully embrace the voice of the patient while adhering to publication best practices and compliance. We welcome and encourage feedback from our industry colleagues to further refine our approaches.

Gavin Jones

Global Lead, Patient Centricity, OPEN Health





There is a joint consensus across regulators, researchers, medical communications professionals, patients and caregivers that it is essential to include the patient voice across all research domains. Applied to publications, this directive is driving a gradual evolution in processes to incorporate the patient voice. Some quality research and guidance exist to provide the initial framework for positive partnerships with patient communities.

“There's been a move away from health care provider-led scientific exchange toward a more diverse, inclusive approach that includes patients and caregivers.”

Karen King

Executive Vice President Medical and Scientific Services at OPEN Health

Although research and guidance exist, we remain at a stage where, as a community of industry professionals, we are challenged to implement practical approaches that provide positive outcomes and experiences for all stakeholders, while continuing to deliver robust scientific outputs.

“Everyone is excited and has great intentions, but there's a lack of practical guidance,” said Imogen Allred, a Senior Medical Writer at OPEN Health.

Our aim is to move this vital conversation forward, while using and building upon existing research and best practices. Here, some of our leading experts in both publications and patient engagement offer a cross-functional overview on enabling positive patient partnerships that deliver scientific rigor and deep patient insight.



Needed: A Thoughtful Approach to Patient Inclusion in Publications

As a fundamental step, any effort to include patient voices must ensure that the needs of the patient community are consistently respected. Although such communities will be committed to helping to build a trusting relationship, we must also recognize patients' often limited resources and the emotional challenges of sharing personal stories and insights. We must work to establish relationships centered on listening to patients and caregivers.

“Understand their viewpoints and give them space to educate you. Offer opportunities to ask questions whilst also actively listening. Respect their other commitments.”

Sumira Riaz

Center of Excellence Lead, Patient Engagement at OPEN Health

Never overlook or rush these seemingly simple first steps. **Trust and transparency** are crucial to effective partnerships with patient communities and patient-advocacy groups.

“Establishing trust and transparency must start with the first interaction,” said Alex Dubois, Senior Vice President for Patient Engagement at OPEN Health and a board member of the CARES Foundation, the only patient-advocacy group dedicated to the congenital adrenal hyperplasia community.

"[The] industry needs to be honest, and how they engage with patients and advocacy groups should mirror where they are in the drug-development process. Patients and their families don't want to get too deeply involved if a company's program is still early stage. Don't ask for too much early on; manage expectations; make sure your goals align."

Alex Dubois

Senior Vice President for Patient Engagement at OPEN Health and a Board Member of the CARES Foundation

It is also important to establish expectations and clarify roles and responsibilities upfront. "You don't want to get someone on board, have them commit fully, do a lot of work, and then have to go back and tell them you can't find somewhere to publish this work," Riaz said. The industry should identify appropriate outlets and understand authorship guidelines before recruiting patient authors.

Many patients have limitations that affect their ability to access and process the written word. Accessibility should be at the forefront of publication planning, particularly with patient authors; it is our responsibility to work with these authors to identify which methods

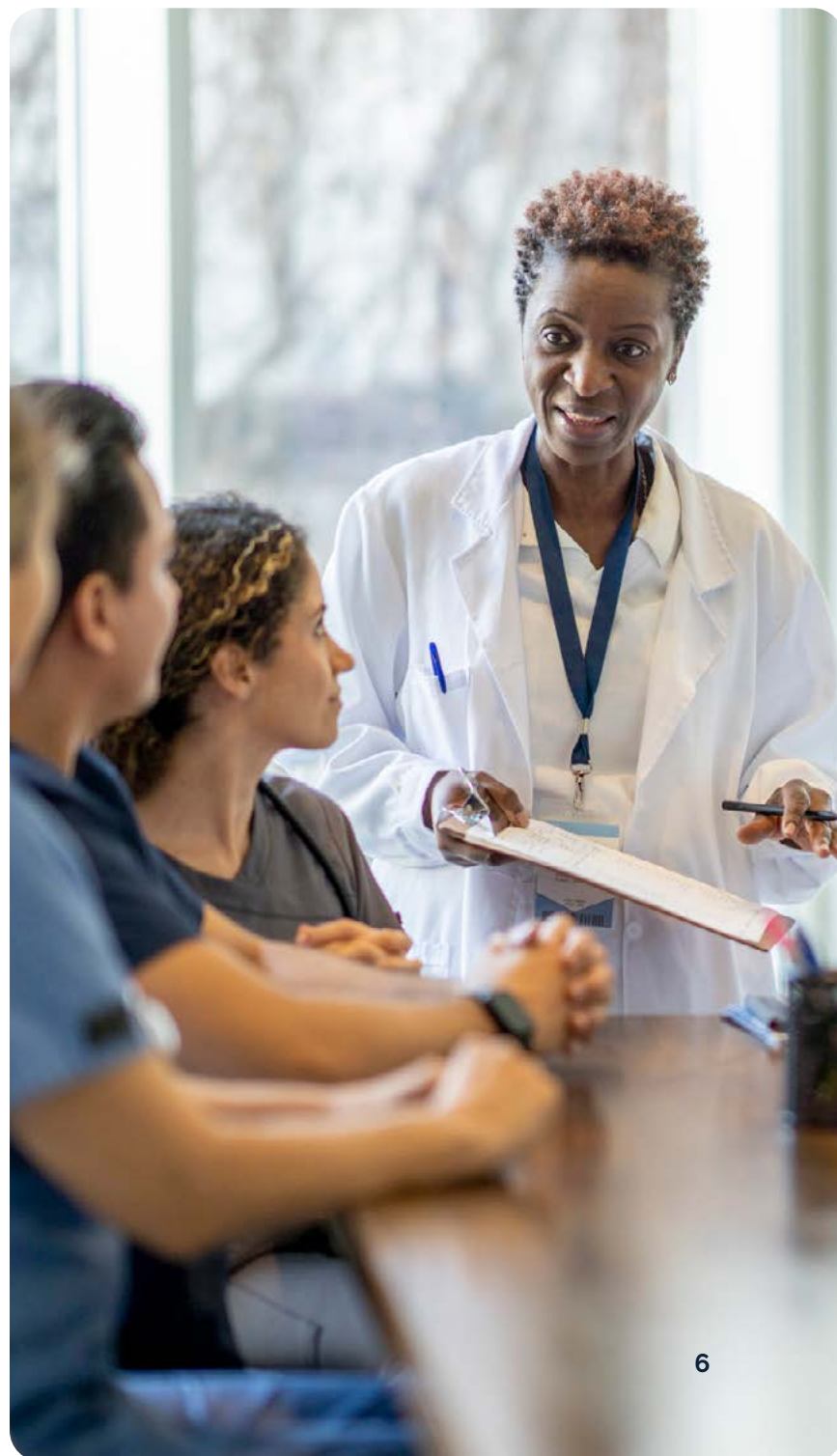
of communication are most suitable for them and facilitate this. Where needed or requested, text should be provided in the local language, in appropriate fonts and sizes, and include audio options.

We wanted at this point to acknowledge the topic of remuneration of patients to recognize their time and expertise in contributing to publications. Given the evolving landscape, and individual company positions toward it, we will reflect on the different perspectives and observe developing consensus.

Understandably, individual pharmaceutical organizations approach this with caution because paying a patient to co-author a publication runs the risk of perceived or actual inducement and bias. However, from another viewpoint, relying on the goodwill of advocates to invest time and effort in supporting the development of publications is unsustainable and may well limit uptake of patient participants. Loss of income due to the time commitments toward the publication, or inability to participate for patients building a career in advocating for a disease, could lead to low levels of patient involvement in publications, with the loss of all the prospective insight and value that their perspectives could bring to our scientific understanding.

Given the validity and potential effect of both viewpoints, we must continue to build on the consensus that is developing to find an appropriate path toward resolution of this important topic. In the International Society for Medical Publication Professionals (ISMPP) working group on Plain-Language Summaries (PLS),¹ it recommends: “Lay reviewers should be offered appropriate payment for their expertise and time.” In the 2022 Good Practice Publication (GPP) guidelines, it says: “Author agreements may state that authors will not receive payment in exchange for listing their name on a publication byline; however, this statement does not automatically disqualify from authorship professional medical writers or any other person earning a salary from professional activities that may confer authorship. Nor should such a statement be interpreted as a prohibition for compensating patients or other participants in publication activities, such as patient advocates or SC members, for their time.”²

This is an evolving landscape where we need to continue to collaborate to gain further consensus and confidence in developing consistent approaches. To note, and if it is deemed appropriate to remunerate patients, then it should always be based on fair-market value, and we must adhere to regional and local guidance on how to effectively and compliantly apply this. For example: <https://nationalhealthcouncil.org/fair-market-value-calculator/>



How To Identify Representative Patients

01

Contact patient-advocacy organizations

Patient-advocacy organizations have close relationships with patients and families, as well as deep knowledge of patient needs, treatment goals and frustrations. Partnering with your advocacy colleagues and connecting with an established patient-advocacy organization is a great way to establish meaningful partnerships with a patient community. Close liaison with your colleagues will assist in efficient engagement recognizing the limited resources these groups often have.

02

Build trust

Get to know the members of these organizations, and thoughtfully listen to them to better understand their objectives and priorities. Be open to sharing your objectives, articulating where you see value in collaboration, and answer questions truthfully and transparently. Give the organization space and time to make decisions, and be flexible in your plans so you can meet their needs.

03

Identify representative patient characteristics

The patients most active in advocacy organizations or most eager to contribute are not necessarily the most representative voices. "The input we want may not necessarily be available with the patients who come forward," said Jasmine Malone, Head of Patient Content at OPEN Health. "Patient involvement needs to reflect the average patient." Identify the demographics — age, sex, race, socioeconomic status, health literacy — of typical patients. Include caregivers' voices where appropriate.

04

Be inclusive

Facilitate inclusion among the patients who have the lived experience you need, rather than accepting the most easily accessible patients. Addressing barriers to participation can increase the size and diversity of your patient pool. "Patients experiencing serious disease and those from lower socioeconomic backgrounds can't easily participate, which is to the detriment of the overall quality of patient voice that you get," Malone said. "It's up to the professional stakeholders to ensure you get the right level of inclusion."

When — and How — To Involve Patients in Publications

According to the 2022 GPP guidelines, “Patients and patient advocates may be included in publication planning and development, including as authors or contributors to publications, as appropriate to the topic or therapeutic area.”²

Applying this guidance into practical advice, OPEN Health experts have identified three primary points for patient involvement:

01

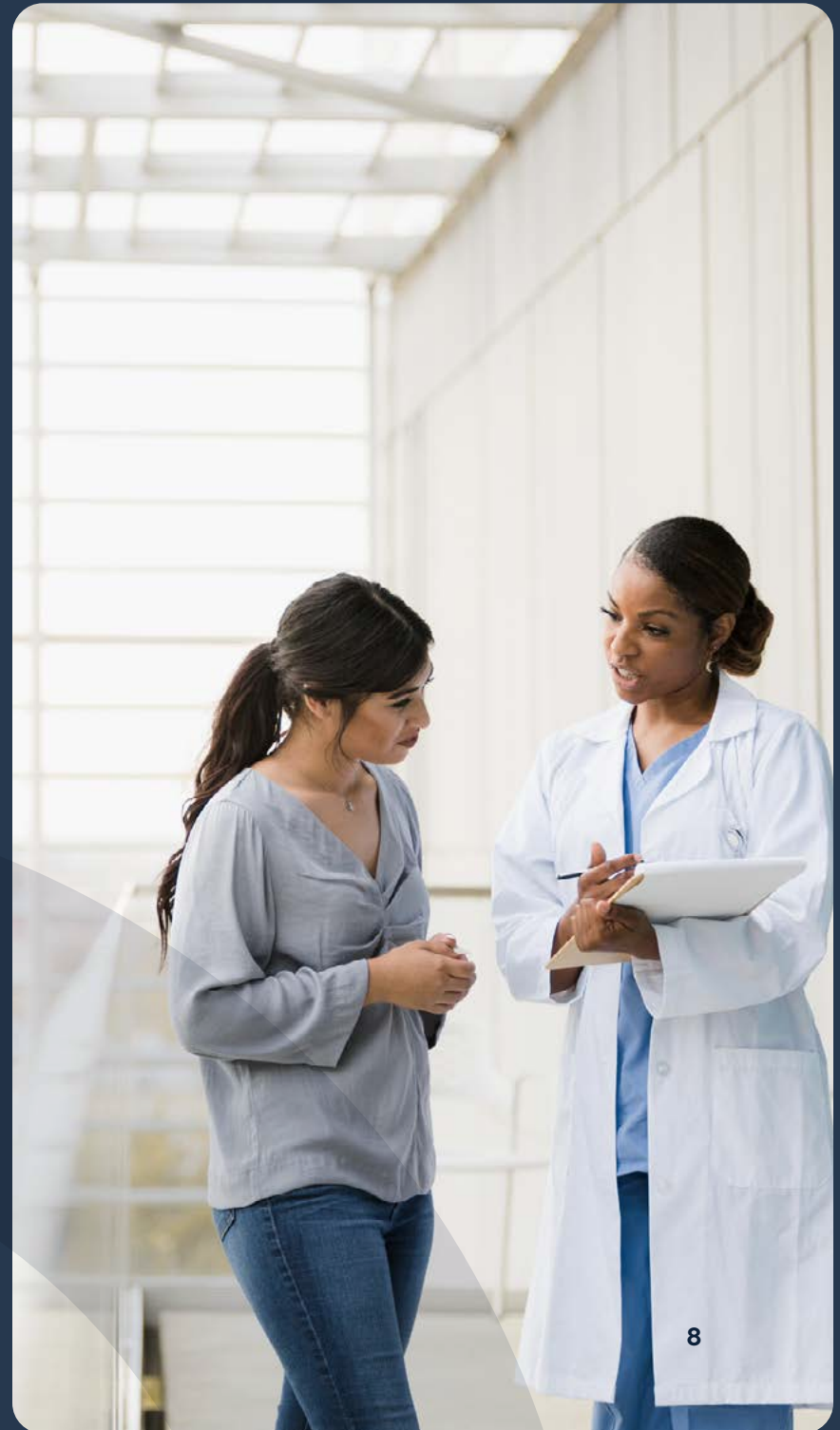
Publication
planning

02

Publication
development

03

Post-publication
engagement





Publication Planning: Direction and Consultation

Ideally, patients should be involved from the start and sit on advisory groups at very early-stage development. Incorporating patient voices early can help researchers identify priorities for research and design studies relevant to patients' lived experience, including meaningful endpoints.

The patient voice should be heard throughout the product life cycle, and that should include input regarding how to best communicate clinical trial and real-world evidence to patients. "That's not the norm at present," King said, but "that's where we want to get to."

Involving patients in publication steering committees must also include the building of relationships with these patients and providing education on the role of publications, as well as thinking creatively about how to maximize the patient voice in committee meetings. Engaging with patients on publication steering committees can help the wider publication team and authors understand patients' social reality, including their attitudes, beliefs and motivations. Patient perspectives can help the team plan manuscripts that center on patient voices. It can also lead the team to prioritize other types of publications relevant to patient communication.

Publication Development: Patient Authorship and Review

Although patient authorship is important and demonstrably enriches articles, that does not mean their involvement is a requirement in every situation.

“Patient involvement and authorships don't need to be all or nothing. There can be a happy middle. You probably don't need to include a patient author if you're developing a manuscript looking at complete response rates for a new oncology product. But if that same study also included a patient-reported outcome measure, such as patient costs, losses in productivity or absenteeism, you may want to include a patient author if they meet authorship criteria.”

Beth Lesher

Senior Director in Evidence & Access at OPEN Health

Although we should continue to strive to include the patient as an author whenever appropriate, patient authorship requires both adherence to GPP guidance as it relates to authorship and a level of pragmatism within the professional publication community regarding realistic expectations for patient authors.

Depending on when patients or their caregivers are approached to join a study or a publication team, they may not meet all criteria necessary for authorship. Guidelines for authorship should be carefully considered, and guidance related to those criteria should be reviewed and discussed with patients involved in a publication. The International Committee of Medical Journal Editors recommends that authorship be based on the following four criteria:³

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis or interpretation of data for the work.
2. Drafting the work or revising it critically for important intellectual content.
3. Final approval of the version to be published.
4. Agreement 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.

There are ways to include the patient voice in different types of publications that move beyond traditional manuscripts. For example, including a patient perspective or commentary section alongside a publication allows the patient voice to be heard while also reaching a range of audiences. PLS are another method to facilitate the patient voice and present complex data in a way that a larger audience will better understand. Recognizing the importance of the patient voice, some congresses now allow submission of abstracts by all patient authors, which, if accepted, provides an opportunity for these patient authors to directly present a poster or oral presentation. Although these types of presentations are still novel and uptake is unclear, the fact that a growing number of publication options incorporate patient voices highlights the impetus for such publications. The number of options is likely to increase over time, offering ever more opportunities for patient involvement.

It is also possible to adjust the nature of the manuscript itself to facilitate patient authorship. “One of the most exciting things I’ve worked on was a podcast manuscript that was a discussion between the patient and physician,” Allred said. “The audio and manuscript — a transcription of the discussion, fully referenced with an abstract — were available on the journal website, and the podcast was shared via Spotify and Apple podcasts as well.” Such innovative approaches may eliminate some of the hurdles of traditional write-and-review publication development.

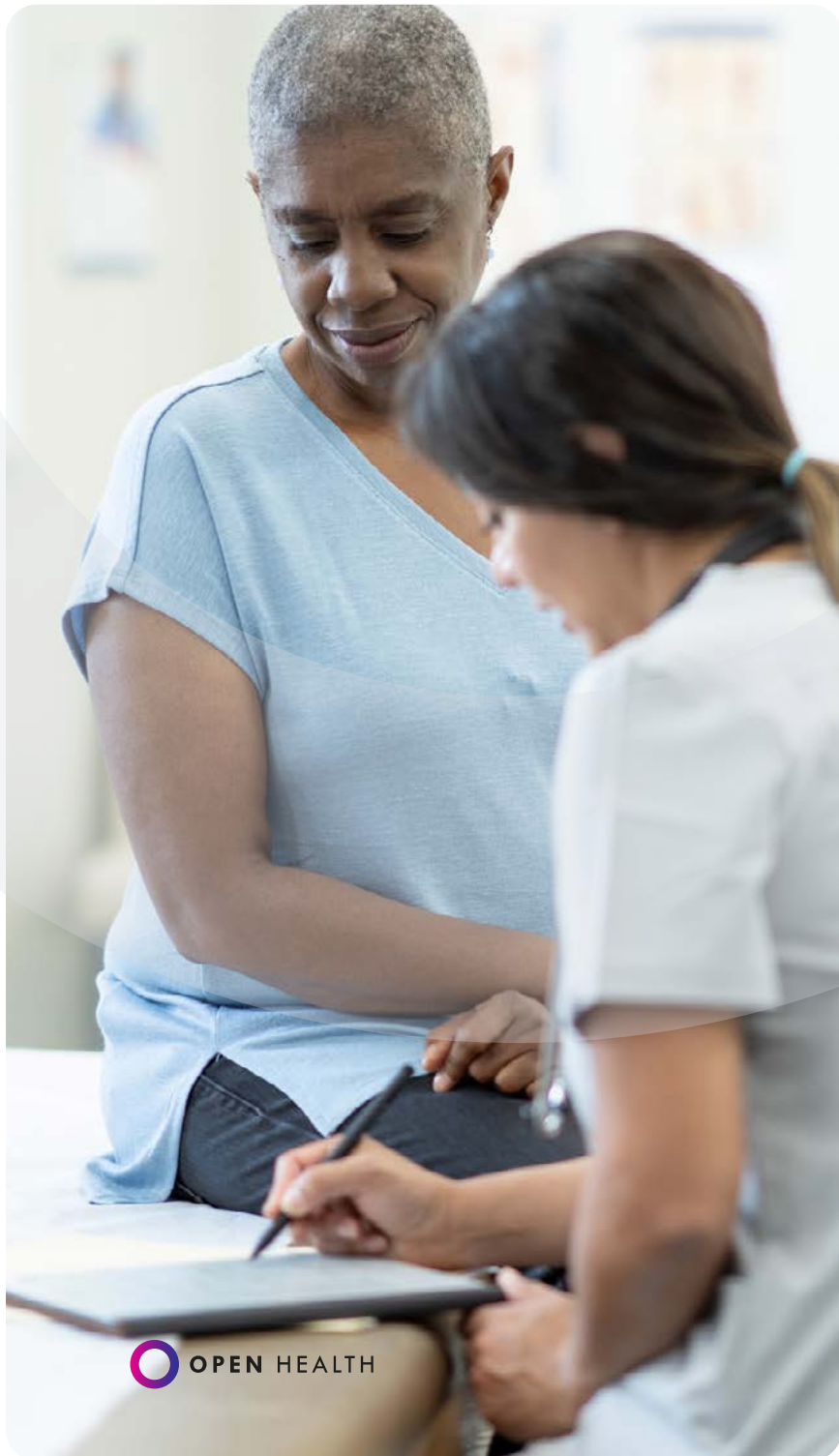


Finally, when considering how we can involve patients in publication development, we must also ensure we understand how best to incorporate patient authors into reviews. As all authors are expected to read and review the manuscript to fulfill authorship criteria, you may need to alter your processes to effectively involve patient authors. Careful consideration of the questions we want to ask the patient will give us insights into how the data is meaningful to them. To facilitate the review and maximize efficiency, we recommend scheduling or spending time with patient authors to answer their questions and to maintain an open dialogue. It is

especially important to understand how the patient author best prefers to engage in the review, because you may need to take special circumstances into consideration. For example, patients with limited vision may not be able to review work shared via email attachments or software programs.

"In some cases, we've re-formatted documents so they work with screen readers. We've also made phone calls, read content to patients and asked them verbally for feedback," Allred said. The publication team may need to build in extra time to facilitate patient involvement.





Patient Authorship Not Appropriate? You Can Still Include Patient Voices

Patients or caregivers who do not, or cannot, meet authorship criteria can still be encouraged to participate in manuscript development and may contribute information that will help the authors to include the patients' point of view in the discussion of the study's impact. In such cases, the patient's (or caregiver's) role should be acknowledged. Alternatively, or in addition, patients could help with the development of manuscript extenders and PLS.

PLS of scientific articles are written in easy-to-understand, nontechnical language. At present, PLS vary widely in content, format and quality, and "people have different viewpoints as to whom the plain-language summary is targeting," Allred said. Although some people believe that PLS are intended for nonspecialist health care professionals, Allred recommended "writing a plain-language summary with a layperson in mind." Indeed, that was also the view of an ISMPP working committee and expert stakeholder group that recently published guidance and insights around the key questions about PLS.¹

Most biopharmaceutical companies work with medical communications agencies that have expert writers trained and tested to write in plain language alongside authors and, potentially, patients. This approach is also recommended to ensure that the PLS is truly representative of the original publication and that all appropriate checks and balances are in place from a compliance perspective.

If it is not appropriate to involve a patient advocate in the development of a PLS, "it is critical to involve patients in the review of the draft document," Allred said, because they are intimately familiar with the terminology commonly used and understood by patients. There are many options for PLS, from abstract PLS on QR codes on posters in congresses with a patient track to PLS accompanying original articles or even stand-alone PLS following an original article. Our key advice is: Don't assume a

journal won't run a PLS if it hasn't done so before. "Many are very open to doing so but haven't gotten there yet," King said.

Besides PLS, other publication extenders, such as animated publication summaries, visual abstracts and infographics can be developed in plain language. These bite-size content pieces are typically used for time-poor or nonspecialist healthcare professionals (HCPs); however, such formats can also be particularly useful for communicating with patients. Indeed, text-based PLS (useful for translation into local language) are often supplemented with infographics, short videos or podcasts, which can help patients understand and remember facts and data. In addition, the use of short audio summaries and narrated PLS slides can assist patients with low vision, for whom longer pieces of written text or images present logistical challenges.

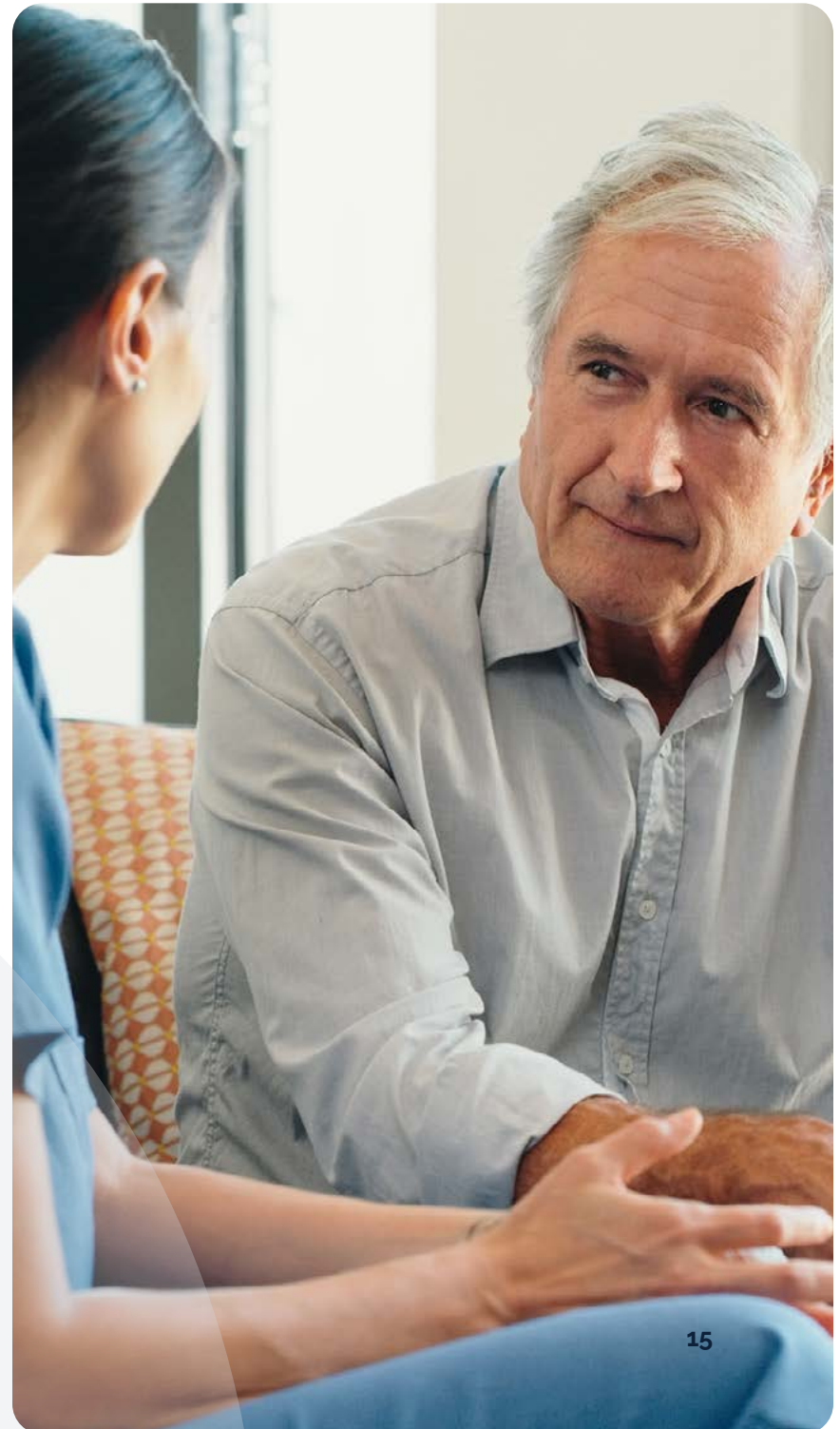


Enhance Accessibility

Patients want — and need — to understand scientific data that can affect their health.

PLS should be available in local languages and multiple formats, including visual and audio. “Adding voiceover to a video makes it even more accessible,” King said. We must have an ambition that PLS, plain-language videos and other materials intended for patients be published Open Access.

Remember that patients' ability to access and understand medical information can be affected by their emotional state as well. “When you're creating content, know that you may be creating content for someone who is having a really difficult day,” Malone said. Patient input can help you select the proper terminology and strike a patient-friendly tone.





Post-Publication Engagement: Information Dissemination

Patients are well positioned to share health information with other patients and health care providers.

“Patients and families who live with rare conditions often educate ourselves and bring things forward to our physicians,” Dubois said. Congenital adrenal hyperplasia, the condition that affects Dubois’ son, is a small part of his endocrinologist’s practice, so Dubois is often aware of new clinical trials and research before her son’s physician.

Advocacy organizations and patients can “use their platform to share with their community, particularly when they have been invested and involved,” Riaz said. PLS can be shared via social media, community newsletters and during patient events.

Patients can also be involved in the dissemination of information to professional audiences. Consider including audio slides featuring patient voices, for instance, during presentations.

Assess the Impact of Patient Involvement

Assessing the short-term effect of publications can be challenging because online engagement with articles typically fluctuates and changes over time. We often turn to basic quantitative metrics, such as website hits and article views, which can be compared between articles that do and do not include the patient voice. However, the picture this generates can be one-dimensional and may not capture all levels of engagement.

Soliciting feedback from the patient community provides deeper insight than looking at the number of page views. “Speak directly to the patients who have been involved so you can understand how they feel about it,” Allred said. “Do they feel like it was a success? In the short term, that’s most important.” Furthermore, feedback is a two-way street, and an open dialogue with patients — not only about how they view the resulting publication but also from us about the effect and importance of their input — ensures that patients feel their voice matters. Building relationships with patient-advocacy groups is key to maintaining these open dialogues; partnering with an agency that has strong ties may help when soliciting honest feedback that can help improve processes for all involved.

Ultimately, inclusion of patients in publications may fundamentally change how we conduct research and assess the success of clinical trials and health economics and outcomes research.

“In the long term, the real measure of success will be how the patient voice changes our approach to clinical trials, real-world evidence studies and the reporting of data. What patients consider important does not always align with outcome measures in clinical trials. Although I don’t think this is something we’ll be able to measure for a number of years, I am excited and hopeful about the changes that may happen.”

Imogen Allred

Senior Medical Writer at OPEN Health



Embracing the Patient Voice

“Understanding patients’ unmet needs and what it’s like to live with these diseases on a day-to-day basis is so important.”

Alex Dubois

Senior Vice President for Patient Engagement at OPEN Health and
a Board Member of the CARES Foundation

Involving patients throughout the publication process offers another opportunity to build trust with patient communities and will help ensure that clinical and health economic and outcomes research becomes more accessible. When patients are better informed, researchers and clinicians gain a better understanding of the patient experience, and patients can, if they wish, participate in their health care decisions as equal partners.

We are on a journey to unlock the full value of embracing the patient voice in publications. We believe this will be achieved through thoughtful patient engagement along with scientific rigor and good publication practices. When planning your publications with your authors, please consider how OPEN Health can help deliver positive outcomes for all.



Sources

1. Lobban, D. et al. "Plain language summaries of publications of company-sponsored medical research: what key questions do we need to address?" <https://www.tandfonline.com/doi/full/10.1080/03007995.2021.1997221> (March 2023)
2. DeTora, L.M. et al. "Good Publication Practice (GPP) Guidelines for Company-Sponsored Biomedical Research: 2022 Update." <https://www.acpjournals.org/doi/10.7326/M22-1460> (March 2023)
3. International Committee of Medical Journal Editors. "Defining the Role of Authors and Contributors." (2023). <https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html> (March 2023)



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